Executive Summary

Section 1 - Promoting family planning
Section 2 - Making pregnancy safer
Section 3 - Reproductive tract infections and sexually transmitted infections
Section 4 - Unsafe abortion
Section 5 - Promoting sexual and reproductive health of adolescents
Section 6 - Gender and reproductive rights in reproductive health
Section 7 - Technical cooperation with countries
Section 8 - Implementing best practices
Section 9 - Monitoring and evaluation
Section 10 - Communication and dissemination of information
Section 11 - Clinical trials and informatics support

Appendix 1 – Staff of the Department, December 2001
Section 1
Promoting family planning
Research on the development of methods of fertility regulation

C. d’Arcangues, P.D. Griffin, H. von Hertzen, K.M. Vogelsong, M. Mbizvo, E. Vayena

INTRODUCTION

In 1995, approximately 570 million couples worldwide regularly used a method of family planning. Because use does not necessarily mean acceptance, this statistic offers only a glimpse at the behaviours that determine a couple’s decision to use a method of fertility regulation. Nearly half the users of a reversible method discontinue its use within a year owing to a variety of reasons, including health concerns and the occurrence of an unplanned pregnancy. On the other hand, at least 120 million couples do not use any method of family planning, despite expressing a desire to space or limit the number of their children. Obstacles to the use of contraceptive methods include an ambivalence towards modern contraception, especially attributed to a fear of side-effects, and the lack of access to high-quality services. Experts have determined that the availability of improved or totally new methods of family planning could lead to a significant public health benefit and could meet the needs and demands of millions of men, women and families.

The Programme’s research on improved and new methods of fertility regulation provides one of the several inter-connecting building blocks required for the delivery of quality family planning services. The Programme has pursued high-priority leads for new methods and approaches that are easier to use and simplify service delivery, are associated with fewer and less severe side-effects, and respond to the needs of various users including men. The Programme’s goals link this work to the introduction of methods and subsequent large-scale trials of their safety and efficacy. Users’ perspectives are gathered during the product development, introduction and routine service provision phases; together with clinical trial data, this information provides input into the development of norms, guidelines and other tools for providers and for family planning acceptors.

EMERGENCY CONTRACEPTION

Specific objectives of research

Over the past decade, the Programme has been in the forefront of research on new technologies for emergency contraception. The aim is to further improve the safety, efficacy, acceptability and ease of service delivery of these methods. As taking two doses of levonorgestrel 12 hours apart is not very practical, simpler regimens are being tested. Research has continued to further confirm the efficacy of the intrauterine device (IUD) and a 10 mg dose of mifepristone. New compounds are also being tested. The Programme’s research has also stimulated other organizations to launch activities in this area. An international Consortium on Emergency Contraception was founded in 1996 and now includes a total of 29 member organizations.

Progress

Levonorgestrel

Research on levonorgestrel is continuing in three multicentre studies.

- A large, randomized, double-blind, multinational study was completed during 2001, which investigated the efficacy and side-effects of a single dose of 1.5 mg levonorgestrel compared to two 0.75 mg doses taken 12 hours apart and to a single 10 mg dose of mifepristone, when given up to 120 hours following unprotected intercourse. A total of 4136 women were enrolled from 15 family planning clinics in China, Finland, Georgia, Hungary, India, Mongolia, Slovenia, Sweden, Switzerland and the United Kingdom. The results of the study will be published in 2002.
• The 12-hour interval between the two tablets of levonorgestrel is sometimes impractical, and a double-blind, multicentre study in China is therefore investigating whether this interval could be increased to 24 hours, as this may be more convenient for women. The recruitment of over 2000 women for this trial is expected to be completed by the end of 2001.

• Three centres in Nigeria participated in the previous multicentre study on levonorgestrel and the Yuzpe regimen, and the two-pill levonorgestrel regimen of emergency contraception has now been registered in that country. A seven-centre study is ready to be launched in Nigeria to investigate the efficacy and side-effects of a one-dose regimen of 1.5 mg of levonorgestrel compared to a two-dose regimen (0.75 mg taken at an interval of 24 hours). This study will include a total of 3150 women and is expected to be completed by the end of 2003.

Mifepristone

The Programme has collaborated with Chinese investigators in further evaluating the efficacy of the 10 mg dose of mifepristone. During a three-year collaborative initiative funded by The Rockefeller Foundation, a randomized, double-blind study was carried out with 3052 women in 10 centres around China. The results indicated that the doses of 10 mg and 25 mg of mifepristone are equally effective with a raw pregnancy rate of 1.1%. The treatments led to very few, if any, reported side-effects. Failure rates were correlated with the time gap since unprotected intercourse \( (P=0.02) \), as shown in Figure 1.1. Women treated after 48 hours had a risk of pregnancy 2.3 times higher than women treated within 48 hours (relative risk: 2.3; 95% Confidence interval [CI]: 1.2–4.5). After this study, the 10 mg dose was registered for emergency contraception in China.

In order to determine whether low-dose mifepristone is more effective than levonorgestrel, the Programme carried out a large, multinational, double-blind study comparing the efficacy and side-effects of 10 mg of mifepristone and two treatments of levonorgestrel, as described above.

IUD in emergency contraception

Several reports on the use of an IUD for emergency contraception suggest that the method could be highly effective for this indication. However, due to lack of prospective, well-conducted studies on the efficacy and side-effects of the IUD as a means of emergency contraception, it is not possible to give any recommendations regarding its use. Thus, a large, multicentre study of the efficacy, side-effects and acceptability of the TCu380A IUD for this indication was launched in China.

A total of 1883 women were recruited and followed up for one year after IUD insertion. In this study, the IUD was 100% effective as a method of emergency contraception when inserted up to 120 hours following unprotected intercourse. Short-term side-effects and removal rates up to 12 months after insertion did not differ from those seen in studies of interval insertion of the copper IUD.

New projects initiated during the year

Mifepristone

The Programme has given technical assistance to a large study launched by Chinese scientists to further evaluate the efficacy and safety of the 10 mg dose of mifepristone. It is planned to recruit a total of 4000 women in 30 centres.

Gestrinone

Gestrinone is registered and used in more than 40 countries for the treatment of endometriosis. In addition to its antigonadotrophic activity, the compound also has some anti-progestogenic activity. It is anticipated that due to its long duration of action—gestrinone is administered twice weekly in the management of endometriosis—one dose of the drug might be sufficient for effective emergency contraception.

A randomized, double-blind study was launched in China to compare 10 mg of gestrinone with 10 mg of mifepristone for emergency contraception when administered up to 120 hours after unprotected intercourse. The study will include 1200 women and will be completed in 2002.
Mechanism of action studies

Several research initiatives have been planned together with the Programme’s collaborating centres to investigate the possible mechanisms of action of emergency contraceptives. As fecund cycles cannot be investigated in the human, a study was launched in Santiago, Chile to test the feasibility of the *Cebus apella* monkey as a model for this research.

Another study in Chile is examining the effects of a single dose of 1.5 mg of levonorgestrel on follicular growth and ovulation. In addition, the pharmacokinetics as well as levels of the steroid in endometrial tissue will be examined after oral and vaginal administration of this dose of levonorgestrel.

**SIX-MONTHLY, NONSTEROIDAL, INJECTABLE IMMUNOCONTRACEPTIVE FOR WOMEN**

Specific objectives of research

The development of a totally new method of contraception, based on a controlled and time-limited immune response to reproduction-specific molecules, has been the subject of extensive investigation supported by a number of international and national agencies for several decades.

It was recognized that the development of this totally novel approach to contraception was a long-term, high-risk endeavour but the perceived advantages of, and potential demands for, a safe and effective immuncontraceptive—free of the metabolic and other side-effects associated with long-acting methods based on steroid hormones—were considered more than sufficient to justify the effort and investment.

Progress

Studies have been carried out during the past year to evaluate the performance characteristics and likely clinical acceptability of three formulations of the human chorionic gonadotrophin (hCG) immunocontraceptive.

- Calcium sulfate hemihydrate–dextran sulfate matrix system: The most encouraging data during the past year have been obtained using a new particulate, slow-release delivery system in which the immunogens are incorporated in a composite inorganic/biopolymer matrix formed from calcium sulfate hemihydrate and dextran sulfate. In initial studies in rabbits, it was shown that immunization can be achieved with a single injection of the conjugate-containing matrix particles suspended in a small volume of the water-in-oil emulsion. This approach has elicited a good immune response with a high level of antibodies being sustained for at least six months. Injection-site reactions in most of the animals involved in these studies, especially in those receiving medium-to-low doses of the preparation, were either absent or within a clinically acceptable range.

New projects initiated during 2001

A dose-finding study was recently initiated in rabbits to determine the local reactions resulting from a single injection of the matrix preparation. Treatment started in early November 2001, autopsies commenced in early December 2001, and the preliminary assessment of the histopathology will be carried out in mid-February 2002.

Subject to a satisfactory outcome of this study, approval will be sought from the Medical Products Agency in Stockholm, Sweden to initiate a Phase I clinical trial of this formulation during the first half of 2002.

**INJECTABLE HORMONAL CONTRACEPTIVES**

Specific objectives of research

A number of long-acting injectable esters of levonorgestrel were prepared in a chemical synthesis programme conducted by the US National Institute of Child Health and Human Development (NICHD) and the Programme in the late 1970s and early 1980s. One of these, levonorgestrel butanoate, is being investigated as a possible improved alternative to depot-medroxyprogesterone acetate (DMPA).

The service provision of injectables would be facilitated if their use could be initiated on the same day of the cycle. At present, the first injection of the monthly injectable Cyclofem is administered within the first 5 days of the menstrual cycle, whereas the first injection of DMPA is given as late as day 7. A study was carried out to evaluate the likely contraceptive efficacy of Cyclofem when first administered on day 7 of the cycle.
Progress

Levonorgestrel butanoate

Additional clinical trials to further evaluate the safety and efficacy of levonorgestrel butanoate have been on hold for several years pending the investigation of formulation problems. These have largely been resolved now but more recent legal problems are still preventing the custom preparation of clinical trial batches.

Discussions have taken place during the past year with various contacts in the pharmaceutical industry to review alternative strategies for obtaining clinical trial supplies of levonorgestrel butanoate to enable the next stage of clinical testing to be carried out. These discussions are in progress and no new projects were initiated with levonorgestrel butanoate during 2001.

Cyclofem: initiation of Cyclofem treatment

A study was undertaken to test whether the first injection of the once-a-month combined injectable contraceptive, Cyclofem, could safely be administered as late as day 7 of a menstrual cycle—as is the practice with other injectable contraceptives such as DMPA—without jeopardizing its high level of efficacy. The clinical trial was initiated by Family Health International (FHI) in three Latin American centres, and the Programme supported the inclusion of a Chinese centre to address possible ethnic differences. Ovarian activity and cervical mucus changes were monitored in 158 women randomly allocated to receiving the first injection on day 5 or on day 7 of their menstrual cycle.

In all centres it was observed that, after receiving the first injection on day 5, women had limited or no ovarian activity. In contrast, of those women in the Latin American centres who received the first injection on day 7, 18% showed follicular growth and 5% ovulated; only 3% of women in the Chinese centre, who received the initial injection on day 7, showed some evidence of follicular growth. With regard to cervical mucus, women who received the injection on day 5 exhibited fair or poor mucus quality and poor sperm penetration. Three per cent of those who received the injection on day 7 showed good mucus or good sperm penetration at some point during the two weeks following the injection. Thus, administering the first injection on day 7 of the cycle does not provide the same inhibition of ovarian activity and of mucus quality and sperm penetration as when given on day 5. But the theoretical risk of pregnancy after receiving the first injection on day 7 would be expected to remain low.

Combined Vaginal Ring

Specific objectives of research

Acceptability studies show that women need long-acting methods of contraception that do not require daily interventions and that are under the user’s control. The vaginal ring is one approach that meets these needs. Most steroid hormones are absorbed efficiently through the vaginal wall and can be released from a silastic ring. The ring can be easily inserted in the vagina, checked, removed and replaced by the woman herself. It can be worn continuously for a number of weeks; its use is not related to coitus; it provides a constant rate of drug release resulting in a steady plasma level of the minimum dose required for contraception; metabolic side-effects are reduced by avoiding the first-pass effect through the liver; and upon removal, fertility rapidly returns.

Progress

The Population Council will launch a Phase III clinical trial of a combined contraceptive vaginal ring releasing 150 µg of norethisterone and 15 µg of ethinyl estradiol daily over the course of a year. The Programme is planning to provide support to two clinical research centres in this trial.

Basic research on Implantation

Specific objectives of research

An anti-implantation or menstruation-inducing agent is an attractive approach to fertility regulation since it needs to be taken only on one occasion in any menstrual cycle, and then only on an “as needed” basis or as a back-up method, for example, in the case of condom breakage. Such a method would be free of the logistical problems and side-effects associated with the use of many existing methods of family planning and, because of its infrequent use, should be relatively inexpensive and, therefore, affordable by women in many parts of the world.

A collaborative initiative in the area of basic research in implantation was established at the end of 1998 between The Rockefeller Foundation and the Programme. The primary objective of this research initiative is to identify promising leads for development, in eventual collaboration with industry, as novel anti-implantation or menstruation-inducing agents, which are woman-controlled, effective, safe and acceptable in their mode of administration and their mechanism of action.

The focus of the research is on: (i) the implantation window in the primate, at the endometrial level; (ii) the development and demise of the primate corpus luteum; and (iii) preimplantation embryo–uterus–corpus luteum interactions. The work is being done in a network of 6 centres in Australia, China, Germany, India, United Kingdom and USA, with financial support
Section 1 - Promoting family planning

and technical supervision being provided by The Rockefeller Foundation and the Programme, respectively.

Progress

During 2001, further information has been obtained on the complicated and interactive structural and functional changes that occur in the monkey corpus luteum and in the mouse, monkey and human uterus at the site and time of implantation. These changes include both increased and decreased production of specific molecules, the proliferation of blood vessels, and the controlled destruction of certain cell types.

New projects initiated during 2001

Studies carried out during the past year include chemical and immunological inhibition of the function of some of the molecules whose production is increased during implantation or whose appearance seems to be restricted to the implantation site. Some evidence was obtained of an antifertility effect resulting from these various interventions, but the numbers of animals used in these experiments were small and the results, therefore, were not statistically significant. Other studies are under way to investigate the impact of these interventions, both locally at the cellular level using immunohistochemical and histopathological tests, and systemically by measuring changes in the expected patterns of circulating hormones, especially estrogen and progesterone.

Further studies are planned involving larger numbers of animals and a variety of treatment modalities, including single molecules and combinations of molecules, to further investigate their antifertility potential.

The annual meeting of the initiative’s investigators and Project Review Committee was held in Melbourne, Australia, in December 2001. In accordance with the established format, this meeting was convened as a joint activity with the investigators engaged in the Research Program on Monthly Methods for Women of the Contraceptive Research and Development Program’s Consortium for Industrial Collaboration in Contraceptive Research (CONRAD/CICCR). The meeting started with a two-day symposium during which the WHO/Rockefeller Foundation and CONRAD/CICCR-supported investigators presented and discussed the results obtained in their projects during the past year. This was followed by a one-day brainstorming session involving both sets of investigators, the Project Review Committee and local collaborators. During this session, the composite data were reviewed, promising individual leads for further development were identified, and additional lines of research were proposed. The meeting concluded with a one-day meeting of the Project Review Committee to assess the progress reports and plans for future work submitted by the 6 centres in the Initiative.

BASIC RESEARCH ON ENDOMETRIAL BLEEDING

Specific objectives of research

A large proportion of the more than 15 million women using progestogen-only methods of contraception endure the irregularities in vaginal bleeding that these methods induce. This has significant implications on their sexual life and impacts on the sociocultural, economic and, for some, religious dimensions of their lives. Few options are available to women to prevent or alleviate this problem. The administration of estrogens is only moderately beneficial and negates some of the benefits of a progestogen-only method. Non-steroidal anti-inflammatory drugs have positive effects but are often too expensive or not locally available. As a result, counselling is the main assistance that women who experience bleeding irregularities can expect from providers.

Various mechanisms related to breakthrough bleeding

Figure 1.2. Schematic diagram of proposed mechanisms of endometrial breakthrough bleeding resulting from continuous exposure to exogenous progestogens
have been proposed as described in Figure 1.2. Clearly, there is a need to better understand the mechanisms of menstruation and of irregular bleeding and how these are affected by contraceptive steroids, particularly progestogens. This will provide the necessary knowledge to formulate appropriate treatments and to develop new methods free of these side-effects.

**Progress**

Two studies were undertaken to assess the effects of different treatments on progestogen-induced prolonged bleeding. A double-blind, placebo-controlled trial was completed in Santiago, Chile, testing the efficacy of mifepristone in improving the vaginal bleeding pattern of Norplant users. After Norplant insertion, 120 subjects who complained of prolonged bleeding received 100 mg of mifepristone or placebo on two consecutive days at intervals of 30 days over a period of six months and were followed for a total of 13 months. Treatment with mifepristone significantly reduced the incidence and duration of prolonged bleeding episodes. A mild beneficial effect persisted after the end of treatment. One pregnancy occurred in the mifepristone-treated group.

A second double-blind, randomized, placebo-controlled, clinical trial was conducted to test the effect of vitamin E as an antioxidant, and of low-dose aspirin as an anti-inflammatory agent, alone and in combination, on Norplant-induced prolonged bleeding. Participating centres were located in Beijing (China), Jakarta (Indonesia), Santiago (Chile), Santo Domingo (Dominican Republic) and Tunis (Tunisia). Analysis of data from 480 subjects indicated that treatment with vitamin E had no beneficial effect on bleeding patterns. Although treatment with low-dose aspirin often led to a more rapid cessation of prolonged bleeding episodes, significant differences were rarely observed. Further detailed analysis of the data is ongoing.

A systematic review of the evidence for the efficacy of various therapies in the treatment or prevention of progestogen-induced irregular endometrial bleeding is being supported by the Programme, as one of the reviews conducted through the Fertility Regulation Group of the Cochrane Collaboration. The protocol for the review was reviewed and accepted in 2001 and published in *The Cochrane Library*, Issue 5, 2002. The review should be completed by mid-2002.

**New projects initiated during 2001**

To implement the recommendations for further research made at the 1999 meeting on “Steroids and Endometrial Breakthrough Bleeding,” cosponsored by the Programme and the US NICHD, a project proposal entitled “Studier on the role of progestins in endometrial breakthrough bleeding” was reviewed, approved and funded in 2001. This three-year project proposes to investigate, in vitro, the nature of the estrogen and progesterone receptors in human microvascular endothelial cells and the responses of these cells to estrogen, progesterone and levonorgestrel. Additional studies will focus on the production and activation of matrix metalloproteinases (MMPs) in the endometrium and the regulation of their production and activation by progestogens. Finally, a mouse model of menstruation will be used to evaluate the effects of levonorgestrel on endometrial breakdown or fragility, and to investigate whether treatment with MMP inhibitors can limit these effects. These studies will provide new insights into the cellular and molecular mechanisms that underlie progestogen-induced breakthrough bleeding.

**MALE HORMONAL CONTRACEPTION: CLINICAL AND SOCIAL SCIENCE RESEARCH**

**Specific objectives of research**

Programme managers, policy-makers and donors are becoming progressively more aware of the need for, and public health benefits of, increased male participation in family planning activities. The Programme, in collaboration with its partners, has established and maintained a leadership role in the development of male contraceptives. This is a step forward toward the goal of increased shared responsibility in this area, as articulated at the International Conference on Population and Development (ICPD). In order to maximize the impact of available funding, the research agenda must identify and exploit the leads that are feasible and most promising. The reversible male contraception method that is believed to be the closest to clinical application is a hormonal method that suppresses spermatogenesis to azoosperma or severe oligozoosperma, resulting in temporary infertility. The work of the Programme in such clinical trials is complemented by a portfolio of accompanying acceptability and behavioural research.

**Progress**

**Androgen alone**

The Programme, together with the State Family Planning Commission of China, funded a Phase II trial of the androgen, testosterone undecanoate (TU), in 2001. This was based on the successful results of the Phase II trial of the contraceptive efficacy of this injectable androgen in Chinese men. The 10-centre Phase III study will evaluate the contraceptive effects of the androgen when it is administered as a 1000 mg initial loading dose, followed by 500 mg at four-week intervals, in 1000 men. Recruitment of subjects has been initiated.

**Androgen/progestin combination**

A Phase II trial to evaluate the suppression of spermatogenesis following administration of the androgen/progestin combination, TU + DMPA, to Indonesian men is nearly complete. The study compares the efficacy of the administration of 500 mg TU at six-week intervals with that of a regimen of 500 mg TU injected at six-week intervals + 250 mg DMPA.

Research on the development of methods of fertility regulation
administered at 12-week intervals. Preliminary results indicate that the addition of DMPA to the androgen suppresses sperm concentrations more quickly and completely to a level of infertility in this population (Figure 1.3).

The initiation of a multicentre Phase II/III trial of TU combined with the progestin norethisterone enantate (NET-EN) was delayed due to the nonavailability of the study compounds. Negotiations with the manufacturer are ongoing and the trial may begin in 2002. The study will be funded and conducted in collaboration with the CONRAD Program.

**Behavioural and social science research**

In association with the clinical trial of the TU + DMPA regimen, a study to assess users’ perspectives and acceptability of use of the study compounds is being conducted. Instruments were developed to assess acceptability of the study products and any changes in behaviour or sexual function as reported by the study participants or their partners. Data available to date indicate that the participants and their wives find the regimens to be acceptable. One-third of the volunteers had participated in a trial of a male hormonal contraceptive 10 years earlier; these men were interested in learning their current health status. Other men expressed a desire to relieve their partners of the responsibility for family planning. While men did report pain at the injection site, they described it as being short-lived. Many men reported increased sexual activity and energy levels following trial initiation. Data analysis will be completed in 2002.

The Programme is also supporting studies on users’ perspectives of the TU + NET-EN regimen in Italy. Preliminary results indicate that the administration of the hormonal combination according to any of the tested doses or intervals does not negatively affect mood or sexual behaviour. Study recruitment and data analysis will be completed in 2002.

**New projects initiated during 2001**

Based on the positive and encouraging effects of the administration of TU + DMPA on the suppression of spermatogenesis (described above), an expansion of this trial—intended to simplify the injection regimen, lengthen the interval between the injections, and determine the lowest effective doses of both TU and DMPA—was designed for implementation at sites in China, India and Indonesia. The regimens to be tested are: (i) 500 mg TU + 150 mg DMPA administered at eight-week intervals; and (ii) 500 mg TU + 250 mg DMPA administered at eight-week intervals. The protocol has been approved and the trial is expected to begin in the Indonesian centres in early 2002.

**BASIC SCIENCE LEADS TOWARD THE DEVELOPMENT OF NOVEL APPROACHES TO MALE FERTILITY REGULATION**

**Specific objectives of research**

As a complement to the clinical research related to the regulation of male fertility, the Programme supports innovative, goal-oriented basic research on male physiology related to spermatogenesis and spermiogenesis. Potential research targets include the identification, characterization and manipulation of developmental events such as acrosome and flagellar formation, the expression and function of sperm-specific proteins, and specific intracellular pathways or events required for sperm function. Investigators are encouraged to focus on the unique aspects of their research that have implications for male contraceptive development.

**Progress**

**Delivery of antibodies to the male reproductive ducts to achieve immunocontraception**

This study seeks to determine whether a sufficient titre of antibody can be delivered to the lumen of the male reproduc-

![Figure 1.3. Sperm concentrations in Indonesian men during the course of administration of either 500 mg TU at 6-week intervals (TU alone) or 500 mg TU at 6-week intervals + 250 mg DMPA at 12-week intervals (TU + DMPA)]
tive ducts to saturate a target antigen, in order to achieve immunocontraception. Initial results obtained using tetanus toxin as an antigen indicated that immunoglobulin G (IgG) and immunoglobulin A (IgA) do enter the rete testes and prostatic fluids of the mouse and rat; however, the concentrations delivered are relatively low, depend on the route of immunization, and vary between animal species. The investigators immunized animals using a recombinant antigen previously shown to be important for the fertility of the guinea pig, PH-20. No antifertility effects were observed when either male or female mice or rabbits were immunized. Whether sufficient antibody can access the male reproductive tract to effect immunocontraception remains unconfirmed.

Inhibition of sperm–zona pellucida binding in humans by gonadotrophin-releasing hormone (GnRH) antagonists

The results of this study have demonstrated that the inhibitory effect of GnRH antagonists on sperm–zona pellucida binding is achieved via a reduction in the number of sperm that bind to the zona, and not to the pattern of sperm movement, frequency of sperm–zona collisions, or the number or quality of acrosome-reacted spermatozoa. These data suggest that the antagonists may somehow inhibit zona receptors on the sperm plasma membrane and that, therefore, the endogenous ligand may be involved in the recognition of the zona. Additional experiments demonstrated that several distinct transcripts for the GnRH receptor are present in rat and mouse testicular germ cells, indicating that GnRH or a GnRH-like peptide does normally act on these cells. Fertilization was significantly reduced in female rats treated with GnRH antagonists; in vitro, oocytes that were incubated with sperm and GnRH antagonists were less likely to be fertilized than controls incubated with sperm alone. A follow-on proposal, focusing on the further identification and characterization of the sperm GnRH receptor, has been solicited.

Investigation of the possible presence of the progesterone receptor isoform C at the level of the human sperm plasma membrane

The main objective of this study has been to characterize and clone a sperm membrane progesterone receptor. The investigators have extracted RNA from selected human spermatozoa, and have performed reverse transcriptase polymerase chain reaction (RT-PCR) on these samples using oligonucleotides designed from different regions of the human progestosterone receptor RNA sequence. Evidence to date seems to exclude the possibility that a DNA transcript corresponding to the specific membrane progesterone receptor is present in human sperm; the investigators have hypothesized that post-transcriptional or post-translational modifications of the genomic receptor may occur. In order to establish the novelty of the receptor, additional funding will be provided to repeat the work on protein purification and sequencing, as the small amount of protein used in the initial studies makes the interpretation of results difficult. Additional support will be considered in the event that a novel protein is identified.

New projects initiated during 2001

Thirteen outline proposals were received in response to the second announcement inviting proposals on basic science research that leads towards male fertility regulation. Following an initial review by the Subcommittee to Review Male Basic Science Research Proposals, ten investigators were invited to submit full proposals for peer review. At a meeting held in July 2001, the Committee recommended funding of three of these proposals; the Scientific and Ethical Review Group (SERG) endorsed this recommendation.

Antispermatogenic effects of luteinizing and thyroid hormones

The co-administration of luteinizing hormone and thyroxine seems to restore testosterone synthesis in aged Brown Norway rats; at the same time, this regime arrests spermatogenesis prior to the round and elongated spermatid stage. The objectives of the proposed research are to demonstrate the reproducibility of this antispermatogenic phenomenon in a more traditional and relevant animal model (three-month-old Sprague Dawley rats), and to provide preliminary data on the mechanism of such a response.

The prostasome as a potential new target for fertility regulation in men

Prostasomes are secreted by the prostate gland and adhere and fuse to sperm cells. Infertile men with antisperm antibodies all have antibodies to prostasomes and these antibodies appear to have an agglutinating effect on sperm in vitro. The goal of the proposed research is to identify and sequence individual prostasome proteins, in the hope that one or more may be specific to the male reproductive tract and be a suitable target for a contraceptive approach. In the first year of funding, the objectives will focus on the identification of prostasome proteins which are detected by sperm-agglutinating autoantibodies in sera from immunologically infertile men and the definition of some of the specific prostasome gene sequences which produce the proteins against which the human autoantibodies are produced.

Human sperm mitogen-activated protein kinase (MAPK) cascades and their role in sperm functions

Natural and potential sperm ligands are being used to investigate the presence and role of a series of kinases in ligand-stimulated human sperm function. This work is particularly interesting given the preliminary data obtained on a novel kinase in progesterin-stimulated sperm. Milestones to be achieved in the first year of work include the identification of novel sperm MAPK which are activated by known sperm ligands and confirmation that the proteins are indeed sperm-specific; the cloning and microsequencing of novel MAPK; and the demonstration of a role for MAPK in human sperm flagellar motility and acrosome reaction.
Annex 1a

RESEARCH GROUP ON POST-OVULATORY METHODS FOR FERTILITY REGULATION IN 2001

Members

György Bártfai, Albert Szent-Györgyi Medical University, Szeged, Hungary
Cheng Linan, Shanghai Institute of Family Planning Technical Instruction, Shanghai, China
Luigi Devoto, University of Chile, Santiago, Chile
Kristina Gemzell-Danielsson, Karolinska Hospital, Stockholm, Sweden
Ho Pak-Chung, University of Hong Kong, Hong Kong Special Administrative Region of China (Chairman)
Jayasree Sengupta, All India Institute of Medical Sciences, New Delhi, India

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>Members</td>
<td>4</td>
<td>67</td>
<td>1</td>
</tr>
<tr>
<td>Women</td>
<td>2</td>
<td>33</td>
<td></td>
</tr>
</tbody>
</table>

from:

AFRO 1 17
AMRO 17
EMRO 1 17
EURO 1 17
SEARO 1 17
WPRO 2 33

Collaborating agency scientists

David Grimes, Family Health International, Research Triangle Park, NC, USA
Trent MacKay, National Institute of Child Health and Human Development, Bethesda, MD, USA
Annex 1b

RESEARCH GROUP ON IMMUNOCONETRACEPTIVES IN 2001

Members

John Beale, Cranbrook, Kent, United Kingdom
Marc Bygdeman, Karolinska Hospital, Stockholm, Sweden
Richard Elton, Tuscon, AZ, USA
Warren Jones, Flinders Medical Centre, Adelaide, Australia (Chairman)
Rob Loblay, Clinical Immunology Research Centre, Sydney, Australia
Viveca Odlind, University Hospital, Uppsala, Sweden
Susan Pierce, Northwestern University, Evanston, IL, USA
Faye Schrater, Smith College, Project on Women and Social Change, Northampton, MA, USA
Shobha Sehgal, Postgraduate Institute of Medical Education and Research, Chandigarh, India
Gennadi Sukhikh, International Institute of Biological Medicine, Moscow, Russian Federation

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>Members</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Women</td>
<td>1</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>AFRO</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>AMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td>1</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td>1</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>WPRO</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Collaborating agency scientist

Doug Colvard, Contraceptive Research and Development Program (CONRAD), Arlington, VA, USA
Annex 1c

RESEARCH GROUP ON METHODS FOR THE REGULATION OF MALE FERTILITY IN 2001

Members

Richard Anderson, MRC Human Reproductive Sciences Unit, Edinburgh, United Kingdom
Kiagus Arsyad, Sriwijaya University, Palembang, Indonesia
Hermann Behre, Martin Luther University, Halle, Germany
William Bremer, University of Washington, Seattle, WA, USA
Gu Yi-qun, National Research Institute for Family Planning, Beijing, China
Ilpo Huhtaniemi, University of Turku, Turku, Finland
Peter Liu, Concord Hospital, Concord, Australia
Robert McLachlan, Prince Henry’s Institute of Medical Research, Clayton, Victoria, Australia
Maria Cristina Meriggiola, University of Bologna, Bologna, Italy
Nukman Moeloek, University of Indonesia, Jakarta, Indonesia
Eberhard Nieschlag, Institute for Reproductive Medicine, Münster, Germany
Somnath Roy, National Institute of Health and Family Welfare, New Delhi, India
Lynette Sigola, University of Zimbabwe, Harare, Zimbabwe
Sigrid von Eckardstein, Institute for Reproductive Medicine, Münster, Germany
Christina Wang, Harbor-University of California at Los Angeles Medical Center, Torrance, CA, USA (Chairwoman)
Frederick Wu, University of Manchester, Manchester, United Kingdom

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number % of total</td>
<td>Number % of total</td>
<td>Number % of total</td>
<td></td>
</tr>
<tr>
<td>Members</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 31</td>
<td>11 69</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 6</td>
<td>3 19</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

from:

| AFRO     | 1 6 |
| AMRO     | 2 13 2 |
| EMRO     | 7 44 7 |
| SEARO    | 3 19 |
| WPRO     | 1 6 |

Sub-Committee members for the Review of Male Basic Science Research

Stella Campo, Endocrinology Research Centre (CEDIE), Buenos Aires, Argentina
Patricia Cuasnicu, Institute of Biology and Experimental Medicine, Buenos Aires, Argentina
Anton Grootegeest, Erasmus University Rotterdam, Rotterdam, the Netherlands
David Hamilton, University of Minnesota Medical School, Minneapolis, MN, USA
Norman Hecht, University of Pennsylvania, Philadelphia, PA, USA
Ilpo Huhtaniemi, University of Turku, Turku, Finland (Chairman)

Collaborating agency scientists

Mark Barone, EngenderHealth, New York, NY, USA
Douglas Colvard, Contraceptive Research and Development Program (CONRAD), Arlington, VA, USA
Henry Gabelnick, Contraceptive Research and Development Program (CONRAD), Arlington, VA, USA
Amy Pollack, EngenderHealth, New York, NY, USA
Robert Spirtas, National Institute of Child Health and Human Development, Bethesda, MD, USA
Jeffrey Spieler, United States Agency for International Development, Washington, DC, USA
Annex 1d

WHO/ROCKEFELLER FOUNDATION INITIATIVE ON IMPLANTATION RESEARCH IN 2001

Members

Ruben Gonzalez, Boston Biomedical Research Institute, Watertown, MA, USA
Michael Harper, The Consortium for Industrial Collaboration in Contraceptive Research (CICCR), Arlington, VA, USA
Hideharu Kanzaki, Kansai Medical University, Osaka, Japan
Stephen Killick, The Princess Royal Hospital, Hull, United Kingdom
John White, Hammersmith Hospital, London, United Kingdom

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>Members</td>
<td>5</td>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>2</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td>2</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td>1</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Collaborating agency scientists

Mahmoud Fathalla, The Rockefeller Foundation, Assiut, Egypt
Evelyn Majidi, The Rockefeller Foundation, New York, NY, USA
Annex 2a

RESEARCH GROUP ON POST-OVULATORY METHODS FOR FERTILITY REGULATION

Scientists in 2001

Principal investigators

Oyunbileg Amindavaa, State Research Centre on Human Reproduction and Maternal and Child Health, Ulaanbaatar, Mongolia
Dan Apter, The Family Federation of Finland, Helsinki, Finland
David Baird, University of Edinburgh, Edinburgh, United Kingdom
György Bártfai, Albert Szent-Györgyi Medical University, Szeged, Hungary
Stan Becker, Johns Hopkins University, Baltimore, MD, USA
Shakuntala Bhatnagar, National Institute of Health and Family Welfare, New Delhi, India
Len Blackwell, Massey University, Palmerston North, New Zealand
James Brown, Royal Women's Hospital, Melbourne, Australia
Henry Burger, Prince Henry's Institute of Medical Research, Melbourne, Australia
Marc Bygdeman, Karolinska Institute, Stockholm, Sweden
Cheng Li-cun, Shanghai Changning Obstetrics and Gynaecology Hospital, Shanghai, China
Cheng Linan, Shanghai Institute of Family Planning Technical Instruction, Shanghai, China
Cheng Wei-yu, Tianjin Municipal Research Institute for Family Planning, Tianjin, China
Magdalena Chu Villanueva, Peru University, Lima, Peru
Horacio Croxatto, Chilean Institute of Reproductive Medicine, Santiago, Chile
Olukayode Dada, Ogun State University Teaching Hospital, Sagamu, Nigeria
Hernan Delgado, Institute of Nutrition of Central America and Panama, Guatemala City, Guatemala
Madeleine de Rosas-Valera, Health & Management Information System, Manila, Philippines
Luigi Devoto, University of Chile, Santiago, Chile
Ding Ju-hong, Jiangsu Family Planning Research Institute, Nanjing, China
Kristina Gemzell-Danielsson, Karolinska Institute, Stockholm, Sweden
Ho Pak Chung, University of Hong Kong, Hong Kong, Special Administrative Region of China
Archil Khomassuridze, Zhordania Institute of Human Reproduction, Tbilisi, Georgia
Rosemary Kirkman, University Hospital of South Manchester, Manchester, United Kingdom
Laszlo Kovacs, Albert Szent-Györgyi Medical University, Szeged, Hungary
Pablo Lavin, University of Chile, Santiago, Chile
Frank Lüdicke, University of Geneva, Geneva, Switzerland
Nicholas Mascie-Taylor, University of Cambridge, Cambridge, United Kingdom
Suneta Mittal, All India Institute of Medical Sciences, New Delhi, India
Ernest Ng, University of Hong Kong, Hong Kong, Special Administrative Region of China
Cora Ngai, University of Hong Kong, Hong Kong, Special Administrative Region of China
Cui Nian, Sichuan Family Planning Research Institute, Chengdu, China
Maria Elena Ortiz, Catholic University of Chile, Santiago, Chile
Alenka Pretnar-Darovec, University Medical Centre, Ljubljana, Slovenia
Song Si, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Chandrika Subasinghe, The Family Planning Association of Sri Lanka, Colombo, Sri Lanka
Kamani Tennekoon, University of Colombo, Colombo, Sri Lanka
Wang Jie-dong, National Research Institute for Family Planning, Beijing, China
Wu Shang-chun, National Research Institute for Family Planning, Beijing, China
## Research on the development of methods of fertility regulation

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>All</td>
<td>24</td>
<td>62</td>
<td>4</td>
</tr>
<tr>
<td>Women</td>
<td>15</td>
<td>38</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>28</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>

### Other scientists

- Bao Gui-xia, Shanghai Changning Obstetrics and Gynaecology Hospital, Shanghai, China
- Maria Condrea, University of Geneva, Geneva, Switzerland
- Fang Pei-yang, Wuxi Maternal and Child Health Hospital, Wuxi, China
- Robert Garfield, University of Texas Medical Branch, Galveston, TX, USA
- Kathy Kennedy, Denver, CO, USA
- Brigette Kramer, University of Geneva, Geneva, Switzerland
- Sunesh Kumar, All India Institute of Medical Sciences, New Delhi, India
- Lena Marions, Karolinska Institute, Stockholm, Sweden
- Shao-Qing Shi, University of Texas Medical Branch, Texas, USA
- Wang Yi-fang, Wuxi Maternal and Child Health Hospital, Wuxi, China
- Wei Fei-ying, Shanghai Changning Obstetrics and Gynaecology Hospital, Shanghai, China
- Wu Er-ruo, National Research Institute for Family Planning, Beijing, China
- Xiao Bilian, National Research Institute for Family Planning, Beijing, China
- Zhu Peng-di, National Research Institute for Family Planning, Beijing, China

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>All</td>
<td>8</td>
<td>57</td>
<td>6</td>
</tr>
<tr>
<td>Women</td>
<td>6</td>
<td>43</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>14</td>
</tr>
</tbody>
</table>

### Other scientists from:

- AFRO: 1
- AMRO: 6
- EMRO: 1
- EURO: 4
- SEARO: 4
- WPRO: 13

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>All</td>
<td>8</td>
<td>57</td>
<td>6</td>
</tr>
<tr>
<td>Women</td>
<td>6</td>
<td>43</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>14</td>
</tr>
</tbody>
</table>

### Other scientists from:

- AFRO: 1
- AMRO: 6
- EMRO: 3
- EURO: 3
- SEARO: 1
- WPRO: 7

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>All</td>
<td>8</td>
<td>57</td>
<td>6</td>
</tr>
<tr>
<td>Women</td>
<td>6</td>
<td>43</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>14</td>
</tr>
</tbody>
</table>

### Other scientists from:

- AFRO: 1
- AMRO: 6
- EMRO: 3
- EURO: 3
- SEARO: 1
- WPRO: 7
Annex 2b

RESEARCH GROUP ON LONG-ACTING SYSTEMIC AGENTS FOR FERTILITY REGULATION

Scientists in 2001

Principal investigators

Hany Abdel-Aleem, Assiut University, Assiut, Egypt
Rim Ben Aissa, Research Centre for Human Reproduction, Tunis, Tunisia
Vivian Brache, PROFAMILIA, Santo Domingo, Dominican Republic
Gu Sujuan, Beijing Municipal Research Institute for Family Planning, Beijing, China
Rebecca Massai, Chilean Institute of Reproductive Medicine (ICMER), Santiago, Chile
Peter Rogers, Monash Medical Centre, Clayton, Australia
Lois Salamonsen, Prince Henry's Institute of Medical Research, Clayton, Australia
Sri Bekt Subakir, University of Indonesia, Jakarta, Indonesia
Julianto Witjaksono, University of Indonesia, Jakarta, Indonesia
Sugito Wonodirekso, University of Indonesia, Jakarta, Indonesia

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All 8</td>
<td>80</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>Women 5</td>
<td>50</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>

from:
AFRO
AMRO 2 | 20 | 2 |
EMRO 2 | 20 | 2 |
EURO
SEARO 3 | 30 | 3 |
WPRO 1 | 10 | 2 | 20 | 3 |

Other scientists

Biran Affandi, University of Indonesia, Jakarta, Indonesia
Frank Alvarez, PROFAMILIA, Santo Domingo, Dominican Republic
Melissa Brasted, Prince Henry's Institute of Medical Research, Clayton, Australia
Horacio Croxatto, Chilean Institute of Reproductive Medicine (ICMER), Santiago, Chile
Kate Curtis, Centers for Disease Control and Prevention, Atlanta, GA, USA
Soledad Diaz, Chilean Institute of Reproductive Medicine (ICMER), Santiago, Chile
Laneta Dorflinger, Family Health International, Research Triangle Park, NC, USA
Lindsay Edouard, United Nations Population Fund, New York, NY, USA
Mawaheb Tawid El-Mouelhy, Cairo Family Planning Association, Cairo, Egypt
Anibal Faundes, CEMICAMP, Campinas, Sao Paolo, Brazil
Ian Fraser, Queen Elizabeth II Research Institute for Mothers and Infants, Sydney, Australia
Henry Gabelnick, Contraceptive Research and Development Program (CONRAD), Arlington, VA, USA
Anna Glasier, Family Planning and Well Woman Services, Edinburgh, United Kingdom
Han Li-Hui, Beijing Hospital of Gynaecology and Obstetrics, Beijing, China
Anita Hardon, University of Amsterdam, Amsterdam, the Netherlands
Martha Hickey, Imperial College School of Medicine, London, United Kingdom
Carlos Huezo, International Planned Parenthood Federation, London, United Kingdom
Rebecca Jones, Prince Henry's Institute of Medical Research, Clayton, Australia
Alex Jordan, U.S. Food and Drug Administration, Rockville, MD, USA
### RESEARCH GROUP ON LONG-ACTING SYSTEMIC AGENTS FOR FERTILITY REGULATION

**Other scientists (continued)**

- Rose Kithinji, Kenyatta National Hospital, Nairobi, Kenya
- Hayet Mansour, Research Centre for Human Reproduction, Tunis, Tunisia
- Marion Marsh, Prince Henry’s Institute of Medical Research, Clayton, Australia
- Tekle-Ab Mekbib, Marie Stopes International, Addis Ababa, Ethiopia
- Olav Meirik, Ave Luis Thayer Ojeda, Santiago, Chile
- Suellen Miller, The Population Council, New York, NY, USA
- Nuriye Ortayli, University of Istanbul, Istanbul, Turkey
- Ida Proemomo, University of Indonesia, Jakarta, Indonesia
- Kathleen Rodgers, University of Southern California, Los Angeles, CA, USA
- Eka Rusdianto, University of Indonesia, Jakarta, Indonesia
- Prasad Shastri, Massachusetts Institute of Technology, Cambridge, MA, USA
- Irving Sivin, The Population Council, New York, NY, USA

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>14</td>
<td>45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>7</td>
<td>23</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>from:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>2</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>5</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td>2</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td>1</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td>3</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>1</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex 2c

RESEARCH GROUP ON IMMUNOCONTRACEPTIVES

Scientists in 2001

Principal investigators

Richard Ascione, Apton Corporation, Woodland, CA, USA
James Hampton, Peninsula Laboratories, San Carlos, CA, USA
Vernon Stevens, Ohio State University, Columbus, OH, USA

Other scientists

Faz Chowdury, Apton Corporation, Loughborough, United Kingdom
Peter Fagan, Quintiles Pharmaceutical Services, Edinburgh, United Kingdom
Frederick Frye, Comparative Medical, Surgical and Pathology Consultation, Davis, CA, USA
Stephen Grimes, Apton Corporation, Woodland, CA, USA
Susan Hagan, Apton Corporation, Loughborough, United Kingdom
Pravin Kaumaya, Ohio State University, Columbus, OH, USA
Dov Michaeli, Apton Corporation, Woodland, CA, USA
John Powell, Ohio State University, Columbus, OH, USA
Peter Rees, Huntingdon Life Sciences, Huntingdon, United Kingdom
Theo de Roij, Apton Corporation, Tervuren, Belgium
Peter White, Nova Laboratories Limited, Leicester, United Kingdom

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
RESEARCH GROUP ON METHODS FOR THE REGULATION OF MALE FERTILITY

Scientists in 2001

**Principal investigators**

Kiagus Arsyad, Sriwijaya University, Palembang, Indonesia  
Gianni Forti, University of Florence, Florence, Italy  
Gong Yaqi, Family Planning Research Institute of Sichuan, Chengdu, China  
Gu Yi-Qun, National Research Institute for Family Planning, Beijing, China  
Russell Jones, The University of Newcastle, New South Wales, Australia  
Chandindrami Handagama, University of Tennessee, Knoxville, TN, USA  
Maria Cristina Meriggiola, University of Bologna, Bologna, Italy  
Nukman Moeloek, University of Indonesia, Jakarta, Indonesia  
Patricio Morales, University of Antofagasta, Antofagasta, Chile  
Zvi Naor, Tel-Aviv University, Ramat Aviv, Israel  
Ove Nilsson, Uppsala University, Uppsala, Sweden  
Anthony Swerdlow, Institute of Cancer Research, Sutton, United Kingdom  
Anthony Tan, University of Indonesia, Jakarta, Indonesia  
Frederick Wu, University of Manchester, Manchester, United Kingdom

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>7</td>
<td>50</td>
<td>7</td>
</tr>
<tr>
<td>Women</td>
<td>1</td>
<td>7</td>
<td>3</td>
</tr>
</tbody>
</table>

**Other scientists**

Elisabetta Baldi, University of Florence, Florence, Italy  
Richard Blye, National Institute of Child Health and Human Development, Bethesda, MD, USA  
James Bootman, Bootman Chemical Safety Ltd., Norfolk, United Kingdom  
Pawan S. Chauhan, Indian Council of Medical Research, Mumbai, India  
Chen Zhen-Wen, National Research Institute for Family Planning, Beijing, China  
Cheng Li-Fa, Henan Family Planning Research Institute, Henan, China  
Antonietta Costantino, S. Orsola Hospital, Bologna, Italy  
Juan Diaz, The Population Council, Campinas, Brazil  
Rosalie Elespuru, U.S. Food and Drug Administration, Rockville, MD, USA  
Yuris Erenpreiss, Family and Sexual Health Center, Riga, Latvia  
Ralph Heywood, The Larches, The Lanes, Huntingdon, United Kingdom  
Peter Kasper, Federal Institute for Drugs and Medical Devices, Bonn, Germany  
George Kass, University of Surrey, Surrey, United Kingdom  
Li Han-Min, Birth-Control Institution, Guizhou, China  
Liang Xiaowei, National Research Institute for Family Planning, Beijing, China  
Michaela Luconi, University of Florence, Florence, Italy
### Section 1 - Promoting family planning

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>13</td>
<td>52</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Women</td>
<td>2</td>
<td>8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*from:*
- AFRO
- AMRO: 1 (4)
- EMRO
- EURO: 1 (4)
- SEARO: 1 (4)
- WPRO: 11 (44)

Peng Lin, Yunnan Family Planning Research Institute, Yunnan, China
Chris Powell, Vernalis Research Limited, Wokingham, United Kingdom
Song Shu-Xiu, Hebei Family Planning Research Institute, Hebei, China
Tong Jian-Sun, Jiangsu Family Planning Institute, Jiangsu, China
Wen Ren-Qian, Family Planning Research Institute, Guangdong, China
Yao Kang-Shou, Zhejiang Institute of Planned Parenthood Research, Zhejiang, China
Kathryn Yount, Emory University, Atlanta, GA, USA
Yu Guobin, Anhui Family Planning Institute, Anhui, China
Zhao Heng, National Research Institute for Family Planning, Beijing, China
Annex 2e

WHO/ROCKEFELLER FOUNDATION INITIATIVE ON IMPLANTATION RESEARCH IN 2001

Scientists

Principal investigators

Peter Kaufmann, University of Aachen, Aachen, Germany
Liu Yi-Xun, State Key Laboratory of Reproductive Biology, Institute of Zoology, Beijing, China
Lois Salamonsen, Prince Henry's Institute of Medical Research, Clayton, Australia
Jayasree Sengupta, All India Institute of Medical Sciences, New Delhi, India
Stephen Smith, The Rosie Maternity Hospital, Cambridge, United Kingdom
Richard Stouffer, Oregon Regional Primate Research Center, Beaverton, OR, USA

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>2</td>
<td>33</td>
<td>4</td>
</tr>
<tr>
<td>Women</td>
<td>1</td>
<td>17</td>
<td>1</td>
</tr>
</tbody>
</table>

from:

AFRO
AMRO
EMRO
EURO
SEARO
WPRO

| | | |
| | 1 | 17 |
| | 2 | 33 |
| | 1 | 17 |
| 1 | 17 | 2 |
Annex 3a

RESEARCH GROUP ON POST-OVULATORY METHODS FOR FERTILITY REGULATION - EMERGENCY CONTRACEPTION

Publications in 2001


Annex 3b

RESEARCH GROUP ON LONG-ACTING SYSTEMIC AGENTS FOR FERTILITY REGULATION

Publications in 2001

Long-acting methods of fertility regulation


Basic research on endometrial bleeding


Hampton AL, Rogers PAW, Affandi B, Salamonsen LA. Expression of the chemokines, monocyte chemotactic protein (MCP)-1 and MCP-2 in endometrium of normal women and Norplant ® users does not support a central role in macrophage infiltration into endometrium. Journal of Reproductive Immunology, 2000, 49:115–132.


Annex 3c

RESEARCH GROUP ON METHODS FOR THE REGULATION OF MALE FERTILITY

Publications in 2001


Annex 3d

RESEARCH GROUP ON NATURAL REGULATION OF FERTILITY

Publications in 2001


Research on users’ perspectives

I.H. Shah, I.K. Warriner, S. Jejeebhoy

INTRODUCTION AND OBJECTIVES

As part of the global effort to achieve improved levels of reproductive health through informed policies, programmes and services, an understanding of men’s and women’s reproductive health needs and preferences as well as the constraints to the use of services has become increasingly important. Perspectives and needs of users are shaped by their interactions with providers, the available reproductive health services and supplies, and their assessment of the dual risks of unwanted pregnancy and sexually transmitted infections (STIs). Their reproductive health behaviour, including contraceptive practice and acceptability of various methods, is also influenced by the quality of the care they receive and the sociocultural context of these services.

The primary focus of the Department’s work in this area is to better understand men’s and women’s reproductive health decision-making, and their needs and perspectives on reproductive health technologies and services. Several projects focus on various aspects of users’ perspectives, some of which are supported under a social science research initiative on quality of care.

RESEARCH ACTIVITIES

Specific objectives of research

Research on users’ perspectives aims to better understand men’s and women’s reproductive health decision-making, and their needs and perspectives on reproductive health technologies and services. Several projects focus on various aspects of users’ perspectives, some of which are supported under a social science research initiative on quality of care.

Progress

Family planning in the era of HIV/AIDS

In a pioneering attempt to assess the interactions between family planning and risk behaviour related to HIV/AIDS, a multicountry research project has been ongoing in six eastern and southern African countries where the HIV epidemic is greatest: Kenya, South Africa, United Republic of Tanzania, Uganda, Zambia and Zimbabwe. The study is designed to address three main objectives: (i) to determine the perspectives of sexually active individuals about the dual risks of STIs (including HIV/AIDS) and unintended pregnancy; (ii) to develop strategies that sexually active individuals would consider appropriate, practical and effective in coping with these risks; and (iii) to explore opportunities for, and constraints to, behavioural change. New findings from South Africa were made available in 2001 and are reported here.

The study was conducted in one urban and one rural site in KwaZulu Natal province. Both sites are relatively impoverished, suffer from poor infrastructure, and high rates of HIV infection have been recorded among women attending
antenatal clinics. The study involved three phases: (i) focus group discussions (FGDs); (ii) a survey of 622 sexually active women 18–35 years of age and 523 sexually active men; and (iii) follow-up in-depth interviews. Findings indicate that respondents are nearly universally knowledgeable about leading contraceptive methods (condoms, oral contraceptives, injectables and female sterilization) and have a favourable attitude toward family planning. The majority of respondents cited condom use as being protective against HIV/AIDS and most were aware that condom use provides dual protection against unwanted pregnancy and HIV/AIDS.

However, despite high levels of awareness of the risks of HIV/AIDS, strong moral condemnation of condom use within stable relationships or monogamous marriages inhibits behavioural change. For example, opposition to condom use was commonly noted in many FGDs.

"Condoms are known. Most of the men don’t want them. They fight with us when we talk about condoms," (rural woman, contraceptive user).

Unlike in five other participating countries, sexual violence and rape were noted in South Africa as major barriers to protection against unwanted pregnancy and STIs.

"AIDS is also a problem because you can try and protect yourself and use a condom but you can get it [AIDS] if somebody rapes you. If a person rapes you, he doesn’t have time for a condom," (urban woman, contraceptive user).

As in many other countries, condom use is associated with promiscuity and is sometimes thought to encourage it. Fatalistic attitudes and misconception about the safety of the condom coupled with the belief that responsible and moral people do not contract AIDS further deepen the chasm between preventive and risky behaviour. Nonetheless, 42% of all respondents reported having ever used a condom and there are signs that dual protection is acceptable to some respondents. Of the 476 men and women who had ever used a condom, 63% reported using the condom in addition to another method of family planning.

In 2001, results from the FGDs and in-depth interviews were synthesized for the six countries (see Box 1.1).

A separate study examined the relationship between women’s status, sexual behaviour, and HIV/AIDS in Cameroon. Little is known about the mechanisms linking a woman’s status to her ability to protect herself from risky sexual behaviour, including HIV infection. The study found that women of higher status were more likely to communicate with their partners and negotiate preventive measures against HIV/AIDS. These findings support the concept of women’s economic and educational advancement as protection against HIV infection through increased ability to negotiate safer sexual behaviours.

Choice, discontinuation and switching of contraceptive

Family planning policy-makers and managers in low-income countries have typically promoted highly effective methods of contraception at the expense of less effective ones, including barrier methods. The advent of the HIV epidemic, together with increasing awareness of the incidence of other STIs and their role as cofactors in HIV transmission, represents a powerful new consideration in the relative priority given to different methods of contraception by family planning providers. Specifically, barrier methods (mainly the male condom) assume new importance because of their dual role in pro-

---

Box 1.1. Summary of common findings from in-depth interviews in Kenya, South Africa, Uganda, United Republic of Tanzania, Zambia and Zimbabwe

- Compared with men, women are less able to protect themselves against HIV/AIDS.
- Gender norms prevent women from gaining control over their own bodies and being able to discuss matters relating to sex with their husbands. Protective behaviour such as requests for condom use, an HIV test, or refusing sex are all fraught with the risk of suspicion, violence, or abandonment.
- There was a general consensus that women could do nothing or, at most, could attempt to suggest condom use/HIV test (with accompanying risks).
- Dual methods would not be usable by the majority of those interviewed.
- Very few respondents approved of using condoms simultaneously with other methods in order to prevent pregnancy and HIV/STIs, and argued that it made no sense to use two methods to prevent pregnancy.

"Using two methods would be a clear indication that we do not trust each other. The fact that we are using condoms shows that one of us is worried about contracting a disease from the other, so one has been unfaithful. If we are using a method to prevent pregnancy, I don’t see any use for the condom," said a Kenyan rural woman.
tecting against unwanted pregnancy and STIs. In the increasing number of countries where HIV has spread into the general heterosexual population, there is a strong public health rationale for vigorous promotion of the condom as a contraceptive method within stable relationships, including marriage.

A study was carried out in collaboration with scientists from the University of London School of Hygiene and Tropical Medicine to reassess the condom as a contraceptive. This study also sought to identify the consequences of more widespread use of this method, in terms of the incidence of unwanted births and future demand for abortion. The paper was presented at the XXIV General Population Conference of the International Union for the Scientific Study of Population (IUSSP) in August 2001, and covered: (i) an examination of worldwide trends in condom use; (ii) characteristics of condom users compared to pill users; (iii) comparison of discontinuation and failure rates with the pill and the condom; and (iv) consequences of failure (e.g. abortion, unwanted births) and events following discontinuation of use for reasons that implied dissatisfaction with the methods. The paper also assessed the probable implications of the potential demand for abortion and the incidence of unwanted births in the future if a widespread shift occurred in contraceptive method choice from highly effective methods such as the pill towards the condom.

Data from 16 countries participating in the Demographic and Health Surveys (DHS) were analysed. Four of the 16 countries are classified by UNAIDS as having generalized HIV epidemics (Dominican Republic, Guatemala, Kenya and Zimbabwe). A further five have concentrated epidemics (Brazil, Colombia, Nicaragua, Paraguay and Peru), while the remaining seven are currently classified as having a low prevalence of HIV. Typically, only 1–6% of all users rely on condoms, the main exceptions being Bangladesh (8%), Colombia (9%), Paraguay (13%) and Turkey (13%). At 12 months of use, condoms are more likely than the pill to be discontinued because of failure or method-related reasons. In addition to failure and desire for a child, the major reasons stated for stopping condom use are familiar: the wish to switch to a more effective method, objections by the husband, and inconvenience.

Adjusting for place of residence, women's level of education, the age and number of living children at the start of use as well as the desire for another child, the relative risk of discontinuation by the 12th month due to failure in using the condom is 70 percentage points higher than in using the pill. On average, in these 16 countries, only 32% of condom use episodes lasted more than 12 months compared with 54% of pill episodes. When set against the public health need for vastly increased condom use in countries with generalized HIV epidemics, these results are disappointing. Not only is the condom a rarely used method in marriage but also one that is abandoned within 12 months by almost two-thirds of married couples. Since desire for a more effective method is a commonly stated reason for discontinuation, it argues in favour of a "double-method" approach to protection: simultaneous use of the condom together with another method such as the pill or an injectable. However, there is little evidence to suggest that this strategy is feasible or attractive in low-income countries. Liberalizing restrictions on abortion and making emergency contraception and safe abortion accessible would, therefore, seem called for, according to the authors.

**Social science research initiative on quality of care**

A research initiative on quality of care was launched in 2000, focusing on supporting research to assess the quality of reproductive health services from the perspectives of clients, potential clients, providers and/or objective standards of care. Additionally, the initiative sought proposals designed to assess the effects of improved service quality on intermediate outcomes (e.g. provider behaviour; client knowledge, satisfaction and behaviour, especially with regard to the continuation of contraceptive use). Research that explores the quality of care in the relatively under-studied areas of reproductive health—for example, maternal health, providers' perspectives, abortion or STI treatment—is especially encouraged.

In some developing countries, family planning providers deny contraceptives to nonmenstruating clients, believing that contraceptives may harm an unrecognized pregnancy. In 2001, a study addressing this barrier to access of contraceptive methods was implemented in Mali and Senegal and find-
ings are expected for the year 2002. The study consists of the implementation of a six-question checklist for providers, using WHO approved criteria for ruling out pregnancy. It will determine whether this simple and safe intervention improves access to family planning services and should be used more widely.

Research on sexual behaviour

The pandemic of HIV/AIDS has brought forth the importance of sexual behaviour. A number of studies supported under the social science research initiatives on “Sexual Behaviour and Reproductive Health” and on the “Role of Men in Reproductive Health” provide insights into the patterns of sexual behaviour and the levels and differentials in high-risk behaviour. However, obtaining reliable and valid data on sexual behaviour remains a major methodological challenge.

A study carried out in Shanghai, China examined the accuracy of the reporting of premarital sexual activity by comparing data from two periods in time. The study investigators asked respondents if they had engaged in premarital sex at the time of application for a marriage license and, again, at the respondent’s home 4–6 weeks later. The results indicate that underreporting rates were higher at the initial visit than at the follow-up. A number of factors may explain the discrepancy, including the possibility that respondents felt freer to acknowledge premarital sex once they were married. Nonetheless, these findings flag the importance of exploring optimal procedures to obtain reliable reporting of sexual behaviour.

New projects initiated during 2001

Quality of care

Two new projects on quality of care selected from 15 submissions, were initiated during 2001.

The area of quality of maternity care is an important focus of research for women in developing countries, particularly in Turkey where maternal and infant health indicators have lagged behind economic development. The study will assess the quality of antenatal and postpartum care in three different types of hospitals providing services to low- and middle-income women in Istanbul. The project will examine indicators of quality of care from providers’ perspectives and clients’ experiences, using several methods to collect data, ranging from in-depth interviews, exit interviews, examination of facility records and individual medical records, and direct observation of provider and client interactions. Findings from the study will provide programme- and policy-makers with data to assist in the development of strategies to strengthen services and improve quality of care.

Providers’ perspectives are frequently overlooked in studies of quality of care. A study will document providers’ attitudes and gain a deeper understanding of how providers’ perspectives on quality of care compare with clients’ views on the same in Egypt, Peru and Uganda. A parallel FRONTIERS study on users’ perspectives is also being implemented in these countries; and findings from the providers’ perspectives study will complement data on clients’ perspectives from the FRONTIERS study. The project will examine the following under-researched areas: providers’ definitions of quality; perceptions of services rendered; perceptions of clients’ view of services rendered; perceptions of clients in general; providers’ motivation; and providers’ perceptions of their work environment.

Study findings will be of assistance for the designing of supervisor training systems in these countries, and will be of relevance in other developing countries. Dissemination of findings and discussion of interventions will be undertaken with, among others, the national ministry of health, local non-governmental organizations, donor agencies and family planning training institutions.

Social science policy research briefs and dissemination of findings

Launched in 1999 by the Programme, the series of Social science research policy briefs continued in 2001. The briefs are intended to highlight the policy relevance and programmatic impact of social science research, and to build the analytical capacity and technical writing skills of in-country investigators through extensive collaboration during the development of this publication. A brief on the role of emergency contraception in reducing the induced abortion rate in Shanghai, China was produced in 2001. It is based on a study that investigated the knowledge, attitudes and acceptability of emergency contraception (anordrin, IUD, levonorgestrel) among women seeking surgical termination of first-trimester pregnancy. Although knowledge of emergency contraception was low, 86% of the respondents would be willing to use emergency contraception and expressed their preference for obtaining it from drugstores. Hypothetically, if these women had used levonorgestrel-only emergency contraception, had been aware of their contraceptive failure and had had access to emergency contraception, 60% of the induced abortions could have been averted.

In 2001, a special issue of the Asia-Pacific Population Journal was devoted entirely to the studies in South Asia supported under a collaborative research initiative by The Ford Foundation, The Rockefeller Foundation and the Special Programme. The issue included 14 papers covering topics such as health-seeking behaviour, maternal health, and users’ perspectives on reproductive health, technologies and services. Copies of the journal were widely distributed among policymakers and other interested parties in South Asia.

TECHNICAL COOPERATION WITH COUNTRIES

Extensive technical cooperation was provided to the project “Improving the Quality of Reproductive Health Care” in China.
This project is central to the Chinese National Comprehensive Programmes undertaken by the State Family Planning Commission. Technical cooperation with other countries entailed assisting, in-country, with the implementation of social science projects or with the revision/publication of manuscripts.
Annex 1

SPECIALIST PANEL FOR SOCIAL SCIENCE AND OPERATIONS RESEARCH ON REPRODUCTIVE HEALTH IN 2001

Members

Kofi Awusabo-Asare, University of Cape Coast, Cape Coast, Ghana (Co-chairman)
Mario Bronfman, National Institute for Public Health, Cuernavaca, Mexico
Sahar el-Tawilla, American University of Cairo, Cairo, Egypt
Aykut Turkiz Gokgol, Willows Foundation, Istanbul, Turkey
Gu Baochang, China Family Planning Association, Beijing, China
Veronica Kaune, John Snow Inc./Mothercare/Bolivia, La Paz, Bolivia
Mike Koenig, Johns Hopkins University, Baltimore, MD, USA (Co-chairman)
Akim Jasper Mturi, University of Natal, Durban, South Africa
Leela Visaria, Institute of Economic Growth, New Delhi, India

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>Members</td>
<td>9</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>5</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

from:

| AFRO     | 2 | 20 |       | 2 |
| AMRO     | 2 | 20 | 1 | 10 | 3 |
| EMRO     | 1 | 10 |       | 1 |
| EURO     | 1 | 10 |       | 1 |
| SEARO    | 2 | 20 |       | 2 |
| WPRO     | 1 | 10 |       | 1 |

Collaborating agency scientists

John B. Casterline, The Population Council, New York, NY, USA
Ondina Fachel Leal, Ford Foundation, Rio de Janeiro, Brazil
Sarah Harbison, US Agency for International Development, Washington, DC, USA
Vasantha Kandiah, United Nations Population Division, New York, NY, USA
John Townsend, The Population Council, Washington, DC, USA
## Annex 2

### SCIENTISTS IN 2001

#### Principal investigators

<table>
<thead>
<tr>
<th>Principal Investigators</th>
<th>Institution and Affiliation</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samina Ali</td>
<td>Maternity and Child Welfare Association of Pakistan, Lahore, Pakistan</td>
<td>Pakistan</td>
</tr>
<tr>
<td>Paul Bakutuwwidi</td>
<td>Centre d’Information Technique et de Recherche pour le Development, Kinshasa, Zaire</td>
<td>Zaire</td>
</tr>
<tr>
<td>Aysen Bulut</td>
<td>University of Istanbul, Istanbul, Turkey</td>
<td>Turkey</td>
</tr>
<tr>
<td>Sandra Cali</td>
<td>Department of Public Health, Marmara University, Istanbul, Turkey</td>
<td>Turkey</td>
</tr>
<tr>
<td>Fatimata Diallo</td>
<td>Cellule de recherche en santé de la reproduction au Mali, Bamako, Mali</td>
<td>Mali</td>
</tr>
<tr>
<td>Thierno Dieng</td>
<td>Centre de formation et de recherche en santé de la reproduction, Dakar, Senegal</td>
<td>Senegal</td>
</tr>
<tr>
<td>Graciela Dominguez</td>
<td>Centro de Estudios de Población, Buenos Aires, Argentina</td>
<td>Argentina</td>
</tr>
<tr>
<td>Maria Garate</td>
<td>Branoe SA, Lima, Peru</td>
<td>Peru</td>
</tr>
<tr>
<td>Monica Gogna</td>
<td>Centro de Estudios de Estado y Sociedad, Buenos Aires, Argentina</td>
<td>Argentina</td>
</tr>
<tr>
<td>Pimonpan Isarabhakdi</td>
<td>Mahidol University, Salaya, Nakorn Prathom, Thailand</td>
<td>Thailand</td>
</tr>
<tr>
<td>Madgalena Kleincaek</td>
<td>Educacion Para el Mejoramiento de la Calidad de Vida, Santiago, Chile</td>
<td>Chile</td>
</tr>
<tr>
<td>Liu Yun-rong</td>
<td>National Research Institute for Family Planning, Beijing, China</td>
<td>China</td>
</tr>
<tr>
<td>Sarah Loza</td>
<td>Social Planning, Analysis and Administration Consultants, Cairo, Egypt</td>
<td>Egypt</td>
</tr>
<tr>
<td>Pranitha Maharaj</td>
<td>University of Natal, Durban, South Africa</td>
<td>South Africa</td>
</tr>
<tr>
<td>Osegbemi Makanjuola</td>
<td>University of Jos, Jos, Nigeria</td>
<td>Nigeria</td>
</tr>
<tr>
<td>Amir Mehryar</td>
<td>Institute for Research in Planning and Development, Tehran, Iran</td>
<td>Iran</td>
</tr>
<tr>
<td>Farid Midhet</td>
<td>The Asia Foundation, Islamabad, Pakistan</td>
<td>Pakistan</td>
</tr>
<tr>
<td>Janet Molzan Turan</td>
<td>University of Istanbul, Istanbul, Turkey</td>
<td>Turkey</td>
</tr>
<tr>
<td>Frank Mugisha</td>
<td>Institute of Public Health, Kampala, Uganda</td>
<td>Uganda</td>
</tr>
<tr>
<td>William Muwava</td>
<td>Union for African Population Studies, Dakar, Senegal</td>
<td>Senegal</td>
</tr>
<tr>
<td>Andrew Mushinge</td>
<td>University of Zambia, Lusaka, Zambia</td>
<td>Zambia</td>
</tr>
<tr>
<td>Peter Mwarogo</td>
<td>Development Communications Support Programme, Nairobi, Kenya</td>
<td>Kenya</td>
</tr>
<tr>
<td>K.A. Narayan</td>
<td>Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry, India</td>
<td>India</td>
</tr>
<tr>
<td>Marilyn Nations</td>
<td>Tropical Institute of Applied Social Medicine, Fortaleza, Brazil</td>
<td>Brazil</td>
</tr>
<tr>
<td>Salif Ndiaye</td>
<td>Recherches-Sud, Dakar, Senegal</td>
<td>Senegal</td>
</tr>
<tr>
<td>Stella Neema</td>
<td>Makerere Institute of Social Research, Kampala, Uganda</td>
<td>Uganda</td>
</tr>
<tr>
<td>Somchai Niruthisard</td>
<td>Chulalongkorn Hospital, Bangkok, Thailand</td>
<td>Thailand</td>
</tr>
<tr>
<td>Silvina Ramos</td>
<td>Centro de Estudios de Estado y Sociedad, Buenos Aires, Argentina</td>
<td>Argentina</td>
</tr>
<tr>
<td>Helen Rees</td>
<td>University of Witwatersand, Beritsha, South Africa</td>
<td>South Africa</td>
</tr>
<tr>
<td>Mburano Rwenge</td>
<td>Institut de Formation et de Recherche Démographique, Yaoundé, Cameroon</td>
<td>Cameroon</td>
</tr>
<tr>
<td>Peter Riwa</td>
<td>Healthscope Tanzania Ltd., Dar-es-Salaam, United Republic of Tanzania</td>
<td>Tanzania</td>
</tr>
<tr>
<td>Alejandro Villa</td>
<td>Centro de Estudios de Estado y Sociedad, Buenos Aires, Argentina</td>
<td>Argentina</td>
</tr>
<tr>
<td>Wei Yuan</td>
<td>Shanghai Institute of Planned Parenthood Research, Shanghai, China</td>
<td>China</td>
</tr>
<tr>
<td>Xiao Yu</td>
<td>Sichuan Family Planning Research Institute, Chengdu, China</td>
<td>China</td>
</tr>
<tr>
<td>Zhao Peng-Fei</td>
<td>Shanghai Institute of Planned Parenthood Research, Shanghai, China</td>
<td>China</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>36</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>17</td>
<td>47</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>from:</th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>15</td>
<td>42</td>
</tr>
<tr>
<td>AMRO</td>
<td>7</td>
<td>19</td>
</tr>
<tr>
<td>EMRO</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>EURO</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>SEARO</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>WPRO</td>
<td>4</td>
<td>11</td>
</tr>
</tbody>
</table>

### Developing countries

- Number: 36
- % of total: 100

### Countries in transition

- Number: 17
- % of total: 47

### Developed countries

- Number: 17
- % of total: 47

- Number: 36
- % of total: 100

### Totals

- Number: 36
- % of total: 100
Annex 3

PUBLICATIONS IN 2001


Zhao P, Liu S, Qian H. Improving quality of service at public STI clinics is key to promoting correct care-seeking behaviour, safer sexual activity and condom use. *Sexually Transmitted Diseases* (in press).
Research on the safety and effectiveness of contraceptives

T.M.M. Farley, P.J. Rowe

INTRODUCTION

Most of the information on the safety and clinical performance of methods of fertility regulation is generated in developed countries and it may not be appropriate to extrapolate it to developing countries. The health and social situations are very different and there may be interactions with endemic conditions not seen in the developed countries. To address these issues, the Department carries out research on the safety and performance of methods of fertility regulation in developing countries. Clinical trials leading to product registration are conducted under ideal conditions with carefully screened and monitored volunteers. These may not reflect actual conditions when the products are made available to a wider population of users. Therefore, observational epidemiological methods must be used to study the safety and effectiveness under actual conditions of use. This evidence forms the basis for the development and promotion of norms, guidelines and training materials for the use of different methods of fertility regulation and for the development of high-quality family planning services. Progress in those areas is summarized in the section on “Promoting family planning norms and tools”.

OBJECTIVES

The overall objectives of the work on the safety and efficacy of existing methods of fertility regulation are: (i) to collect evidence on the safety and effectiveness of different methods of contraception among women and men in developing countries; and (ii) to address unanswered questions on a priority basis on existing methods of fertility regulation when used in developing countries.

RESEARCH ACTIVITIES

Progress

Prostate cancer and vasectomy

Studies from the USA in the late 1980s and early 1990s on the potentially increased risk of prostate cancer in vasectomized men, raised questions about the long-term safety of the procedure. The Programme sponsored a multinational research project to assess whether there was any evidence for an increased risk of prostate cancer among vasectomized men in three developing countries—China, Nepal and the Republic of Korea.

In collaboration with Family Health International (FHI), the Programme undertook a multicentre, hospital-based, case-control study in these three countries where vasectomy is common. The study involved 353 cases of prostate cancer, of which 294 had histopathologically confirmed cancer, as determined by the study reference pathologist. A total of 879 controls were matched to these cases. The overall risk of prostate cancer was 1.21 (95% Confidence interval [CI] 0.79–1.87) in vasectomized compared with nonvasectomized men. Risk increased with the time since the procedure (0.75 for 10–19 years, 1.21 for 20–29 years and 1.39 for 30 or more years), though the trend was not statistically significant. If there were an increased risk of prostate cancer attributable to vasectomy, the excess mortality would be about 1 additional prostate cancer death per 100 000 vasectomized men (upper 95% confidence limit: 4 additional cases). The final manuscript from this study will be published in 2002.
Family Health International (FHI), the US National Institute of Child Health and Human Development (NICHD) and the Programme jointly funded a national, multicentre, case–control study of prostate cancer and vasectomy, coordinated by the Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand. The main phase of this study was launched in 1997 and data collection has now been completed. The study involved 784 cases of histologically confirmed prostate cancer (stages T2 or above) and 217 with early stage disease (T1) within the age range of 40–74 years. Overall, 26% of the age-matched controls were vasectomized, corresponding to an age-standardized prevalence of 44% (standardized on the age distribution of New Zealand men aged 40–74 years). There was no evidence of any increased risk of prostate cancer with vasectomy. The study report has been submitted for publication.

The results from interviews with the control group of men confirm the high rates of vasectomy reported from the earlier surveys of women in New Zealand. The country has one of the highest rates of vasectomy in the world (Figure 1.5). The majority of men were vasectomized in the 1970s when they were aged between 35 and 44 years of age. Since the country has a large number of men who were vasectomized more than 20 years ago, it is an ideal population in which to study the long-term safety of the procedure.

The reassuring results on the lack of association between prostate cancer and vasectomy from the two studies conducted in different populations confirm the safety of the procedure. Similarly, earlier concerns in the 1980s about a potential increased risk of cardiovascular disease many years following vasectomy were shown to be unfounded.

**Cervical cancer and steroid hormone contraception**

The Programme contributed funds for a pooled analysis of case–control studies of cervical cancer conducted in eight countries in the period 1985–1997 under the umbrella of the International Agency for Research on Cancer (IARC), Lyon, France. These studies used biopsy specimens or cervical exfoliated cells to assess whether the cases or controls were infected with the human papillomavirus (HPV). The key analyses were restricted to cases and control women who were HPV-positive, now known to be necessary for the development of cervical cancer. Women who had used hormonal contraceptives for a period of 5–9 years had a 2.8-fold increased risk of cervical cancer, while women who had used hormonal contraception for 10 or more years had a 4-fold increased risk. These risks are somewhat higher than previous estimates and must be interpreted cautiously, but they are consistent with the body of scientific literature that has persistently shown an excess risk with long-term use of combined oral contraceptives (OCs). It was previously thought that the elevated risk observed in many studies may have been due to residual confounding and inadequate adjustment for behavioural factors, but restricting the analysis to HPV-positive cases and controls should minimize such an effect. One limitation of the studies included in the pooled analysis was that they collected no information on the exact type of hormonal contraceptive used. For example, the authors were not able to distinguish between combined OCs and progestogen-only oral or injectable contraceptives. Since depot-medroxyprogesterone acetate (DMPA) has not been shown to be associated with an increased risk of cervical cancer, the estimates given may have underestimated the true effect among HPV-positive women. However, the results based on all cases and controls showed a 1.9-fold increased risk for long-term hormonal contraceptive users, after adjustment for HPV status, a result which is more consistent with previous studies.

It has been known for many years that long-term combined OC users are at higher risk of cervical cancer, but whether this increased risk is biological or behavioural, or both, has been uncertain, as has the magnitude of the risk. In developed countries, it is possible to carefully monitor women who
have used OCs for long periods; however, where cervical cancer screening and control programmes are inadequate or nonexistent, these results are more worrisome. In March 2002, the Department is convening a consultation to review the available evidence regarding the relationship between hormonal contraceptives, HPV infection and cervical cancer, and will consider the range of risks and cervical cancer incidence rates at which any excess risk becomes a public health concern.

Efficacy of a combined condom and emergency contraception regimen

The effectiveness of male condoms to prevent unwanted pregnancy is high when they are used consistently and correctly, with annual failure rates in the range of 1–2%. However, typical use pregnancy rates are considerably higher (10–20%, depending on the setting), and could potentially be improved by providing ready access to emergency contraception (EC) in the event that a condom was not used or was perceived to have broken or leaked. To study whether providing condom users with EC to take at home as required, investigators in Shanghai and Tianjin, China, conducted a cluster randomized trial between 1997 and 1998 of condom use with and without EC. The purpose of this trial was to study whether condom users should be provided with EC to take at home as required. Volunteers were recruited from different factories and work units and were randomly assigned to two groups: one was provided with condoms alone and the other with condoms plus EC (two 0.75 mg levonorgestrel tablets). Volunteers from the same factory or work unit received the same intervention and all were followed up at monthly intervals for one year.

A total of 1513 women received condoms alone and 1575 the combined condom plus EC regimen. Overall 2942 (95.3%) completed the study, the majority of discontinuations stemming from personal reasons or a desire to change the method. Two women in the combined condom plus EC group stopped because of side-effects. A total of 45 pregnancies occurred, with a 12-month cumulative pregnancy rate of 1.50 (SE 0.32) per 100 women in the combined group and 1.49 (SE 0.33) in the condom alone group. The analysis and interpretation of the data are complicated by the observation that the combined regimen appeared significantly better than the condom alone regimen in one centre and significantly worse in the other. In addition, the cluster randomized design complicates the analysis and computation of standard errors. The methodological questions raised by the design are being addressed together with a group of statisticians in London, and a definitive analysis and interpretation of the results is expected in 2002.

Bone density and progestogen-only contraception

Worldwide, over 30 million women are estimated to be currently using progestogen-only contraceptives, including injectables, implants, vaginal rings, the levonorgestrel-releasing intrauterine device (IUD) and oral preparations. Concerns have been raised that progestogen-only preparations can decrease bone mineral density and thus increase the subsequent risk of osteoporotic fracture. It is unclear whether any decrease noted with the current use of progestogen-only contraception is transient or persists.

Investigators at the Reproductive Health Research Unit, Durban, South Africa are conducting a prospective study of the impact of progestogen-only contraception among women in the age ranges of 15–19 years and 45–49 years. The younger age group covers the period of maximal bone mass acquisition, and any decrease due to progestogen-only contraception may affect the peak bone mass achieved. In the older age group, a transient decrease in bone mass with progestogen-only contraception may result in a woman starting her menopause-related decline in bone mass on an already low bone mineral density.

The study has recruited over 425 women in the 15–19 years age range and 190 women in the 42–49 years age range distributed over four user groups: DMPA, norethisterone enantate (NET-EN), combined OC, and nonhormonal methods. Since most young women in South Africa are given the two-monthly injectable preparation, it was difficult to identify young DMPA users. All women will be followed at six-monthly intervals for five years. The baseline data on bone mineral density (Figure 1.6) show that the younger women are still acquiring bone mass, and their levels are lower than the levels seen in the women aged 42–49 years. None of the women in the younger age group had previously used any hormonal contraceptive method.

HIV and steroid contraception

The Programme is sponsoring a multicentre study in Brazil, Kenya, Thailand and Zimbabwe to assess the impact of different contraceptive methods on the clinical course of HIV infection. Women with HIV infection are invited to participate in an observational cohort study with six-monthly follow-up visits for four years. Study end-points include progression of HIV disease, the incidence of opportunistic infections, and changes in CD4 cell counts. These will be analysed according to the contraceptive methods used.

Recruitment to the study has been slower than expected, partly as a result of the requirement that women have a CD4 count at least 500 cells/mm$^3$ at enrolment, and partly because the study is unable to offer volunteers much care and support for their HIV infection, in particular, antiretroviral therapy. Over 5000 women have been screened for HIV infection and almost 300 enrolled. The majority of volunteers use hormonal contraception (primarily DMPA in Nairobi and combined OCs in Harare); nonhormonal methods are used by less than 20% of the study cohort. Recruitment and follow-up will continue in 2002.
Section 1 - Promoting family planning

Sequelae of induced abortion

To evaluate the impact of a first-trimester induced abortion on the risk of low birth weight and preterm birth in a subsequent pregnancy, a prospective pregnancy-based cohort study was conducted by investigators in Shanghai, China. They recruited a total of 2953 nulliparous pregnant women who came for antenatal care in the first 9 weeks of pregnancy. Of these, 1235 had a history of one and 267 of two or more previous first-trimester induced abortions.

The overall incidence of low birth weight was 1.7%, and was higher in those women with a history of abortion compared with the reference cohort (Table 1.1). After controlling for potential confounders in logistic regression analysis, the relative risks (RR) were 1.7 (95% CI: 0.8–3.3) for low birth weight, 2.0 (95% CI: 0.9–4.7) for term low birth weight and 1.0 (95% CI: 0.6–1.5) for preterm birth following an induced abortion. Birth weight in the abortion cohort was on average 38.5 g higher than in the reference cohort following adjustment for the year of recruitment, occupation, education, age, sex of the infant, maternal body size at recruitment, prior contraceptive use and gestational age. The study shows that previous surgically induced abortion did not significantly increase the risk of low birth weight or preterm birth. The results from this study, which was performed in a population at low risk of adverse pregnancy outcome, may not be applicable to other settings.

To assess the impact of medically induced abortion on subsequent pregnancy outcome, a three-centre study in China enrolled women in early pregnancy with a history of a single mifepristone-induced abortion (index cases) and compared them with a similar group of women with a history of a single surgically induced abortion, as well as a group of primigravid women.

A total of 14 656 pregnant women were recruited from Beijing (34.8%), Chengdu (32.4%) and Shanghai (33.6%). All were recruited within the first 16 weeks of pregnancy, and had three follow-up interviews at 28–30 weeks of pregnancy, at delivery and between 4 and 6 weeks after delivery. Altogether 118 women (0.8%) were lost to follow-up (70 before, and 48 after 28 weeks), 359 had a spontaneous and 94 an induced abortion, and there was one hydatidiform mole. Among those women followed up beyond 28 weeks, there was a total of 505 preterm deliveries (3.6%). The rate was slightly lower in those women with a history of medically induced abortion, with an RR of 0.76 (95% CI: 0.61–0.96) compared with women with no history of abortion. The RR remained unchanged after adjustment for demographic characteristics of the women. There was no difference between those with a history of medically or surgically induced abortion (RR 0.94 [0.73–1.19]). Among the term deliveries, only 135 had a birth weight below 2500 g with a similar incidence in the three study groups (Table 1.2).

Table 1.1. Outcome of pregnancy following medically or surgically induced abortion (Che et al., Obstetrics and Gynecology, 2001, 21:270)

<table>
<thead>
<tr>
<th></th>
<th>Reference cohort (no abortion)</th>
<th>Abortion cohort</th>
<th>Both cohorts combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean birth weight (kg)</td>
<td>3.335</td>
<td>3.371</td>
<td>3.353</td>
</tr>
<tr>
<td>Low birth weight (&lt;2.5 kg (%)</td>
<td>1.4</td>
<td>2.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Pre-term delivery (&lt;259 days) (%)</td>
<td>3.2</td>
<td>3.5</td>
<td>3.4</td>
</tr>
<tr>
<td>Term low birth weight (&lt;2.5 kg and ≥259 days) (%)</td>
<td>0.7</td>
<td>1.1</td>
<td>0.9</td>
</tr>
<tr>
<td>Sex of the infant (% of boys)</td>
<td>54.2</td>
<td>52.9</td>
<td>53.6</td>
</tr>
</tbody>
</table>

Figure 1.6. Bone mineral density among women in South Africa (baseline)
This study confirms the excellent outcome of pregnancy among women in China observed in previous studies and demonstrates no adverse effects of previous medical or surgical abortion on the course or outcome of a subsequent pregnancy. The final results from the study are being written up for publication in an international journal. The wealth of data collected in the study on the course and outcome of pregnancy in primiparous women will be further analysed.

**Long-term safety and effectiveness of intrauterine devices**

Up to 160 million women worldwide use IUDs as their preferred method of family planning. IUDs have the advantage of being long-acting and relatively easy to remove, with a rapid return of fertility upon removal. The demonstration of their long-term safety and efficacy is an important aspect of the work of the Programme.

The long-term follow-up of cohorts of women using the copper-releasing TCu380A device continued. In the period 1989–1998, a total of 5953 women had this device inserted as part of Programme-sponsored randomized trials comparing the safety and effectiveness of different devices. The majority of the insertions took place in the period 1990–1991. The first large cohort of users completed 10 years of use at the end of 2001, and over 500 are expected to complete 12 years of use by the end of 2002. The Programme will continue to follow users up to 15 years from insertion, thus providing unique information on long-term contraceptive safety and efficacy of this device. Previous data from the Programme’s research have been used to progressively extend the approved lifespan of the device from the initial three to ten years.

The randomized comparative study of the TCu380A and the Multiload (ML) 375 copper-releasing device started in the early 1990s, and the interim 10-year results are shown in Table 1.3. Both devices are highly effective in preventing pregnancy and have similar overall continuation rates. However, the intrauterine pregnancy rate with the TCu380A is about half the rate of the ML 375 device at all times since insertion (Figure 1.7). There were few ectopic pregnancies, none of which occurred beyond the fifth year of use.

Interim six-year data on the clinical performance of the 20 µg/day levonorgestrel-releasing IUD (Mirena) compared with the TCu380A device were presented in the *Annual technical report 2000*. The levonorgestrel-releasing device had high rates of device removal for menstrual-related reasons, in particular amenorrhoea. The overall continuation rate at six years was 42.7% for the levonorgestrel device and 68.5% for the TCu380A. These rates were based on only a small number of women completing six years of use, and will be updated in early 2002.

**New projects initiated during 2001**

**Randomized trial of two implantable contraceptives for women**

The most extensive data on the safety and effectiveness of implantable contraceptives refer to the six-capsule levonorgestrel-releasing Norplant device. There have been reports of difficult and time-consuming removals of the device, and implants with fewer units have been developed and are likely to replace Norplant. While the two-rod five-year levonorgestrel-releasing Jadelle has been compared with Norplant in a moderately-sized multinational study, and the single-rod etonorgestrel-releasing Implanon with Norplant in a single-country study, there have been no formal comparisons between Jadelle and Implanon. This was identified as a high research priority by the technical consultation convened to review the available data on the safety and effectiveness of implantable contraceptives (see below).

The Programme has designed a multinational randomized comparative trial of Jadelle and Implanon to be implemented in 8–10 centres, of which 7 or 8 will be in developing countries. The primary objectives are to compare the clinical performance of the devices in terms of contraceptive efficacy and assess their acceptability as reflected in the method continuation rates and reasons for discontinuation. The impact on vaginal bleeding patterns, common adverse effects and

<table>
<thead>
<tr>
<th>Number of women</th>
<th>Medically induced abortion</th>
<th>Surgically induced abortion</th>
<th>No history of abortion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss to follow-up (%)</td>
<td>0.97</td>
<td>0.61</td>
<td>0.83</td>
</tr>
<tr>
<td>Pre-term delivery (%)</td>
<td>2.85</td>
<td>3.69</td>
<td>3.04</td>
</tr>
<tr>
<td>Low birth weight [&lt;2.5 kg] (%)</td>
<td>0.98</td>
<td>1.19</td>
<td>0.94</td>
</tr>
<tr>
<td>Birth weight (kg) Mean (SD)</td>
<td>3.341 (0.414)</td>
<td>3.376 (0.412)</td>
<td>3.384 (0.419)</td>
</tr>
</tbody>
</table>
any difficulties of insertion or removal will be assessed. A total of 1000 women will be randomly allocated to each device and followed up for three years, the approved lifespan of Implanon. Since the two devices have different periods of efficacy, all women randomized to Implanon will be given the option of a new implant (either Implanon or Jadelle) at the end of three years.

The Post-Marketing Surveillance of Norplant study published in 2001 showed that there were some differences in the incidence of minor health problems among the Norplant users compared with controls (users of nonhormonal IUDs or sterilization). While a randomized trial of the two implants will demonstrate whether there are any clinical differences between the devices, it will be important to place these differences...
in context. An equal number of IUD users will, therefore, be enrolled and followed up in each site as a concurrent non-hormonal control group. The study is expected to start enrolment in mid-2002 with follow-up completed by end 2005.

**Effectiveness of female condoms**

The female condom provides protection against pregnancy as well as sexually transmitted infections (STIs). It can be used either as a main method of pregnancy and STI prevention, or as a back-up when a woman’s partner refuses to use a male condom. The information on the effectiveness of the female condom in preventing pregnancy is based on three studies, one conducted in the USA and Latin America, one in the United Kingdom and one in Japan. None of the studies included a comparison group of women using a different contraceptive method.

In order to generate more information on the efficacy of the female condom as a contraceptive, the Programme has initiated a multicentre comparative study in China, Nigeria and South Africa. Women attending family planning clinics who intend to use male condoms as their main contraceptive method are informed about the female condom and invited to participate in the follow-up study. An age-matched group of male condom users are enrolled as a control group, and all women are followed at monthly intervals for six months. In 2001, the study instruments and procedures were prepared, pilot-tested in the three sites, and finalized after the pilot test. The main phase of the study will start in early 2002, and, following a small pilot study to assess how best to recruit and retain volunteers, a fourth site in Panama may be included. The female condom has not previously been introduced in Panama, necessitating the adaptation of training materials developed in other countries.

This study is complementary to the research to assess the effectiveness of the female condom in preventing STIs (see the chapter on “Reproductive tract infections and sexually transmitted infections”).

**Safety of female condom reuse**

In June 2000, the Department, in partnership with UNAIDS, convened a consultation on the possibility of the safe reuse of female condoms. The polyurethane device is very strong but expensive and there have been reports of a limited amount of reuse by some women in South Africa. Investigators from the Reproductive Health Research Unit developed a protocol of washing, drying and relubricating the female condom and reported successful reuse in up to 50 female sex workers.

The consultation strongly recommended that used condoms should be disinfected before washing in order to protect the user from further exposure to pathogens. However, the consultation was unable to make any recommendation regarding reuse until further information was available on the effect of bleach disinfection on the female condom, and the minimum amount of bleach required to disinfect used condoms. The Programme sponsored two series of studies, one on the structural integrity of female condoms subjected to repeated cycles of disinfecting, washing, drying and lubrication, and another on the necessary concentration and duration of soak to kill gonococci, chlamydia and HIV that might be found on the condoms after intercourse.

The first series of experiments was completed in 2000 and demonstrated that female condoms could withstand seven cycles of chemical and physical challenge with minimal loss of structural integrity. However, the condoms were more likely to have holes than fresh ones, most probably caused by repeat handling. The second series of experiments on disinfection of condoms was conducted in the National Reference Centre for Sexually Transmitted Diseases, Johannesburg, South Africa and the new results will be considered at a consultation in January 2002.

**NORMS AND TOOLS**

**Specific objectives/targets**

The work on the development and dissemination of norms and tools is reported in another chapter on “Promoting family planning norms and tools”, but some specific activities undertaken under the umbrella of the work on safety and effectiveness of contraceptive methods are reported here. These include reviews on the safety and effectiveness of implantable contraceptive methods, a review of the safety of the spermicide nonoxynol-9, and a methodological issue regarding the analysis and presentation of results from contraceptive trials.

**New norms/tools developed**

**Consultation on implantable contraceptives for women**

The first scientific publication on a progestogen-releasing contraceptive implant for women was published in 1969. The first implant, Norplant, was approved in 1983 by the Finnish drug regulatory authority, and several other implants have been approved since that date. Altogether over 60 countries have registered implants for female contraception and they have been used by an estimated 11 million women worldwide.

In view of the increasing importance of implants for women, a consultation to review the available evidence on their safety and effectiveness was convened by the Programme in May 2001.

There is extensive information on the five-year levonorgestrel-releasing implants Norplant and Jadelle from studies conducted in developed and developing countries, addressing metabolic and clinical outcomes, including adverse effects,
Section 1 - Promoting family planning

Service requirements and users’ perspectives. These data demonstrate the high contraceptive effectiveness of these implants. The data available on levonorgestrel-releasing implants manufactured and approved in China suggest that the clinical performance of these devices is similar to the internationally registered devices, but the data available to the consultation were insufficient for a full safety assessment. Data on the three-year etonorgestrel-releasing implant Implanon are less extensive than for Norplant or Jadelle, but suggest that this implant has a high contraceptive effectiveness and a satisfactory safety profile. Since the safety and effectiveness information about all implants was generated on women who were known to be healthy, there is an urgent need to assess their safety profile among women with pre-existing medical conditions.

Provision of contraceptive implants requires good-quality family planning services, particularly to ensure strictly aseptic insertion and removal of the implants. This requires an adequate number of providers trained in counselling with demonstrated skills for implant insertion and removal. The more recent devices using one or two capsules or rods are easier to insert and remove, thus reducing the risk of complications and associated programme costs.

The background papers prepared for the meeting (listed in Annex 3), together with the summary report, will be published in 2002.

Safety of nonoxynol-9

There is intense work under way to develop a safe and effective microbicide that could be used to protect women against the risk of acquiring HIV infection through vaginal intercourse and the Programme is contributing to this global work (see the chapter on “Reproductive tract infections and sexually transmitted infections”).

The spermicide nonoxynol-9 (N-9) has been used for contraceptive purposes for more than 30 years. It was shown to have virucidal properties in vitro and had the potential to be made rapidly available to women in developing countries, if demonstrably able to provide protection against HIV in women. The Joint United Nations Programme on HIV/AIDS (UNAIDS) sponsored a multicountry randomized double-blind study of a vaginal gel containing 52.5 mg of N-9 compared with a similar vaginal gel not containing N-9 among women at high risk of HIV infection. Preliminary results from the study (van Damme, XIIIth International AIDS Conference, Durban, South Africa, July 2000) showed that the users of the N-9-containing gel had an unexpected 1.5-fold higher risk of HIV infection than those using the comparison gel. This disappointing result signalled the end of N-9 as a potential method to reduce the risk of HIV infection, but also raised questions about the safety of N-9 when used for family planning purposes among women at lower risk of HIV infection than those who were enrolled in the study.

The Programme offered to convene a technical consultation to review all available evidence regarding the risks and benefits of N-9 and the extent of use of the product, and to assess the implications of this information for different types of users (occasional as well as regular users in both high- and low-HIV prevalence settings). The consultation was delayed until October 2001, awaiting the final analysis from the UNAIDS-sponsored study. The final report from the meeting will be published in 2002 and its dissemination coordinated with other agencies concerned with family planning and reproductive health.

The consultation concluded that N-9 containing spermicides provided no protection against HIV infection, nor against other STIs, such as gonorrhoea and chlamydia. Given the possibility that N-9 increases the risk of acquiring HIV infection, it is not advisable to use N-9 for prevention of pregnancy in settings where women are at high risk of HIV. However, a woman known to be at low or no risk of HIV infection could safely use spermicides containing N-9, if this were a woman’s preferred option. It was noted that the contraceptive effectiveness of spermicides was not high compared with other available contraceptive methods. In addition, there was no evidence that N-9 lubricated condoms provided any additional protection over silicone-lubricated condoms against pregnancy or STIs, and the consultation recommended that such condoms not be promoted. The conclusions of the consultation will be incorporated into the recommendations regarding the medical eligibility criteria for access to contraception.

Analysis of competing risks data

The life-table technique is widely used to summarize and present information from prospective studies of contraceptive methods. The technique allows information from participants who have not been followed sufficiently long and are still using their contraceptive method to be incorporated in the analysis. Such “right-censored” observations are typical of most prospective studies where individuals enter the cohort at different times and not all individuals have experienced an end-point (or “failed”) before the analysis can be completed. In a contraceptive trial, the main end-point is the occurrence of involuntary pregnancy, but couples or women stop using or change their contraceptive method for many reasons, either because they no longer need contraception, or because they prefer to change to another method. The rates of, and reasons for, method discontinuation are important factors in the assessment of the performance of a contraceptive method. Since most modern contraceptive methods are highly effective, efficacy is generally not the reason for stopping their use. There are other reasons (perception of safety, convenience of use, etc.) for this, which are of greater importance than efficacy in terms of acceptability and continuation of use of a method. These other reasons are regarded as “competing risk factors” as causes of discontinuation of methods.
There are several well established ways of analysing time-to-event data where an individual is subject to several competing causes for failure. Standard methods of analysis using multiple decrement life-table methods have been adopted since the 1960s. Following theoretical developments in statistical methods, there has been renewed interest in a seldom-used technique of summarizing data—the cumulative incidence rate. In particular, Tai and colleagues (Statistics in Medicine, 2001, 20:3589-3600) used data from a published WHO trial of two IUDs to show how estimated method discontinuation rates based on cumulative incidence were smaller than those based on the more commonly used Kaplan-Meier estimates. The extent of the difference depended in a nonstraightforward way on the rates of discontinuation for other reasons. The authors argued for a wider use of the cumulative incidence in the analysis and presentation of contraceptive trials. The implications for such a recommendation are far reaching—the corpus of data on contraceptive effectiveness, which forms the basis for many policy decisions and recommendations on contraceptive methods, would have to be recalculated using the new technique. The amount of work involved would be enormous and policymakers and users would be very confused. In particular, the cumulative incidence rate is always less than the conventional estimate, and all contraceptive methods would appear to have greater contraceptive efficacy than before.

The Programme sponsored a simulation study of the difference between the two methods of analysis of competing risks data which formed the basis of a discussion of the strengths and weaknesses of the two approaches (Farley et al., Statistics in Medicine, 2001, 20:3601-3610). The conventional estimate (complement of the Kaplan-Meier) corresponds to a hypothetical rate where discontinuations for other reasons did not occur, while the cumulative incidence estimates the rate of discontinuations in the presence of other competing causes. The Kaplan-Meier estimates are more appropriate when estimating the effectiveness of a contraceptive method, but the cumulative incidence may be more appropriate when making programmatic decisions regarding contraceptive methods. It remains to be seen whether clinicians, scientists and policy-makers prefer to remain with the conventional method facilitating comparison with existing data, or whether the cumulative incidence estimate gains in popularity for the presentation of contraceptive studies.
Annex 1

SPECIALIST PANEL FOR EPIDEMIOLOGICAL RESEARCH IN REPRODUCTIVE HEALTH

Members

Maria del Carmen Craviotto, National Institute of Nutrition, Mexico City, Mexico
Valerie Beral, Radcliffe Infirmary, Oxford, United Kingdom
Tsungai Chipato, University of Zimbabwe, Harare, Zimbabwe
Gao Ersheng, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Phil Hannaford, University of Aberdeen, Aberdeen, United Kingdom (Chairman)
David Skegg, University of Otago, Dunedin, New Zealand

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developing countries</td>
<td>3</td>
<td>50</td>
</tr>
<tr>
<td>Women</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Countries in transition</td>
<td>3</td>
<td>50</td>
</tr>
<tr>
<td>Developed countries</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Totals</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members</td>
<td>3</td>
<td>50</td>
</tr>
<tr>
<td>Women</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>AMRO</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td>2</td>
<td>33</td>
</tr>
<tr>
<td>SEARO</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>WPRO</td>
<td>1</td>
<td>17</td>
</tr>
</tbody>
</table>

Collaborating agency scientists

Ann Duerr, Centers for Disease Control and Prevention, Atlanta, GA, USA
Silvia Franceschi, International Agency for Research on Cancer, Lyon, France
Irv Sivin, The Population Council, New York, NY, USA
Jennifer Smith, International Agency for Research on Cancer, Lyon, France
Robert Spirtas, National Institute of Child Health and Human Development, Bethesda, MD, USA
Annex 2

SCIENTISTS IN 2001

Principal investigators

Ahmed Abdennadher, Office National de la Famille et de la Population, Tunis, Tunisia
Eliana Amaral, UNICAMP, Campinas, Brazil
Simon Alexaniants, Armenian Centre of Maternal and Child Health Protection, Yerevan, Armenia
Amaury Andrade, Federal University of Juiz de Fora, Juiz de Fora, Brazil
György Bártfai, Albert Szent-Györgyi Medical University, Szeged, Hungary
Istvan Batár, University Medical School of Debrecen, Debrecen, Hungary
Mags Beksinska, Reproductive Health Research Unit, Durban, South Africa
Cao Xiaoming, Tianjin Municipal Research Institute for Family Planning, Tianjin, China
Chen Zhu ping, Ren Ji Hospital, Shanghai, China
Cheng Yimin, National Research Institute of Family Planning, Beijing, China
Craig Cohen, University of Nairobi Health Science Campus, Nairobi, Kenya
Brian Cox, University of Otago, Dunedin, New Zealand
Oluwakayode Dada, Centre for Research in Reproductive Health, Sagamu, Nigeria
Reinprayoon Damrong, Chulalongkorn Hospital, Bangkok, Thailand
Fan Hui-min, Beijing Obstetrics and Gynaecology Hospital, Beijing, China
Anibal Faundes, Centre for Research and Control of Maternal and Infant Disease, Campinas, Brazil
Glenda Fehler, National Reference Centre for Sexually Transmitted Diseases, Johannesburg, South Africa
Feng Zhuang-chong, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Marie-Louise Hammarsström, Umeå University, Umeå, Sweden
Ho Jialiang, Family Planning Institute of Guangdong, Guangzhou, China
Hong Kang, Xuan Wu Hospital, Beijing, China
Orawan Kiriwat, Siriraj Hospital, Bangkok, Thailand
Pablo Lavín, Hospital Ramon Barros Luco-Trudeau, Santiago, Chile
Liu Xiaozhang, Family Planning Research Institute of Sichuan, Chengdu, China
Luo Lin, Family Planning Research Institute of Sichuan, Chengdu, China
Luo Shi-yuan, Family Planning Research Institute of Sichuan, Chengdu, China
Elsebeth Lynge, Institute of Public Health, University of Copenhagen, Denmark
Alexio Mashu, University of Zimbabwe School of Medicine, Harare, Zimbabwe
Christina Mwachari, Kenya Medical Research Institute, Nairobi, Kenya
Peng Dunren, Tianjin Municipal Research Institute, Tianjin, China
Ernesto Pizarro, Hospital José Joaquin Aguirre, Santiago, Chile
Alenka Pretnar-Darovec, Gynaecological Clinic, Ljubljana, Slovenia
Qian Shao-chen, Jiangsu Family Health Institute, Nanjing, China
Atisook Ronachai, Siriraj Family Health Research Centre, Bangkok, Thailand
Eyra Ruiz, Centro de Investigación en Reproducción Humana, Panama, Panama
Veronica Schiappacasse, Chilean Institute of Reproductive Medicine, Santiago, Chile
Inga Sjöberg, Umeå University, Umeå, Sweden
Jaisamrn Unnop, Chulalongkorn University, Bangkok, Thailand
Patricia Valdes, University of Frontera, Temuco, Chile
Yang Xiulan, International Peace Maternity and Child Health Hospital, Shanghai, China
Wei Yuying, Family Planning Research Institute, Tong-ji Medical University, Wuhan, China
Wu Yu-ming, Peking Union Medical College, Beijing, China
Wu Shangchun, National Research Institute for Family Planning, Beijing, China
Wei Yuan, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Yue Min Zhao, Tianjin Municipal Research Institute for Family Planning, Tianjin, China
Zhang Shaozhen, Xin Hua Hospital, Shanghai, China
Section 1 - Promoting family planning

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>38</td>
<td>83</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Women</td>
<td>20</td>
<td>43</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>6</td>
<td>13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>8</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>SEARO</td>
<td>4</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>19</td>
<td>41</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other scientists

Mohamed Ali, London School of Hygiene and Tropical Medicine, London, United Kingdom
Tsedmaa Baatar, State Research Centre on Maternal and Child Health and Human Reproduction, Ulaanbaatar, Mongolia
Luis Bahamondes, Centre for Research and Control of Maternal and Infant Disease, Campinas, Brazil
Ron Ballard, Centers for Disease Control and Prevention, Atlanta, GA, USA
Emily Banks, Imperial Cancer Research Fund, Oxford, United Kingdom
Queen Cebekhulu, Reproductive Health Research Unit, Durban, South Africa
Limmie Chang, Imperial College of Science, Technology and Medicine, London, United Kingdom
Chen Gui-ying, National Research Institute for Family Planning, Beijing, China
Chen Xiao qin, Family Planning Research Institute of Sichuan, Chengdu, China
Chen Yuan qing, Family Planning Research Institute of Sichuan, Chengdu, China
Patricia Claeyss, International Centre for Reproductive Health, Ghent, Belgium
Cui Nian, Family Planning Research Institute of Sichuan, Chengdu, China
Karen Davis, University of Texas Medical Branch, Galveston, TX, USA.
Ding Ju-hong, Jiangsu Family Health Institute, Nanjing, China
Ding Wan-hua, Jiangsu Family Health Institute, Nanjing, China
Walter Vitor da Fonseca, Institute of Woman and Child Health, Fortaleza, Brazil
Soledad Diaz, Chilean Institute of Reproductive Medicine, Santiago, Chile
Fan Guang-sheng, Peking Union Medical College, Beijing, China
Fan Xin lin, Family Planning Research Institute of Sichuan, Chengdu, China
Fang Hui Ian, Tong-ji Medical University, Wuhan, China
Gan Xian qin, International Peace Maternity and Child Health Hospital, Shanghai, China
Gao Ya jie, Tianjin Municipal Research Institute for Family Planning, Tianjin, China
John Geroff, Enersol Pty Ltd., Annandale, NSW, Australia
Han Li hui, Beijing Obstetrics and Gynaecology Hospital, Beijing, China
Jiang Lin-lin, Ren Ji Hospital, Shanghai, China
Orawan Kiriwat, Siriraj Family Health Research Centre, Bangkok, Thailand
Carlo La Vecchia, Instituto di Ricerche Farmacologiche, Milan, Italy
Li Zhi fang, Family Planning Research Institute of Sichuan, Chengdu, China
Liu Zhong hua, Family Planning Research Institute of Sichuan, Chengdu, China
Györgyi Meszaros, Albert Szent-Györgyi Medical University, Szeged, Hungary
Abdel Malek M’Hamdi, Ariana Centre for Human Reproductive Research, Tunis, Tunisia
Olav Meirik, Chilean Institute of Reproductive Medicine, Santiago, Chile
Ni Ming-hong, Ren Ji Hospital, Shanghai, China
Jorn Olsen, The Danish Epidemiology Science Centre, Aarhus, Denmark
Pan Xin-Ian, Peking Union Medical College, Beijing, China
Mojca Pirc, Gynaecological Clinic, Ljubljana, Slovenia
Mike Pope, The Female Health Company, London, United Kingdom
Bill Potter, Stapleford Scientific Services, Cambridge, United Kingdom
Neil Poulter, Imperial College School of Medicine, London, United Kingdom
Annex 2 (continued)

SCIENTISTS IN 2001

Other scientists (continued)

Mirjana Puksic, Gynaecological Clinic, Ljubljana, Slovenia
Stane Pusenjak, Gynaecological Clinic, Ljubljana, Slovenia
Erdenetungalag Radnaabazar, State Research Centre on Maternal and Child Health and Human Reproduction, Ulaanbaatar, Mongolia
Helen Rees, Chris Hani Baragwanath Hospital, Soweto, South Africa
Primoz Res, Gynaecological Clinic, Ljubljana, Slovenia
James J. Schlesselman, Sylvester Comprehensive Cancer Center, Miami, FL, USA
Alejandra Silva, University of Frontera, Temuco, Chile
Emma Slaymaker, London School of Hygiene and Tropical Medicine, London, United Kingdom
Song Li juan, Tianjin Municipal Research Institute, Tianjin, China
Sun Hong-zhu, National Research Institute for Family Planning, Beijing, China
Tao Jin-Zhang, Jiangsu Family Health Institute, Nanjing, China
Jaisamrarn Unnop, Chulalongkorn Hospital, Bangkok, Thailand
Gail Walker, Sylvester Comprehensive Cancer Center, Miami, FL, USA
Wang Yue-bao, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Weng Li-Ju, Peking Union Medical College, Beijing, China
Wong Hong, Xin Hua Hospital, Shanghai, China
Wu Ming-hu, Beijing Obstetrics and Gynaecology Hospital, Beijing, China
Wu Mu-zhen, Peking Union Medical College, Beijing, China
Wu Shi Zhong, Sichuan Provincial Family Planning Research Institute, Chengdu, China
Wu Yue-zhe, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Xiao Ling, Family Planning Research Institute of Sichuan, Chengdu, China
Xie Li, Family Planning Research Institute of Sichuan, Chengdu, China
Yang Bang yuan, International Peace Maternity and Child Health Hospital, Shanghai, China
Yun Ming-ming, Jiangsu Family Health Institute, Nanjing, China
Yun Ming rong, Family Planning Research Institute of Sichuan, Chengdu, China
Zhang Wen hao, Tianjin Municipal Research Institute, Tianjin, China
Zhao Dan ping, Tianjin Municipal Research Institute, Tianjin, China
Zhu Xia-ling Zhu, Beijing Obstetrics and Gynaecology Hospital, Beijing, China
Zhuang Liu-qi, International Peace Maternity and Child Health Hospital, Shanghai, China

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>Members</td>
<td>47</td>
<td>69</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Women</td>
<td>29</td>
<td>43</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>2</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>5</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td>5</td>
<td>7</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>SEARO</td>
<td>2</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>38</td>
<td>56</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex 3

PUBLICATIONS IN 2001


**Background papers prepared for consultation on implants**


Chikamata D, Miller S. Health services at the clinic level and implantable contraceptives for women. *Contraception* (in press).


Promoting family planning norms and tools

H.B. Peterson, S. Johnson, K. Church

INTRODUCTION

Reproductive and sexual health care, including family planning services and information, is recognized not only as a key intervention for improving health but also as a human right. All individuals have the right to access, choice and the benefits of scientific progress. These rights cannot be guaranteed without the full support of the relevant health services. The quality of care provided greatly influences the use of family planning and reproductive health services generally. However, many family planning programmes have to improve substantially their quality of care. The Department contributes to their efforts by developing evidence-based guidelines and support materials for providers and clients that focus explicitly on ensuring a high quality of accessible, acceptable and affordable family planning services.

OVERALL OBJECTIVE

The overall objective is to create evidence-based guidelines for family planning, using the formal guidelines process being established by WHO, and to encourage providers and health systems to make best practices in family planning an integral part of service delivery. This objective will be achieved through the following:

- establishing the context for norms and tools within a programme of research for promoting family planning;
- creating a system for developing guidelines based on the best available evidence and ensuring that they are kept up-to-date; and
- developing a package of core materials for promoting family planning.

Establishing the context

The context for developing norms and tools in family planning is based on a framework that links the four major goals of the Department in family planning, namely:

- to develop new and improved methods of contraception (including methods for dual protection);
- to evaluate the safety and efficacy of existing methods;
- to assess the sociocultural and behavioural determinants of successful family planning; and
- to translate available evidence into guidelines that are successfully used at country level.

The first three goals are supported by research programmes and the fourth is based on the findings derived from these programmes and other relevant research. Thus, the findings from social sciences research, and from safety and efficacy research feed directly into the evidence base for norms and tools. As new methods are developed and evaluated, safety and efficacy research as well as research on acceptability of the method likewise become part of the evidence base. Further, a feedback loop exists between the guidelines and the research priorities. Key gaps in evidence are identified as available evidence is appraised, synthesized and considered for guidelines and some of these gaps, in turn, become research priorities.

The creation of evidence-based guidelines, while important, is insufficient to ensure the delivery of quality services in family planning. The dissemination, adaptation and utilization of these guidelines is also critical. Thus, the ultimate impact of
guidelines will be contingent on the development of strategies for successfully implementing best practices in family planning. The needs of users at the country level will, in turn, help determine priorities for creating and implementing the guidelines (Figure 1.8).

Creating a system

The Department’s Medical eligibility criteria for contraceptive use and the Selected practice recommendations for contraceptive use are based on evidence and expert consensus. The Department is developing a system for ensuring that the guidelines and the recommendations remain up to date as new evidence comes forth (Figure 1.9). The proposed system would include five steps as follows:

- identify new, relevant evidence through ongoing, comprehensive literature searches;
- determine the quality (and validity) of the evidence;
- determine the originality of the evidence;
- decide whether the new evidence warrants a change in the guidelines and their recommendations; and
- provide electronic updates on the Department’s web site as appropriate, and determine the need to convene an expert working group to formally reassess the guidelines.

Developing a package

The Medical eligibility criteria for contraceptive use and the Selected practice recommendations for contraceptive use are the evidence- and consensus-based foundation of WHO’s family planning guidance. They are intended for policy-makers, family planning programme managers and the scientific community, and aim to assist in the preparation of guidelines for service delivery. The Medical eligibility criteria for contraceptive use provides guidance regarding who can safely use contraceptive methods. The appropriate medical eligibility criteria are determined for women with over 50 conditions. The Selected practice recommendations for contraceptive use provides guidance regarding how to safely and effectively use contraceptive methods. Recommendations include instructions on when and how to start contraceptives and what to do in problem situations.
The Decision-making tool for family planning clients and providers and the Handbook for family planning providers will be derived primarily from the Medical eligibility criteria and the Selected practice recommendations. They are intended to improve the quality of the family planning encounter. The Client and provider materials include training and education aids to support the use of the guidance (Figure 1.10).

The Family and community practices and the Managerial and service delivery resources will be developed to enhance the capacity of the community and the health system to provide quality family planning services. The Client–provider interaction resource will compile best evidence from social science research on how to meet the needs of the family planning client (Figure 1.10).

NEW NORMS AND TOOLS

Medical eligibility criteria for contraceptive use

The document Improving access to quality care in family planning: medical eligibility criteria for contraceptive use was published on the Department’s web site in February 2001 and printed in May 2001. This document updates the first edition, which was published in 1996 following two Scientific Working Group meetings held in Geneva in 1994 and 1995. The 1996 document was an important first step in the process for improving access to high-quality care in family planning by reviewing the medical eligibility criteria for selecting methods of contraception. It has provided guidance to national family planning/reproductive health programmes in the preparation and revision of national medical and service provision guidelines based on the recommendations for initiating and continuing the use of each contraceptive method. Arabic, Chinese, French, Indonesian, Russian, Spanish and Viet Namese versions were printed in 1998–1999. With the help of the United States Agency for International Development (USAID) and other collaborating partners, this document has been used by some 55 countries in the preparation and revision of national service delivery guidelines for family planning. The Department has worked in South Africa and Zambia to facilitate this process.

The 2000 revision of this document summarizes the main recommendations of a Scientific Working Group meeting held in Geneva on 8–10 March 2000. The Working Group brought together 32 participants from 17 countries, including representatives of several agencies and organizations. It reviewed new evidence obtained primarily from a systematic detailed review of the most recent literature contained in the MEDLINE database. The purpose of the review was to identify direct evidence for the appropriateness of contraceptive method use by women with selected conditions. Information on indirect evidence or theoretical considerations was not obtained. Programmatic implications of the classification of the various conditions were also considered by the Working Group.

The revised document covers the following family planning methods: low-dose combined oral contraceptives, combined injectable contraceptives, progestogen-only pills, depot-medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN), Norplant implants I and II, emergency contraceptive pills, copper intrauterine devices (IUDs),
levantorgestrel-releasing IUDs, IUDs for emergency contraception, barrier methods, fertility awareness-based methods, coitus interruptus, lactational amenorrhea method, and female and male sterilization.

**Essential care practice guide for family planning**

The *Essential care practice guides* (ECPGs) are a synthesis of the latest information to define essential interventions that will have the greatest impact on improving reproductive health. The ECPGs are designed to support three technical areas: pregnancy, childbirth and neonatal care; family planning; and prevention of sexually transmitted infections (STIs) and HIV infection.

The target audience for the ECPG for family planning is health workers at the primary level working in facilities with limited resources. This ECPG will describe and facilitate the key elements of the client–provider interaction in the provision of family planning services for adolescents, women and men. Accordingly, this ECPG is entitled *Decision-making tool for family planning clients and providers*. It will be derived from and supported by the *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use*. In addition, the ECPG will be supported by the *Handbook for family planning clients and providers*, training and educational materials for clients and providers, and an adaptation guide.

The primary objective of the ECPG for family planning is to create and facilitate the use of a normative tool that:

- promotes the client's informed choice and role in family planning service delivery;
- enables providers to apply evidence-based best practices in the client–provider interaction during delivery of family planning services;
- provides the technical information necessary for optimal delivery of nonsurgical contraceptive methods; and
- encourages providers and health systems to promote best practices in client–provider interaction as an integral part of service delivery.

The guiding principles to support these objectives are:

- the process for decision-making of family planning is client-driven and interactive;
- the client's needs as expressed by the client are met to the extent possible;
- evidence-based best practices in client–provider communication are used;
- technical information needed for appropriate choice and for safe and effective use of family planning methods is provided;
- the discussion and process are tailored to the needs of the individual client with the provider's statements or actions depending, as much as possible, on the client's previous answer or statement; and
- the client is enabled to express her/his purposes as quickly as possible and the provider to respond appropriately, as quickly as possible.

The ECPG for family planning has, to date, been developed in partnership with INTRAH/PRIME, the Johns Hopkins University (JHU) School of Public Health Population Information Program and the JHU Center for Communication Programs. The general approach of the ECPG was discussed with INTRAH/PRIME regional staff, including trainers and providers, for a preliminary assessment of the usability of the ECPG by this target audience. The response from this group was very positive, and they expressed interest in incorporating the ECPG into their country programmes. The first draft was completed, and reviewed by experts in client–provider interaction for the process component in July 2001. The technical content was then reviewed during an expert working group meeting in October 2001. Pretesting and field-testing of the ECPG will be carried out in 2002.

**Selected practice recommendations for contraceptive use**

The document *Selected practice recommendations for contraceptive use* will be published on the Department's web site and submitted for printing in the first half of 2002. It is one of the two key evidence-based, consensus guidelines produced by the Department for improving the quality of care in family planning service delivery. Whereas its counterpart, the *Medical eligibility criteria for contraceptive use* addresses who can safely and effectively use contraceptive methods, i.e. in identifying the medical appropriateness of contraceptive choices for women with certain medical conditions, the *Selected practice recommendations for contraceptive use* addresses how to safely and effectively use contraceptive methods. Practical guidance is provided on common clinical issues, for example, what should a woman do if she misses a dose of the oral contraceptive pill. Both of these guidelines are developed and revised based on a system that ensures an ongoing review of relevant new evidence. When evidence warrants,
the guidelines are updated electronically but are pending expert working group meetings and subsequent printed revisions.

The Selected practice recommendations for contraceptive use summarizes the main recommendations of a Scientific Working Group meeting held in London, United Kingdom on 3–6 October 2001. The Working Group brought together 33 participants from 16 countries, including representatives of several agencies and organizations. It reviewed new evidence obtained primarily from a systematic detailed review of the most recent literature contained in the MEDLINE database. The purpose of the review was to identify direct evidence to address key common clinical challenges represented by the questions listed below. Information on indirect evidence or theoretical considerations was not obtained. Programmatic implications of the recommendations were also considered by the Working Group. The questions addressed by the Working Group were as follows:

- When can a woman start combined oral contraceptives?
- What can a woman do if she misses a dose of combined oral contraceptives?
- What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives or progestogen-only pills?
- When can a woman start combined injectable contraceptives?
- When can a woman have repeat combined injectable contraceptive injections?
- When can a woman start progestogen-only pills?
- What can a woman do if she misses a dose of progestogen-only pills?
- What can a woman do if she vomits after taking emergency contraceptive pills?
- When can a woman start progestogen-only injectables—DMPA or NET-EN?
- When can a woman have repeat progestogen-only injectables—DMPA or NET-EN?
- What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable—DMPA or NET-EN?
- When can a woman start using an implant?
- What can be done if a woman experiences menstrual abnormalities when using implants?
- When can a woman have repeat progestogen-only injectables—DMPA or NET-EN?
- What can be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease (PID)?
- What should be done if a woman using a copper-bearing IUD is found to be pregnant?
- Should prophylactic antibiotics be used for copper-bearing IUD insertion?
- What can a Standard Days Method user do if she has menstrual cycles outside the 26–32-day range?
- What examinations or tests should be done routinely before providing a method of contraception?
- How many pill packs (combined or progestogen-only pills) should be given at initial and return visits?
- What is the appropriate follow-up for combined oral contraceptive, progestogen-only pill, implant and IUD users?
- How can one be reasonably sure that a woman is not pregnant?
Section 2
Making Pregnancy Safer
Generating new evidence for maternal and perinatal health

J. Villar, M. Gülmezoglu, M. Merialdi, C. Lissner

INTRODUCTION

There is considerable agreement that, although health services could incorporate effective treatments and emergency medical and surgical strategies to reduce maternal and perinatal mortality, many effective interventions remain under-utilized (a gap between evidence and practice). A lack of preventive action for pregnancy-specific conditions remains, particularly the leading causes of severe morbidity and mortality (a gap between preventive and curative care). This is in contradiction to the major progress made in other areas of medicine in the past decade, including related disciplines such as human genetics. The Department’s 1998–2003 programme of work in maternal and newborn health is oriented to providing evidence that will contribute to close these gaps.

The Department’s Scientific and Technical Advisory Group (STAG) identified priority research areas in maternal health taking into account the Department’s comparative advantage. It was felt that the Department has credibility and neutrality at country level and is in a strong position to make an impact through the implementation of evidence-based programmes. The capacity-building effort of the Programme during the past decades has strengthened a network of collaborating institutions in a large number of developing countries. In collaboration with this network, the Programme possesses the skills and resources to conduct high-priority research that is unlikely to be conducted individually by research institutions in developing countries. In 1999 STAG approved a programme of work for maternal health research to be implemented between 1998 and 2003. This is now well

| Table 2.1. Maternal health interventions evaluated during 2001 with leading/active participation of the Programme |
|-----------------|-----------------|-----------------|
| Antenatal care  | 5               | 24,678          |
| Postpartum haemorrhage | 9 | 18,530          |
| Caesarean section* | 5 | 142,000         |
| Treatment of pre-eclampsia** | 31 | 10,000 |
| The WHO Reproductive Health Library evaluation | 2 | 80,000 | Ongoing |
| Prevention of pre-eclampsia | 6 | 8,500 | Ongoing |
| Total | 283,708 |

* in collaboration with WHO Regional Office for the Americas
** being conducted by the UK Medical Research Council, with funding support from the Programme
under way, and all major objectives should be achieved by the end of the six-year period. The Programme has demonstrated its research capacity by implementing this work plan and successfully completing several large multicentre trials evaluating medical and nonmedical maternal health interventions (Table 2.1); some of these trials are definitive trials on the subject. By the time the last trials of this series will be completed, over 280 000 woman/newborn pairs will have been studied over a period of five years. A detailed description of the progress made in each specific area is presented in the following sections.

**SPECIFIC OBJECTIVES OF RESEARCH**

The goal of this programme of work is to reduce maternal morbidity and mortality through the development of acceptable and affordable evidence-based health programmes. Implementation of the maternal health research programme is achieved by: (i) evaluating the effectiveness of practices; (ii) improving the understanding of sociocultural factors influencing maternal health care; (iii) reviewing methodological issues related to maternal health research; (iv) conducting follow-up studies of the populations included in pregnancy-related research; (v) evaluating the implementation strategies of research results; and (vi) stimulating fundamental research on outstanding obstetric problems of global importance. In addition, during 2001, following a rigorous epidemiological methodology, activities were initiated for the preparation of a summary description of the epidemiology of maternal morbidity in developing countries. These data will be compiled in a formal publication and should contribute to the efforts in mapping maternal ill-health and improving service coverage (see Table 2.2).

### Table 2.2. The potential for lowering maternal mortality of interventions reviewed or planned for review by the Programme

<table>
<thead>
<tr>
<th>Cause</th>
<th>Rate in population (%)</th>
<th>Effective intervention(s)</th>
<th>Maternal deaths that would be prevented (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eclampsia</td>
<td>0.7–0.19</td>
<td>Magnesium sulfate</td>
<td>3–8</td>
</tr>
<tr>
<td>Antepartum haemorrhage</td>
<td>1.2</td>
<td>Surgery, intensive care, blood transfusion</td>
<td>14</td>
</tr>
<tr>
<td>Postpartum haemorrhage</td>
<td>2.5–3</td>
<td>Routine uterotonics, removal of placenta, blood transfusion</td>
<td>5–12</td>
</tr>
<tr>
<td>Obstructed labour</td>
<td>15.4*</td>
<td>Assisted delivery, caesarean section</td>
<td>20</td>
</tr>
<tr>
<td>Unsafe abortion</td>
<td>13</td>
<td>Safe abortion</td>
<td>28 (CI 17–39)</td>
</tr>
</tbody>
</table>

*Primiparous women only.

**PROGRESS**

**Evaluating effectiveness of practices**

*The WHO randomized controlled trial for the evaluation of a new antenatal care programme*

The Programme completed this large, multicentre, randomized controlled trial in 1999 in collaboration with four institutions in developing countries (Argentina, Cuba, Saudi Arabia and Thailand). This new antenatal care programme limits the tests, clinical procedures and follow-up actions to those scientifically demonstrated to be effective in improving maternal and newborn outcomes. The selected antenatal care activities for women showing no signs of complications are distributed over four visits during the course of pregnancy. There were 53 antenatal care units (24 678 women) randomly allocated to provide either the new programme of antenatal care or the traditional programme presently in use. The new antenatal care model was found to be as effective as the standard model, could be implemented without major resistance from women and providers, and may also be able to reduce costs.

In 2001, the final data analyses of the clinical evaluation, women/provider satisfaction and economical evaluation components of this trial were completed and several papers were published, including the corresponding systematic review of all available information from randomized trials. The comparison of the economics of providing the two models showed that there was a difference in costs (money and time) for both women and providers. In the new model, for example, the costs per pregnancy were 6–15% lower overall than with the...
standard model. Moreover, the waiting time for women at outpatient services was also recorded to be lower with the new model.

Additional papers on epidemiology of syphilis and risk factors for bleeding in early pregnancy, have been submitted for publication in scientific journals. An extensive dissemination effort of the results was initiated through presentations at meetings and symposia as well as special regional and country meetings. The manual for the implementation of the new WHO antenatal care model has been published, as have the supporting materials to be used for incorporating the results of this research project into services. The four countries where the trial was conducted are expected to adopt the new antenatal care model in 2002, and other countries are likely to follow.

The WHO multicentre randomized trial of misoprostol in the management of the third stage of labour

This multicentre, double-blind, randomized controlled trial to study the efficacy of misoprostol in the management of third stage of labour was launched by the Programme in 1997 and completed in 2000. It compared the efficacy of two regimens (a single dose of 600 mg of misoprostol vs a 10 IU dose of oxytocin given intramuscularly or intravenously) in reducing postpartum blood loss of ≥1000 ml. The key findings of the misoprostol trial were:

- oxytocin 10 IU, administered either intramuscularly or intravenously, is the uterotonic of choice for the management of third stage of labour; and
- compared with oxytocin, misoprostol was associated with greater blood loss and more side-effects.

Overall trial coordination was done by the Programme with collaborating centres in Argentina, China, Egypt, Ireland, Nigeria, South Africa, Switzerland, Thailand and Viet Nam. A total of 18,530 women were enrolled in these countries. The results of this trial demonstrate that 10 IU oxytocin (intravenous or intramuscular) is preferable to 600 mg oral misoprostol in the active management of the third stage of labour in hospital settings, where active management of the third stage of labour is the norm. The main reports were published in 2001 and included the systematic review of all evidence from randomized controlled trials in this area. During 2002, dissemination of effective strategies to prevent and treat postpartum haemorrhage will be implemented in Mexico and South Africa.

The Latin American randomized controlled trial of mandatory second opinion for the reduction of the rate of caesarean section

This trial was implemented in Latin America in collaboration with the Latin American Centre of Perinatology and Human Development (CLAP). The biomedical component was mostly funded with a grant from the European Community to the collaborating centres, while the Programme provided technical and financial support for the satisfaction and perception component of the trial. Within the framework of cluster randomization, the trial evaluated an intervention that consisted of a mandatory second opinion to be requested before every non-emergency caesarean section, based on the best available evidence about effective and safe management of childbirth.

Thirty-four hospitals from five Latin American countries participated in the trial: Argentina (18), Brazil (6), Cuba (4), Guatemala (2) and Mexico (4). Data regarding the primary outcomes, opinions about the mode of delivery and the social context of caesarean section in Latin America have been analysed and several reports submitted for publication. These data show that, contrary to the hypothesized reduction of 25% in caesarean section rates, only a marginal decline was observed.

The trial of magnesium sulfate for the prevention of eclampsia: reducing the human and health service burden of pre-eclampsia

This trial, known as the “Magpie Trial”, compared magnesium sulfate with placebo for the treatment of women with pre-eclampsia. Primary outcome measures were eclampsia and death of the mother or baby. The effects on other measures of serious maternal and neonatal morbidity were also assessed, as was the use of health service resources. Recruitment to the study began in July 1998 and involved women and clinicians from 150 hospitals in 31 countries. After approximately 10,000 women were recruited, the study was stopped in November 2001 on the recommendation of the Data and Safety Management Committee who considered that sufficient evidence was available to conclude that magnesium sulfate was beneficial. This is now the biggest-ever conducted trial of anticonvulsants for the treatment of pre-eclampsia.
The Magpie study settles the issue for magnesium sulfate. The 4968 women in the study who received an injection of magnesium sulfate had a 58% lower risk of eclampsia and an up to 45% lower risk of dying than the 4958 women given placebo. Side-effects were only minor: neither the mothers nor their babies have so far shown any serious adverse effects from the treatment. The results were published in June 2002. These data in conjunction with the previous eclampsia trial clearly demonstrate that magnesium sulfate is the drug of choice for the prevention as well as treatment of eclampsia and its fetal complications.

A randomized, double-blind, controlled trial of calcium supplementation provided during pregnancy to women with deficient calcium intake for the prevention of pre-eclampsia

The protective effect of calcium supplementation provided during pregnancy to women with deficient calcium intake has been identified in the literature as a very promising preventive strategy for pre-eclampsia. It is being evaluated by the Programme in a trial in populations with low calcium intake—the most likely to benefit from such a nutritional intervention (1.5 g of calcium a day). The trial is being conducted in Argentina, Egypt, India, Peru, South Africa and Viet Nam. A baseline survey of calcium intake included over 500 women of the pregnant population served by selected clinics and hospitals in these countries and demonstrated that the mean calcium intake is less than 600 mg/day, or approximately 50% of the 1200 mg/day recommended for pregnant women. The total sample size of the trial is expected to be 8500 women and the primary objective is the reduction in the incidence of pre-eclampsia. By June 2002, more than 3000 women had been randomized to two arms of the trial, which is expected to be completed in 2003.

Systematic reviews of the literature

Systematic reviews are conducted within the framework of the "WHO Programme to Map Best Reproductive Health Practices" activity (for details, see the chapter on "Implementing best practices"). Review topics are selected on the basis of their importance for developing countries, and scientists from these countries take the responsibility for preparing and maintaining these reviews. As part of this effort to synthesize evidence for the effectiveness of maternal health care interventions, seven systematic reviews have been updated. Also, four full new reviews and two review protocols were published in accordance with The Cochrane Library requirements, by staff of the Programme or by scientists from developing countries with support from the Programme. These systematic reviews were published in the 2001 issue of The Cochrane Library as well as The WHO Reproductive Health Library, No. 5, 2002. The main areas in which systematic reviews have been prepared through this effort are:

- treatment of anaemia during pregnancy
- management of impaired fetal growth during pregnancy
- prevention of postpartum haemorrhage by prostaglandins
- treatment of retained placenta
- routine antenatal care
- screening and alternative treatments for asymptomatic and symptomatic bacteriuria during antenatal care
- administration of vaginal misoprostol for induction of labour.

Furthermore, a comprehensive review of the effectiveness of antenatal care in preventing maternal mortality and serious morbidity was conducted and published as a supplement to the journal Paediatric and Perinatal Epidemiology.

Improving the understanding of sociocultural and economic factors influencing maternal health care

Women’s and providers’ perceptions of the quality of antenatal care

Women’s and providers’ perceptions of the quality of antenatal care were assessed alongside the WHO Antenatal Care trial in collaboration with the Latin American office of The Population Council and the National Perinatal Epidemiology Unit, Oxford University, Oxford, United Kingdom. During this study, information was obtained by applying both qualitative and quantitative research methodologies. A sample of 1600 pregnant women and all antenatal care providers participating in the trial were included. The qualitative care component
Systematic review of options for financing maternal health care

In 2001, the Department made progress in the preparation of A systematic review of options for financing maternal health care. The review aims to identify the range of organizational forms, or approaches, to finance maternal health care and document the impact of each one on the utilization of maternal health services, the quality and equity of the services provided and, finally, the scheme's sustainability. For each organizational form identified, the key issues surrounding revenue collection, pooling and purchasing were examined. The study is poised to assist policy-makers by illustrating and appraising the full range of documented interventions to increase the availability of resources for the provision of maternal health care in developing countries. The study took a strictly scientific “systematic review” approach in order to ensure that it is as comprehensive as possible and to minimize bias.

Paquete madre–bebé—modelo de estimación de costos (Spanish-language version of the Mother–baby package costing spreadsheet)

In 1999, the Department developed the Mother–baby package costing spreadsheet, a tool that estimates the cost of implementing, at the district level, a package of interventions to reduce maternal and newborn mortality and morbidity. The tool is targeted at district- and national-level planners and managers. The spreadsheet is based on the interventions identified in WHO’s Mother–baby package.

In 2001, the spreadsheet tool was translated into Spanish in order to provide planners and managers in Spanish-speaking countries with tools for estimation of cost. This will not only facilitate application, but also support economic research capacity building in these countries. The translation was carried out by the Instituto Nacional de Salud Pública de México, which will also be applying it in one low-income district of Mexico. The spreadsheet, as well as this illustrative Mexican application, will be published in Spanish in 2002. Additional information about the spreadsheet is available on the Department’s web site.

Cost of maternal health

Estimates of the district, national or global cost of providing essential maternal and newborn health care are critical to advocacy efforts at both global and national levels. They also play an important role in cost–effectiveness studies on comprehensive health, such as those based on the “burden of disease”. However, there is scarce information available on the cost of providing maternal health services. In 2001, the Department prepared a review of the evidence on the cost of maternal health services and interventions. All available published information on the cost of maternal care was collated in a systematic fashion. The report will be published in 2002.

Economic evaluation of a rational package for antenatal care conducted alongside a multicentre, randomized controlled trial

This economic evaluation was completed in collaboration with the University of East Anglia, Norwich, United Kingdom and the London School of Hygiene and Tropical Medicine, London, United Kingdom. The overall objective was to assess whether the new four-visit WHO model of antenatal care tested in the WHO Antenatal Care trial was more cost–effective than the existing level of service, both for women using the service and for health care providers.

A further aim was to examine the factors that may lead to differences between the cost–effectiveness estimates for the countries that took part in the economic study, and to assess transferability of the results. To this end, data were also collected in an additional centre in KwaZulu Natal, South Africa and combined with data from the WHO trial centres.

Final data analysis was completed during 2001, which showed that the new WHO model reduced service costs and saved time for women. Several papers reporting the main findings were presented at professional meetings and submitted for publication to leading health economics journals. The results were distributed to the participating institutions for their consideration and possible implementation of the recommendations.

Reviewing research methodology related to maternal health

Heterogeneity of meta-analysis of randomized controlled trials

This is a follow-up of previous work evaluating the predictability of meta-analyses of the results of large trials in perinatology. Eighty-four independent meta-analyses published in The Cochrane Library’s Pregnancy and Childbirth module were evaluated, and the factors affecting methodology to be used when there is heterogeneity of results from different trials were explored. A paper was published in 2001, and an evaluation of the statistical tests used in meta-analyses with heterogeneity of trial results is under preparation.

Methodological consideration for the design, analysis and meta-analysis of cluster randomization trials

This activity was conducted in collaboration with the Depart-
ment of Epidemiology and Biostatistics, University of Western Ontario, Canada. Utilizing the experience gained from the WHO Antenatal Care trial, statistical issues related to design of the trial, sample size and power calculations, taking into account stratification and clustering in the design, were reviewed and two methodological papers published in statistical journals in 2001. The new software ACLUDEST, now commercially available, was published by the Programme’s Clinical Trials and Informatics Support group and distributed to collaborating centres. It is useful for sample size calculations and analysis formulae for the cluster randomized design, not available in standard statistical packages.

**Clinical trials methodology**

The WHO multicentre, randomized controlled trial to evaluate the use of misoprostol in the management of the third stage of labour, mentioned above, presented special methodological challenges. The methods of sequence generation, concealment and blinding used in this trial were described in a paper to be published in a clinical trials journal. The paper also described how the possible existence of ascertainment bias in the main outcomes was assessed. The method of allocation concealment used in the trial offers a practical and convenient mechanism of drug administration in a hospital delivery ward that can be used even in remote settings in developing countries. The experience gained in the multicentre trial will be used at the local level to improve research methods.

**Conducting follow-up studies of populations included in pregnancy-related research**

The possibility of an intrauterine programming of diseases later in life, including various chronic conditions, has attracted considerable interest recently. This hypothesis is supported by a growing number of observational studies, most of which have been conducted in populations from developed countries. Concerns have been raised about the methodological limitations of these epidemiological studies, which used data from hospital records from decades ago, and included small numbers of intrauterine growth-retarded newborns. The Programme is testing these hypotheses in collaboration with two institutions in Latin America using perinatal and childhood/adolescent data, prospectively collected in large cohorts of children.

**The effect of high calcium exposure in utero on blood pressure during late childhood: long-term follow-up of subjects enrolled in a randomized controlled trial**

This is a prospective, follow-up study of 600 children 12 years of age, born to women enrolled in a double-blind, randomized, placebo-controlled trial of calcium supplementation during pregnancy. It explores the long-term effect of calcium supplementation during pregnancy on the offspring’s blood pressure during pre-adolescence, particularly among children with high body mass index. Standardized blood pressure, clinical anthropometric measures, and morbidity history were obtained at follow-up for the children and their mothers. The study was completed in 2001 with a follow-up loss of less than 10% eligible children, 12 years after the children were born. Data were analysed and results submitted for publication in 2001. The study found that, contrary to the first follow-up results at age 7 when a beneficial effect in terms of lowered blood pressure was recorded, there was no such effect at age 12.

**The Guatemalan perinatal follow-up study**

This study was conducted within the context of a Long-term Institutional Development (LID) Grant provided by the Programme. The study is a long-term follow-up of a subsample of 14,847 newborns originally included in the Guatemalan Perinatal Study conducted between April 1984 and January 1986. The present follow-up includes a sample of newborns that showed evidence of intrauterine growth retardation at birth and a corresponding control group of normal birthweight infants. These children were between 12 and 14 years of age when contacted for the follow-up study. The objective is to compare attained growth by anthropometric measures, blood pressure levels and morbidity experiences. Blood samples were taken in a subsample of the children. There is a maternal component of the study that explores the reproductive patterns of the mothers after the index pregnancy and the socioeconomic characteristics of these women at the time of the follow-up.

Data collection was completed in 2000 and plans for analysis and publication were prepared and partially implemented in 2001. This data set was also used to explore questions related to maternal and fetal risk factors for obstructed labour and caesarean section, including the growth of the woman during her childhood. It was confirmed that shorter maternal height was a strong predictor of the risk of obstructed labour. Also, the increases in fetal growth, comparable to that attributable to improved nutrition during pregnancy, are associated with a larger decrease in the risk of perinatal distress relative to the increase in risk of intrapartum caesarean delivery for the mother. A report was published in 2001, and the results of a comprehensive analysis of the data will be published in 2002.

**Follow-up of the Magpie trial study population**

Preparatory activities are under way in collaboration with the investigators conducting the Magpie trial (for the prevention of eclampsia), to conduct a follow-up study of children up to 2 years of age born to mothers enrolled in the trial. Growth, development and morbidity will be evaluated in this follow-up study to be initiated in 2002. External funding has been obtained from the UK Medical Research Council and other donors, which will be complemented by the Programme’s support to three collaborating centres in developing countries.
Evaluating implementation strategies of research results

A randomized controlled trial to evaluate a programme promoting evidence-based medicine based on the WHO Reproductive Health Library

In order to evaluate the uptake of information from the WHO Reproductive Health Library (RHL) with subsequent changes in health care practices, a randomized controlled trial of an educational outreach strategy is being undertaken, using maternal care practices as indicators (for details, see the chapter on “Implementing best practices”). The trial is being conducted in 40 maternity departments in Mexico and Thailand. The objective of the trial is to change or increase the use of effective obstetric practices as recommended in RHL 2001. Baseline data collection started in April 2001. The intervention will be completed in 2002, and evaluation of the impact of the trial is expected to be completed by early 2003.

Stimulating fundamental research on outstanding obstetric problems of global importance

There are two highly prevalent maternal morbidities in developing countries for which there is very little concrete pathophysiological knowledge on which to base preventive and therapeutic interventions—hypertensive disorders of pregnancy and impaired fetal growth. Currently available interventions consist largely of symptomatic treatment for the mother and intensive care of a preterm or growth-impaired infant. It is unlikely that morbidity and costs can be reduced without identifying effective preventive measures. Moreover, because severe pre-eclampsia and impaired fetal growth are relatively rare in developed countries, research in these areas has been neglected. To identify new preventive strategies, considerable efforts will be needed in implementing basic research in order to understand the pathophysiological processes.

As the Programme does not have the resources or the capability to conduct this research alone, it established contact with researchers and funding agencies already active in these areas in order to estimate and identify concrete opportunities for collaborative research. In 2001, a meeting to review and identify promising areas was organized in collaboration with the University of Pittsburgh, USA and several leading institutions in developing countries. The protocols were submitted to donors for funding. However, it also became clear that the scientific community was looking to the Programme to lead the development of a comprehensive programme project that would include activities ranging from the implementation of effective treatments at country level to basic sciences research worldwide. A coordinated effort of this magnitude has been undertaken for the first time ever. Thus, a new research and service programme entitled “Global Programme to Conquer Pre-eclampsia–Eclampsia” was launched. This activity has been developed in collaboration with a network of institutions in both developing and developed countries and in consultation with the WHO Advisory Committee on Health Research. The proposed programme of activities is based on the concept of systematic reviews and priority research areas, and is now under review for special funding in different agencies.

Mapping the magnitude of maternal ill-health

As a first priority, the Department’s activities in maternal health research are concentrated on findings interventions to treat and prevent the leading causes of maternal mortality. To complement these activities, a systematic review of epidemiological data from 1995 to 2001, documenting the magnitude of maternal morbidity and mortality in developing countries, is now under way (for details, see the chapter on “Monitoring and evaluation”). This, now completed, systematic review includes two stages: (i) the summary of all data from WHO trials and other related comprehensive data sets collated after 1995; and (ii) a search strategy to augment these data with the addition of all published papers, electronic databases and additional documents from WHO Regional Offices and other agencies.

A generic data collection form has been developed in order to extract data from any located epidemiological studies by age, country, type of study and quality assessment criteria. In 2001, a draft of the document, discussing results from the first stage, was made available for internal and external evaluation and will be published in 2002. The second stage was initiated in 2002. Furthermore, a consultation was organized in 2002 to evaluate statistical aspects and approaches for pooling these data, in order to summarize all the information for use at the service level. The outcomes of the project will be updated indicators of the incidence, prevalence, case fatality, relative risk, attributable risk and sequelae of morbidity conditions related to pregnancy focused on populations in developing countries.

NEW PROJECTS INITIATED IN 2001

Treatment of postpartum haemorrhage

In developing countries, as many as 40 maternal deaths per 100 000 births in rural areas are due to postpartum haemorrhage. Among the drugs used to treat this complication, preliminary studies have suggested that the use of misoprostol might be a promising strategy. African centres that are part of the WHO collaborative network of research institutions, are developing a protocol for a comprehensive programme of research to address the issues of effectiveness, risks and optimal dosage of misoprostol in the treatment of postpartum haemorrhage. Systematic reviews of randomized and nonrandomized trials are being prepared, and a multicentre, randomized trial to evaluate the effectiveness of misoprostol for the treatment of postpartum haemorrhage will be implemented according to the review results.
Screening and treatment for urinary tract infection during pregnancy

Activities similar to the misoprostol research programme are being developed by a collaborating centre in Thailand to initiate a comprehensive programme for evaluating the most effective strategies for the screening and treatment of urinary tract infection during pregnancy. The research programme will include all the methodological steps ranging from the systematic review of publications evaluating screening techniques to the implementation of clinical trials and health service research (including cost analysis) of treatment modalities.
Annex 1

RESEARCH GROUP ON MATERNAL AND PERINATAL HEALTH IN 2001

Members

Andres de Francisco, Global Forum for Health Research, World Health Organization, Geneva, Switzerland
Jo Garcia, Institute of Health Sciences, Oxford, United Kingdom (Chairwoman)
Wendy Graham, Aberdeen Maternity Hospital, Aberdeen, United Kingdom
Ellen Hodnett, University of Toronto, Toronto, Canada
Angela Kamara, Regional Prevention of Maternal Mortality Program, Dzorwulu, Ghana
Marc Keirse, The Flinders University of South Australia, Adelaide, Australia
Pious Ngassa, WHO Centre for Research in Human Reproduction, Yaoundé, Cameroon
Pious Okong, Nsambya Hospital, Kampala, Uganda
Silvina Ramos, Centro de Estado y Sociedad, Buenos Aires, Argentina
Fiona Stanley, Telethon Institute for Child Health, Perth, Australia

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>Members</td>
<td>4</td>
<td>40</td>
<td>6</td>
<td>60</td>
</tr>
<tr>
<td>Women</td>
<td>2</td>
<td>20</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>3</td>
<td>30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>1</td>
<td>10</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td>3</td>
<td>30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>2</td>
<td>20</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex 2

SCIENTISTS IN 2001

Principal investigators

Hany Abdel-Aleem, Assiut University Hospital, Assiut, Egypt
Olayiwola Adetoro, Ogun State University, Sagamu, Nigeria
Yacceob Al-Mazrou, Ministry of Health, Riyadh, Saudi Arabia
Muneera Al-Osimi, Ministry of Health, Jeddah, Saudi Arabia
Hassan Ba’aqeel, King Khalid National Guard Hospital, Jeddah, Saudi Arabia
Leiv Bakketeig, University of Bergen, Bergen, Norway
Per Bergsaj, University of Bergen, Bergen, Norway
Liana Campodonico, Centro Rosarino de Estudios Perinatales, Rosario, Argentina
Guillermo Carrol, Centro Rosarino de Estudios Perinatales, Rosario, Argentina
Linan Cheng, International Peace Maternity and Child Health Hospital, Shanghai, China
Allan Donner, University of Western Ontario, London, Ontario, Canada
Leila Duley, Institute of Health Sciences, Oxford, United Kingdom
Diana Elbourne, London School of Hygiene and Tropical Medicine, London, United Kingdom
Ubaldo Farnot, Hospital Gineco-Obstetrico “America Arias”, Havana, Cuba
Julia Fox-Rushby, London School of Hygiene and Tropical Medicine, London, United Kingdom
Justus Hofmeyr, University of Witwatersrand, Johannesburg, South Africa
Chusri Kuchaisit, Khon Kaen University, Khon Kaen, Thailand
Ana Langer, The Population Council, Mexico DF, Mexico
Pisake Lumbiganon, Khon Kaen University, Khon Kaen, Thailand
Matthews Mathai, Christian Medical College and Hospital, Vellore, India
Miranda Mugford, University of East Anglia, Norwich, United Kingdom
Nguyen Thi Nhu Ngoc, Hung Vuong Hospital, Ho Chi Minh City, Viet Nam
Manorama Purwar, The Government Medical College and Hospital, Nagpur, India
Georgina Rojas, Hospital Gineco-Obstetrico “America Arias”, Havana, Cuba
Maria Ximena Rojas, Universidad Javeriana, Bogotá, Colombia
Mariana Romero, Centro Rosarino de Estudios Perinatales, Rosario, Argentina
Nelly Zavaleta, Instituto de Investigacion Nutricional, Lima, Peru

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>20</td>
<td>74</td>
<td>7</td>
</tr>
<tr>
<td>Women</td>
<td>11</td>
<td>41</td>
<td>4</td>
</tr>
</tbody>
</table>

from:

<table>
<thead>
<tr>
<th>Region</th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>AMRO</td>
<td>8</td>
<td>30</td>
</tr>
<tr>
<td>EMRO</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>EURO</td>
<td>6</td>
<td>22</td>
</tr>
<tr>
<td>SEARO</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>WPRO</td>
<td>2</td>
<td>7</td>
</tr>
</tbody>
</table>

Generating new evidence for maternal and perinatal health
Annex 3

Publications in 2001


Generating new evidence for maternal and perinatal health


**SYSTEMATIC REVIEWS PUBLISHED IN THE COCHRANE LIBRARY IN 2001**

**New reviews**

Abalos E, Duley L, Steyn DW, Henderson-Smart DJ. Antihypertensive drug therapy for mild to moderate hypertension during pregnancy.

Cuervo LG, Mahomed K. Treatments for iron deficiency anaemia in pregnancy.

Duley L, Gülmezoglu AM. Magnesium sulfate versus lytic cocktail for eclampsia.

Minini L. Review of screening tests, choice of antibiotic and treatments for asymptomatic bacteriuria.

**Reviews updated**

Carroli G, Bergel E. Umbilical vein injection for management of retained placenta.

Gülmezoglu AM, Forna F, Villar J, Hofmeyr GJ. Prostaglandins for prevention of postpartum haemorrhage.

Gülmezoglu AM, Hofmeyr GJ. Betamimetics for suspected impaired fetal growth.

Gülmezoglu AM, Hofmeyr GJ. Hormones for suspected impaired fetal growth.

Gülmezoglu AM, Hofmeyr GJ. Maternal nutrient supplementation for suspected impaired fetal growth.
Annex 3 (continued)

Hofmeyr GJ, Gülmezoglu AM. Vaginal misoprostol for cervical ripening and induction of labour.

Protocols

Adetoro O, Hofmeyr GJ. Prophylactic antibiotic administration in pregnancy to prevent infectious morbidity and mortality.
Kulier R, Gülmezoglu AM, de Onis M, Villar J. Vitamin A supplementation in pregnancy.
Implementation of evidence-based programmes


INTRODUCTION

The International Conference on Better Health for Women and Children through Family Planning (Nairobi, October 1987) triggered worldwide momentum to reduce maternal and perinatal mortality and launched the Safe Motherhood Initiative. Ten years later, in 1997, a review of this Initiative concluded that little had been achieved in terms of reduction of maternal and infant mortality worldwide. More stringent and action-oriented interventions were needed.

Against this background, “Making Pregnancy Safer” was identified by WHO as one of 11 priorities of the Organization. It aims to contribute to the achievement of the goals of the Safe Motherhood Initiative. Basically, Making Pregnancy Safer is a two-pronged intervention: a strong research component to generate evidence, which is translated into action by the component entitled Implementing evidence-based programmes. Work during the year in the latter component is being reported here and focuses on progress in the development of norms and tools and on country cooperation in Making Pregnancy Safer “spotlight” countries.¹

The implementation of evidence-based programmes is being achieved mainly through WHO Regional and Country Offices with the indispensable collaboration of partners. In effect, achievements as well as ongoing activities hinge on several factors—developing the Making Pregnancy Safer draft project proposal for discussion among partners, developing a hierarchy of Making Pregnancy Safer aims using the logical framework, conducting normative work to generate norms and tools for quality services, drafting an advocacy and communication paper, drafting a working guide in the area of family and community practices, and providing support to build technical and institutional capacity at both regional and country levels to manage quality and gender-responsive Making Pregnancy Safer programmes.

NORMS AND TOOLS

On the basis of available evidence, the Department has developed a number of normative tools and instruments meant for adaptation and use by countries to achieve a better quality of services. These tools and instruments include standards, training tools, managerial tools and other materials as described below.

Standards

Standards for newborn care

In 2001, the Department developed standards for newborn care at first-level facilities in developing countries. These provide guidance on the essential components needed to assure quality of care during pregnancy and the perinatal period, and on how to organize services for the newborn in resource-limited settings. This document complements the Essential care practice guide for pregnancy, childbirth and newborn care. The standards will be internally and externally reviewed; and, where evidence is not available, issues will be finalized in consensus meetings on key interventions during 2002. A second set of standards for newborns in need of special care is in preparation and will focus on the practices relevant to referral facilities.

¹Making Pregnancy Safer “spotlight” countries: Bolivia, Ethiopia, Indonesia, Lao People’s Democratic Republic, Mauritania, Moldova, Mozambique, Nigeria, the Sudan and Uganda.
Standards for maternal care

The work on standards for maternal care commenced in 2001, with similar objectives as those of the previous tool but aimed at improving maternal care. This document will be finalized during 2002 and will be part of the document entitled Standards for maternal and newborn care.

Training tools

Midwifery modules

Midwifery modules for students and teachers of midwifery, a set of five modules, has been revised in view of new evidence, the manual for Managing complications in pregnancy and childbirth: a guide for doctors and midwives and other recent WHO guidance documents. Suggestions from an external peer review conducted in 2001 have also been included. These five modules will be ready in early 2002. A second subset consisting of two new modules has been developed and aims at increasing further the competency of midwives to manage the major maternal “killers”. These new modules are Management of incomplete abortion and Vacuum extraction delivery. The first has been field-tested and revised accordingly. Final editing is expected to take place in early 2002 after the external review process has been completed. The Vacuum extraction delivery module will be incorporated into the module on Management of obstructed labour, as recommended at the external review in November 2001. This work will commence in January 2002 in collaboration with relevant partners. It is anticipated that the revised modules and those on Management of obstructed labour and on Management of incomplete abortion (including post-abortion care) will be ready for distribution in 2002.

Essential care practice guide (ECPG) for pregnancy, childbirth and newborn care

The ECPG for pregnancy, childbirth and newborn care is a practice guide for clinical decision-making. It is intended for skilled birth attendants at all levels of health care, with a special focus on those practising at the primary level. It sets out WHO recommendations for essential routine as well as emergency care during pregnancy, childbirth, the postpartum period and for the newborn, as well as for postabortion care. The ECPG is based on evidence, where available, or on expert opinion. It focuses on major maternal and neonatal killers (eclampsia, haemorrhage, puerperal sepsis, obstructed labour and postabortion complications).

The ECPG also incorporates initial management of HIV and malaria, and addresses issues related to violence and adolescent pregnancy. Sections on advice and counselling are included to guide health workers in their communication with women and families in this connection. A generic counselling booklet to complete the ECPG has been designed to highlight key messages for women and their families including birth preparedness, home care of the mother and newborn, and the detection of emergency signs and care-seeking behaviour.

The ECPG will also be useful to trainers and educators for integrating these essential elements of care into the national curricula and in-service training programmes.

Field-testing of the ECPG began in 2001, with selected sections being tested in clinical settings in Indonesia and the Philippines. The ECPG was further reviewed for accuracy, completeness, usefulness, clarity and appropriateness. The next version will be prepared in early 2002 based on the comments received.

Supporting material being developed include evidence papers, a user guide and an adaptation guide to assist countries in using the ECPG effectively.

The revised ECPG will be field-tested with intended providers in selected countries. Selected components will be validated and a methodology for this is under development. Operations research will be organized as needed to answer the research questions that may arise. The ECPG will be part of the WHO “Syndromic Approaches” aiming to provide countries with harmonized guidelines addressing illnesses in newborns, infants, pregnant women and adolescents, and HIV-related adult illnesses.

Efforts are ongoing to harmonize the Integrated management of childhood illness (IMCI), developed by the Department of Child and Adolescent Health and Development, with the ECPG for newborn care during the first week of life.

Managing complications in pregnancy and childbirth: a guide for doctors and midwives

The document Managing complications in pregnancy and childbirth: a guide for midwives and doctors was completed and printed in 2000. The manual was written to provide health workers with evidence-based knowledge for managing complications in pregnancy and childbirth, and to assist them in making rapid clinical assessments and decisions. The manual is designed to be used for the bedside treatment of life-threatening emergencies during pregnancy, childbirth and the postpartum period. The manual is divided into three major sections: (i) section one outlines the clinical principles of managing serious complications in emergency situations; (ii) section two describes the symptoms by which women with complications present themselves; and (iii) section three describes the procedures that may be necessary in the management of each complication.

The manual was prepared in collaboration with the Johns Hopkins Program for International Education on Gynecology and Obstetrics (JHPIEGO), and is endorsed by the United Nations Population Fund (UNFPA), the United Nations Chil-
The recommendations of these guidelines are included in the EPCG for pregnancy, childbirth and newborn care, the ECPG for reproductive tract infections, and the Standards for newborn care.

Clinical guidelines for management of pregnant women with HIV

The document Clinical guidelines for management of pregnant women with HIV was developed in 2001. The objective of these guidelines is to facilitate the integration of prevention of mother-to-child HIV transmission into existing health systems in countries. The guide has been field-tested in Ethiopia and Thailand, and was presented at the East, Central and South African Association of Obstetricians and Gynaecologists’ (ECSAOGS) Congress in Addis Ababa in November 2001. Publication is planned during 2002.

Strategic framework for malaria control during pregnancy in the African Region

During 2001, the Department worked in close collaboration with the WHO Roll Back Malaria/Malaria in Pregnancy Team and AFRO, and developed a document entitled Strategic framework for malaria control during pregnancy in the African region. This tool aims to support countries in revising their national strategies and guidelines that address issues related to malaria in pregnancy, in order to integrate the latest available evidence. As a follow-up to the strategic framework document, operational guidelines will be developed and field-tested in the African region in the course of 2002.

Management tools

During 2001, the Department, in collaboration with relevant WHO Departments, focused on identifying the necessary management tools that will assist countries in ensuring that their health systems respond to the needs of women and newborns, with a view to reducing maternal and neonatal morbidity and mortality. This work of enhancing the existing management tools and efforts related to health systems development will continue in 2002, and culminate in the production of the series of tools described below.

Making pregnancy safer planning guide

The Department has initiated plans to develop a Making pregnancy safer planning guide, which will specify the health systems requirements (including health system functions such as logistics, supplies, etc.) for the recommended maternal and newborn health interventions. The guide will enable health managers and programmers to better plan and implement key interventions for the reduction of maternal and neonatal mortality. It will also describe the planning processes necessary for budgeting, monitoring and evaluation. Users will be able to select the most relevant processes, methods and tools, and adapt them to their own capacities, resources and local context. This work is expected to be completed in 2002.
Making pregnancy safer planning workshop manual

The Making pregnancy safer planning workshop manual will assist district managers and planners to plan and conduct a planning workshop for the development of an operational maternal and newborn health plan. The manual comprises a facilitator’s guide as well as workshop materials for participants. The first draft of the workshop manual has been completed and reviewed during 2001, and will be supplementary to the Making pregnancy safer planning guide. It is intended for field-testing in 2002.

Essential health technology package for making pregnancy safer

The Department has also worked in close collaboration with WHO’s Department of Health Service Provision and the WHO Collaborating Centre for Medical Technology and Equipment in Cape Town, South Africa in the ongoing development of the Essential Health Technology Package (EHTP). The EHTP is both a methodology and a tool, and comes as a CD-ROM software package for a defined set of interventions. The package is designed to assist resource planning through simulations of needs assessment analysis, procurement, technology management as well as cross-departmental planning. The EHTP does not prescribe clinical practice, neither does it set health priorities nor prescribe resource levels, but it does provide a bridge between strategic and operational planning. The software is currently being adapted for country use in two Making Pregnancy Safer spotlight countries (Moldova and Mozambique) and completion is envisaged in 2002.

Mother–baby package costing spreadsheet

This spreadsheet tool that estimates the cost of implementing a package of interventions to reduce maternal and newborn mortality and morbidity at the district level was translated into Spanish in 2001. Further details are available in the previous chapter on “Generating new evidence for maternal and perinatal health”.

A set of modules aiming at strengthening midwifery services

The 1999 Joint WHO/UNFPA/UNICEF/World Bank statement on reduction of maternal mortality emphasizes the importance of skilled care during pregnancy, childbirth and the postpartum period. To address this issue, a set of guidelines relating to “Strengthening Midwifery Services” has been developed. It comprises:

- Strengthening midwifery services background paper
- Legislation and regulation: making safe motherhood possible
- Competencies for midwifery practices
- Developing standards to assist practitioners provide quality midwifery care
- Guidelines for the development of midwifery education programmes
- Guidelines for the development of programmes for the education of midwife teacher.

These documents have been refined in 2001, following internal and external reviews. They are expected to be ready for field-testing in early 2002.

A technical meeting on “Strengthening Midwifery Services” was held in December 2001 to synchronize relevant materials and activities, as well as to identify relevant issues for further consideration. Future work will focus on developing strategies to enable countries to assess their needs and develop appropriate plans of action to strengthen midwifery services. These strategies will address the barriers to effective provider performance. The tool will be developed and field-tested in 2002.

In addition, efforts have begun to create an inventory of activities being undertaken by WHO and its partners on strengthening midwifery services. One such activity includes reaching an agreement with partners on future actions to support the WHO Making Pregnancy Safer project.

Other Making Pregnancy Safer tools and approaches

Guideline on investigating maternal deaths and severe complications of pregnancy

During 2001, the Department finalized the Guideline on investigating maternal deaths and severe complications of pregnancy. This document has been prepared to provide guidance to health planners, managers and other health professionals on how to investigate maternal deaths and severe morbidity. The specific objectives of this guide are: (i) to
describe a range of investigative tools or methods for the investigation of maternal deaths; (ii) to provide guidance on the selection of investigative tools appropriate for use in different settings and circumstances; and (iii) to promote the dissemination and use of the information generated. The ultimate aim of this guide is to increase awareness and knowledge of the magnitude as well as the causes of maternal mortality and complications of pregnancy. The approaches for investigating maternal deaths and severe complications described in this guide have been developed mainly for developing countries where levels of maternal morbidity are at their highest. Case reviews from a wide range of countries are provided as examples. The guide has undergone extensive review and will be published in 2002.

The Making Pregnancy Safer web site

The Making Pregnancy Safer web site was established in 2001 and will be further developed during 2002.

The Safe motherhood newsletter

The publication Safe motherhood: a newsletter of worldwide activity was reviewed in 2001. Revisions will be carried out in 2002. It is expected that the publication of the newsletter will resume to three issues per year.

Individual, family and community issues in maternal and newborn health

During 2001, an informal consultation was held with WHO partners to better identify the means by which the Making Pregnancy Safer project can collaborate with and support ongoing work with individuals, families and communities to contribute to improvements in maternal and newborn health. Key recommendations provided to the Department include: better integration of the “Family and Community Practices” component into the Making Pregnancy Safer strategy; and the development of a background and strategy paper which defines concepts, guiding principles, objectives and strategies.

The development of the concept and strategy paper will be a priority in 2002. In addition, ongoing efforts will continue to collect and disseminate experiences, methodologies and lessons learned in working with individuals, families and communities to improve maternal and newborn health. In close collaboration with its partners, WHO will commence work to identify key family and community practices in the area of maternal and newborn health, based on evidence and consensus. To accompany the dissemination of these practices, a guide will be developed. This guide will provide orientation as to the processes which can be used within countries to work with these practices such that local priorities, realities and needs are reflected.

Finally, efforts related to strengthening community involvement in improving the quality of services will continue. The different methodologies and experiences of involving individuals and groups in the definition, implementation and ongoing monitoring of the quality of services will be discussed in a consultation beginning in early 2002. A methodological guide will be developed.

Advocacy and communication strategy for making pregnancy safer

Work on defining an advocacy and communication strategy for making pregnancy safer at all levels (local, national, regional and international) started in 2001. A draft has been prepared and will be finalized during 2002. The objective of this strategy paper is to define the means by which the Making Pregnancy Safer initiative can advocate support to maternal and newborn health issues among governments and all interested parties. This document will clearly identify issues, objectives/outputs, targets, techniques and advocacy tools, and will assist countries in developing their own advocacy strategy on making pregnancy safer issues. Production of this generic advocacy tool is planned for 2002.

Assessing safe motherhood from a human rights perspective: a tool for making pregnancy safer

An assessment tool has been developed in order to bring a human rights perspective into the goals and objectives of the Making Pregnancy Safer initiative. This will assist a national multi-stakeholder team to review laws, policies and health system considerations against the major health outcome indicators (for details, see the chapter on “Gender and reproductive rights in reproductive health”).

TECHNICAL COOPERATION WITH COUNTRIES

The main purpose of the Making Pregnancy Safer initiative is to provide technical and policy support to countries. The project has enabled the Department to collaborate proac-
Section 2 - Making Pregnancy Safer

The Making Pregnancy Safer initiative is providing technical and policy support to strengthen government capacity to plan, design and implement effective evidence-based technical and health systems interventions. It will also help to identify the necessary processes and actions at the individual, family and community levels to improve maternal and newborn health in the spotlight countries. As part of its technical support to these countries, the initiative has:

- supported the development of a comprehensive national reproductive health/Safe Motherhood/Making Pregnancy Safer strategy and plan in Indonesia, Mozambique and Nigeria. In Indonesia, the national Making Pregnancy Safer strategy was launched in November 2001 by the Minister of Health with all the provincial authorities, and the next step is to support the implementation of this strategy in selected districts;

- supported the review and revision of supportive policies, regulations and laws related to safe motherhood in Mauritania and Mozambique. A pilot project on "Integrating Human Rights into Making Pregnancy Safer" has started in Mozambique (see the chapter on "Gender and reproductive rights in reproductive health");

- supported the development and adoption of evidence-based national norms, standards and tools related to maternal and newborn care in all ten spotlight countries. The Government of Bolivia has decided to use the standards provided in Managing complications in pregnancy and childbirth: a guide for doctors and midwives as an official document for technical norms in maternal and newborn health. All WHO Regions have been mobilized in the distribution of this manual. Field-testing of the ECPG has started in Indonesia and the Philippines, and will be extended to another three countries during 2002. This process is the first stage of implementation of revised norms and standards at all levels of care, aimed to increase the access of all pregnant women and their newborns to skilled attendance during pregnancy and childbirth;

- assisted in identifying and applying cost–effective interventions for safe motherhood in all ten countries. Ethiopia is piloting Making Pregnancy Safer cost–effective interventions in four regions;

- assisted in coordinating safe motherhood plans and activities in all ten countries. The Ethiopian government, for instance, has requested Making Pregnancy Safer management staff to assist in coordinating interested parties with the objective of implementing the best strategy, maximizing efforts and collecting lessons learned in a coherent and efficient way;

- supported activities aimed at maximizing resources available for safe motherhood in all ten countries. A regional meeting on Partnertships for Making Pregnancy Safer was organized by AFRO in October 2001 in Kampala, Uganda. Key partners attending this meeting reached a consensus on future activities for better coordination and collaboration in maternal and newborn health activities;

- linked with other programmes that are involved in areas of work relevant to safe motherhood such as HIV/AIDS, malaria, blood safety, and others in all ten countries. AFRO organized a regional meeting with WHO’s Roll Back Malaria initiative with the objective of supporting countries in the revision of their national policies for malaria in pregnancy. The Clinical guidelines for management of pregnant women with HIV was field-tested in Ethiopia;

- provided support for implementing sectorwide approaches in a number of countries including Bolivia, Indonesia, Mozambique and Uganda;

- assisted in formulating the National Health Systems Development plans of Bolivia, Ethiopia, Indonesia, Mauritania and Moldova;

- supported the implementation of the United Nations Development Assistance Framework (UNDAF) in Mozambique and Uganda under the umbrella of the respective national strategies for poverty reduction in these countries; and

- assisted in building research capacity, and planned for operational research related to the implementation of key Making Pregnancy Safer interventions.

Although the Making Pregnancy Safer initiative is in its initial phase and limited to the ten spotlight countries, it is perceived as credible, highly acceptable and in a strong position to make an impact through the implementation of "best-buys".

The lessons learnt are being carefully documented to support future efforts to expand the work to a larger number of countries.
Section 3
Reproductive tract infections and sexually transmitted infections
Reproductive tract infections and sexually transmitted infections

T.M.M. Farley, N. Broutet, J. Mandala, I.M. Malonza, B. Deperthes

INTRODUCTION

Reproductive tract infections (RTIs), including sexually transmitted infections (STIs), are responsible for a considerable burden of reproductive ill-health, both directly and through their ability to increase the risk of transmission or acquisition of the human immunodeficiency virus (HIV). Approximately 340 million curable STIs are estimated to occur worldwide each year, and many millions of incurable viral STIs occur annually, including an estimated 5 million new HIV infections. WHO’s contribution to the reduction of the disease burden associated with RTIs and STIs extends across all the core functions of the Organization: advocacy, information management, research and evidence, technical cooperation and policy support, setting norms and standards, and developing new technologies, tools and guidelines.

The objectives of the Department in the area of RTIs and STIs are: (i) to initiate key epidemiological research on the effectiveness and use of male and female condoms to prevent STIs; (ii) to advocate for improved services for the prevention and management of RTIs in reproductive health care settings, including the use of dual protection; (iii) to develop vaginal microbicides for prevention of STIs including HIV; (iv) to generate key evidence on the acceptability, safety and effectiveness of interventions to prevent mother-to-child transmission (MTCT) of HIV; and (v) to assist countries to plan and implement programmes for the prevention of MTCT of HIV.

RESEARCH ACTIVITIES

Microbicides

Objectives and rationale

Safe, effective and acceptable, self-administered, topical preparations with microbicidal activity are likely to have a major positive impact on reproductive health, especially in areas with a high prevalence of STIs, including HIV. A large number of microbicidal compounds and formulations are currently under investigation and development in both the private and public sectors. For this reason, the Programme has decided not to become directly involved in exploratory research for new product leads, but instead to collaborate in the clinical testing of promising preparations as they reach this stage of development.

One such preparation, cellulose sulfate gel, has been shown to have good spermicidal and anti-HIV activity in vitro, and has been tested for local tolerance in animal studies and in a Phase I clinical trial in women volunteers carried out by the Contraceptive Research and Development Program (CONRAD), Arlington, VA, USA.

Progress

A protocol for an expanded Phase I clinical trial of the cellulose sulfate gel has been drawn up in collaboration with CONRAD. This protocol covers the twice-daily application of the gel over a period of 7 days and will be conducted in two cohorts of women. The first cohort will be required not to...
have intercourse or use other vaginal products for the duration of the study, whereas the second cohort will be expected to have at least two acts of intercourse during the study period. Tolerance to the product will be established by direct questioning and colposcopic examinations. This study will also assess the acceptability of the product in terms of its ease of use and its general performance profile.

During the past year, the Programme convened an investigators’ meeting to review the protocol, case record forms and procedures to be used in the expanded Phase I clinical trial which will be carried out in three centres in India, Nigeria and Uganda. Following this meeting, the protocol and study instruments have been revised and the revisions approved by the institutional and national authorities as well as by WHO.

The Phase I trial was initiated in Uganda in December, and is expected to start in the other two centres in early 2002.

Efficacy of female condoms for the prevention of STIs

Objectives and rationale

There are limited data on the effectiveness of female condoms to prevent the sexual transmission of HIV or other infectious diseases. Since the device has been shown to be impervious to such organisms in laboratory studies, it is assumed that the condoms will also provide protection during sexual intercourse. However, there are no clinical data to support this, and the Programme has been exploring ways to address this gap in knowledge. Since the male condom is the best-known method for reducing the risk of STIs, any research on condom effectiveness must include a comparison with the male condom. This research on the effectiveness of the female condom in preventing STIs is complementary to the research on the prevention of pregnancy using the device (see the chapter on “Research on the safety and effectiveness of contraceptives”).

Progress

In 2001, the Programme developed a protocol to assess, through a randomized trial, the comparative effectiveness of male and female condoms in reducing the risk of infection with Neisseria gonorrhoeae, Chlamydia trachomatis or Trichomonas vaginalis among women at high risk of infection. After discussions with experts and potential investigators, the study design was considered impractical since it would be difficult to obtain adequate information on sexual behaviour or the infection status of the women’s partners. Moreover, randomizing volunteers to exclusively use male or female condoms was unlikely to be acceptable. The Specialist Panel on Epidemiological Research in Reproductive Health therefore recommended a consultation to consider ways in which information on the efficacy and effectiveness of female condoms could be assessed.

The Programme convened a three-day Research Group meeting in November 2001 to discuss the extent of knowledge regarding condom efficacy and effectiveness, the methodological difficulties in obtaining more information on either male or female condoms, and opportunities to collect more data. The Group outlined various options for different designs, and recommended that a study be implemented among female sex workers—vaginal swabs would be collected before and after each act of intercourse as well as the condoms used. In this way, the infection status of the partner could be assessed, and the swabs before and after acts of intercourse with infected partners could be examined to look for the presence of any new infectious organisms in the vagina. Implemented in a setting where both male and female condoms were used and where the prevalence of infection among the women’s clients was high, such a design would provide comparative information on the efficacy of the two types of condoms in preventing exposure to the sexually transmitted pathogens in a reasonably short time. It was unclear whether this design could also be used to study the efficacy of male and female condoms in reducing the risk of other STIs, such as HIV, herpes simplex virus or human papillomavirus.

Mortality in HIV-infected mothers who breastfeed

Objectives and rationale

A secondary analysis of data from a randomized trial in Nairobi, Kenya on the safety of breast and replacement feeding by mothers with HIV infection (Nduati et al., JAMA, 2000, 283:1167–1174) revealed a threefold higher mortality rate within the first two years of delivery among mothers assigned to breastfeeding compared with those assigned to replacement feeding (Nduati et al. Lancet, 2001, 357:1651–1655). It is unclear why HIV-infected women who breastfeed might be at an increased risk of death, but if the results are confirmed by other studies, then advice and care for mothers with HIV infection may need to be revised. As part of the Department’s regular review of emerging scientific evidence and its possible policy implications, a statement was prepared in collaboration with the Child and Adolescent Health and
Development (CAH) and HIV/AIDS Departments and published in the The Lancet in June 2001 soon after the publication of the article by Nduati et al.

The Department also considers ways to rapidly obtain more information on mortality in HIV-infected mothers and has entered into a collaboration with teams of investigators who have completed studies on MTCT of HIV.

**Progress**

All available data on the risk of HIV transmission through breastfeeding have been compiled into a common database by the Breastfeeding and Infant HIV Transmission Study (BIHTS) sponsored by the Pediatric, Adolescent, and Maternal AIDS Branch of the United States National Institute of Child Health and Human Development (NICHD). Working closely with the team which is conducting an individual record meta-analysis of the risk of transmission according to infant feeding pattern, the Department developed a methodology and analysis plan to assess the risk of the mother dying according to different feeding patterns. The final data have now been compiled into a suitable form for the new analysis and the results are expected in early 2002.

**Combination antiretroviral therapy and prevention of MTCT of HIV**

**Objectives and rationale**

The rate of MTCT of HIV is approximately 35% in populations where prolonged breastfeeding is the norm and no antiretroviral (ARV) prophylaxis is given. Roughly 5% of transmissions occur in utero, 15% intrapartum and 15% during breastfeeding. In utero and intrapartum transmissions can be reduced by half, from roughly 20% to under 10%, using short-course ARV regimens. The postpartum period is responsible for a 15% risk of transmission in cases where children are breastfed for 18–24 months. As a consequence, the proportion of children infected by 18–24 months of age, despite having benefited from a short-course prophylactic ARV regimen, is around 20%. This rate remains far higher than the 2–5% transmission rate obtained in developed countries, which has been achieved through the use of potent ARV regimens that maximally suppress viral load, elective caesarean section and the avoidance of breastfeeding.

Mothers with HIV infection are advised to avoid breastfeeding altogether or to breastfeed for a short time only, provided they have access to safe, affordable and sustainable infant formula and water to prepare the replacement feed. However, for many women this is not an option and complete avoidance of breastfeeding may not be acceptable to them or their families.

There is an urgent need to explore ways in which breastfeeding by HIV-infected mothers can be made safer, partly so that the infant can get maximum benefit from the breast milk, and partly so that women who are not able to avoid breastfeeding may breastfeed their infants with minimal risk.

Since infants whose mothers die are themselves at higher risk of death, failure to provide life-saving care in the form of ARV therapy for mothers may result in few children's lives saved, as well as a poor quality of life for the infants who are orphaned. It is ethically questionable to consider mothers with HIV infection merely as vectors that may transmit infection to their infants—mothers require care and support for their own disease. Now that effective ARV treatments are becoming affordable in developing countries, it is possible to consider providing life-saving treatment to those mothers who require it. In addition, providing effective care may significantly increase the uptake of interventions for prevention of MTCT of HIV since mothers will perceive a clear benefit for themselves.

Little is known about the safety and effectiveness of combination ARV therapy in preventing MTCT of HIV in resource-limited settings, or of the impact that combination therapy may have on the health of mothers.

**Progress**

The Department convened a Research Group on the Prevention of MTCT of HIV in December 2001. The Group discussed the need for further research in this area to review the activities of other research teams and to identify an acceptable and ethically sound way of addressing key outstanding questions. The meeting was attended by scientists and policy-makers from selected developing countries with high prevalence rates of HIV infection, advocates for people living with HIV/AIDS (PLWHA) and for women's rights, and experts from collaborating agencies.

There is considerable research under way to assess whether providing immunological or ARV prophylaxis to the infant reduces the risk of acquiring HIV. Some groups are studying the potential for protection offered by different forms of postexposure prophylaxis, while others are studying extended prophylactic regimens—during the breastfeeding period, or during the period of mixed feeding as the infant is being weaned from breast milk when the risk of transmission is thought to be highest. Similarly, several teams are studying the impact of different infant feeding patterns on the risk of transmission through breast milk—exclusive compared with mixed breastfeeding—or the impact of abrupt weaning. No other teams are studying the effects of providing ARV therapy for the mother as a way of both improving her own health and reducing the risk of HIV transmission through breast milk by suppressing her viral load.

Since the rate of MTCT of HIV has been shown to be higher among mothers at a more advanced state of the disease, the new protocol stratifies women according to their CD4 counts. Women with high CD4 counts (above 500 cells/mm³), who have only a small risk of transmitting HIV to their infants, will...
be provided with one of the existing short-course prophylactic regimens, such as zidovudine (ZDV) or nevirapine (NVP). Women with low CD4 counts (below 200 cells/mm³) require ARV therapy for the management of their HIV disease and will be provided with a triple combination therapy through pregnancy, delivery, the breastfeeding period and beyond, for as long as they require it. Women with intermediate stage disease (CD4 counts in the range of 200–500 cells/mm³) will be randomized to receive either a standard short-course prophylaxis with ZDV or NVP, or will receive triple combination therapy for up to 6 months provided that they continue to breastfeed. Any woman who requires therapy during the study period, either because her CD4 count has fallen below 200 cells/mm³ or she has developed AIDS, will be given triple therapy. All women will be given appropriate infant feeding counselling according to WHO recommendations, and free replacement feeding will be provided to those who choose this option. All women and their infants will be followed for two years from delivery to assess morbidity and mortality in both mothers and infants.

While providing long-term care for HIV-infected women and their partners is beyond the scope and resources of the Department, partnerships are being developed with non-governmental organizations (NGOs), local care and support groups, and public and private health care sectors in the study sites to provide care in the post-study period. It is inequitable and possibly unethical not to make provision for long-term care and access to treatment for the women who volunteer to participate in the research.

The details of the study protocol, the mechanisms and procedures for implementing the research and the necessary infrastructures are being developed. It is planned to initiate the first steps of the research in early 2002.

**Simple diagnostic tests for STIs**

**Objective and rationale**

The current capacity to definitively diagnose the most important RTIs in women remains limited, especially in resource-constrained settings. Rapid diagnostic tests that are suitable for use without a complex laboratory infrastructure could be of great value in the screening for, and management of, RTIs and the prevention of complications. More than 40 rapid diagnostic tests are on the market, but little is known about their performance under field conditions and their suitability for use in health care services in developing countries.

**Progress**

The Department is participating in evaluating the performance of selected rapid diagnostic tests in collaboration with the Sexually Transmitted Disease Diagnostic Initiative (SDI) within the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR). Tests for the diagnosis of syphilis in antenatal care and for the diagnosis of gonorrhoea and chlamydia among symptomatic STI patients are being evaluated. The projects will commence in 2002.

In addition to evaluating the performance of the tests, utility studies are planned to assess the cost-effectiveness of using such rapid diagnostic tests in reproductive health care settings. The results from these studies will guide national or provincial programme managers to determine the suitability of rapid diagnostic tests in the different health care settings.

**NORMS AND TOOLS**

**Specific objectives/targets**

The Department is currently developing tools in two main areas where existing health care services for reproductive health can contribute to the reduction of HIV transmission and to the improved prevention and management of RTIs. While reproductive health care settings are not the only opportunity to impact on the HIV and STI epidemics, they provide an important resource on which the interventions can be based, and are a complement to HIV and STI prevention programmes targeted at specific high-risk groups.

**Development of new norms/tools**

**Standardized information on infant feeding**

While considerable progress has been made in identifying practical and affordable ARV prophylactic regimens to reduce the risk of in utero and intrapartum transmission of HIV from an infected mother to her infant, little advance has been made in reducing the risk of transmission through breast milk. In many resource-poor settings, replacement feeding can be a dangerous and expensive option, in addition to being poorly tolerated, culturally and socially.

Although the risk of HIV transmission through breastfeeding is well established, the substantial benefits of breastfeeding are also well documented. Compared with replacement feeding, breastfeeding has consistently been shown to reduce infant morbidity and mortality associated with infectious diseases. In addition to its anti-infective properties, breast milk contains all the nutritional requirements necessary for the infant’s first six months of life. One concern about advocating replacement feeding for infants born to HIV-infected mothers is that this will undermine the promotion of breastfeeding among women who are known to be not infected with HIV, as well as among those women whose HIV infection status is not known.

Factors associated with an increased risk of HIV transmission through breast milk include high maternal viral load, advanced stage of disease, seroconversion in the mother during breastfeeding, prolonged breastfeeding, high volume of breast milk ingested, the presence of any breast pathology
such as mastitis, breast abscess or cracked nipples, or oral thrush in the infant. One study has shown that mixed feeding carries a higher risk of HIV transmission than exclusive breastfeeding, though this result has yet to be confirmed by other research.

All studies published to date on the risk of HIV transmission through breast milk used slightly different methodologies to record infant feeding patterns, breast pathology and/or infant morbidity. These differences severely limit any comparisons between studies or a comprehensive meta-analysis of all aspects of transmission through breastfeeding. In order to facilitate the comparison of data on transmission of HIV through breastfeeding between ongoing and planned studies, the Department developed a tool to record information in a standardized manner. This work was done in collaboration with WHO’s Department of Child and Adolescent Health and Development, and the Academy for Educational Development in Washington, DC, USA.

The methodology and instruments used in recently completed studies of breastfeeding transmission, lactational amenorrhoea, and health and nutrition surveys were reviewed and a set of common definitions and instruments to record the minimal essential information was drafted. The instrument was reviewed by experts in research on HIV, breastfeeding and infant nutrition, and then pilot-tested in eight sites from seven countries (Brazil, Burkina Faso, Côte d’Ivoire, India, Kenya, South Africa and Zimbabwe). Following the pilot test a workshop was convened in Gaborone, Botswana in March 2001 and the final version of the tool was accepted. The tool includes a standard nomenclature for, and definitions of, infant feeding patterns, a description of breast pathologies relevant to HIV transmission, a set of core questionnaires to be included in future research studies, the minimal timing and intervals for data collection, and suggested categories for the analysis and presentation of data.

The tool was finalized and published in 2001, and disseminated through direct contacts with HIV research teams as well as the web sites of the Department and WHO’s Department of Child and Adolescent Health and Development. An article describing the rationale for, and development of, the tool was published in a special issue of Statistics in Medicine in December 2001 (Gaillard P, Piwoz E, Farley TMM, Statistics in Medicine, 2001, 20:3527–3535). The tool has been adopted as the core of the infant feeding instruments by eight newly developed studies and the proposed methods for analysis and presentation of data are being used by two studies currently under way. Further experience with this infant feeding tool will allow for the intended review of its usefulness, strengths and limitations and the preparation of a revised tool for future research on this topic.

New work undertaken on the development of norms/tools

**Clinical guides for the management of pregnant women with HIV infection**

In 1999, the Department was asked to develop a series of clinical guides to help implement interventions to prevent MTCT of HIV, to provide appropriate care and support for the HIV-infected mother, and to give advice on infant feeding options. The guides were drafted subsequent to a workshop in 2000, and reviewed by experts in WHO and in countries with experience of managing pregnant women with HIV infection. The guides have been divided into four separate, but complementary booklets: Voluntary counselling and testing for HIV in pregnant women, Antenatal care for HIV-infected women, Labour and delivery care for HIV-infected women, and Post-pregnancy care of HIV-infected mothers and their infants. Care has been taken to ensure compatibility with existing WHO guides, for example, those on voluntary counselling and testing, pregnancy and childbirth, and infant feeding and counselling. The development of the guides has highlighted issues on which WHO policies and guidance are unclear, in particular, the optimal immunization schedule for infants born to mothers with HIV infection, and the most appropriate algorithms for testing for HIV infection in pregnancy. Work is under way with the relevant WHO departments to build a consensus on such issues.

The final comments from the reviewers were compiled into a field-test version which has been distributed to selected countries, clinical staff and midwives with experience of counselling and care of women with HIV infection. With the collaboration of the WHO Regional Office for Africa (AFRO) in Harare and experts from the Chris Hani Baragwanath Hospital, Soweto, South Africa the field test has been completed in Ethiopia and Thailand, and will be undertaken in the Bahamas, Guyana and Kenya in early 2002. The guides will be finalized following the field test and disseminated through
WHO Regional and Country Offices, national AIDS control programmes, national and international professional societies and through the Departmental web site. It is planned to translate the guides into French, Spanish and Portuguese and disseminate them in a wide range of countries.

The guides will be reviewed and updated on a regular basis as new information on the prevention of MTCT of HIV becomes available and new WHO policies and guidance are issued.

**Psychosocial support for HIV-infected mothers and families**

The Department is developing a series of materials to provide psychosocial support for HIV-infected mothers and their families. The basis for the materials is an expert review of the literature and experience with providing psychosocial support in resource-limited settings, a guide to assess the psychosocial needs of women with HIV infection and their families, a guide on how to provide appropriate psychosocial support, and a tool to evaluate psychosocial support programmes. The Department is working closely with AFRO in Harare and with a local NGO—the Zimbabwean AIDS Prevention and Support Organization (ZAPSO) which is implementing a demonstration project on psychosocial support for HIV-infected mothers and their families. The tools developed in Zimbabwe will be generalized and used as the basis for developing generic tools for psychosocial support in other settings.

**Integration of RTI prevention and management in reproductive health settings**

In cooperation with the Population Council’s FRONTIERS Project, the Department, together with the Joint United Nations Programme on HIV/AIDS (UNAIDS), funded six case studies on the integration of STI prevention and care into reproductive health services. The objective of the studies was to document programmatic approaches where effective integration has taken place, the lessons learned during their implementation, and the cost in financial and human terms. The Department provided technical support to three studies that specifically focused on integration of congenital syphilis control in antenatal care programmes. The other studies focused on STI case management in primary health care settings. Studies on the control of congenital syphilis were undertaken in Bolivia, Kenya and South Africa. The reports were received in 2001. Two of these studies formed the basis for the FRONTIERS intervention trial to increase male involvement in reproductive health through the initial involvement of men in screening for antenatal syphilis.

The reports underscore the difficulty in integrating services when additional tasks are introduced into existing services, particularly when they are aimed at health goals that are different from the existing services. Supervision, financial and managerial support, and periodic reinforcement are required before an additional task can be safely assumed to be integrated.

Some of the country reports are being published individually in international journals, while a compendium of the reports will be submitted to the *Bulletin of the World Health Organization* which is planning a special issue on congenital syphilis. The issue will highlight the poor effectiveness of most efforts to control congenital syphilis, despite the availability of affordable and effective tests and treatments. Analogies will be drawn between the above situation and current initiatives to reduce the risk of MTCT of HIV. Underlying both is the fact that the limitations of the health care system severely restrict the options to integrate new, evidence-based interventions.

**Programme guidance tool on improved RTI management**

The RTI Programme Guidance Tool, developed in partnership between the Department and the Population Council's
Section 3 - Reproductive tract infections and sexually transmitted infections

HORIZONS Project, was field-tested in Brazil, Cambodia and Latvia in 2000, and in Ghana in 2001. This tool is an adaptation of the Programme’s Strategic Approach for Contraceptive Technology Introduction to programmatic decisions on STI control and management. It considers a broad range of programmatic interventions and helps programme managers to identify the information required to decide on the most appropriate interventions for their national context. In the light of experience from the field trials, the RTI Programme Guidance Tool is being re-written in a simplified, more user-friendly version and will be ready for printing and distribution in the first half of 2003.

In addition, an evaluation of the RTI Programme Guidance Tool is also being designed. While it is difficult to define objective indicators for the impact of the RTI Programme Guidance Tool, follow-up with programme managers in two of the field-test countries revealed that many key findings of the RTI Programme Guidance Tool assessment have already been implemented. Additional evidence of the impact of the RTI Programme Guidance Tool is required, and a formal evaluation will consequently be carried out in the four field-test countries (Brazil, Cambodia, Latvia and Ghana). China will use the procedures of the RTI Programme Guidance Tool to define the appropriate level of integrated services for the different health care settings. This is part of the country’s plan to integrate RTI management into the services provided through the State Family Planning Commission. This fifth field test in China will provide an opportunity to collect information on the impact of the tool prospectively, rather than retrospectively, as in the other field-test countries.

Proposals for operations research that arose from the application of the RTI Programme Guidance Tool in Cambodia and Latvia have been developed and approved during the past year. They will be implemented in 2002. Additional proposals from Brazil and Ghana may be developed during 2002, with funding to be provided by the HORIZONS Project.

New norms/tools initiated

Essential care practice guide for reproductive tract infections

Building on the work of the RTI Programme Guidance Tool, the Department initiated, in 2001, the development of an Essential care practice guide for the management of reproductive tract and sexually transmitted infections (ECPG RTI) in reproductive health care settings. This will be a companion volume to the ECPG for pregnancy, childbirth and newborn care and the ECPG for family planning.

The goal of the ECPG for RTIs is to provide guidance for the management of RTIs in women and men presenting to reproductive health care services (family planning or maternal and child health), primary health care settings that provide family planning, or maternal and child health services. The guide will cater for clients who present for advice and counselling without any symptoms or with infection-related complaints, as well as for symptomatic patients seeking treatment. The ECPG will include guidance for providers at the first point of contact in reproductive health care services. This guidance will include not only diagnosis and treatment of RTIs but also basic principles of provider–client interaction, as well as partner referral and counselling for prevention of future infection, including dual protection.

The nature of the advice and services offered to clients depends on the local situation in terms of disease prevalence, resistance patterns and the resources available for diagnosis and management. Therefore, the ECPG for RTIs will also include a second-level guide aimed at national or provincial programme managers who determine the standards of care and approaches applicable in the different settings in their countries. The first-level guide will include a series of algorithms and approaches tuned to the different settings determined by, for example, the prevalence of cervical pathogens in women seeking treatment for vaginal discharge, sexual behaviour patterns, cultural norms about sex and sexual matters, and the facilities available. The second-level programme manager’s guide will include guidance on how to adapt and use the ECPG for RTIs for maximum benefit for their own national or local situation. This guide will help programme managers to find and interpret national and local data on RTI/STI and the important behaviours surrounding it in order to select the best alternatives for use at the first point of care.

The work on the ECPG for RTIs is being closely coordinated with WHO’s HIV/AIDS Department which is responsible for STI prevention and case management. Their existing guides—for example, the use of syndromic management for STI prevention and case management. Their existing guides—for example, the use of syndromic management for symptomatic cases in high-prevalence settings—will be incorporated, where relevant, into the ECPG for RTIs.

The field-testing of the ECPG for RTIs will be initiated in 2002.

TECHNICAL COOPERATION WITH COUNTRIES

Global Distance Learning Network on the prevention of MTCT of HIV

In 2000, the Department availed of the facilities of the World Bank Global Distance Learning Network (GDLN) to create and run a series of videoconferences that allowed countries to exchange information and experiences in implementing MTCT prevention interventions. As part of its support of the UNAIDS/WHO/UNICEF Inter-Agency Task Team on MTCT, the Department evaluated the GDLN sessions in March 2001, and has a new series of nine videoconferences planned for the period January–July 2002. These will include three sessions for English-speaking African countries, three sessions for French-speaking African countries and three sessions for Asian countries.
Annex 1

RESEARCH GROUP ON EFFECTIVENESS OF MALE AND FEMALE CONDOMS FOR THE PREVENTION OF STIs IN 2001

Members

Mags Beksinska, Reproductive Health Research Unit, Durban, South Africa
Patricia Claeys, International Centre for Reproductive Health, Ghent, Belgium
Oluwakayode Dada, Centre for Research in Reproductive Health, Sagamu, Nigeria
Yves Lafort, Institute of Tropical Medicine, Antwerp, Belgium
Mary Latka, The New York Academy of Medicine, New York, NY, USA
Saiqa Mullick, Reproductive Health Research Unit, Durban, South Africa
Eddy Van Dyck, Institute of Tropical Medicine, Antwerp, Belgium
Bea Vuylsteke, Projet RETRO-CI, Abidjan, Côte d’Ivoire

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>Members</td>
<td>4</td>
<td>50</td>
<td>4</td>
<td>50</td>
</tr>
<tr>
<td>Women</td>
<td>3</td>
<td>38</td>
<td>2</td>
<td>25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>From:</th>
<th>Developing countries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
</tr>
<tr>
<td>AFRO</td>
<td>4</td>
</tr>
<tr>
<td>AMRO</td>
<td>1</td>
</tr>
<tr>
<td>EMRO</td>
<td>3</td>
</tr>
<tr>
<td>EURO</td>
<td>1</td>
</tr>
<tr>
<td>SEARO</td>
<td>3</td>
</tr>
<tr>
<td>WPRO</td>
<td>1</td>
</tr>
</tbody>
</table>

Collaborating agency scientist

Maurizio Macaluso, Centers for Disease Control and Prevention, Atlanta, GA, USA
Annex 2

RESEARCH GROUP ON MOTHER-TO-CHILD TRANSMISSION OF HIV IN 2001

Members

Isidore Adeyanju, National AIDS Programme, Cotonou, Benin
Andrew Agabu, National AIDS Commission, Lilongwe, Malawi
François Dabis, Université Victor Segalen Bordeaux 2, Bordeaux, France
Raman Gangakhedkar, National AIDS Research Institute, Pune, India
Jeanne Gapiya, Association Nationale de Soutien aux Séropositifs et Sidéens, Bujumbura, Burundi
Geert Haverkamp, National AIDS Therapy and Evaluation Centre, University of Amsterdam, Amsterdam, the Netherlands
Peter Iliff, Zvitambo Project, Harare, Zimbabwe
Eugénie Kayirangwa, Ministry of Health, Kigali, Rwanda
Nicolas Meda, Centre Muraz, Bobo-Dioulasso, Burkina Faso
Françoise Ndayishimiye, Project GIPA, Bujumbura, Burundi
Sunanda Ray, Southern Africa AIDS Information, Harare, Zimbabwe
John Shao, Kilimanjaro Christian Medical Center, Moshi, United Republic of Tanzania
Roger Shapiro, Botswana–Harvard Partnership, Boston, MA, USA
Margaret Siwale, Lusaka Trust Hospital, Lusaka, Zambia
Philippe Van de Perre, Centre Hospitalier Régional Arnaud de Villeneuve, Montpellier, France

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>Members</td>
<td>11</td>
<td>73</td>
<td>4</td>
<td>27</td>
</tr>
<tr>
<td>Women</td>
<td>4</td>
<td>27</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

from:

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>10</td>
<td>67</td>
</tr>
<tr>
<td>AMRO</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>EMRO</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>EURO</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>SEARO</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>WPRO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Collaborating agency scientists

Anne Duerr, Centers for Disease Control and Prevention, Atlanta, GA, USA
Lynne Mofenson, National Institutes of Health, Rockville, MD, USA
Ellen Piwoz, Academy for Educational Development, Washington, DC, USA
Miriam Rabkin, MTCT plus, Columbia University, New York, NY, USA
Annex 3

SCIENTISTS IN 2001

Principal investigators

Oluwakayode Dada, Centre for Research in Reproductive Health, Ogun State University, Sagamu, Nigeria
Siripon Kanshama, Ministry of Health, Nonthaburi, Thailand
Florence Mirembe, Department of Obstetrics and Gynaecology, Makerere University, Kampala, Uganda
Chander Puri, Institute for Research in Reproduction, Mumbai, India

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>4</td>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>2</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>2</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td>2</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other scientists

Chitwarakorn Anupong, Ministry of Public Health, Nonthaburi, Thailand
Lalit Bhutani, Sitaram Bhartia Institute of Science and Research, New Delhi, India
Stanley Blanco, United States Agency for International Development (USAID), La Paz, Bolivia
Florence Carayon, Family Health International, Research Triangle Park, NC, USA
Shanta Chilänge, Institute for Research in Reproduction, Mumbai, India
Inam Chitsike, National MTCT Technical Group, Harare, Zimbabwe
Moshira El-Shafei, Cairo Technical Office, Cairo, Egypt
Patricia García, School of Public Health, Universidad Peruana Cayetano Heredia, Lima, Peru
Glenda Gray, University of Witwatersrand, Johannesburg, South Africa
Sarah Hawkes, Population Council South and East Asia Regional Office, New Delhi, India
Kamal Hazari, Institute for Research in Reproduction, Mumbai, India
Liz Lindsay, University of Victoria, Sidney, Canada
James McIntyre, University of Witwatersrand, Johannesburg, South Africa
André Meheus, Epidemiology and Community Medicine, University of Antwerp, Antwerp, Belgium
Jane Mutambirwa, University of Zimbabwe, Harare, Zimbabwe
Clemensia Nakabiito, Department of Obstetrics and Gynaecology, Makerere University, Kampala, Uganda
Ibra N’Doye, Institut d’hygiène, Dakar, Senegal
Daisy Nyamukapa, National AIDS Control Programme, Harare, Zimbabwe
Lawrence Odusoga, Department of Obstetrics and Gynaecology, Ogun State University Teaching Hospital, Sagamu, Nigeria
Donata Origo, Zimbabwean AIDS Prevention and Support Organization, Harare, Zimbabwe
Bina Pandey, Department of Obstetrics and Gynaecology, Makerere University, Kampala, Uganda
Telma Queiroz, Projeto HIV/DST, Fundação Nacional de Saúde, Fortaleza-Ceará, Brazil
Robert Rice, Family Health International, Research Triangle Park, NC, USA
Richard Steen, Durham, NC, USA
Marleen Temmerman, International Centre for Reproductive Health, Ghent, Belgium
Teodora Elvira Wi, Philippine National AIDS Council Secretariat, Department of Health, Santa Cruz, Manila, the Philippines
Irina Yacobson, Family Health International, Research Triangle Park, NC, USA
Guang Zeng, Chinese Academy of Preventive Medicine, Beijing, China
### Annex 3 (continued)

### SCIENTISTS IN 2001

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>21</td>
<td>75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>13</td>
<td>52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>10</td>
<td>36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>3</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td>1</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>SEARO</td>
<td>5</td>
<td>18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>2</td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex 4

PUBLICATIONS IN 2001


Section 4
Unsafe abortion
Unsafe abortion

I.H. Shah, H. von Hertzen, I.K. Warriner

INTRODUCTION

The Department’s work on abortion is guided by the Programme of Action adopted at the International Conference on Population and Development (ICPD) held in 1994, which urges countries and organizations to address the health consequences of unsafe abortion and to ensure that, in circumstances where abortion is legal, such abortion is safe. It has been estimated that in addition to approximately 80 000 women who die each year as a consequence of unsafe abortion, another 5 million suffer temporary or permanent disability.

The overall strategy of the Department’s work on preventing unsafe abortion is to:

- generate scientifically sound evidence on prevalence and practices of abortion;
- translate that evidence into norms, tools and guidelines;
- improve technologies and interventions to make abortion safer; and
- assist in the development of programmes and policies to reduce unsafe abortion.

The Department’s activities are designed to address the priorities identified by two consultations on abortion held in August and September 2000, and by the 2001 meeting of the Scientific and Technical Advisory Group (STAG). Research activities encompass documenting the global dimensions of unsafe abortion and its associated morbidity and mortality, studies to understand the context and determinants of unsafe abortion, studies to develop improved methods of nonsurgical abortion, and a study to evaluate the evidence for expanding access to safe abortion through the training of mid-level providers. Also addressed are the development of technical and managerial guidelines for safe abortion services, the development and implementation of guidelines for midwives and other mid-level providers, and technical support to countries to improve abortion care.

RESEARCH ACTIVITIES

Specific objectives of research

The Department conducts research to document the global dimensions of unsafe abortion by gathering and analysing data on unsafe abortion and investigating its determinants and consequences. In doing so, it compiles and maintains data on the incidence of unsafe abortion and abortion-related mortality and morbidity. Work also focuses on exploring the determinants of abortion and the pathways to unsafe abortion as well as the safety and acceptability of abortion provided by mid-level providers.

The overall aim of research on abortion technologies is to improve the efficacy, safety and acceptability of existing methods with a special focus on the needs of developing countries. Invasive procedures for termination of pregnancy, even when carried out by trained personnel and under good clinical conditions, are not without risk to the woman. When these procedures are carried out by untrained personnel under poor clinical conditions, the risks of injury, infection and death rise dramatically. Although vacuum aspiration by a trained provider is among the safest surgical procedures, sufficient numbers of trained providers may not be available to women in developing countries. Nonsurgical abortion may
be more appropriate in these circumstances, keeping in mind that follow-up surgical procedures are needed in only 5% of cases. To meet this aim of expanding access to safe abortion in circumstances where abortion is not against the law, the Department has continued to carry out research on non-surgical abortion in order to determine: (i) the lowest effective dose of mifepristone; (ii) the most suitable prostaglandin analogue as well as its dose and route of administration; and (iii) the most appropriate regimens at different stages of pregnancy.

**Progress**

In addition to a number of new projects initiated in 2001, the Department’s work has progressed in a number of key areas. Progress in research is described below; developments in guidelines, tools and technical cooperation with countries are included in the relevant sections.

**Estimating the prevalence of unsafe abortion**

Reliable data on abortion and unsafe abortion are needed by policy-makers and health planners to address public health needs. In countries where abortion is restricted by law, collecting data on unsafe, induced abortion and its consequences is a challenging task and requires innovative methodologies. Qualified health professionals with access to abortion cases were interviewed during a study in Colombo District, Sri Lanka and the findings were made available in 2001. Different levels of estimates were produced based on varying assumptions. The estimate—40 abortions annually per 1000 women of reproductive age—is comparable to the regional-level estimates for South-East Asia and supports the use of this methodology. In countries where induced abortion is restricted and data are not available, interviewing health professionals provides an alternative means of collecting these data.

**Investigating the dynamics of recourse to induced abortion**

With support from the Programme, a research project has investigated the dynamics of abortion in Matlab, Bangladesh where an integrated family planning and maternal and child health (MCH) programme has been in operation since 1977. The main purpose of this study was to examine whether integration of family planning with MCH services, i.e. by increasing access to contraceptives, has an effect on the incidence of abortion. Several findings from this project were previously reported. New findings have emerged in 2001 on the effects of sex preference on contraceptive use, abortion and fertility. From the early 1980s to the mid-1990s, contraceptive use increased from 40% in 1983 to 64% in 1993, as did recourse to abortion—from an abortion ratio of 16 in 1982–86 to 24 in 1992–95, while fertility declined. Sex preference had an impact on recourse to abortion, especially with the decline in the desired number of children, but not on contraceptive use. There was, however, no evidence to suggest sex-selective abortion.

**Assessing attitudes to abortion**

In many developing countries, the views and opinions of physicians have a powerful impact on whether and what type of reproductive health services are provided to clients. In Argentina, there is no national family planning programme and the law regarding abortion is very restrictive. A study was completed in this country that explored the perspectives of physicians (obstetricians and gynaecologists) on providing abortion under different conditions and on its depenalization as well as on the quality of care provided to women with complications from unsafe abortion. Data were collected, through a self-administered questionnaire, from 467 physicians working at public hospitals that serve a low-income population in Buenos Aires. The response rate was 84%. A majority (79%) of respondents agreed that depenalizing abortion would decrease maternal deaths due to unsafe abortion, and 80% considered that the law should not penalize abortion in cases where there was risk to a woman’s health, incest or rape and fetal malformations. Most (77%) asserted that women with complications due to unsafe abortion should always be treated with medical competence and without any discrimination. Overall, most of the providers were in favour of depenalizing abortion under a number of circumstances, and only a small (9%) group held the view that abortion should be restricted under any circumstances.

**Determining optimal regimens for non-surgical abortion**

Preceding the discovery of the antiprogestin mifepristone, the Programme tested prostaglandin-alone regimens (sulprostone, gemeprost and meteneprost were available at that time) for termination of early pregnancy. This research, however, did not lead to a practical and acceptable regimen: repeated high doses of these prostaglandins were needed to reach acceptable efficacy rates and the treatment caused troublesome side-effects, which were not acceptable to most women who participated in these studies. When mifepristone became available, the Programme tested this new compound for termination of pregnancy, but discovered that it was not sufficiently effective when used alone. The Programme then combined mifepristone and a prostaglandin analogue in a sequential regimen, and this approach resulted in a viable alternative to surgical abortion. This sequential regimen is now in routine use in most European countries, China, Israel, Tunisia and the USA. The Programme has continued to develop the regimen to make it more affordable for developing countries.

A more recent objective is to develop an effective and acceptable misoprostol-only regimen for early first- as well as second-trimester abortions. The benefits of routine priming of the cervix with misoprostol are also being investigated in a new study on whether the safety of the vacuum aspiration procedure can be further improved.

Results from two multicentre studies of early medical abortion were published during 2001. These studies investigated...
the efficacy of mifepristone doses lower than the manufacturers’ recommended dose of 600 mg in an effort to reduce costs.

An earlier WHO study showed that mifepristone in doses of 600 mg, 400 mg and 200 mg, followed 48 hours later by the prostaglandin gemeprost, had similar efficacies when administered up to 56 days of pregnancy (British Medical Journal, 1993, 307:532–537). Recently, a double-blind, randomized, multinational study was carried out in ten centres (Chandigarh, India; Edinburgh, United Kingdom; Havana, Cuba; Shanghai, Tianjin and Hong Kong Special Administrative Region [SAR], China; Ljubljana, Slovenia; Stockholm, Sweden; Szeged, Hungary; Tbilisi, Georgia) to compare the efficacy and side-effects of 200 mg and 600 mg of mifepristone followed by 1 mg gemeprost administered vaginally at 57–63 days’ gestation. A total of 896 women participated in the study. The complete abortion rate with the lower dose of mifepristone was similar to that with the higher dose (92.4% vs 91.7%). The relative risk of failure to achieve a complete abortion with the 200 mg dose compared to the 600 mg dose was 0.9 (95% confidence interval [CI]: 0.6–1.4). The timing of abortion and the incidence of side-effects were comparable in both groups, with the exception of nausea reported at one-week follow-up, which was reported more frequently by women in the higher-dose group (Acta Obstetricia et Gynecologica Scandinavica, 2001, 80:447–451).

Another randomized, double-blind study was carried out to compare the efficacy and side-effects of 50 mg and 200 mg of mifepristone followed by either 0.5 mg or 1.0 mg gemeprost among 1224 women requesting medical abortion at ≤57 days from the last menstrual period. This study included centres in 13 cities: Aberdeen, United Kingdom; Chandigarh, India; Edinburgh, United Kingdom; Havana, Cuba; Shanghai, Tianjin and Hong Kong SAR, China; Ljubljana, Slovenia; Lusaka, Zambia; Singapore; Stockholm, Sweden; Szeged, Hungary; and Tbilisi, Georgia. During the interim analysis, the efficacy for the lowest dose regimen (mifepristone 50 mg followed by 0.5 mg gemeprost) was discovered to be below the predetermined cut-off set as a stopping rule in the study. A total of 249 women were enrolled in this unsuccessful regimen and 325 in each of the other regimens.

The abortifacient efficacy was related to the dose of mifepristone: the crude complete abortion rates were 87.6% and 92.3% in the 50 mg and 200 mg groups, respectively. There was an effect of gemeprost on the efficacy but it was not statistically significant: 88.7% and 91.4% in the 0.5 mg and 1.0 mg groups, respectively. The effect of gemeprost was greater with the lower dose of gemeprost, but the difference was not statistically significant ($P = 0.49$ for the interaction). The relative risk of failure to have a complete abortion with the lower dose of mifepristone was 1.6 (95% CI: 1.1–2.3) times that with the higher dose. In all, 2.3% of women had vacuum aspiration due to heavy bleeding and six women (0.5%) were given blood transfusions. The conclusion from this study was that a single dose of 50 mg of mifepristone followed by 0.5 mg of gemeprost is inadequate for medical abortion.

Acceptability studies show that many women prefer oral administration of drugs. However, a previous study clearly demonstrated that 0.4 mg of oral misoprostol after pretreatment with mifepristone was not effective enough in pregnancies with a gestational age longer than seven weeks (British Journal of Obstetrics and Gynaecology, 2000, 107:524–530). Thus, a study was carried out to test whether repeated administration of oral misoprostol after pretreatment with mifepristone could improve the clinical efficacy. The effects of this regimen on the duration and amount of postabortion bleeding were also evaluated.

This randomized, double-blind study involved three misoprostol regimens administered 48 hours after 200 mg of mifepristone: (i) an initial oral dose of 0.8 mg continued with an oral dose of 0.4 mg twice daily for 7 days; (ii) an initial vaginal dose of 0.8 mg continued with an oral dose of 0.4 mg twice daily for 7 days; and (iii) a vaginal dose of 0.8 mg. The recruitment target was 2250 women, 750 women for each of the three categories of amenorrhoea: (i) up to 49 days; (ii) 50–56 days; and (iii) 57–63 days.

A total of 2219 women were recruited for the study in 15 centres (Beijing, Hong Kong SAR and Shanghai, China; Chandigarh, Mumbai and New Delhi, India; Helsinki, Finland; Ho Chi Minh City, Viet Nam; Ljubljana, Slovenia; Oslo, Norway; Singapore; Stockholm, Sweden; Szeged, Hungary; Targu-Mures, Romania; and Ulaanbaatar, Mongolia). In addition to assessing the efficacy and side-effects, a brief questionnaire was included in the study to collect data on women’s opinions of the regimen, their assessment on whether they would feel confident using the regimen at home, and whether they would prefer home use should they be given the choice.

The analysis of the efficacy was completed by end-2001. When considering undetermined cases as failures, the crude complete abortion rate in the oral group (starting and continuing: O/O) of misoprostol was 92.3%, compared to 93.5% for the vaginal-only (V) group and 94.7% in the group that started with vaginal but continued with oral misoprostol (V/O). The relative risk of failure to achieve complete abortion in the O/O group compared to the V/O group was 1.5 (95% CI: 1.0–2.2). The relative risk of failure to achieve complete abortion in the V group compared to the V/O group was 1.2 (95% CI: 0.8–1.9).

The risk of failing to abort among women with amenorrhoea of ≥57 days was almost three times higher in the O/O group (relative risk [RR]=2.8, 95% CI: 1.3–5.8), and over two times higher in the V group (RR=2.2, 95% CI: 1.0–4.7) when compared with the V/O group. The differences were not significant among women with amenorrhoea of ≤49 days and between 50 and 56 days.
Unsafe abortion

The difference in the median length of bleeding (12–13 days) was not significant in the three groups. Also, 25% of the women in all three groups bled for more than 17 days.

The study suggests that the vaginal route of misoprostol is more effective than the oral route to achieve complete abortion among women with ≥57 days of amenorrhoea, and that continuing prostaglandin for one week improves the efficacy of the method significantly, but does not influence the duration of postabortion bleeding.

New projects initiated during 2000

Several projects have been initiated following the identification of research priorities during the meeting on Priorities and Needs in the Area of Unsafe Abortion in August 2000, the Technical Consultation on Abortion in September 2000, and the meeting of STAG in 2001. These include an updating of data on unsafe abortion, a study of the safety and effectiveness of abortion performed by mid-level providers, and research into the prevalence of abortion and pathways to abortion in Togo. In addition, several new multicentre clinical trials were developed for launch in early 2002. These will address the development of misoprostol-only regimens for the termination of pregnancy in early first trimester as well as in the second trimester; the advantages and disadvantages of routine priming of the cervix with mifepristone; and a four-arm study comparing the efficacy of 100 mg and 200 mg of mifepristone followed by 0.8 mg vaginal misoprostol either 24 hours or 48 hours later.

Updating data on unsafe abortion worldwide

The number of unsafe abortions and other abortion-related indicators are among the most difficult reproductive health data to estimate. As part of the Department’s commitment to maintain up-to-date data on unsafe abortion worldwide, the 1998 document Unsafe abortion: global and regional estimates is being updated. The final product will provide estimates of unsafe abortion, globally and by region, and of maternal mortality due to unsafe abortion.

Estimating the prevalence of abortion and its role in fertility decline

Two priorities highlighted during the recent consultations on abortion—(i) documenting the incidence of abortion, and (ii) research on pathways to abortion—are being addressed by a new study. The study will measure the prevalence of abortion and its impact on fertility levels, and study the pathways to abortion among women living in Lomé, Togo. Currently, the legislation in Togo permits abortion only when necessary to save a woman’s life. Fertility levels have declined to a greater extent in Lomé than in other parts of Togo, but increases in the prevalence of contraceptive use are too small to sufficiently explain the change. The investigators will examine the characteristics and circumstances of women seeking abortions, and determine the extent to which abortions are used to limit or space births and hence affect fertility levels in Lomé. The project will employ both qualitative and quantitative research methods, including a community survey of 4500 women, in-depth interviews and focus group discussions.

Assessing the safety and efficacy of mid-level providers of abortion

In developing countries, access to safe abortion services is a challenge for many women facing an unwanted pregnancy. Of the approximately 55 000 unsafe abortions that occur worldwide every day, 95% of them take place in developing countries. Complications arising from unsafe abortion contribute to nearly one-fourth of the maternal deaths in some developing countries. In circumstances where abortion is legal, the law generally restricts the provision of abortion to physicians and, in some cases, requires additional training and certification. For a variety of geographical, financial and social reasons, millions of women turn to abortion provided by nonphysicians who may not be clinically trained in abortion techniques, including midwives, paramedics and traditional birth attendants. The consequences of unsafe abortion for women’s health, including life-threatening or lifelong complications, are substantial and result in significant costs to the health care system and its resources.

One approach to reduce unsafe abortions and their consequences is to expand the provision of abortion services to include trained mid-level providers, or nonphysicians among those qualified to perform abortions in circumstances where abortion is legal. The terms “nonphysician” and “mid-level providers” refer to a broad range of nonphysician health workers including midwives, nurses, clinical officers, physician assistants and paramedics, among others, whose training and responsibilities differ from one country to another but who are involved in the provision of reproductive health care or primary health care services.

In areas where the shortage of physicians is severe, expanding and decentralizing abortion services would greatly increase women’s access to safe abortion services and also help to conserve resources. However, evidence suggesting that trained nonphysicians are able to perform abortions as effectively as physicians is sparse and often anecdotal. There is a lack of rigorous studies comparing abortion outcomes by different types of providers. Specifically, there is a need for a controlled, randomized trial to investigate the safety of abortions provided by medically trained and government-certified mid-level providers compared to those performed by physicians, in several different sociocultural settings. Although policy-makers in several developing countries have expressed an interest in expanding the provision of abortion services, many are reluctant to initiate change in the absence of evidence indicating that mid-level providers are as competent as physicians. This study is to be the first of its kind in a developing country and will provide policy-makers with the necessary data for them to address expanding the provision of abortion services.
This study will focus on one outcome variable—complications from abortions. Using an experimental study design, this trial will collect evidence on complication rates from abortions performed by nonphysicians and compare them to those arising from abortions performed by physicians.

The study will take place in two developing countries, South Africa and Viet Nam, where mid-level providers can legally carry out abortions and where first-trimester abortions are currently legally performed by both physicians and nonphysicians. The study will be conducted in Marie Stopes International (MSI) clinics in both countries to ensure comparability between clinics and countries.

**Nonsurgical abortion with misoprostol alone**

The wide availability and reasonably low price of misoprostol compared to other prostaglandin analogues have contributed to its use, and also to a renaissance of research for a prostaglandin-only method of pregnancy termination with this compound in countries where mifepristone has not been available. Preparations were carried out to launch a randomized, multicentre trial in early 2002 involving 2100 pregnant women (up to 63 days of gestation) requesting legal termination of pregnancy. The study will be carried out in 11 centres in Armenia, Cuba, Georgia, India, Mongolia and Viet Nam. Eligible women who wish to join the study will be randomly allocated to four treatment groups. Women in all the treatment groups will receive three doses of 0.8 mg of misoprostol, which will be administered either sublingually or vaginally and at either 3-hour or 12-hour intervals. The four regimens will be compared in respect of their effectiveness for inducing complete abortion, induction-to-abortion interval, acceptability and occurrence of side-effects. The clinical phase of the study is expected to last one year.

**Nonsurgical abortion using a sequential regimen of mifepristone and misoprostol**

Another medical abortion study will compare two doses of mifepristone, 100 mg and 200 mg, followed by 0.8 mg of vaginally administered misoprostol either 24 hours or 48 hours later, when used for the termination of early pregnancy in women experiencing amenorrhea of up to 63 days (from the last menstrual period). The four regimens will be compared with respect to the following main outcomes—effectiveness in inducing complete abortion relative to the length of gestation, frequency of side-effects and the duration of bleeding. This study will include 2100 women in 14 centres in China, Hungary, Mongolia, Romania, Slovenia, South Africa, Sweden, Viet Nam, Yugoslavia and Zambia. It is anticipated that the clinical phase of this study will also require one year.

**Routine priming of the cervix with misoprostol**

A randomized, double-blind, multicentre study will be conducted to test whether routine preoperative treatment with 0.4 mg of misoprostol administered vaginally three hours prior to vacuum aspiration reduces complications such as cervical injury, uterine perforation, severe haemorrhage, incomplete evacuation, pelvic infection, etc. This study will include a total of 5000 women up to 12 weeks of pregnancy, who will be recruited in 14 centres in Armenia, China, Cuba, Hungary, India, Mongolia, Romania, Slovenia and Viet Nam. Recruitment is estimated to continue for a year.

**Misoprostol-alone regimens for second-trimester abortion**

The two consultations on the Department’s activities in the area of abortion recommended that effective regimens should also be developed for termination of second-trimester pregnancy. To this end, a protocol was developed for a randomized, double-blind, multicentre study which will involve 680 pregnant women requesting legal termination of pregnancy during the second trimester (14–20 weeks’ amenorrhoea). Women will be randomized to receive up to 5 doses of 0.4 mg misoprostol either vaginally or sublingually every 3 hours. Twelve centres in Armenia, Georgia, Hungary, India, Slovenia, South Africa, Viet Nam and Zambia will participate in this study. The recruitment for the study is expected to require six months and the results should be available by the end of 2002.

**NORMS AND TOOLS**

**Specific objectives**

The development of norms and tools for preventing unsafe abortion and for accessing safe abortion and postabortion care are designed to provide policy-makers and medical practitioners with guidelines for improving the quality of care.

**Midwifery module on the Management of incomplete abortion**

The package of Midwifery modules containing training material aimed at increasing the competency of midwives and other mid-level health workers to manage the major maternal “killers” was developed and distributed over the past several years. It was considered important to develop additional modules to effectively strengthen the capacity of midwives and other health workers. One of these new modules, Management of incomplete abortion, includes postabortion care. The material consists of a complete trainers’ manual and a separate student-notes manual. In 2001, the module was drafted and made consistent with other training material developed by Ipas. The Management of incomplete abortion module has been field-tested and revised. The final version has been subjected to external peer review as part of a technical meeting held in Geneva, Switzerland in 2001 and is anticipated to be published by April 2002.

This module targets midwives as part of the updating and
upgrading of their skills and those of other mid-level providers who require training in reproductive health, including postabortion care. French and Spanish versions of this module are expected. The module will be distributed as part of the Midwifery modules package which remains in high demand, and is currently being reprinted.

Technical and policy guidance on safe abortion

In September 2000, the Department convened a Technical Consultation on Safe Abortion as part of a process to elaborate a technical and policy guidance document to assist Member States and other participants to implement the ICPD+5 key action stated in paragraph 63.iii: “In circumstances where abortion is not against the law, health systems should train and equip health-service providers and should take other measures to ensure that such abortion is safe and accessible. Additional measures should be taken to safeguard women’s health.” (Key Actions for the Further Implementation of the Programme of Action of ICPD). The background document prepared for the Consultation was considerably reworked during 2001, and a detailed review process has been undertaken. Final revisions are being carried out.

Following an introductory chapter that provides an overview of the issues involved, the document covers three aspects of providing safe abortion care within the limits of the law. “Clinical care for women undergoing abortion” reviews the clinical aspects of providing high-quality abortion services, including diagnosis of pregnancy, selection and provision of an appropriate abortion method and postabortion care, and gives recommendations on abortion methods and the characteristics that influence their safety, efficacy and optimal use. “Putting services in place” provides guidance on the essential elements needed to put good quality, legal abortion services in place, covering topics such as assessment, national norms and standards, elements of care at each level of the health system, training and certification, monitoring and evaluation, and financing. “Legal and policy, and contextual considerations” lays out a policy framework to ensure access to safe abortion services to the full extent of the law, covering topics such as the legal grounds for abortion, creating an enabling policy context and removing unnecessary barriers to appropriate care.

It is anticipated that the document will be useful to a broad spectrum of those working in reproductive health, from health programme managers and those responsible for putting services in place, to nongovernmental organizations (NGOs) at the service, information and advocacy levels. Over the next biennium, the Department will support the dissemination of the document essentially through the WHO Regional Offices and through collaboration with partner NGOs. Initial support will be provided to ensure translation of the English-language monograph into the other five official languages of the United Nations (Arabic, Chinese, French, Russian and Spanish), as well as into other languages such as Portuguese and Viet Namese. The Department will also support WHO Regional and Country Offices in providing specific technical support to country and regional processes such as workshops or operations research, as requested. It will also continue to network with NGOs such as Ipas, the International Women’s Health Coalition (IWHC) and Reproductive Health Alliance Europe (RHAIE) in follow-up and dissemination activities related to the monograph.

New work and progress on systematic reviews of abortion

In 2001, three Cochrane systematic reviews addressing safe abortion were completed. Two reviews evaluate the comparisons of different surgical methods to evacuate incomplete abortions and to terminate first-trimester pregnancies. The third systematic review compares surgical and medical methods of first-trimester pregnancy termination. The review on routine antibiotic use for incomplete abortion has been updated. The first two reviews will be included in the WHO Reproductive Health Library No. 5, to be released in March 2002. The third review is currently in press and will be published in The Cochrane Library in 2002. References for these reviews are in Annex 3 of the chapter on “Implementing best practices”.

TECHNICAL COOPERATION WITH COUNTRIES

Improving abortion care in Viet Nam: policy and practice

In 1997, the Programme supported a national strategic assessment of issues related to abortion and abortion services in Viet Nam. This assessment recommended a variety of actions to reduce recourse to abortion and to improve the quality of abortion services, including postabortion family planning. In response to the assessment, the Viet Namese Ministry of Health began a series of activities to implement the recommendations of the assessment, and included commitments to the same in the recently published National Reproductive Health Strategy for 2001–2010.

In mid-2001, the Department received a proposal submitted by the Ministry of Health for the development and testing of a quality, client-centred abortion care model that could be replicated at all levels of the health system in Viet Nam. This Comprehensive Abortion Care (CAC) project will be implemented by the Ministry of Health, the Institute for the Protection of Mothers and Newborns, Hanoi and the Tu Du Obstetrics and Gynaecology Hospital, Ho Chi Minh City. The CAC project is being jointly funded by The Ford Foundation, Ipas and WHO with technical assistance provided by Ipas and WHO.

In the first phase of the project, WHO and Ipas are supporting the development of Viet Namese national standards and guidelines for abortion service delivery and the development of a service delivery package for improving the quality of
comprehensive abortion care based on these standards and guidelines. These guidelines and service delivery protocols will be tested and revised prior to their further dissemination, including training for utilization at the more peripheral levels of service delivery.

**Improving abortion care in Romania: policy and practice**

In November 2001, the Department assisted the Ministry of Health in Romania to conduct a strategic assessment of issues related to abortion in order to identify appropriate research and programme interventions to reduce the recourse to abortion and to improve the quality of abortion services in the public and private health care sectors. A final report will review the findings and provide recommendations for a number of key issues. These are expected to include recommendations for strategies to decrease recourse to abortion through strengthening the availability of contraceptives both at sites providing abortions as well as through training of family physicians in contraception, the broader promotion of emergency contraception and the strengthening of family planning information, education and communication campaigns including use of mass media. Recommendations for improving abortion service delivery will focus on increasing the safety of the procedure through the introduction of improved technologies for surgical abortion as well as the potential introduction of medical abortion. The report will also address strategies to reduce financial barriers for women related to contraception and abortion.

**Establishment of an International Consortium on Medical Abortion**

In June 2001, a meeting was organized by RHAE, in partnership with the Reproductive Health Technologies Project, with support from the Wallace Global Fund and the Swedish International Development Cooperation. The meeting assessed the feasibility of establishing an International Consortium on Medical Abortion and was attended by 38 individuals from 12 countries, including two staff members of the Department.

The participants reviewed the availability and use of medical abortion worldwide, the experiences with its introduction, and considered the ways in which different organizations could work together to address the challenges in introducing medical abortion more broadly. The group concluded that there was a demonstrable need for an International Consortium on Medical Abortion focusing on the needs of developing countries, and reached a consensus on its mission and objectives.

The mission of the International Consortium on Medical Abortion will be to increase access to safe abortion and promote choice of abortion method by making medical abortion more widely available where it is legal.
Annex 1 (a)

SPECIALIST PANEL FOR SOCIAL SCIENCE AND OPERATIONS RESEARCH ON REPRODUCTIVE HEALTH IN 2001

Members

See Annex 1 of “Research on users’ perspectives” in Section 1, “Promoting family planning”.

Section 4 - Unsafe abortion

Annex 1 (b)

RESEARCH GROUP ON POST-OVULATORY METHODS FOR FERTILITY REGULATION IN 2001

Members

See Annex 1a of "Research on the development of methods of fertility regulation" in Section 1, "Promoting family planning".
Annex 2 (a)

RESEARCH GROUP ON SOCIAL SCIENCE AND OPERATIONS RESEARCH - UNSAFE ABORTION

Scientists in 2001

Principal investigators

Radheshyam Bairagi, International Centre for Diarrhoeal Disease Research, Dhaka, Bangladesh
Piyadasa Hewage, Department of Geography, University of Ruhuna, Matara, Sri Lanka
Nguyen Dinh Loan, Department of Maternal and Child Health/Family Planning, Hanoi, Viet Nam
Tran Thi Phuong Mai, Department of Maternal and Child Health/Family Planning, Ministry of Health, Hanoi, Viet Nam
Mihaela Poenariu, East European Institute of Reproductive Health, Targu-Mures, Romania

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>All</td>
<td>4</td>
<td>80</td>
<td>1</td>
</tr>
<tr>
<td>Women</td>
<td>2</td>
<td>40</td>
<td></td>
</tr>
</tbody>
</table>

from:
AFRO
AMRO
EMRO
EURO
SEARO
WPRO

Other scientists

Catalin Andrei, Institute of Health Services Management, Bucharest, Romania
Radu Belou, National College of Physicians, Bucharest, Romania
Cosmina Blai, East European Institute of Reproductive Health, Targu-Mures, Romania
Ionela Cozos, East European Institute of Reproductive Health, Targu-Mures, Romania
Daniela Draghici, Women’s Coalition for Reproductive Health, Bucharest, Romania
Monica Dunarintu, Marie Stopes, Bucharest, Romania
Mihai Horga, Ministry of Health and Family, Bucharest, Romania
Nguyen Thi My Huong, Institute for the Protection of Mother and Newborn, Hanoi, Viet Nam
Virginia Ionescu, Marie Stopes, Bucharest, Romania
Borbala Koo, Society of Education and Contraception and Sexuality, Bucharest, Romania
Dan Lazarescu, National College of Physicians, Bucharest, Romania
Luminita Marcu, Institute of Mother and Child Care, Bucharest, Romania
Doina Ocnuar, Ministry of Health and Family, Bucharest, Romania
Cristian Posea, Society of Obstetrics and Gynaecology, Bucharest, Romania
Silviu Predoi, Ministry of Health and Family, Bucharest, Romania
Florina Prundaru, East European Institute of Reproductive Health, Targu-Mures, Romania
Lia Rugar, National Women's League, Cluj, Romania
Raluca Teodoru, Youth for Youth, Bucharest, Romania
Adrian Vaduva, Society of Obstetrics and Gynaecology, Bucharest, Romania
Liu Zhifang, Tianjin Municipal Research Institute for Family Planning, Tianjin, China
### Section 4 - Unsafe abortion

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>2</td>
<td>10</td>
<td>18</td>
<td>90</td>
</tr>
<tr>
<td>Women</td>
<td>4</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>2</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>18</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>20</td>
<td>90</td>
</tr>
</tbody>
</table>
Annex 2 (b)

RESEARCH GROUP ON POST-OVULATORY METHODS FOR FERTILITY REGULATION - UNSAFE ABORTION

Scientists in 2001

Principal investigators

Simon Alexsaniants, Armenian Research Centre of Maternal and Child Health Protection, Yerevan, Armenia
Karine Arustamian, Armenian Research Centre of Maternal and Child Health Protection, Yerevan, Armenia
Nguyen Huy Bao, Hanoi Obstetric and Gynaecology Hospital, Hanoi, Viet Nam
György Bártfai, Albert Szent-Györgyi Medical University, Szeged, Hungary
Heather Brown, Chris Hani Baragwanath Hospital, Johannesburg, South Africa
Marc Bygdeman, Karolinska Institute, Stockholm, Sweden
Valsamma Chacko, S.A.T. Hospital, Thiruvanathapuram, India
Carina Chan chi wai, University of Hong Kong, Hong Kong, Special Administrative Region of China
Evelio Cabezas Cruz, "Eusebio Hernandez" Gynaecology and Obstetrics Teaching Hospital, Havana, Cuba
Cheng Linan, Shanghai Institute of Family Planning Technical Instruction, Shanghai, China
Kim Dickson-Tetteh, Chris Hani Baragwanath Hospital, Johannesburg, South Africa
Erdenetungalag Radnaabazar, State Research Centre on Human Reproduction and Maternal and Child Health, Ulaanbaatar, Mongolia
Fang Aihua, International Peace Maternity and Child Health Hospital, Shanghai, China
Kristina Gemzell-Danielsson, Karolinska Institute, Stockholm, Sweden
Manuel Gomez Alzugaray, National Institute of Endocrinology, ‘Cmde. Fajardo’ Hospital, Havana, Cuba
Sarala Gopalan, Postgraduate Institute of Medical Education and Research, Chandigarh, India
Nguyen Duc Hinh, Institute for the Protection of Mother and Newborn, Hanoi, Viet Nam
Ho Pak Chung, University of Hong Kong, Hong Kong, Special Administrative Region of China
Helena Honkanen, Helsinki University Central Hospital, Helsinki, Finland
Mihai Horga, Medical Research Centre, Targu Mures, Romania
Nguyen Thi My Huong, Institute for the Protection of Mother and Newborn, Hanoi, Viet Nam
To Minh Huyong, Hanoi Obstetric and Gynaecology Hospital, Hanoi, Viet Nam
Fridtjof Jerve, Ulleval Hospital, Oslo, Norway
Aleksandra Kapamadzija, Clinical Centre Novi Sad, Novi Sad, Serbia, Federal Republic of Yugoslavia
Christine Kaseba, University Teaching Hospital, School of Medicine, Lusaka, Zambia
Archil Khomassuridze, Zhordania Institute of Human Reproduction, Tbilisi, Georgia
Laszlo Kovacs, Albert Szent-Györgyi Medical University, Szeged, Hungary
Liu Yinkun, Liver Cancer Institute, Zhong Shan Hospital, Shanghai, China
Suneeta Mittal, All India Institute of Medical Sciences, New Delhi, India
Nguyen Thi Nhu Ngoc, Hung Vuong Hospital, Ho Chi Minh City, Viet Nam
George Okeov, Armenian Research Centre of Maternal and Child Health Protection, Yerevan, Armenia
Nguyen Thi Ngoc Phuong, Tu Du Hospital, Ho Chi Minh City, Viet Nam
R.N.V. Prasad, National University of Singapore, Singapore
Alenka Pretnar-Darovec, University Medical Centre, Ljubljana, Slovenia
Augustin Rosca, East European Institute of Reproductive Health, Cluj Napoca, Romania
Rashmi Shah, Institute for Research in Reproduction, Mumbai, India
Song Si, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Biu Suong, Hanoi Obstetric and Gynecology Hospital, Hanoi, Viet Nam
Oi-shan Tang, University of Hong Kong, Hong Kong, Special Administrative Region of China
Hoang thi Diem Tuyet, University of Hong Kong, Hong Kong, Special Administrative Region of China
Nguyen Duc Vy, Institute for the Protection of Mother and Newborn, Hanoi, Viet Nam
Wu Shang-chun, National Research Institute for Family Planning, Beijing, China
### Section 4 - Unsafe abortion

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>28</td>
<td>67</td>
<td>10</td>
<td>24</td>
</tr>
<tr>
<td>Women</td>
<td>18</td>
<td>43</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td><strong>from:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>3</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>2</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td>10</td>
<td>24</td>
</tr>
<tr>
<td>SEARO</td>
<td>4</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>19</td>
<td>45</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Other scientists

José Carbonell, Meditarrânia Médica, València, Spain  
Constantin Enciuレスcu, Center of Public Health Targu-Mures Targu-Mures, Romania  
Qiao Gen-mei, National Research Institute for Family Planning, Beijing, China  
Attila Kereszturi, Albert Szent György Medical University, Szeged, Hungary  
Nguyen Thi Ngoc Khanh, Institute for the Protection of Mother and Newborn, Hanoi, Viet Nam  
Miroslava Mirkovic, Clinical Center Novi Sad, Novi Sad, Serbia, Federal Republic of Yugoslavia  
Nair Rajasekharan, S.A.T. Hospital, Thiruvanathapuram, India  
Helen Rees, Chris Hani Baragwanath Hospital, Johannesburg, South Africa  
Janette Rodriguez, “Eusebio Hernandez” Gynaecology and Obstetrics Teaching Hospital, Havana, Cuba  
Eric Schaff, University of Rochester, Rochester, NY, USA  
Allan Templeton, University of Aberdeen, Aberdeen, United Kingdom  
Pham Viet Thanh, Tu Du Hospital, Ho Chi Minh City, Viet Nam  
Le Thanh Thuy, Hanoi Obstetric and Gynecology Hospital, Hanoi, Viet Nam  
George Tsertsvadze, Zhordania Institute of Human Reproduction, Tbilissi, Georgia  
Tamar Tsoreteli, Zhordania Institute of Human Reproduction, Tbilissi, Georgia  
Alejandro Velazco, “Eusebio Hernandez” Gynaecology and Obstetrics Teaching Hospital, Havana, Cuba  
Jelka Vukelic, Clinical Center Novi Sad, Novi Sad, Serbia, Federal Republic of Yugoslavia

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>8</td>
<td>47</td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>Women</td>
<td>4</td>
<td>24</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td><strong>from:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>1</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>2</td>
<td>12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>SEARO</td>
<td>1</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>4</td>
<td>24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex 3

RESEARCH GROUP ON SOCIAL SCIENCES AND OPERATIONS RESEARCH - UNSAFE ABORTION

Publications in 2001


Hewage P. Cases of induced abortion reported to the health professionals in Colombo district. *Journal of the Faculty of Humanities and Social Sciences*, University of Ruhuna, Sri Lanka (in press).


Annex 4

RESEARCH GROUP ON POST-OVULATORY METHODS OF FERTILITY REGULATION - UNSAFE ABORTION

Publications in 2001


Indian Council of Medical Research Task Force. A multicentre randomised comparative clinical trial of 200 mg RU486 (mifepristone) single dose followed by either 5 mg 9-methylene PGE2 gel (meteneprost) or 600 µg oral PGE1 (misoprostol) for termination of early pregnancy within 28 days of missed menstrual period. Contraception, 2000, 62:125–130.


Section 5
Promoting sexual and reproductive health of adolescents
INTRODUCTION

Adolescence is a time of transition from childhood to adulthood, during which young people experience changes following puberty, but do not immediately assume the roles, privileges and responsibilities of adulthood. Experiences of adolescence vary by age, sex, marital status, class, region and cultural context. Moreover, social, economic and political forces are rapidly changing the ways in which young people must prepare for adult life. These changes have enormous implications not only for adolescents' education, employment, marriage, childbearing, but also for their sexual and reproductive health and behaviour. Thus, as a group, adolescents have sexual and reproductive health needs that differ from those of adults in important ways, and which remain poorly understood or served in most parts of the world. Neglect of this population has major implications for the future, since sexual and reproductive behaviours during adolescence have far-reaching consequences for people's lives as they develop into adulthood.

OBJECTIVES

The Department's work on promoting adolescent sexual and reproductive health concentrates on addressing these gaps, with the objective of enabling the experience of healthy sexual development and maturation and enhancing the capacity for equitable and responsible relationships. The main focus is on promoting research and enhancing the evidence base on the sexual health situation and needs of adolescents. This includes intervention research on the optimal provision of health and information services, and related activities that are intended to strengthen research capacity and to disseminate findings. At the same time, technical and managerial tools and advocacy materials developed for reproductive health in the population at large are also designed to address the unique needs of adolescents.

The work of the Department in this area is carried out in collaboration with the Department of Child and Adolescent Health and Development, the department responsible for coordinating WHO's work on adolescent sexual and reproductive health issues.

RESEARCH ACTIVITIES

SPECIFIC OBJECTIVES OF RESEARCH

The aim is to support research that addresses factors that contribute to positive sexual and reproductive health outcomes, especially those that can be influenced by appropriate interventions in developing countries. Consequently, the focus is on behavioural research, both social science and operations, largely supported by the ongoing social science research initiative on the topic.

PROGRESS

Social science research initiative on adolescent sexual and reproductive health

In 2001, 33 research projects in 24 countries continued to study the social and behavioural aspects of adolescent sexual and reproductive health in different developing country settings. These ongoing projects were approved in 2000 or earlier. As described in earlier reports, the themes under investigation are: (i) sexual risk behaviours, their correlates and consequences; and (ii) health-seeking behaviour, quality of care and provider perspectives. Some preliminary findings are given below.

Initial study findings

Findings from two studies shed light on risky and rarely
researched sexual behaviours among adolescents—sex for gifts or money and coerced sex. In a qualitative study among out-of-school adolescents in the United Republic of Tanzania, both females and males acknowledged the practice of providing gifts and money to female sexual partners. Typically, young males reported that they were able to convince partners to engage in sex only through promises of money or gifts. They perceived money, and not romance, to be the primary motivation underlying the consent to sex by out-of-school girls. Interestingly, although several females in the study acknowledged that recent sexual encounters had been accompanied by material gain, they attributed a different meaning to this practice. Not a single female reported that she had consented to sexual intercourse out of material motivation. Rather, in group discussions and in-depth interviews, female participants clarified that exchange of gifts did not necessarily entail a quid pro quo for sexual favours, but was a symbol of a partner’s love and commitment; gifts were sought to “test if a boy is serious with his sexual proposal”, as a strategy “to test if a boy really loves her”.

A study on sexual coercion of in-school and apprenticed adolescents in Ibadan, Nigeria highlights the occurrence of a range of unwanted experiences, including unwanted touch, attempted unwanted sex and experience of forced sex among both female and male adolescents. As reported in Figure 5.1 below, female apprentices clearly fared worst and female students only slightly better, with about 40% experiencing unwanted touch, and 19% and 11%, respectively, reporting coerced sex. Notably, young males, albeit fewer, also reported the experience of unwanted sexual advances and 9% and 7% of male students and apprentices, respectively, reported the experience of forced sex. The leading perpetrators of sexual coercion reported by females were a boyfriend or a known (or at least identifiable) adult male residing in the community. Adolescent males also reported coercion by adult males in the community (and in some cases a boyfriend), and some reported unwanted touching by a girlfriend or female peer.

A prospective study in Fortaleza, Brazil, explored the consequences of pregnancy in adolescence by comparing two groups of adolescents attending a health facility—one group for receiving antenatal care and the second for postabortion care. The adolescents were followed up at one year and five years following the pregnancy. Preliminary findings related to differences in self-esteem and schooling status, although employment, relationships with partners, and contraception and subsequent fertility experiences will also be explored. Findings suggest that while sociodemographic characteristics of the two groups were relatively similar, adolescents who continued the pregnancy were more likely to drop out of school than those who opted for abortion. Yet, those who underwent induced abortion reported significantly lower levels of self-esteem, a difference attributed in part to the circumstances surrounding the unwanted pregnancy and abortion-seeking in a setting where abortion is legally restricted. While these differences continued to be manifested at one and five years post pregnancy, they had narrowed considerably: about three-fifths of young women in both groups reported high self-esteem, and about one-third were still students (Figure 5.2).

Several studies have explored the service environment, including the obstacles young people face in acquiring contraceptive and other sexual and reproductive health services, and the perspec-
providers. Table 5.1 summarizes selected findings on the perspectives of providers from studies in four Asian countries: China, Laos, Myanmar and Thailand. Providers in all four settings recognized, in theory, the changing sexual norms and the need to provide information, counselling, and contraceptive and other services to unmarried youth. However, their attitudes and perceptions revealed an ambivalence about serving unmarried youth.

**Network activities**

A network of researchers supported under the social science research initiative on adolescent sexual and reproductive health was established in 2000. This was done to initiate a forum for the exchange of ideas and information, as well as a means of providing technical support to individual researchers. Network activities, with the objective of being responsive to members’ suggestions, have included:

- the updating of both the synopsis of ongoing research supported by this initiative and the annotated bibliography of relevant materials;
- the maintenance of a limited documentation centre and facilities to provide researchers with any material they are unable to access;
- the finalization of core instruments (focus group discussion, in-depth interview guides and a survey questionnaire) for the study of adolescent sexual risk behaviours intended for researchers to adapt according to the thematic focus of their research and cultural acceptability; and
- project visits to, and meetings with, investigators in selected countries.

**Analysis workshops**

One goal of the network was to bring together researchers at critical stages of their research to discuss and sharpen analysis plans, for report-writing and the dissemination of findings. As most researchers had reached the analysis stage by mid-2001, three analysis workshops were conducted and attended by:

- three investigators studying sexual coercion, along with three resource persons in Jakarta, Indonesia;
Promoting sexual and reproductive health of adolescents

- fifteen Latin American researchers, as well as nine grantees of The Ford Foundation (this workshop was conducted in Spanish and Portuguese and included 12 resource persons from Brazil);

- nineteen Asian, African and European researchers, and nine resource persons (this workshop was coorganized with the Institute for Population and Social Research, Mahidol University in Bangkok, Thailand).

The above workshops were conducted with the support of The MacArthur Foundation, The Ford Foundation’s Jakarta office and Rio de Janeiro offices, and The Wellcome Trust.

Dissemination

**Findings of studies supported by the social science research initiative**: In addition to being published in peer-reviewed journals (Annex 3), findings from several projects supported by this research initiative have been disseminated at seminars and conferences. Some highlights are as follows:

- The following findings from four studies have been published in *Reproductive Health Matters*: (i) the perspectives of adolescent boys on the risks of unwanted pregnancy and sexually transmitted infections (STIs) in Kenya; (ii) the perspectives of adolescent females and males on sexual coercion in Ibadan, Nigeria; (iii) sexual behaviour and contraceptive use among unmarried, young migrant women in China; and (iv) the views of Chinese parents on contraception services for unmarried youth.

- The findings of four studies as well as an overview on young males in Africa, commissioned by the Department, have been published in the *African Journal of Reproductive Health*.

- Findings from two Latin American studies were presented at the Conference of the International Union for the Scientific Study of Population, Salvador, Brazil, August 2001, and the International Conference on Unwanted Pregnancy and Induced Abortion and Public Health Implications for Latin America and the Caribbean, Cuernavaca, Mexico, November 2001. One study explored the perceptions of pregnancy among adolescents of different socioeconomic status in Mexico, while the second explored the consequences of pregnancy in adolescence for young women in Brazil.

- Findings from a study of dual-risk perception among low-income adolescents in Jakarta, Indonesia were presented at a dissemination workshop by the researcher herself as well as by members of the youth research team.

- A synthesis of the findings of studies on young people was published as an Occasional Paper of the Department. These studies were supported through the 1990s and have been reported earlier.

Other reports and documents that were completed and disseminated in 2001 include:

- the core instruments, the annotated bibliography, the synopsis of ongoing research and the Occasional Paper mentioned above (all available on the Department’s web site);

- WHO’s Department of Child and Adolescent Health and Development published the proceedings of a meeting held in 2000 on the health and development needs of male adolescents and young men, including findings from the Department’s research initiative on adolescent sexual and reproductive health.

In addition, a volume under preparation synthesizes most of the 45 major presentations and panel discussions at the international conference entitled “Adolescent Reproductive Health: Evidence and Programme Implications for South Asia” held in Mumbai, India in November 2000.

**Global Forum for Health Research session**: The Department organized a session at the 2001 meeting of the Global Forum for Health Research that addressed adolescent sexual and reproductive health. The objective of this session, entitled “Preventing risky sexual behaviour among young people: findings from social and behavioural research”, was to highlight the evidence from developing countries on factors hypothesized to play an important role in enhancing sexual and reproductive health among young people. Presentations addressed such issues as overcoming gender double standards and power imbalances, understanding young people’s lives and factors that constrain and facilitate sexual health, effectiveness of programmes imparting life skills and sexuality education, and obstacles to timely and appropriate health-seeking among young people. Presentations summarized the situation, identified gaps, and made recommendations for programmes and policies. The session was well attended and generated a lively discussion.

**Operations research on improving reproductive health services for adolescents in French-speaking African countries**

As described in earlier reports, an operations research project to evaluate and improve reproductive health services for adolescents has been ongoing in several French-speaking sub-Saharan countries. The project is designed to include three phases: (i) a baseline survey of adolescent users of health services and the quality of services offered; (ii) an intervention strategy to be developed from the findings of the baseline survey to address the information needs of adolescents, train service providers or modify existing services in order to make them more youth-friendly; and (iii) a post-intervention survey to evaluate the intervention. While the
Programme is facilitating and coordinating this regional initiative and provides support for research capacity strengthening, funding for each country project is being raised locally. A unique feature is the constitution of multidisciplinary research teams and the active participation of youth representatives in each.

In 2001, research activities were initiated in Benin and Cameroon. Following the completion of baseline surveys in 2000 and the dissemination of findings from the formative research at local and national levels, interventions have been under preparation in Côte d’Ivoire and Guinea.

With the Programme’s collaboration, the centre in Senegal was included in the USAID-funded project “FRONTIERS in Reproductive Health” (along with Bangladesh, Kenya and Mexico) in a study of reproductive health services for youth. Selected findings were presented in earlier reports. In 2001, the study team was engaged in three types of interventions: training of health personnel on adolescent health issues; training in, and development of, activities for peer counselors; and designing and supporting the implementation of school-based family-life education programmes.

The project also contributed to the development of tools for these activities, and related training workshops were conducted by WHO’s Department of Child and Adolescent Health and Development in collaboration with this Department and the local study team. These tools are now available for French-speaking countries.

Capacity building has been the underlying principle of this operations research project. For example, representatives of youth organizations participated in the research training courses for research teams organized by the Department. These representatives were then engaged in conducting the research. Capacity-building activities also included technical assistance visits from study coordinators.

**NEW PROJECTS INITIATED DURING 2001**

**Social science research initiative on adolescent sexual and reproductive health**

A total of nine new projects were supported in nine countries. These studies include several unique features. For example, researchers in Goa, India will conduct a prospective study that follows young adolescents aged 12–16 years over an 18-month period and explores their risk behaviours, and the extent to which behaviours observed at the follow-up can be explained by the situational factors observed in earlier adolescence. Investigators in Poland will examine the ways in which adolescents deal with the conflicting messages on sexuality offered by the church and the conservative political leadership on the one hand, and the popular and youth culture on the other.

Few studies on sexual and reproductive health issues among adolescents have been conducted in the WHO Eastern Mediterranean Region. Two studies will be initiated—one in the Syrian Arab Republic that explores reproductive health awareness, norms and attitudes and their correlates among secondary school-going female and male adolescents; and a second in the Islamic Republic of Iran that explores, in a community-based study of adolescent boys, not only awareness of, and norms surrounding sexual health, but also sexual experience and the correlates of risky sexual behaviour.

Two other studies focus on risk behaviours of adolescents in vulnerable settings: those displaced by an earthquake that hit parts of Colombia in 1999, and those growing up in situations of conflict in South Africa. Both studies will explore the risk and protective factors, and the ways in which contextual vulnerability impinges upon risk-taking behaviours and the ability to exercise choice.

The health-seeking needs of married adolescent females and implications for special programmatic adaptations are explored in a study conducted in the slums of Dhaka, Bangladesh, a setting marked by early marriage. Complementing this is a study in north-east Brazil that explores the obstacles to sexual and reproductive health-seeking among unmarried adolescent females. Another study explores health-seeking behaviour in the context of pregnancy and outcomes, including induced abortion, among adolescent females in an area of Kenya characterized by high levels of maternal and infant mortality, low contraceptive prevalence, and early initiation of sexual activity.

**Regional research initiative on reproductive health needs of young migrants in the Greater Mekong region**

A regional research initiative is ongoing in one major city in each of the five countries of the Greater Mekong region, namely, China (Yunnan Province), the Lao People’s Democratic Republic, Myanmar, Thailand and Viet Nam. This ini-

**Study on bone mass and hormonal contraception**

An ongoing study in Durban, South Africa, explores the extent to which use of hormonal contraception at 15–19 years of age, a period that is critical for bone mass acquisition, may depress peak bone mass achieved and put young women at potentially greater risk of osteoporosis in later life. This is a five-year longitudinal study, among young (15–19 years) and older women (42–49 years) on the impact of depot-medroxyprogesterone acetate (DMPA), norethisterone enanthe (NET-EN) and combined oral contraceptives on bone mass density, with a comparison group of women not using any hormonal contraception (for details, see the chapter on “Research on the development of methods of fertility regulation”).
tiative aims to assess the reproductive health needs of a growing but vulnerable and marginalized subpopulation, i.e. young migrants. The study explores risk and health-seeking behaviours as well as service and information needs. In addition to enhancing knowledge about young migrants in this region, this initiative intends to strengthen research capacity through intraregional networking.

Research on pre-adolescent girls reporting vaginal symptoms

Studies are being undertaken in Mongolia in response to reports from providers about the unusually high levels of lower genital tract infection among pre-adolescents. Symptoms may have been observed by the adolescents themselves, or perceived by their mothers. One study explores the perceptions of about 500 mothers of these pre-adolescents concerning vaginal discharge in general and their daughter's complaint in particular. A second study will examine about 500 pre-adolescents for the presence of discharge and any signs of lower genital tract infection, and screen specimens for Neisseria gonorrhoeae, Chlamydia trachomatis, Trichomonas vaginalis, Candida spp. and anaerobes.

NORMS AND TOOLS

Specific objectives

In the development of norms and tools intended to enhance the reproductive health of individuals in general, it is recognized that adolescents are not only more likely than adults to experience risky outcomes, but may also require different approaches in terms of service and care provision. These issues are highlighted in the guidelines and other tools for programming and capacity-building that have been developed by the Department. Other norms and tools relating to adolescent sexual and reproductive health needs are developed by WHO's Department of Child and Adolescent Health and Development.

Tools developed

Every tool developed by the Department for the promotion of reproductive health includes a special section on the unique needs of adolescents. For example:

- **Essential care practice guides** relating to maternal and newborn health describe a minimum set of interventions for antenatal, delivery, newborn, postpartum and postabortion care, in normal situations, for common complications and basic emergency care. Although this material (chart booklets, job aids, eventually manuals and training material) targets all women who are, or recently have been, pregnant, they devote specific attention to the needs of adolescents. These guides were field-tested in 2001.

- **Guidelines on the medical eligibility criteria for family planning** provide guidance on the issues specific to adolescents, as do other tools in family planning, advocacy materials, guidelines on the prevention of unwanted pregnancies and unsafe abortions, and technical and managerial guidelines on management of abortion complications.

- Guidelines on the management of STIs address the special needs of adolescents.

- The Department also developed **Condom standards and specifications** and guidelines on condom programming, with particular emphasis on the needs of adolescents.

The training curriculum *Transforming health systems: gender and rights in reproductive health*, developed in collaboration with partners, provides support for adolescent sexual and reproductive health programming at national levels. This support includes the presentation of case examples of adolescent sexual and reproductive health issues in order to sensitize participants to address adolescent needs within their programmes and services. The course is currently being run annually in five countries/regions and the curriculum is being translated into Chinese and Spanish.

A pocket guide for policy-makers and programme managers is under development. This pocket guide draws on the overview document entitled *Advancing safe motherhood through human rights* (WHO 2001) and will assist national-level managers to address the key rights issues for adolescents and other special groups.

Strategies for sexual health education, provision of appropriate sexual health services and age-appropriate sexual health information and communication strategies will be addressed, in an upcoming consultation and subsequent publication, "Promoting sexual health".

LINKS WITH THE WHO DEPARTMENT OF CHILD AND ADOLESCENT HEALTH AND DEVELOPMENT

The Department continues to interact with WHO's Department of Child and Adolescent Health and Development in several activities. There is continuous dialogue towards a consensus on research and other priorities. Staff of this Department participated in a priority-setting meeting organized by the Department of Child and Adolescent Health and Development to obtain the perspectives of all relevant WHO Departments, and provided extensive comments and suggestions on the documents produced on adolescent sexual and reproductive health issues. Once again, there has been collaboration in many areas—on the operations research project assessing reproductive health services for adolescents in French-speaking sub-Saharan countries, on the identification of general research priorities as well as in the review of proposals and selection of specific research
projects, and on the development of norms and tools including the *Essential care practice guide for pregnancy, childhood and newborn care* and other guidelines of the Integrated Management of Pregnancy and Childbirth—to incorporate the special measures that health workers need to take in the management and care of adolescents.
Annex 1

SPECIALIST PANEL FOR SOCIAL SCIENCE AND OPERATIONS RESEARCH ON REPRODUCTIVE HEALTH IN 2001

See Annex 1 of the “Research on users’ perspectives” in Section 1 “Promoting family planning”.
Annex 2

SCIENTISTS IN 2001

Principal investigators for the social science research initiative on Adolescent Sexual and Reproductive Health

Akosua Adomako Ampofo, Institute of African Studies, University of Ghana, Legon, Ghana
Ademola J. Ajuwon, African Regional Health Education Centre, University of Ibadan, Ibadan, Nigeria
Ayse Akin, Hacettepe University Medical Faculty, Ankara, Turkey
Luisa Alvarez Vazquez, National Institute of Endocrinology, Havana, Cuba
Patsy Bailey, Family Health International, Research Triangle Park, NC, USA
Dominique Behague, Departamento de Medicina Social, Universidade Federal de Pelotas, Rio Grande do Sul, Brazil
Zenilda Vieira Bruno, Maternidade Escola Assis Chateaubriand, Fortaleza, Brazil
Cui Nian, Sichuan Family Planning Research Institute, Chengdu, China
Ana Paula dos Reis, Federal University of Bahia, Salvador, Brazil
Gao Ersheng, Shanghai Institute of Planned Parenthood Research, Shanghai, China
José Carlos Gomes Dos Anjos, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil
Helen Gonçalves, Universidade Federal de Pelotas, Rio Grande do Sul, Brazil
Ana Cristina Gonzalez Velez, SISMA-MUJER, Bogotá, Colombia
Caridad Teresita Gracia-Alvarez, National Institute of Endocrinology, Hospital Fajardo, Havana, Cuba
Amir Hodzic, Center for Education and Counselling of Women (CESI), Zagreb, Croatia
Elena Hurtado, CEISAR, Guatemala City, Guatemala
Ko Ko Zaw, Department of Medical Research, Yangon, Myanmar
Chaohua Lou, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Cecilia McCallum, Federal University of Bahia, Salvador, Brazil
Maung Maung Toe, Department of Medical Research, Yangon, Myanmar
Sunil Mehra, Mamta Health Institute for Mother and Child, New Delhi, India
Patricia Merlo, Instituto Mexicano de Investigacion de Familia y Poblacion, AC, Mexico, DF, Mexico
Laurike Moeliono, Centre for Societal Development Studies (CSDS), Atma Jaya Catholic University of Indonesia, Jakarta, Indonesia
Alejandro Andres Moyano, Centro de Estudios de Población (CENEPI), Buenos Aires, Argentina
Soori Nnko, National Institute for Medical Research, Mwanza, United Republic of Tanzania
Charles Nzioka, Department of Sociology, University of Nairobi, Nairobi, Kenya
Sekat Bahar Ozvans, Hacettepe University Medical Faculty, Ankara, Turkey
Manuela de la Pena Vega, Asociacion Multidisciplinaria de Investigacion y Docencia en Poblacion (AMIDEP), Lima, Peru
Cristian Peroza Feliu, University of Chile, Santiago, Chile
Susan Pick, Instituto Mexicano de Investigacion de Familia y Poblacion, Mexico, DF, Mexico
Laurie Ramiro, College of Arts and Sciences and Clinical Epidemiology Unit, University of the Philippines, Manila, the Philippines
Marcela Sanchez Buitrago, PROFAMILIA, Bogotá, Colombia
R Savithri, Mamta Health Institute for Mother and Child, New Delhi, India
Claudio Stern, Centro de Estudios Sociologicos, El Colegio de Mexico, Mexico City, Mexico
Vanhpanom Sychareun, Faculty of Medical Sciences, National University of Laos, Vientiane, Lao People’s Democratic Republic
Anand Tamang, Centre for Research on Environmental Health and Population Activities (CREHPA), Kathmandu, Nepal
Arunrat Tangmunkongvorakul, The Center for Public Health Research, Chiang Mai University, Chiang Mai, Thailand
Nilar Tin, Department of Health, Ministry of Health, Yangon, Myanmar
Supra Wimbart, Dr Sardjito General Hospital, Gadjah Mada University, Yogyakarta, Indonesia
Ariel Mino Worobiej, Centro de Estudios Rurales Interdisciplinarios (CERI), Asuncion, Paraguay
Shi-Zhong Wu, Sichuan Family Planning Research Institute, Chengdu, China
Zheng Zhenzhen, Institute of Population Research, Peking University, Beijing, China
Zulaela, Dr Sardjito General Hospital, Gadjah Mada University, Yogyakarta, Indonesia


**Annex 2 (continued)**

**SCIENTISTS IN 2001**

**Principal investigators for the Team on Technical Support to Countries**

Mariame Ba, University Hospital "Le Dantec", Dakar, Senegal  
Mamadou Baldé, University Hospital “Donka”, Conakry, Guinea  
Virgile Capo-Chichi, CERRHUD, Cotonou, Benin  
Ibrahima Diallo, Coordonnateur du projet EVF dans le scoutisme, Dakar, Senegal  
Diomandé Gondo, National Institute of Public Health, Abidjan, Côte d’Ivoire  
Robinson Mbu, University of Yaoundé I, Yaoundé, Cameroon

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>All</td>
<td>49</td>
<td>98</td>
<td>1</td>
</tr>
<tr>
<td>Women</td>
<td>28</td>
<td>56</td>
<td>1</td>
</tr>
<tr>
<td><strong>from:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>10</td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td>AMRO</td>
<td>18</td>
<td>36</td>
<td>1</td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td>3</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>SEARO</td>
<td>10</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>8</td>
<td>16</td>
<td></td>
</tr>
</tbody>
</table>

**Other scientists**

Wendy Baldwin, National Institutes of Health, Bethesda, MD, USA  
Sarah Bott, Los Angeles, California, USA  
Meiwitta Budharsana, Ford Foundation, Jakarta, Indonesia  
Zairo Cheibub, Universidade Federal Fluminense, Niteroi, Brazil  
John Cleland, London School of Hygiene and Tropical Medicine, London, United Kingdom  
Annabel Erulkar, The Population Council, Nairobi, Kenya  
Brigida Garcia, Centro de Estudios Demograficos y de Desarrollo Urbano, El Colegio de Mexico, Mexico, DF, Mexico  
Monica Gogna, Centro des Estudios de Estado y Sociedad, Buenos Aires, Argentina  
Philip Guest, The Population Council, Bangkok, Thailand  
Maria Luiza Heilborn, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, Brazil  
Dale Huntington, The Population Council, New Delhi, India  
Ondina Fachel Leal, The Ford Foundation, Rio de Janeiro, Brazil  
Erin McNeill, Family Health International (Europe), Edinburgh, United Kingdom  
Bob Magnani, Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA  
Cecilia de Mello e Souza, Universidade Federal do Rio de Janeiro, Rio de Janeiro, Brazil  
Edith Pantelides, Centro de Estudio de Población, Buenos Aires, Argentina  
Pertti Pelto, Pune, India  
Chai Podhisita, Institute for Population and Social Research, Mahidol University, Nakorn Prathom, Thailand  
Armando H. Seuc, Instituto Nacional de Angiología y Cirugía Vascular, Havana, Cuba  
Luiza Souza, The Ford Foundation, Rio de Janeiro, Brazil  
John Townsend, The FRONTIERS Project, The Population Council, Washington, DC, USA  
Christine Varga, The Australian National University, Canberra, Australia  
Bencha Yoddumnern-Attig, Institute for Population and Social Research, Mahidol University, Nakorn Prathom, Thailand
## Section 5 - Promoting sexual and reproductive health of adolescents

### Developing countries

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>16</td>
<td>70</td>
</tr>
<tr>
<td>Women</td>
<td>10</td>
<td>43</td>
</tr>
</tbody>
</table>

### Countries in transition

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>7</td>
<td>30</td>
</tr>
<tr>
<td>Women</td>
<td>4</td>
<td>17</td>
</tr>
</tbody>
</table>

### Developed countries

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

#### from:

- **AFRO**: 1 (4)
- **AMRO**: 9 (39)
- **EMRO**: 4 (17)
- **EURO**: 2 (9)
- **SEARO**: 6 (26)
- **WPRO**: 1 (4)
Annex 3

PUBLICATIONS IN 2001


Bayley P, Bruno Z. Consecuencias del embarazo y aborto entre las adolescentes del nordeste de Brasil: 1 año y 5 años después. Presented at the *International Conference on Unwanted Pregnancy and Induced Abortion and Public Health Implications for Latin America and the Caribbean*, 12–14 November 2001, Cuernavaca, Mexico.


Section 6
Gender and reproductive rights in reproductive health
Gender and reproductive rights in reproductive health

J. Cottingham, A. Martin Hilber, M. Colombini

INTRODUCTION

The International Conference on Population and Development (ICPD, 1994) and the Fourth World Conference on Women (FWCW, 1995) both clearly emphasized the need for promoting gender equity and equality in reproductive health policies and programmes, as well as the promotion and protection of human rights. These agreements were reinforced in the five-year reviews of both conferences held in 1999 and 2000, respectively. Key issues for the future included: measures aimed at promoting and achieving gender equality and equity in a systematic and comprehensive manner (ICPD+5 paragraph 39); the incorporation of sexual and reproductive health issues in the work of relevant United Nations bodies on indicators for the promotion and protection of the human rights of women (ICPD+5 paragraph 40); and the protection and promotion of human rights, for example, by establishing or strengthening regulatory and enforcement mechanisms, to ensure that all health services and workers conform to ethical, professional and gender-sensitive standards in the delivery of women’s health services (Beijing+5 paragraph 107 g). In order to contribute explicitly to these goals, the Department carries out a number of specific projects to promote gender equity and reproductive rights.

Objectives

The work of the Department in this area aims to:

- identify, develop and evaluate strategies and mechanisms for promoting gender equality and human rights in reproductive health research, programming and technical support;
- support countries to ensure that reproductive health programmes and policies respect, protect and fulfil human rights and promote gender equity and equality; and
- ensure that the promotion of gender equity and equality and human rights principles are integrated into the Department’s work.

The Department is guided in this work by the Gender Advisory Panel (GAP), a group of independent, external experts from different disciplines and regions.

ASSESSMENT OF LAWS AND POLICIES IMPACTING REPRODUCTIVE HEALTH

Specific objectives

The respect, protection and fulfilment of human rights related to sexual and reproductive health can only be achieved if national laws and policies reflect a recognition of these rights, either implicitly or explicitly. There is evidence to show that laws which violate human rights—such as the specific restriction of access to health services which only women need, for example, those relating to pregnancy and childbirth, thus violating their right to nondiscrimination—have a negative impact on health (Royston E and Armstrong S, Preventing maternal deaths. Geneva, WHO, 1989). The absence of laws and policies which protect human rights—such as prohibition of female genital mutilation, punishment and social condemnation of perpetrators of violence against women—has also been shown to contribute to negative health outcomes. Thus the corollary, taking concrete action to ensure that people’s rights are protected through the laws and policies surrounding whatever public health intervention is being proposed,
could be expected to have a positive impact on health. This is one important reason to use an explicit rights-based approach to health interventions. The Department is therefore working both at the country and the international level to integrate human rights and examine laws and policies related to different aspects of reproductive health, in order to help identify areas where such laws and policies might be adapted to help improve reproductive and sexual health. The objectives of this area of work are as follows:

- elaborate and implement a methodology for integrating human rights into aspects of reproductive health interventions through country pilot-projects; and
- develop evaluation mechanisms including indicators for measuring the impact of integrating human rights (a rights-based approach).

Progress

Integrating human rights into Making Pregnancy Safer: a pilot project in Mozambique

The Making Pregnancy Safer and human rights pilot-project, conceived in collaboration with the Harvard School of Public Health’s François Xavier Bagnoud Center for Health and Human Rights, is an effort to bring human rights principles into maternal and perinatal mortality reduction activities on a national scale. The hypothesis is that the value added by such efforts at the national level will be an increased multi-sectoral understanding and political commitment to maternal and perinatal mortality reduction, demonstrated by improved legal and normative standards for access and care for pregnant women and newborns. At the provincial level, adding human rights may help to better target marginalized populations with specific interventions and services more appropriately and, ultimately, more equitably.

In 2001, the WHO Making Pregnancy Safer initiative in Mozambique sought to integrate a human rights perspective into the national maternal and perinatal mortality and morbidity reduction strategy and operational plan. Through consultation and partnership, the WHO Making Pregnancy Safer Team succeeded in securing the commitment of the Ministry of Health and the interest of its principal implementing partners in reproductive and family health—the United Nations Population Fund (UNFPA), the United Nations Children’s Fund (UNICEF), the World Bank and a number of bilateral agencies—to review and improve the legal, policy and regulatory aspects of the operational plan from a human rights perspective. This interest and commitment translated into a Making Pregnancy Safer national workplan that will use human rights methods to identify, support and develop as necessary, the principles of the Making Pregnancy Safer global initiative at country level.

In order to bring a human rights perspective into the goals and objectives of the Making Pregnancy Safer initiative in Mozambique, an assessment tool has been developed to assist a national multistakeholder team to review laws, policies and health system considerations against the major health outcome indicators. Organized by internationally recognized human rights bodies such as the Right to Health, the tool frames maternal and perinatal mortality and morbidity issues in terms of the country’s past performance and its plans to respect, protect and fulfill its treaty obligations to ensure, for instance, the right to access basic and emergency obstetric care services. In addition to the review and analysis, a methodology has been developed for the use and implementation of the analysis.

The assessment tool will be applied in Mozambique in the next biennium. National and provincial workshops will be held to discuss the findings and identify key interventions to be undertaken. The process will also assist the Ministry in identifying and institutionalizing the use of indicators that can better measure its efforts to respect, protect and fulfill their human rights obligations associated with maternal and perinatal mortality reduction.

Indicators for measuring/evaluating rights-based approaches

Growing out of the pilot project in Mozambique is the need to develop ways of evaluating the added value of using a rights-based approach, beyond the moral imperative. In the short run, it is unlikely that this approach can demonstrate any impact on health outcomes as such. However, there are other dimensions that could be measured, such as the extent to which processes are participatory, ensure nondiscrimination, or are governed by mechanisms for accountability, all of which are necessary under human rights principles.

The Department has convened a small working group in order to elaborate such measurements for sexual and reproductive health. This group will review the approaches to measuring sexual and reproductive human rights and identify selected and specific indicators for use in evaluating/measuring the success of integrating human rights into reproductive health. The deliberations of this working group will be fed into the broader WHO wide-level discussion on indicators for the right to health, and further, into a larger meeting scheduled for the first part of 2002 on reproductive rights within the Family and Community Health (FCH) cluster as a whole.

NORMS AND TOOLS FOR ADDRESSING GENDER AND RIGHTS IN REPRODUCTIVE HEALTH

Specific objectives/targets

In this area of work, the Department focuses on tools which will provide guidance for: (i) understanding the depth and challenge of human rights as they relate to sexual and reproductive health, including specific tools related to gender equity and equality, and (ii) specific gender- and rights-
related issues such as sexual health. It also focuses on collaboration with the UN human rights system for monitoring the application of human rights to sexual and reproductive health.

Norms/tools developed

Advancing safe motherhood through human rights

This document, prepared by four international human rights lawyers from the University of Toronto, Toronto, Canada, was published as an Occasional Paper by the Department. The purpose of this discussion document is to explore how human rights, long established in national constitutional and other national laws and international human rights treaties can be applied to advance safe motherhood. It is intended to contribute to national initiatives to promote compliance with human rights principles, and to national and international dialogues on the development and application of a human rights approach to advance the cause of safe motherhood. It has been distributed to all the partners of the Department, and is being used as a reference document for many of the activities in the area. Since the document is a lengthy and technical one, a user-friendly, “pocket-guide”-style version is currently in preparation and will be published in 2002.

New work undertaken on norms/tools under development

Technical monograph on sexual health

The only existing official definition of “sexual health” dates back to 1975 in a WHO Technical Report entitled *Education and treatment in human sexuality: the training of health professionals.* However, in view of the major developments over the past 25 years—the emergence of the HIV pandemic, the recognition of violence including sexual violence, the development of effective and safe methods of contraception and fertility regulation, and medications to overcome some sexual dysfunctions—there is clearly an urgent need for a new global technical and strategic document that would well reflect these developments.

The Department is therefore elaborating a new monograph on sexual health in collaboration with the World Association of Sexology. Information from a series of commissioned regional background documents is being incorporated into a draft monograph, along with key issues raised and debated at four regional round-table discussions held in 2001 with WHO Regional Offices. The draft document will be debated at an international consultation in January 2002, where it is hoped that consensus will be reached on a definition of sexual health and on effective strategies for promoting sexual health within the health sector.

The international consultation and finalization of the document are likely to lead to a series of regional activities to elaborate the appropriate regional content of strategies to promote sexual health. Over the next biennium, the Department will provide feasible technical support.

UN Human Rights Treaty Bodies: collaboration to support norms and standards within the human rights framework

Over the past year, the Department has worked closely with the UN Office of the High Commissioner for Human Rights (OHCHR) to ensure that reproductive and sexual health are adequately taken up by the various human rights committees. In June 2001, the Department contributed substantially to a meeting on “The application of human rights to reproductive and sexual health”, organized jointly by UNFPA and OHCHR. The purpose was to assess the progress since the previous meeting in 1996, and to discuss further measures and strategies to be used by Treaty Bodies, in conjunction with other relevant actors (UN agencies and nongovernmental organizations), in the monitoring and strengthening of reproductive and sexual health. The meeting recommended, among other things, closer collaboration between Treaty Bodies, WHO and UNFPA in the form of briefing sessions on key issues in reproductive and sexual health, and the timely provision of pertinent information on specific countries.

In June 2001, the Department contributed substantially to a meeting on “The application of human rights to reproductive and sexual health”, organized jointly by UNFPA and OHCHR. The purpose was to assess the progress since the previous meeting in 1996, and to discuss further measures and strategies to be used by Treaty Bodies, in conjunction with other relevant actors (UN agencies and nongovernmental organizations), in the monitoring and strengthening of reproductive and sexual health. The meeting recommended, among other things, closer collaboration between Treaty Bodies, WHO and UNFPA in the form of briefing sessions on key issues in reproductive and sexual health, and the timely provision of pertinent information on specific countries.

The Department, together with the UNFPA-seconded officer working within OHCHR, held two briefing sessions in 2001, one to the Human Rights Committee (HRC) and one to the Committee on Economic, Social and Cultural Rights (CESCR), focusing on global trends and indicators in reproductive health and, in particular, maternal mortality, unsafe abortion, HIV/AIDS and sexually transmitted infections (STIs),
adolescent sexual and reproductive health, and violence against women. These resulted in an agreement to elaborate specific actions to be taken over the next two years.

Over the next biennium, the Department will:

- continue to coordinate with other relevant departments in WHO, the WHO Health and Human Rights focal point, WHO Regional and Country Offices and UNFPA to ensure provision of information about sexual and reproductive health for a few selected countries reporting to CESCR;

- conduct briefing sessions on sexual and reproductive health for the other Treaty Bodies;

- explore with WHO Regional and Country Offices the feasibility of supporting specific countries in implementing the “concluding comments” from CESCR or other Treaty Bodies; and

- work with the Department of Child and Adolescent Health and Development to introduce issues related to adolescent sexual and reproductive health into their training activities on the Convention on the Rights of the Child, which are being run with WHO Regional Offices.

**TECHNICAL COOPERATION WITH COUNTRIES**

**Training curriculum on gender and rights in reproductive health**

The initiative to elaborate this 3-week training curriculum is a collaborative effort between WHO, the François Xavier Bagnoud Center for Health and Human Rights (Harvard School of Public Health, Boston, MA, USA), and the Women’s Health Project at the University of Witwatersrand (Johannesburg, South Africa). Briefly, the initiative aims to build institutional capacity in training centres around the world to offer regionally-appropriate, high-quality training in gender and rights in reproductive health, covering aspects of research, service delivery and policy development.

During 2001, the 490-page training curriculum was reviewed by independent experts, refined, edited and finalized. The English version was published at the end of 2001. A CD-ROM version will also be made available. Mandarin and Spanish versions are being translated and adapted by two of the regional collaborating institutions, the Yunnan Reproductive Health Research Association (YRHRA, China) and the Centre for the Study of State and Society (CEDES, Argentina), respectively. These translations are being financially supported by the Department, and (in the case of China) by The Ford Foundation.

In 2001, the Key Centre for Women’s Health in Society (KCWHS, Australia) and the Centre for African Family Studies (CAFS, Kenya), each ran the course for the third time. The Women’s Health Project (South Africa) ran its fifth course, this time using the revised curriculum. All three courses were well received. As part of its plans to give technical support to new regional centres, the Department sponsored three staff from the Ahdaf Women’s University in Khartoum, the Sudan to participate in the southern African course. It is possible that the course will be run in southern African countries over the next biennium. CEDES and YRHRA both expect to run the course in 2002.

The curriculum will be disseminated in a targeted manner through WHO Regional Offices, collaborating centres and other training institutions who have already expressed an interest in response to a brochure distributed during the year. A summary of the contents, including the module briefs, will be put on the Department’s web site.

Over the next biennium the Department plans to:

- encourage and give technical support to the centre in the Sudan and one other country to run the course for countries of their region;

- give continued technical support to those centres already running the course, as requested; and

- develop short-course adaptations for use with specific countries or organizations (as described below).

**Short training courses on gender and rights in reproductive health**

The Department is being increasingly solicited for technical support to short training courses in gender issues and rights related to sexual and reproductive health. In 2001, a one-day workshop was conducted with the International Confederation of Midwives (ICM) Africa Congress in Harare, Zimbabwe. ICM will continue this series and host another pre-conference workshop on violence in 2002.
In October, the Commonwealth Medical Association (CMA) conducted a consultation for representatives of national medical associations on “Medical ethics and human rights—promoting an ethical and rights-based approach to providing sexual and reproductive health services, with special reference to the position in developing countries”. The Department was invited to contribute. There are now plans for similar short training courses at the national level.

Since 2000, the Department has been a member of the study group on sexual and reproductive health and rights of the International Federation of Gynaecology and Obstetrics (FIGO) and has provided technical support to country-level projects and regional workshops.

Over the next biennium, the Department will continue to give technical support to ICM, CMA and FIGO on the development and running of national-level short training courses on gender and rights in reproductive and sexual health.
## Annex 1

### MEMBERS OF THE GENDER ADVISORY PANEL IN 2001

Marge Berer, Reproductive Health Matters, London, United Kingdom (*Chairwoman*)  
Soledad Diaz, Chilean Institute of Reproductive Medicine (ICMER), Santiago, Chile  
Thein Thein Htay, Ministry of Health, Department of Health, Yangon, Myanmar  
Sharad Iyengar, Action Research and Training for Health (ARTH), Udaipur, India  
Wanda Nowicka, Federation for Women and Family Planning, Warsaw, Poland  
Khama Rogo, Ipas, Nairobi, Kenya  
Angeline Faye Schrater, Florence, MA, USA  
Rashidah Shuib, University of Sains Malaysia, Kelantan, Malaysia  
Makhosazana Xaba, Ipas, Johannesburg, South Africa  
Zhang Kaining, Yunnan Reproductive Health Research Association (YRHRA), Kunming, China

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>Members</td>
<td>7</td>
<td>70</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Women</td>
<td>4</td>
<td>40</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>

*from:*  
AFRO 2 20 2  
AMRO 1 10 2  
EMRO  
EURO 1 10 1 10 2  
SEARO 2 20 2  
WPRO 2 20 2
Annex 2

SCIENTIST IN 2001

Sofia Gruskin, François Xavier Bagnoud Center for Health and Human Rights, Harvard School of Public Health, Boston, MA, USA
Annex 3

PUBLICATIONS IN 2001


Section 7
Technical cooperation with countries
Overview

A. Ntabona, M. Mbizvo

OVERVIEW OF ACTIVITIES IN TECHNICAL COOPERATION WITH COUNTRIES

The main objective of the Department in its work on technical cooperation with countries is to assist countries to enhance their capacity to develop and implement national and regional research and programmatic activities aimed at improving reproductive health. Specifically, the aims are:

- to assist developing countries to identify areas where research is required to address reproductive health needs;
- to support national planning and programming, including the introduction of reproductive health technologies and the adaptation and application of practice guidelines essential for improving reproductive health;
- to provide assistance to developing countries to strengthen their research capacity, and to disseminate and apply the results of reproductive health research; and
- to collaborate with countries in monitoring the effects of policies and initiatives related to health sector reforms on reproductive health programmes and outcomes.

Highlights of achievements in 2001

- An international consultation was organized in Geneva in December 2001 within the context of the Memorandum of Understanding (MoU) signed between the Department, the United States Agency for International Development (USAID), and the Population Council's FRONTIERS project. This MoU is based on the recognized need for programmatically focused research that complements normative and basic research, and the need to develop the capacity of programme managers to demand and use research to improve reproductive health programme operations. The meeting brought together 77 participants, including representatives from international agencies and local and regional organizations involved in reproductive health research and training in the developing world and Eastern Europe.
- The first of a series of planned regional symposia for policy-makers, programme managers and directors of research institutions was held in Nairobi, Kenya, in September 2001 for the WHO Regions of Africa and the Eastern Mediterranean. Participants made a strong call for more visibility to the pivotal role of reproductive health programmes and services in the ongoing efforts to strengthen national health systems in the Regions. They also stressed the need to improve collaboration between policy-makers, managers and researchers in the development and testing of appropriate models of integrated reproductive health services through operational research.
- Collaboration with WHO Regional Offices focused mainly on supporting regional efforts to promote operational research on a wide range of issues, including, for example, community-based interventions on maternal health; scaling-up of cervical cancer screening by visual inspection with acetic acid (VIA); the involvement of male adolescents and young adults in reproductive health; and operational strategies, models and tools for client-centred integrated services.
Continued support for research, research capacity strengthening and reproductive health programme development activities was provided to selected countries in each of the six WHO Regions, as follows:

- Overall 14 Long-term Institutional Development (LID) Grants and 12 Resource Maintenance Grants (RMGs) were awarded to the network of collaborating research institutions. Research Training Grants (RTGs) were also awarded to 35 scientists from these institutions, most of whom received their training within their respective regions.

- With support from the Programme and national and international sources, up to 379 research projects have been initiated or are ongoing in these institutions and a total of 524 research articles were published. Furthermore, 388 congress abstracts were presented at national, regional and international scientific events to disseminate the research results.

- The first meeting of the Regional Advisory Panel (RAP) for Eastern Europe, the Newly Independent States and Central Asian Republics was held in September 2001 in Copenhagen, Denmark following approval of the Panel's establishment by the Programme's Policy and Coordination Committee. Among other things, the Panel reviewed and endorsed the strategy paper prepared by the WHO Regional Office for Europe. This paper covered sexual and reproductive health for the Region, and related programmes supported by the WHO Regional Office for Europe on maternal and neonatal health, adolescent sexual and reproductive health, gender mainstreaming and other ongoing research and training projects.

The Department continued to provide support to national-level decision-making for improving the quality of reproductive health care and services through the three-stage process of the "Strategic Approach":

- The field guide for implementing the strategic assessment (Stage I) was published, and web pages on the overview of the Strategic Approach, related country experiences and links to relevant publications are available on the Department's web site.

- Support was provided to action research for testing interventions (Stage II) in Bolivia, China, Ethiopia, Lao People's Democratic Republic, Myanmar and Zambia. Scaling-up of tested interventions (Stage III) is under way in Bolivia, Brazil, Viet Nam and Zambia. Adaptations of the strategic planning process continued in additional areas of reproductive health, including reproductive tract infections (RTIs), maternal and newborn health, abortion, and issues related to HIV/AIDS prevention and cervical cancer.

- Following advice from the Department's Scientific and Technical Advisory Group (STAG), initial funding was approved for 2002/2003 in order to examine the impact of the systems and organizational changes brought about by health sector reform initiatives on the utilization and quality of reproductive health services. To this effect, a proposal for a three-year research initiative was submitted to The MacArthur Foundation and was approved for partial funding. This initiative will commence in 2002.

Several research and programmatic activities were supported jointly in selected countries by different thematic teams and the technical cooperation team within the Department. These activities served as an entry point for research capacity strengthening and programme development in the areas of fertility regulation; maternal and perinatal health, including the prevention of mother-to-child transmission (MTCT) of HIV infection; field-testing of new tools; evidence-based medicine and implementing best practices; and interagency support to programme planning and evaluation.

**INTERREGIONAL ACTIVITIES AND COLLABORATION WITH REGIONAL OFFICES**

**Introduction**

The Department continued to make significant contributions to the capacity of countries to address their reproductive health needs through fostering interregional research and technical cooperation. Research and programmatic work was carried out by national academic, research and service institutions in cooperation with WHO Regional and Country Offices, governments, nongovernmental organizations (NGOs) and other partners.

The main objective is to cooperate with countries on regional reproductive health research and programme priorities. Activities that are undertaken are based on the assessments of regional experts who advise on priorities for research, and strategies for the research and technical capacity strengthening. This includes the testing and implementation of selected interventions that are derived from research evidence.

**Highlights of progress in interregional activities during 2001**

**Regional symposium for policy-makers, programme managers and research directors**

At its February 2000 meeting, STAG recommended, among other things, that greater utilization of research findings would be achieved by including policy-makers and reproductive health programme managers in advocacy and other efforts to disseminate research results. In line with the above, presentations on the Department's efforts towards research capacity strengthening were made at the Commonwealth Regional Health Ministers Conference in October 2000 in Swaziland. Further, an initiative was launched with a series of symposia for policy-makers, programme managers and directors of
research institutions receiving research capacity-strengthening grants from the Programme. The first symposium was held in Nairobi, Kenya in September 2001 for the WHO Regions of Africa and the Eastern Mediterranean. Health Ministers welcomed this initiative and recommended having similar meetings at national levels. Other recommendations were: (i) policy-makers and programme managers should give greater priority to reproductive health research and its utilization, and should make a greater commitment to its funding; (ii) the research agenda should respond to both current and future reproductive health problems in the regions; and (iii) WHO should increase its support to research capacity building and provide guidelines for the translation of research findings into programme activities. The full report of the meeting will be published in 2002.

Consultation on reproductive health operations research capacity building

This consultation was held in Geneva in December 2001 within the context of a memorandum of understanding signed between the Department, USAID, and the Population Council’s FRONTIERS project. It was organized to respond to the recognized need for programmatically focused research that complements formative and basic research, and to the need to develop the capacity of programme managers to use research to improve reproductive health programme operations. The meeting brought together 77 participants, including representatives from international agencies and local and regional organizations involved in reproductive health research and training in the developing world and in Eastern Europe. Based on experiences shared, they came to a consensus on the issues of needs and priority operations research in reproductive health; the profiles of managers and researchers who will benefit from operations research training; and the assistance needs of potential training centres in operations research. The participants also suggested areas for closer inter-agency collaboration to jointly support the initiatives. The full report of the meeting will be available in 2002.

Agency consultation for UNFPA-funded technical advisory programme/country support team specialists in reproductive health

The annual consultation between WHO experts in reproductive health working on the country support teams (CSTs) of the United Nations Population Fund (UNFPA) and WHO Headquarters staff was held in December 2001, after a gap of four years. It enabled the experts concerned: (i) to be updated on the strategic directions, objectives and functions of different units within the Department and the Family and Community Health Cluster; (ii) to share experiences and lessons learned from their activities in advising governments; and (iii) to further review, and make recommendations on, strategies for maximizing the effectiveness of functions of technical bodies such as CSTs in supporting national reproductive health and population programmes. Future activities within this context will depend on the outcome of the restructuring of the UNFPA-supported Technical Advisory Programme (TAP) currently in progress.

Regional Advisers in Reproductive Health meeting

The second of the series of goal-oriented meetings between WHO Regional Advisers in Reproductive Health and the Department was hosted by the Pan-American Health Organization (PAHO). The theme of this meeting was “Programming for Male Involvement in Reproductive Health” and included the thematic areas of promotion of family planning, improving maternal health, prevention of sexually transmitted infections (STIs)/HIV and violence against women. Presentations embraced regional experiences, research findings, programme designs, region-specific case models, lessons learnt and implications for policy and programmes aimed at including men in reproductive health. Recommendations of the meeting will be published in 2002. The theme for the 2002 meeting will be on “The Impact of Health Sector Reforms on Reproductive Health”.

Collaboration with WHO Regional Offices

Work was undertaken in collaboration with WHO Regional Offices in the areas of maternal health, men’s roles in reproductive health and other operations research activities. Table 7.1 provides a summary of collaborative activities with WHO Regional Offices in 2001.

Research capacity strengthening

A number of activities were undertaken across the WHO Regions as a follow-up to the In-depth Review of Research Capacity Strengthening undertaken in 2000-2001. Information brochures on each grant and the relevant application forms were developed and introduced. Work was continuing on other follow-on activities.

WHO Collaborating Centres

During 2001, there were 53 officially designated WHO Collaborating Centres for Research and Technical Cooperation in Human Reproduction. Another 26 centres, although not officially designated, also collaborated with the Department.

Planned Activities

The future plans for interregional activities will take into account recommendations of health ministers and programme managers from the respective regions. Meetings of health ministers, programme managers and research directors in the WHO Region of the Americas and in the WHO Regions of South-East Asia and Western Pacific have been planned. Other planned activities include:

- interregional workshops on research programme management and translation of research findings into coun-
try programmes and policy;

• collaborative research with WHO Regional Offices; and

• an interregional consultation on the impact of health sector reforms on reproductive health.

<table>
<thead>
<tr>
<th>Overview</th>
</tr>
</thead>
</table>

| Africa | — Operations research protocol for community-based interventions for reduction of maternal mortality  
— Cervical cancer screening by visual inspection with acetic acid: operations research in rural districts of selected East, Central and Southern African countries |
| Americas | — Enhance men’s role and participation in reproductive health in Central America  
— Integrated response to sexual and reproductive health of male adolescents and young adults in Latin America  
— Development of an operational model and tools for client-friendly, integrated sexual and reproductive health services |
| Asia and the Pacific | — Operations research on unmet needs in family planning and community- and facility-based interventions for making pregnancy safer  
— Systematic introduction of guidelines on medical eligibility criteria for contraceptive use and other guidelines on family planning and maternal health |
| Eastern Mediterranean | — Total Quality Management: an approach to promote maternal and neonatal health in the Eastern Mediterranean countries  
— Regional research initiatives on improving adolescent reproductive health and on behavioural changes in relation to female genital mutilation |
| Europe | — Support to courses on Research Training in Reproductive Medicine and Reproductive Biology and in operations research  
— Development of a reproductive health strategy for the Eastern European Region  
— Support to the integration of sexually transmitted infection services into reproductive health services |

Table 7.1. Areas identified for collaboration during 2001
Annex 1

PUBLICATIONS IN 2001


INTRODUCTION

The Department has been developing, testing and refining a "Strategic Approach" to improve the quality of care of reproductive health services. Although originally developed to address contraceptive introduction, the methodology has been adapted to address a range of reproductive health services. This Approach has three stages.

Stage I employs a systems perspective to assess: (i) the existing contraceptive method mix, other options for fertility regulation and current and possible future reproductive health interventions; (ii) the extent of the coverage, quality of care and capabilities of the service delivery system; and (iii) the needs and perspectives of current and potential users. The assessments of the need for contraceptive introduction are designed to assist programmes in deciding whether there is a need to introduce one or more new methods, to expand the use of existing and perhaps underutilized methods, or to withdraw any inappropriate technologies, and deciding on how the overall quality of care of services could be improved. The assessments use a qualitative methodology and a participatory approach involving programme managers, service providers, researchers and others with an interest in improving reproductive health, including women's and youth organizations and other nongovernmental organizations (NGOs).

A strategic assessment gives rise to a variety of recommendations concerning reproductive health policies, the strengthening of the quality of care in service delivery, the service delivery infrastructure and the management of programmes and activities. Stage II research is a means of testing, on a limited scale, the recommendations concerning the introduction of technologies or other interventions to improve the quality of care in service delivery.

The purpose of Stage III is to disseminate and apply the research findings generated in the Stage II action research to policy development and planning for wider implementation. Based on an evaluation of the Stage II research experience and findings, decisions are made on the appropriateness of expanding method introduction and/or replicating other tested interventions on a larger scale.

MAIN AREAS OF WORK

The main areas of work on the Strategic Approach included the dissemination and support for use of the Strategic Approach by countries, adaptation of the Strategic Approach to other areas of reproductive health, and replication and scaling-up.

With regard to its application to introduction of contraceptives, sufficient experience has been gained in the assessment and Stage II testing of interventions. Thus, efforts are focusing on dissemination and the promotion of use of the Strategic Approach by countries, as well as the testing and synthesizing of lessons learned in the Stage III scaling-up process. A second area of activity is the adaptation and testing of the application of the methodology to other specific areas of reproductive health, such as reproductive tract infections (RTIs) including HIV/AIDS, maternal and newborn health, abortion and cervical cancer. Here, the work is focused on the adaptation and development of tools for Stage I strategic assessments, as well as Stage II projects to test interventions to improve the quality of care of services in these specific reproductive health areas. As these activities move to Stage III, they are expected to contribute to the further development of knowledge and provide guidance for programme managers on successful scaling-up of lessons learned from pilot interventions. A third closely related stream
is the use of the methodology in simultaneously addressing a broad range of reproductive health issues (i.e. conducting comprehensive strategic assessments).

**Dissemination, advocacy and capacity building**

During 2001, work on a draft field guide entitled *Making decisions about contraceptive introduction: a guide for conducting assessments to broaden contraceptive choice and improve quality of care* has continued with further field-testing in Guatemala and Romania. The field guide will be published in early 2002. In addition, work began on the adaptation of the field guide for use in strategic assessments related to maternal and newborn health.

The first of three regional workshops, intended to advocate for utilization of the Strategic Approach and to train national experts in the implementation of strategic assessments, was implemented by the nongovernmental organization (NGO) Reprolatina in Bolivia during 2001. Participants included senior country policy-makers and programme managers, and representatives from NGOs and women’s organizations from Bolivia, Chile, Cuba, Guatemala and Paraguay, as well as the Pan-American Health Organization (PAHO) and the Population Council. Participants from this workshop led the team that subsequently conducted a strategic assessment in Guatemala (described below), and the Department, in collaboration with the Reprolatina Project, is providing continuing support to the participants in the development of plans and proposals for strategic assessments in Chile, Cuba and Paraguay. Regional workshops for countries in Africa and Asia will be held in the first half of 2002, implemented in collaboration with WHO regional partners including the International Council for the Management of Population Programmes (ICOMP) and the Population Council, Nairobi, Kenya, as well as the respective WHO Regional Offices and Country Support Teams of the United Nations Population Fund (UNFPA). These workshops will contribute to the ongoing efforts to build regional capacity by using the individuals who have participated in Strategic Approach activities, as resource people for promoting and providing technical assistance to the process in neighbouring countries.

As in previous years, country experiences with implementation of the Strategic Approach have continued to be documented and disseminated through a variety of mechanisms. In 2001, the *Asia-Pacific Journal of Population* published an issue devoted to the use of Strategic Approach with a lead article giving an overview of the Strategic Approach, as well as individual papers presenting the experience with its utilization in the Lao People’s Democratic Republic (Lao PDR), Myanmar and Viet Nam. Other articles concerning country experiences with the Strategic Approach are included in the list of publications at the end of this chapter. Presentations on the Strategic Approach were made at a number of national and international workshops during 2001. For example, a presentation was given at the Global Leadership Program in Reproductive Health organized by the Partners in Population and Development programme at the Cairo Demographic Center and attended by participants from nine countries in the WHO Region of the Eastern Mediterranean. Other presentations were made in China, the Dominican Republic,
India, Guatemala, Kenya, Romania, Uganda and the USA, as well as in international meetings in Geneva, Switzerland.

The Department’s web site now contains web pages devoted to the Strategic Approach, with a description of country experiences, and links to publications including country assessment reports and the field guide as well as to the web sites of collaborating partners.

**Adaptation of the Strategic Approach**

Work is continuing on the adaptation of the Strategic Approach to address other reproductive health issues. The Department has continued working with the Population Council’s HORIZONS Project on an adaptation of the Strategic Approach to address issues related to sexually transmitted infections (STIs) and other RTIs. In 2001, a strategic assessment of abortion-related issues was conducted in Romania, and an assessment related to both maternal health and family planning was conducted in Guatemala. The Strategic Approach is being adapted by other partners as well. For example, EngenderHealth is assisting Bolivia to use the methodology to address issues related to the screening and treatment of cervical cancer, while the office of the Population Council, Brazil supported an assessment of HIV prevention in the border regions of Brazil. In addition, future collaboration with the Program for Appropriate Technology in Health (PATH) is planned to support utilization of the methodology to address the introduction of a range of reproductive health technologies.

There is a growing recognition of the need for a methodology and tools to assist countries in strategic planning and programming for comprehensive reproductive health services. In recent years, experience with the adaptation of the strategic assessments to address broader reproductive health concerns has been gained in Ethiopia, Myanmar and, most recently, in Lao PDR. ICOMP, in collaboration with the Population Council, Bangkok and the Department, will be testing further modifications of the methodology for comprehensive reproductive health assessments in Yunnan, China and Rajasthan, India in 2002.

**Stage III: replication and scaling-up**

A proposal for a series of activities on the topic of scaling-up of health interventions, titled “From pilot projects to policies and programs: strategies for scaling up innovations in health service delivery”, was submitted to The Rockefeller Foundation. This proposal requested support for two team residencies and a conference intended to develop strategies to facilitate more effective use of small-scale testing of reproductive health service innovations. The first team residency took place in December 2001. The purpose of this residency was to discuss two reviews of the social science and development literature related to scaling-up of pilot projects, as well as the experience and lessons learned to date with the implementation of Stages II and III of the Strategic Approach. In addition, a larger conference was planned to examine and synthesize existing knowledge about how to enhance scaling-up of service delivery research for broader policy and programme development. This conference is scheduled to take place in September 2002. These efforts are expected to produce two outputs: (i) scientific papers documenting the lessons learned from research and experience on the utilization of evidence-based service delivery innovations for policy and programme development; and (ii) a practical guide for policy-makers, programme managers, researchers, technical experts and donors intended to facilitate the scaling-up of small-scale service innovations.

**COUNTRY EXPERIENCES DURING 2001**

**Ongoing activities in Africa**

**Ethiopia**

The first of several Stage II activities has been the development of a project to investigate strategies to expand access to coitally-dependent methods of contraception and dual protection for youth. The two-year project is being implemented by the Family Guidance Association of Ethiopia in response to findings from the assessment that sexually active youth were not interested in using routine contraceptives, but desired coitally-dependent methods. The study is using the introduction of the female condom and emergency contraception, as well as the reintroduction of the male condom and vaginal foaming tablets, as a means for enhancing the overall quality of youth-centred services. The project is strengthening providers’ and peer educators’ knowledge of all contraceptive methods, increasing knowledge of youth regarding family planning and options for STI prevention and emphasizing dual protection. The study is funded by the
Section 7 - Technical cooperation with countries

United States Agency for International Development (USAID) with technical support provided by the Population Council and the Department.

A second activity in 2001 was an evaluation of previous efforts in Ethiopia to introduce Norplant. UNFPA and the Ministry of Health requested technical assistance from the Population Council and WHO to design and conduct this evaluation, prior to making decisions regarding further procurement of Norplant. The evaluation concluded that further introduction of Norplant should be supported, and recommended critical interventions to ensure Norplant was being provided with appropriate quality of care. Based on the results of the evaluation, UNFPA and USAID have placed new orders for Norplant kits, and the Ministry of Health is taking steps to implement key recommendations from the report.

In 2002, the Department and the Population Council, Nairobi will provide technical support to the Ministry of Health in an exercise to develop a National Reproductive Health Strategy.

Zambia

A Stage II study has tested interventions to enhance contraceptive choice and quality of care in Zambia in eleven rural health centres, located in three districts in the rural Copperbelt region. Following a baseline situation analysis, the project has introduced the injectable contraceptive depot-medroxyprogesterone acetate (DMPA) and emergency contraception, as well as offered to train providers in the provision of all available methods, including field-based training for insertion of intrauterine devices (IUDs). Providers were also trained in the syndromic management of sexually transmitted diseases (STDs). This has been supported by the development of self-training manuals for providers, and newsletters to share management interventions and successful innovations among participating districts and health centres. An end-of-project evaluation showed that providers in project sites have better technical skills, are more likely to use information, education and communication (IEC) materials, provide more information to clients and spend more time interacting with clients, than they did at baseline or in comparison with providers in the control centres. As a result, the number of new acceptors doubles each month and the method mix in the intervention centres has broadened, as compared to baseline and the control sites.

Following the final project workshop, a Stage III project was developed to replicate the strategy and the lessons learned in all health centres in all of the districts in the Copperbelt region. Funding is being provided by USAID and technical support will be provided by the Population Council and the Department.

A separate study investigating alternative sources for the provision of emergency contraception was also completed. This study showed that pharmacists were the most popular source of both information and supplies of emergency contraception for urban clients of all ages. However, the quality of information provided to clients remained inadequate. The Ministry of Health is now reviewing the data, prior to registration of Postinor-2 to evaluate its efficacy as an emergency contraceptive.

Ongoing activities in Asia

China

The Department of Science and Technology of the State Family Planning Commission requested support from the Department to conduct a strategic assessment in Chongqing, China to address the issue of contraceptive introduction, with an emphasis on IUD technologies available in the national family planning programme. Numerous important findings and recommendations emerged. Some of the key themes included the need: (i) to strengthen providers’ capacity to provide all contraceptive methods with improved quality of care; (ii) to reduce the number of types of IUDs provided in the national programme and to improve aspects of care related to both insertion and removal; (iii) to strengthen the diagnosis and management of RTIs in the context of family planning health services; and (iv) to review a number of the contraceptive products available with regard to either the quality of their manufacture and/or their long-term safety.

Figure 7.2. Clients reported improved satisfaction with reproductive health services at project health centres
The findings, conclusions and recommendations were presented at a dissemination workshop held in Chongqing and at a second national-level workshop which brought together national stakeholders to discuss priorities and formulate plans for interventions and further research to address the recommendations. The report is being published in Chinese and English, and a summary of the report will be published in the Chinese Journal of Family Planning. Follow-up activities are beginning with a review of the safety and efficacy of IUDs and hormonal contraceptive methods provided through the national family planning programme, with the goal of selecting fewer and more effective products for provision in the programme. Following the development of new technical service delivery guidelines, a process being supported by the Consortium for Implementing Best Practices, a Stage II project will test a package of interventions recommended by the assessment to improve informed choice and quality of care.

**Lao People’s Democratic Republic**

Implementation of a Stage II project has been delayed, so as to integrate this research with other activities planned through WHO’s Making Pregnancy Safer (MPS) initiative. This project sought to strengthen the availability and utilization of essential obstetric care at the district and community levels, to test the approaches to strengthening outreach by district-level health staff to the health centre and community-level reproductive health services.

**Myanmar**

A Stage II research project is developing a district-level model for improving the quality of care of family planning and other reproductive health services. Project activities include: (i) the development of new information, education and communication (IEC) materials and activities; (ii) training for public sector basic health staff, private general practitioners, private drug shop staff, township- and community-level members of a national nongovernmental organization, the Myanmar Maternal and Child Welfare Association (MCWA); (iii) a community advocacy component; and (iv) efforts to strengthen the management capabilities related to planning, supervision and logistics of township-level and health centre staff.

The project is being implemented in two districts with differing geographic conditions, ethnic composition and reproductive health needs.

During 2001, the provider training curriculum developed by the project was utilized by the Ministry of Health in the training of health staff throughout Myanmar and the IEC materials developed by the project are being adopted by UNFPA for use in project activities in 120 districts. In late 2001, a mid-project evaluation was conducted. Initial review of the data indicates improved knowledge and skills of providers as well as motivation to provide quality services. However, it also suggests necessary modifications to the content of provider training and increased efforts in the area of community information.

**Viet Nam**

A Stage II study assisted the Government of Viet Nam to develop a strategy for introducing DMPA and, at the same time, strengthen the quality of family planning and reproductive health service delivery. This project developed training curricula and materials for providers, improved family planning IEC materials, and trained providers and community-level workers, emphasizing counselling and provision of balanced information, in addition to technical information on all available contraceptive methods. The project also worked on approaches to strengthen management of services, including the development of supervision tools.

A Stage III project to replicate and scale up the interventions tested initially in three provinces in Stage II is under way. The introduction of DMPA is being implemented in 21 of the 53 provinces in Viet Nam where government or donor support for strengthening health service delivery is already available. As in Stage II, the Stage III project is being undertaken as a collaborative effort between the Ministry of Health, the National Committee for Population and Family Planning and the Viet Nam Women’s Union. It is jointly funded, primarily by the German Gesellschaft für Technische Zusammenarbeit (GTZ) and UNFPA, with the Department providing technical support through ICOMP.
The Ministry of Health has also begun implementing a project to follow up the recommendations of a second strategic assessment which focused on issues related to reducing the recourse to abortion and improving the quality of care of abortion services. This project is described in the chapter on “Unsafe abortion”.

**Ongoing activities in Eastern Europe**

**Romania**

A strategic assessment related to reducing the recourse to abortion and improving the quality of care of family planning and abortion services was conducted in November 2001 in Romania. This activity is described in the chapter on “Unsafe abortion”.

**Ongoing activities in Latin America**

**Bolivia**

A Stage II study attempted to strengthen family planning and related reproductive health service delivery, while introducing DMPA and Cyclofem, in La Paz and Santa Cruz, Bolivia. Interventions focused on provider training, strengthening the management of services, and the development of community participation in guiding service delivery. A final evaluation documented that family planning services have become more accessible and the number of new acceptors was dramatically higher in participating health centres, as compared to those not involved in the project.

Lessons learned and materials developed through the project are now being used by the Ministry of Health in the country-wide introduction of DMPA supported by the United Kingdom Department for International Development (DFID), with technical assistance provided by the Population Council, Brazil and the NGO Reprolatina.

**Brazil**

The Stage II project had demonstrated that expansion of reproductive choice can occur at the municipal level within existing resource constraints. The Stage III project tested the replicability of activities in four additional municipalities. Efforts to expand and replicate activities and approaches to additional municipalities in the north and south of the country are continuing through the Reprolatina Project, an activity funded by the Bill and Melinda Gates Foundation through the NGO Reprolatina, the University of Michigan and the Population Council, Brazil.

**Guatemala**

The Ministry of Public Health and Social Welfare of Guatemala collaborated with the Department to implement a strategic assessment to identify priority interventions that would improve access to and quality of family planning and maternal health services, with emphasis on emergency obstetric care. The strategic assessment was conducted in October 2001 in five “departments” of Guatemala.

Many findings and recommendations emerged from the assessment. Key findings include: (i) there remain major barriers to accessing maternal health services in rural areas, especially for indigenous populations; (ii) there is an urgent need to develop functioning referral and emergency transport mechanisms for obstetric emergencies from rural areas as well as to improve the quality of emergency obstetric care at referral centres outside the capital city; (iii) although a relatively broad range of family planning methods are provided through public and NGO clinics and private pharmacies, there is a need to improve the quality of services provided, to expand access to services to the more peripheral service delivery sites and to strengthen referral; and (iv) there is a need to expand IEC campaigns and to provide more information and counselling to users so that they can make better informed choices among the available contraceptive methods.

The findings and recommendations will be discussed at a national dissemination workshop to be held in Guatemala City in February 2002. The team members, along with national and local officials from the Ministry of Health, NGO representatives, donor agencies and other key stakeholders will discuss priorities and identify plans for interventions based on the recommendations of the assessment.

**THE IMPACT OF HEALTH SECTOR REFORMS ON REPRODUCTIVE HEALTH**

Major changes in health systems have been promoted by health reforms designed and implemented by governments and international donors in recent years. Health reforms have been promoted as a means of achieving many of the objectives of health systems, including improvements in equity, quality, effectiveness, efficiency and financial soundness.
Generally, the reforms have involved significant changes in the financing, payments, organization and regulation of health systems. These broad system changes are likely to have important influences on sexual and reproductive health programmes and gender related-issues, and pose challenges to the future development of interventions to promote and ensure reproductive health. To date, there has been very little reliable and convincing research on the impact of general system reforms on reproductive health services, reproductive health outcomes or on the sexual and reproductive health rights of individuals. Most of the current literature on the issue emphasizes the scarcity of concrete knowledge.

STAG stressed the importance of examining the interaction between health reforms and the impact of these initiatives on the utilization and quality of reproductive health services. Thus, initial funding was approved for the 2002–2003 biennium and a proposal was developed for a three-year research initiative. This was submitted to The MacArthur Foundation for partial funding, and the initiative is expected to commence in 2002.
### Annexe 1

#### SCIENTISTS IN 2001

**Principal investigators**

Ayo Ajayi, The Population Council, Nairobi, Kenya  
Margarita Diaz, Reprolatina, Campinas, Brazil  
Philip Guest, The Population Council, Bangkok, Thailand  
Mihai Horga, Ministry of Health, Bucharest, Romania  
Thein Thein Htay, Department of Health, Yangon, Myanmar  
Fang Ke-juan, Shanghai Institute of Planned Parenthood Research, Shanghai, China  
Lee Soua Kou, Maternal and Child Institute, Vientiane, Lao People’s Democratic Republic  

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number % of total</td>
<td>Number % of total</td>
<td>Number % of total</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>7 88</td>
<td>1 13</td>
<td>8</td>
</tr>
<tr>
<td>Women</td>
<td>2 25</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>1 13</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>AMRO</td>
<td>1 13</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td>1 13</td>
<td>1</td>
</tr>
<tr>
<td>SEARO</td>
<td>2 25</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>WPRO</td>
<td>3 38</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

**Other scientists**

Tracy Baird, Ipas, Carrboro, NC, USA  
Thomas Bossert, Harvard School of Public Health, Boston, MA, USA  
Marc Bygdeman, Karolinska Hospital, Stockholm, Sweden  
Francisco Cabral de Oliveira, CEMICAMP, Campinas, Brazil  
Trinh Dinh Can, National Committee for Population and Family Planning, Hanoi, Viet Nam  
Maria Dolores Castro, La Paz, Bolivia  
Miriam Cardona, President’s Office for Women, Guatemala City, Guatemala  
Marta Chajal, APROFAM, Guatemala  
Carlos Cipriani, Epidemiological Research Centre in Sexual and Reproductive Health, Guatemala City, Guatemala  
Dalila de la Cruz, APROFAM, Guatemala  
Francois Deniaud, Paris, France  
Do Thi Thanh Nhan, Viet Nam Women’s Union, Hanoi, Viet Nam  
Constantin Enculescu, East European Institute of Reproductive Health, Targu-Mures, Romania  
Rodica Fagarasan, East European Institute of Reproductive Health, Targu-Mures, Romania  
Anibal Faundes, CEMICAMP, Campinas, Brazil  
Michele Gardner, The Population Council, Yangon, Myanmar  
Cheng Jieshan, Family Planning Research Institute, Chongqing, China  
Edgar Kestler, Epidemiological Research Centre in Sexual and Reproductive Health, Guatemala City, Guatemala  
Nu Aye Khin, Maternal and Child Welfare Association, Yangon, Myanmar  
Nguyen Dinh Loan, Ministry of Health (MCH/FP), Hanoi, Viet Nam  
Tran Thi Luong, Ministry of Health, Hanoi, Viet Nam  
Tran Thi Phuong Mai, Ministry of Health, Hanoi, Viet Nam  
Miguel Marroqin, Ministry of Public Health and Social Welfare, Guatemala
Mi Guoqing, Division of Technical Instruction, Department of Science and Technology, State Family Planning Commission, Chongqing, China
Jorge Monroy, Guatemalan Association of Sexual Education, La Paz, Guatemala
Theing Myint, Department of Health, Yangon, Myanmar
Nancy Newton, Takoma Park, MD, USA
Lidia Ortiz, President’s Office for Women, Guatemala City, Guatemala
Mihaela Poenariu, East European Institute of Reproductive Health, Targu-Mures, Romania
Lilian Ramirez, Epidemiological Research Centre in Sexual and Reproductive Health, Guatemala City, Guatemala
Claudia Rosales, Guatemalan Association of Sexual Education, Guatemala City, Guatemala
Ruth Simmons, University of Michigan, Ann Arbor, MI, USA
John Skibiak, The Population Council, Nairobi, Kenya
Bela Szabo, East European Institute of Reproductive Health, Targu-Mures, Romania
Liza Vielman, The Population Council, Guatemala City, Guatemala
Wu Shangchun, Scientific Research Institute, State Family Planning Commission, Beijing, China
Xiao Shaobo, Department of Science and Technology, State Family Planning Commission, Beijing, China
Xie Zhenming, Population and Information Research Centre, Beijing, China
Mary Zama, Ministry of Health, Lusaka, Zambia
Zhang Minghua, Division of Science Research, State Family Planning Commission, Beijing, China
Zhou Weijin, Institute of Planned Parenthood Research, Shanghai, China
Thet Thet Zin, Department of Health, Yangon, Myanmar

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>32</td>
<td>76</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>Women</td>
<td>20</td>
<td>48</td>
<td>3</td>
<td>7</td>
</tr>
</tbody>
</table>

from:
AFRO  2  5
AMRO  14  33
EMRO
EURO  4  10
SEARO  4  10
WPRO  12  29
Annex 2

PUBLICATIONS IN 2001


The main objective of the Department’s activities in this area is to strengthen the research capacity of institutions in the WHO Regions of Africa and the Eastern Mediterranean to enhance their potential to implement reproductive health research relevant to national and regional needs and to facilitate their participation in the global research effort.

The strategy continued to focus on the strengthening of selected institutions and the stimulation of interest in reproductive health research in various countries.

The main elements of the strategy are:

- development of subregional “Centres of Excellence”, which are capable of assisting weaker centres, especially those in least developed countries (LDCs);
- promotion of networks through “South-to-South” and “South-to-North” links;
- improvement of research protocol development, research management and scientific writing;
- promotion of intraregional training;
- stimulation of interest in sexual and reproductive health issues in LDCs, French-speaking Africa and the Eastern Mediterranean Region;
- promotion of resource mobilization for research capability-strengthening activities in the two Regions;
- strengthening research skills in the social sciences; and
- promoting “targeted” research on major reproductive health problems and on the needs of LDCs.

RESEARCH ACTIVITIES

Overall research output

The eight centres supported with Long-term Institutional Development (LID) Grants or Resource Maintenance Grants (RMGs) are involved in projects which address regional and national reproductive health priorities. From a total of 48 studies, three projects (6%) were implemented with support from the Programme’s capacity-building grants (LID, RMG and Re-entry Grants). Six projects (13%) were carried out at the centres with support from national sources. The participation of the regional centres in the global research effort is exemplified by the four projects (8%) conducted in these collaborating institutions with support from Thematic Groups of the Department. Likewise, the institutional strengthening efforts deployed by the Programme in its regional centres have enhanced their capacities for fundraising from other international agencies, to address topics of global or local relevance. Thirty-five projects (73%) carried out in these regional centres received support from international agencies other than WHO.

Thirty-one per cent of the projects were mainly epidemiological or social science projects, another 31% were clinical research projects, 25% (12 projects) were basic science studies and 13% (six projects) focused on operations research designs. All thematic areas were studied, but the highest numbers of projects were on maternal health (10), HIV/AIDS (9) and family planning (9). Many projects dealt with several thematic areas concurrently.
Regional research initiatives

Research on female genital mutilation

Department-supported work on female genital mutilation (FGM) focuses on the obstetric sequelae of FGM, as well as the sociocultural context of the practice. The objective is to increase knowledge, particularly on the frequency of the reproductive health consequences of FGM, in order to improve advocacy and programming as well as to develop, test and disseminate tools for research into various aspects of FGM.

The research on obstetric sequelae of FGM is a multicountry, multicentre, prospective cohort study, based at a number of maternity units and obstetric departments in Burkina Faso, Ghana, Kenya, Nigeria, Senegal and the Sudan. It aims to provide reliable information regarding the health consequences of FGM. The primary objectives are to estimate the incidence of obstetric complications among women with FGM giving birth in hospital and to evaluate the relationship between different types of FGM and obstetric complications. A subsidiary objective is to obtain clinical information relevant to the prevention and treatment of obstetric complications in women with FGM.

All women with singleton pregnancies admitted to the participating centres for delivery are approached for recruitment into the study and those recruited undergo an examination to determine their FGM status prior to delivery. Women admitted to the study are followed through labour and delivery up until six weeks after their discharge from hospital. Information is also obtained regarding the health and anthropometric measures of their infants born.

The study is observational in nature, and no active interventions are expected on the part of the staff, apart from examining the women and gathering information.

The pilot phase of the study was conducted between December 2000 and the end of February 2001. Overall, 1919 women were recruited in the pilot phase. Figure 7.5 shows the distribution of the different types of FGM among the volunteers recruited at each study site.

A meeting of the principal investigators who participated in the pilot phase and the study consultants took place in April 2001 in Geneva, Switzerland. The main objectives of the meeting were: (i) to assess the pilot phase of the study; (ii) to identify difficulties and suggest alternatives and/or solutions; and (iii) to outline the implementation plan for the main phase. The meeting critically reviewed and amended all study procedures and instruments according to the experience of the pilot-phase study. The following were the key outcomes of the meeting.

The information derived from the pilot phase on possible complications during the 6-week follow-up of mothers and infants, was not large enough to justify the efforts put in place to ensure that the mothers came for follow-up with their infants. Therefore, it was decided to limit the follow-up in the main study to the time in hospital. FGM type III was found in all centres except Nigeria, and represented a large proportion of cases in Burkina Faso and the Sudan.

The sample size requirements for the main phase were reviewed. It was decided that the objectives could be met by recruiting a total of 20 000 women. Since FGM type III is concentrated in Burkina Faso and the Sudan, it was calculated that in order to have sufficient cases of type III FGM, these countries should recruit 9000 and 6000 subjects, respectively. The main phase of the study will be conducted in 28 sites in Burkina Faso (5), Ghana (3), Kenya (3), Nigeria (7), Senegal (6) and the Sudan (4).

The duration of the main phase was shortened from 18 months, as originally planned, to 12 months. Progress will be reviewed after six months to see if data collection needs to be extended to 15 months in some or all of the centres.

The Senegal team decided to extend the study nationally and include a total of nine sites. The additional three centres will be funded by the WHO Country Office in Senegal. It was agreed that participating centres in Senegal will continue data collection for six additional months in order to have the required sample size. The Department will provide the questionnaires and data management facilities for the extension.

The implementation plan and budget for the main study were approved by the Specialist Panel in Epidemiological Research in Reproductive Health and the Programme’s Scientific and Ethical Review Group (SERG). Data collection started at all sites in November 2001.

Although there is growing information on FGM, much of it is fragmentary and from secondary sources. There is, therefore, a need for an in-depth study to understand...
the sociocultural diversity and complexity of FGM and its consequences, in order to design culturally meaningful and workable programmes towards advocacy and intervention strategies. Protocol development for studies examining these sociocultural aspects continued in 2001 and proposals will be initiated.

**Operations research on improving reproductive health services for adolescents**

In 2001, the operations research project to evaluate and improve reproductive health services for adolescents continued in five French-speaking sub-Saharan countries: Benin, Cameroon, Côte d’Ivoire, Guinea and Senegal. The Programme is facilitating and coordinating this regional initiative and is providing support for the research capacity strengthening aspects of the project. However, the funding for each country project is being raised locally. A characteristic feature of the project is its implementation by multidisciplinary research teams and the active participation of youth representatives in each team.

In Senegal, the Programme is collaborating with the FRONTIERS in Reproductive Health Project funded by the United States Agency for International Development (USAID). The FRON- TIERIS Project has assumed the entire funding for the research and interventions in Senegal, within one of its own projects. This FRONTIERS-supported project has a broader focus and is also being carried out in Bangladesh, Kenya and Mexico.

More details on this project are given in the chapter on “Promoting sexual and reproductive health of adolescents”.

**Adolescent reproductive health in the WHO Region of the Eastern Mediterranean**

In response to the recommendations of the intercountry workshop on adolescents’ needs and perspectives in reproductive health in WHO’s Eastern Mediterranean Region, the Department has collaborated with the Regional Office since 2000 to provide technical support for the development of research proposals in the Islamic Republic of Iran, Oman, and the Syrian Arab Republic.

More details on this work are given in the chapter on “Promoting sexual and reproductive health of adolescents”.

**Studies on community involvement in improving continuation of maternal care**

The Regional Advisory Panel (RAP) for the African and Eastern Mediterranean Regions had, in its previous meetings in 1998 and 1999, agreed that a multicountry operations research study on maternal health should be initiated to examine the perceptions of pregnant women, communities and health personnel on pregnancy complications. Ensuing action would focus on developing appropriate strategies, including the use of antenatal care visits for preparing birth plans for pregnant women and exploring ways of assuring skilled attendance at delivery. As a special feature, the study would look at the role of men in maternal health care. The issue of community involvement in maternal health had been identified in the February 2000 joint planning meeting between the Regional Office for Africa (AFRO) and WHO Headquarters as one of the projects of common interest that should be developed.

A prototype protocol, developed by the Department in collaboration with African researchers, has been sent to several countries for review and adaptation. Currently, these adapted protocols are being prepared in Nigeria, South Africa and Uganda, and the projects are expected to start in 2002.

**A randomized, double-blind study to compare two regimens of levonorgestrel in emergency contraception in Nigeria**

Research carried out by the Programme in the area of emergency contraception has aimed at finding agents that are more effective and/or have fewer side-effects than the hormonal methods presently in use. The objective of the present project is to compare the efficacy and side-effects of two treatments: (i) levonorgestrel administered in two doses of 0.75 mg at a 24-hour interval; and (ii) levonorgestrel administered in one dose of 1.5 mg. It would be a major practical advantage if levonorgestrel could be given in one single dose, because this would simplify the treatment and increase the compliance and acceptability. The study will be conducted in seven centres in Nigeria.

In addition, the project will serve as a training ground in clinical research conducted in accordance with Good Clinical Practice and it will play a role in developing a network of centres for clinical research in Nigeria. Finally, the project will contribute to spreading awareness of emergency contraception in various areas in Nigeria, and to collecting national data on the use of levonorgestrel for emergency contraception.

**DEVELOPMENT OF HUMAN RESOURCES**

**Workshops and short courses**

**WHO-sponsored international semenology workshop**

The fifth semenology workshop was held in December 2001 at the University of Stellenbosch, Cape Town, South Africa for ten participants from Ethiopia, Kenya, Nigeria, Tunisia, South Africa and Zimbabwe. All participants successfully completed both the theoretical and practical examinations. The objective of the workshop was to establish an internationally accepted standard for the evaluation of human semen as described in the WHO manual, *WHO laboratory manual for the examination of human semen and sperm–cer-
Section 7 - Technical cooperation with countries

vical mucus interaction and publications from the centre that describe sperm morphology. This will ensure repeatable and reliable results on human semen analyses and will also contribute to enhancing the results of WHO-sponsored clinical trials. A second objective of the workshop was to extend the existing semen quality control network in Africa. Since 1997, a total of 49 persons have participated in this course. All participants have been subsequently enrolled in the Continuous Quality Control programme coordinated by the University of Stellenbosch.

Regional training course for French-speaking countries in Africa

As indicated in the Department’s Annual technical report 2000, more than 120 health professionals from French-speaking Africa have taken this course since 1993 in order to acquire the necessary skills for developing research protocols and research implementation. In 1997, results of the post-training evaluation pointed to the need for the training of trainers who could duplicate the training at national level. However, one of the constraints to this approach was the lack of a standardized training manual in French. Support to the development of such a manual continued during 2001, whereby various modules of the training manual have been further tested during training workshops held in Côte d’Ivoire, Guinea and Tunisia.

Courses on gender and reproductive health

These courses were conducted in Kenya and South Africa. Details of the courses are given in the chapter on “Gender and reproductive rights in reproductive health”.

Regional workshop on ethical issues in research in reproductive health

The Department’s fourth workshop on this subject was held in November 2001 in Cairo, Egypt. This was in response to the recommendation by the Programme’s Scientific and Ethical Review Group that the Programme organize regional workshops devoted to the principles and practice of ethics in research on human subjects in the field of human reproduction. These workshops are intended for participants from centres collaborating with the Programme. The general purpose of the Cairo workshop was to stimulate discussion on and encourage ethical practices in reproductive health research. Reproductive health research in this context includes biomedical, social science and epidemiological research involving human subjects, covering such areas as maternal health, fertility regulation, infertility, sexual behaviour, sexually transmitted diseases and HIV infection. There were 37 participants from institutions in ten countries (Egypt, Lebanon, Islamic Republic of Iran, Oman, Pakistan, Saudi Arabia, the Sudan, Syrian Arab Republic, Tunisia and Yemen) in the Eastern Mediterranean Region, collaborating in Programme-supported or Programme-related research. The participants included reproductive health researchers, programme managers or planners, representatives of consumers’ groups and of women’s groups and other individuals who were either current or potential members of local or national ethical review committees. Three of the six faculty members were also from countries in the WHO Eastern Mediterranean Region.

Regional workshop on infertility management

Since infertility is a priority issue in the African and Eastern Mediterranean Regions, RAP recommended a workshop for the development of a multicountry study of operational research on infertility management at the primary and secondary levels of health care. Preparations were completed in 2001 and the workshop will take place in early 2002 in Nairobi, Kenya. The objectives of the workshop are:

- to define best practices and formulate solutions to the management of infertility in a limited-resource setting at both primary and secondary levels;
- to review past experiences, identify best practices, outline perspectives for the future and draw up a blueprint for the improved management of infertility in countries with limited resources; and
- to formulate a preventive strategy for infertility in the two Regions.

Research Training

Research training grants (RTGs)

In 2001, six researchers were awarded grants from the Programme: one each from Nigeria and Uganda at the London School of Tropical Medicine and Hygiene, London, United Kingdom for a Master’s course in reproductive and sexual health research; one from Côte d’Ivoire at the Free University of Brussels, Brussels, Belgium for a course on health systems research; one from Nigeria at the University of Edinburgh, Edinburgh, United Kingdom, for studies in andrology; one from Cameroon at the National Institute of Studies in Demography (INED), Paris, France; and one from Cameroon, who is to start a Master’s course in biostatistics at the University of Ibadan, Ibadan, Nigeria.

M.Sc. course in biostatistics, University of Ibadan, Ibadan, Nigeria

Since 1999, the Programme has supported an M.Sc. course in biostatistics at the University of Ibadan, Ibadan, Nigeria, which trains professional biostatisticians for biomedical research groups in Africa. The Programme’s support includes capacity building to strengthen the academic staff and enhancing computer facilities and library resources. In the academic year 2000–2001, eight students successfully completed the course. The course now attracts students from other African countries and ten foreign students have been accepted for the 2001–2002 academic year.
Training provided by the centres

Training abroad of staff from Programme-supported centres was complemented by the training programmes organized by the centres themselves for professional and technical staff from national institutions, including service providers. The eight centres receiving research capacity strengthening support have provided individual training to 11 staff from other local institutions. Forty-five fellows participated in formal courses while 878 persons attended short, group-learning activities such as seminars and workshops organized by these centres.

DISSEMINATION OF RESEARCH FINDINGS

The dissemination of relevant research findings is a pre-requisite to their adaptation and utilization by reproductive health programmes and services. Research results have to be shared with, and validated by, international and local scientific communities, and the most direct mechanism is their publication in peer-reviewed journals and presentations at scientific events.

During the reporting period, a total of 27 research articles (25 original papers and two review articles) were published and seven books or book chapters were authored by staff from the eight centres receiving capacity strengthening support. Likewise, 11 presentations were made at national, regional or international scientific events.

SUMMARY OF COUNTRY ACTIVITIES

During 2001, the Department collaborated with 35 institutions or research groups in 23 countries of the African and Eastern Mediterranean Regions. A brief description of the main developments at country level is given in Table 7.2.

OTHER ACTIVITIES

Regional directories of reproductive health

Data collection for a reproductive health research directory for the French-speaking African countries was initiated in 2001 by the African Network of Reproductive Health Research (RESAR). This was a follow-up to the training workshop held in November 2000 in Ouagadougou, Burkina Faso for participants of 12 French-speaking African countries. The purpose of this initiative is twofold: (i) to improve dissemination of research findings; and (ii) to promote networking. The directory is expected to be widely disseminated through the Internet and CD-ROMs.

An informal consultation for a reproductive health research directory in the Eastern Mediterranean Region was held in WHO's Regional Office for the Eastern Mediterranean (EMRO) in August 2001. It was attended by the country coor-
### Table 7.2. Summary of country activities in the WHO Regions of Africa and Eastern Mediterranean

<table>
<thead>
<tr>
<th>Country</th>
<th>Grants, institutions and activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>Operations research on adolescents—a regional research project</td>
</tr>
</tbody>
</table>
|               | *Small grant*—The Centre for Research in Human Reproduction and Demography (CERRHUD) of the Department of Obstetrics and Gynaecology, University of Benin, Cotonou:  
|               | • provides statistical support to adolescent study in other countries                                                                                                                                                    |
| Burkina Faso  | Obstetric sequelae of FGM—Centre Hospitalier National Yalgado Ouedraogo, Ouagadougou                                                                                                                                                 |
| Cameroon      | Operations research on adolescents—a regional research project                                                                                                                                                                       |
|               | The African Reproductive Health Research Network (RESAR):  
|               | • organizes research methodology courses and develops manuals for French-speaking countries                                                                                                                                          |
| Côte d'Ivoire | Operations research on adolescents—a regional research project                                                                                                                                                                       |
|               | *LID Grant 1998–2002*—National Research Cellule on Reproductive Health in the National Institute of Public Health in Abidjan, member of RESAR                                                                                                      |
| Egypt         | *LID Grant 1992–2002*—The Egyptian Fertility Care Society (EFCS). EFCS is an affiliate of the Egyptian Medical Association and its research network includes all University and Ministry of Health teaching hospitals:  
|               | • completed research on clinic-based assessment of incidence of RTI in women as well as on the efficacy and side-effects of progestogen-only injectable contraceptives as perceived by users  
|               | • continued research on improving postabortion care  
|               | • initiated a project on long-term side-effects of FGM  
|               | • conducted one training-of-trainers workshop in curriculum development, teaching methods and evaluation of teaching in reproductive health and family planning for 28 core university faculty members from 14 universities of Egypt  
|               | • held a communication training workshop for researchers and policy-makers  
|               | • edited and translated into Arabic the textbook *Essentials of contraceptive technology* by Hatcher et al.                                                                                                                              |
|               | • prepared a policy briefing and a mass media advocacy plan for efforts aiming at the eradication of FGM in Egypt  
|               | • provided technical assistance to the Republic of Yemen in collaboration with the WHO Regional Office for the Eastern Mediterranean Region, for expanding the contraceptive methods mix |
| Ethiopia      | *LID Grant 1990–1994, Pre-LID Grant in 2001*—Department of Obstetrics and Gynaecology, University of Addis Ababa, Addis Ababa:  
|               | • in March 2001, action was taken to develop an operational plan for the research unit  
|               | • familiarization visit of senior staff to an active research centre in October 2001 (Reproductive Health Research Unit, University of Witwatersrand, Johannesburg, South Africa)                      |

1 This activity is reported in detail elsewhere in the report

2 FGM—female genital mutilation
<table>
<thead>
<tr>
<th>Country</th>
<th>Grants, institutions and activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghana</td>
<td>Obstetric sequelae of FGM[^1]—Rural Help Integrated, Bolgatanga</td>
</tr>
</tbody>
</table>
| Guinea                          | Operations research on adolescents[^1]—a regional research project *Pre-LID Grant in 2001*—The Reproductive Health Research Cellule (Cellule de Recherche en Santé de la Reproduction en Guinée, CERREGUI) is part of RESAR:  
  • organized two research methodology workshops for the development of research proposals on five themes that had been identified as research priorities in a national workshop in 2000.                                                                                                                                |
| Iran (Islamic Republic of)      | *Small Grant*—National Research Centre for Reproductive Health, Deputy Ministry for Research Affairs, Ministry of Health and Medical Education, Tehran  
  Support to protocol development for research on adolescent reproductive health[^1], Ministry of Health, Tehran                                                                                                                                                                                                                       |
| Kenya                           | Obstetric sequelae of FGM[^1]—Kenyatta National Hospital, Nairobi  
  *Small Grants*—National Centre for Research in Reproduction (NCRR). This centre comprises four units: the Department of Obstetrics and Gynaecology, University of Nairobi; the Reproductive Biology Unit in the Department of Animal Physiology, University of Nairobi; the Institute of Primate Research of the National Museums of Kenya; and the Reproductive Health Research Unit (RHRU) of the Kenya Medical Research Institute (KEMRI) |
| Mozambique                      | *LID Grant from 1989 to 1999*—The Department of Obstetrics and Gynaecology, National University of Maputo, Maputo:  
  • in January 2001, an in-depth evaluation of the centre was conducted  
  • a significant number of professional staff has been trained  
  • important research activities undertaken in reproductive health using a “twinning” arrangement with a counterpart department in Uppsala University, Uppsala, Sweden  
  • expanding to population-/community-based research  
  • need identified for training in operations research                                                                                                                                                                                                                                                                   |
| Nigeria                         | Obstetric sequelae of FGM[^1]—National Hospital for Women and Children, Abuja and University of Benin City Hospital, Benin City  
  *Small Grants*—Department of Obstetrics and Gynaecology, University of Ibadan, Ibadan Department of Obstetrics and Gynaecology, University of Benin, Benin City; Department of Obstetrics and Gynaecology, University of Jos, Jos Department of Obstetrics and Gynaecology, University of Lagos, Lagos  
  *LID Grant 1999–2003*—Centre for Research in Reproductive Health, Obafemi Awolowo College of Health Sciences, Ogun State University Teaching Hospital, Sagamu:                                                                                                                                                                                                                     |

[^1]: This activity is reported in detail elsewhere in the report

*Contd...*
<table>
<thead>
<tr>
<th>Country</th>
<th>Grants, institutions and activities</th>
</tr>
</thead>
</table>
| Nigeria (cont’d)     | • conducting community-based research in reproductive health  
                      • coordinating a national multicentre study to compare two doses of levonorgestrel for emergency contraception  
                      • organized training on ethical issues in reproductive health for 75 staff members.  
                      M.Sc. course in Biostatistics¹—Ibadan Department of Epidemiology, Medical Statistics and Environmental Health  
                      The Programme provided support to the scientific meeting of the Society of Obstetricians and Gynaecologists of Nigeria (SOGON)  
                                                                 |
| Oman                 | The programme provides support for development of protocols for research on adolescent reproductive health, Ministry of Health¹  
                                                                 |
| Pakistan             | Small Grants—National Research Institute of Fertility Control (NRIFC), Ministry of Population Welfare, Government of Pakistan, Karachi Reproductive Physiology Laboratory, Department of Biological Sciences, Qaid-i-Azam University, Islamabad  
                                                                 |
| Saudi Arabia         | Preparatory phase for a workshop on needs assessment in reproductive health and research—Department of Obstetrics and Gynaecology, Jeddah  
                                                                 |
| Senegal              | Operations research on adolescents¹—a regional research project  
                      Obstetric sequelae of FGM¹—Université Cheick Anta Diop, Dakar  
                      LID Grant for 1999–2003—The Department of Obstetrics and Gynaecology at Le Dantec Hospital, University of Dakar, Dakar and the International Centre for Training and Research in Reproductive Health (CEFOREP), which is attached to the said Department:  
                      • continued research on postabortion care and on natural family planning  
                      • organized a research methodology course and a scientific writing workshop for the Department’s staff  
                                                                 |
| South Africa         | Small Grant—Reproductive Health Research Unit (RHRU), Chris Hani Baragwanath Hospital, Soweto, Johannesburg  
                      Research methodology course¹—RHRU, Johannesburg  
                      Semenology course¹—University of Stellenbosch, Cape Town  
                      Feasibility study for African Reproductive Health Research Network¹—RHRU, Johannesburg  
                      Preparations for LID Grant—Effective Care Research Unit (ECRU) in the Department of Obstetrics and Gynaecology of the East London Hospital complex which consists of Cecilia Makiwane Hospital in Mdantsane and Frere Hospital in East London:  
                      • focus on clinical trials designed to answer relevant questions on reproductive health  
                                                                 |

¹This activity is reported in detail elsewhere in the report

Contd...
<table>
<thead>
<tr>
<th>Country</th>
<th>Grants, institutions and activities</th>
</tr>
</thead>
</table>
| Sudan                    | Resource Maintenance Grant—Department of Obstetrics and Gynaecology, University of Khartoum, Khartoum:  
  - has an active endocrinology/microbiology laboratory  
  - conducted community-based research on FGM and published a book on the findings, in collaboration with UNFPA  
  - conducted two research methodology courses.  
  Obstetric sequelae of FGM\(^1\)—University of Khartoum, Khartoum                                                                 |
| Syrian Arab Republic     | The Programme provided support to protocol development for research on adolescent reproductive health,\(^1\) Ministry of Health                                                                                                                                                           |
| Tunisia                  | LID Grant for 1998–2002—The Centre for Research in Human Reproduction, Tunis, which belongs to the National Office of Family and Population (ONFP):  
  - initiated a national reproductive health research network  
  - coordinating a study on the diagnosis and prevention of sexually transmitted infections (STIs) in Morocco and Tunisia with the objective of developing a regional strategy and setting up a regional reference laboratory for STIs  
  - held a workshop on research methodology for the research network members  
  - one staff member served as faculty for the International Course on Epidemiology and Statistics, held in Dakar, Senegal |
| Uganda                   | Resource Maintenance Grant—The Department of Obstetrics and Gynaecology of Makerere University, Kampala:  
  - collaborated extensively with many institutions at international level  
  - completed a randomized, clinical trial demonstrating the efficacy of nevirapine in prevention of mother-to-child transmission (MTCT) of HIV; the results of the study have been widely disseminated and regularly discussed at national as well as at international levels, leading to the planning of national MTCT prevention strategies;  
  - members of the Ugandan research team are being invited by other African countries to assist them in setting-up similar MTCT programmes  
  - held a scientific writing workshop                                                                                                             |
| Zambia                   | Small Grant—Department of Obstetrics and Gynaecology of the University of Zambia, based in the Teaching Hospital in Lusaka                                                                                                                   |
| Zimbabwe                 | Resource Maintenance Grant—Department of Obstetrics and Gynaecology, University of Zimbabwe, Harare:  
  - 23 ongoing research projects  
  - 22 scientific publications  
  - integrating the findings of the operational research project on the visual inspection for cancer of the cervix into the cervical cancer screening programme in Zimbabwe                                                                 |

\(^1\)This activity is reported in detail elsewhere in the report.
There is an urgent need to update, expand and maintain the African Reproductive Health Research Directory that was compiled in 1998. This will be part of the network’s activities.

### HIGHLIGHTS OF JOINT ACTIVITIES ON PROGRAMMATIC ISSUES

A number of other activities that were carried out in collaboration with other partners, either within the Department or other international agencies, are summarized in Table 7.3. Details of these activities are given in other chapters of this *Annual technical report 2001*.

### PLANNED ACTIVITIES

Activities planned for the next year can be summarized under the following main lines of work:

- through institutional development grants, support and maintain institutions currently collaborating with the Department in order to enable them to undertake research projects relevant to their identified reproductive health needs and priorities;
- promote and strengthen regional research networks working on key issues such as HIV/AIDS, maternal health, adolescent reproductive health, FGM and cervical cancer; and
- promote dissemination and utilization of tools developed by the Department.

---

### Country

<table>
<thead>
<tr>
<th>Country</th>
<th>TCC support and activities in the research centres</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zimbabwe</td>
<td>Resource Maintenance Grant&lt;br&gt;The Department of Obstetrics and Gynaecology, University of Zimbabwe, Harare&lt;br&gt;- has 23 ongoing research projects and 22 publications; and&lt;br&gt;- is integrating the findings of the operational research project on the visual inspection for cancer of the cervix into the cervical cancer screening programme in Zimbabwe and considered for other countries.</td>
</tr>
</tbody>
</table>

*the activity is reported in detail elsewhere in the report*
Table 7.3. Joint activities on programmatic issues

<table>
<thead>
<tr>
<th>Department thematic group or collaborating agency</th>
<th>Activity</th>
<th>Countries participating in the activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promoting family planning</td>
<td>Pregnancy prevention in the era of HIV/AIDS</td>
<td>Kenya, South Africa, United Republic of Tanzania, Uganda, Zambia and Zimbabwe</td>
</tr>
<tr>
<td>Making pregnancy safer (MPS)</td>
<td>Making Pregnancy Safer initiative</td>
<td>Ethiopia, Mauritania, Mozambique, Nigeria, Uganda and the Sudan</td>
</tr>
<tr>
<td>Planning and programming in collaboration with AFRO</td>
<td>Use of misoprostol in the third stage of labour</td>
<td>Egypt, Nigeria and South Africa</td>
</tr>
<tr>
<td>Reproductive tract infections including cervical cancer and infertility</td>
<td>A training initiative in evidence-based reproductive health care</td>
<td>African Region</td>
</tr>
<tr>
<td>Collaboration with other UN agencies</td>
<td>Two descriptive case studies on screening for and treatment of syphilis in pregnant women</td>
<td>Kenya and South Africa</td>
</tr>
<tr>
<td>Department collaboration with Inter-Agency Working Group (IAWG) for reproductive health in refugee situations</td>
<td>Prevention of MTCT of HIV</td>
<td>Kenya, South Africa and Uganda</td>
</tr>
<tr>
<td></td>
<td>Infant feeding and impact of infant feeding choices on maternal morbidity/mortality</td>
<td>Kenya, South Africa and Uganda</td>
</tr>
<tr>
<td></td>
<td>Field-testing and finalization of clinical guides for the management of pregnant women with HIV infection</td>
<td>Ethiopia and South Africa</td>
</tr>
<tr>
<td>Technical cooperation with countries</td>
<td>Field-testing of guidelines for “Clinical management of rape survivors”</td>
<td>United Republic of Tanzania</td>
</tr>
<tr>
<td></td>
<td>Sexual and gender-based violence (SGBV)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>United Nations High Commissioner for Refugees organized a meeting to review and update SGBV protocols and procedure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>First regional symposium for policy-makers, programme managers and heads of research institutions, and workshop for heads of research institutions</td>
<td>All countries in the WHO African and Eastern Mediterranean Regions with research institutions receiving research capacity strengthening from the Programme</td>
</tr>
<tr>
<td></td>
<td>Participation in the evaluation of the reproductive health components of UNFPA-funded national population programmes</td>
<td>Angola, Gambia and Sao Tome</td>
</tr>
<tr>
<td></td>
<td>Stages I, II, and III of the Strategic Approach to reproductive health</td>
<td>Ethiopia, South Africa and Zambia</td>
</tr>
<tr>
<td></td>
<td>Total Quality Management of maternal health</td>
<td>WHO Eastern Mediterranean Region</td>
</tr>
</tbody>
</table>
### Annex 1

**REGIONAL ADVISORY PANEL FOR AFRICA AND THE EASTERN MEDITERRANEAN IN 2001**

Asya Al-Riyami, Department of Research and Studies, Ministry of Health, Muscat, Sultanate of Oman  
Mariame Ba, Department of Obstetrics and Gynaecology, University of Dakar, Dakar, Senegal  
Hassan Ba’aqeel, Department of Obstetrics and Gynaecology, King Khalid National Guard Hospital, Jeddah, Saudi Arabia  
(Chairman)  
Hyam Bashour, Department of Community Medicine, Faculty of Medicine, Damascus University, Damascus, Syrian Arab Republic  
Kim Dickson-Tetteh, Reproductive Health Research Unit, Department of Obstetrics and Gynaecology, Chris Hani Baragwanath Hospital, Johannesburg, South Africa  
Faysal El-Kak, American University of Beirut, Faculty of Health Sciences, Beirut, Lebanon  
Alex Ezeh, African Population and Health Research Centre, Nairobi, Kenya  
Mohammed Kanaan, Social Health Department, Reproductive Health Programme, Ministry of Public Health, Beirut, Lebanon  
Bailah Leigh, National AIDS Control Programme, Ministry of Health and Sanitation, Freetown, Sierra Leone  
Gunilla Lindmark, Section of International Maternal and Child Health (IMCH), Department of Women’s and Children’s Health, Uppsala University, Uppsala, Sweden  
Boniface Nasah, Society of African Gynaecologists and Obstetricians (SAO), Buea, Cameroon  
Babatunde Osotimehin, The Social Science and Reproductive Health Network, University College Hospital, Ibadan, Nigeria  
Christine Sekadde-Kigondu, Department of Obstetrics and Gynaecology, University of Nairobi, Kenyatta National Hospital, Nairobi, Kenya  
Christiane Welffens-Ekra, Department of Obstetrics and Gynaecology, University Hospital Yopougon, Abidjan, Côte d’Ivoire

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>All</td>
<td>13</td>
<td>93</td>
<td>1</td>
</tr>
<tr>
<td>Women</td>
<td>6</td>
<td>43</td>
<td>1</td>
</tr>
</tbody>
</table>

**from:**  
AFRO 8 57 8  
AMRO  
EMRO 5 36 5  
EURO 1 7 1  
SEARO  
WPRO

**Collaborating agency scientist**

Marie-Hélène Bouvier-Coll, French National Institute of Health and Medical Research (INSERM), Paris, France
Annex 2

SCIENTISTS COLLABORATING IN 2001

African Region

Michel Akotionga, Maternité du Centre Hospitalier National Yalgado Ouedraogo, Ouagadougou, Burkina Faso
Eusebe Alihonou, Centre of Research in Human Reproduction and Demography, National University of Benin, Cotonou, Benin
Mamadou Baldé, University Hospital of Donka, Conakry, Guinea
Antonio Bugalho, Department of Obstetrics and Gynaecology, Maputo Central Hospital, Maputo, Mozambique
Virgile Capo-Chichi, Centre of Research in Human Reproduction and Demography, National University of Benin, Cotonou, Benin
Zvavahera Chirenje, Department of Obstetrics and Gynaecology, University of Zimbabwe, Harare, Zimbabwe
Olukayode Dada, College of Health Sciences, Ogun State University, Sagamu, Nigeria
Fadel Diadhiou, Faculty of Medicine and Pharmacy, University of Dakar, Dakar, Senegal
Djibril Diallo, Faculté de Médecine et de Pharmacie, Université Cheikh Anta Diop de Dakar, Dakar, Senegal
Osato Giwa-Osagie, College of Medicine, University of Lagos, Lagos, Nigeria
Guyo Jaldesa, University of Nairobi, College of Health Sciences, Kenyatta National Hospital Campus, Nairobi, Kenya
Joseph Karanja, University of Nairobi, College of Health Sciences, Kenyatta National Hospital Campus, Nairobi, Kenya
Christine Kaseba, Department of Obstetrics and Gynaecology, University of Zambia, Lusaka, Zambia
Kassahun Kiros, University of Addis Ababa, Addis Ababa, Ethiopia
Mairo Mandara, National Hospital for Women and Children, Abuja, Nigeria
Florence Mirembe, Department of Obstetrics and Gynaecology, Makerere University, Kampala, Uganda
Kwasi Osei-Agyarko, Rural Help Integrated, Bolgatanga, Ghana
Oladosu Ojengbede, Department of Obstetrics and Gynaecology, University of Benin Teaching Hospital, Benin City, Nigeria
Augustin Otu, Department of Obstetrics and Gynaecology, University of Benin, Benin City, Nigeria
James Oyieke, Department of Obstetrics and Gynaecology, University of Nairobi, Nairobi, Kenya
René Perrin, African Network of Reproductive Health Research, Cotonou, Benin
Justine Tantchou, African Network of Reproductive Health Research, Yaoundé, Cameroon
Marguerite Te Bonle, National Research Cellule of Reproductive Health, National Institute of Public Health, Abidjan, Côte d’Ivoire
Emmanuel Wango, Reproductive Biology Unit, University of Nairobi, Nairobi, Kenya
K. Monique Wasunna, Centre for Clinical Research, Kenya Medical Research Institute, Nairobi, Kenya

Eastern Mediterranean Region

Badar Uddin Abbasi, National Research Institute of Fertility Control, Karachi, Pakistan
Rim Ben Aissa, Research Centre for Human Reproduction, National Office for Family and Population, Tunis, Tunisia
Samia Charrouh, PAPFAM Project, League of Arab States, Cairo, Egypt
Sahar El-Tawila, Social Research Centre, American University, Cairo, Egypt
Abdulazis Gerais, Department of Obstetrics and Gynaecology, University of Khartoum, Khartoum, the Sudan
Ezzeldin Hassan, The Egyptian Fertility Care Society, Cairo, Egypt
Samina Jalali, Department of Biological Sciences, Qaid-i-Azam University, Islamabad, Pakistan
Khaled Louhichi, Population Research Unit, League of Arab States, Cairo, Egypt
Mohamed El Fadil Saad, Faculty of Medicine, University of Khartoum, Khartoum, the Sudan
Sami Saad, Department of Obstetrics and Gynaecology, Shatby Maternity Hospital, Alexandria, Egypt
Fahimeh Ramezani Tehrani, National Research Centre in Family Planning, Ministry of Health and Medical Education, Tehran, Islamic Republic of Iran
The WHO Region of the Americas

E. Ezcurra

INTRODUCTION

Strengthening the research capacity of institutions in the WHO Region of the Americas was undertaken to further enhance their potential to implement reproductive health research relevant to national and regional needs, and to facilitate their participation in the global research effort.

The main goals established by the Regional Advisory Panel (RAP) for the 2000–2001 biennium were: (i) to continue strengthening research capacity in Programme-supported collaborating institutions in the WHO Region of the Americas, by promoting and supporting the implementation of well-designed research projects in topics relevant to national and regional reproductive health problems; and (ii) to promote the dissemination and utilization of relevant research findings.

The following strategies were selected for attaining this goal:

• implementation of regional and national reproductive health research and participation in the global research effort, particularly through the strengthening of regional and national research networks in basic reproductive biology, clinical/epidemiological investigations and social sciences;

• development and strengthening of human resources; and

• increased dissemination of relevant research results to facilitate their adaptation and utilization in reproductive health programmes and services.

The main activities implemented under these strategies are described in the following section.

RESEARCH ACTIVITIES

Overall research output

The 11 centres supported with research capacity-strengthening grants were involved in projects which address regional and national priorities. From the overall number of 132 studies during 2000 (the last year for which complete data are available), 10 projects (8%) were implemented with support from the Programme’s capacity-building grants (Long-term Institutional Development, Resource Maintenance and Re-entry Grants). Fifty-two projects (39%) were carried out at the centres with support from national sources. The participation of the regional centres in the global research effort is exemplified by the 19 projects (14%) conducted in these collaborating institutions with support from Thematic Groups of the Department. Also, the institutional strengthening efforts deployed by the Programme in its regional centres have enhanced their capacities for fundraising from other international agencies to address topics of global or local relevance. During 2000, 51 projects (38%) carried out in these regional centres received support from international agencies other than WHO.

With respect to capacity developed to address research issues from different methodological approaches, it is worth noting that, from the 132 research studies, 48 (36%) were epidemiological or social science projects, an increase of nearly 10% over the 1999 figures.

Projects directly supported with research capacity-strengthening grants

The Long-term Institutional Development (LID) Grant awarded to the Instituto de Medicina y Biologia Experimental de Buenos Aires, Argentina is centered on the project: “Epididy-
mal proteins that participate in gamete interaction and their potential use for male fertility regulation. The first specific aim of the project (Aim A) was to study the potential contraceptive use of an already identified epididymal protein (protein DE) which mediates gamete fusion. During the first three years of the grant, protein DE was cloned, sequenced and expressed as a functional protein in a prokaryotic system. Recent evidence revealed that DE has significant homology with a human epididymal protein also involved in gamete fusion. The tissue specificity and immunogenicity of DE, its role in fertilization, the possibility of producing the antigen in large amounts by recombinant DNA technology, and the existence of its functional homologue in humans, strongly support the potential use of this epididymal protein for the future development of immunocontraceptives suitable for human use. Considering that no single antigen may provoke the immune response required for a contraceptive method, the second aim of this project (Aim B) was to identify and characterize novel epididymal proteins involved in gamete interaction. The recent development of a cDNA expression library towards human epididymis will allow further characterization of the proteins at a molecular level.

The Guatemalan Research Centre on Epidemiologic Research is the second recipient of the three LID Grants awarded during the biennium. The Centre’s activities during this period focused on the project “Strategic assessment to identify priority interventions that would improve access to and quality of family planning, maternal and neonatal care in Guatemala”. A background paper was produced by the Centre and discussed at the planning workshop held in August 2001, in which a wide representation of key national stakeholders participated. The strategic assessment was carried out in October 2001 in five departments of Guatemala, representative of the nation’s cultural, ethnic and social characteristics. Further details on the strategic assessment may be found in the report on “Policy and programme issues”.

The third recipient of a LID Grant is the Centre for Population Studies (CENEP) in Buenos Aires, Argentina which coordinates the regional social sciences network. The network has a twofold purpose. First, it disseminates information on social sciences research relevant to reproductive health, on training opportunities, scientific meetings, etc. In the 2000–2001 biennium, the network published 21 newsletters and four bulletins; a web page was designed and made operational in November 2001. Furthermore, CENEP librarians prepared a CD-ROM with a bibliography on Social Aspects of Human Reproduction (1990–2001), incorporating information from the library’s holdings, the network’s Bulletin and from a review of journals. The CD-ROM will be available in January 2002 to the members of the network.

The second main task of CENEP is the coordination of the regional, multicentre research project on “Reality and beliefs in the sexual and reproductive decision-making process: men’s perceptions and behaviour” which includes social science groups from Argentina, Bolivia, Cuba and Peru. Two of the four final country reports are ready for review, and the remaining two should be completed by the end of the year. Preliminary results and methodological issues related to the study have been disseminated in presentations made by local teams in two national and seven international events.

Progress of research programmes mostly cofunded by other sources

Projects on maternal and neonatal health research

A Resource Maintenance Grant (RMG) was awarded to the Centro Rosarino de Estudios Perinatales (CREP), Rosario, Argentina to facilitate the coordination and the implementation of regional research in maternal and neonatal health and support its role as a regional training centre. Only basic, core support was provided—neither specific projects nor training activities were funded. During the 2000–2001 biennium, CREP completed seven research projects and disseminated their results in ten original articles published in international, peer-reviewed journals. With respect to training, staff from the Centre organized 14 evidence-based medicine courses, 12 offered in different locations within Argentina and two abroad.

Projects covering all areas of reproductive health

Resource Maintenance Grants were also awarded to five research institutions in Brazil, Chile (2), Cuba and Peru to assist in the implementation of comprehensive reproductive health research programmes. Basic reproductive immunology, contraception, maternal and child health, reproductive tract infections and adolescent reproductive health were some of the topics covered. The scientific output of these five institutions in 2000 (data on 2001 are not yet available) amounts to 72 original articles published in 38 national and 34 international journals.

DEVELOPMENT OF HUMAN RESOURCES

In 2001, 14 scientists from regional centres received grants to undergo training in the areas of reproductive epidemiology, reproductive medicine, the social sciences and molecular biology. In addition to grants directly awarded by the Programme, six fellows (5 women) from Argentina (3), Brazil (1), Costa Rica (1) and Nicaragua (1) received grants from PLACIRH to undertake training within the Region.

Resources for Training Grants continued to be awarded to the Institute of Nutrition in Mexico City and to the National Institute of Public Health, Cuernavaca, Mexico to support regional postgraduate courses in reproductive biology and reproductive epidemiology, respectively.

Table 7.4 summarizes the overall number of training grants awarded in the 2000–2001 biennium. Nineteen fellows (10 women) received grants for short- and long-term training, mostly (11) in centres located in Latin America.
Training abroad of staff from the supported centres was complemented by extensive training programmes organized by the centres themselves for professional and technical staff from national institutions, including service providers. In 2000, the 11 centres provided individual training to 76 staff from other local institutions. A total of 216 fellows participated in formal courses and 1480 attended short, group-learning activities such as seminars and workshops organized by the centres receiving research capacity-strengthening support.

**DISSEMINATION OF RESEARCH FINDINGS**

**Scientific publications**

During 2000, a total of 197 research articles (174 original papers and 23 review articles) were published, and 56 books and book chapters were authored by staff from centres receiving capacity-strengthening support. Furthermore, 286 presentations were made in national, regional or international scientific events and 28 official reports were presented to national and international authorities and agencies. Figure 7.6 shows the distribution of publications and presentations in national/regional and international journals and meetings.

**Dissemination of results from regional research initiatives**

Of particular importance are the information dissemination activities related to the two regional research initiatives completed in the present biennium: (i) acceptability of emergency contraception in Brazil, Chile and Mexico; and (ii) the role of men in the decision-making process that affects reproductive health: a multicentre study in Argentina, Bolivia, Cuba and Peru, mentioned above.

With respect to the study on emergency contraception, the results of the study have been widely disseminated. In addition to the nine presentations in scientific events—four academic and training activities and five scientific publications undertaken by the three teams of investigators—activities of information dissemination and advocacy have been intensive, particularly in Chile (see Box 7.1).
COUNTRY REPORTS

In 2001, the Department collaborated with 20 institutions in 10 countries of Latin America: Argentina, Bolivia, Brazil, Chile, Colombia, Cuba, Guatemala, Mexico, Peru and Venezuela. A brief description of the main developments at country level follows.

Argentina

Support has continued to the Centre for Perinatal Studies (CREP) in Rosario. CREP conducts research in the areas of maternal and infant health, adolescent health and reproductive health epidemiology, and serves as a training and research methodology referral centre for the country and the Region of the Americas.

The Centre for Population Studies (CENEP) in Buenos Aires is the coordinator and one of the study sites of the regional multicountry social science study on men’s perceptions and behaviour with respect to decision-making processes affecting sexual and reproductive health.

The Institute for Experimental Biology and Medicine in Buenos Aires continues to develop basic sciences research in the field of male fertility.

The Centro de Estudios de Estado y Sociedad (CEDES) in Buenos Aires coordinated the social science component of the regional initiative on caesarean section.

Bolivia

Bolivian investigators associated with the Centre for Social Research, Appropriate Technology and Training (CISTAC), La Paz participated in the four-country research initiative on men’s perceptions and behaviour in respect of decision-making processes affecting sexual and reproductive health. The final country report is expected to be ready in January 2002.

Brazil

The Campinas Centre for Research and Control of Maternal and Infant Disease (CEMICAMP) of the University of Campinas has been the main recipient of Programme support in the country. Grants cover the work undertaken on training in research methodology and on research in clinical epidemiology and social science issues relevant to contraceptive introduction and other aspects of women’s reproductive health. CEMICAMP took part in the clinical and social sciences studies concerned with the regional caesarean section trial and is implementing a Programme-supported study on counselling in family planning services.

Chile

Two institutions in Santiago continued to receive support: the Chilean Institute of Reproductive Medicine (ICMER) and the Unit of Reproductive Biology and Development at the Catholic University of Chile. These centres also participate in Programme-supported institutional development activities and act as regional training centres.

Box 7.1. Emergency contraception in Chile: research and advocacy

The background document prepared to launch the research project was used as reference material for the draft of a proposed law on sexual and reproductive rights submitted to the Chilean parliament in October 2000.

In view of the public controversy caused by the attempted registration of a dedicated product for emergency contraception (EC) in Chile in February 2001, the project’s investigators and other staff from the Chilean Institute of Reproductive Medicine (ICMER) took part in numerous debates on EC conducted on television, radio and in the written press. The opinions and views of the subjects who participated in the project were sought and voiced through the mass media.

The protocol on pregnancy and STI/HIV/AIDS prevention after rape was prepared as a spin-off of the study and was widely disseminated among the Ministries of Health and Justice, the National Women’s Secretariat, legal medical services, parliamentarians, nongovernmental organizations, etc.

Work was done to raise awareness on the need for guidelines for the use of EC among victims of sexual violence and for inclusion of contraception and EC within the recommendations of the Inter-Ministerial Commission on Prevention of Adolescent Pregnancy.
Colombia

The Centre at the University del Valle in Cali is receiving Programme support to take part in the "Magpie" trial coordinated by Oxford University, Oxford, United Kingdom, that evaluates the use of magnesium sulfate for the treatment of pre-eclampsia.

Cuba

Support to activities in Cuba is channelled through the National Coordinating Network for Research in Human Reproduction, which comprises the National Institute of Endocrinology, the Hospital America Arias, the Ramon Gonzalez Coro Hospital and the National Centre for Sex Education (CENSEX).

The National Institute of Endocrinology continues to conduct basic sciences research in the area of reproductive immunology. The Institute's Social Sciences Unit implemented the four-country regional research initiative on "Men's perceptions and behaviour in respect of decision-making processes affecting sexual and reproductive health" and is also active in global research in the field of adolescent reproductive health.

The America Arias Hospital participated in both the clinical and social sciences components of the regional caesarean section study.

Guatemala

The Guatemalan Research Group in Reproductive Health based at the San Juan de Dios Hospital, Guatemala City received support mainly to develop a reproductive health research programme focused on the country's research priorities. The Guatemalan centre also participated in both the clinical and social sciences components of the regional caesarean section study. A strategic assessment was conducted in 2001 to identify priority interventions that would improve access to and quality of family planning, maternal and neonatal care in Guatemala.

Mexico

The Department of Reproductive Biology in the National Institute of Nutrition, Mexico City is the main recipient of Programme support in the country. The Institute and its collaborating centres receive major support from national authorities including the Ministry of Health, which has extensive national programmes for the improvement of reproductive health. The Institute is also actively involved with the various Thematic Groups of the Department and other international funding agencies. In 2001, the Institute continued to receive a Basic Resources for Training Grant, as partial support for its extensive participation in research training.

Another grant is to the two-year M.Sc. degree programme in reproductive epidemiology organized by the National Institute of Public Health at its centre in Cuernavaca. The course has graduated students over the past ten years from Programme-supported centres in Argentina, Chile, Cuba, Guatemala, Mexico, Panama, Peru and Venezuela.

Peru

The Programme supported two centres affiliated to the Peru University Cayetano Heredia in Lima which serves as a resource and training centre in reproductive health. Research carried out by the Institute of Research on Altitude, presently receiving a Resource Maintenance Grant, includes studies in the areas of reproductive health of adolescents, reproduction at high altitude and reproductive immunology.

The Institute for Population Studies in Lima was one of the sites of the four-country, regional social science research initiative on "Men's perceptions and behaviour in respect of decision-making processes affecting sexual and reproductive health".

Venezuela

The Programme collaborates with the Foundation for the Study of Mother and Child (FUNDAMATIN), a private, non-profit organization based at the Maternity Concepción Palacios in Caracas. FUNDAMATIN received support to take part in the "Magpie" trial coordinated by Oxford University, Oxford, United Kingdom, that evaluates the use of magnesium sulfate for the treatment of pre-eclampsia.

PLANNED STRATEGIES

One new strategy that was identified as of top priority was the need to strengthen capacity in the area of operations research: regional centres that will be involved in these activities and training opportunities for fellows from regional centres will be identified. Some preliminary work has been done in collaboration with the FRONTIERS initiative of the Population Council to develop a curriculum for a regional training course in operations research.

Special emphasis will continue to be placed on the dissemination and utilization of research findings, particularly those resulting from regional research initiatives. At the same time, the regional networks will identify topics of relevance to countries and to the Region to initiate the process of launching new initiatives.
Annex 1

MEMBERS OF THE REGIONAL ADVISORY PANEL FOR THE AMERICAS

Members

Carlos Cáceres, REDESS Jovenes, Lima, Peru
Stella Campo, Hospital de Niños, Buenos Aires, Argentina
Adolfo Diez, Hospital del Mar, Barcelona, Spain
William Fraser, Laval University, Quebec, Canada
Ana Cristina González, Santafé de Bogotá, Colombia
Sylvia R. Guendelman, School of Public Health, University of California, CA, USA (Chairwoman)
Luis Rosero Bixby, Universidad de Costa Rica, San Jose, Costa Rica
Silvia Salinas, La Paz, Bolivia
Jim Trostle, Trinity College, Hartford, CT, USA

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
</tr>
<tr>
<td>Members</td>
<td>5</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>3</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>5</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Collaborating agency scientists

Luis Bahamondes, PLACIRH, Mexico City, Mexico
Roberto Rivera, Family Health International, Research Triangle Park, NC, USA
Raffaela Schiavon, The Population Council, Mexico City, Mexico
Annex 2

SCIENTISTS IN 2001

Principal investigators

Gloria Alvarado, Institute for Scientific Investigation, Durango, Mexico
Amaury Andrade, Centre for Reproductive Biology (CBR), Juiz de Fora, Brazil
Susana Bassol, University of Coahuila, Torreon, Mexico
Stella Campo, Endocrinology Research Centre (CEDIE), Buenos Aires, Argentina
Guillermo Carroli, Centre for Perinatal Studies (CREP), Rosario, Argentina
Horacio Croxatto, Chilean Institute of Reproductive Medicine (ICMER), Santiago, Chile
Patricia Cuasnicu, Institute for Biology and Experimental Medicine (IBYME), Buenos Aires, Argentina
Ricardo Deis, Reproduction and Lactation Laboratory (LARLAC), Mendoza, Argentina
Luigi Devoto, Institute for Maternal and Child Health Research (IDIMI), Santiago, Chile
Oscar Diaz, National Institute of Endocrinology, Havana, Cuba
Graciela Etchegoyen, Centre for Applied and Experimental Endocrinology (CENEXA), La Plata, Argentina
Freddy Febres, Foundation for the Study of Mother and Child (FUNDAMATIN), Caracas, Venezuela
Franklin Garcia, Centre for Social Research, Appropriate Technology and Training (CISTAC), La Paz, Bolivia
Gustavo Gonzales, Peru University Cayetano Heredia, Lima, Peru
Ellen Hardy, Centre for Research and Control of Maternal and Infant Disease (CEMICAMP), Campinas, Brazil
Bernardo Hernández, National Institute of Public Health, Cuernavaca, Mexico
Edgar Kestler, Epidemiologic Research Centre, Guatemala City, Guatemala
Fernando Larrea, National Institute of Nutrition, Mexico City, Mexico
Carlos Moreno, Centre for Research in Human Reproduction, Panama City, Panama
Gladys Muñoz, Simón Bolivar University, Caracas, Venezuela
Carlos Nagle, Centre for Medical Education and Clinical Investigation (CEMIC), Buenos Aires, Argentina
Edith Pantelides, Centre for Population Studies (CENEP), Buenos Aires, Argentina
Silvina Ramos, Centre for the Study of the State and Society (CEDES), Buenos Aires, Argentina
Oscar Rojas, University of Valle, Cali, Colombia
Carmen Romero, Hospital J.J. Aguirre, Santiago, Chile
María Serrón-Ferré, Pontifical Catholic University, Santiago, Chile

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>26</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>11</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
INTRODUCTION

The WHO Regions of South-East Asia and the Western Pacific comprise 46 countries distributed over a very wide territory, representing a huge and diverse population (about 60% of the world’s total) and a variety of reproductive health profiles. The three broad objectives of the Department in this complex geographical area are: (i) to ensure that the needs of developing countries therein are reflected in all activities of the Department and that they receive technical and financial support to strengthen their capacity to undertake research in reproductive health; (ii) to apply evidence-based decision-making in programme development; and (iii) to implement appropriate interventions to improve reproductive health care and services.

Although significant progress has been made in strengthening research capabilities which have brought about changes in reproductive health care policies and services in many countries of these Regions, the Department is currently faced with two major challenges. First, the human, technical and financial resources currently available to these Regions are grossly inadequate for responding to the enormous diversity of reproductive health status of the huge population, especially in Asia.

Second, translating the reproductive health approach into concrete action is a daunting task and includes, among others, raising public awareness and harnessing political commitment and community involvement; expanding integrated services and ensuring their accessibility to women and to a wide range of hitherto neglected users (men, young people, marginalized populations); strengthening the capacity for programme monitoring and evaluation; and establishing an enabling national reproductive health research system and culture.

RESEARCH CAPACITY-STRENGTHENING GRANTS AWARDED IN 2001

Table 7.5 shows the list of countries and centres that have received Long-term Institutional Development (LID) Grants and Resource Maintenance Grants (RMGs) during 2000–2001.

In addition, during 2000–2001, 14 Research Training Grants (RTGs) were given to scientists from developing countries in the Regions. Twelve of them were trained within the Regions. In recent years, centres in China, India, Malaysia, Singapore and Thailand have hosted an increasing number of trainees in a variety of research disciplines requiring significant understanding of local public health issues and cultural values. These include community-based studies using epidemiological or social science skills for which there is a pressing need to provide training in a similar cultural setting.

OUTPUTS GENERATED BY THE CENTRES IN 2001

As in previous years, collaboration between the Department and the grant recipient institutions in the Regions has been productive and successful in 2001, as evidenced by:

—ongoing research projects supported by the Department 51
—symposia/workshops/training courses/scientific meetings 24
—publications including original papers, review articles and abstracts 427

A notable example is the 11th Annual Conference of the Indian Society for the Study of Reproduction and Fertility,
Table 7.5. Type of grants awarded and names of recipient centres in 2000–2001

<table>
<thead>
<tr>
<th>Type of grant</th>
<th>Country</th>
<th>Recipient centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term Institutional Development (LID)</td>
<td>Indonesia</td>
<td>West Indonesian Reproductive Health Development Centre (WIRHDC), Faculty of Medicine, University of North Sumatra, Medan</td>
</tr>
<tr>
<td>Grant</td>
<td></td>
<td>Reproductive Health Research Centre, Airlangga University, Surabaya</td>
</tr>
<tr>
<td>Lao People’s Democratic Republic</td>
<td>Maternal and Child Health Centre, Ministry of Health, Vientiane</td>
<td></td>
</tr>
<tr>
<td>Mongolia</td>
<td>State Research Centre on Mother and Child Health and Human Reproduction, Ulaanbaatar</td>
<td></td>
</tr>
<tr>
<td>Myanmar</td>
<td>Department of Medical Research, Ministry of Health, Yangon</td>
<td></td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>National Coordination Committee for Research on Reproductive Health, Colombo, which has four multidisciplinary Task Forces located in Colombo, Galle, Jaffna and Peradeniya</td>
<td></td>
</tr>
<tr>
<td>Viet Nam</td>
<td>Hung Vuong Hospital, Ho Chi Minh City</td>
<td></td>
</tr>
<tr>
<td>Resource Maintenance Grant (RMG)</td>
<td>China</td>
<td>National Coordinating Board with eight institutes</td>
</tr>
<tr>
<td></td>
<td>India</td>
<td>All India Institute of Medical Sciences (AIIMS), New Delhi</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Institute for Research in Reproduction (IRR), Mumbai</td>
</tr>
<tr>
<td></td>
<td>Thailand</td>
<td>Family Health Division, Department of Health, Ministry of Public Health, Bangkok</td>
</tr>
</tbody>
</table>

held in conjunction with the Consortium on National Consensus for Emergency Contraception in New Delhi, India in January 2001, which was attended by more than 100 participants. It was jointly organized by the All India Institute of Medical Sciences (a WHO Collaborating Centre for Research in Human Reproduction), New Delhi, the Indian Council for Medical Research and the Indian Ministry of Health and Family Welfare.

PROGRESS ON REGIONAL RESEARCH INITIATIVES

National research institutions networks

Networks have been established between research institutions in three countries (China, Sri Lanka and Thailand). These networks play a leading role in setting priorities for reproductive health research at national and institutional levels and in determining the goals and objectives of national reproductive health programmes.

In China, for example, the National Coordinating Board, which brings together eight research institutions, has helped to formulate the Chinese National Reproductive Health Programme for the next decade comprising four comprehensive, community-based components on: (i) improving the quality of contraceptive care; (ii) intervention for reproductive tract infections; (iii) healthy baby promotion; and (iv) integrated reproductive health services in western China.

These are: (1) National Research Institute for Family Planning (NRIFP), Beijing; (2) Shanghai Institute of Planned Parenthood Research (SIPPR), Shanghai; (3) Peking Union Medical College Hospital (PUMCH), Beijing; (4) Institute of Population Research, Peking University (IPRPU), Beijing; (5) Tianjin Municipal Research Institute for Family Planning (TMRIFP), Tianjin; (6) Family Planning Research Institute of Zhejiang (FPRIZ), Hangzhou; (7) Family Planning Research Institute of Sichuan (FPRIS), Chengdu; (8) National Evaluation Centre for the Toxicology of Fertility Regulation Drugs (NTC), Shanghai.
An international conference was jointly organized by the Chinese Government and the WHO Country Office in Beijing on 5–9 June 2001 with the dual objective of presenting the goals, workplan and the expected outcomes of these national programmes and seeking national and international partnerships for their implementation.

The Thai network comprises three university departments of obstetrics and gynaecology and seven regional hospitals. Support to this network was completed in 1999.

Research in reproductive health in Sri Lanka has been undertaken by four multidisciplinary groups and these are coordinated by a National Committee for Research on Reproductive Health based in Colombo.

Intraregional cooperation networks

This mechanism is being set up with support from the Department in order to utilize the respective strengths of the more mature institutions in the two Regions. The objective is to involve them in creative ways to assist in strengthening reproductive health research and national reproductive health programmes in their neighbouring developing countries with similar demographic and cultural identities.

Each network includes one or two “advanced” developing countries and several “less-developed” countries, as well as advanced institutes from developed countries with a view to optimizing the existing resources within the Regions.

Both South-to-South and North-to-South networks have been strengthened. One example of the latter is the twinning programme between the Prince Henry’s Institute of Medical Research, Melbourne, Australia and the Shanghai Institute of Planned Parenthood Research, Shanghai, China.

Regional joint research networks

Several regional joint research programmes were initiated during the biennium in order to stimulate regional networking and thus render research capacity-strengthening efforts more cost-effective.

Scientists in advanced research institutes of developing countries in the two Regions serve as coordinators for these regional joint research projects, and scientists from less-developed countries participate in these projects in order to learn how to develop well-designed research projects and generate data of local value.

The implementation stages of the following two regional joint research programmes are the most advanced:

• "Collaborative reproductive epidemiology research: patterns and predictors of caesarean section in Asia" is a ten-country joint research programme (Bangladesh, China, Indonesia, Mongolia, Myanmar, Nepal, the Philippines, Sri Lanka, Thailand and Viet Nam). This study was initiated in mid-2000 with the objectives of determining the complication rates with vaginal deliveries compared to elective and to emergency caesarean sections. In addition, average costs incurred by the patients for the three procedures will be estimated, as will the predictors for elective and emergency caesarean sections among the social variables of the patient, the obstetrician and the hospital.

• “Regional research initiative on adolescent migrants and reproductive health in the Greater Mekong region” is a five-country joint research programme (China, Lao People’s Democratic Republic, Myanmar, Thailand and Viet Nam). This study, which started in early 2000, will identify adolescent migrant populations, and interview selected groups on their motivation for migration, their knowledge and perceptions of reproductive health, and their access to reproductive health services.

Finally, a joint plan of action, including both regional and country-specific activities, was prepared during the regional technical/training workshop on prevention of cervical cancer held in Kuala Lumpur, Malaysia on 26–31 March 2001. The workshop was jointly organized by the WHO Collaborating Centre for Research in Human Reproduction at the Department of Obstetrics and Gynaecology, Cantonal University Hospital of Geneva, the WHO Regional Office for the Western Pacific and the Department.

HIGHLIGHTS OF JOINT ACTIVITIES ON PROGRAMMATIC ISSUES

Improving the quality of reproductive health care

The Department has developed “The Strategic Approach to improving the quality of care of reproductive health services” which involves three stages, as described in the chapter on “Policy and programme issues”.

During 2000–2001, the main activities carried out in the Regions within the context of the Strategic Approach were as follows:

• Stage I. Strategic assessments were conducted in:
  —China: on introduction of contraceptives with an emphasis on intrauterine devices, and
  —Indonesia: on the evaluation of the introductory activities supported by the International Consortium for Emergency Contraception.

• Stage II: Action research is almost completed in:
  —Lao PDR: where it focuses on strengthening the availability and utilization of essential obstetric care at the
district and community levels; and

—Myanmar: where it aims at developing a district-level model for improving the quality of family planning services.

• Stage III: Scaling-up is currently ongoing in:

—Viet Nam: to facilitate a wider introduction of the injectable contraceptive depot-medroxyprogesterone acetate (DMPA), while improving the quality of care in provision of all contraceptive methods.

**Adaptation and application of norms and tools**

The Department, in collaboration with its partners, worked on a strategy to implement best practices (IBP) through support to the dissemination, adaptation and utilization (the DAU process) of technical guidance documents. To promote this process, two national workshops were held in Beijing, China with the participation of 45 senior family planning managers from ten provinces. The IBP process has been detailed in the chapter on “Implementing best practices”.
Annex 1

REGIONAL ADVISORY PANEL FOR ASIA AND THE PACIFIC IN 2001

Members

Victor H.H. Goh, Department of Obstetrics and Gynaecology, National University of Singapore, Singapore (Chairman)
Sri Hatmadji, Demographic Institute, Faculty of Economics, University of Indonesia, Jakarta, Indonesia
John Hearn, Research School of Biological Sciences, Australian National University, Canberra, Australia
Nasreen Huq, Naripokkho, Dhaka, Bangladesh
Matthews Mathai, Christian Medical College and Hospital, Vellore, Chennai, India
Than Than Tin, Central Women’s Hospital, Institute of Medicine (1), Yangon, Myanmar
Bencha Yoddymnern-Attig, Institute for Population and Social Research, Mahidol University, Nakorn Prathom, Thailand
Xiao Ying Zheng, Institute of Population Research, WHO Collaborating Centre for Reproductive Health and Population Science, Peking University, Beijing, China

Temporary advisers

Diana L.C. Galwaduge, Office of the Provincial Director of Health Services, Sangaraja Mawatha, Kandy, Sri Lanka
Maimunah Bte A. Hamid, Public Health Institute, Ministry of Health, Jalan Bangsar, Kuala Lumpur, Malaysia
Harun-Ar-Rashid, Bangladesh Medical Research Council, Mohakhali, Dhaka, Bangladesh
Sea-Baick Lee, Planned Parenthood Federation of Korea, Yeongdeungpo, Seoul, Republic of Korea

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td><strong>% of total</strong></td>
<td><strong>Number</strong></td>
<td><strong>% of total</strong></td>
</tr>
<tr>
<td>Members</td>
<td>7</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Women</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>63</td>
<td>13</td>
<td></td>
</tr>
</tbody>
</table>
Annex 2

REGIONAL SCIENTISTS

Heads of Centres in 2001

Chen Hailin, National Evaluation Centre for the Toxicology of Fertility Regulating Drugs, Shanghai, China
Virasakdi Chongsuvivatwong, Prince of Songkla University, Hat Yai, Thailand
Nguyen Duc Vy, Institute for the Protection of Mother and Newborn, Hanoi, Viet Nam
Gao Ersheng, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Ge Qin-Sheng, Peking Union Medical College, Beijing, China
Gu Zhongwei, National Research Institute for Family Planning, Beijing, China
Hou Qingchang, Tianjin Municipal Research Institute for Family Planning, Tianjin, China
Liu Xiaozhang, Family Planning Research Institute of Sichuan, Chengdu, China
Delfi Lutan, University of North Sumatra, Medan, Indonesia
Suneeta Mittal, All India Institute of Medical Sciences, New Delhi, India
Piya Netrawichien, Chiang Mai University, Chiang Mai, Thailand
Chander Puri, Institute for Research in Reproduction, Mumbai, India
Janchiv Radnaabazar, State Research Centre on Mother and Child Health and Human Reproduction, Ulaanbaatar, Mongolia
Bouavanh Senesathith, Maternal and Child Health Institute, Ministry of Public Health, Vientiane, Lao People’s Democratic Republic
Harshalal Seneviratne, Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Colombo, Colombo, Sri Lanka
Soe Thein, Department of Medical Research, Ministry of Health, Yangon, Myanmar
Nguyen Thi Thuy, Hung Vuong Hospital, Ho Chi Minh City, Viet Nam
Yang Hua, Family Planning Research Institute of Zhejiang, Hangzhou, China
Zheng Xiaoying, Institute of Population Research, Peking University, Beijing, China

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>19</td>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>8</td>
<td>42</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

from:

AFRO
AMRO
EMRO
EURO
SEARO
WPRO

7
12
INTRODUCTION

It is estimated that the population in the Eastern European Region will decrease by ten million from 1994 to 2025. Fertility has declined from 2.1 children per woman in 1980–1985 to 1.6 children per woman during 1990–1995. Of the 25 countries analysed in the Eastern European Region, 12 have contraceptive prevalence rates (effective methods) of less than 20% and another 12 have rates between 20% and 50%. Nine countries have abortion-to-birth ratios greater than 125 per 100 births and 15 countries have a maternal mortality ratio greater than 30. Thus, the Region’s major reproductive health concerns remain: (i) high levels of maternal mortality and morbidity; (ii) reliance on ineffective traditional methods of contraception; (iii) a large number of repeat abortions per woman; (iv) a growing number of sexually transmitted infections (STIs), including HIV; and (v) poor availability of information and services for reproductive health care.

Objectives

The main objectives of the Department are: (i) to strengthen national capacity in reproductive health research and provide training opportunities in reproductive health for the countries of Eastern Europe, which comprise Eastern and Central European countries, the Newly Independent States and the Central Asian Republics; and (ii) to assist the WHO Regional Office for Europe (EURO) in providing technical support to countries to implement their programmes in reproductive health.

PROGRESS

Regional initiatives and activities

First meeting of the Regional Advisory Panel for Europe, 20–21 September 2001, Copenhagen, Denmark

The Regional Advisory Panel (RAP) met to review the overall reproductive health programmes in both WHO Headquarters and EURO to provide regional input towards WHO’s overall reproductive health programmes and strategies. This being the first meeting of the RAP for Europe, emphasis was placed on brainstorming priorities for the future.

The Panel recommended that efforts be made to draw attention to the immense reproductive health problems in the Region, and that donor agencies be made aware of them. In addition, reproductive health policies should reflect the principles elaborated at the International Conference on Population and Development in 1994. The Panel highlighted the need to include gender and cultural perspectives into reproductive health policies in the Region.

The Panel reviewed and endorsed the WHO/EURO strategy paper on Reproductive Health for the Region, as well as the overall programmes on: Making Pregnancy Safer; adolescent sexual and reproductive health; gender mainstreaming; and the ongoing research projects within the Department.

The Panel also reviewed the proposal to hold a symposium on reproductive health research and agreed, in principle, that it should focus on improving the “quality” of research. Panel
Members supported the proposal of devoting an issue of Entre nous (the WHO European Office newsletter) to reproductive health research.

The proposal for training on gynaecological cancers was reviewed by the Panel which concluded that, although the topic was of relevance to the Region, more attention should be given to why women were not seeking screening rather than focus on screening techniques per se.

Regional research initiatives

In 2001, the Department participated in the pilot project on the “Assessment of reproductive health in relation to radiation exposure around the nuclear test site in Semipalatinsk, Kazakhstan” funded by the United Nations Population Fund (UNFPA). A research proposal for a follow-up study was developed by the Institute of Cancer Research, Sutton, United Kingdom and the project will be launched in 2002.

The study will use data previously collected by public health authorities in the region, on exposure to radiation and health outcomes. Data will be extracted from the original records and digitized in an electronic database.

The study will examine the following outcome variables:

- fertility and birth outcomes in women who were exposed before or during the reproductive age;
- mortality, including from congenital malformations and cancer, in persons exposed in utero, and fertility in these individuals; and
- mortality, including from congenital malformations and cancer, in offspring born after 1957 to women with potential preconceptional exposures during the testing.

Reproductive outcomes will be described according to demographic characteristics and comparisons made between the exposed and control settlements and according to individual radiation dose, age at exposure and time of exposure.

This will be one of the largest studies conducted to determine the effects of radiation exposure on reproductive health.

Regional self-reliance in research training

A course on reproductive operations research methodologies was held in Targu-Mures, Romania on 1–12 October 2001, jointly supported by the Department and the FRONTIERS project and organized by the East European Institute of Reproductive Health, Targu-Mures, Romania. There were 17 participants from eight countries: Czech Republic, Kazakhstan, Latvia, Lithuania, Republic of Moldova, Romania, Russian Federation and Ukraine. The main objective was to prepare a detailed proposal on operations research in reproductive health for possible funding as part of capacity building and networking in Eastern and Central Europe, the Central Asian Republics and the Newly Independent States. A wide range of topics was covered: reduction of caesarean section rate (Czech Republic); adolescent sexual education (Kazakhstan); improving adolescent reproductive health services (Latvia and Republic of Moldova); adolescent sexual health counselling using peers (Lithuania); introducing obstetric and perinatal best practices (Romania); breast feeding education of primary health care physicians (Romania); introduction of Medical eligibility criteria for contraceptive use to primary health care physicians (Romania); introduction of partogram in obstetric care (Ukraine). By the end of the course, participants had successfully completed the first draft of the project proposal.

A Postgraduate Course in Reproductive Medicine and Reproductive Biology was created at the University of Geneva in 1991. This course enables scientists and clinicians to acquire general, structured knowledge in reproductive health, including the social and demographic dimensions of reproductive health problems in both developed and developing countries. It also provides an in-depth knowledge of different methods of modern contraception. The training course aims to provide sufficient knowledge to allow the trainees to initiate research and/or participate in research work appropriate to the reproductive health concerns in their home countries. After successfully completing the compulsory part of the training course and passing the certificate examination, students have the option of continuing their research training in Geneva or participating in a “re-entry” plan. The diploma students who choose to continue their research training in Geneva are required to participate in an in-depth study of a particular aspect of reproductive health.

This two-month course is jointly organized by the WHO Collaborating Centre for Research in Human Reproduction at the University Hospital of Geneva, Switzerland and the Programme. It is taught annually by staff members of the Programme and teachers from the Faculty of Medicine of the University of Geneva, as well as from other universities. Over the past few years, the course has been attended by 30–40 students each year, mainly from developing countries.

PLANNED ACTIVITIES

Support to operations research projects developed at the Targu-Mures course

It is planned to fund and provide technical support to several of the operational research projects developed at the Targu-Mures course. The maximum duration of these research projects is estimated at 14–16 months. A second course on operations research will be held in the Russian Federation in 2003.
Assessment of reproductive health in relation to radiation exposure around a nuclear test site in Semipalatinsk, Kazakhstan

Following the successful completion of the first phase of the project and the development of the research protocol, the Department, serving as the executing agency for this UNFPA-funded three-year research project, will be responsible for providing technical support to the project as well as overseeing its progress.
### Annex 1

**REGIONAL ADVISORY PANEL FOR THE EUROPEAN REGION IN 2001**

**Members**

Ayse Akin, Hacettepe University, Ankara, Turkey  
Elena Baibariana, Russian Academy of Medical Science, Moscow, Russian Federation  
Mihai Horga, Ministry of Health, Bucharest, Romania  
Helle Karro, University of Tartu, Tartu, Estonia (*Chairwoman*)  
Evert Ketting, Netherlands School of Public Health, Utrecht, Netherlands  
Gunta Lazdane, Family Planning Association, Riga, Latvia  
Alfred Merkle, Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), Eschborn, Germany  
Saule Nukusheva, School of Public Health, Almaty, Kazakhstan  
Petr Velebil, Research Institute for Maternal Health, Prague, Czech Republic

<table>
<thead>
<tr>
<th></th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>Members</td>
<td>1</td>
<td>11</td>
<td>6</td>
<td>67</td>
</tr>
<tr>
<td>Women</td>
<td>1</td>
<td>11</td>
<td>4</td>
<td>44</td>
</tr>
</tbody>
</table>

**from:**  
AFRO  
AMRO  
EMRO  
EURO  
SEARO  
WPRO

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>% of total</th>
<th>Number</th>
<th>% of total</th>
<th>Number</th>
<th>% of total</th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>11</td>
<td>6</td>
<td>67</td>
<td>2</td>
<td>22</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

---

Section 7 - Technical cooperation with countries
Section 8
Implementing best practices
Implementing best practices

M. Gülmezoglu, M. Islam, M. Usher-Patel, J. Villar, A. Shah

INTRODUCTION

There is a considerable body of knowledge about how best to provide services, an improved understanding of people’s health-related behaviour, and an increasing awareness of the way in which policies and the broader social environment can promote quality and access to services. However, in recent years, concerns have emerged about the management of this knowledge, specifically the mapping of best practices and the effectiveness of current dissemination processes to help countries in setting policies and implementing programmes to improve the reproductive health of their populations. To address the issue of knowledge management, the Department is working with other agencies and partners on two major projects:

1. The WHO Programme to Map Best Reproductive Health Practices aims: (i) to generate evidence through rigorously conducted research; (ii) to summarize this evidence through systematic reviews; (iii) to disseminate up-to-date, good-quality research evidence; and (iv) to build capacity in evidence-based medicine in countries to enable decision-makers to make the best use of this evidence.

2. The WHO Reproductive Health Library (RHL), now in its fifth year of publication, is becoming a major resource for evidence-based reproductive health care. Although there have been large technological advances in recent years, many developing countries have not yet benefited from the Internet and other electronic technologies to access health care information. There remains a considerable gap in the dissemination of evidence-based, peer-reviewed and high-quality information in areas where it is most needed (Box 8.1). RHL is bridging this gap.

The Cochrane Effective Practice and Organization Group (EPOG) concluded that distribution of written materials and didactic educational sessions are largely ineffective. A strategic and systematic approach is required to identify interventions that effectively address barriers to implementing best practices (IBP). The Department has been working with partner agencies to form a consortium called “The Best Practice Consortium” to help countries implement evidence-based best practices in reproductive health in order to improve the quality of care.

THE WHO PROGRAMME TO MAP BEST REPRODUCTIVE HEALTH PRACTICES

Research activities

Specific objectives

The overall objective of this activity is to generate evidence that will guide future strategies to improve practices. Specifically, the aim is to determine whether electronically provided, up-to-date information on the effectiveness of health care interventions presented through an active dissemination strategy actually changes clinical practice.

Progress

A randomized controlled trial to evaluate a programme promoting evidence-based medicine based on the WHO RHL was initiated in 2001. This trial is comparing an active dissemination strategy through three workshops within a period of six months, to the standard form of information sharing (control group) already established in local settings. Using a cluster (hospital as the unit) randomized trial design, 22 hospitals in Mexico and 18 in Thailand have been allocated...
to intervention and control groups. Baseline data collection included information on clinical practices used for 40,000 women and a “Care Provider Profile” survey. The intervention phase started in October 2001 in both countries. Outcome data collection on another 40,000 women is scheduled to start in August 2002.

**Summarizing evidence**

**Objectives**

Systematic reviews locate, appraise and synthesize evidence from scientific studies in order to provide informative empirical answers to scientific research questions. In addition, by identifying the known and the unknown, they are an invaluable first step before carrying out new primary research. The main characteristic of a systematic review is the use of an *a priori* protocol including an explicit and comprehensive strategy to search, identify, critically appraise and then select studies for inclusion. The systematic reviews are conducted through the Collaborative Review Groups of the Cochrane Collaboration.

**Progress**

In 2001, systematic reviews were conducted on specific issues in:

- maternal health (4 reviews, 7 review updates, 2 protocols);
- fertility regulation (1 review, 1 review update);
- unsafe abortion (3 reviews, 1 review update);
- HIV/AIDS and sexually transmitted infections (STIs) (2 reviews, 1 review update, 1 protocol); and
- health systems (1 review).

Systematic reviews were also initiated on other health questions such as screening/diagnostic tests and prevalence/incidence of morbidities. The first of these studies is a systematic review of the screening tests for pre-eclampsia. A draft protocol was prepared and the full review will be completed in the second half of 2002.

In addition to these review activities, the Department provided seed support to the Cochrane Fertility Regulation Group Editorial Base in Leiden, the Netherlands. This collaboration was further enhanced when reviewers from China and India went to Leiden to work on the reviews they had been conducting.

**Dissemination of evidence-based reproductive health care information: The WHO Reproductive Health Library**

**Objectives**

The objective of The WHO Reproductive Health Library (RHL) is to provide health care workers in developing countries with
an affordable, efficiently-distributed and user-friendly source of up-to-date systematic reviews in reproductive health. RHL is an electronic review journal updated yearly, which focuses on reproductive health problems of high priority for developing countries. Systematic reviews included in RHL are Cochrane reviews, supplemented by commentaries and practice implications of these reviews prepared by researchers from developing countries, or by individuals with extensive knowledge of the conditions of practice in those countries.

RHL is the product of collaboration between the Department, research centres in developing countries and the Cochrane Collaboration.

**Progress**

**Contents:** RHL contents are organized into four sections:

(i) editorials and educational articles relevant to reproductive health in developing countries (3 documents);

(ii) effectiveness summaries for decision-making (6 documents);

(iii) reproductive health database (69 Cochrane reviews, 63 commentaries and 63 practical aspects);

(iv) useful information (Better Births initiative presentation, web links, funding agencies).

**Dissemination:** A concrete dissemination strategy has been followed since the initiation of the RHL project. The strategy incorporates the following elements:

- *Mail distribution.* Utilization of the Department and the WHO Library newsletter mailing lists in a selective manner, encouraging all who receive a copy to subscribe to ensure continued access.

- *Active dissemination without demonstration.* Conference presentations and WHO meetings serve the purpose of raising awareness about RHL and evidence-based medicine.

- *Active dissemination with demonstration.* RHL presentations and workshops are conducted by the Department and by RHL regional editors. Several models of RHL presentations such as the two-hour conceptual presentation, one-day, two-day and four-day presentations are developed, depending on the nature of the meeting. In 2001, RHL presentations took place in Argentina, Bolivia, Denmark (WHO Regional Office for Europe [EURO]), India, Nepal, the Philippines, South Africa, United Republic of Tanzania and Turkey.

The free subscription system has substantially facilitated access to RHL in developing countries. Current global RHL subscriptions reach 9500. The distribution of RHL subscriptions by WHO Region and the increase in subscriptions between 2000 and 2001 are shown in Figure 8.3. The publication of RHL in Spanish, and the active participation of the WHO Regional Office for the Americas (AMRO) and of centres collaborating with the Programme, have all played a major role in increasing subscription in Latin America.

**Translations:** Work on a Chinese version was initiated in collaboration with the Shanghai Institute of Planned Parenthood Research (SIPPR), Shanghai, China. The aim is to have a Chinese RHL available by September 2002. Fundraising efforts for a French version have continued in 2001 but so far these efforts have not been successful. Contacts with Cana-
dian French-speaking groups and local French institutions are continuing.

**Capacity building in evidence-based reproductive health care**

In Africa, an “Evidence-based Reproductive Health Care: Training of Trainers” project was initiated jointly with the WHO Regional Office for Africa (AFRO). The South African Cochrane Centre in Cape Town, South Africa is currently developing a five-day training package. This package will be pilot-tested in early 2002, and country workshops are planned for the second half of 2002 and for 2003. The project includes an in-built evaluation component.

In Latin America, support has been provided to collaborating centres in Rosario, Argentina and Cali, Colombia to initiate a systematic training and dissemination programme.

In Asia, preparatory activities have been initiated for the establishment of an evidence-based resource centre in the Department of Obstetrics and Gynaecology of Khon Kaen University, Thailand. Support will be provided to this centre to enable it to create a subregional network to disseminate and contribute to RHL.

Spotlight countries of the Making Pregnancy Safer initiative are given priority in all these capacity-building activities. For example, in Africa, initial workshops will be conducted in Mozambique, Nigeria and Uganda, in addition to South Africa and Zambia. Similarly, in Latin America, initial activities have taken place in Bolivia.

**The future**

RHL has become a recognized comprehensive source of evidence-based, up-to-date information in reproductive health. RHL is now incorporated into the medical curriculum of several universities and is a major resource for postgraduate training and college membership examinations. Furthermore, the RHL impact evaluation trial will provide useful insights into changing professional behaviour in underresourced settings. New challenges emerge as RHL, systematic reviews and capacity building in evidence-based reproductive health decision-making activities expand and become more widely known.

The future challenges for the “WHO Programme To Map Best Reproductive Health Practices” are the following:

- Ensure that systematic reviews become an integral first step of all research activities undertaken by the Programme. Ideally, all clinical research protocols should be accompanied by a systematic review supporting the project protocol. This is already the case in maternal and perinatal research, and it will be important to incorporate this into other research areas of the Programme.

- Ensure that the Department’s recommendations for practices and implementation are based on best available evidence from systematic reviews.

- Expand the content of RHL to cover systematic reviews of observational studies, including systematic reviews of morbidities mapping the burden of reproductive ill-health.

- Maintain and improve the quality of RHL. The number and type of documents included in RHL increase every year, with approximately a third of them needing revision and updating. This increase as well as the translations in several languages have already created significant challenges in the management of RHL. By the end of the 2002–2003 biennium, RHL will need to include close to 90 Cochrane reviews, accompanying commentaries and practical aspects, all of which will need to be annually updated. The Spanish and Chinese versions will be developed on the same lines.

- Contribute to creating a critical mass of scientists in developing countries who are knowledgeable and competent in preparing systematic reviews in reproductive health. The training initiative jointly developed with AFRO and the South African Cochrane Centre could be instrumental in achieving this objective.

**IMPLEMENTING BEST PRACTICES**

**Development of the IBP process**

Since mid-1999, WHO, the United States Agency for International Development (USAID) and other partner agencies1 have worked together to develop a practical and structured approach to capturing and applying best practices. The DAU process was developed as a result of discussions on how best to support the dissemination, adaptation and utilization of the products associated with best practices.

The DAU approach is based on lessons learned from past experiences. One such experience has been with the very successful technical guidance document, *Medical eligibility criteria for contraceptive use*, now in its second edition. This document, which introduces best practices for using family planning methods, has been translated into seven languages and has been used to update national policies, guidelines and practices in more than 50 countries.

In addition, a Cochrane systematic review was undertaken to examine the technical and managerial processes associ-
ated with developing the capacity of health systems, projects and programmes to absorb and sustain the implementation of best practices.

Subsequently, the DAU process was revised in order to:

• develop an approach that is more responsive to the information, technical and programmatic needs of the countries; and

• improve the follow-up of country programmes through the implementation of a mentorship and supportive follow-up programme.

The process was renamed the Implementing Best Practice (IBP) process. It can be used at any level of the health care system to improve access to and quality of reproductive health care services. The IBP process will benefit health systems, projects and programmes.

The IBP process identifies key players among service providers, programme managers and policy-makers. It enables them to increase their familiarity with evidence-based best practices in reproductive health, and to work systematically through steps that will lead to positive changes. The result is an improved response to communities’ and individuals’ needs, and a greater programmatic impact.

The key feature of the IBP process is that it encourages change from within the system. It does this by fostering leadership and creative thinking among key players, who build on their experience in order to develop approaches to the introduction and use of best practices. The IBP process develops managerial and technical skills among these leaders, and offers the tools they require to lead and support organizational change. Finally, it encourages continuous improvement through mentorship and supportive follow-up.

**Formation of the IBP Consortium**

The practical application of the IBP initiative has been explored through regional and country meetings (Bangladesh, China, India and Nepal) and feedback has been used to further refine it.

To strengthen the IBP initiative, the agencies formed a Consortium on Implementing Best Practice (the IBP Consortium in mid-2001). Its role will be to promote the use of the IBP process worldwide and to coordinate support to IBP activities in countries. Over time, membership is expected to expand to include a wide variety of stakeholders from country programmes in both developing and developed countries. This unique Consortium of donors and health-focused organizations has come together but this effort needs to be nurtured, sustained and scaled up. The Consortium can leverage the partners’ strengths and organizational reach into developing country health systems. The Consortium will work at the international, regional and country levels and will demonstrate a dynamic model of international cooperation among major organizations. This effort will minimize duplication of effort, maximize the use of donor resources, efficiently use the technical materials and tools developed by partners, promote change from within the system and encourage continuous improvement through mentorship and supportive follow-up.

**IBP achievements during 2001**

The partners involved in the IBP initiative have worked in collaboration with the WHO Eastern Mediterranean Regional Office (EMRO) to prepare an Inter-Country Meeting with Partners and Country Teams. The meeting will involve 120 senior programme managers from nine countries in the Region. The partners have agreed to undertake all activities on a cost-sharing basis and have committed resources to a programme of mentorship and follow-up in order to support the implementation of the IBP process and monitor the achievement of milestones. This meeting was scheduled to take place in Egypt in October 2001, but was postponed to February 2002.

The following materials, developed to support the introduction of the IBP initiative, will be field-tested during the Egypt meeting:

• an advocacy pack containing the IBP paper, advocacy brochure, poster, technology café brochure and two overheads explaining the IBP initiative;

• a series of management exercises and a facilitator’s guide; and

• an annotated bibliography of technical and managerial guidelines, tools and web sites produced by the partner agencies linked to key resource documents. This was developed as a CD-ROM with a search capacity and a two-page summary with power point presentations of the information sessions on specific guidelines (“Mini University” sessions).
Future plans

During 2002, the IBP Consortium will become functional and open to new members from both developing and developed countries. Although the Consortium will identify additional funding sources to support its activities, it will continue to expect all partners to assume roles and responsibilities previously agreed upon and to undertake these activities on a cost-sharing basis. The tools under development will be field-tested during the intercountry meetings due to be held in China, Egypt and India. The IBP Team within the Department will respond to the feedback received, continue to refine the IBP process and finalize the tools currently under development.

The IBP team will start preparing a guide to train regional and country leaders in the use of the IBP process. During 2002, it is planned to pay particular attention to the development and implementation of the mentorship and supportive follow-up programmes in countries in which the IBP initiative has been introduced. The impact of the IBP initiative will be determined by a system that will evolve through the monitoring of the achievement of milestones identified by countries in their planning process.
### Annex 1

**WHO PROGRAMME TO MAP BEST REPRODUCTIVE HEALTH PRACTICES IN 2001**

#### Editorial group

**Regional editors**

Guillermo Carroli, Centro Rosarino de Estudios Perinatales (CREP), Rosario, Argentina  
Linan Cheng, International Peace Maternal and Child Health Institute, Shanghai, China  
Ana Langer, The Population Council, Mexico City, Mexico  
Justus Hofmeyr, University of Witwatersrand, Johannesburg, South Africa  
Pisake Lumbiganon, Khon Kaen University, Khon Kaen, Thailand  
Suneeta Mittal, All India Institute of Medical Sciences, New Delhi, India  
Kenneth Schulz, Family Health International, Research Triangle Park, NC, USA  

#### Country representatives

Mario Festin, University of the Philippines, Manila, the Philippines  
Juan Carlos Vazquez, America Arias Hospital, Havana, Cuba  
Haroldo Capurro, Latin American Center for Perinatology (CLAP)/PAHO, Montevideo, Uruguay  
Manorama Purwar, Clinical Epidemiology Unit, Nagpur, India

<table>
<thead>
<tr>
<th>Country</th>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>10</td>
<td>91</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Women</td>
<td>4</td>
<td>36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>from:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td>1</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>4</td>
<td>36</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td>3</td>
<td>27</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td>2</td>
<td>18</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Annex 2

### SCIENTISTS IN 2001

#### Principal investigators

Ana Langer, The Population Council, Mexico City, Mexico  
Frans Helmerhorst, Cochrane Fertility Regulation Group, Leiden University, Leiden, Netherlands  
Pisake Lumbiganon, Khon Kaen University, Khon Kaen, Thailand

<table>
<thead>
<tr>
<th>Developing countries</th>
<th>Countries in transition</th>
<th>Developed countries</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>% of total</td>
<td>Number</td>
<td>% of total</td>
</tr>
<tr>
<td>All</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Women</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Women</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>from:</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEARO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPRO</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Other scientists

Edgardo Abalos, Centro Rosarino de Estudios Perinatales (CREP), Rosario, Argentina  
Hany Abdel-Aleem, Assiut University, Assiut, Egypt  
Lekan Adetoro, Ogun State University, Sagamu, Nigeria  
Isaac Adewole, Ibadan University, Ibadan, Nigeria  
Zarko Alfirevic, University of Liverpool, Liverpool, United Kingdom  
Fernando Althabe, Latin American Center for Perinatology (CLAP), Montevideo, Uruguay  
Jurandyr Andrade, Faculty of Medicine Ribeirao Preto, University of Sao Paulo, Sao Paulo, Brazil  
Alvaro Atallah, University of Sao Paolo, Sao Paulo, Brazil  
Katherine Ba-Thike, UNFPA Country Support Team, Bangkok, Thailand  
Zulfiqar Bhutta, Aga Khan University, Karachi, Pakistan  
Michel Boulvain, University of Geneva, Geneva, Switzerland  
Eckhart Buchmann, University of Witwatersrand, Johannesburg, South Africa  
Haroldo Capurro, Latin American Center for Perinatology (CLAP), Montevideo, Uruguay  
Guillerme Cecatti, State University of Campinas, Sao Paulo, Brazil  
Edgard Cobo, University of Valle, Cali, Colombia  
Agustin Conde-Agudelo, University of Cali, Colombia  
Peter Cooper, University of Witwatersrand, Johannesburg, South Africa  
Maria del Carmen Cravioto, National Institute of Nutrition, Mexico City, Mexico  
Luis Gabriel Cuervo, University of Javariana, Bogotá, Colombia  
Andres de Francisco, Global Forum for Health Research, Geneva, Switzerland  
Charlotte Ellerton, The Population Council, Mexico City, Mexico  
Anibal Faundes, State University of Campinas, Sao Paulo, Brazil  
Anis Fekih, University of Geneva, Geneva, Switzerland  
Rui Ferriani, Faculty of Medicine Ribeirao Preto, University of Sao Paulo, Sao Paulo, Brazil  
Mario Festin, University of the Philippines, Manila, the Philippines  
Pedro Figueroa-Casas, Rosario University, Rosario, Argentina  
Fariyal Fikree, The Population Council, New York, NY, USA  
Paul Garner, University of Liverpool, Liverpool, United Kingdom  
Teresa González-Cossio, National Institute of Public Health, Mexico City, Mexico
Section 8 - Implementing best practices

Babar Hasan, Aga Khan University, Karachi, Pakistan
Honest Honest, Birmingham Women’s Hospital, Birmingham, United Kingdom
Graham Howarth, University of Pretoria, Pretoria, South Africa
Charlotte Ingram, University of Witwatersrand, Johannesburg, South Africa
Richard Johanson, University of Keele, Stoke-on-Trent, United Kingdom
Edgar Kestler, Epidemiological Research Center in Sexual and Reproductive Health (CIESAR), Guatemala City, Guatemala
Khalid Khan, University of Birmingham, Birmingham, United Kingdom
Roberto Lede, Centro Rosaron de Estudios Perinatales (CREP), Rosario, Argentina
Jerker Liljestrand, World Bank, Washington, DC, USA
Gerhardt Lindeque, University of Uppsala, Uppsala, Sweden
Pisake Lumibiganon, Khon Kaen University, Khon Kaen, Thailand
Kassam Mahomed, University of Adelaide, Port Pirie, Australia
Nandita Maitra, Baroda Medical College, Vadodra, India
Matthews Mathai, Christian Medical College and Hospital, Vellore, India
James McIntyre, University of Witwatersrand, Johannesburg, South Africa
Joy Melnikow, University of Southern California, Davis, CA, USA
Jack Moodley, University of Natal, Durban, South Africa
Stephen Munjanja, University of Zimbabwe, Harare, Zimbabwe
Dina Neeloufer-Khan, University of Geneva, Geneva, Switzerland
James Neilson, University of Liverpool, Liverpool, United Kingdom
Cheryl Nikodem, University of Witwatersrand, Johannesburg, South Africa
Nguyen thi Nhu Ngoc, Hungvuong Hospital, Ho Chi Minh City, Viet Nam
Fathima Paruk, MRC Pregnancy Hypertension Research Unit, University of Natal, Durban, South Africa
Robert Pattinson, Pretoria University, Pretoria, South Africa
Manorama Purwar, Clinical Epidemiology Unit, Nagpur, India
Siddarth Ramji, Maulana Azad Medical College, New Delhi, India
H.P. Sachdev, Maulana Azad Medical College, New Delhi, India
Haroon Salooje, University of Witwatersrand, Johannesburg, South Africa
Lale Say, Istanbul University, Istanbul, Turkey
Nandi Sigfried, South African Cochrane Centre (SACC), Cape Town, South Africa
Louise Spruyt, South African Cochrane Centre (SACC), Cape Town, South Africa
Yawana Tanapat, Pramungkutlao Hospital, Bangkok, Thailand
Jadsada Thinkhamrop, Khon Kaen University, Khon Kaen, Thailand
Jorge Tolosa, Thomas Jefferson University, Philadelphia, PA, USA
Cyril Van Gelderen, Thomas Jefferson University, Philadelphia, PA, USA
Vanchai Vatanasapat, Khon Kaen University, Khon Kaen, Thailand
Juan Carlos Vazquez, America Arias Hospital, Havana, Cuba
Gijs Walraven, Medical Research Council Laboratories, Farafenni Field Station, the Gambia
David Wilkinson, Adelaide University, Whyalla, Australia
Chris Williams, Oxford University, Oxford, United Kingdom
Ray Yip, United Nations Children’s Fund (UNICEF), Beijing, China

|                     | Developing countries | | Developed countries | | Totals |
|---------------------|---------------------|-----------------|-----------------|-----------------|
|                     | Number  | % of total | Number | % of total | Number | % of total |
| All                 | 51      | 73        | 19     | 27        | 70     | 100       |
| Women               | 15      | 21        | 4      | 6         | 19     | 24        |

<table>
<thead>
<tr>
<th>Country</th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>17</td>
<td>24</td>
</tr>
<tr>
<td>AMRO</td>
<td>18</td>
<td>25</td>
</tr>
<tr>
<td>EMRO</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>EURO</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>SEARO</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>WPRO</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Number</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>17</td>
<td>24</td>
</tr>
<tr>
<td>AMRO</td>
<td>18</td>
<td>25</td>
</tr>
<tr>
<td>EMRO</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>EURO</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>SEARO</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>WPRO</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Annex3

PUBLICATIONS IN 2001

Cochrane reviews


Abalos E, Duley L, Steyn DW, Henderson-Smart DJ. Antihypertensive drug therapy for mild to moderate hypertension during pregnancy.

Briggs CJ, Capdeguelle P, Garner P. Strategies for integrating primary health services in middle- and low-income countries: effects on performance, costs and patient outcomes.

Cuervo LG, Mahomed K. Treatments for iron deficiency anaemia in pregnancy.

Duley L, Gülmezoglu AM. Magnesium sulfate versus lytic cocktail for eclampsia.

Forna F, Gülmezoglu AM. Surgical procedures to evacuate incomplete abortion.


Wilkinson D. Nonoxynol-9 for preventing sexually acquired HIV infection (awaiting publication of primary studies).

Wilkinson D. Nonoxynol-9 for prevention of sexually transmitted infections (awaiting publication of primary studies).

Reviews updated

Brocklehurst P, Volmink J, Rutherford G. Antiretroviral therapy for reducing the risk of mother-to-child transmission of HIV infection.

Carroli G, Bergel E. Umbilical vein injection for management of retained placenta.

Cheng L, Gülmezoglu AM, Ezcurra E, Van Look PFA. Interventions for emergency contraception.

Gülmezoglu AM, Forna F, Villar J, Hofmeyr GJ. Prostaglandins for prevention of postpartum haemorrhage.

Gülmezoglu AM, Hofmeyr GJ. Betamimetics for suspected impaired fetal growth.

Gülmezoglu AM, Hofmeyr GJ. Hormones for suspected impaired fetal growth.

Gülmezoglu AM, Hofmeyr GJ. Maternal nutrient supplementation for suspected impaired fetal growth.

Hofmeyr GJ, Gülmezoglu AM. Vaginal misoprostol for cervical ripening and induction of labour.

May W, Ba-Thike K, Gülmezoglu AM. Antibiotics for incomplete abortion.


Protocols

Abdel-Aleem H, Vogelsong K, d’Arcangues C, Gülmezoglu AM. Treatments for irregular bleeding associated with the use of
Annex 3 (continued)

PUBLICATIONS IN 2001

Adetoro O, Hofmeyr GJ. Prophylactic antibiotic administration in pregnancy to prevent infectious morbidity and mortality.

Kulier R, Gülmezoglu M, de Onis M, Villar J. Vitamin A supplementation in pregnancy.


Section 9
Monitoring and evaluation
INTRODUCTION

The monitoring and evaluation area of work includes epidemiological studies to map the burden of reproductive ill-health and the work on "indicators" to monitor progress towards the achievement of international development goals. Tools to provide access to, and training in, reproductive health indicators are also developed. The main objective is to generate and summarize epidemiological data on the burden of reproductive ill-health based on the following principles:

- mapping the burden of reproductive ill-health should contribute to better identification of the needs and allocation of resources and to the identification of research priorities;
- mapping the burden of reproductive ill-health should follow a process that is systematic, comprehensive, transparent, and with an acknowledgement of the limitations, as in any scientific endeavour. Protocols should be made available;
- the systematic review principles that apply to evaluating the effects of health care practices apply to assessing the magnitude of the burden of reproductive ill-health as well.

Reproductive health indicators are important for monitoring international development goals as well as health status levels. Unfortunately, there is a discrepancy between locally relevant indicators and those that are useful for global monitoring purposes. Global indicators, in general, obscure differences in health status within countries, such as those between rural and urban populations, different age groups (e.g. adolescents) and minority groups. Furthermore, there is very limited experience with some of the reproductive health indicators that have been agreed upon. Therefore, it seems that more research and capacity-strengthening efforts are needed before some of these indicators could be regarded as useful.

EPIDEMIOLOGY OF REPRODUCTIVE ILL-HEALTH

Objectives

The overall goal is to map the reproductive morbidities in a comprehensive and systematic fashion. This mapping will provide support for: future research on practices to prevent reproductive morbidities, implementation of evidence-based country programmes, and advocacy. The specific objective is to calculate prevalence/incidence, case-fatality rates, sequelae and attributable fractions of pregnancy and reproductive morbidities from systematic reviews of published or unpublished studies and datasets.

Progress

**Maternal mortality and severe morbidities: a systematic review**

In 2001, a draft monograph outlining the principles, methods and data from WHO datasets and recently published population-based studies has been completed. This working document will include the systematic review of maternal mortality and its causes. The protocol for this review has been completed and the data extraction form reviewed by the Programme’s forms committee. The review aims to measure maternal morbidity and mortality globally, regionally and at the country level. The outcomes of the project will be indicators of the incidence, prevalence, case-fatality rates, relative
risks and sequelae of morbid conditions related to pregnancy, as well as measures of the risk factors.

Data extraction, from 1995–2001, will be completed by end-2002. This review will be included in the WHO Reproductive Health Library (RHL) No. 6 and will be periodically updated.

There is currently limited experience with the systematic reviews of observational data of incidence/prevalence across populations, especially with regard to the techniques of pooling data from such studies. In order to address these issues, a methodological working group has been constituted which will convene in March 2002.

**Maternal mortality estimates**

In 2001, the global, regional and national maternal mortality estimates for 1995 were published by WHO, the United Nations Children’s Fund (UNICEF) and the United Nations Population Fund (UNFPA). A paper describing the method used in producing these estimates, and its strengths and limitations, was also published.

**Skilled birth attendant**

Global, regional and subregional estimates of the percentage of births attended by skilled personnel have been completed in 2001, and the data will be published on the Department’s web site in 2002.

**Anaemia during pregnancy**

The database on the prevalence of anaemia among pregnant women has been updated with new studies, up to end-2001. The data are currently available electronically in the Department's database and will be published on the Department's web site in 2002.

**Perinatal mortality**

Global, regional and country estimates on the incidence of low birth weight, perinatal and neonatal mortality for the period 1995–1999 are being developed. Estimates of the burden of disease, deaths and disability-adjusted life years (DALYs) related to low birth weight and perinatal causes are under revision.

**Maternal health of immigrant populations in Europe**

A review was conducted to document the status of maternal health among immigrant and displaced populations in Europe. Despite the large numbers of women in this situation, the review revealed a scarcity of data in this area. Nevertheless, studies from the Netherlands and the United Kingdom indicate that the immigrant and migrant populations in Europe have reduced access to maternal health services compared to resident populations, and their health status too is less favourable.

**Ectopic pregnancy**

A short review of the prevalence, associated morbidity and mortality from ectopic pregnancy between 1990 and 2001 was also conducted in 2001.

**REPRODUCTIVE HEALTH INDICATORS**

**Objectives**

Reproductive health indicators are used at global, regional and national levels to monitor the reproductive health status of populations. There are 17 global reproductive health indicators that have been agreed upon by international agencies. The Department’s work on mapping the epidemiology of reproductive ill-health will enhance available knowledge of the status of these indicators globally, while the tools developed for the collection and use of these indicators will help in capacity building in countries.

**Progress**

The report of the Second Inter-Agency Meeting on Reproductive Health Indicators for Global Monitoring, which was convened by the Department in July 2000 at the request of the WHO/UNICEF/UNFPA Coordinating Committee on Health (CCH), was published in July 2001 and was widely distributed.

As a follow-up to the meeting, the Department gave technical advice and feedback for two workshops in Africa and Europe. These were organized with a view to decide appropriate regional reproductive health indicators.

Since the July 2000 meeting, the Department has compiled the available data and developed a composite report of the global datasets of the various organizations for the 17 indicators. An interactive CD-ROM of country profiles and a wall-chart mapping the global collection of these indicators will be finalized in early 2002. The “WHO toolkit” for collecting and using the indicators has been reviewed by experts from several agencies and institutions. The final document will be published in 2002.

In 2001, the Department initiated a collaborative project with the University of Aberdeen, Aberdeen, United Kingdom, to develop a computer-assisted training package on selected reproductive health indicators (Computer-assisted learning package on maternal health [CALMAT]). The first phase of this project will be reviewed in January 2002 and future developments will be planned accordingly.

**FUTURE CHALLENGES**

The challenges in the area of monitoring and evaluation can be summarized as follows:
• **Methodological challenges**: systematic reviews of mortalities and morbidities pose new challenges. These relate to data searching, the critical appraisal of identified studies and the methodology of pooling data from observational studies and producing estimates. The Methodology Working Group that will be convened in March 2002 will provide useful insights into this process.

• **Mapping of epidemiology of reproductive ill-health**: in order to understand the true extent of reproductive ill-health, systematic reviews to evaluate the extent of morbidities, sequelae and prognosis of reproductive health conditions have to be conducted. This process was initiated in collaboration with The Department of Obstetrics and Gynaecology, University of Liverpool, Liverpool, United Kingdom. In 2002, systematic reviews of urinary incontinence and uterine prolapse will be conducted.

• **Reproductive health indicators**: the success of chosen indicators in reflecting the reproductive health status of populations remains to be demonstrated. The gap between global goals and locally relevant and operational indicators poses a challenge for international agencies.
Section 10
Communication and dissemination of information
Communication and dissemination of information

J. Khanna, C. Hamill, S. Kolev

INTRODUCTION

Communication is one of the key elements of improving global health. The communication, advocacy and information dissemination group seeks to facilitate access to reproductive health knowledge, within and outside the Department, in support of the WHO mandate and objectives in improving global reproductive health.

As per the strategy for information dissemination and communication presented to the Department’s Scientific and Technical Advisory Group (STAG) in 2001, the communication, advocacy and information group has set itself the following main objectives:

- to develop a strategic, proactive and cost-effective programme for the dissemination and communication of reproductive health knowledge to target audiences and stakeholders;
- to facilitate the transfer of reproductive health knowledge through appropriate strategies and media, focusing on participatory communication;
- to initiate, develop and manage a communication research programme in support of evaluation of the impact of dissemination activities as well as strengthening of dissemination/communication strategies; and
- to initiate advocacy and public relations interventions.

PROGRESS

Production of documents and publications

The following publications/documents were produced and distributed in 2001:

Progress in reproductive health research

The newsletter Progress in reproductive health research has continued to serve as the main instrument for information dissemination to policy-makers, programme managers, scientists and the general public. Two issues of the newsletter were published in 2001. The first was on research on antenatal care and maternal mortality and morbidity, and the second covered research on adolescent sexuality. Issues continue to be translated into Chinese. They are also published on the Department’s web site.

Annual technical report 2000+

For the first time, the Annual technical report was published and distributed in electronic format on CD-ROM. In addition to the Annual technical report 2000, the CD-ROM included Reproductive health programme development: implementing Cairo, biennial report 1998–1999; Reproductive health research at WHO: a new beginning, biennial report 1998–1999; and the Annual technical report 1999. Together, these reports provide a full package of information on the work of the Department from 1998 to 2000. More than 2500 copies of the CD-ROM were distributed, primarily to scientists and to national and international policy-makers. A small number of copies of the Annual technical report 2000 was also produced in print format.
Safe motherhood: a newsletter of global activity

The Safe Motherhood Initiative is a global effort to reduce maternal mortality and morbidity. As part of its contribution to the Initiative, WHO began publishing Safe motherhood: a newsletter of global activity in 1989. In 2001, one issue of the newsletter was prepared which focused on the topic of skilled attendance.

Other documents

The greatly increased number and variety of materials produced during 2001 reflect the Department's success in merging its research and technical support activities. In addition to general programme management activities, the documents address a broad range of health issues such as antenatal care, adolescent sexual health, HIV/AIDS and female genital mutilation (FGM) and deal with cross-cutting issues such as gender; information, education and communication (IEC) activities; monitoring and evaluation; and rights-based approaches. A number of the documents were produced jointly with other departments, notably the Departments of HIV/AIDS and Gender and Women's Health.

The manner in which documents are produced is also being expanded, with more information being made available in CD format and all printed technical documents posted on the Department's web site.

Reproductive health web site

The Department's web site (http://www.who.int/reproductive-health/index.htm) continues to grow and now houses approximately 1600 files. Almost all documents produced by the Department are now available online in a format which is compatible for basic hardware even with poor connectivity and this, furthermore, allows for texts to be downloaded for adaptation at country level. Increasingly, new documents are available on the web site before they are available in printed format. Any modifications made to documents after printing will be reflected in the documents contained on the web site. All documents are available in English and some have French and/or Spanish versions.

Notable additions to the web site this year include web pages on:

- The Strategic Approach to reproductive health
- Reproductive tract infections/sexually transmitted infections including HIV/AIDS
- Making Pregnancy Safer
- Adolescent sexual and reproductive health
- Safe motherhood costing spreadsheet.

An up-to-date What's new on the web? has been designed to help focus users on new additions to the web site. Substantial progress has been made on overhauling the Programme's old web site HRP Online and a new look was created for the Department's home page. The navigational structure and user-friendliness of the web site have also been further improved.

Dissemination of The WHO Reproductive Health Library (RHL) No. 4 and production of RHL No. 5

The fourth issue of RHL was published in February 2001. Later in the year, its Spanish version was also published. A total of 15 000 copies of the English version and 500 copies of the Spanish version were produced. By December 2001, more than 13 000 copies of the English version had been distributed. A key element of the dissemination strategy adopted for RHL has been the free distribution on a subscription basis. Subscriptions to RHL continue to rise rapidly. By December 2001, there were close to 7800 addresses in the mailing list for the English version; an additional 900 people had requested subscription for the Spanish edition. Individual physicians and health workers in developing countries and medical libraries make up almost 80% of the recipients of RHL. Other recipients include institutions and scientists associated with the Department. During 2001, work was started on RHL No. 5, including the digital editing of two training videos to be included in that issue.

Strengthening the capacity for communication and information dissemination of the Programme's Collaborating Centres

The Programme's collaborating centres worldwide are its partners in the conduct of research. The Programme continues to conduct various activities to enhance partnership in communication and dissemination of reproductive health research information as well. The Programme believes that a decentralized approach to communication will be more effective in reaching diverse audiences who speak different languages and use different communication channels.

The Programme’s strategy involves convincing the collaborating centres about the value of communicating research knowledge to the public and policy-makers, strengthening the communication capabilities of individual researchers in the centres (through workshops on scientific writing and effective communication with the mass media), and helping the centres to strengthen their capacity for information management and communication (by providing technical assistance in the setting-up or strengthening of communication units).

Scientific writing workshops

A description of the Programme's scientific writing workshops can be found in the Annual technical report 1995. These workshops focus on the skills involved in writing a scientific research paper and aim to encourage scientists in the
Table 10.1. Documents produced in 2001

<table>
<thead>
<tr>
<th>Programme management documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>RHR proposed Programme budget 2002–2003</td>
</tr>
<tr>
<td>RHR Programme budget 2002–2003</td>
</tr>
<tr>
<td>HRP proposed Programme budget 2002-2003</td>
</tr>
<tr>
<td>HRP Programme budget 2002–2003</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Electronic documents on CD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual technical report 2000 +</td>
</tr>
<tr>
<td>The WHO Reproductive Health Library, No. 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Print documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal mortality in 1995: estimates developed by WHO, UNICEF and UNFPA</td>
</tr>
<tr>
<td>Reproductive health indicators for global monitoring: report of the second inter-agency meeting 17–19 July 2000</td>
</tr>
<tr>
<td>Guidelines for the management of sexually transmitted infections</td>
</tr>
<tr>
<td>Breastfeeding and replacement feeding practices in the context of mother-to-child transmission of HIV: an assessment tool for research and programmes</td>
</tr>
<tr>
<td>Exploring common ground: building a better understanding and a closer alliance between family planning and STI/HIV prevention activities</td>
</tr>
<tr>
<td>Prevention of mother-to-child transmission of HIV. Selection and use of nevirapine.</td>
</tr>
<tr>
<td>New data on the prevention of mother-to-child transmission of HIV and their policy implications</td>
</tr>
<tr>
<td>Management of pregnancy, childbirth and the postpartum period in the presence of FGM</td>
</tr>
<tr>
<td>Integrating the prevention and the management of the health complications of female genital mutilation (FGM) into nursing and midwifery curricula: a teacher's guide</td>
</tr>
<tr>
<td>Integrating the prevention and the management of the health complications of female genital mutilation (FGM) into nursing and midwifery curricula: a student's manual</td>
</tr>
<tr>
<td>Integrating the prevention and the management of the health complications of female genital mutilation (FGM) into nursing and midwifery curricula: a policy guideline</td>
</tr>
<tr>
<td>Transforming health systems: gender and rights in reproductive health: training curriculum for health programme managers</td>
</tr>
<tr>
<td>Manual for the implementation of the new WHO antenatal care model</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occasional Paper series</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexual relations among young people in developing countries: evidence from WHO case studies</td>
</tr>
<tr>
<td>Advancing safe motherhood through human rights</td>
</tr>
<tr>
<td>Promoting reproductive health: lessons learned, future perspectives</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Language versions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critères de recevabilité médicale pour l’adoption et l’utilisation continue de méthodes contraceptives: deuxième édition</td>
</tr>
<tr>
<td>Maternité sans risques : évaluation des besoins. Rev 1</td>
</tr>
<tr>
<td>Nouvelles données concernant la prévention de la transmission du VIH de la mère à l’enfant et leurs implications politiques</td>
</tr>
<tr>
<td>Nuevos datos sobre la prevención de la transmisión maternoinfantil del VIH y sus implicaciones normativas</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documents under field-testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential care practice guide for pregnancy, childbirth and newborn care</td>
</tr>
<tr>
<td>Clinical guides for HIV in maternity settings: voluntary counselling and testing for HIV in the maternity setting</td>
</tr>
<tr>
<td>Clinical guides for HIV in maternity settings: antenatal care for the HIV-infected mother</td>
</tr>
<tr>
<td>Clinical guides for HIV in maternity settings: labour and delivery</td>
</tr>
<tr>
<td>Clinical guides for HIV in maternity settings: postpartum care</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Software package</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACLUSETER. Design and analysis of cluster randomization trials. Version 2.0</td>
</tr>
</tbody>
</table>
Programme’s collaborating centres to publish more papers, especially in international peer-reviewed journals.

During 2001, three scientific writing workshops were conducted: two were held for a total of 30 researchers at the University of Malaya, Kuala Lumpur, Malaysia. The third was conducted at the Shanghai Institute of Planned Parenthood Research in Shanghai, China for 22 junior- and middle-level scientists.

A trainers’ scientific writing workshop was conducted at the Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia. The 12 participants in the workshop were senior teachers in the Faculty of Medicine.

Workshops to improve communication skills and networking with the mass media

The mass media play a vital role in informing the public about new scientific developments, building public opinion on health issues and facilitating the conversion of new findings into policy actions. Therefore, it is important to promote networking between local journalists, scientists, programme managers and policy-makers. The Programme believes that researchers have a responsibility not only to publish their findings in peer-reviewed journals, but also to make their findings known to the general public who are investors in, and beneficiaries of, research. For these reasons, the Programme supports the improvement of communication skills among scientists, programme managers and policy-makers.

In June 2001, a communication workshop was conducted at the Egyptian Fertility Care Society in Cairo, Egypt. The 15 participants included researchers, programme managers, policy-makers and communication experts from the Ministry of Health.

In order to enhance the effectiveness of the communication workshops, plans were developed to conduct these workshops in two stages. In the first workshop, as is the case at present, the focus will be on imparting communication skills. In response to requests from programme managers in these workshops, the training in advocacy skills has been expanded. At the end of the first workshop, all participants will be given specific projects in line with their work, in which they will use their newly-acquired communication skills. In the second workshop, the same participants will return after a period of 3–6 months to discuss their experiences of use of the skills in real life and to further hone their skills.

Evaluation of information products

Safe motherhood newsletter

In 2000, the Department had conducted a survey among the readers of Safe motherhood: a newsletter of global activity. The response rate was very satisfactory. Data analysis was under way in 2001 and results are expected to be available in 2002.

Collaboration

The Department of Communication, Cornell University, Ithaca, NY, USA collaborates with the Programme in a variety of activities including the conduct of communication workshops for scientists.

PLANNED ACTIVITIES

In 2002, the Department will continue to produce its usual serial and nonserial publications, disseminate appropriate public relations material and conduct its scientific writing, communication and information management workshops. Special emphasis will continue to be placed on the development of the Internet web site.

It is planned to conduct scientific writing workshops in China, India and the Islamic Republic of Iran. Other activities to strengthen the communication capacity of collaborating centres will also continue.
Annex 1

PUBLICATIONS IN 2001

Section 11
Clinical trials and informatics support
Clinical trials and informatics support

O. Ayeni, G. Piaggio, A. Peregoudov, S. Landoulsi

INTRODUCTION

The Clinical Trials and Informatics Support group provides technical support in statistics and data processing to the rest of the Department.

Technical support to research activities includes statistical advice in the review and development of research projects, and responsibility for the management and analysis of some single-centre and nearly all multicentre studies carried out by the Programme. The group also coordinates the implementation of Good Clinical Practice (GCP) guidelines in all of the Programme’s research activities. In the area of technical support to countries, the group assists in the formulation, execution and review of institution-strengthening policies in statistics and data processing, and in the organization and conduct of workshops and training courses in these areas for scientists from collaborating institutions. Staff of the Clinical Trials and Informatics Support group provide on-the-project training in research data management and statistical analysis to staff of centres participating in some multicentre studies or carrying out their own single-centre trials. They also contribute to the development of appropriate techniques for the conduct, management and analysis of multicentre research projects in reproductive health in developing countries. Staff members of the group also provide local informatics support to the administrative management of the Department.

The group’s strategy is to coordinate international multicentre studies from Geneva while continuing to enhance the ability of individual centres to handle their own single-centre and national multicentre studies.

SUPPORT TO RESEARCH ACTIVITIES

Specific objectives

The objectives are to provide high-quality and efficient statistical and data-processing support to all research conducted by the Programme, and to ensure statistical and methodological rigour, including adherence to GCP guidelines.

Progress

Support to research projects

Activities carried out by the group in 2001 in support of research projects included:

- technical advice in their development and review;
- statistical design;
- assistance with project organization;
- data processing, monitoring and management;
- data analysis and preparation of statistical reports; and
- participation in the writing of scientific papers resulting from the projects.

A total of 63 research projects were supported by the group. The distribution of these projects by their stage of support at the end of 2001 is shown in Table 11.1.
In addition to the technical support given to these specific projects, all of which are being coordinated in Geneva, support was given to Programme staff with the technical review of projects submitted to them for funding and arrangements for logistic support to projects before launching. The technical review focused mainly on the biostatistical and data processing aspects of the protocol while logistic support arrangements included site-visits to the proposed study and coordinating centres to review facilities and data collection mechanisms.

**Implementation of GCP guidelines in research**

During 2001, efforts continued to formally implement WHO GCP research guidelines throughout the Programme’s research activities. Scientific staff of the Department were organized into groups to edit the 69 Standard Operating Procedures (SOPs) drafted during the previous year. The editing procedure is still in progress and will be completed during the first half of 2002.

### SUPPORT TO INSTITUTION-STRENGTHENING ACTIVITIES

**Objective**

The objective of these activities is to strengthen the statistical and data-processing capabilities of selected developing country institutions to support their own research work.

**Activities**

The following are the highlights of activities during 2001:

**Training courses, seminars and workshops**

A staff member of the group gave lectures on strategies for data analysis of observational studies and randomized controlled trials at the 11th Postgraduate Course for Training in Reproductive Medicine and Reproductive Biology at the WHO Collaborating Centre of the Cantonal Hospital, University of Geneva, Geneva, Switzerland. It was attended by 28 participants.

**Site-visits**

Staff of the group visited the Centre de Recherche en Reproduction Humaine et Démographie (CERRHUD) and the WHO Institut Régional de Santé Publique (IRSP) both in Cotonou, Benin to discuss the possibility of establishing training courses in biostatistics and data processing for French-speaking African countries. Staff of the Department visited the National Research Institute for Family Planning (NRIFP), Beijing, China, to help assess its capabilities to coordinate three research projects of the Rockefeller Foundation Initiative in China. In another visit to Beijing and Shanghai, assistance was provided in the preparation of the Conference on Quality Care in the Chinese family planning programme. Issues related to data management in the context of the collaboration between the State Family Planning Commission (SFPC) and the Department were also discussed.

<table>
<thead>
<tr>
<th>Stage of Support</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the planning stage or just starting: protocol preparation, forms design, data management systems design, supplies distribution</td>
<td>20</td>
</tr>
<tr>
<td>Ongoing studies: data validation, data quality control, study monitoring, interim analysis</td>
<td>12</td>
</tr>
<tr>
<td>Final analysis: final data cleaning, preparation of final analysis</td>
<td>9</td>
</tr>
<tr>
<td>Statistical report drafted, manuscript in preparation, revisions and/or additions to final analysis</td>
<td>13</td>
</tr>
<tr>
<td>Final analysis completed</td>
<td>9</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>63</strong></td>
</tr>
</tbody>
</table>
Annex 1

CONSULTANTS AND TEMPORARY ADVISERS DURING 2001

<table>
<thead>
<tr>
<th>Name</th>
<th>Nationality</th>
<th>Place of assignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virgile Capo-chichi</td>
<td>Benin</td>
<td>Geneva</td>
</tr>
<tr>
<td>Sihem Landoulsi</td>
<td>Tunisia</td>
<td>Geneva</td>
</tr>
<tr>
<td>David Machin</td>
<td>United Kingdom</td>
<td>Geneva</td>
</tr>
<tr>
<td>Alain Pinol</td>
<td>France</td>
<td>Geneva</td>
</tr>
</tbody>
</table>
Annex 2

PUBLICATIONS IN 2001


Appendix 1
Staff of the Department, December 2001

Paul Van Look, Director

Programme Management
Anne Allemand, Secretary¹
Luc Bernier, Reproduction Equipment Operator¹
Catherine d’Arcangues, Medical Officer¹
Paulo dos Santos, Clerk¹, ²
Barbara Kayser, Secretary¹
Craig Lissner, Technical Officer
Michael Mbizvo, Scientist¹
Bérengère Nail, Secretary
Corinne Penhale, Secretary¹
Claire Tierney, Secretary¹, ²
Hazel Ziaei, Secretary¹

Gender Issues and Reproductive Rights
Manuela Colombini, Technical Officer¹, ²
Jane Cottingham, Technical Officer¹
Adriane Martin Hilber, Technical Officer¹, ²
Katie Pellicer, Secretary¹
Jenny Perrin, Secretary¹

Implementing Best Practices
Lucy Adokojok, Secretary²
Åsa Cuzin, Technical Assistant¹
Metin Gulmezoglu, Medical Officer¹
Monir Islam, Medical Officer
Maggie Usher, Technical Officer²

Communication, Advocacy and Information
Annette Edwards de Lima, Clerk
Catherine Hamill, Technical Officer
Teresa Harmand, Assistant (Supplies)¹
Jitendra Khanna, Technical Officer¹
Svetlin Kolev, Information Officer¹, ²
Linda Kreutzer, Clerk¹
Sue Lambert, Secretary
Christine Meynent, Technical Assistant²
Maire Ni Mhearain, Secretary
Nalini Wijesundera, Clerk²

Clinical Trials and Informatics Support
Olusola Ayeni, Statistician¹
Annie Chevrot, Assistant (Statistics)¹
Catherine Hazelden, Assistant (Statistics)¹
Evelyn Jiguet, Clerk¹
Sihem Landoulsi, Programmer Analyst¹
Natalie Maurer, Clerk¹
Alexandre Peregeodov, Programmer Analyst¹
Gilda Piaggio Soto, Statistician¹
Frederick Schlagenhaft, Assistant (Statistics)¹
Milena Vučurević, Assistant (Statistics)¹

Promoting Family Planning
Kathryn Church, Technical Officer²
David Griffin, Scientist¹
Sarah Johnson, Technical Officer²
Gloria Lamprey, Secretary
Lynda Pasini, Secretary¹
Herbert Peterson, Medical Officer
Annie Portela, Technical Officer²
Lynn Sellaro, Secretary¹
Effy Vayena, Technical Officer¹, ²
Kirsten Vogelsong, Scientist¹, ²

Making Pregnancy Safer
Shamilah Akram, Secretary
Luc De Bernis, Medical Officer
Bocar Diallo, Project Manager
Maureen Dunphy, Secretary²
Janette Ferguson, Secretary²
Helga Fogstad, Technical Officer²
Rita Kabra, Medical Officer²
Catherine Legros, Clerk²
Ormella Lincetto, Medical Officer²
Mario Merialdi, Medical Officer¹, ²
Jane Pizot Einwen, Secretary²
Anne Riccio-Fazli, Secretary²
Archana Shah, Technical Officer¹, ²
Della Sherratt, Midwife²
Jose Villa, Medical Officer¹

¹ Staff of the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (see also the companion report entitled Reproductive health research at WHO: biennial report 2000-2001).
² Temporary staff
Monitoring and Evaluation
Ana-Pilar Betran, Medical Officer
Wilma Doedens, Technical Officer
Harriet Kabagenyi, Secretary

Addressing Reproductive Tract and Sexually Transmitted Infections
Maria Agnes Anciano-Muriel, Secretary
Nathalie Broutet, Scientist
Isabelle De Vincenzi, Medical Officer
Bidia Deperthes, Technical Officer
Timothy Farley, Scientist
Sophie Lacroix, Secretary
Isaac Malonza, Medical Officer
Justin Mandala, Technical Officer
Carol Peters, Secretary
Sybil Taylor, Secretary

Preventing Unsafe Abortion
Maud Keizer, Secretary
Janette Marozzi, Secretary
Nicola Sabatini-Fox, Secretary
Iqbal Shah, Scientist
Helena Von Hertzen, Medical Officer
Ina Warriner, Scientist

Technical Support Team
Heli Bathija, Scientist
Jennifer Bayley, Secretary
Catherine Blanc, Secretary
Vanessa Campos, Clerk
David Chikamata, Medical Officer
Enrique Ezcurra, Scientist
Amel Fahmy, Technical Officer
Margrit Kaufmann, Secretary
Alexis Ntabona, Medical Officer
Nini Zotomayor, Secretary

Policy and Programmatic Issues
Mary Broderick, Technical Officer
Peter Fajans, Scientist
Ruth Malaguti, Secretary

1 Staff of the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (see also the companion report entitled Reproductive health research at WHO: biennial report 2000-2001).

2 Temporary staff