Department of Reproductive Health and Research

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THE DEPARTMENT

The Department of Reproductive Health and Research (RHR—referred to in this document as "the Department") sees its mission as helping people to lead healthy sexual and reproductive lives. In pursuit of this mission the Department endeavours to strengthen the capacity of countries to enable people to promote and protect their own health and that of their partners as it relates to sexuality and reproduction and to have access to and receive quality reproductive health services when needed.

The Department of Reproductive Health and Research was created in November 1998 by joining the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP—referred to in this document as "the Programme") and the former WHO Division of Reproductive Health (Technical Support) (RHT). The purpose of bringing these two entities together was to facilitate integration of research and programme development in reproductive health within WHO.

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

The Programme was established in 1972 by WHO. In 1988, the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), and The World Bank joined WHO as the Programme's cosponsors. The four cosponsoring agencies, together with the major financial contributors and other interested parties, make up the Programme's governing body, the Policy and Coordination Committee (PCC), which sets policy, assesses progress, and reviews and approves the Programme's budget and programme of work. Broad strategic advice on the Programme's work is provided by the Scientific and Technical Advisory Group (STAG) (Annex 1). (In 1999, STAG assumed the responsibility for reviewing, and advising on, the work of the whole Department.) The Scientific and Ethical Review Group (SERG) Panel (Annex 2) reviews all projects involving human subjects and research in animals and contributes to ethical debate on matters relating to reproductive health. The Toxicology Panel (Annex 3) is a complementary review body to the SERG Panel. It provides expertise in the evaluation of pharmacokinetic, metabolic, endocrinological, toxicological, teratogenicity, carcinogenicity and mutagenicity studies of drugs or devices developed or studied by the Programme or referred to it for advice. In addition, the Programme has several specialist panels that advise on detailed research strategies.

PROMOTING FAMILY PLANNING

Research on users' perspectives

Research on users' perspectives provides scientifically sound information on the needs and preferences of women and men for reproductive health technologies and services. This information is central to informed policy-making and programmes, and for designing services which better address the needs of users and of potential users. Research findings also provide the basis for developing appropriate evidence-based norms and tools and improving existing, or developing new, reproductive health technologies.

In 2002, a workshop with country investigators was held in Nairobi, Kenya, to review and plan further work on a study

on pregnancy prevention in the era of HIV/AIDS in Kenya, South Africa, Uganda, United Republic of Tanzania, Zambia and Zimbabwe. Findings from Kenya were presented at the XIV International AIDS Conference, held in July 2002 in Barcelona, Spain. Collaboration continued with scientists from the University of London School of Hygiene and Tropical Medicine, London, United Kingdom, on analysis of data from the Demographic and Health Surveys (DHS) on contraceptive choice and discontinuation and switching of methods. Work was also undertaken to estimate the extent of childlessness and primary or secondary infertility using DHS data for 495 000 women from 47 developing countries. Three new projects were launched under the research initiative on quality of care.

Selected highlights

- A study in Kenya showed that communities perceived HIV/AIDS to be a serious problem. Paradoxically, however, the majority of sexually active individuals believed their own risk of HIV to be low or non-existent. Individuals surveyed recommended condom use to prevent the spread of HIV in the community, but the vast majority engaged in risky sexual behaviours, including not using condoms.

- A policy brief was produced based on findings from a study in China. It highlighted the need to provide reproductive health information and services to young female migrants. The policy brief was translated into Chinese and disseminated widely.

- Research on users' perspectives resulted in 12 publications in national or international journals, providing evidence for developing informed policies and programmes.

Research on the development of new methods for fertility regulation

The key objective of the Programme's research on the development of methods of fertility regulation is to broaden the choice of methods for users and potential users, by improving existing approaches and technologies, and by developing entirely new ones. The Programme has successfully collaborated with other funding partners and, in several cases, with the private sector in identifying research and development needs and in designing and executing relevant research in this area. The Programme's portfolio includes work on methods for women and men and ranges from basic research designed to identify novel and innovative approaches, to clinical trials of improved and new methods in a variety of settings; behavioural and acceptability research is also conducted, as appropriate.

Selected highlights

- At the end of 2002, a Phase II study of a combined androgen and progestogen regimen for male hormonal contraception was completed in Indonesia. The definitive results of this study demonstrated that depot-medroxyprogesterone acetate, when used in conjunction with testosterone undecanoate, was an effective and long-acting suppressor of spermatogenesis.

- Investigations of the efficacy of low-dose mifepristone as an emergency contraceptive demonstrated that in Chinese women a 10 mg dose of the antiprogestogen was just as effective as a 25 mg dose; the pregnancy rate following either treatment regimen was 1.1%.

- Preliminary data from studies in monkeys suggested that levonorgestrel will disturb ovulation if given prior to ovulation, but that it seemed to have no effect on pregnancy rates if ovulation had already occurred. These data imply that the primary action of levonorgestrel as an emergency contraceptive is through suppression of ovulation.

- A series of pre-clinical studies on the development of an immunocontraceptive method for women showed that a prototype human chorionic gonadotrophin (hCG) immunogen appeared to be safe, highly immunopotent and stable. An application has been submitted to the regulatory authorities in Sweden to carry out a Phase I clinical trial with this matrix formulation.

- Microspheres appear to be a successful alternative delivery system for a chimeric peptide containing hCG beta subunit for immunocontraception. Recent tests demonstrated that this delivery system could be manipulated to produce a high level of immunogenicity with minimal irritation at the injection site.

- A study to evaluate two possible treatments for the irregular vaginal bleeding patterns in Norplant users demonstrated that neither Vitamin E nor low-dose aspirin provided significant relief from this troublesome side-effect.

- The collaborative initiative between the Programme and The Rockefeller Foundation for basic research in implantation has completed its fourth year. New data obtained on structural and functional changes that occur at the site and time of implantation have been reviewed, and each centre will concentrate efforts on its most promising lead in the upcoming fifth and final year of the initiative.

- The Phase III trial of testosterone undecanoate alone as a male contraceptive was progressing according to schedule in China. This study marks the first-ever Phase III trial of a male hormonal contraceptive method.

Research on safety and effectiveness of contraceptives

The overall objectives of research in the area of safety and efficacy of existing methods of fertility regulation are (i) to assess evidence on the safety and effectiveness of different methods of contraception among women and men with particular emphasis on developing countries, and (ii) to address priority unanswered questions on existing methods of fertility regulation when used in developing countries.

Selected highlights

- Research continued on the safety and effectiveness of the levonorgestrel-releasing intrauterine device and on the long-term safety and effectiveness of the TCu380A intrauterine device.

- A multicountry study was launched on the comparative clinical performance of two second-generation implantable progestogen-only contraceptive methods, Implanon and Jadelle.

- A review on the association between cervical cancer and long-term use of combined oral contraceptives was in progress.

- Research was under way (including a review of available evidence) to assess the safety and practicality of reuse of the female condom.

- Recent research has found that among women with persistent human papilloma virus infection, those who have used hormonal contraceptives for longer than five years are at a higher risk of developing cervical cancer compared with non-users. In order to put these new results in a public health perspective, a consultation was convened in March 2002, which recommended no changes in contraceptive prescribing practice or use since the number of cervical cancers that might result from the use of hormonal methods is likely to be very small.

- A study was started on the contraceptive effectiveness of the female condom compared with the male condom. This study is being assessed in volunteers from family planning clinics in China, Nigeria, Panama and South Africa. A total of 500 women electing to use the female condom as their method of fertility regulation will be enrolled, together with a similar number of male condom users.

Promoting family planning norms and tools

The overall objective of this area of work is to create evidence-based and consensus-driven guidance to support the provision of high-quality family planning services globally.

Selected highlights

- The document *Selected practice recommendations for contraceptive use*—a guide for policy-makers, family planning programme managers and the scientific community—was published. Whereas the previously published document *Improving access to quality care in family planning*: *medical eligibility criteria for contraceptive use* addresses ***who*** can safely and effectively use contraceptive methods, *Selected practice recommendations for contraceptive use* address ***how*** contraceptive methods can be used safely and effectively. The document includes guidance on common clinical issues, such as what a woman should do if she forgets to take one or more of her oral contraceptive pills.

- Initial field-testing was under way of the *Decision-making tool for family planning clients and providers*—an interactive tool derived from and supported by the *Improving access to quality care in family planning*: *medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use.* This decision-making tool is designed for use during the client–provider family planning encounter to help both the client and the provider in choosing the most appropriate method of family planning, including dual protection for those at risk of both pregnancy and HIV/sexually transmitted infections.

- Initial planning was done to develop a handbook for family planning providers, which is intended to provide detailed information to providers on the provision of high-quality family planning services.

- A system was developed for ensuring that family planning guidance is created, and maintained, on the basis of the best available evidence. This system includes a continuous and comprehensive process of identifying, critically appraising, and synthesizing new evidence as it becomes available.

MAKING PREGNANCY SAFER

The Making Pregnancy Safer (MPR) initiative represents WHO's contribution to the global safe motherhood movement. It strives to contribute to the attainment of the United Nations Millennium Declaration targets, which include the reduction of the maternal mortality ratio by three-quarters, between 1990 and 2015, and the reduction by two-thirds of under-five mortality by 2015 through a reduction in the number of newborn deaths.

The work of the Department in this area consists of: (i) conducting research to map effective interventions and to improve the quality of services (see Generating new evidence for maternal and perinatal health); and (ii) providing normative guidance and technical support to countries for

the development, implementation and evaluation of cost-effective interventions to reduce maternal and newborn morbidity and mortality (see Implementation of evidence-based programmes).

Generating new evidence for maternal and perinatal health

The objective of research in this area is to find ways of reducing maternal and perinatal morbidity and mortality by: (i) evaluating promising biomedical and public health interventions; (ii) conducting systematic reviews; (iii) improving the understanding of sociocultural and economic factors that influence maternal health (e.g. studies of cost-effectiveness and quality of care); (iv) reviewing methodological issues; (v) conducting follow-up studies of the populations included in maternal and newborn research (e.g. long-term follow-up studies of babies); and (vi) mapping the magnitude of maternal ill-health.

During 2002, the main reports of several trials were published: the evaluation of a new model for routine antenatal care, the effectiveness of oxytocin in the prevention of postpartum haemorrhage, the treatment of pre-eclampsia with magnesium sulfate, and the strategy for the reduction of unnecessary caesarean sections. Additional publications reported findings on women's and providers' perception of care, and the economic evaluation of interventions tested in these trials. A new project, entitled "From Research to Practice", was initiated to facilitate the implementation of the new WHO antenatal care model and of the prevention of postpartum haemorrhage. Implementation of the new model of antenatal care was under way in Argentina, Brazil, Chile, Cuba, Ethiopia, Haiti, Italy, Oman, Pakistan, Spain, Syrian Arab Republic, Thailand and Zambia.

Selected highlights

- The calcium supplementation trial for the prevention of pre-eclampsia, which was started at the beginning of 2002 and which involved over 6500 women, was nearing completion.

- The results of the so-called "MAGPIE" trial that evaluated the effect of magnesium sulfate for the prevention of eclampsia among 10 141 women, showed that the use of the compound could more than halve the risk of eclampsia. This trial is expected to lead to a major change in practice.

- In order to document the magnitude of maternal ill-health in developing countries a systematic review of epidemiological data, that became available between 1997 and 2002, was being conducted. This unique systematic review will be completed during 2003.

- A new comprehensive collaborative research and service project entitled "Global Programme to Conquer Pre-eclampsia–Eclampsia" was launched. The initial phase of this project includes the preparation of systematic reviews on screening for pre-eclampsia, promising etiological and pathophysiological hypotheses to be tested in future research, and treatment recommendations, including recommendations to treat impaired fetal growth.

Implementation of evidence-based programmes

The foci of this area of work are: (i) development of a strategy for global action on skilled care for pregnant women; (ii) documentation of current knowledge and experience regarding the relationship between maternal and neonatal health and poverty; and (iii) development of a concept and strategy paper for working with individuals, families and communities for improved maternal and neonatal health. Cost–effectiveness studies are also being conducted and are expected to guide recommendations for maternal and neonatal health interventions.

Selected highlights—development of tools and guidelines

- The different tools for the Integrated Management of Pregnancy and Childbirth (IMPAC) were being used in countries through worldwide distribution of the manual entitled *Managing complications in pregnancy and childbirth: a guide for midwives and doctors* and its translation into several languages including Bahasa Indonesia, French, Laotian, Russian and Spanish. The Arabic and Chinese translations of this guide are expected to be completed in 2003. The following tools were in press: *Managing newborn problems: a guide for doctors, nurses and midwives* and *Pregnancy, childbirth and newborn care: a guide for essential practice.* Plans were under way for the adaptation and utilization of these guides in several countries.

- Other clinical and programme tools/guidelines that were being finalized for publication included (provisional titles): *Standards for maternal and newborn care*; *Handbook for communicating and counselling for pregnancy, childbirth and newborn care*; and *Kangaroo mother care: a practical guide*. A manual on surgical obstetrics care for use at the district level was in the field-testing phase.

- A set of education tools/guidelines were also under preparation: the revised WHO midwifery education modules and the *Strengthening midwifery toolkit.* An education and training strategy was being developed with the WHO Department of Child and Adolescent Health and Development for improving health practitioners' performance.

- Several management tools were either under preparation (*Making pregnancy safer planning guide* and *Beyond the numbers: a tool for reviewing maternal deaths and complications*), or were at the field-test-

ing stage (*Making pregnancy safer workshop planning manual*; the *Health and human rights assessment tool for maternal and neonatal health*; and *Making pregnancy safer—essential health technology package*).

Selected highlights—technical support to countries

- The Department continued to help countries: (i) to strengthen their political commitment to, and strategies for, maternal and neonatal health in national health and development plans; and (ii) to review/establish national as well as regional policies and strategies in order to ensure that issues related to maternal and neonatal health are adequately addressed.

- In the area of programme development and implementation, the Department contributed to the strengthening of existing maternal and neonatal health programmes in an increasing number of countries.

- Specific areas that received substantial support in 2002 included: improving provider skills in order to enhance the quality of care; introducing and adapting IMPAC norms and tools into national standards and protocols; improving reporting of maternal mortality and severe morbidity to assess provider performance and improve quality of care.

- The Department collaborated with various partners in establishing or revitalising Making Pregnancy Safer/ Safe Motherhood ministerial committees, taskforces or partners' coordination committees at national level.

- Web pages related to the Making Pregnancy Safer initiative were updated and expanded and an edition of the *Safe motherhood newsletter* that focused on the topic of skilled attendants was published.

CONTROLLING SEXUALLY TRANSMITTED AND REPRODUCTIVE TRACT INFECTIONS

The key objectives of the Department in the area of sexually transmitted infections (STIs) and reproductive tract infections (RTIs) are: (i) to increase the availability of high-quality, culture- and gender-sensitive and non-stigmatizing services for the prevention, care and management of STIs and RTIs and their complications; (ii) to broaden the range of safe, effective and affordable methods to prevent and manage STIs and RTIs and mother-to-child transmission (MTCT) of HIV and STIs; and (iii) to contribute to the strengthening of national health system capacity to deliver these services.

Selected highlights

- Work was under way to develop a comprehensive package of guidelines and tools designed to assist programme managers to plan and implement effective and appropriate interventions to prevent, control and manage STIs and RTIs. The package includes: an STI/ RTI programme guidance tool; STI/RTI management in reproductive health care settings: a guide for essential practice; *Guidelines for the management of sexually transmitted infections* and a set of training modules for the management of sexually transmitted infections.

- The Department held a technical consultation involving academic institutions and the private sector to assess the increasing threat of the herpes simplex virus becoming a major driving force for HIV transmission. The consultation also reviewed the launch of new collaborative work within WHO and with external partners, which aims to accelerate the implementation of research and other strategies to prevent and control genital herpes infection, thus diminishing its impact on HIV transmission.

- A protocol was finalized to study the impact of highly active antiretroviral therapies (HAART) on mother-to-child transmission (MTCT) of HIV and maternal health. This research will address key issues of acceptability, safety and effectiveness of HAART in MTCT prevention and the impact of a triple-combination antiretroviral prophylactic regimen on the rate of MTCT.

- As part of ongoing efforts to develop microbicides to fight STIs/HIV, the Department, in collaboration with CONRAD, is conducting a three-centre randomized double-blind Phase I study of the safety and acceptability of a 6% cellulose sulfate gel compared with placebo among healthy women volunteers in India, Nigeria and Uganda.

- Work was in progress to develop an updated global STI strategy that reflects recent national, regional and global evidence and experience in STI control and its impact on the HIV epidemic. The new strategy is expected to facilitate the dissemination, adaptation and adoption of the recommended policies and strategies for STI prevention, care and control.

PREVENTING UNSAFE ABORTION

The two main objectives of the Department's work in this area are prevention of unsafe abortion and its consequences and assessment of the safety of current abortion procedures. To achieve these objectives, the work plan focuses on generating scientifically sound evidence for providers and policymakers in order to enable them to make informed decisions on implementing best practices and resource allocation. Projects include documentation of global and regional prevalence rates of unsafe abortion and associated morbidity and mortality, social science research to understand better the pathways to safe and unsafe abortion, clinical trials to evaluate medical abortion techniques, the development of guidelines for safe abortion, and technical support on request to countries on issues related to abortion care.

Selected highlights

- A document entitled *Safe abortion: technical and policy guidance for health systems* was completed in 2002 and sent to print. Over the next year, the document will be translated into French, Russian and Spanish, and possibly Portuguese and Romanian.

- As part of the Department's commitment to maintaining up-to-date information on unsafe abortion, new global and regional estimates of unsafe abortion were made available in 2002. The Department's work on estimating unsafe abortion provided inputs to WHO's work on the Global Burden of Disease 2000.

- A national conference was supported in Bucharest, Romania, in April 2002 to disseminate the findings of the 2001 Strategic Assessment on abortion in Romania. The conference included a wide range of stakeholders from across the country, who formulated a new policy requiring all obstetrics/gynaecology departments in the country to provide safe, high-quality abortion services, including post-abortion contraception, at an affordable price set by the Romanian Ministry of Health and Family.

- Results from a study on the pharmacokinetics of sublingual administration of misoprostol suggest great potential for the sublingual route to be developed into a method of medical abortion.

PROMOTING SEXUAL AND REPRODUCTIVE HEALTH OF ADOLESCENTS

The objective of the Department's work on adolescent sexual and reproductive health is to generate evidence for the promotion of healthy sexual development and maturation and strengthening the capacity of adolescents to have equitable and responsible relationships. Activities primarily focus on supporting research and developing the evidence base on the sexual and reproductive health situation and needs of adolescents in developing countries. Related to this work are activities intended to strengthen national capacity for research in this area and dissemination of findings.

Selected highlights

- Analysis of Demographic and Health Survey (DHS) data for never-married young women in Colombia and Peru showed that over the course of the 1990s, an increasing percentage of younger women were sexually active. While use of contraceptives, especially condoms, had increased, there had been an even greater rise in sexual activity and an increasing percentage of young, never-married women had experienced unintended pregnancy and abortion.

- Research undertaken to generate global estimates for unsafe abortion found that nearly 40% of all unsafe abortions occur among women aged 15–24 years. Overall, 7.3 million unsafe abortions were estimated to take place each year in this age group.

- A total of 43 studies were being supported under the social science research initiative on adolescent sexual and reproductive health; 41 were ongoing, with two new studies being initiated in 2002. Thirty-six papers reporting on evidence accumulated through this initiative were published in national and international journals and in the proceedings of two international conferences, held in Bangkok (Thailand) and Kunming (China).

- Various research capacity strengthening activities continued for the network of investigators engaged in research on adolescents, including assistance in developing papers for presentation at conferences and for submission to journals.

- Core instruments developed for the study of adolescent sexual risk behaviours (focus-group discussion guidelines, in-depth interview guides and a survey questionnaire) and an annotated bibliography of relevant materials were provided to a large number of researchers working in this area. These instruments and a related bibliography were also published on the Department's web site.

- Research was under way to investigate: the extent to which hormonal contraception depresses peak bone mass achieved among adolescents, thus placing them at greater risk of osteoporosis in later life; factors underlying reports of unusually high levels of lower genital tract infection among pre-adolescents in Mongolia; and the reproductive health needs of young migrants in the Greater Mekong region.

GENDER AND REPRODUCTIVE RIGHTS IN REPRODUCTIVE HEALTH

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

Selected highlights

- The Department published the CD-ROM version of a document entitled *Transforming health systems: gender and rights in reproductive health*—a three-week training curriculum in gender and rights in reproductive health for health managers—and made arrangements for translation of the English document into Chinese and Spanish.

- A three-day training of trainers workshop was conducted on the rights module from the above curriculum in order to provide additional training to the five regional centres (in Argentina, Australia, China, Kenya and South Africa) that are already running the full course. The aim was to train experienced trainers in running a two- to three-day module on human rights and reproductive health within their region.

- The Department provided to United Nations Treaty Bodies sexual and reproductive health data for a number of countries that were required to report to the Treaty Bodies in 2002 about their adherence to various rights-related international treaties. The main purpose of the United Nations treaty monitoring system is to encourage governments to comply more fully with their legally-binding obligations to respect, protect, and fulfil the human rights enshrined in the various treaties. The Department's concern is to ensure that key sexual and reproductive problems, such as maternal mortality, are included in the monitoring of States' efforts to protect the rights of their citizens.

- The Department is developing a tool to help governments to become more accountable for their international commitments—among others, to international human rights treaties, conventions and consensus document targets—to promote and protect their citizens' rights to maternal and neonatal health care. A study was commissioned to validate the internal consistency of this tool.

- A Technical Consultation on Sexual Health was held, which resulted in the formulation of new definitions of sex, sexuality, sexual health and sexual rights for the field.

- Two reviews were commissioned on *Integration of sexual health into reproductive health services: needs, evidence and implications* (Royal Tropical Institute of the Netherlands, Amsterdam, Netherlands), and *Searching for sex: a systematic literature review of international research related to sexuality and sexual behaviour* (La Trobe University, Melbourne, Australia).

TECHNICAL COOPERATION WITH COUNTRIES

The main objective of the Department in its technical cooperation with countries is to assist countries to enhance their capacity to develop and implement national and regional research and programme activities aimed at improving reproductive health. Specifically, the aims are: (i) to assist developing countries with the identification of areas where research is required to address reproductive health needs; (ii) 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; (iii) to provide assistance to developing countries to strengthen their capacity to undertake research, and to disseminate and apply results of reproductive health research; and (iv) to collaborate with countries in the monitoring of effects of policies and initiatives related to health sector reforms in reproductive health programmes and outcomes.

Overview

- Nineteen Long-term Institutional Development (LID) grants and eight Resource Maintenance Grants (RMGs) were awarded to the network of collaborating research institutions. Research Training Grants (RTGs) were also awarded to 27 scientists from these institutions, most of whom received their training within their respective regions.

- With support from HRP and from national and international sources, up to 204 research projects were ongoing in the above institutions in 2002, and findings from a total of 730 research articles were published and/or disseminated through presentations during the year.

The WHO Regions of Africa and the Eastern Mediterranean

The main objective of the Department in the WHO Regions of Africa and the Eastern Mediterranean is to build and develop the research capacity of institutions in order 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.

In 2001–2002, the Department collaborated with 37 institutions or research groups in 24 countries of the two regions. Six institutions in these countries received Long-term Institutional Development (LID) grants and three received Resource Maintenance Grants (RMGs), while 17 were awarded small grants for library support and the purchase of consumable laboratory supplies. Three centres were participating in regional research projects.

Selected highlights

- A call for proposals on sociocultural aspects of female genital mutilation (FGM) yielded many concept proposals; several of these were selected for further development.

- In 2001 (most recent year for which complete data are available), 72 studies were carried out by the nine centres receiving LID grants or RMGs. Of these projects, 13% received financial support from the Programme, while 51% received support from other international agencies. The highest number of projects concerned maternal health, followed by family planning and HIV/AIDS.

- The nine centres receiving a LID grant or RMG published 57 papers in national and international journals, and staff of these centres served in 53 different advisory roles at national, regional and international levels.

- Ten staff members from these nine centres attended courses outside their home countries and six researchers received a Research Training Grant (RTG).

- Workshops and short courses were organized on several themes: research methodology, semenology, and ethical issues in reproductive health research.

The WHO Region of the Americas

The Department collaborated with eight institutions in the Region of the Americas which are implementing a large number of research projects on topics relevant to regional and national reproductive health problems. Ongoing projects supported by Long-term Institutional Development (LID) grants include basic science work in the area of male fertility, an assessment to identify priority interventions that would improve access to and quality of family planning and of maternal and neonatal health care, and social science research in the area of male involvement in reproductive health.

Selected highlights

- During 2001 (most recent year for which complete data are available), from the overall number of 106 projects, four were implemented with support from the Programme's capacity building grants, 51 with support from national sources (48%), 21 (20%) were supported by the specific work areas of the Department, and 30 (28%) were funded by international agencies other than WHO.

- Ten staff from regional centres underwent training outside their home countries and the eight centres receiving research capacity strengthening support trained in turn 112 professionals and technical staff from other local institutions. Thirty-one fellows participated in formal courses and 653 attended short, group-learning activities, such as seminars and workshops organized by the centres.

- During 2001, a total number of 143 research articles (128 original papers and 15 review articles) were published and 34 books and book chapters were authored by staff from the centres receiving research capacity strengthening support.

- In an effort to enhance the dissemination and utilization of research findings, two national workshops—attended by researchers, policy-makers and other stakeholders—were organized in Argentina and in Peru to disseminate research findings and discuss the policy implications for programmes and services. A regional workshop was convened in coordination with the FRONTIERS Program of the Population Council to bring together researchers and policy-makers to discuss barriers and facilitators to the process of utilization of research findings.

- Steps were taken to strenghten the coordination with the WHO Regional Office for the Americas: during 2002, eight joint missions were undertaken to participate in site visits or in meetings held in various countries of the region.

The WHO Regions of South-East Asia and Western Pacific

The primary strategic objectives of the Department in supporting developing countries in the WHO Regions of South-East Asia and the Western Pacific are to assist the countries of the regions: (i) to identify their needs in national reproductive health policies and programmes for improving reproductive health, and in areas where research is required to address these needs; (ii) to build their own capacity to plan, implement, monitor and evaluate such programmes and policies and to participate in national, regional and global research in accordance with the highest scientific and ethical standards; (iii) to disseminate and apply the results of reproductive health research and to adopt, adapt and implement new updated norms, standards, tools and approaches; and (iv) to develop appropriate strategic approaches to improving the quality of reproductive health services. Through such support, the countries will ultimately develop and sustain their ability to address a broad range of reproductive health research and service-related areas, and to establish and strengthen an enabling national reproductive health research system and research culture. Continued development of relevant skills for enhancing national leadership, priority-setting, advocacy, communication, networking, negotiation, use of research results and partnerships is an integral part of the process.

Selected highlights

- The Programme continued to provide institution-based support in nine countries through award of seven Long-term Institutional Development (LID) grants and four Resource Maintenance Grants (RMGs).

- Three new Research Training Grants (RTGs) were awarded to scientists from China (2) and Mongolia (1), one of whom will be trained within the region.

- Two regional joint research programmes involving most of the recipients of LID grants were in the process of being implemented.

The WHO Region of Europe, including Central and Eastern Europe, the Newly Independent States and Central Asian Republics

The main objectives of the Department in the WHO European Region are: (i) to strengthen national capacity in reproductive health research, with a particular focus on providing training opportunities for scientists in the countries of Central and Eastern Europe, the Newly Independent States and 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.

Selected highlights

- The second meeting of the European Regional Advisory Panel (RAP), was held at The Netherlands School of Public Health, Utrecht, Netherlands, on 29–30 May 2002.

- The Programme continued to provide support to the former participants in the first WHO/FRONTIERS course on operations research to help them to implement their research proposals.

- Continued technical support was provided for country adoption and adaptation of WHO evidence-based policies and standards for maternal and newborn care. Clinical guidelines on evidence-based medicine and appropriate use of technologies were issued, targeting specific categories of health care providers and were used in Kazakhstan, Republic of Moldova, Turkmenistan, and Uzbekistan.

- Support was provided to a retrospective study that is reviewing some examples of interventions that had an influence on the reduction of maternal mortality in Europe. The report on this study will be available in 2003.

- Preparatory steps were undertaken for the second WHO/FRONTIERS course on operations research to be held at the Kazakhstan School of Public Health, Almaty, Kazakhstan, in April 2003, for Russian-speaking scientists.

- Technical support was provided to the postgraduate course on reproductive medicine and reproductive biology, organized annually by the WHO Collaborating Centre, University of Geneva, Geneva, Switzerland.

Policy and programme issues

The Department's objectives in this area are to review, develop and test methodologies to assist countries in the planning and implementation of reproductive health services. Central to this work are the testing, refinement and promotion of the Strategic Approach[1] to improving the quality of care of reproductive health services.

Selected highlights

- Dissemination of the Strategic Approach in 2002 included the implementation of regional training workshops in Africa and Asia. A field guide for implementing strategic assessments was published, as was as a document providing an overview of the Strategic Approach and summarizing experiences with its implementation in 18 countries.

- The Strategic Approach continued to be adapted for strategic planning in a range of areas of reproductive health: for example, in Bolivia, the approach was used to address issues related to cervical cancer screening and treatment; and in Yunnan, China, an assessment was made of comprehensive, integrated reproductive health services, with emphasis on access and utilization of services by the poor. In Romania and Viet Nam, interventions recommended in prior assessments of issues related to abortion are currently being tested.

- Stage II activities were ongoing in China, Ethiopia, Myanmar and Viet Nam. Scaling-up of tested interventions was under way in Stage III activities in Bolivia, Brazil, Viet Nam and Zambia.

- An initiative examining the impact of health sector reforms on reproductive health services and outcomes began with development and implementation by the World Bank Institute of a course on this topic for Departmental, regional office and country office staff. The Department also collaborated with the South African Women's Health Project on their "Sexual rights and reforms" project, conducting regional and global literature reviews of existing knowledge concerning the relationships between health reforms and reproductive health.

MONITORING AND EVALUATION

Monitoring and evaluation activities aim: (i) to map maternal and newborn morbidities and mortality in a comprehensive and systematic manner; and (ii) to develop tools to facilitate

[1]The Strategic Approach is a three-stage process to assist national-level decision-making to improve the quality of care of reproductive health service. Stage I strategic assessments examine users' needs and perspectives, the available technologies and services, and the capacity of the service delivery system, so as to determine appropriate strategies for improving the quality of care. Stage II involves action research to design and test optimal models for introducing or re-introducing technologies or services. Stage III uses research results and lessons learned in Stage II for policy and programme development and the scaling-up of activities.

the collection and distribution of data on indicators to monitor progress towards the achievement of the Millennium Development Goals (MDGs) for improving maternal health.

Selected highlights

- Substantial progress was made in the systematic review of epidemiological evidence on maternal morbid conditions and mortality. The methodological challenges of summarizing data from observational studies have been discussed within a methodology working group. Over 9000 published and unpublished reports from 1997 were evaluated for possible inclusion in the review, and data were extracted from 417 that fulfilled the inclusion criteria. It is expected that for the entire period 1997–2002, evaluation of around 60 000 reports will result in the inclusion of approximately 3000 articles in this unique systematic review, which will be completed in mid-2003. This is the first ever systematic attempt to map the situation of a group of medical conditions with data.

- The global, regional and subregional estimates of the proportions of births attended by a skilled health worker were updated and published on the Department's web site.

- A systematic review to estimate the prevalence, associated factors and consequences of genital organ prolapse was initiated, and the first draft was completed.

- An analysis of levels, trends and differentials of antenatal care in developing countries using data from the Demographic Health Surveys (DHS), the Multiple Indicator Cluster Surveys (MICS) and the Pan Arab Project for Child Development (PAPCHILD) surveys from 1990–2001 was completed.

- A database of reproductive health indicators to provide up-to-date information at the national, regional and global levels of the 17 reproductive health indicators short-listed for global monitoring was under development and will be published on the Department's web site in early 2003.

IMPLEMENTING BEST PRACTICES

The Department is the leading institution in the efforts to map best reproductive health practices and to develop a strategic approach that helps developing country health professionals to capture, adapt according to their needs and apply best practices. The activities of the Department in this area include primary research, research synthesis, dissemination and capacity strengthening in evidence-based decision-making worldwide.

Selected highlights

- The randomized controlled trial of an active dissemination strategy for evidence-based reproductive health information using *The WHO Reproductive Health Library* (RHL) was ongoing in 40 hospitals in Mexico and Thailand. The intervention has been completed and data collection on clinical outcome was under way. A qualitative research component evaluating the experiences of staff was being developed.

- Eight new Cochrane reviews and three Cochrane review protocols were published. Nine systematic reviews were updated. Six systematic reviews were under way.

- Subscriptions to RHL exceeded 12 000 in 2002 and a total of 29 000 copies in English and Spanish were distributed. Work was progressing on the Chinese translation of RHL, which is expected to be published in 2003.

- RHL editors and scientists from partner institutions conducted more than 100 RHL presentations or workshops worldwide.

- The training initiative developed jointly with the WHO Regional Office for Africa and the South African Cochrane Centre was pilot-tested and the first workshop was held in South Africa.

Implementing Best Practices (IBP) Initiative

The Department is leading the development of a programme to support the adaptation and application of best practices, known as the Implementing Best Practices (IBP) Initiative. This collaborative partnership aims to use innovative strategies to support the transfer of knowledge, harmonize approaches and reduce duplication of efforts at country level in order to help health care professionals access and apply the latest research and best practices in reproductive health.

Selected highlights

- All 17 partners have agreed to sign a Memorandum of Understanding to form the Implementing Best Practice Consortium. The Department will act as the Secretariat for the first two years of operation.

- The IBP Initiative continued to attract more members in 2002, including two country-based nongovernmental organizations.

- In collaboration with the WHO Regional Office for the Eastern Mediterranean Region the IBP Initiative was introduced to seven country teams from Egypt, Jordan, Lebanon, Pakistan, Palestine, Turkey and Yemen at a meeting held in Cairo, Egypt, in 2002. The country teams

have initiated action to implement the plans they agreed to during this meeting and IBP partners are providing a programme of supportive follow-up.

COMMUNICATION, ADVOCACY AND DISSEMINATION OF INFORMATION

Through this area of work, the Department seeks to facilitate access to reproductive health knowledge within and outside the Department.

Selected highlights

- A total of 23 information products were issued.
- The Department's annual technical report for 2001 and two biennial reports for 2000–2001 were published in electronic format on an elegantly designed, interactive CD-ROM.
- Issue No. 5 of *The WHO Reproductive Health Library* was issued and widely distributed.
- The Department's web site continued to grow and, in December 2002, housed some 3300 pages.
- In a workshop in Mumbai, India, 20 scientists were trained in how to write good scientific research articles.
- Twenty senior faculty members of a collaborating institute in India were trained in teaching scientific writing.
- Twenty-two physicians were trained in communication skills in a workshop in Malaysia.

CLINICAL TRIALS AND INFORMATICS SUPPORT

This area of work relates to the provision of statistical and data-processing support for all multicentre and some single-centre research projects undertaken by the Programme. It also provides support to research capability strengthening in the formulation and execution of institution strengthening policies in biostatistics and data processing. Informatics support is also provided to the administration and management area of the Department.

Selected highlights

- Statistical data and entry support was provided to 68 single and multicentre projects.
- Work continued on the editing of Standard Operating Procedures drafted for implementation of the WHO Good Clinical Practice guidelines in all of the Programme's research activities.
- Work was ongoing on methodological research on statistical issues related to cluster randomization trials and on the meta-analysis of observational studies.
- The statistical and data-processing capabilities of selected collaborating institutions were strengthened.

Annex 1

SCIENTIFIC AND TECHNICAL ADVISORY GROUP IN 2002

Members

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Angela Kamara, Regional Prevention of Maternal Mortality Programme, Accra, Ghana
Hoda Rashad, The American University in Cairo, Cairo, Egypt
Reijo Vihko, The Academy of Finland, Helsinki, Finland
Xiao Shaobo, State Family Planning Commission, Beijing, China

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	5	45			6	55	11
Women	2	18			2	18	4
from:							
AFRO	2	18					2
AMRO					3	27	3
EMRO	2	18					2
EURO					2	18	2
SEARO							
WPRO	1	9			1	9	2

Annex 2

SCIENTIFIC AND ETHICAL REVIEW GROUP PANEL IN 2002

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Carlos Simon, Institute of Infertility, Valencia University, Valencia, Spain
Sonia Tabacova, National Centre of Hygiene, Ecology and Nutrition, Sofia, Bulgaria
Godfrey B. Tangwa, University of Yaoundé I, Yaoundé, Cameroon
Zhao Baige, State Family Planning Commission, Beijing, China

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	13	43	1	3	16	53	30
Women	6	20	1	3	5	17	12
from:							
AFRO	3	10					3
AMRO	3	10			5	17	8
EMRO	1	3					1
EURO	1	3	1	3	8	27	10
SEARO	3	10					3
WPRO	2	7			3	10	5

Annex 3

TOXICOLOGY PANEL IN 2002

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Alex Jordan, Division of Reproductive and Urologic Drug Products, Food and Drug Administration, Rockville, MD, USA
Shirley Price, University of Surrey, Guildford, United Kingdom
Sonia Tabacova, National Centre of Hygiene, Ecology and Nutrition, Sofia, Bulgaria

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	1	17	1	17	4	67	6
Women			1	17	1	17	2
from:							
AFRO							
AMRO					1	17	1
EMRO							
EURO			1	17	3	50	4
SEARO	1	17					1
WPRO							

Section 1
Promoting family planning

Users' perspectives in the context of reproductive health

I.H. Shah and I.K. Warriner

INTRODUCTION

As part of the global effort to achieve improved levels of reproductive health through informed policies, programmes and services, understanding men's and women's reproductive health needs and preferences as well as the constraints to the use of services has become increasingly important. The 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 the acceptability of various methods, are also influenced by the quality of the care they receive, their perceptions and attitudes and the sociocultural context of these services.

The primary objective of the Department's work in this area is to understand better men's and women's behaviours and perspectives as users or potential users of reproductive health services and emerging or currently available fertility regulating methods. The second objective is to understand the constraints and sociocultural contexts that influence users' practices, behaviours and perspectives. The third objective is to address neglected aspects of quality of care that have an important bearing on the access to and use of reproductive health services. Findings on users' perspectives provide policy-makers and programme managers with evidence-based recommendations for improving care. The findings also indicate the acceptability of reproductive health services and technologies for both users and potential users while identifying the unmet needs of clients. The Department's work also covers selected issues related to infertility, which is an integral, but often neglected, aspect of reproductive health.

RESEARCH ACTIVITIES

Specific objectives of research

Research on users' perspectives aims to understand better men's and women's reproductive health decision-making, and their needs for and perspectives on reproductive health technologies and services. 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 most severe: Kenya, South Africa, Uganda, United Republic of Tanzania, Zambia and Zimbabwe. The project is designed to address three main objectives: (i) to determine the perspectives of sexually active individuals on 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.

An analysis workshop with country investigators was held in Nairobi, Kenya, on 3–8 March 2002, jointly sponsored by the African Population and Health Research Centre, Nairobi, Kenya. The main objectives of the workshop were: (i) to review results from the study; (ii) to plan and initiate further analysis and write-up; and (iii) to develop plans for dissemination and further work.

The workshop consisted of a series of focused discussions, individual presentations, and individual work with investigators and resource persons. Discussions focused on issues associated with the questionnaire, defining concepts from items measured in the questionnaire, and addressing ways to integrate findings from the qualitative data into overall findings. Drafts of research papers were developed, based on interpretations of preliminary findings and their programmatic implications. Investigators submitted papers to an upcoming International Union for the Scientific Study of Population (IUSSP) conference, Taking Stock of the Condom in the Era of HIV/AIDS, to be held in Gaborone, Botswana, in July 2003.

Findings from the Kenyan component of the study were presented at the XIV International AIDS Conference held in Barcelona, Spain, in July 2002. The data were collected during 1998–2000 from sexually active individuals in Nakuru district, Kenya. Four male and eight female focus group discussions (FGDs), were conducted, and a household survey consisting of a structured questionnaire was administered to couples comprising 1422 male and female respondents in total (743 men and 679 women; the partners of 64 men could not be interviewed). In-depth interviews were held with 40 survey respondents selected for their high risk behaviours. Findings confirm that HIV/AIDS is perceived as a very serious community problem.

> *"It is a big problem because almost every month we bury someone who died of AIDS. That means that AIDS cases have really increased in this area" (male, rural).*

> *"HIV/AIDS is a very serious problem in this area. You are aware that there are many soldiers here as well as women who are not married. In such a situation, there is no control over sex, and this results in the high spread of AIDS" (male, married, rural).*

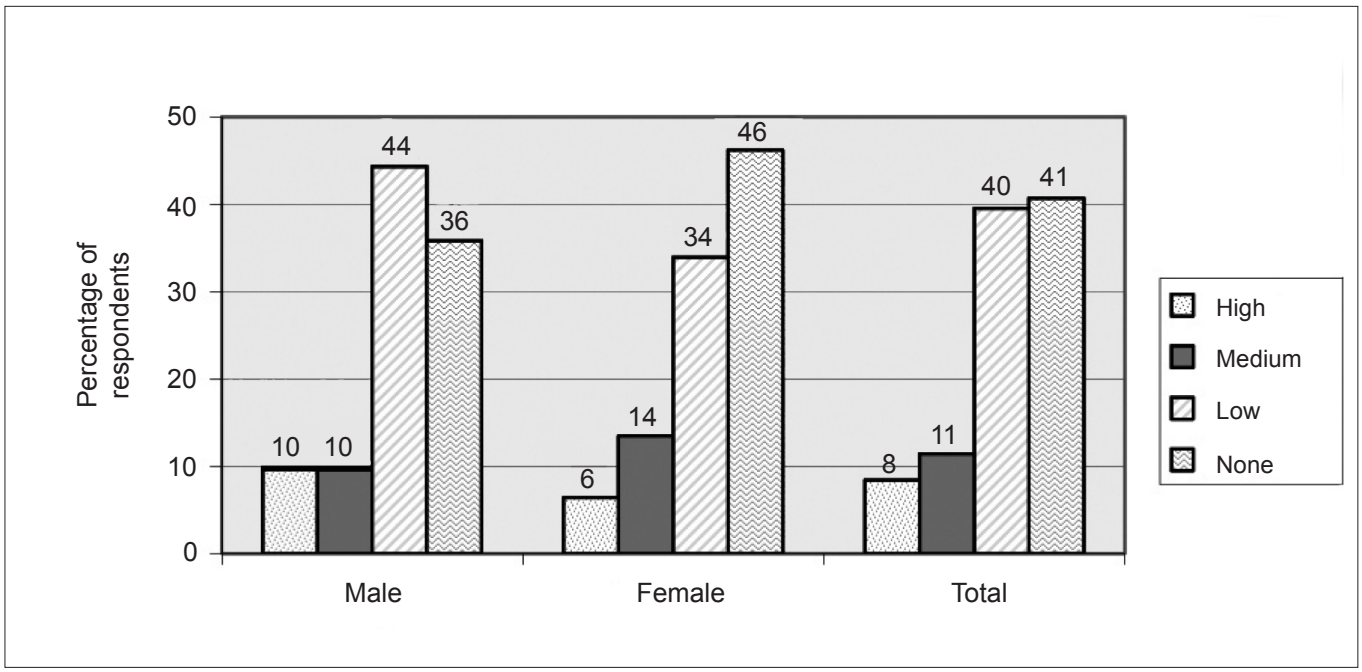
Nonetheless, participants in the study felt their own risk of contracting HIV to be low. Figure 1.1 presents data on study participants' own assessment of their risk of contracting HIV/AIDS. Less than 10% felt that their risk was high and approximately 40% of sexually active individuals felt that they were at no risk of contracting the disease. Although the majority of participants were aware that condom use prevents the spread of HIV/AIDS, condom use was low. Only one in three who had casual sexual partners reported using the condom.

The study concluded that HIV/AIDS is perceived to be highly prevalent and to be a serious problem in the study community. Paradoxically, personal risk of HIV is perceived to be low or non-existent. Individuals recommend condom use to prevent HIV in the community but nevertheless engage in risky sexual behaviour without using condoms themselves. Condom use in long-term relationships is perceived to imply a lack of mutual trust.

Improving family planning services to reduce unwanted pregnancies

Findings from a Chinese study on ways to provide better family planning services in order to improve contraceptive use-effectiveness, and to reduce unwanted pregnancies and induced abortion, were made available in 2002. The background to the study is as follows. In 1993, the Chinese State Family Planning Commission initiated an "informed choice" programme to upgrade quality of care and respond to users' needs and demands. In 1995, the Jiangsu Family Planning

Figure 1.1. Perceived level of personal risk of HIV infection among respondents in Kenya, by sex



Commission conducted a pilot intervention to improve and integrate family planning services with reproductive health care for clients. Four villages in Jiangsu Province were selected to receive the intervention and four comparable villages were selected as controls. About 1000 eligible women in each of the intervention villages and control villages were interviewed in 1993. A follow-up survey was conducted in 1998. As part of the project, providers were given intensive training in examinations, conducting regular follow-ups and in reproductive health knowledge. Service settings and equipment were upgraded and facilities were equipped with televisions, videotapes, handbooks, computers, etc. Clients were provided with tools for informed decision-making, were given information about the proper use of contraceptives, and were provided with a greater choice of modern methods.

Findings demonstrated that, compared to the control villages, women in the intervention villages had a higher percentage of IUD use (78% vs. 65%), and more women shifted from traditional to more effective methods during the experiment. A higher percentage of women chose their contraceptive methods by informed choice compared to the control group (19% vs. 2%) and there was a higher continuation rate of contraceptive use over 60 months (75% vs. 61%). Furthermore, a much lower percentage of women in the intervention group who already had one child had an induced abortion (11% vs. 22%) as a result of lower contraceptive failure and unwanted pregnancy during the experiment. The same model for improving quality of services could be duplicated in other areas. The paper was presented at the Sixth Asia-Pacific Social Sciences and Medicine Conference (APSSAM), in Kunming, China, on 14–18 October 2002.

Understanding women's status and condom use

Findings from a study on "Culture, Gender, Sexual Behaviours and STI/AIDS" conducted in central and west Cameroon among 1679 men and women aged 15–49 years will be published in the next issue of *International Family Planning Perspectives*. The study compared sexual risk behaviours from two very different ethnic groups, the Beti, where relatively permissive sexual norms prevail in society, and the Bamileke, where more conservative mores prevail. Multivariate logistic regression models were used to analyse the effects of women's, men's, and couples' education levels on condom use initiated by women, and the effects of interspousal communication on condom use. In both populations, analyses demonstrate that the probability of condom use increases with men's and women's educational levels. Other factors significantly associated with greater condom use among women include: a smaller age gap between women and their partners; increased frequency of discussion about sexual matters; and increased women's decision-making power within couples. Interestingly, pregnancy prevention was reported as the most common (72%–82%) reason for the use of the condom by both men and women in the two ethnic groups. In spite of the major differences in sexual norms and cultural mores, attitudes toward condom use and sexual behaviours in the two ethnic groups were broadly similar. These and other findings on the relationship between women's status and condom use are noted as being critically important for the development of effective AIDS prevention programmes, irrespective of the ethnicity of the population.

Improving knowledge of STIs and condom use

Further findings from a study on sexual behaviour and condom use in China became available in 2002. The study examined the effectiveness of a video-based reproductive health education intervention in increasing knowledge of STIs and condom use, and in improving attitudes towards condom use among 2266 male STI clients attending a large STI clinic in Shanghai from May to December 1998. Study participants were randomly assigned to one of three groups: (i) regular treatment (control group); (ii) regular treatment and video viewing; and (iii) regular treatment, video viewing, and participating in a discussion group facilitated by a physician. Data on knowledge of STIs and attitudes toward condom use were collected at baseline and at 2 to 3 weeks following the intervention.

Results showed a very significant relationship between higher scores and participating in either the video group or the video and discussion group. The findings indicate that video-based interventions have a significant impact on clients' knowledge of STIs and favourable attitudes toward condom use. Video viewing is an inexpensive, feasible and practical approach to education about STIs and condom use, and shows promise for integration into different STI clinic settings.

Social science research initiative on quality of care

In 2000, a research initiative on quality of care was launched, focusing on supporting research that seeks 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, client satisfaction, or client behaviour with regard to the continuation of contraceptive use). Research that explores quality of care in such relatively under-studied areas of reproductive health as maternal health, providers' perspectives, abortion or STI treatment, was especially encouraged.

Ongoing studies include: (i) the quality of maternal care in Turkey; (ii) provider perspectives on family planning quality of care in Egypt, Peru, and Uganda; (iii) barriers to contraceptive access in Mali and Senegal; and (iv) improving quality of care in STI clinics in Shanghai, China. Results are expected in 2003–2004.

New projects initiated during the year

Quality of care

One new project on quality of care was approved from 13 submissions that were reviewed during 2002.

A number of variables affect the quality of reproductive health services. The main objective of this newly approved Argentinian study is to evaluate the quality of family planning care in three hospitals in Buenos Aires by comparing, among other factors, the experiences of both Argentinian and foreign women. Specific objectives include: (i) defining users' expectations and evaluations of reproductive health services; (ii) assessing the quality of care using the Quick Investigation of Quality (QIQ) method; and (iii) developing new indicators of quality of care as appropriate. The study will use several methodologies. In-depth interviews and structured interviews using the QIQ method will be conducted with 90 clients, 30 per facility, half of whom are migrants. Fifteen providers, including doctors, nurses, and administrative personnel, will also be interviewed. In addition, non-participant observation of the three study sites will be conducted to assess facility conditions, adequacy of supplies, etc.

Social science policy briefs and dissemination of findings

The series of *Social science research policy briefs,* launched in 1999 by the Programme, continued in 2002. 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 these publications.

A brief on the reproductive health information and service needs of young female migrants in China was produced in 2002. The brief is based on a study that investigated the knowledge, attitude, and practice of young female migrants to five large Chinese cities (*Reproductive Health Matters*, 2001, 9:118–127). The methodology was entirely qualitative: 22 focus group discussions and 58 in-depth interviews were conducted with young migrant women. In addition, key informant interviews were conducted with 16 health providers and personnel from floating-population management offices.

Major findings suggest that premarital sex is no longer taboo in the study population and that norms and behaviours are changing; nonetheless, self-reporting of premarital sexual experience is relatively uncommon. Knowledge about contraceptives among female migrants is low, as is method use. Consequently, unwanted pregnancy and induced abortion are not uncommon among the sexually active. Policy recommendations include the need to make reproductive health information and services in urban areas accessible to young migrant workers. Registration offices could provide young migrants with information about family planning methods and services, and employers of migrants could distribute pamphlets produced by the local government family planning and health departments. Finally, urban family planning workers could visit workplaces where large numbers of migrants are employed to offer reproductive health information and services.

Infertility and childlessness in developing countries

In collaboration with Opinion Research Cooperation (ORC) Macro, work has been undertaken on a comparative report on "Infecundity, infertility and childlessness in less developed countries". Demographic and Health Surveys data from nationally representative surveys conducted in 1995–2000 in 47 developing countries were analysed. Data were collected from 495 000 women between the ages of 15 and 49 years. Topics covered in the analyses included the level of childlessness, primary involuntary infertility, self-reported infecundity, secondary involuntary infertility, secondary infecundity, and differentials and trends in childlessness and infertility. Overall, 2.5% of couples in the developing world, excluding China, were estimated to experience primary involuntary infertility. Important regional, socioeconomic, and demographic differentials were noted. Results were presented at the Second Global Conference on Infertility in the Third Millennium: Implications for the Individual, Family and Society, held in Prague, Czech Republic, on 16–17 November 2002. The report is expected to be issued by mid-2003.

Future work plans

In the coming years, the work on users' perspectives will focus on four major activities. First, the results from the multicountry study on "Pregnancy prevention in the era of HIV/STIs" will be summarized and disseminated. Country papers from the study will be presented at the upcoming IUSSP conference, Taking Stock of the Condom in the Era of HIV/AIDS, to be held in Gaborone, Botswana, in July 2003. A report with comparative results and policy implications will be completed for publication and dissemination.

Second, in collaboration with staff of the University of London School of Hygiene and Tropical Medicine, London, United Kingdom, a compendium will be developed to provide comparative information on contraceptive use, continuation and switching in developing countries. This compendium will also provide information on such key aspects as unmet need, unwanted fertility, postpartum contraceptive protection, and antecedents of sterilization.

Third, research proposals on quality of care and on users' perspectives on reproductive health services and technologies will continue to be considered for support.

Fourth, a comparative report on involuntary childlessness and infertility in developing countries will be completed and published.

TECHNICAL COOPERATION WITH COUNTRIES

Technical cooperation with countries in 2002 primarily concerned the research workshop held in Nairobi, described above. Technical assistance was also provided to the State Family Planning Commission of China and its affiliate institutions on the implementation of the Quality of Care project, including activities on informed choice. As part of the team visiting Uzbekistan, the Secretariat participated in discussions on gaps in research and capacity building needs in that country. Missions were also undertaken to China, Thailand and Turkey to respond to requests for technical assistance in social science research on users' perspectives.

Annex 1

SPECIALIST PANEL FOR SOCIAL SCIENCE AND OPERATIONS RESEARCH ON REPRODUCTIVE HEALTH

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	8	89			1	11	9
Women	4	44					4
from:							
AFRO	2	22					2
AMRO	2	22			1	11	3
EMRO							
EURO	1	11					1
SEARO	2	22					2
WPRO	1	11					1

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Annex 2

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Janet Molzan Turan, University of Istanbul, Istanbul, Turkey
Frank Mugisha, Institute of Public Health, Kampala, Uganda
William Muhwava, Union for African Population Studies, Dakar, Senegal
Andrew Mushingeh, University of Zambia, Lusaka, Zambia
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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	32	100					32
Women	15	47					15
from:							
AFRO	13	40					13
AMRO	6	19					6
EMRO	4	13					4
EURO	3	9					3
SEARO	2	6					2
WPRO	4	13					4

Annex 3

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Development of improved and new methods of fertility regulation

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INTRODUCTION

In 2001, the United Nations Population Division reported that approximately 648 million couples worldwide regularly used a method of family planning. Because use does not necessarily mean acceptance, this statistic offers only a glimpse of the behaviours that determine a couple's decision to use a method of fertility regulation. Nearly one-half of users of a reversible method discontinue use within a year, for 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 ambivalence towards modern contraception, especially because of the fear of side-effects, and 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 for fertility regulation provides one of the several interconnecting 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, that are associated with fewer and less severe side-effects, and that 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 a basis for the development of norms, guidelines and other tools for providers and for family planning acceptors.

RESEARCH ACTIVITIES

Emergency contraception

Specific objectives of research

For the past ten years, the Programme has been in the forefront of research on new technologies for emergency contraception. The aim is to improve further the safety, efficacy, acceptability, and ease of service delivery of methods for this indication. After demonstrating the superiority of levonorgestrel (LNG) over the regimen of combined oral contraceptives, the aim was to simplify further the LNG regimen and to compare it to low-dose mifepristone. The efficacy and safety of the copper-IUD and gestrinone are being assessed as alternative methods of emergency contraception.

Progress

Levonorgestrel

Previous research by the Programme has demonstrated that a single 10 mg dose of mifepristone and two 0.75 mg doses of LNG taken 12 hours apart are effective for emergency contraception. A new three-arm, randomized study investigated the efficacy and side-effects of these two methods, compared with a single 1.5 mg dose of LNG, when given up to 120 hours after unprotected intercourse. A total of 4136 women were enrolled at 15 family planning clinics in Asia and Europe. Of 4071 women with known outcome, pregnancy rates did not differ among treatment groups and were 1.6 % in women given mifepristone, 1.5 % in women assigned single-dose LNG, and 1.8 % in women assigned two-dose LNG (see Table 1.1). Side-effects were mild and did not differ greatly between the groups; most women menstruated within two days of the expected date. The results of this ran-

domized, double-blind multinational study were published in *The Lancet* in December 2002. Women and providers can benefit immediately from these new findings, since the now widely accepted LNG-only regimen will become even easier to use in a single dose. Guidelines for emergency contraception need to be modified accordingly.

A double-blind, multicentre study carried out in collaboration with investigators in Hong Kong Special Administrative Region of China compared the effectiveness of two regimens, one with a 12-hour interval between the two doses of LNG and one with a 24-hour interval. The study included over 2000 women; results will be available by mid-2003.

LNG is also being studied in a seven-centre study in Nigeria. The efficacy and side-effects of a one-dose regimen of 1.5 mg will be compared to a two-dose regimen of 0.75 mg taken twice, with a 24-hour interval between doses. This study will include a total of 3150 women and is expected to be completed by the end of 2003. An additional aim of this study is to develop the capacity of the centres to carry out research according to Good Clinical Practice (GCP) standards.

Mifepristone

Based on the above and previous results, mifepristone does not seem to have any advantages over LNG, in terms of effectiveness or side-effects. In addition to more frequent delays in menses, women in the mifepristone group also had a high pregnancy risk after treatment. The research conducted to date suggests that, from the service delivery point of view, mifepristone may be a less feasible and less acceptable method.

To test further the low-dose mifepristone regimen for emergency contraception, the Programme collaborated with Chinese investigators in a three-year initiative funded by The Rockefeller Foundation. Two large multicentre trials were carried out during this initiative.

The first trial, a randomized, double-blind study, compared the effectiveness and side-effects of 10 mg and 25 mg doses of mifepristone among 3052 women in 10 centres. The results of the study indicated that the two doses are equally effective, with a crude pregnancy rate of 1.1%. The treatments led to very few, if any, reported side-effects. Women treated after 48 hours following unprotected sex had a risk of pregnancy 2.3 times higher than women treated within 48 hours (relative risk = 2.3; 95% confidence interval 1.2 to 4.5; p=0.02). The results were published in December 2002 in the journal *Human Reproduction*.

The second trial is a prospective study of the efficacy and side-effects of 10 mg mifepristone among nearly 5000 women in 30 centres. The results are being analysed and should be available in early 2003.

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 antiprogestogenic activity. It is anticipated that, owing to its fairly long duration of action, one dose of gestrinone might be sufficient for effective emergency contraception.

A randomized, double-blind study is continuing 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. Recruitment has been slower than anticipated because emergency contraception is now widely available in China and women do not necessarily come to family planning clinics when they need it.

Mechanism of action studies

Several studies are being undertaken by the Programme's collaborating centres to investigate possible mechanisms of action of emergency contraceptives. A study in Santiago, Chile, is looking at the effects of LNG in the *Cebus apella* monkey. Preliminary results suggest that, if administration takes place before ovulation, ovulation is disturbed; however, the progestogen seems to have no effect on pregnancy rates if it is administered after ovulation has occurred.

Another study in Chile examined the effects of a single 1.5 mg dose of LNG on follicular growth and ovulation in the human. The pharmacokinetics as well as the levels of the steroid in endometrial tissue were examined after oral and vaginal administration. The results should be available in early 2003.

Table 1.1. Efficacy of mifepristone and two regimens of levonorgestrel as emergency contraceptives

Group	Women	Observed pregnancies	Rate
Mifepristone 10 mg	1359	21	1.55 %
LNG 1.5 mg x 1	1356	20	1.47 %
LNG 0.75 mg x 2	1356	24	1.77 %

Six-monthly, non-steroidal, 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.

The research being supported by the Programme in this area is the development of an immunocontraceptive based on, and directed against, hCG. The objective of this work is to develop a long-acting, non-hormonal method of contraception that could provide perhaps as much as six months of protection following a single injection and which would be free of the endocrine and other metabolic disturbances often experienced with long-acting steroid hormone preparations currently on the market and under investigation.

Progress

An application was submitted to the regulatory authorities in Sweden in May 2002 to carry out a Phase I clinical trial with the current formulation of the hCG immunocontraceptive. A manufacturer meeting the required regulatory requirements has been identified and preparation of the clinical trial supplies is awaiting the availability of funds. The initiation of the second stage of the preclinical safety studies, to run in parallel with the first stage of the Phase I clinical trial, is also awaiting the availability of funds. In 2002, the development work on this project was mainly concerned with supporting the forthcoming Phase I clinical trial in Sweden, as described below.

Dose–response studies

Several doses of the new matrix delivery system for the hCG immunogen were tested in rabbits, with each dose administered twice at an interval of 24 weeks. All doses elicited putatively protective levels of antibodies by four weeks which, at higher doses, were sustained for 24 weeks. Tissue reactions were considered to be within clinically acceptable limits.

Adequate antibody levels were also elicited when the dose of the booster injection was half that of the initial injection, with the added advantage that the frequency and severity of the tissue reactions were reduced. These studies are continuing in order to identify the optimal dose regimen.

Stability testing

The immunopotency of the matrix formulation was tested using freshly prepared particles, and particles stored at 4°C for 12 months and for more than 24 months. The antibody profiles elicited by these three batches of materials were nearly identical. Additional testing of material stored for two years is in progress.

Studies for improving manufacturing procedures

Preparing materials for the forthcoming clinical trial has required weighing very small quantities of the matrix particles for the individual doses. To make the weighing easier and more accurate, larger amounts of particles with a reduced loading of immunogens, or the addition of “blank” particles to keep the immunogen dose constant, have been tested.

The expected level of antibody was elicited by these materials but the tissue reactions were greater than those of the standard preparation.

Testing of chimeric peptides in microspheres

During the past two years, studies have been conducted to test the immunogenicity and safety of chimeric immunogen peptides, containing B-cell epitopes of hCG beta subunit and at least one T-cell epitope from tetanus toxoid or measles protein, formulated in polylactide/glycolide microspheres and administered in phosphate buffered saline. This approach requires the preparation of separate microspheres containing adjuvant and the mixing of the two before use. The incorporation of an inorganic salt into the same microspheres as the immunogens might be an alternative to the adjuvant in that this formulation elicits high levels of antibodies that are sustained for several months from a single injection with minimal tissue reaction at the injection site.

New projects initiated during the year

Testing an improved formulation for manufacture

The method currently used to manufacture the hCG immunocontraceptive involves weighing doses of dry particles into sterile syringes and mixing them with the emulsion vehicle (containing the adjuvant compound) immediately prior to injection. The weighing of small amounts of particles is difficult and would not be practical for large-scale manufacturing. Mixing at the time of injection could introduce errors in the mixing procedure or improper dosing.

During the past year, tests have been conducted on the immunogenicity of a fully formulated preparation stored at 4°C for periods of up to 270 days. A test of material stored for 360 days is in progress. The data obtained so far indicate that this preparation is equally immunogenic in rabbits after storage at this temperature for up to 9 months. In addition, no change in the physical appearance of the formulation was noted. These data suggest that it may be possible to prepare a stable preformulated version of the hCG immunocontraceptive which could be developed and provided in a “ready to use” form.

Injectable hormonal contraceptives

Specific objectives of research

A number of long-acting injectable esters of LNG were prepared in a chemical synthesis programme conducted by the National Institute of Child Health and Human Development (NICHD) of the United States National Institutes of Health (NIH) and the Programme, in the late 1970s and early 1980s. One of these, LNG butanoate (LNG-B), is being investigated as a possible improved alternative to depot-medroxyprogesterone acetate (DMPA), which could be used for female and/or male contraception.

Progress

Levonorgestrel butanoate

Discussions have taken place with collaborating agencies and industry in connection with the preparation of supplies of LNG-B for use in pharmacokinetic and pharmacodynamic studies and for comparative efficacy studies with DMPA. Suitable sites have been identified for the bulk manufacture and processing of the steroid. The terms and conditions under which the production of clinical trial supplies will be prepared are under discussion.

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 meets these needs. It has several positive attributes: most steroid hormones are absorbed efficiently through the vaginal wall and can be released from a Silastic ring; the ring can be easily inserted and replaced by the woman herself; it can be worn continuously for a number of weeks; its use is not coitally related; 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. The Programme has discontinued its development of a levonorgestrel-releasing vaginal ring and is planning to support the Population Council's efforts to develop a combined contraceptive vaginal ring.

Progress

The Population Council will launch a Phase III clinical trial of a combined contraceptive vaginal ring that releases 150 µg of nestorone and 15 µg of ethinyl estradiol daily over the course of a year. The initiation of the trial has been delayed owing to the need to establish analytical methods for inprocess quality control and quality assurance assessments for large-scale manufacture. The trial is scheduled to begin in 2004; the Programme is planning to provide support to two clinical research centres.

Basic research on implantation

Specific objectives of research

An anti-implantation or menses-inducing agent is an attractive approach to fertility regulation since it would need to be taken only on one occasion in any menstrual cycle, and then only on an as-needed basis or as a backup method—for example, in the case of condom breakage. Such a method would be free of the logistical problems and side-effects associated with many existing methods of family planning and, because of its infrequent use, should be relatively inexpensive.

A collaborative initiative in the area of basic research in implantation was established in 1998 between The Rockefeller Foundation and the Programme, with financial support being provided by The Rockefeller Foundation and technical oversight being provided by the Programme.

The primary objective is to identify promising leads for development, in eventual collaboration with industry, of novel anti-implantation or menses-inducing agents which would be woman-controlled, effective, safe and acceptable in their mode of administration and their mechanism of action.

The continuing 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 carried out in a network of six centres in Australia, China, Germany, India, the United Kingdom and the USA.

Progress

During the past year, 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 the year

Further studies have been carried out to investigate the spatial and temporal expression of genes and their products in the pregnant and non-pregnant uterus and in the corpus luteum.

Further evidence of an antifertility effect was obtained when antibodies raised against angiogenic factors were administered to monkeys at a fixed and predetermined time

post ovulation. Future studies are planned, involving larger numbers of animals, higher doses of antibodies and a variety of treatment regimens, to further investigate their antifertility potential.

Studies are continuing in all six centres with an emphasis to be placed during this final year of the initiative on the most promising leads in each location.

Basic research on endometrial bleeding

Specific objectives of research

A large proportion of the more than 20 million women using progestogen-only methods of contraception endure the irregularities in vaginal bleeding that these methods induce. This has significant implications for their sexual lives 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. As a result, counselling is the main assistance that women who experience bleeding irregularities can expect from providers. Clearly, there is a need to understand better the mechanisms of menstruation and of irregular bleeding, and how these are affected by contraceptive steroids, particularly progestogens, in order to formulate appropriate treatments and to develop new methods free of these side-effects.

Progress

A 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). Treatment with vitamin E had no beneficial effect on bleeding patterns in the study population. Although treatment with low-dose aspirin often led to a more rapid cessation of prolonged bleeding episodes, significant differences were rarely observed.

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, through the Fertility Regulation Group of the Cochrane Collaboration. The protocol for the review was published in the Cochrane Library Issue 1, 2002, available on CD-ROM and online. The review is ongoing and should be completed in early 2003.

A basic science project, "Studies on the Role of Progestogens in Endometrial Breakthrough Bleeding", was initiated in 2002. It was designed to provide insight into the cellular and molecular mechanisms that underlie progestogen-induced breakthrough bleeding. In the first year of this three-year project, it has been found that progesterone receptors are expressed by human myometrial microvascular endothelial cells in culture, but no changes in cellular gene expression resulted from ligand stimulation of these receptors. Chemokines stimulate the migration and activation of leukocytes, which are important mediators of endometrial breakdown. Additional data from the study have demonstrated that the specific chemokine, fractalkine, is found in uterine luminal and glandular epithelial cells and in decidualized stromal cells, with maximal production occurring in the secretory phase in cycling women. In endometria of women using DMPA or Mirena (the levonorgestrel-releasing IUD), fractalkine was strongly expressed in the decidualized stroma; uterine tissue from women using Norplant exhibited lower-than-normal levels of this chemokine. Fractalkine may therefore contribute to the endometrial fragility seen in women using these methods. Preliminary evidence using a mouse model of menstruation indicates that doxycycline, a broad-spectrum matrix metalloproteinase inhibitor, does not alter the integrity of blood vessels when given from day 5 to day 16 of decidualization, as induced by chronic progesterone exposure.

Male hormonal contraception—clinical and social science research

Specific objectives of research

The family planning community is becoming increasingly aware of the need for, and public-health benefits of, male participation. The Programme has taken a leadership role in the development of male contraceptives, as a step toward the goal of increased shared responsibility in this area. A research agenda in male contraceptive development must identify and exploit the leads that are feasible and show the most promise, such as a hormonal method that suppresses spermatogenesis and produces temporary infertility. The Programme's clinical trials are complemented by acceptability and behavioural research.

Progress

Androgen alone

A Phase III study of the safety and contraceptive efficacy of the injectable androgen, testosterone undecanoate (TU), was initiated in late 2001. This four-year trial will evaluate the effects of a monthly injection of 500 mg TU on the fertility of 1000 men, from 10 centres in China. Volunteers receive monthly injections of TU (1000 mg in the first injection and 500 mg thereafter) and are followed for sperm suppression during the first 6 months (Suppression phase). If sperm concentrations are suppressed to ≤ 1 million/ml, the volunteers continue to receive monthly injections and are followed for contraceptive efficacy for 24 months (Efficacy phase). If sperm concentrations are not adequately suppressed, the volunteer is discontinued from the study; all men who discontinue early for any reason are followed until their sperm concentrations return to levels generally considered to be fertile

(20 million/ml or more). The study is progressing according to schedule, though no preliminary data are available yet (Table 1.2).

Table 1.2. Current status of 1040 volunteers enrolled in Phase III trial of TU alone as a male contraceptive

Study Phase	Number of Volunteers
Suppression (first 6 months)	175
Efficacy (24 months)	681
Early discontinuation:	
Lost to follow-up	45
Change in contraceptive method	35
Inadequate response	34
Missed injection	31
Other	39
Total	**1040**

Androgen/progestogen combinations

This year saw the completion of a Phase II trial to evaluate the suppression of spermatogenesis resulting from the administration of an androgen/progestogen combination, TU + DMPA, to Indonesian men. The study compared the efficacy of the administration of 500 mg TU at 6 week intervals with that of the same regimen of TU combined with 250 mg DMPA administered at 12 week intervals. The combined regimen was more effective than TU alone and suppressed sperm counts to a level of infertility in all study participants. The duration of sperm suppression was longer than anticipated; all volunteers were followed until their sperm concentrations recovered to fertile levels. In order to simplify the injection regimen, lengthen the interval between injections, and determine the lowest effective doses of both TU and DMPA, the study will be revised and expanded when a new formulation of TU is available.

The initiation of a multicentre Phase IIb trial of TU combined with the progestogen norethisterone enanthate (NET-EN) was again delayed due to the non-availability of the study compounds. The protocol has been finalized and negotiations with the manufacturer are ongoing. The study would be funded and conducted in collaboration with CONRAD.

Behavioural and social science research

In conjunction with the clinical trial of the TU + DMPA regimen in Indonesia, a study to assess users' perspectives and acceptability of the study compounds was completed. The study participants and their wives generally found the regimens to be acceptable. Reasons for participating included the opportunity to have a health check and the desire to relieve partners of the responsibility for family planning. Many men did report short-lived pain at the injection site and increased sexual activity and energy levels during the study.

The Programme is supporting a study to pilot test instruments to assess the acceptability of, and mood or behavioural changes following, the administration of the TU + NET-EN regimen as a potential contraceptive in Italian men. Instruments have been developed and validated; preliminary evidence indicates that sexual behaviour and mood are not altered as a result of the hormonal administration. Data collection will be completed in early 2003.

New projects initiated during the year

A protocol to evaluate the pharmacokinetics and pharmacodynamics of a novel formulation of TU is under development. The Xianju Pharmaceutical Corporation, Zhejiang, China, has developed a high-concentration preparation of the steroid; this will allow the injection volume to be halved and should reduce pain at the injection site and improve acceptability. A study of the pharmacokinetics of this formulation in monkeys is under review; the clinical trial will begin once the monkey study is completed (expected to be in 2003).

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 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 required to focus on the unique aspects of their research with implications for male contraceptive development.

Progress

In 1998/99 and 2000/01, the Programme issued calls for proposals for basic science activities targeted toward the identification of a novel male contraceptive approach. The following activities were approved through a competitive peer-review process and are currently ongoing.

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 reproductive ducts to saturate a target antigen, in order to achieve immunocontraception. Results indicate that Immunoglobulin G and Immunoglobulin A do enter the rete testes and prostatic fluids of the mouse and rat. The investigators are

currently using a preparation of sperm surface antigen to immunize male mice and to prepare antibodies that will be used to assess whether sufficient antibody enters the male reproductive ducts to saturate these antigens.

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

In order to characterize and clone a sperm membrane progesterone receptor, the investigators have extracted ribonucleic acid (RNA) from selected human spermatozoa and have performed reverse transcriptase polymerase chain reaction (RT-PCR) on these samples using oligoprimers designed from different regions of the human progesterone receptor RNA sequence. Since it seems that a deoxyribonucleic acid (DNA) transcript corresponding to the specific membrane progesterone receptor is not present in human sperm, post-transcriptional or post-translational modifications of the genomic receptor may occur. The study is now investigating the novelty of the receptor protein.

Anti-spermatogenic effects of luteinizing and thyroid hormones

Data from this pilot study indicate that, in three-month-old Sprague Dawley rats, thyroxin, administered continuously by means of a subcutaneous pump, exerts an anti-spermatogenic effect. Studies are ongoing to determine the optimal doses of the two peptide hormones, with respect to arresting spermatogenesis and maintaining androgen concentrations.

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

Work in the first year of this study has demonstrated that, of 116 infertile men with anti-sperm antibodies, 97% have antibodies against prostasomes. This suggests that prostasomes are a major target for anti-sperm antibodies. Eighty-five per cent of these men had antibodies to proteins of 70–75 kDa; 80% reacted with a protein of 50–55 kDa. These two potential immunogens may therefore be candidates as antifertility targets. Work is ongoing to identify the proteins and genes of interest.

Human sperm mitogen-activated protein kinase 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 in this study. Initial results have demonstrated localization of kinases and their upstream regulators in human sperm. Inhibitors of these enzymes seem to alter sperm motility and ligand-induced stimulation of the sperm acrosome reaction *in vitro*.

Annex 1a

RESEARCH GROUP ON POST-OVULATORY METHODS FOR FERTILITY REGULATION IN 2002

Members

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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

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	4	67	1	17	1	17	6
Women	2	33			1	17	3
from:							
AFRO							
AMRO	1	17					1
EMRO							
EURO			1	17	1	17	2
SEARO	1	17					1
WPRO	2	33					2

Annex 1b

RESEARCH GROUP ON IMMUNOCONTRACEPTIVES IN 2002

Members

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Marc Bygdeman, Karolinska Hospital, Stockholm, Sweden
Richard Elton, Tuscon, AZ, USA
Warren Jones, Flinders Medical Centre, Adelaide, Australia *(Chairman)*
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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	1	10	1	10	8	80	10
Women	1	10			3	30	4
from:							
AFRO							
AMRO					3	30	3
EMRO							
EURO			1	10	3	30	4
SEARO	1	10					1
WPRO					2	20	2

Collaborating agency scientist

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Annex 1c

RESEARCH GROUP ON METHODS FOR THE REGULATION OF MALE FERTILITY IN 2002

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Nukman Moeloek, University of Indonesia, Jakarta, Indonesia
Christina Wang, Harbor-University of California at Los Angeles Medical Center, Torrance, CA, USA *(Chairwoman)*
Frederick Wu, University of Manchester, Manchester, United Kingdom

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	3	27			8	73	11
Women					2	18	2
from:							
AFRO							
AMRO					2	18	2
EMRO							
EURO					5	45	5
SEARO	2	18					2
WPRO	1	9			1	9	2

Subcommittee for the review of male basic science research

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Annex 1d

WHO/ROCKEFELLER FOUNDATION INITIATIVE ON IMPLANTATION RESEARCH IN 2002

Members

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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

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members					5	100	5
Women							
from:							
AFRO							
AMRO					2	40	2
EMRO							
EURO					2	40	2
SEARO							
WPRO					1	20	1

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 2002

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-György Medical University, Szeged, Hungary
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
Horacio Croxatto, Chilean Institute of Reproductive Medicine, Santiago, Chile
Olukayode Dada, Ogun State University Teaching Hospital, Sagamu, Nigeria
Dai Jiejie, Medical Primate Research Centre of China, Kunming, China
Luigi Devoto, University of Chile, Santiago, Chile
Ding Ju-hong, Jiangsu Family Planning Research Institute, Nanjing, China
Robert Garfield, University of Texas Medical Branch, Galveston, TX, USA
Kristina Gemzell-Danielsson, Karolinska Hospital, Stockholm, Sweden
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
Frank Lüdicke, University of Geneva, Geneva, Switzerland
Lena Marions, Karolinska Institute, Stockholm, Sweden
Suneeta 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
Maria Elena Ortiz, Catholic University of Chile, Santiago, Chile
Alenka Pretnar-Darovec, University Medical Centre, Ljubljana, Slovenia
Shi Shao-Qing, University of Texas Medical Branch, Galveston, TX, USA
Song Si, Shanghai Institute of Planned Parenthood Research, Shanghai, China
Wang Jie-dong, National Research Institute for Family Planning, Beijing, China
Wu Shang-chun, National Research Institute for Family Planning, Beijing, China

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	16	57	4	14	8	29	28
Women	10	36	1	4	3	11	18
from:							
AFRO	1	4					1
AMRO	3	11			2	7	5
EMRO							
EURO			4	14	6	22	10
SEARO	1	4					1
WPRO	11	40					11

Annex 2a (continued)

Other scientists

Bao Gui-xia, Shanghai Changning Obstetrics and Gynaecology Hospital, Shanghai, China
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Fang Pei-ying, Wuxi Maternal and Child Health Hospital, Wuxi, China
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Ho Pak Chung, University of Hong Kong, Hong Kong Special Administrative Region of China
Sunesh Kumar, All India Institute of Medical Sciences, New Delhi, India
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

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	9	75			4	33	12
Women	6	50			2	17	8
from:							
AFRO							
AMRO							
EMRO							
EURO					3	25	3
SEARO	1	8					1
WPRO	8	67					8

Annex 2b

RESEARCH GROUP ON LONG-ACTING SYSTEMIC AGENTS FOR FERTILITY REGULATION

Scientists in 2002

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 Bekti Subakir, University of Indonesia, Jakarta, Indonesia

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	6	75			2	25	8
Women	5	62			1	12	6
from:							
AFRO							
AMRO	2	25					2
EMRO	2	25					2
EURO							
SEARO	1	12					1
WPRO	1	12			2	25	3

Other scientists

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
Rebecca Jones, Prince Henry's Institute of Medical Research, Clayton, Australia
Hayet Mansour, Research Centre for Human Reproduction, Tunis, Tunisia
Marion Marsh, Prince Henry's Institute of Medical Research, Clayton, Australia

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	3	50			3	50	6
Women	1	17			3	50	4
from:							
AFRO							
AMRO	2	33					2
EMRO	1	17					1
EURO							
SEARO							
WPRO					3	50	3

Annex 2c

RESEARCH GROUP ON IMMUNOCONTRACEPTIVES

Scientists in 2002

Principal investigators

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

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists					3	100	3
Women							
from:							
AFRO							
AMRO					3	100	3
EMRO							
EURO							
SEARO							
WPRO							

Other scientists

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

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists					11	100	11
Women					1	9	1
from:							
AFRO							
AMRO					5	45	5
EMRO							
EURO					6	55	6
SEARO							
WPRO							

Annex 2d

RESEARCH GROUP ON METHODS FOR THE REGULATION OF MALE FERTILITY

Scientists in 2002

Principal investigators

Kiagus Arsyad, Sriwijaya University, Palembang, Indonesia
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Gu Yi-Qun, National Research Institute for Family Planning, Beijing, China
Chandindrami Handagama, University of Tennessee, Knoxville, TN, USA
Russell Jones, The University of Newcastle, New South Wales, Australia
Maria Cristina Meriggiola, University of Bologna, Bologna, Italy
Nukman Moeloek, University of Indonesia, Jakarta, Indonesia
Zvi Naor, Tel-Aviv University, Ramat Aviv, Israel
Ove Nilsson, Uppsala University, Uppsala, Sweden
Anthony Tan, University of Indonesia, Jakarta, Indonesia

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	5	50			5	50	10
Women					2	20	2
from:							
AFRO							
AMRO					1	10	1
EMRO							
EURO	1	10			3	30	4
SEARO	3	30					3
WPRO	1	10			1	10	2

Other scientists

Elisabetta Baldi, University of Florence, Florence, Italy
Hermann Behre, International Society of Andrology, Halle, Germany
Richard Blye, National Institute of Child Health and Human Development, Bethesda, MD, USA
Cheng Li-Fa, Henan Family Planning Research Institute, Henan, China
Antonietta Costantino, S. Orsola Hospital, Bologna, Italy
Patricia Cuasnicu, Institute of Biology and Experimental Medicine, Buenos Aires, Argentina
Gustavo Doncel, CONRAD, Norfolk, VA, USA
Ralph Heywood, Huntingdon Life Sciences, Huntingdon, United Kingdom
Li Han-Min, Birth-Control Institution, Guizhou, China
Liang Xiaowei, National Research Institute for Family Planning, Beijing, China
Lin Peng, Yunnan Family Planning Research Institute, Yunnan, China
Michaela Luconi, University of Florence, Florence, Italy
Sabrina Ritchie, American Society of Andrology, Walnut Creek, MN, USA
Song Shu-Xiu, Hebei Family Planning Research Institute, Hebei, China
Tong Jian-Sun, Jiangsu Family Planning Institute, Jiangsu, China
Gerhard van der Horst, University of the Western Cape, Bellville, South Africa
Donald Waller, College of Pharmacy, Chicago, IL, USA
Ronald Weiss, University of Ottawa, Ottawa, Ontario, Canada
Wen Ren-Qian, Family Planning Research Institute, Guandong, China
Xiao Hong, Asian Journal of Andrology, Shanghai, China
Yao Kang-Shou, Zhejiang Institute of Planned Parenthood Research, Zhejiang, China

Annex 2d (continued)

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Yu Guobin, Anhui Family Planning Institute, Anhui, China
Zhao Heng, National Research Institute for Family Planning, Beijing, China

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	13	54			11	46	24
Women	2	8			5	21	7
from:							
AFRO	1	4					1
AMRO	1	4			6	25	7
EMRO							
EURO					5	21	5
SEARO							
WPRO	11	46					11

Annex 2e

RESEARCH GROUP ON NATURAL REGULATION OF FERTILITY

Scientists in 2002

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
Hernan Delgado, Institute of Nutrition of Central America and Panama, Guatemala City, Guatemala
Kathy Kennedy, Denver, CO, USA
Pablo Lavin, University of Chile, Santiago, Chile
Nicholas Mascie-Taylor, University of Cambridge, Cambridge, United Kingdom
Cui Nian, Sichuan Family Planning Research Institute, Chengdu, China
Chandrika Subasinghe, The Family Planning Association of Sri Lanka, Colombo, Sri Lanka
Kamani Tennekoon, University of Colombo, Colombo, Sri Lanka

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	6	55			5	45	11
Women	4	36			1	9	6
from:							
AFRO							
AMRO	2	18			2	18	4
EMRO							
EURO					1	9	1
SEARO	3	27					3
WPRO	1	9			2	18	3

Annex 2f

WHO/ROCKEFELLER FOUNDATION INITIATIVE ON IMPLANTATION RESEARCH

Scientists in 2002

Principal investigators

Peter Kaufmann, University of Aachen, Aachen, Germany
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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

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	2	33			4	67	6
Women	1	17			1	17	2
from:							
AFRO							
AMRO					1	17	1
EMRO							
EURO					2	33	2
SEARO	1	17					1
WPRO	1	17			1	17	2

Annex 3a

RESEARCH GROUP ON POST-OVULATORY METHODS FOR FERTILITY REGULATION

Publications in 2002

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Annex 3b

RESEARCH GROUP ON LONG-ACTING SYSTEMIC AGENTS FOR FERTILITY REGULATION

Publications in 2002

Long-acting methods of fertility regulation

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Annex 3c

RESEARCH GROUP ON METHODS FOR THE REGULATION OF MALE FERTILITY

Publications in 2002

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Annex 3d

RESEARCH GROUP ON NATURAL REGULATION OF FERTILITY

Publications in 2002

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Annex 3e

WHO/ROCKEFELLER FOUNDATION INITIATIVE ON IMPLANTATION RESEARCH

Publications in 2002

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Annex 3e (continued)

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Safety and effectiveness of existing methods of fertility regulation

T.M.M. Farley and J. Schmidt

INTRODUCTION

Most of the information on the safety and clinical performance of methods of fertility regulation is generated in developed countries and it is not necessarily appropriate to extrapolate to developing countries. The health and social situations are very different and there may be different interactions with endemic conditions. To address these issues, the Programme carries out research on the safety and effectiveness of existing methods of fertility regulation by reviewing the existing evidence and building the evidence base on the safety and performance of fertility regulating methods in developing countries. Clinical trials leading to product registration are conducted under ideal conditions with carefully screened and monitored volunteers. These may not reflect what happens when the products are made available to a wider population of users, and observational epidemiological methods must be used to study safety and effectiveness under actual conditions of use. The 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 other chapters in the section on Promoting family planning.

Objectives

The overall objectives of the work on the safety and effectiveness 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 priority unanswered questions on existing methods of fertility regulation when used in developing countries.

RESEARCH ACTIVITIES

Progress

Breast cancer and breastfeeding

The Programme supported The Collaborative Group on Hormonal Factors in Breast Cancer in compiling individual patient data from epidemiological studies of breast cancer. The database includes more than 50 000 cases of breast cancer and almost 100 000 women without the disease. The relationships between breast cancer and hormonal contraception, hormone replacement therapy and family history have been investigated. A new analysis addressed the impact of breastfeeding and its duration on breast cancer risk.

Data on 50 302 women with breast cancer and 96 973 controls from 47 studies in 30 countries were used. Women with breast cancer had, on average, fewer births than controls (2·2 vs. 2·6). Furthermore, fewer parous women with cancer than parous controls had ever breastfed (71% vs. 79%), and their average lifetime duration of breastfeeding was shorter (9·8 vs. 15·6 months). The relative risk of breast cancer decreased by 4·3% (95% confidence interval 2·9–5·8; $p<0·0001$) for every 12 months of breastfeeding. There was a decrease of 7·0% (5·0–9·0; $p<0·0001$) for each birth. The size of the decline in the relative risk of breast cancer associated with breastfeeding did not differ significantly for women in developed and developing countries, and did not vary significantly by age, menopausal status, ethnic origin, the number of births a woman had, nor her age when her first child was born.

It was estimated that the cumulative incidence of breast cancer in developed countries would be reduced by more than half, from 6·3 to 2·7 per 100 women by age 70, if women had the average number of births and lifetime duration of breastfeeding that had been prevalent in developing countries until recently. Breastfeeding could account for almost two-thirds of this estimated reduction in breast cancer incidence. The lack of or short lifetime duration of breastfeeding typical of women in developed countries makes a major contribution to the high incidence of breast cancer in these countries.

Bone mineral density and progestogen-only contraception

Worldwide, over 20 million women are estimated to be currently using progestogen-only contraceptives, including injectables, implants, vaginal rings, the levonorgestrel-releasing intrauterine device and oral preparations. Concerns have been raised that progestogen-only preparations can decrease bone mineral density and thus increase subsequent risk of osteoporotic fracture. It is unclear whether any decrease noted with 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 15–19 years and 42–49 years. The younger age group covers the period of maximal bone mass acquisition, and any decrease caused by 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 from a lower level.

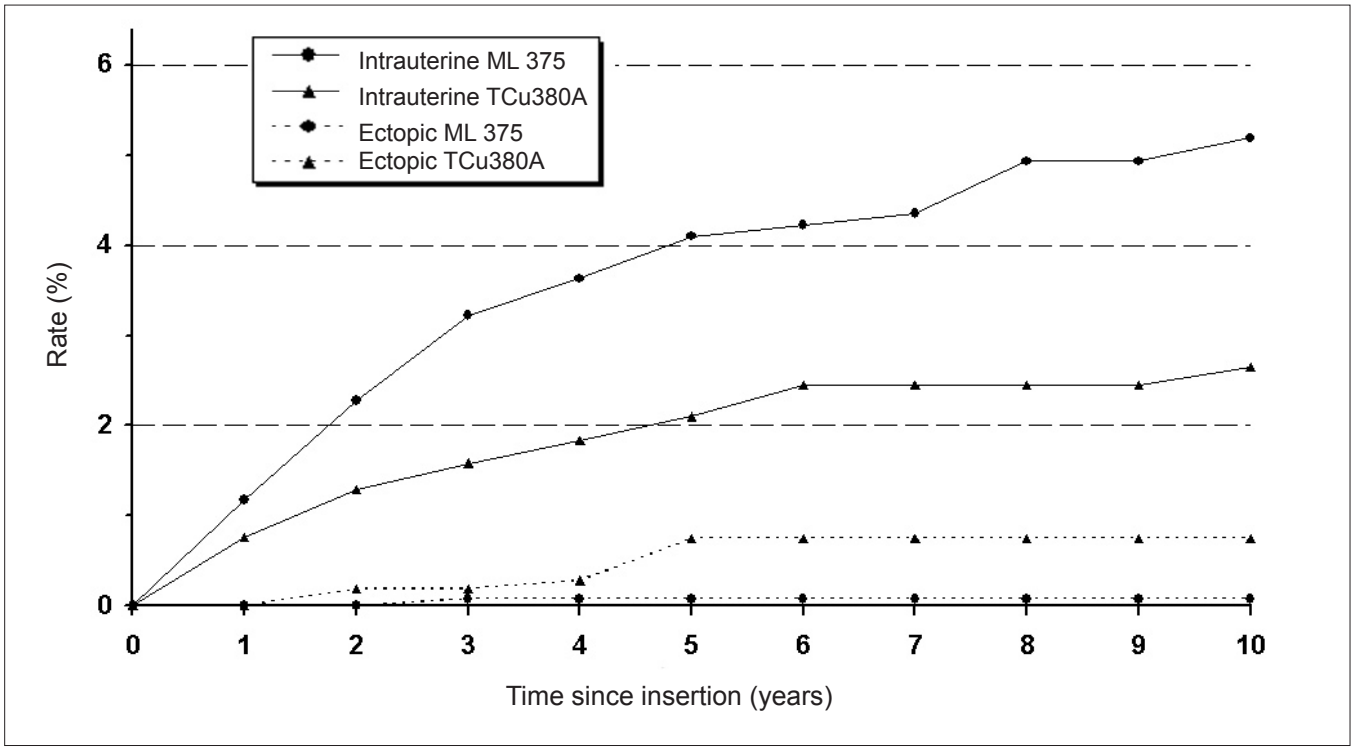
The study has completed recruitment of at least 100 women in each of eight subgroups: depot-medroxyprogesterone acetate (DMPA), norethisterone enanthate (NET-EN), combined oral contraceptive (OC), and non-hormonal method users in each of the two age groups. Most young women in South Africa are given the two-monthly injectable NET-EN, so it was difficult to identify young DMPA users. All women are being followed at six monthly intervals up to five years. Among the younger women, body weight increased by about 2% over one year in all groups, with a greater increase among the combined OC users. There was a slight decline in bone mineral density among the OC users and an increase among the other groups. However, the differences were not significant after adjustment for difference in body weight. Interpretation of these data is difficult since there are large ethnic differences in the composition of the hormonal method user groups.

Long-term safety and effectiveness of copper intrauterine devices

Up to 240 million women worldwide use intrauterine devices (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 TCu 380A device continued. In the period

Figure 1.2. Cumulative intrauterine and ectopic pregnancy rates by device (interim data, cut off July 2002)



1989 to 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 have completed 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 life span of the device from the initial three to ten years. It is anticipated that the 12 and 15 year data will be used to extend the approved life span even further.

The randomized comparative study of the TCu 380A 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, although the intrauterine pregnancy rate with the TCu 380A is about half the rate of the ML 375 device at all times since insertion (Figure 1.2). There were few ectopic pregnancies, none of which occurred beyond the fifth year of use.

Just over half (54%) the women taking part in the trial are in China. These women had an overall continuation rate of 55 per 100 after 10 years of use compared with only 15 per 100 among women from the other countries (Table 1.4). The pregnancy rates with both devices were higher among women in China than in the other countries, consistent with observations from previous multinational research on IUDs conducted by the Programme.

Clinical performance of the levonorgestrel-releasing intrauterine device

The clinical performance of the 20 µg/day levonorgestrel (LNG)-releasing IUD (Mirena) compared with the TCu 380A device is being assessed in a multicentre study involving a total of 3815 insertions. The interim results six years after insertion are presented in Table 1.5. The pregnancy rate for the LNG device is significantly lower than for the TCu 380A, but there is a high rate of device removal for menstrual related reasons, in particular amenorrhoea, with the LNG-releasing device. The overall continuation rate at six years was 42.7 per 100 women for the LNG device and 68.5 per 100 women for the TCu 380A.

HIV and steroid contraception

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

By November 2002, 372 women had been enrolled in Bangkok (Thailand), Harare (Zimbabwe) and Nairobi (Kenya). Recruitment to the study was not possible in Brazil since few patients had CD4+ counts of at least 500 cells/mm^3 and antiretroviral therapy (ART) is available nationally for

Table 1.3. Cumulative net probabilities (standard error) of discontinuation and continuation rates per 100 women at 10 years of use (interim data, cut off July 2002)

	TCu 380A	Multiload 375	P-value
Total pregnancy	3.4 (0.5)	5.3 (0.7)	0.029
- Ectopic pregnancy	0.8 (0.3)	0.1 (0.1)	0.011
- Intrauterine pregnancy	2.7 (0.5)	5.2 (0.7)	0.002
Expulsions	11.2 (1.0)	14.8 (1.2)	0.023
Total medical removals	29.9 (1.4)	28.9 (1.5)	0.80
- Pelvic inflammatory disease	0.4 (0.2)	0.5 (0.2)	0.82
Loss to follow-up	12.7 (1.0)	12.2 (1.1)	0.72
Continuation rate	40.1 (1.3)	37.4 (1.3)	0.14
Woman–years	10,164	10,014	
Number of women completing interval	291	271	

Table 1.4. Cumulative net probabilities (standard error) of discontinuation and continuation rates per 100 women at ten years of use (interim data, cut off July 2002)

	Chinese centres		Non-Chinese centres	
	TCu 380A	ML 375	TCu 380A	ML 375
Total pregnancy	4.0 (0.7)	6.7 (0.9)	2. 1 (0.6)	2.1 (0.6)
- Ectopic pregnancy	0.9 (0.4)	0.1 (0.1)	0.3 (0.2)	-
- Intrauterine pregnancy	3.1 (0.5)	6.6 (0.9)	1.8 (0.6)	2.1 (0.6)
Expulsions	11.4 (1.2)	16.3 (1.4)	9.9 (1.8)	9.8 (1.6)
Total medical removals	20.1 (1.5)	17.5 (1.6)	52.0 (3.3)	53.8 (3.3)
- Pelvic inflammatory disease	-	-	1.6 (1.2)	1.6 (0.8)
Loss to follow-up	5.9 (0.9)	6.8 (1.1)	25.9 (2.7)	21.8 (2.6)
Continuation rate	57.5 (1.7)	52.8 (1.8)	14.9 (1.6)	15.2 (1.6)
Woman–years	6780	6672	3365	3343
Number of women completing interval	238	214	53	57

all patients. The majority of women enrolled use hormonal contraception (primarily DMPA in Nairobi and combined OCs in Harare). Non-hormonal methods are used by 25% of the study cohort. Recruitment will continue to the end of 2003. The rates of CD4 decline are much steeper in Bangkok and Harare than in Nairobi (Figure 1.3), possibly reflecting the impact of different HIV subtypes.

As a result of increasing access to sustainable ART in the study sites, the protocol is being modified to introduce ART in a structured way to women in the cohort as they become eligible for therapy. This will permit a preliminary assessment of differences in clinical response to ART by type of hormonal contraception.

HIV and vaginal epithelium

Progestogen-only contraception has been associated with increased susceptibility to HIV infection. In a study in Umeå, Sweden, to assess the impact of different contraceptive methods on the vaginal epithelium, vaginal biopsies were taken from 15 women using combined OCs, DMPA or Norplant, and from 15 women not using hormonal contraception. The vaginal epithelium was thicker in all hormonal contraceptive user groups compared with controls and exhibited a distended hyperplastic superficial layer. The frequency of intraepithelial vaginal leukocytes was increased in DMPA users compared with controls; a marginal comparitive increase was seen in the Norplant users, and no increase in combined OC users. This difference may reflect a higher frequency of subclinical infections in DMPA users, or behavioural differences between women using the different methods. Full results are expected in 2003.

New projects initiated during the year

Randomized trial of two implantable contraceptives for women

The first paper on a progestogen-releasing contraceptive implant was published in 1969. The first implant, Norplant, was approved in 1983 by the Finnish drug regulatory authority. Norplant is now registered in over 60 countries, and an estimated 11 million women worldwide have used the method. Several newer implant systems releasing different synthetic progestogens have been developed or are under development. Because of the increasing importance of implantable contraceptives for women, the Programme convened an expert consultation on these methods in May 2001. The background papers prepared for this consultation were published in 2002, in the journal *Contraception* (see page 48).

The most extensive data on safety and effectiveness cover the six-capsule levonorgestrel-releasing Norplant device. There have been reports of difficult and time-consuming

removals. Implants with fewer units have been developed, including the two-rod 5-year levonorgestrel-releasing Jadelle and the 3-year single-rod etonogestrel-releasing Implanon. While Jadelle has been compared with Norplant in a moderately sized multinational study, and Implanon with Norplant in a single-country study, there have been no formal comparisons between the two newer devices.

The Programme is implementing a multinational randomized comparative trial of Jadelle and Implanon to determine differences in clinical performance and contraceptive efficacy. Primary endpoints include pregnancy rates, incidence of adverse effects, method acceptability and continuation rates. A total of 2000 women will be enrolled and randomly assigned to use one of the two implants. While non-reproductive system complaints such as headache, dizziness, skin alterations and mood changes are commonly associated with progestogen-only implants, their interpretation is difficult. Therefore, in addition to the implant users, an age-matched cohort of 1000 women who use the TCu 380A IUD will be enrolled in parallel with the randomized study. These women will provide data on the incidence of non-reproductive system complaints in users of a non-hormonal method in order to place the observations from the implant users in context.

Ten sites in nine countries are participating: Australia, Brazil, Chile, China (Beijing and Shanghai), Dominican Republic, Hungary, Thailand, Turkey and Zimbabwe. Preparations for the trial are almost complete and recruitment will start in early 2003 and last up to one year. Final results on the key study endpoints three years after insertion will be available in early 2007.

Structural integrity of female condoms

The high cost of the female condom limits its widespread use. Reuse has been reported by women unable to afford or access an adequate supply of female condoms. WHO convened a consultation in January 2002 to review data on the safety and practicality of reuse (see also page 60) during which the question of the impact of different potential lubricants on the structural integrity of the female condom was raised.

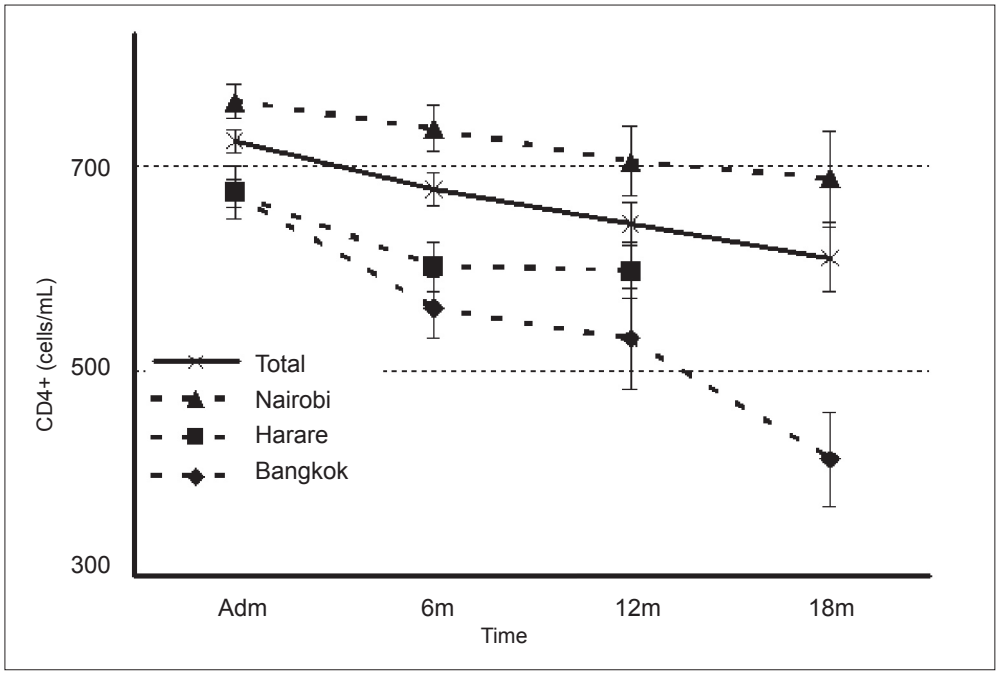
There is limited choice of lubricants available to female condom users. In studies conducted to date, corn oil has been used to relubricate the condoms but it is not known whether this or other potential lubricants have any deleterious effect on the condoms. A study was undertaken to screen a wide range of potential lubricants, including two often used as sexual lubricants (Vaseline and Baby Oil), eleven commonly available household oils (sunflower, olive, corn, coconut, rape seed, palm, grape seed, mustard, groundnut), two fats (lard and shortening) and Canestan Cream (a vaginal antifungal ointment).

Sections of polyurethane film were cut from a single roll and soaked for four days with each lubricant. No samples showed any deterioration in tensile strength compared with controls. The only exception was Canestan Cream, which resulted in a 10% drop in tensile strength, most probably caused by one of the excipients. This decrease is unlikely to affect adversely the female condom in normal use.

Table 1.5. Cumulative net probabilities of discontinuation (standard error) per 100 women at six years of use (interim data, cut off August 2002)

	TCu 380A	20 µg LNG device	P-value
Total pregnancy	2.0 (0.4)	0.5 (0.2)	0.001
- Ectopic pregnancy	0.1 (0.1)	-	0.002
- Intrauterine pregnancy	1.8 (0.4)	0.5 (0.2)	0.162
Expulsions	8.3 (0.8)	7.6 (0.8)	0.52
Pelvic inflammatory disease	0.1 (0.1)	0.3 (0.1)	0.29
Menstrual reasons	11.0 (0.9)	35.8 (1.4)	< 0.001
- Amenorrhoea	0.5 (0.3)	23.5 (1.3)	< 0.001
- Reduced bleeding	3.1 (0.5)	10.9 (1.0)	< 0.001
- Increased bleeding	7.2 (0.7)	5.4 (0.7)	0.085
Total device-related removals	25.6 (1.2)	47.8 (1.3)	< 0.001
Loss to follow-up	7.7 (0.7)	5.5. (0.7)	0.029
Woman–years	7334	6308	
Number completing interval	580	464	

Figure 1.3. Decline in CD4+ cell counts (cells/mL) by centre



Given the wide range of oils tested it is highly probable that any vegetable oil will be compatible with the female condom and further testing is unnecessary. Of greater concern is the potential for certain lubricants to adversely affect the vagina or penis during intercourse.

NORMS AND TOOLS

Specific objectives and targets

Work on the development and dissemination of norms and tools is reported in the chapter on Norms and guidelines for use of methods of fertility regulation, but specific activities undertaken under the umbrella of the work on safety and effectiveness of contraceptive methods are reported here. The relationship between hormonal contraceptives and cervical cancer, and the safety of female condom reuse are reviewed.

New norms and tools developed

Cervical cancer and steroid hormone contraception

The question of whether the use of OCs is causally associated with an increased risk of cervical cancer has been highly controversial. A WHO scientific group concluded in 1990, as part of a comprehensive review of hormonal contraception and cancer, that use of OC for more than 5 years was associated with a modest (1.3- to 1.8-fold) increase in the risk of cervical cancer. However, it was unclear whether that risk reflected a biological relationship or was attributable to other factors, such as differences in lifestyle between contraceptive method users, or patterns of sexually transmitted infections (STIs), particularly with human papilloma virus (HPV). New results published in early 2002 showed that among women who tested positive for HPV infection, those who had used hormonal contraceptives for between 5 and 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. In order to put these new results in a public health perspective, and in the context of evidence from other research regarding the relationship between cervical cancer and hormonal contraception, the Programme convened a consultation in March 2002.

Persistent infection with specific HPV types is now recognized to be the underlying cause of cervical cancer. However, since few women with HPV infection (a common, transient viral infection) ever develop cervical cancer, other factors such as smoking and high parity, are also considered important. Since 1990, studies have shown an increased risk of carcinoma *in situ* and invasive carcinoma in long-term users of combined OCs. The increased risk appears to be confined to women with persistent HPV infection and is thought to be about twice as high after long-term use (5 years or more) of combined OCs.

The consultation recommended no changes in contraceptive prescribing practice or use. The number of cervical cancers that result from OC use is likely to be very small. All contraceptive methods, including OCs, carry health risks as well as benefits. For young, healthy women who do not smoke, the health benefits of OCs far exceed the risks. Many cases of cervical cancer are preventable through use of appropriate screening practices. Where screening services are available, OC users should use them in the same way as other women. However, in many settings screening services are not available; pregnancy-associated morbidity and mortality risks are often high in such settings and combined OCs are one of the

few contraceptive methods widely available. Furthermore, since parity is a risk factor for cervical cancer, use of OCs may reduce the risk of cervical cancer attributable to parity. The consultation concluded that women should not be denied use of OCs simply because they do not have access to cervical cancer screening services. In such settings the risk associated with unwanted pregnancy would likely exceed the risk of cervical cancer for the majority of women.

Female condom reuse

The high cost of the female condom is a barrier to its widespread use. Reuse has been reported by women who cannot afford or have inadequate access to female condoms. The Programme has sponsored research on the practicality and safety of reuse practices in order to provide guidance to programme managers and potential users, and convened a consultation on reuse in June 2000. Following this consultation, new research was initiated on whether female condoms could withstand repeated bleach disinfection, washing and drying, on the minimum bleach disinfection required to inactivate STIs, and on the impact on the vagina of reusing disinfected female condoms. The new data were reviewed at a second consultation in January 2002.

The 2002 consultation revised and simplified the previous protocol on bleach disinfection, washing and drying, and recommended that used female condoms be soaked for a period of 2–5 minutes in a bleach solution of 1:19 household bleach to water (0.25% sodium hypochlorite solution) before further handling. They also recommended that individual female condoms be used no more than five times. A final reuse protocol was issued for adaptation to local conditions. This protocol must be demonstrated to be understandable and safe to apply before female condom reuse can be recommended and promoted in different settings. In many contexts, reuse of the female condom could expose both the woman and her male partner to more risks, particularly if reuse undermined confidence in female condoms, and/or resulted in less use of male condoms or fresh female condoms. In some contexts, promoting reuse may result in more protected acts of intercourse, while in others a reuse protocol would be impossible to apply safely. Decisions about the utility and risks and benefits of introducing a female condom reuse protocol must ultimately be made at the country or local level.

WHO issued a statement in July 2002[1] on the conclusions of the consultation and is developing guidelines on specific practical issues to be considered by programme managers who intend to evaluate the feasibility and applicability of female condom reuse in particular settings.

[1]WHO information update: considerations regarding reuse of the female condom. Available online at: http://www.who.int/reproductive-health/rtis/reuse.en.html

Annex 1

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	4	36			7	64	11
Women	1	9			3	27	4
from:							
AFRO	1	9					1
AMRO	2	18					2
EMRO							
EURO					5	45	5
SEARO							
WPRO	1	9			2	18	3

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Annex 2

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Annex 2 (continued)

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	45	82	5	9	5	9	55
Women	21	38	1	2	4	7	26
from:							
AFRO	7	13					7
AMRO	11	20					11
EMRO	1	2					1
EURO	1	2	5	9	3	5	9
SEARO	4	7					4
WPRO	21	38			2	4	23

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	46	75	5	8	10	16	61
Women	30	49	2	3	4	7	36
from:							
AFRO	1	2					1
AMRO	3	5			4	7	7
EMRO	1	2					1
EURO	1	2	5	8	5	8	11
SEARO	2	3					2
WPRO	38	62			1	2	39

Annex 3

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Norms and guidelines for use of methods of fertility regulation

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

INTRODUCTION

Family planning programmes are facing the challenge of finding better ways to deliver high-quality family planning services to the millions of people who would use family planning if they had access to it. However, many family planning programmes have substantial progress to make in improving quality of care. The Department is contributing to these efforts by creating four cornerstones of evidence-based and consensus-driven guidance for family planning. This new series includes two guidelines—*Improving access to quality care in family planning: medical eligibility criteria for contraceptive use* (referred to as *Medical eligibility criteria for contraceptive use*) and *Selected practice recommendations for contraceptive use*. There are also two tools—the *Decision-making tool for family planning clients and providers* and the *Handbook for family planning providers.* A system has also been created to ensure that this global family planning guidance is based on the best available evidence through a continuous, systematic process of identifying, critically appraising, and synthesizing new evidence as it becomes available.

The creation of evidence-based guidelines and tools alone, while important, is insufficient to assure that family planning services are improved. The ultimate impact of the Department's norms and tools will be contingent on the development of successful strategies for implementation.

OVERALL OBJECTIVE

The overall objective of the Department's work in this area is to create evidence-based and consensus-driven guidance to support the provision of high-quality family planning services globally.

This objective will be achieved by:

- establishing the context for norms and tools within a programme of research for promoting family planning;
- developing the four cornerstones of evidence-based guidance 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;
- developing an implementation strategy for and providing support for countries adopting and adapting WHO's family planning guidance.

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 effectiveness of existing methods;
- to assess the sociocultural and behavioural determinants of successful family planning; and
- to translate available evidence into guidelines that are used successfully 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 both social sciences research and 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 these methods are included in the evidence base. Furthermore, 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.

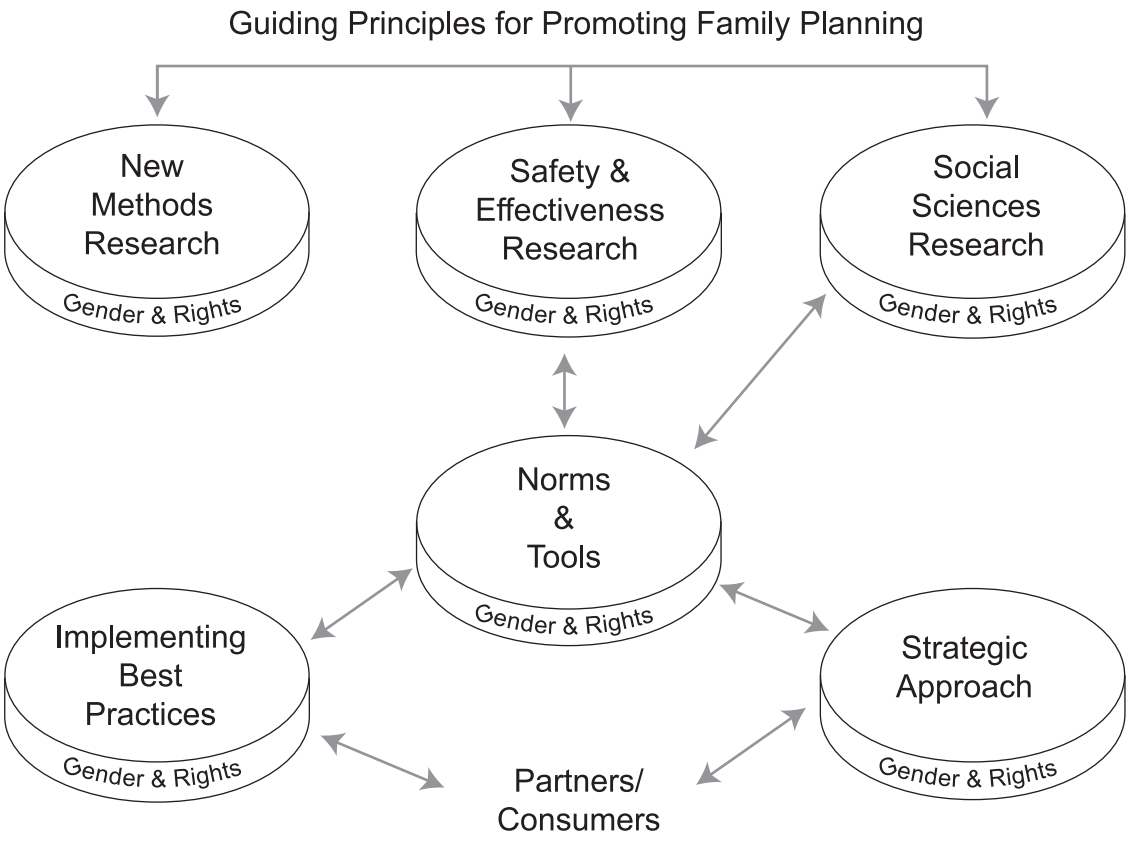
The creation of evidence-based guidelines, while important, is insufficient to ensure the delivery of quality services in family planning. The process of dissemination, adaptation and utilization of guidelines is also critical. Thus, the ultimate impact of guidelines will be contingent on the development of strategies for successfully implementing best practices in family planning. The Implementing Best Practices Initiative and the Strategic Approach to the Introduction of Contraceptive Technologies, discussed elsewhere in this report, are examples of such strategies and are currently being implemented. The needs of users at the country level will, in turn, help determine priorities for creating and implementing guidelines (Figure 1.4).

Developing the four cornerstones of evidence-based guidance for promoting family planning

The *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use* are the first two cornerstones 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, thus providing guidance for guides. The *Medical eligibility criteria for contraceptive use* provides guidance regarding *who* can safely use contraceptive methods. Appropriate medical eligibility criteria are determined for women with over 50 conditions. The *Selected practice recommendations for contraceptive use* provides guidance regarding *how* to use contraceptive methods safely and effectively. Recommendations include instructions on when and how to start contraceptives and what to do in problem situations. These two guidelines will be updated with recommendations from working group meetings in 2003 and 2004, and published by the end of 2004.

The *Decision-making tool for family planning clients and providers* and the *Handbook for family planning providers* are the third and fourth cornerstones of WHO's family planning

Figure 1.4. Schematic presentation of the role of different areas in the development of norms and tools to promote family planning



guidance, and will be derived primarily from the *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use*, but also include best evidence from social science research on how to meet the needs of the family planning client. They are intended to be used during the family planning encounter to improve the quality of care, thus providing 'guidance for health care providers'. These two tools will also be accompanied by an adaptation guide, training package, and client materials.

Creating a system

The *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use* are evidence-based and consensus-driven guidelines. They provide recommendations made by an expert working group based on an appraisal of relevant evidence. They are reviewed and updated in a timely manner.

A system has been developed to assure that this global family planning guidance is created—and maintained—based on the best available evidence (Figure 1.5). This system includes a continuous and comprehensive process of identifying, critically appraising, and synthesizing new evidence as it becomes available. The system is a collaborative effort between the Department, the Johns Hopkins University Bloomberg School of Public Health's Center for Communication Programs (JHU/CCP) and the Centers for Disease Control and Prevention/WHO Collaborating Centre for Reproductive Health (CDC/WHOCC).

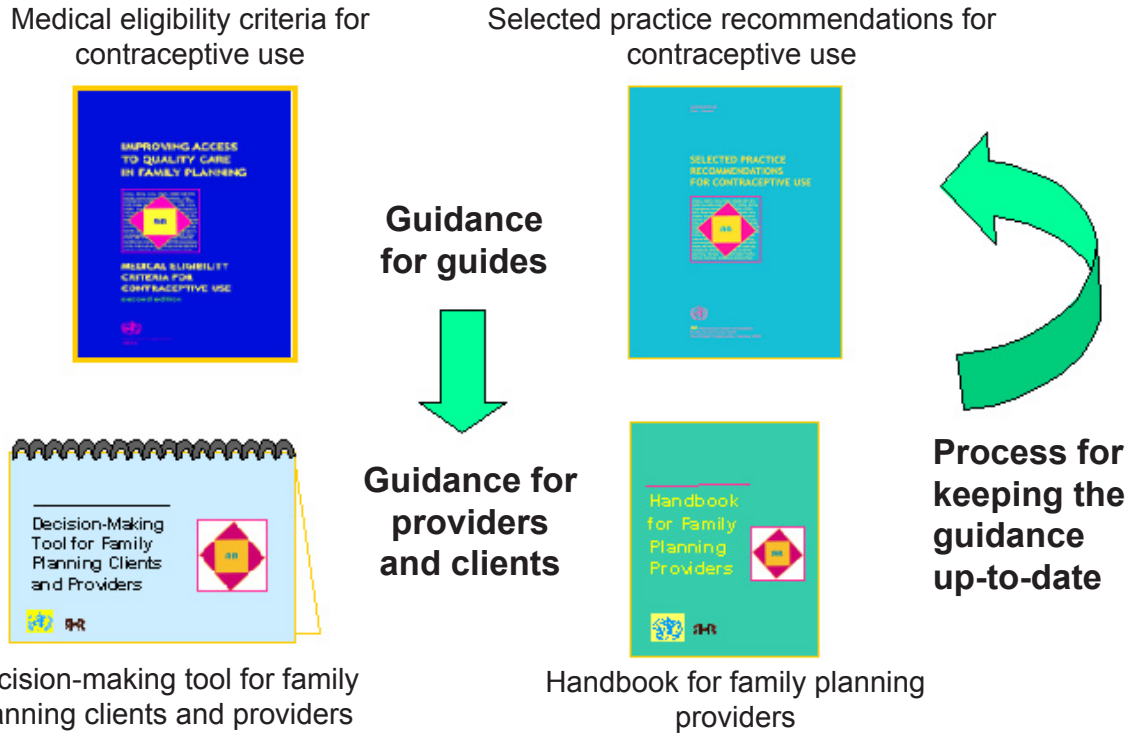
The initial activity of the system will be conducted by JHU/CCP, and will consist of an ongoing, comprehensive bibliographic search using the POPLINE database to identify studies that may be of relevance to the guidance. This will be achieved by: (i) screening input to the POPLINE database (averaging 850 records per month) to identify research reports that may be relevant; (ii) posting bibliographic information to a database; and (iii) categorizing the bibliographic data according to the research issue it addresses.

The second activity of the system will be conducted by CDC, and will consist of: (i) determining which new pieces of evidence are relevant; (ii) critically appraising new evidence; (iii) sending critical appraisals for peer review and subsequently creating final appraisals; and (iv) conducting systematic reviews. CDC will also assist WHO in determining whether the newly synthesized evidence is sufficient to warrant an update of existing recommendations.

The third activity of the system will be conducted by WHO, and will consist of activities i–iv above for CDC, as well as determining whether an update of the guidance is warranted pending the next expert working group meeting to update the *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use.* Updates will be provided electronically pending the next printing of the guidance.

The system was piloted in September and October 2002 and was in full operation by November 2002.

Figure 1.5. The four cornerstones of evidence-based guidance and the system to ensure that the guidance remains up to date and based on the best available science



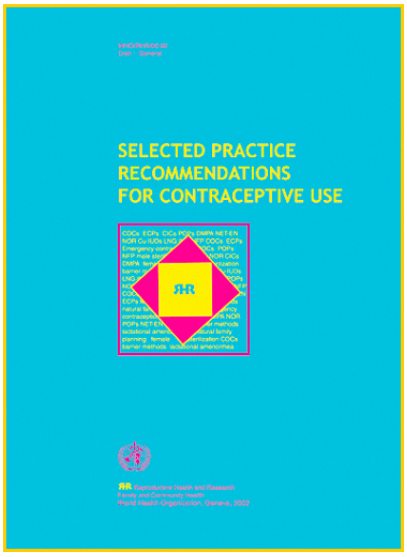
Developing an implementation strategy

To be sure that the guidance has impact on the delivery of services in family planning, the Department needs to provide technical assistance and support for effective implementation, including adaptation of the guidance for local context and training in its use. The Department is therefore committed to strengthening the technical link between the creation and the implementation of its guidance, working with regional and country offices and global partners to assure maximum impact.

While evidence-based guidelines such as the *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use* may require minimal adaptation to be useful at country level, tools such as the *Decision-making tool for family planning clients and providers* invariably require adaptation prior to adoption and use. During 2002, the Department initiated field-testing of the *Decision-making tool for family planning clients and providers* in Indonesia, Mexico, South Africa, and Trinidad and Tobago. Based on this experience, training and adaptation guides for implementation are being developed.

NEW NORMS/TOOLS DEVELOPED: SELECTED PRACTICE RECOMMENDATIONS FOR CONTRACEPTIVE USE

The document *Selected practice recommendations for contraceptive use,* published in 2002, is one of the two key evidence-based, consensus guidelines produced by the Department for improving quality of care in family planning service delivery. Its counterpart, the *Medical eligibility criteria for contraceptive use* addresses *who* can safely and effectively use contraceptive methods, identifying the medical appropriateness of contraceptive choices for women with certain medical conditions, whereas the *Selected practice recommendations for contraceptive use* address *how* to use contraceptive methods safely and effectively. Practical guidance is provided on common clinical issues, for example, what a woman should do if she misses oral contraceptive (OC) pills. Both of these guidelines are developed and revised using a system that ensures an ongoing review of new relevant evidence. When new evidence warrants change, the guidelines are updated electronically pending expert working group meetings and subsequent printed revisions.



The *Selected practice recommendations for contraceptive use* document 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 addressing key common clinical challenges represented by the questions listed below. Indirect evidence or theoretical considerations were not reviewed. 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 OCs?
- What can a woman do if she misses combined OCs?
- What can a woman do if she vomits and/or has severe diarrhoea while using combined OCs 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 progestogen-only pills?
- What can a woman do if she vomits after taking emergency contraceptive pills?
- When can a woman start the progestogen-only injectables depot-medroxyprogesterone acetate (DMPA) or norethisterone enanthate (NET-EN)?
- When can a woman have repeat DMPA or NET-EN?
- What can be done if a woman has menstrual abnormalities when using DMPA or NET-EN?
- When can a woman start using an implant?
- What can be done if a woman experiences menstrual abnormalities using implants?

- When can a copper-bearing intrauterine device (IUD) be inserted?
- What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD?
- What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease?
- What should be done if a woman using a copper-bearing IUD is found to be pregnant?
- Should prophylactic antibiotics be provided 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 follow-up is appropriate for combined OC, progestogen-only pill, implant and IUD users?
- How can one be reasonably sure that a woman is not pregnant?

The companion to this document, the *Medical eligibility criteria for contraceptive use,* has been published in nine languages and used in dozens of countries in the preparation and revision of national service delivery guidelines for family planning. The *Selected practice recommendations for contraceptive use* is expected to have an equally far-reaching impact. The Clinical Effectiveness Committee of the Faculty of Family Planning and Reproductive Health Care of the Royal College of Obstetricians and Gynaecologists, London, United Kingdom, has already met to consider these recommendations and to determine how best to update their current guidance. These recommendations are meant to be adapted as needed for local circumstances prior to adoption. When feasible and appropriate, the Department will provide technical assistance in this process.

NEW WORK UNDERTAKEN ON NORMS/TOOLS UNDER DEVELOPMENT: THE DECISION-MAKING TOOL FOR FAMILY PLANNING CLIENTS AND PROVIDERS

The *Decision-making tool for family planning clients and providers* and the *Handbook for family planning providers* are two tools that are part of WHO's evidence-based guidance for family planning. These tools are designed to be used during the family planning encounter to support both the provider and the client.

The *Decision-making tool* will be derived from and supported by the *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use*. In addition, training and educational materials for clients and providers, and an adaptation guide will be developed to support the tool.

The primary objectives of the *Decision-making tool* are:

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

The guiding principles supporting these objectives are to ensure that:

- the process for family planning decision-making is client-driven and interactive;
- the client's needs *as expressed by the client* are met to the greatest possible extent;
- 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 the process are tailored to the needs of the individual client with provider's statements or actions depending, as much as possible, on the client's previous answer or statement; and that
- the client is enabled to express her/his purposes quickly in the encounter and the provider to respond appropriately.

The *Decision-making tool* has been developed in partnership with JHU/CCP, with technical input from many other experts in reproductive health and health communication. It has undergone expert reviews on the counselling/communication component, as well as the technical information it contains. A field-testing draft was finalized in September 2002 and Phase I field-testing began the following month. Phase I field-testing involves meetings with providers to get initial feedback on the usability of the tool. Phase II will include

initial adaptation or translation, and involve feedback from both the client and the provider. Phase III will include impact evaluation of the use of the tool and be conducted once the tool has been adapted and adopted.

Phase I testing has been undertaken with partner organizations in Indonesia (Sustaining Technical Achievements in Reproductive Health [STARH] Project of JHU/CCP), Mexico (Population Council and JHU/CCP), South Africa (Reproductive Health Research Unit of the University of Witwatersrand), and Trinidad and Tobago (International Planned Parenthood Federation). Phase II began in January 2003 in Indonesia and Mexico. Feedback on the tool from both clients and providers will be obtained using observational techniques, interviews and focus group discussions.

NEW NORMS/TOOLS INITIATED: THE HANDBOOK FOR FAMILY PLANNING PROVIDERS

The *Handbook for family planning providers* will be a companion to the *Decision-making tool for family planning clients and providers*, intended to give in-depth and detailed information for providers on the provision of high-quality family planning services. It will include a comprehensive overview of counselling approaches and messages, and technical information needed not only for family planning, but also for dual protection against pregnancy and HIV/ STIs. The handbook will be based on the *Essentials of contraceptive technology* of JHU/CCP, and will be developed through a consensus process led by WHO and the Implementing Best Practices Consortium. This process will bring together experts in the field to review evidence and to achieve consensus. The group will address, in particular, key controversies and inconsistencies in current guidance to enhance the likelihood that providers are given sound and consistent messages.

This handbook is in the initial planning stages. It will be completed by the end of 2004 and incorporate the latest WHO recommendations from the updates of the *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use*.

Section 2
Making pregnancy safer

Generating new evidence for maternal and perinatal health

J. Villar, M. Gülmezoglu, M. Merialdi

INTRODUCTION

There is widespread 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 underutilized (a gap between evidence and practice). In addition, there is still a lack of preventive action for pregnancy-specific conditions, particularly the leading causes of severe morbidity and mortality (a gap between preventive and curative care). This is in contrast to the major progress made in other areas of medicine in the last decade, such as the mapping of the human genome. The 1998–2003 programme of work was oriented to provide evidence for mapping the best maternal and perinatal health practices. The Department's Scientific and Technical Advisory Group (STAG), supported by the WHO Maternal and Perinatal Health Research Committee, identified maternal health priority research areas, taking into account WHO's advantages such as its credibility and neutrality at country level and its network of collaborating institutions in developing countries.

STAG approved a Programme of Work for Maternal Health Research to be implemented between 1998 and 2003, which is now almost completed (Table 2.1). A detailed description of the progress made in each specific area is presented in the following sections.

RESEARCH ACTIVITIES

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 strategic component is achieved by: (i) evaluating effectiveness of practices; (ii) improving 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.

Progress

Evaluation of 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). The new WHO antenatal care (ANC) model limits the tests, clinical procedures and follow-up actions to those scientifically demonstrated to be effective in improving maternal and newborn outcomes. The selected ANC activities are distributed over four visits during the course of pregnancy. The trial included 53 antenatal care units (24 678 women) randomly allocated to provide either the new programme of antenatal care or the traditional programme in use at that time. The new ANC model was found to be as effective as the standard model, could be implemented without major resistance from women and providers, and may reduce cost.

In 2002, an extensive dissemination effort of the results was conducted, including presentations at several international meetings and symposia and at special regional and country

meetings. The manual for the implementation of the new WHO ANC model was published also in 2002 with other supporting materials and included in a document to be used as a tool for incorporating the results of this research project into services.

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

This multicentre, double-blind, randomized controlled trial compared the efficacy of a single oral dose of 600 µg of misoprostol to an intramuscular or intravenous 10 IU dose of oxytocin in the context of active management of the third stage of labour.

Overall trial coordination was done by the Programme with collaborating centres in Argentina, China, Egypt, Ireland, Nigeria, South Africa, Switzerland, Thailand, and Viet Nam. The results of this trial demonstrate that 10 IU oxytocin (intravenous or intramuscular) is preferable to 600 µg misoprostol taken orally 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. Reports on effectiveness, side-effects, pharmacokinetics, milk concentration of misoprostol and the systematic review of all evidence from randomized controlled trials were published.

During 2002, dissemination of effective strategies to prevent postpartum haemorrhage was carried out. It is now considered that WHO has covered all the research gaps in this area and that a complete set of evidence is now available for implementing programmes for the *prevention* of postpartum haemorrhage. However, the identification of the best *treatments* for this condition remains a challenge to be addressed.

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

Within the framework of a cluster randomization model, the trial evaluated an intervention that consisted of a mandatory second opinion, based on the best available evidence about effective and safe management of childbirth, to be requested before every non-emergency caesarean section.

Thirty-four hospitals from five Latin American countries participated in the trial: Argentina (18), Brazil (6), Cuba (4), Guatemala (2) and Mexico (4). The trial failed to demonstrate a clinically significant reduction in caesarean section rate associated with the intervention in these hospitals. The negative result of the trial has contributed to a delay in the publication of the main results, as is often the case, but efforts are being made to avoid this publication bias.

Data have been collected and analysed regarding the primary outcomes, and women's and providers' opinions about the mode of delivery and the social context of caesarean section in Latin America. Several reports have been submitted for publication in 2002.

Table 2.1. Maternal health interventions with leading participation of the Programme, evaluated up to 2002

	Countries	Women	Status
Antenatal care	4	24 678	Published
Postpartum haemorrhage (prevention)	9	18 530	Published
Treatment of pre-eclampsia*	31	10 141	Published
Caesarean section	5	149 276	Publications submitted
Reproductive Health Library evaluation	2	76 053	Ongoing (evaluation phase)
Prevention of pre-eclampsia (calcium)	6	8500	Ongoing (final recruitment phase)
Prevention of pre-eclampsia (treatment of hypertension)	5	1600	In preparation
Screening and treatment of urinary tract infection	4	18 000	In preparation
Postpartum haemorrhage (treatment)	4	1000	In preparation
TOTAL	25**	307 778	

* The Programme was not responsible for the management of this trial. Hence the countries involved are not part of the total.
* * Some countries have been involved in more than one study.

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

This trial compared magnesium sulfate with placebo for the treatment of women with pre-eclampsia. Primary outcome measures were eclampsia and the death of 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. It was stopped in November 2001 after 10 141 women had been recruited, on the recommendation of the Data and Safety Management Committee who considered that the effectiveness of magnesium sulfate in preventing eclampsia and in reducing maternal mortality had been proved. The trial was the largest ever conducted of anticonvulsants for the treatment of pre-eclampsia, supporting the effectiveness of magnesium sulfate. The results were published in *The Lancet* in June 2002 and disseminated worldwide, including in an editorial jointly published in the *British Medical Journal* by WHO, the International Federation of Gynecology and Obstetrics (FIGO) and the International Society for the Study of Hypertension.

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

The protective effect of calcium supplementation during pregnancy provided to low calcium intake women has been proposed as a promising preventive strategy for pre-eclampsia. It is now being evaluated by the Programme in an adequately sized 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 primary objective of the trial is the reduction of pre-eclampsia.

The trial is being conducted in Argentina, Egypt, India, Peru, South Africa and Viet Nam. A baseline survey of calcium intake of the pregnant populations served by the selected clinics and hospitals in these countries included over 500 women, and demonstrated that the mean calcium intake is less than 600 mg/day, or approximately 50% of the 1200 mg/day dose recommended for pregnant women. The total sample size of the trial is expected to be 8500 women. By December 2002, almost 6500 women had been recruited, of whom approximately 2500 have already delivered. It is expected that the trial will be completed in 2003.

Systematic reviews

Systematic reviews are conducted within the framework of the WHO Programme to Map Best Reproductive Health Practices (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 the reviews. In the area of maternal health care interventions, seven systematic reviews have been updated, and three full reviews and two review protocols have been published following *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 2002 issues of *The Cochrane Library*, and will be included in the forthcoming issues of *The WHO Reproductive Health Library* (RHL). The reviews addressed prophylactic antibiotics during pregnancy; prevention of postpartum haemorrhage by prostaglandins; nutritional interventions (calcium, vitamin A); and care during and after caesarean section (fluids, antibiotics).

Overview of evidence of effectiveness

The Programme was invited to participate in the Wellcome Trust/United States Agency for International Development (USAID) initiative, Nutrition as Prevention Strategy Against Adverse Maternal Pregnancy Outcomes, and to prepare, as background documents, two overviews of systematic reviews of nutritional interventions during pregnancy to prevent and treat maternal morbidity, mortality, preterm delivery and intrauterine growth impairment. The meeting was intended to produce the guidelines for future strategies in maternal health to be implemented by those agencies. The two overviews have been accepted for publication in the *Journal of Nutrition* in 2003: *Nutritional interventions during pregnancy for the prevention or treatment of maternal morbidity and preterm delivery: an overview of randomized controlled trials*; and *Nutritional interventions during pregnancy for the prevention or treatment of impaired fetal growth: an overview of randomized controlled trials*.

Improvements in 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. A sample of 1600 pregnant women and all antenatal care providers participating in the trial were included. The two main papers of this component were published in 2002. The results showed that clients and providers generally accepted the new WHO antenatal care model. These publications have been incorporated in the full set of documents of the WHO Antenatal Care Trial and are now being disseminated.

The economic evaluation of a rational package for ANC 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. Its overall aim was to assess whether the new programme of ANC 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 in the cost–effectiveness estimates for the countries that took part in the economic study, and to assess the 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.

Individual reports from each participating centre were published during 2001–2002. A paper reporting the main findings was submitted for publication to a leading health economics journal and results were distributed to the participating institutions for implementation of the recommendations.

Review of research methodology related to maternal health

Heterogeneity in meta-analyses of randomized controlled trials

An evaluation of the statistical tests used to evaluate heterogeneity of trial results in meta-analyses was initiated in 2002. Results of this unique research work in statistical sciences will be available in 2003.

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

This activity was conducted in collaboration with the Department of Epidemiology and Biostatistics, University of Western Ontario, London, Ontario, Canada. Utilizing the experience gained in the WHO Antenatal Care Trial, work continued on statistical issues related to trial design, sample size and power calculations. One methodological paper was accepted for publication and will be published in 2003.

Clinical trials methodology

The WHO multicentre randomized controlled trial to evaluate the use of misoprostol in the management of the third stage of labour (see above) presented special methodological challenges. The methods of sequence generation, allocation concealment and blinding used in this trial were described in a paper that also describes 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 developing country settings. A similar strategy is going to be used in the multicentre trial evaluating treatment for asymptomatic bacteriuria in pregnancy. All trials planned are inspired by the principle that it is better to collect 10 times less data in 10 times more patients.

Methodology for meta-analysis of observational studies

Work is being done on the methodology of meta-analysis of observational studies, to be applied in the systematic review of mapping the magnitude of maternal ill-health (see below). Programme staff participated in two workshops on Meta-analysis of Observational Studies organized by l'Institut de la Santé et de la Recherche Médicale (INSERM) in France. Two methodological papers are to be published in 2003.

Follow-up studies of populations included in pregnancy-related research

The possibility of intrauterine programming of diseases that appear later in life, including various chronic conditions, continues to attract considerable interest. The hypothesis arose from the results of observational studies, most of them conducted among populations from developed countries. However, there are concerns about the methodological limitations of these epidemiological studies, which used data from hospital records from decades ago and included only small numbers of intrauterine growth-retarded newborns. There are also concerns over inconsistencies in the results. The Programme is exploring some of these issues 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 pre-adolescent children born to women enrolled in a previously conducted 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 late 2001 with a loss of follow-up of less than 10% of eligible children, 12 years after the children were born. Contrary to the results of previous follow-up studies, no effect on blood pressure as related to calcium supplements was observed. These observations are in agreement with a recent systematic review and reflect the inconsistency in results which has affected this research based on the Barker's hypothesis or Fetal Origins of Adult Disease hypothesis. A paper has been submitted for publication.

Follow-up of the "MAGPIE" trial study population

This is a follow-up study of children born to mothers enrolled in the "MAGPIE" trial up to two years of age. Growth, development and morbidity will be evaluated. External funding has been obtained from the United Kingdom Medical Research Council and other donors and this will be complemented by the Programme's support to three collaborating centres in developing countries (Colombia, Cuba, and Nigeria).

Evaluation of the implementation strategies of research results

A randomized controlled trial to evaluate a programme promoting evidence-based medicine based on RHL

In order to evaluate the uptake of information from RHL and 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).

Implementation of the new ANC model

The new WHO ANC model uptake has been positive with independent implementation under way in several countries. In Thailand, the implementation of this model will be monitored and evaluated in Khon Kaen after one year of implementation to assess the scale of success and any barriers to implementation.

Stimulation of 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 knowledge of pathophysiology 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. Considerable efforts will be needed in implementing basic research aimed at understanding their pathophysiological processes, in order to identify new preventive strategies.

Therefore, in collaboration with a network of institutions in both developing and developed countries, a new comprehensive research and service programme entitled "Global Programme to Conquer Pre-eclampsia–Eclampsia", based on the concept of systematic reviews and priority research areas, was launched. Implementation started in 2002. The initial phase includes the preparation of systematic reviews on screening of pre-eclamspia, promising etiological and pathophysiological hypotheses to be tested in future research, and treatment recommendations, including recommendations to treat impaired fetal growth. One of these reviews was conducted during 2002 and the results are currently being summarized and prepared for publication. The second systematic review will be initiated during 2003.

To address the issues of impaired fetal growth, a conference is being organized to consider a multinational effort to generate international reference fetal growth standards. A proposal has been submitted to The Rockefeller Foundation and a protocol prepared. This will be a WHO inter-cluster research effort and will involve the Department, the Department of Nutrition for Health and Development, and the Department of Noncommunicable Diseases Prevention and Health Promotion.

Mapping the magnitude of maternal ill-health

The systematic review of epidemiological evidence for maternal morbidity and mortality

The Department's activities in maternal health research are concentrated on the prevention of maternal mortality and its leading causes. In addition, a systematic review of epidemiological data, that became available between 1997 and 2002, is being conducted (for details, see the chapter on Monitoring and evaluation). This unique systematic review will be completed during 2003.

Global monitoring system of maternal and perinatal health

This project aims to create a network of randomly selected institutions that will monitor maternal and perinatal health services worldwide, using a simplified data collection instrument. These surveys will focus on one issue at a time and will be repeated periodically, e.g. every two years. The first survey will be conducted in 2003 and will focus on the relationship between the mode of delivery and perinatal outcomes.

Radiation and reproductive health: assessment of reproductive health in relation to radiation exposure around the nuclear test site in Semipalatinsk

Radiation has the potential to influence reproductive outcome negatively in three ways. Direct irradiation of the embryo or the fetus could influence the outcome of the pregnancy and/or the health of the baby and could have carcinogenic effects which become manifest in later life. Irradiation of the gonads can lead to genetic effects, which in turn could affect the health of the offspring. Irradiation of the gonads can also affect fertility, through radiation-induced death of germinal cells. However, very few data are available on this subject which has important implications for the reproductive health of people with occupational or accidental exposure to radiation.

The Programme, the Institute for Cancer Research in the United Kingdom and the Research Institute for Radiation Medicine and Ecology in Kazakhstan collaborated on a major research effort, launched in 2001 with financial support of UNFPA, to investigate the consequences for reproductive health of exposure to radiation in the area of Semipalatinsk in Kazakhstan. This study is a retrospective comparative assessment of reproduction-related health effects caused by exposure to radioactive fallout from nuclear weapons testing in the Semipalatinsk region. This area was a nuclear weapons testing site from 1947 to 1989, which resulted in considerable radioactive contamination of large territories, and in radiation exposure to the inhabitants of Semipalatinsk. Identification of source documents and data collection were initiated in 2002.

The study focuses on outcomes of three time windows of exposure that are of particular concern with regard to reproductive health: fertility and birth outcomes in relation to radiation exposure before or during reproductive age; infant and child mortality in relation to exposure *in utero* and in early life; and infant and child mortality in unexposed children from exposed parents (genetic effects). It is a longitudinal investigation of an unselected group of people in exposed and control settlements who were alive at the time of the highest exposure levels (i.e. when potential radiation-induced reproductive health effects would have been most severe). It studies various reproductive health measures and will provide analyses of these measures according to individual radiation doses. It is one of the largest studies yet undertaken on reproductive health in relation to exposure to nuclear fallout.

From research to action

Concern has been expressed at the difficulties of transforming research results into improved practice. In this context a project was initiated, called “From Research to Action”, that includes active large-scale dissemination at local level of the main results of the research projects conducted by WHO and the operational or other research methodologies needed to facilitate or evaluate the implementation processes. In 2002, for example, efforts to introduce the new WHO ANC model began in Argentina, Brazil, Chile, Cuba, Ethiopia, Haiti, Italy, Oman, Pakistan, Spain, Syrian Arab Republic, Thailand and Zambia. In seven of these countries (Brazil, Chile, Ethiopia, Haiti, Oman, Syrian Arab Republic and Zambia) the request to initiate local implementation came spontaneously from ministry officials or health care managers after they learned about the new model from the scientific literature.

The new WHO ANC model has been formally introduced to all national offices of FIGO and the Royal College of Obstetricians and Gynaecologists in the United Kingdom. A formal online interactive course for training staff worldwide in the introduction of the new WHO ANC model is under preparation in collaboration with experts from the Boston University School of Medicine, Boston, MA, USA, and will be implemented during 2003. It is planned that this on-line approach will also be applied to the dissemination of the research results of the “MAGPIE” and misoprostol/oxytocin trials during 2003.

New projects initiated in 2002

A randomized controlled trial evaluating strategies for the treatment of postpartum haemorrhage

In developing countries, as many as 40 maternal deaths per 100 000 births in rural areas are caused by postpartum haemorrhage. Preliminary studies have suggested that a promising strategy of drug treatment for this complication would be misoprostol used together with oxytocin. Centres from Africa that are part of the WHO collaborative network of research institutions, and the Medical Research Council of the United Kingdom, are developing a protocol for a comprehensive programme to address the issues of effectiveness, risks, and optimal dosage of misoprostol in the treatment of postpartum haemorrhage. Systematic reviews of randomized and non-randomized trials have been prepared. A multicentre randomized trial to evaluate the effectiveness of misoprostol for the treatment of postpartum haemorrhage is being prepared for implementation in Gambia, Nigeria, South Africa, and Zambia. The trial will be coordinated by local institutions with technical support and funding from the Programme.

A randomized controlled trial evaluating strategies for the routine screening and treatment of urinary tract infection during pregnancy

With technical and financial support from the Programme, activities are being developed by a collaborating centre in Thailand to implement a comprehensive programme for evaluating the most effective strategies for screening, laboratory procedures and treating urinary tract infection during pregnancy. The research programme will include all the methodological steps from the systematic review of publications evaluating screening techniques, which has now been completed, to the implementation of a clinical trial and health service research (including cost analysis) of different screening and treatment modalities. Preparatory activities were initiated during 2002 and the trial will be implemented during 2003.

Ancillary and explanatory studies to the WHO trial of calcium supplementation in low calcium intake women for the prevention of pre-eclampsia

The Steering Committee of the WHO trial of calcium supplementation approved three ancillary studies that will provide important data to explain the results of the main trial. These studies will be conducted as independent initiatives of the collaborating centres, with consultants from the Baylor College of Medicine, Texas, USA, the University of Cincinnati, Ohio, USA, and the Universidad Catolica de Chile, Santiago, Chile, taking part. The studies will focus on the relationship

between calcium supplementation and fetal growth, fetoplacental blood flow and markers of pre-eclampsia and calcium metabolism. All of the studies are funded mainly by external agencies through competitive grant proposal mechanisms.

The future

The Programme and its network of collaborating centres completed in 2002 most of the maternal health research approved by STAG for the 1998–2003 period. The first challenge for 2003 is to complete this programme fully and satisfactorily, including some of the medium-priority areas for which funding was not initially available.

The second challenge remains how to transfer this knowledge into practice in many developing countries. The process of dissemination of knowledge and increasing service coverage to all pregnant women remains a major challenge of the interphase between research and practice.

The third challenge is to implement and maintain long-term capacity building efforts in maternal health research, allowing countries both to conduct their own priority research and to be part of global initiatives. Initial efforts began in 2002.

The fourth challenge is to complete, and incorporate into RHL, the maternal morbidity and other systematic reviews of observational data begun in 2002. This requires identifying and tabulating available information, applying the best statistical techniques for pooling observational studies, and disseminating the results through RHL.

The fifth challenge is even more formidable. There is still a considerable gap in the understanding of most of the specific pregnancy-related conditions, which hinders the implementation of effective prevention programmes. One example is the case of pre-eclampsia/eclampsia. The pathophysiology of this disease remains largely unknown and there are no effective preventive and curative strategies other than delivery. Large numbers of pregnant women are treated with antihypertensive drugs for moderate hypertension during pregnancy, although the effectiveness of this therapy is unclear. The “Global Programme to Conquer Pre-eclampsia-Eclampsia” is aimed at this gap.

The sixth challenge—severe morbidity, such as chronic anaemia, fistulae, gynaecological infections, pyelonephritis, chronic renal diseases, chronic pelvic pain and uterine prolapse—affects large numbers of women. Some of these conditions can be prevented or treated effectively, while for others considerable epidemiological, etiologic, therapeutic and health service research is needed. There are no effective preventive measures for preterm labour and prelabour rupture of membranes, pregnancy-specific conditions that are leading causes of newborn morbidity and mortality. These conditions (associated with up to 24% of all neonatal deaths) are related to infections in most epidemiological studies. Yet randomized controlled trials have failed to demonstrate the effectiveness of maternal antibiotic treatment in their prevention in the general pregnant population or among those with laboratory evidence of infection.

Finally, recent evidence from developed and developing countries suggests intra- and inter-generational effects of pregnancy-related events. For example, there is evidence of an association between obstructed labour and short stature, as well as fetal malnutrition and chronic diseases in adult life. The latter effects, if confirmed in populations from developing countries, could have great importance for those countries in their epidemiological transition, where ischaemic heart disease is already the second most common cause of death.

This short review demonstrates that although health services at all levels can now incorporate effective treatments and emergency medical and surgical strategies to reduce maternal mortality and severe morbidity, there is still an alarming lack of scientific understanding of pregnancy-specific conditions. This is particularly true for conditions related to the prevention of leading causes of morbidity and mortality. The review also points to the lack of a good understanding of the epidemiology of these conditions in developing countries.

In summary, the challenges that are expected to be faced in the next mid-term programme of work are:

- to identify gaps in knowledge by means of systematic reviews and to conduct the required research;
- to evaluate alternative mechanisms for changing medical practices which could contribute to closing the gap between evidence and practice;
- to initiate long-term research capacity building focused on maternal and perinatal issues;
- to implement the global epidemiological surveillance system of maternal and perinatal morbidity in developing countries; and
- to contribute to the scientific effort of moving from palliative care to prevention of pregnancy-related conditions, which is the goal of public health.

Annex 1

RESEARCH GROUP ON MATERNAL AND PERINATAL HEALTH IN 2002

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	3	33			6	66	9
Women	1	11			4	44	5
from:							
AFRO	2	22					2
AMRO	1	11			1	11	2
EMRO							
EURO					3	33	3
SEARO							
WPRO					2	22	2

Annex 2

SCIENTISTS IN 2002

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	21	66			11	34	32
Women	11	34			5	16	16
from:							
AFRO	2	6					2
AMRO	9	28			4	13	13
EMRO	4	13					4
EURO					7	22	7
SEARO	4	13					4
WPRO	2	6					2

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Implementation of evidence-based programmes

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INTRODUCTION

The Making Pregnancy Safer (MPR) initiative represents WHO's strengthened contribution to the global safe motherhood movement. It emphasizes the importance of improving health systems in order to attain long-term sustainable and affordable results in improving the well-being of women and newborns. In line with the United Nations Millennium Development Goals (MDGs), the goal of MPR is to contribute to the improvement of maternal and newborn health. The specific targets are to contribute towards the reduction of the maternal mortality ratio by three-quarters between 1990 and 2015, and to contribute to the reduction, by two-thirds, of under-five mortality by 2015, through reduction in the number of newborn deaths.

Work in MPR consists of: (i) conducting research to map effective interventions and improve the quality of services; and (ii) providing normative guidance and technical support to countries for the development, implementation and evaluation of cost-effective interventions to reduce maternal and newborn morbidity and mortality. This latter component is called *Implementation of evidence-based programmes.*

Work is being undertaken at both WHO headquarters and country level through WHO regional and country offices, in close collaboration with partners. During the past year, *Implementation of evidence-based programmes,* the subject of this document, has involved: (i) developing tools and guidelines based on research findings; (ii) assisting countries in introducing them to achieve a genuine shift from outdated approaches to best practices; (iii) developing appropriate strategies for working with women, their families and communities; and (iv) providing technical support to build institutional capacity at both national and regional levels to develop and effectively manage gender-sensitive programmes that are responsive to the countries' needs.

STRATEGIC FOCUS

During the past year, the MPR team continued to develop and refine further the overall strategy and vision of the Making Pregnancy Safer initiative. The *Making pregnancy safer—strategy paper for discussion* will be finalized in 2003, reflecting the areas of focus described below.

Global action for skilled attendants for pregnancy, childbirth and the newborn

In 2002, MPR prepared an advocacy document proposing a global movement for increasing access to skilled attendants during pregnancy, childbirth and the postpartum period for which five strategies and five stakeholders have been identified: the 5+5 strategy (Figure 2.1).

The availability of skilled staff to provide effective coverage both overall as well as for the more disadvantaged and under-resourced populations is the most challenging issue for developing countries and one where support is needed.

A joint document on skilled attendants, being developed with the International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM), will be published in early 2003. Contacts have also been established with the private sector and philanthropic organizations to explore their interest and possible commitment towards championing a global movement for enhancing levels of skilled care for pregnant women and their newborns.

Individual, family and community issues in maternal and neonatal health

In 2002, a concept and strategy paper, *Working with individuals, families and communities* (IFC) *to improve maternal and*

Figure 2.1. Global action for skilled attendants for pregnant women: the 5+5 strategy

newborn health, was produced by the MPR global team and key partners. The aim of working at the IFC level is to contribute to the empowerment of women, men, families and communities to improve maternal and neonatal health, as well as to increase access to and utilization of quality skilled care. Strategies have been identified that target the factors known to contribute to health inequities and poor maternal and neonatal health, as have been a set of promising interventions, as identified from the literature and field experiences. This area of work will be incorporated into the larger MPR strategy and workplan, and related concepts integrated into MPR research as well as norms and tools. In 2003, discussions will continue with regions and countries to strengthen their efforts in this area.

Maternal and neonatal health and poverty

Work began to better understand and delineate the relationship between maternal and neonatal health and poverty. The findings of this work will be formulated into a policy that aims to ensure the wider coverage of maternal and neonatal health to include marginal and poorer segments of society. It will also identify cost-effective interventions and strategies, as well as delineate the benefits of investing in maternal and neonatal health, especially as a supporting activity in the overall framework of poverty reduction strategies. Collaboration is being established with the World Bank and the United Nations Population Fund (UNFPA). A report and policy briefs will be developed in 2003, drawing from approximately 12 background papers.

Cost–effectiveness studies of maternal and neonatal health interventions

The MPR team is currently working in collaboration with the WHO Effectiveness, Quality and Costs (EQC) team within the Department of Global Programme on Evidence for Health Policy in reviewing and conducting cost–effectiveness studies of maternal and neonatal health interventions listed in *The WHO Reproductive Health Library* (RHL) (both those that are cost-effective and those that are expensive with small or negative effects on health). This work is intended to provide policy-makers with information on the cost–effectiveness of maternal and neonatal health services that will enhance decision-making and improve planning of services. The EQC team is currently compiling data on costs and effectiveness from 17 subregions in the world that have been grouped on the basis of epidemiology, infrastructure and economic situation. It has been decided to begin by conducting cost–effectiveness studies of a set of 12 *marker interventions for making pregnancy safer (Table 2.2).* These marker interventions have been drawn from the list of interventions in RHL for which there is the highest level of evidence and without which it will not be possible to ensure the health and survival of mothers and newborns; additionally, the marker interventions can be measured through most health information systems. The underlying assumption in choosing these interventions as markers is that, if these interventions are in place, other beneficial forms of care are also likely to be available. Conversely, if these marker interventions are not in place, the level of care offered will most likely be inadequate. This work will continue in 2003.

Maternal and neonatal health in the context of health sector reform—case studies

There is a need to share lessons and develop an experience-based framework on successfully integrating maternal and neonatal health issues into health sector reform efforts. Through the development of case studies, MPR intends to see if and how maternal and neonatal health issues have been adequately included in the design and implementation of health sector reforms. This document will include vignettes (constraints, lessons learnt and success stories) from selected countries, and will highlight policy and/or operational issues to be considered when designing, developing, implementing and evaluating health sector reforms for making pregnancy safer. The literature review and selection of countries to be included in the case studies was completed in 2002. The case studies, as well as the report and policy briefs, will be finalized in 2003.

Developing health systems profiles

The MPR initiative is making efforts to increase the knowledge base and understanding of key elements of health sys-

Table 2.2. The 12 marker interventions for making pregnancy safer

	Intervention
1.	Women have social support during labour and birth
2.	Breastfeeding is initiated within one hour after birth
3.	Every newborn is immediately dried and kept warm to protect against hypothermia
4.	The WHO antenatal care package is used for all pregnant women
5.	Magnesium sulfate is used to treat severe pre-eclampsia and eclampsia
6.	A partogram is used to identify obstructed labour
7.	Oxytocin is used for all women as part of the active management of third stage of labour
8.	Antibiotic prophylaxis is used for women undergoing caesarean delivery
9.	Manual vacuum aspiration is used for management of incomplete abortion and induced abortion up to 12 weeks of amenorrhoea (in circumstances where it is not against the law)
10.	The kangaroo mother care of skin-to-skin contact is used for all low birth weight babies
11.	Assisted delivery (including caesarean section) is performed in cases of obstructed labour
	Where malaria is endemic or HIV-prevalence is high, other markers may be added:
12a	All pregnant women receive Intermittent Preventive Treatment for malaria during pregnancy
12b	All pregnant and postnatal women and newborns sleep under insecticide-treated bed nets
12c	All pregnant women are offered voluntary counselling and testing for HIV. Women who are HIV-positive are provided with specific interventions to reduce HIV transmission to their infant and relevant care and support. Women who are HIV-negative are counselled on how to remain uninfected.

tems, such as laws, policies, socioeconomic, sociocultural and demographic parameters, before developing and implementing maternal and neonatal health programmes. MPR is developing health system profiles in order to lay the basis for monitoring progress later and evaluating achievements as needed. Health system profiles will also enable easier comparison within and among countries using appropriate parameters and procedures. In 2002, work commenced on Ethiopia, Indonesia, Mozambique and Nigeria. The health system profile template will be finalized for adaptation and use for planning purposes by other countries in 2003. It is also planned to make the health system profiles available on the MPR web site.

Mapping midwifery services in the world

The MPR team began efforts in 2002 to compile data on midwifery services worldwide. This work will enable more detailed analysis of service coverage, equipment and staffing patterns of health facilities, adequacy of policies and regulations regarding midwifery, and quality of data. It will assist in identifying gaps that may exist and inform decisions on models of care needed to provide quality midwifery services. It is expected that the work will help in the benchmarking of numbers of skilled attendants at birth, as well as indicating countries where more in-depth analysis related to midwifery services is needed.

The work in this area will be conducted in close collaboration with countries, WHO regional offices and country offices and other WHO departments, such as Health Service Provision, as well as partners such as ICM, the International Council of Nurses (ICN), FIGO and relevant nongovernmental organizations (NGOs). The database will be established and a draft report will be completed by the end of 2003.

NORMATIVE TOOLS AND GUIDELINES

Based on available evidence, the MPR team has, in close collaboration with partners, developed a number of normative tools and guidelines. These are meant for countries to use to improve quality of care. They include clinical, training and managerial tools and other materials, as described below.

Clinical tools and standards

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

This manual was published in 2001 to give skilled providers at the referral level knowledge on managing complications in pregnancy and childbirth, and to assist them in making rapid clinical assessments and decisions. United Nations agencies and professional organizations have endorsed the document. Worldwide distribution continued in 2002 with translations into French, Indonesian, Laotian, Russian and Spanish. The Arabic and Chinese translations will be completed in 2003. Several regional workshops have been held in order to plan introduction of the manual at country level with governments and professional organizations. The plans also contemplate the revision of national standards of care and monitoring of changes in providers' practice. Additional workshops are planned for 2003.

Managing newborn problems: a guide for doctors, nurses and midwives

This manual provides protocols to assist health care providers at the district hospital in making rapid clinical assessments and decisions, and implementing effective clinical interventions for preterm newborn infants including those with life-threatening conditions. It was prepared in collaboration with Maternal and Newborn Health/Johns Hopkins Program of International Education in Gynecology and Obstetrics (JHPIEGO). Consultation and review with experts from more than 30 countries were held throughout the development process during 2002. Printing and distribution is expected in early 2003.

Pregnancy, childbirth and newborn care: a guide for essential practice

This is a practice guide for clinical decision-making and also for preventive measures at home and in the community. It sets out WHO recommendations for essential routine and emergency care for women and newborns during pregnancy, childbirth and the postnatal period, as well as for post-abortion care. It also integrates the management of malaria, HIV, anaemia and tuberculosis in connection with maternal and neonatal health care. It is intended for skilled attendants at all levels of health care, with a special focus on the primary care level. The guide is also foreseen to be useful to trainers and educators for integrating essential care into national curricula and in-service training programmes.

In 2002, reviews were completed and finalized. The layout and navigation tools to facilitate its use have been improved. Workshop materials for introduction of the tool were also developed and tested with providers in pilot areas. A draft adaptation guide has also been developed to assist countries in adapting the tool to country needs and circumstances. The tool will be published in mid 2003.

Handbook for communicating and counselling for pregnancy, childbirth and newborn care

The aim of this handbook is to assist health care providers to communicate effectively and counsel for decision-making on the key information from the *Pregnancy, childbirth and newborn care: a guide for essential care*. A first draft was developed in 2002 emphasizing a self-learning approach for communication and counselling. The document is to be field-tested in early 2003, and will be reviewed by regional representatives and other experts in the field. A final version will be available by December 2003.

Standards for maternal and neonatal care

The *Standards for maternal and neonatal care* is a generic guideline aimed at establishing evidence-based standards of care during pregnancy, childbirth and the postpartum period. The document, developed in collaboration and consultation with a number of departments, regions and experts, is intended for policy-makers and programme managers at national, district and facility levels. It will help countries to define their own standards for maternal and neonatal care.

In addition to discussing clinical standards, the document has been expanded to include a set of health service delivery standards. Issues related to the role of individuals, families and communities and the interface between health services and the community will also be strengthened.

Internal and external advisers reviewed the document in 2002. Publication is expected for 2003. Subsequently, technical assistance will be provided to countries in adapting and implementing the standards, including, where appropriate, incremental adaptation. The standards will be updated regularly as new evidence becomes available.

Kangaroo mother care (KMC): a practical guide

This guide was developed in 2002, drawing on the experience gained over the last 20 years. It provides practical advice on when and how the KMC method can best be applied. It is intended for health professionals caring for low-birth-weight and preterm newborn babies in first referral hospitals with limited resources. It also provides decision-makers and planners at the national and local levels with essential information for deciding on the appropriateness of KMC for their health system and identifying what is required to implement it successfully. The finalized version of the guide has been printed and a limited number of copies were distributed in 2002. Broader dissemination is planned for early 2003.

Guideline on prevention and control of maternal and congenital syphilis

An existing *Guideline on prevention and control of maternal and congenital syphilis* presents the magnitude of the syphilis problem worldwide, and guidance on its prevention and

control in pregnancy. The recommendations of this guideline are included in the other MPR norms and tools.

During 2002, under the leadership of the Department's team on "Controlling sexually transmitted and reproductive tract infections", a consultation was held in Geneva, Switzerland, to review several articles on maternal and congenital syphilis that are to be published in a special issue of the *Bulletin of the World Health Organization*. The guideline was also reviewed and it was decided that a shorter and updated version should be produced in 2003 (for details, see the chapter on Controlling sexually transmitted and reproductive tract infections).

Clinical guidelines for management of pregnant women with HIV

During 2002, the MPR team worked in close collaboration with the Controlling sexually transmitted and reproductive tract infections team to finalize the *Clinical guidelines for management of pregnant women with HIV*. The objective of these guidelines is to facilitate the integration of the prevention of mother-to-child transmission (MTCT) of HIV into countries' existing health care systems. The guide was field-tested in 2002 and will be published in mid 2003.

HIV inventory and reference guide on HIV

During 2002, the MPR team collaborated with the Department of HIV/AIDS on the development of a guide provisionally entitled: *Reference guide on HIV-related care: treatment and support for HIV-infected women and their children*. This guide focuses on formal global recommendations developed and endorsed by WHO and the US Center for Disease Control and Prevention (CDC). It will be published in 2003.

Strategic framework for malaria control during pregnancy in the WHO African Region

During 2002, the MPR team worked in close collaboration with the WHO Roll Back Malaria (Malaria in Pregnancy) team and the WHO Regional Office for Africa (AFRO) to finalize the *Strategic framework for malaria control during pregnancy in the WHO African Region.* The framework aims to contribute to the achievement of the Abuja goal of 60% coverage of pregnancies with Intermittent Preventive Treatment and insecticide-treated nets by 2005. The tool provides policy-makers and national programme managers with guidance on prevention and case management of malaria in pregnant women, still the main adult target group in Africa. An English version was finalized in 2002 and will be published in early 2003. Translation into French and Portuguese is expected in 2003. Also, detailed guidelines will be developed as a companion document during 2003.

MPR will also collaborate to develop a framework on *Monitoring and evaluation of malaria during pregnancy* at the health facility level. This tool will be pilot-tested in 2003.

Surgical care at the district hospital

During 2002, the MPR team worked in close collaboration with the Department of Blood Safety and Clinical Technology to develop a manual on *Surgical care at the district hospital.* This manual provides practical guidance on surgical procedures that are commonly performed by non-specialist clinicians working in first-level referral hospitals with limited resources. The objective of this manual is to improve the quality of surgical care, particularly in essential procedures in surgery, obstetrics, gynaecology, orthopaedics, anaesthesia and trauma. Field-testing of the manual will begin in 2003.

Training tools

The revised WHO midwifery education modules

This set of manuals was initially designed to assist teachers to improve the skills of midwives in dealing with major obstetric problems as well as to strengthen their skills for working with the community. The set has been updated to be in line with new evidence, to better integrate issues related to HIV prevention and to ensure consistency with the MCPC manual. A new module on *Management of incomplete abortion—education material for teachers of midwifery* has also been developed to complete the set. The completed revised set will be available in the early part of 2003.

Strengthening midwifery toolkit

In addition to the above revised WHO midwifery education modules, MPR has developed a toolkit for assisting policy-makers and decision-makers at the national level in dealing with wider aspects of strengthening midwifery. The toolkit consists of six separate guidance documents, each dealing with a different aspect of work that is critical for strengthening midwifery. There is also a simple needs assessment tool for helping users to prioritize actions. The full toolkit includes:

- Strengthening midwifery: a background paper including an appendix containing a simple needs assessment tool
- 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
- Competencies for midwifery practice guidelines for the development of programmes for the education of midwife teachers.

The kit will be available for dissemination and use in the first half of 2003.

MPR education and training strategy and tools

MPR is developing a strategy for improving health practitioners' performance. The framework underpinning this strategy is being developed with the Child and Adolescent Health and Development Department with input from other departments within WHO and from JHPIEGO.

In addition, MPR is collaborating with the Department of Child and Adolescent Health and Development in the production of a set of tools for strengthening the capacity of teachers of health practitioners. They are intended for national capacity building workshops, especially in areas of training. This tool set will be available in mid-2003 as a printed publication and in a CD-ROM package.

Management tools

The MPR team continues to work in active collaboration with partners to develop management tools and approaches to assist countries in ensuring that health programmes respond to the needs of women and newborns, especially the poor and vulnerable. Building on existing materials and efforts related to health systems development, this work will continue in 2003 and culminate in a series of tools.

Beyond the numbers: reviewing maternal deaths and complications for making pregnancy safer

In 2002, work began to revise and update a draft guideline on investigating maternal deaths and complications of pregnancy. The revised document, *Beyond the numbers: reviewing maternal deaths and complications for making pregnancy safer,* is for health planners, managers and other health professionals. The specific objectives of the guide are: (i) to describe a range of approaches to the investigation of maternal deaths, and (ii) to provide guidance on the selection of appropriate approaches to different settings and circumstances. The ultimate aim of these approaches is to increase awareness and knowledge of the causes of maternal mortality and pregnancy complications so that appropriate action can be taken in terms of improved quality clinical care, increased access to services, improved service management, etc. The approaches can be applied at community, facility, district or national level. Case studies from a wide range of countries are also provided as examples. The guide has undergone extensive review in 2002 and will be published in 2003.

MPR planning guide

The *MPR planning guide* is intended to assist health managers and planners to better plan and implement key interventions for maternal and newborn health. It will help them to select the most relevant processes, methods and tools and adapt these to their own capacities, resources and local context. The guide will address health systems requirements, in line with the WHO health systems performance framework, and will complement the clinical tools of the Department. It will describe the planning processes including budgeting, monitoring and evaluation. A first draft of the guide will be completed and field-tested in 2003.

MPR planning workshop manual

The *MPR planning workshop manual* will assist district managers and planners to conduct a workshop for the development of an operational district maternal and neonatal health health plan. The manual is intended to be user-friendly and comprises a pre-workshop manual as well as a workshop guide that includes materials for the participants. A first draft was completed, technically reviewed and field-tested during 2002. It will be used as accompanying material to the *MPR planning guide.* Both documents will be field-tested together during 2003.

MPR—essential health technology package

The *MPR—essential health technology package* builds on the *Mother-baby package: costing spreadsheet*, and is being developed in close collaboration with the Department of Organization of Health Service Delivery and the WHO Collaborating Centre for Essential Technologies for Health in Cape Town, South Africa. It is a CD-ROM software package for resource planning of the maternal and neonatal health interventions recommended in the Essential care practice guide and the *Standards for maternal and neonatal care*. The package is designed to assist resource planning through simulations of needs assessment analysis, procurement, technology management, and cross-departmental planning. Field tests of a simplified generic version began in 2002. The package will be technically reviewed by experts and finalized in 2003, with country adaptation in several of the MPR spotlight countries.

Health and human rights assessment tool for maternal and neonatal health

Under the leadership of the Department's Gender and Reproductive Rights (GRR) team, the MPR team has collaborated in the development of a tool that uses a rights-based approach to assessing and addressing the legal, policy, regulatory and practice aspects that influence maternal and neonatal health. A focus for technical support to countries will be on capacity building to use human rights as a framework for integrating maternal and neonatal health issues in national development plans. Field-testing of the tool has begun in Switzerland and will begin in Mozambique in 2003 (for details, see the chapter on Gender and reproductive rights in reproductive health).

TECHNICAL SUPPORT TO COUNTRIES

A major thrust of the work of MPR is to provide technical and policy support to countries for the development, implementation and evaluation of national plans to improve maternal and neonatal health and thereby reduce maternal and newborn morbidity and mortality. Activities continued in the 10 MPR spotlight countries, and have been increasingly implemented in other countries. These activities build on existing in-country efforts to improve maternal and newborn health.

This section summarizes progress and achievements made through the provision of support by the MPR teams (in WHO Headquarters, regional and country offices) at the policy and strategy level, as well as at the programme development and implementation level.

Policy and strategy

At the policy and strategy level, support provided to countries has: (i) contributed to increased political commitment for maternal and neonatal health in national health and development plans and; (ii) reviewed/established national and regional policies and strategies to ensure that issues related to maternal and neonatal health are adequately and strategically addressed. In this regard:

- In addition to official government declarations reaffirming the priority of making pregnancy safer in national health plans, assessments of laws, policies and regulations have commenced to identify barriers to priority maternal and neonatal health services in all ten MPR spotlight countries (Bolivia, Ethiopia, Indonesia, Lao People's Democratic Republic, Mauritania, Mozambique, Nigeria, Republic of Moldova, Sudan, and Uganda), as well as in such countries as Albania, Kazakhstan, Turkmenistan and Uzbekistan. In the latter four countries, efforts have been made to change policy in order to ensure free emergency obstetric care. In the Republic of Moldova, following the revision of the legal framework for the provision of post-abortion care, a decision was made to issue additional regulation in order to ensure the wide use of manual vacuum aspiration. This is in addition to ensuring that maternal and neonatal health services become part of the basic package of services in the compulsory health insurance scheme provided by the Government.

- In Indonesia, groups of village midwives, "Bidan Di Desa" (BDD) were trained, mainly with support from the World Bank. During the period under review (2002), support has been provided to review the staffing situation of maternity facilities and identify gaps, and introduce the IMPAC tools in order to update the skills of trained village midwives. As a result of policy dialogue initiated at the country level with MPR support, a presidential decree (No. 77/2000) allowed the three-year BDD contracts to be renewed twice, rather than only once, effectively postponing a decision concerning the future of BDD. One immediate consequence of this decree has been that about 50 000 BDD have been placed so far in villages. Recently, the policy was revised again to allow BDD to renew their contracts without limit, provided the Government deems their performance to be adequate. This will aid the Government's efforts to integrate village midwives into the public, government-paid health care system. The objective set by this country and by Sudan is to achieve a coverage of one midwife for every village by the year 2006.

- National and sub-national Reproductive Health/Safe Motherhood strategies have been reviewed, developed and are currently being implemented in countries such as Albania, Bolivia, Cambodia, China, Djibouti, Ethiopia, Indonesia, Kazakhstan, Lao People's Democratic Republic, Mauritania, Mongolia, Morocco, Mozambique, Nigeria, Papua New Guinea, Philippines, Republic of Moldova, Sudan, Tunisia, Uganda, Uzbekistan, Viet Nam and Yemen. Efforts are also under way in AFRO and in the WHO Regional Offices for Europe (EURO) and the Western Pacific (WPRO) to develop adolescent sexual and reproductive health strategies.

- Fruitful dialogue with the Council of Europe has led to the development of a draft document on maternal morbidity in which it is recommended that countries in the European Region implement MPR as a key strategy to enhance maternal and neonatal health, and reduce maternal-newborn mortality and morbidity. AFRO has developed an advocacy tool for MPR in 2002, using the REDUCE model, that includes policy briefs, leaflets, videos and presentation slides. The tool is targeted at policy-makers and decision-makers to raise awareness and resources for maternal and neonatal health in countries. It has been further adapted for national use in Mauritania, Mozambique, Nigeria and Uganda. The WHO Regional Office for South-East Asia (SEARO) published policy guidance and information kits. In the Eastern Mediterranean Region, Sudan conducted a series of workshops for policy-makers at national level and in pilot states/districts. Technical workshops for policy-makers from 11 countries in the Region of the Americas have been held on effective maternal and neonatal health interventions, including that of essential obstetric and neonatal care, and on the importance of increasing the proportion of births attended by skilled attendants.

Strengthening of maternal and neonatal health programmes

MPR team efforts have contributed to the extension of safe motherhood programmes beyond the 10 MPR spotlight countries, the strengthening of existing maternal and neonatal health programmes and, in many countries, the expansion of national geographic coverage of maternal and neonatal health services.

- National Programme Officers or Focal Points for MPR have been established at the ministries of health in the following countries to ensure improved coordination and accelerated implementation of maternal and neonatal health plans: Bolivia, Ethiopia, Kazakhstan, Lao People's Democratic Republic, Mauritania, Mozambique, Nigeria, Republic of Moldova, Sudan, Uganda and Uzbekistan.

- Support has been provided to increase the numbers of skilled attendants in several countries: (i) in Haiti, the WHO Regional Office for the Americas (AMRO) assisted with the reopening of the School of Midwifery; (ii) in Sudan, student intake in the long-term national training plan for midwives has increased from 300 to 1755 per year; (iii) revision or strengthening of midwifery curricula has been ongoing in 2002 in Bangladesh, Lao People's Democratic Republic, Mozambique and Sudan; (iv) in the Syrian Arab Republic, efforts have been ongoing to improve the skills of health workers in neonatal resuscitation, control of newborn infections and health care of newborns in critical conditions; and (v) EURO and AFRO conducted MPR training of trainers workshops in essential obstetric care and life-saving skills in several countries.

- Efforts have begun to disseminate, adapt and use IMPAC tools (such as *Managing complications of pregnancy and childbirth* and *Essential care practice guide*) in several countries in 2002. This has required the review of national norms, standards and protocols in Albania, Bangladesh, Bolivia, Cambodia, China, Indonesia, Kazakhstan, Kyrgyzstan, Lao People's Democratic Republic, Mongolia, Nepal, Nigeria, Philippines, Republic of Moldova, Sudan, Tajikistan, Uganda, Uzbekistan and Viet Nam.

- Assessments of provider performance and quality of services have been conducted in Bolivia, Republic of Moldova and Sudan. Plans to enhance provider skills were developed in these countries in 2002. EURO has also developed assessment follow-up tools for training, which have been field-tested in the Russian Federation, while building regional capacity through the participation of seven other countries in the use of these tools. In Afghanistan and Djibouti, activities have focused on improving health staff skills in emergency and standard obstetric case management, particularly in rural areas.

- Training on maternal death audits has been implemented in Cambodia, China and Mongolia to improve management and provision of maternal and newborn services. SEARO held a regional consultation on investigating maternal deaths with the representation of policy-makers and planners from different countries.

- In the European Region, technical support and regional courses have been provided to strengthen national capacity to improve crucial aspects of health systems, such as the availability of equipment, supplies and facilities. This has taken place in Albania, Armenia, Georgia, Kazakhstan, Lithuania, Republic of Moldova, Russian Federation, Tajikistan and Uzbekistan. A regional course for top-level clinicians and decision-makers on evidence-based maternal and neonatal health care has been developed in 2002. Training on quality of care was conducted in Georgia and the Republic of Moldova. Audit of quality of care has been conducted in the latter country during 2002. Recommendations for follow-up were presented to the Ministry of Health and implementation has started. An MPR documentation centre has also been established in the Republic of Moldova.

- In the Eastern Mediterranean Region, collaboration has been ongoing since 1999 with CDC in developing managerial skills at district and peripheral levels through integrating total quality management approaches in maternal and perinatal health care. The initiative was field-tested in 2002 and will be disseminated in early 2003.

- An emergency health care plan for the northern Caucasus was developed in 2002, which includes MPR, "Promoting Effective Perinatal Care" and "Integrated Management of Childhood Illnesses".

- In the African Region, efforts were made to accelerate the development of national reproductive health subprogrammes with the assistance of UNFPA, the United Nations Children's Fund (UNICEF) and the World Bank, among others.

- Regional consultations were organized by AFRO, SEARO and WPRO to select a minimum package of indicators for the monitoring and evaluation of maternal and neonatal health programmes including MPR interventions in the respective regions.

- The WHO Regional Office for the Eastern Mediterranean (EMRO) has, in collaboration with CDC, developed training materials on the use of data for decision-making in maternal and perinatal health care. These materials were disseminated to all the Member States in the region in 2002. Family health surveys are being conducted in Djibouti and Yemen to update the database on maternal and neonatal health and strengthen the national programmes on the protection and promotion of maternal and perinatal health in these countries. Efforts are currently in place within some states of Sudan to improve data on service utilization in hospitals, as well as to pilot a community-based information system.

- The MPR team has collaborated in the preparation of protocols for a multicountry study in the African Region to look at community and facility interventions to reduce the "three delays". Community-level interventions will aim at increasing involvement and support for maternal

and neonatal health from individuals (including males), families and the community as a whole.

- Technical and policy support was provided to enhance the role of women, men, families and communities in improving maternal and neonatal health. In Sudan, the Sudanese Women's Union was included in the development and implementation of skilled attendant plans in the communities; in Bolivia, workshops were conducted to equip community leaders, women's groups and peasants' associations with skills for promoting the use of health care services during pregnancy, childbirth and the postnatal period; in the African Region, a framework is being developed to support community actions that have an impact on the health of pregnant women and their newborns; in EURO, an initial inventory of information, education and communication materials in reproductive health and making pregnancy safer has been conducted.

- MPR/Safe Motherhood ministerial committees, taskforces or partners coordination committees at national level have been established or revitalised and are meeting to a greater extent on a routine basis in all of the regions, namely within the following countries: Albania, Bangladesh, Bolivia, Ethiopia, India, Indonesia, Myanmar, Nepal, Nigeria, Mauritania, Mozambique, Republic of Moldova, Sudan, Uganda and Uzbekistan.

- Partner collaboration with UN agencies and NGOs has been established at global, regional and country levels in efforts to reduce maternal-newborn morbidity and mortality in line with the MDGs. A joint consensus document, entitled *Regional strategy for maternal mortality and morbidity reduction,* has been developed and approved by AMRO, UNICEF, UNFPA, the Inter-American Development Bank, the World Bank, and Family Care International, and Member States, to be distributed soon in the Region of the Americas. In the Eastern Mediterranean Region, a joint plan of action for making pregnancy safer has been developed in 2002 to be implemented jointly by EMRO and UNICEF's Middle East and North Africa Regional Office (MENARO). A joint UNICEF and WHO strategy for the European Region has been established for the prevention of MTCT of HIV. The MPR initiative, and the programmes of HIV/AIDS and Child and Adolescent Health and Development within UNICEF and WHO will implement the strategy in 2003. Collaboration has been established with UNICEF and other partners (including CDC) to adopt international definitions of perinatal and infant mortality in the European Region.

OTHER ACTIVITIES

- The MPR web site has been further developed during 2002 and can be accessed at: http://www.who.int/reproductive-health/MNBH/index.htm.

- The *Safe motherhood newsletter* serves as a platform for information sharing and continued dialogue among partners. Each edition is centred on a specific theme. The most recent issue published in 2002, for example, focused on the need for skilled attendants. The newsletter will continue to be produced twice a year beginning in 2003.

- MPR contributed to the development of the WHO document *Strategic directions for improving child and adolescent health*. The document includes reference to the importance of maternal health and care for child and adolescent health. It will be presented at the World Health Assembly in 2003.

- The MPR team has worked with the Department of Nutrition for Health and Development in developing an *Infant and young child feeding strategy*, which was presented at the World Health Assembly in 2002. Practical implications of the strategy have been included in MPR norms and tools, and MPR will thus play an important role in supporting the implementation of the strategy in countries.

- MPR participated in the preparatory meeting (convened in Stockholm, Sweden in 2002), for the United Nations Special Session on Children, held in New York, NY, USA, in May 2002, and in the Special Session itself (New York, NY, USA, May 2002). At these events, MPR contributed to a special session on the newborn, followed the Ad Hoc Committee deliberations and advocated, at all opportunities, for action to support the need for skilled attendants to ensure a healthy start in life.

- The MPR team has contributed to the development of a global framework and plan of action for the *Strategic directions for strengthening nursing and midwifery services,* developed in response to the World Health Assembly resolution 54.12 adopted in May 2001. This work has been spearheaded by the Department of Health Services Provision. As an integral part of this work, MPR participated in the Global Advisory Group Meeting for Nursing and Midwifery in October 2002. MPR is working closely with the Department of Health Services Provision to ensure that aspects of this plan of action are integrated in all relevant areas of work in MPR.

- MPR has collaborated with the Human Resources team in the Department of Health Services Provision on *Human resources and national health systems: shaping the agenda for action*. The MPR team contributed to the development of a background document and took part in a workshop in December 2002. As a result of this workshop, it has been suggested that the Human Resources for Health (HRH) framework, intended to diagnose human resources problems, be tested by applying it to maternal and neonatal health and to plan appropriate

human resources interventions to achieve the related MDGs. Collaboration in this area will also include working with the World Bank in 2003 on relevant HRH policy issues.

- MPR collaborated with the Department of Communicable Disease Surveillance and Response, with the Department of HIV/AIDS and with other teams in the Department to prepare a lecture on "The role of surveillance in preventing consequences of transmissible diseases during pregnancy" in an international course organized by the Swiss Tropical Institute, Basel, Switzerland. Collaboration with the Swiss Tropical Institute continues to support and strengthen studies related to surveillance of transmissible diseases during pregnancy.

- MPR has collaborated with the Department of Child and Adolescent Health and Development in the formation of a working group on adolescents and pregnancy. A background document has been prepared and a consultant hired to review the literature on *Strategies for ensuring adequate access and good quality of care for pregnant adolescents*.

- MPR worked with the Departments of HIV/AIDS and Roll Back Malaria to develop a framework for integrating activities for the prevention of HIV among infants and young children and malaria control among pregnant women within existing maternal and newborn health services (i.e. antenatal care, delivery care and postnatal care). MPR will play an important role in supporting the implementation of the proposed framework in selected African countries. This is expected to provide key knowledge for integrating these activities in other countries.

- MPR has also collaborated with the Department of Communicable Disease Control, Prevention and Eradication on the development of the WHO strategy on *Use of praziquantel during pregnancy*.

THE WAY FORWARD

Building on current work, achievements, constraints and lessons learnt, MPR will continue to focus on areas of work which are critical for the success of the initiative in contributing to progress towards the MDGs. This section highlights MPR's strategic direction and areas of work for the future. As pointed out below, it is foreseen that MPR will move forward with a strengthened global MPR team (headquarters, regions and countries) and in close collaboration with other UN agencies and partners in maternal and neonatal health.

- **Reviewing and updating the *Making pregnancy safer discussion paper*.** MPR plans to review the *Making pregnancy safer discussion paper* in 2003, in line with the strategic focus of the initiative and lessons learnt so far at global, regional and country levels.

- **Developing and implementing evidence-based norms and tools.** Attention will continue to be given to the development and implementation of evidence-based norms, guidelines, standards and tools for maternal and neonatal health clinical services. However, an increased emphasis will be placed on providing support to countries on adaptation and use of these norms and tools in order to ensure effective implementation of best practices for maternal and neonatal health interventions. In addition to clinical norms, guidelines on strengthening the management, leadership and negotiation skills of maternal and neonatal health managers and planners will also be developed and made available for adaptation and use in national programmes for the delivery of effective, equitable and efficient maternal and neonatal health programmes. Guidance will also be developed for improving the interface between the health delivery system and communities as well as for increasing the capacities of women, families and communities for improved maternal and neonatal health. Guidance on maternal and neonatal health policies, laws and regulations that are gender-sensitive, respect cultural diversity and are responsive to the needs of the people will also be developed.

- **Expanding and strengthening maternal and neonatal health programmes through technical support.** MPR will increasingly provide technical and policy support to strengthen national capacity to plan, design and implement effective evidence-based maternal and neonatal health programmes, including service delivery, management and community interventions. Special focus will be placed on providing technical support to strengthen the leadership and negotiation capacity of health teams at national and district levels to help them develop maternal and neonatal health programmes. Current national Poverty Reduction Strategy Papers (PRSPs), Sector-wide Approaches (SWAPs) and Health Sector Reforms (HSRs) will be reviewed in order to develop strategies for improving access to maternal and neonatal health services, especially among the poor and other vulnerable groups. Emphasis will also be placed on providing guidance to countries on human resource development policies and the strategies necessary to achieve the MDG indicator on the proportion of births attended by skilled health personnel. Technical support will be scaled up to include additional countries as selected by the regional offices.

- **Increasing political commitment for maternal and neonatal health through advocacy.** MPR will continue to seek support among interested parties at global, regional and country levels, to increase resources, promote consistent, equitable and evidence-based policies, and ensure that safe motherhood is kept high on the agenda. Special efforts will be made to increase and maintain political commitment and priority focus to maternal and neonatal health in national development

plans with a focus on increased access for the poor, and a strong emphasis on the availability and accessibility of skilled attendants. There will be an associated need to develop and equip partners, governments and senior management with advocacy tools, skills and evidence-based advocacy materials to focus on priority interventions and strategies for making pregnancy safer at country, regional and international levels.

- **Partnership building and improved collaboration.** MPR will galvanize dynamic partnerships and collaborations at global, regional and country levels among United Nations agencies, bilateral and lending agencies, professional associations, public, private and civil society to strengthen and improve commitment to and coordination of maternal and neonatal health plans and activities. There will be an emphasis on ensuring that safe motherhood, including skilled attendants for maternal and neonatal health, is kept high on the health and development agenda. At country level, MPR will contribute towards the effective coordination of maternal and neonatal health work and toward the integration of maternal and neonatal health in national policies, for instance PRSPs and HSRs, United Nations Development Assistance Frameworks (UNDAFs), SWAPs, etc. Furthermore, efforts will be intensified to enhance effective coordination of work within the MPR global team in 2003. Mechanisms will be put in place to improve communication and sharing of information in order to improve coordination of all MPR work.

- **Providing guidance on improving data sets and data collection systems for monitoring maternal and neonatal health.** MPR will continue to conduct global monitoring of maternal and perinatal health indicators in order to monitor progress towards universally agreed goals and milestone, e.g. MDGs and ICPD targets. MPR will also monitor and evaluate implementation of the work supported by the initiative, including assessment of maternal and neonatal health programmes at country level in order to document progress and lessons learnt. The initiative will also provide technical guidance to countries on improving monitoring of maternal and perinatal health outcomes as well as monitoring of maternal and neonatal health programmes and services.

Annex 1a

MATERNAL AND NEONATAL HEALTH STRATEGIC COMMITTEE IN 2002

Yusuf Ahmed, Department of Obstetrics and Gynaecology, School of Medicine, Lusaka, Zambia
Mohammed Ali Baldo, Ministry of Health, Riyadh, Saudi Arabia
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Siddarth Ramiji, Mulana Azad Medical College, New Delhi, India
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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	11	79			3	21	14
Women	1	7			3	21	4
from:							
AFRO	3	21					3
AMRO	1	7			1	7	2
EMRO	2	14					2
EURO					2	14	2
SEARO	2	14					2
WPRO	2	14			1	7	3

Collaborating agency scientists

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Annex 1b

MATERNAL–NEWBORN HEALTH AND POVERTY ADVISORY GROUP IN 2002

Members

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	3	21			11	79	14
Women	1	7			6	42	7
from:							
AFRO	1	21					1
AMRO					4	28	4
EMRO							
EURO					7	49	7
SEARO	2	14					2
WPRO							

Collaborating agency scientists

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Section 3

Controlling sexually transmitted and reproductive tract infections

Controlling sexually transmitted and reproductive tract infections

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INTRODUCTION

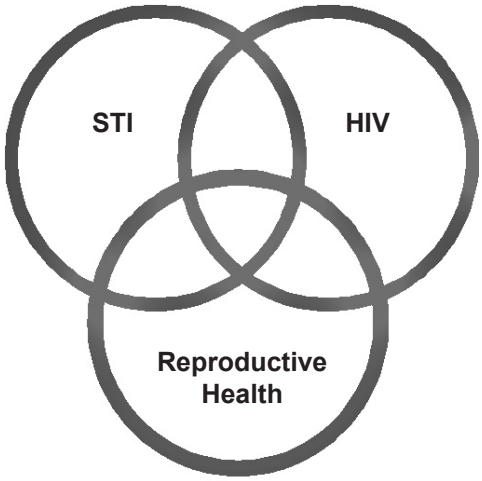
Sexually transmitted and reproductive tract infections (STIs and RTIs) are responsible for a considerable burden of reproductive ill-health worldwide, both directly and through their ability to enhance the risk of transmission or acquisition of the human immunodeficiency virus (HIV). Some 340 million 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 role in contributing to the reduction of the disease burden associated with STIs and RTIs extends across all WHO core functions: advocacy, information management, research and evidence, technical cooperation and policy support, setting norms and standards, and developing new technologies, tools and guidelines.

In May 2002, the Department assumed responsibility for all WHO's STI and RTI work with the transfer of the Unit for STI from the HIV/AIDS Department. This has provided the opportunity to take a coherent view of WHO's strategies and policies for STI control, including global advocacy, country support and technical issues (research, guideline development and normative functions) with the overall aim of prevention and care of STIs, RTIs and their complications. The Department has identified the need to position STI control as a separate, though overlapping, component of a comprehensive approach to sexual and reproductive health and HIV control (Figure 3.1).

In the 1960s and 1970s, STIs were mainly considered from the point of view of infertility and stigmatized on other fronts—STI control was a component of family planning and reproductive health programmes. In the 1980s, the management of STIs was identified as one of the key approaches to controlling the HIV pandemic, but the focus of many HIV/AIDS programmes has since turned to other issues such as expansion and sustainability of antiretroviral therapies and care, overshadowing the importance of STIs.

The revised mandate of the Control of Sexually Transmitted and Reproductive Tract Infections Team in the Department is to promote and develop guidelines and tools for STI and RTI policy, programme planning and implementation; to establish the evidence for new and improved STI and RTI control strategies; to conduct research on the prevention of mother-to-child transmission (MTCT) of HIV and other STIs; and to advocate for and conduct research on the development and deployment of safe and effective microbicides. In order to fulfil this mission, the Team collaborates with a number of partners within the Organization, WHO country and regional offices, international agencies, research networks and non-governmental organizations (NGOs).

Figure 3.1. Components and areas of work in a comprehensive model of sexual and reproductive health and HIV control



RESEARCH ACTIVITIES

Female condoms

Objective and rationale

The female condom provides a means of protection for women when male condoms are not available or not acceptable. The method is under the control of the woman and requires no, or less, cooperation from her male partner. WHO's female condom research addresses whether female condoms provide equivalent protection against pregnancy and STIs as male condoms.

Progress

A contraceptive effectiveness study is being conducted in Chengdu (China), Durban (South Africa), Panama City (Panama) and Sagamu (Nigeria). Five hundred women choosing the female condom for contraception will be enrolled, and compared with a similar number of male condom users. The study participants will be followed monthly for six months and two-monthly thereafter to one year.

The main phase started in August 2002. By the end of November 2002, 528 women had been admitted, 68% of whom chose to use the female condom. After one week, 75% of novice female condom users decided to continue using the device. The remaining 25% switched to male condoms. Recruitment of women to use female condoms for contraception in Panama and South Africa is expected to take longer since many potential volunteers already use male condoms or hormonal contraception.

The first-month follow-up visit was completed by 409 women (159 and 250 in the male and female condom groups, respectively). Fifty-seven women (51 in the female condom group) withdrew after the first week training period, mainly because of partner objection or discomfort during intercourse. Three-quarters reported difficulties using fingers to insert the device, leading to discomfort from incorrect positioning. Twenty requests for emergency contraception—9 in the male and 11 in the female condom group—have occurred, the main reasons being breakage (male condom group) or slippage or incorrect insertion (female condom group). No pregnancies have been reported.

In China, more female condom users will be recruited because of the high discontinuation rate. In Nigeria, potential volunteers are more interested in the female than male condom and identifying a matching number of male condom users may be difficult.

Biological markers are an extremely sensitive method of assessing whether condoms prevent exposure to semen or STIs during intercourse. Postcoital Prostate Specific Antigen (PSA) levels have been used to compare the efficacy of male and female condoms in preventing exposure to semen. WHO extended the concept to detect whether any exposure to sexually transmitted pathogens occurs following intercourse with an infected partner.

A study will be conducted in sex workers in South Africa using self-administered vaginal swabs before and after intercourse, and the used condom will be assessed for signs of infection in the ejaculate. Pilot projects to assess the acceptability and practicality of the study will start in 2003. The first study will assess whether volunteers are willing to participate in the study, the frequency of intercourse, and the STI prevalence among their male clients. The second study will assess the performance of self-collected vaginal swabs compared with swabs collected by a clinician in the detection of sexually transmitted pathogens. This information will be used to plan the main study.

Prevalence of STIs and RTIs

Objective and rationale

The data currently available to describe the etiology and prevalence of important RTIs remain limited, especially in resource-constrained settings. The capacity of researchers in such settings needs strengthening so that countries can conduct high-quality research to target programmatic interventions. The Department provides technical and financial support to studies on RTI prevalence in the Asia-Pacific region, identified as a priority topic by the Department's Asia-Pacific Regional Advisory Panel.

Progress

Three studies assessing the prevalence of STIs and RTIs have been or are nearly completed and the final papers are being prepared.

In Viet Nam, a multicentre, cross-sectional study on the prevalence of lower genital tract infections in 1000 women aged 18–44 years attending maternal and child health and family planning clinics in Hanoi during 1998 was completed. Results showed a 4.4% prevalence for *Chlamydia trachomatis* (*C. trachomatis*), 1.3% for *Trichomonas vaginalis* (*T. vaginalis*), 11% for Candida species, 3.5% for bacterial vaginosis (BV). No gonococcal infections were identified. Lower genital tract infection was not associated with reported symptoms of vaginal discharge.

A study in Mongolia on mothers' knowledge, perception and health-seeking behaviours related to their prepubertal daughters' vaginal discharge is nearly completed. This study was undertaken because high proportions of prepubescent girls were diagnosed with abnormal discharge at the State Research Centre on Mother and Child Health and Human Reproduction, Ulaanbataar. Seven hundred prepubertal girls, accompanied by their mothers, who attended the centre with a complaint of vaginal discharge, were enrolled in the study. Final analyses will include knowledge and per-

ceptions among the mothers regarding their daughters' vaginal discharge, contributing factors to perceived high rates of vaginal discharge in this age group, and factors influencing health-seeking behaviours.

A study in Vientiane, Lao People's Democratic Republic, on the prevalence of RTIs in antenatal clinic patients in two central hospitals is near completion, with final analyses expected in 2003. Five hundred pregnant women of 20 or fewer weeks gestation attending their first antenatal care visit were included, 250 from the Mother and Child Hospital and 250 from Sethathirath Hospital.

A new study on the prevalence of lower genital tract infections in rural women in Sichuan province, China, will start in 2003. Two thousand rural married women between 20 and 49 years of age will be recruited. The prevalence of and risk factors for *C. trachomatis*, *Neisseria gonorrhoeae* (*N. gonorrhoeae*), syphilis, human papilloma virus, herpes simplex virus 2 (HSV2), *T. vaginalis* and bacterial vaginosis will be assessed. Demographic characteristics and marital, obstetric, contraceptive, sexual and medical history will be obtained from a structured interview prior to physical examination. Study participants will be recruited in 2003, with analysis of the results in 2004.

A similar cross-sectional study will be conducted on the prevalence of RTIs in 700 women aged 15–49 years attending the family planning clinic at Central Women's Hospital in Yangon, Myanmar. Demographic, contraceptive, sexual, obstetric and medical histories will be collected and followed by physical examination and laboratory diagnostics to assess the prevalence of *T. vaginalis*, candida, bacterial vaginosis, *N. gonorrhoeae*, *C. trachomatis*, syphilis and HSV2. This study will enrol participants in 2003, with completion in 2004.

Pelvic inflammatory disease following induced abortion

Objective and rationale

A multicentre nested case-control study on the incidence and risk factors for pelvic inflammatory disease (PID) following induced abortion will be embedded in a study on surgical abortion which will evaluate the effect of vaginal administration of 400 µg of misoprostol prior to vacuum aspiration abortion on complications. The misoprostol study is a randomized double-blind controlled trial among women seeking termination of pregnancy before 12 completed weeks of gestation. Five thousand women will be recruited in 14 centres in nine countries, and followed-up 7 and 14 days after abortion. The risk of post-abortion upper genital tract infection resulting from pre-existing RTIs will be assessed in the nested study, which will also explore the effectiveness of different screening or antimicrobial administration strategies prior to induced abortion to prevent infections.

Progress

One hundred eighty cases with four controls per case are expected. The study will be implemented in 2003 together with the misoprostol trial.

Antiretroviral therapy, MTCT and mother's health

Objective and rationale

Despite recent advances in ways of reducing the risk of MTCT of HIV, and an expansion of programmes using single-dose nevirapine to reach more pregnant women, transmission rates remain persistently higher in developing than developed countries, and acceptability remains low. The acceptability, safety and effectiveness of triple-combination antiretroviral (ARV) prophylaxis to reduce MTCT are being addressed in research conducted by the Department.

Progress

The protocol to study the impact of Highly Active Antiretroviral Therapy (HAART) on MTCT and mother's health was further developed in 2002. The main objective is to assess the efficacy, tolerability and acceptability of a triple antiretroviral combination containing zidovudine (ZDV), lamivudine (3TC) and nevirapine (NVP) given for at least seven months (from 34 weeks gestation to 6 months postpartum) to HIV-positive pregnant women with CD4+ cell counts below 500 cells/mm^3, compared to ZDV plus NVP prophylaxis for one month. The specific objectives are:

- to prevent MTCT in populations where breastfeeding is the predominant mode of infant feeding despite offer of free breast-milk substitute;
- to reduce HIV-related morbidity and increase two-year survival among HIV-positive mothers; and
- to reduce two-year morbidity and increase survival among children born to HIV-positive mothers.

The study will offer a comprehensive approach to MTCT prevention, but the intervention and study objectives differ according to the clinical stage of disease in the mother. Thus the study includes:

- An observational study describing health outcomes among women with WHO clinical stage 4 or CD4+ count <200 cells/mm^3 receiving the triple combination regimen and their newborns. Such women will be offered life-long ARV therapy.
- A multicentre randomized controlled clinical trial comparing the short ZDV plus NVP regimen given from 34 weeks pregnancy to delivery with the triple combination regimen given from 34 weeks pregnancy to 6 months postpartum, associated with rapid weaning of the child

at 6 months, among women with CD4+ counts between 200 and 500 cells/mm^3 (and clinical stage lower than 4).

- An observational study assessing the effectiveness of the MTCT-prevention package including the short ZDV plus NVP regimen, among women with more than 500 CD4+ cells/mm^3 (and clinical stage lower than 4).

Principal investigators and collaborating research agencies met in November 2002 to review draft study instruments and issues related to study implementation. It is expected that study instruments will be ready by March 2003 and enrolment will begin in May or June 2003.

Sites identified for the study include: The Network of AIDS Research of Southern and Eastern Africa study clinic in Nairobi, Kenya, with financial support from the Centers for Disease Control and Prevention (CDC) and the US National Institutes of Health (NIH); The Coast General Hospital, in partnership with the International Centre for Reproductive Health, both in Mombasa, Kenya, with partial financial support from the Belgian Directorate General for International Cooperation; The Kilimanjaro Christian Medical Centre in Moshi, United Republic of Tanzania; the Centre Muraz in Bobo-Dioulasso, Burkina Faso, with support for research expected from the French Agence Nationale de Recherche sur le SIDA, although additional funds are required to accelerate and expand the MTCT-prevention facilities.

These four sites will enrol 1500 HIV-positive women, while 2500 are required to achieve the study objectives. Additional sites in Cotonou (Benin), Harare (Zimbabwe), Kigali (Rwanda), and Kinshasa (Democratic Republic of the Congo) are under consideration.

Safety of antiretroviral regimens to prevent MTCT of HIV

Objective and rationale

Transient emergence of resistant HIV strains has been reported following short prophylactic regimens to prevent MTCT, particularly with single-dose nevirapine. The objective is to discover whether this resistance has any negative impact on the efficacy of therapeutic antiretroviral regimens when such treatment is initiated months or years later.

Progress

A study protocol to assess the clinical response of women initiating combination antiretroviral therapy has been drafted. The study will be conducted in sites where MTCT-prevention interventions have been available for several years and standard ARV therapies are being offered to women who require treatment. Identification of potential study sites and principal investigators, together with further development of detailed study procedures and instruments will be undertaken in early 2003.

Safety of cellulose sulfate

Objective and rationale

There is a need to expand the range of available female-controlled methods to prevent STIs including HIV. Microbicides, used in the vagina or rectum, offer such a possibility. Approximately 50 promising candidate products are under development, 15 of them in clinical research. In partnership with CONRAD, WHO is implementing a three-centre randomized double-blind Phase I study of the safety and acceptability of cellulose sulfate gel compared with K-Y Jelly among healthy women volunteers in Kampala (Uganda), Mumbai (India), and Sagamu (Nigeria). The products are applied in 3.5 ml doses twice daily for 7 days, in a cohort of 30 women in each centre not having sexual intercourse (cohort I), followed by a similar cohort of women having intercourse (cohort II). The study endpoints are symptoms and signs of irritation of the external genitalia, cervix, and vagina, and epithelial disruption as seen on colposcopy.

Progress

Recruitment of volunteers for cohorts I and II was completed in Kampala in September 2002. Two volunteers were lost to follow-up; two discontinued due to onset of menses, and one discontinued gel application complaining of vaginal itching. In Sagamu, cohort I was completed in July 2002 with no premature discontinuations and 22 volunteers had been enrolled in cohort II by mid-November. In Mumbai, the study started in July and 19 volunteers had been recruited into cohort I by November. No serious adverse events have been reported. Some of the mild adverse events reported include vaginal itching, vaginal discharge and vaginal bleeding (not considered to be associated with gel application). The study is expected to be completed by April 2003.

NORMS AND TOOLS

Specific objectives/targets

The objectives of the norms and tools developed by the Department are to increase the availability of high-quality, culture- and gender-sensitive and non-stigmatizing services for the prevention, care and management of STIs/RTIs and their complications, to broaden the range of safe, effective and affordable methods of preventing and managing STIs/RTIs and MTCT of HIV and other STIs, and to contribute towards the strengthening of national health system capacity to deliver these services.

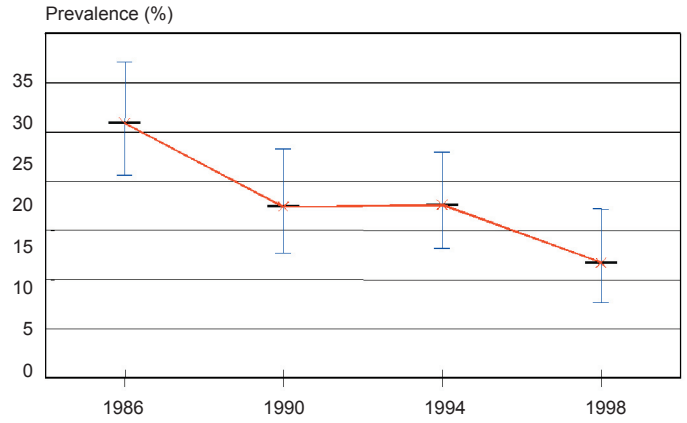
New norms/tools developed

During 2002, the Team continued the development and assessment of tools and guidelines for the prevention and management of STIs and RTIs. A wide range of guides and guidelines have been developed and others are in progress or under discussion for 2003.

Conceptual framework of STI/RTI control for programme managers

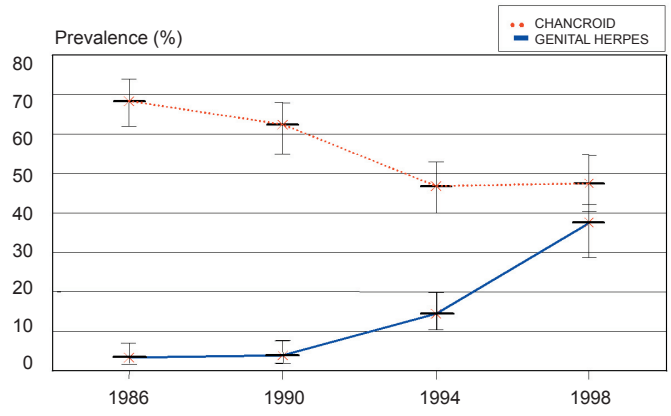
To provide an overall picture of STI control strategies of proven effectiveness, WHO is developing a conceptual framework of STI/RTI control for programme managers. This guide, currently in draft form, covers the basic elements of an STI/RTI control strategy, together with a summary of the tools and guides available. It will help managers in planning development and implementation of a control strategy adapted to the particular social and epidemiological conditions of the country or setting in question. The draft framework will be ready in early 2003 for external review by experts and programme managers before being finalized and disseminated to programme managers during 2003.

Figure 3.2. Prevalence of positive syphilis serology (RPR) by year of study in South Africa[1]



[1] Htun Y, Ballard R. Management of genital ulcer diseases (GUD) in South Africa: aetiology of GUD among mine workers in South Africa (1986 to 1998). Presented at the WHO Consultation on Improving the Management of Sexually Transmitted Infections, 28–30 November 2001 (unpublished).

Figure 3.3. Prevalence of chancroid and genital herpes by year of study in South Africa[1]



[1] Htun Y, Ballard R. Management of genital ulcer diseases (GUD) in South Africa: aetiology of GUD among mine workers in South Africa (1986 to 1998). Presented at the WHO Consultation on Improving the Management of Sexually Transmitted Infections, 28–30 November 2001 (unpublished).

STI/RTI programme guidance tool

This decision-making tool is an adaptation of the Strategic Approach for contraceptive technology introduction (found in the WHO document, *Making decisions about contraceptive introduction* [WHO/RHR/02.11]) to the problems of STI and RTI control and management. It considers a broad range of programmatic interventions and assists programme managers in identifying information required to make decisions on the interventions most appropriate to their national context. With the experience gained in field trials in Brazil, Cambodia, Ghana and Latvia, the *STI/RTI programme guidance tool* has been rewritten in a simplified, more user-friendly way for distribution in 2003. It is currently being piloted in selected provinces in China to identify and implement appropriate interventions for STI/RTI control.

STI/RTI management in reproductive health care settings: a guide for essential practice (ECPG)

Clients presenting to reproductive health facilities such as family planning, antenatal care or some other primary health care services have different patterns of risk factors for, and prevalence of, STIs and RTIs from patients presenting with STI complaints to specific STI services. The ECPG for STI/RTI provides a comprehensive approach to STIs and RTIs (including counselling, prevention, screening, case-finding, and management) adapted to the needs of such clients. The guide is compatible with other guides and tools developed by the Department, including the essential practice guide for pregnancy and childbirth, that for family planning, as well as the syndromic approach to STI management which is specifically targeted at the needs of patients presenting with complaints and/or symptoms of acute STI.

The ECPG for STI/RTI includes three documents:

1—a practical guideline for health care providers (narrative document and pocket guide);

2—an implementation and adaptation guideline for programme managers; and

3—training guidelines for health care providers.

The health care providers' practical guide is ready for field-testing in Brazil, China, India, Jamaica, Kenya, and Latvia. The programme managers' guideline will help programme managers to identify and interpret national and local data on STIs/RTIs and behaviours determining their epidemiology. The programme managers' guideline will be developed and field-tested in

2003 together with the training manual to complement other STI/RTI manuals.

Updated STI management guidelines

The syndromic approach developed by WHO has been a key element in STI management in resource-limited settings. New data on genital ulcer disease (GUD) epidemiology and experience with management of vaginal discharge syndromes were reviewed at a consultation of STI experts to update the WHO *Guidelines for the management of sexually transmitted infections*.

Recent data point to a worldwide increase in the prevalence of sexually transmitted HSV2 which is a major cause of GUD, especially in the developing world. This is substantiated by data from China, South Africa, Sri Lanka, and Uganda.

In South Africa the contribution of syphilis and chancroid to GUD have declined while HSV2 has increased (Figures 3.2 & 3.3).

HSV2 is the major cause of GUD in men and women attending STI clinics in Sri Lanka (Figure 3.4), while syphilis constitutes only 3% of pathogens in men and none in women, and no chancroid was detected in men or women.

Syphilis was highly prevalent in the setting studied in China, and HSV2 was responsible for 31% of ulcers alone or concomitantly with syphilis (Figure 3.5).

The main change to the GUD management flowchart included in the *Guidelines for the management of sexually transmitted infections* was to include HSV2 treatment where seroprevalence is 30% or higher. This treatment provides symptomatic relief, decreases viral shedding and decreases the duration of symptoms. WHO was urged to advocate for access to affordable STI drugs, including the HSV2 antiviral drug, acyclovir. Similarly, WHO was asked to facilitate development of rapid diagnostic tests for HSV2 to help countries assess prevalence in various populations.

Despite the difficulty of distinguishing vaginal and cervical infections in women presenting with vaginal discharge, the consultation agreed that syndromic management remains the recommended STI case-management approach, especially in resource-constrained settings. To avoid high levels of over-treatment for cervical infection in women with vaginal discharge, decisions on treatment for gonorrhoea and Chlamydia should be based on the prevalence of these infections. WHO was urged to develop guidelines and tools to assist programme managers calculate the prevalence of infection below which syndromic management is not cost-effective.

The consultation recommended: (i) that azithromycin be removed as treatment for gonococcal infections following some early reports of resistance, but that it should be continued for treatment of chlamydial infections; and (ii) that training and supervision were critical components of STI management.

STI management guidelines adapted to meet the needs of adolescents and of children were developed in collaboration with the WHO Department of Child and Adolescent Health and Development.

Training modules for the management of STIs

To improve the quality of STI care at country level, WHO developed workbooks and tools for countries to use or adapt, and to train health personnel in STI management. Following a survey of the use and adaptation of the training modules and the new elements in STI epidemiology and management strategies, Ashford Open Learning, United Kingdom, was contracted in May 2001 to produce seven modules and a trainers' guide, including hard copies, a CD-ROM version and an interactive CD-ROM-based e-learning version. The tool, provisionally entitled *Training modules for the management of sexually transmitted infections,* will be available in the first quarter of 2003.

Assessment of cost–effectiveness tool

In 2002, the Department finalized and sponsored the assessment in Thailand of a cost–effectiveness tool for MTCT-prevention. The tool had been prepared for the Joint United Nations Programme for HIV/AIDS (UNAIDS). The assessment concluded that the tool was well-defined, user-friendly and could be used by a non-health economist.

Clinical guides for the management of pregnant women with HIV infection

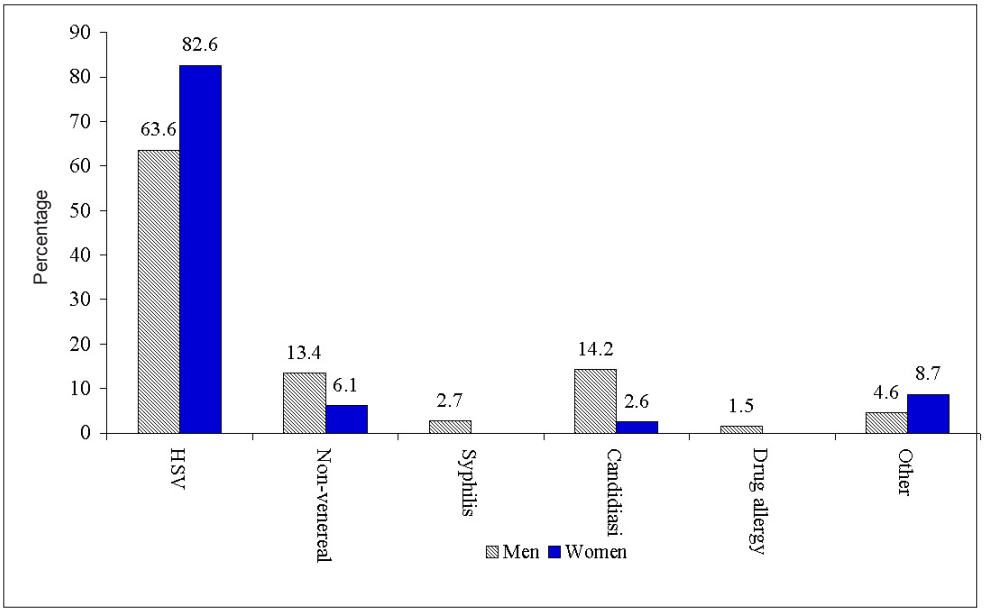
The Department developed a set of *Clinical guides for the management of pregnant women with HIV infection*, consisting of four separate but complementary booklets, namely: *Voluntary counselling and testing for HIV in pregnant women*; *Antenatal care for HIV-infected women*; *Labour and delivery care for HIV-infected women*; and *Post-pregnancy care of HIV-infected mothers and their infants*. The target audience ranges from policy-makers to health care providers in central or peripheral health facilities in resource-limited settings. The guides help providers implement programmes to prevent MTCT of HIV and provide appropriate care and support for HIV-positive mothers.

In 2001 and 2002, the guides were field-tested in urban and rural areas in the Bahamas, Ethiopia, Guyana, Kenya, and Thailand. The field-testing revealed the need for adaptation of some WHO policies and guides (e.g. on feeding options and immunization schedules for infants born to HIV-positive mothers). The adapted policies and the field-testing experience were consolidated into the final version of the guides in 2002 in collaboration with the WHO Regional Office for Africa (AFRO) and experts from the Chris Hani Baragwanath

Hospital, Johannesburg, South Africa. The English version will be ready for distribution in mid 2003.

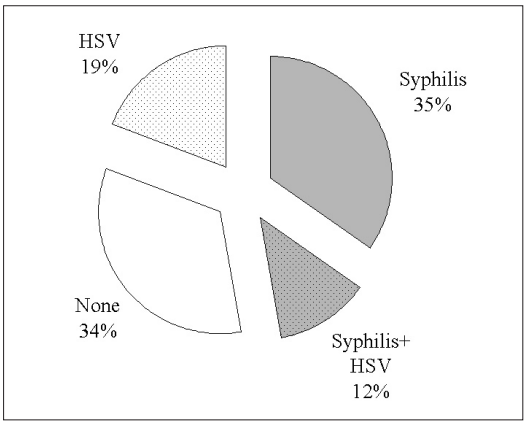
It is anticipated that the guides will be translated into French, Spanish and Portuguese and disseminated to many countries. The guides will be reviewed and updated as new information on the prevention of MTCT of HIV becomes available and new WHO policies and principles are issued.

Figure 3.4. Genital ulcer profile: Sri Lanka[1]



[1] Abeyewickreme I. Genital ulcer syndrome: Sri Lanka experience. Presented at the WHO Consultation on Improving the Management of Sexually Transmitted Infections, 28–30 November 2001 (unpublished).

Figure 3.5. Main causes of GUD in a sample of STI patients in China[1]



[1] Wang QQ, Mabey D, Peeling RW, Tan ML, Jian DM, Yang P, Zhong MY, Wang GJ. Validation of syndromic algorithm for the management of genital ulcer diseases in China. *International Journal of STD and AIDS*, 2002, 13:469–474.

Psychosocial support for HIV-positive mothers and families

Psychosocial support is a fundamental need for people diagnosed with HIV, but is seldom considered in MTCT-prevention programmes. The Department commissioned a systematic review of psychosocial support for HIV-positive mothers and their families, which revealed large gaps in scientific and programmatic knowledge. A psychosocial support demonstration project was established in Chitungwiza, near Harare, Zimbabwe, by the Zimbabwe AIDS Prevention and Support Organisation and AFRO, with support from the Department and Italian funds. The project was evaluated in November 2002. Conclusions will be presented in Harare in early 2003 and the key elements will be used as a model for replication in other countries. A guidance tool on how to provide psychosocial support for HIV-positive mothers will be developed and field-tested in two countries in 2003.

New work undertaken on norms/tools under development

Bulletin of the World Health Organization *special issue on maternal and congenital syphilis*

Three case studies on maternal and congenital syphilis conducted between 1999 and 2001 in Bolivia, Kenya, and South Africa showed that national congenital syphilis control programmes were hampered by difficulties in operations, policy and financing. Key issues included:

- the magnitude of the problem;
- the failure of policy and programme implementation, including lack of financial, technical and operational support to programmes at country level;
- whether congenital and maternal syphilis were perceived as a problem considering that pregnant women and their newborn infants tended to be followed by different health care providers, that the social implications of syphilis infections were severe, and that patient motivation was poor;

- whether the tools available were adapted to the objectives of the programmes; and

- the effectiveness and robustness of diagnostic tools and the effectiveness of treatment.

Seven articles addressing the failures and challenges of syphilis control and elimination have been submitted for a special issue of the *Bulletin of the World Health Organization*.

A 2000 draft guideline, *Maternal and congenital syphilis: an outline for prevention and control,* was reviewed by an expert meeting in October. The document will be shortened, updated and revised as a reference document, the key elements of which will be incorporated into relevant tools and guidelines being developed by the Department.

New norms/tools initiated

Development of a global strategy for STI prevention and control

WHO works with national governments, international donors, implementing agencies and other UN agencies to implement effective STI control policies and guidelines at country level. To facilitate dissemination, adaptation and adoption of the recommended policies and strategies, WHO is developing an updated global STI strategy that reflects recent evidence and experience in STI control and its impact on the HIV epidemic accumulated at national, regional and global levels. The previous global strategy covered the period 1997 to 2001. The updated strategy will include elements for countries to consider as part of their national strategy as well as an assessment of the role WHO should adopt to best support national and international STI control measures in partnership with countries and other agencies. The process for updating the strategy commenced with compilation of new elements and issues in the area of STI prevention, control and care. A series of consultations with WHO regional offices, international partners and selected country programme managers will be undertaken in 2003. The updated draft strategy will be available in late 2003.

Country adaptation of global STI management protocols

The WHO *Guidelines for the management of sexually transmitted infections* and the ECPG for STI/RTI reflect global recommendations for the management and control of STIs in different health care settings. Countries are encouraged to adapt these guidelines and develop national guidelines based on available evidence and cultural norms for their country or setting. To facilitate this process, AFRO and the Department are collaborating with the London School of Hygiene and Tropical Medicine, London, United Kingdom, and Family Health International, Research Triangle Park, NC, USA, to develop guidance for countries embarking on the adaptation and implementation process.

At the same time, work has begun on a decision tree to help managers decide whether syndromic management of women with vaginal discharge will be cost-effective in their setting, balancing the costs of treatment against the costs of STI sequelae prevented (including PID, infertility, or ectopic pregnancy). This decision-tree will provide managers with a rationale for adaptation, especially for the syndromic management of cervical infection in women presenting with vaginal discharge.

Male latex condom specification and guidelines for procurement

In January 2002, the Department held a meeting with the United Nations Population Fund (UNFPA), the United States Agency for International Development (USAID), the United Nations Children's Fund (UNICEF), CDC, the Program for Appropriate Technology in Health (PATH) and John Snow Inc. to update publications on male latex condoms. Three technical papers were prepared reviewing evidence on condom size, safety and efficacy, and the technical basis for the WHO male latex condom specifications. These background materials were discussed at an Informal Technical Consultation to update the *Male latex condom: specification and guidelines for procurement,* convened in May 2002 in Johannesburg, South Africa, in collaboration with AFRO, UNFPA, UNAIDS, Family Health International and the Reproductive Health and Research Unit, Chris Hani Baragwanath Hospital, Johannesburg. Thirty-four participants from four regions and 13 countries took part, representing donor and international agencies, NGOs and social marketing organizations, manufacturers, bulk procurement agencies, testing laboratories, national regulatory boards, research institutes and country programme managers. In July 2002, with support from the Secretariat of the International Standardisation Organization Technical Committee 157 and the Malaysian National Regulatory Board, the Department convened a meeting for a final review of the document which is widely used by both private and public sectors throughout the world.

In 2003, the Department will continue to work with collaborating agencies on the development of technical materials and a dissemination strategy to support the adaptation and use of guidelines at national level. An Internet-based helpline for programme managers will also be initiated.

Strategies to increase access to affordable STI drugs and commodities

Drugs

The global interest in increasing access to affordable medicines and the recent initiatives within the World Trade Organization provide the opportunity to improve access to effective

medicines and commodities for STI care and prevention. The Team has adopted a three-step process to increase access to STI drugs.

The first step is the inclusion of greater choice of STI medicines in the WHO *Model list of essential medicines*. The initial proposal is to include azithromycin for the treatment of uncomplicated genital *C. trachomatis* infection and valaciclovir for the treatment of genital herpes. Médecins Sans Frontières have also submitted a proposal for the use of azithromycin to cover Chlamydia infection and trachoma.

Azithromycin is an azalide macrolide with an oral bioavailability that provides sustained high antibacterial levels in a wide range of tissues, including the urogenital tract in both men and women. Because of its long half-life (68 hours) its tissue concentration is maintained for several days. It has been shown to be as effective as doxycycline in the management of *C. trachomatis* and equally well tolerated. The high-efficacy single-dose therapy and limited side-effects of azithromycin mean that the drug can be used for the management of STIs, especially in populations where compliance and follow-up may pose problems.

For HSV2 treatment valaciclovir may be taken in a twice-daily dosage regimen in contrast to aciclovir which must be administered at four- to six-hourly intervals. The efficacy of valaciclovir is similar to that of aciclovir, and there is no significant difference in adverse events between the two drugs.

The second step is the development of a position paper on STI drugs, which discusses issues and concerns relating to the global provision of effective drugs, in particular questions of availability, affordability, equity and the use of generic drugs.

The third step is to develop and disseminate a guidance tool on how to increase access to, and sustainability of, STI drugs at country level.

These tools will provide countries with information to assist in the procurement of affordable, high-quality STI drugs, an essential element of an effective STI control strategy.

Commodities

In response to requests from the Inter-Agency Group on Commodity Security, the Department has been working in collaboration with UNFPA and the Unit of Policy, Access and Rational Use in WHO's Department of Essential Drugs and Medicines Policy (EDM) to develop an *Essential list of reproductive health medicines and commodities*. Work has been undertaken to define the technical basis for such a list, which will then be incorporated into the WHO *Model list of essential medicines*. The Department is also discussing with EDM and PATH the development of guidelines to increase access and sustainability of all essential reproductive health drugs and commodities through the development of information resource centres, guidelines and tools that help countries to procure affordable, high-quality regulated reproductive health drugs and commodities. The position paper on STI drugs and the experience gained in developing specifications and quality assurance measures for the male latex condom will feed into the development of these materials and tools.

STI/RTI prevalence tool to adapt guidelines in country

Risk assessment methods based on socioeconomic, demographic, clinical, and behavioural indicators lack the sensitivity and specificity to predict which STI clients are at high risk of STI/RTI infection and therefore in greater need of testing and treatment. In high-risk populations, many clients will be considered high risk according to the risk assessment algorithms, resulting in unnecessary treatment of many women. Studies have shown that risk assessment is of limited benefit in low-risk populations, such as among family planning and antenatal clinic attendees.

In view of the low validity of this risk-assessment methodology, objective data on STI/RTI prevalence at the health facility level are needed, to estimate the likelihood that an individual patient is infected. This will permit management guidelines to be adapted and used appropriately. A review of the protocols for STI/RTI prevalence studies has been undertaken and will be assessed at a consultation before being finalized and published in 2004.

Cost–effectiveness of syndromic management of STIs in women

Effective STI control programmes are essential in resource-limited countries, both to reduce the burden of STIs and their sequelae, as well as to prevent HIV transmission. Currently, gold standard methods for the diagnosis and treatment of STIs are neither practical nor possible in most clinical settings in resource-limited countries. Syndromic management offers an alternative approach. However, over-treatment of women for STIs when a non-sexually transmitted endogenous infection (or some other cause) is the cause of their symptoms remains a problem in many settings where the syndromic management algorithm has been evaluated. Hawkes et al. (*The Lancet,* 1999, 354(9192):1776–1781) found that the proportion of cost spent on over-treatment was extremely high in a setting of low STI prevalence (<1% *N. gonorrhoeae* and *Chlamydia* and <2% *Trichomonas*, in women presenting with vaginal discharge) in rural Bangladesh. In addition to wasting resources, over-treatment is poorly accepted by health service providers and individual patients. Particularly controversial is the syndromic management of women complaining of genital discharge syndromes in settings of low STI prevalence. In order to inform rational policy making, WHO is compiling a review of the published evidence on the use of the syndromic approach in resource-limited settings. The review and tools will be published and disseminated in early 2003.

TECHNICAL COOPERATION WITH COUNTRIES

Implementation of the programme guidance tool

The *STI/RTI Programme guidance tool* (see page 104) was developed, tested and applied in Brazil, Cambodia, Ghana and Latvia. During 2002, work focused on implementing the recommendations identified in each country. An evaluation of the process started in Cambodia. Implementation of the tool in China started in Guandong and Yunnan Provinces in April 2002, and the first assessment workshop will be held in February 2003. Further requests to implement the tool have been received from Kosovo (Serbia and Montenegro) and South Africa.

Prevalence of STIs and RTIs in reproductive health settings

Technical and financial assistance has been provided (in collaboration with the Technical Support to Countries Team) to institutions in resource-constrained settings to estimate the prevalence of STIs and RTIs among women attending reproductive health care services, such as family planning clinics, general gynaecological services and antenatal care settings (for details of completed and ongoing projects, see the section on research activities, above). Current data describing the etiology and prevalence of important RTIs remain limited, especially in resource-constrained settings. The capacity of researchers in such settings needs strengthening in order for countries to conduct high-quality research to target programmatic interventions, as well as monitor the impact of programmes. Adaptation of the ECPG for STI/RTI under development (see the section on norms and tools, above) is based on such prevalence and etiological data. The Team has provided technical and financial support to RTI prevalence studies in the Asia-Pacific region, identified as a priority theme by the Regional Advisory Panel.

New studies requiring technical support are being planned in China, Mongolia, Myanmar and Viet Nam. The objectives of the studies vary, but include assessment of the association between *C. trachomatis* and ectopic pregnancy in Mongolia and Myanmar, and assessment of the infectious etiology of post-abortion complications in China. Another study in Mongolia is linked with a plan to introduce national coverage of syphilis serological screening among pregnant women in antenatal clinics. There is a need to monitor the progress of the coverage and the effectiveness of this campaign. The results of this study will be used to develop a health policy aimed at reducing congenital syphilis and complications of syphilis with the cooperation of the Ministry of Health of Mongolia. Two studies in Ho Chi Minh City, Viet Nam, propose to assess the prevalence of RTIs and STIs among family planning attendees and pregnant women seeking antenatal care. The final protocols will be developed during 2003.

Assessment of integration of STI services into reproductive health

The Ministry of Health in Botswana embarked, in the early 1990s, on integration of STI prevention and management with reproductive health services. A joint mission between the Department and AFRO to Botswana was conducted to assess national policies and actual levels of integration, focusing particularly on the syndromic approach to STI management and dual protection.

Recommendations from the mission included: the need to review national STI management guidelines with special reference to genital ulcer desease; a review of the national policy on anti-herpes drugs; finalization of national policies on integration of STI services with reproductive health services; dissemination of policy guidelines and service standards for sexual and reproductive health to all levels of the health service and to stakeholders; and a regular review of national maternal and child health and family planning services, as well as of the prevalence and incidence of STIs in order to facilitate prompt review of national policies and programmes. The Department will continue to provide technical support to AFRO to conduct evaluations in other countries in the region, as well as to assist countries to implement the recommendations.

Technical and financial support to the Masaka trial in Uganda

WHO provided partial technical and financial support to the Masaka community intervention trial in Uganda from its inception in 1994 to its conclusion in 2001. This community-based study aimed to evaluate the impact on HIV incidence of a standardized and replicable information, education and counselling behavioural intervention, with and without improved management and syndromic treatment of STIs.

The trial demonstrated a significant reduction in syphilis incidence and prevalence of gonococcal infections in the intervention arms of the trial, but these reductions did not translate into a reduced HIV incidence. The trial complements the results from the previous STI intervention trial in Rakai, Uganda, during 1994–1998 which also demonstrated an impact on a curable STI (high titre syphilis) with no reduction in HIV incidence.

By contrast, the Mwanza trial conducted in the United Republic of Tanzania in 1991–1995 demonstrated an impact on HIV incidence, as well as syphilis incidence. The apparently conflicting results from the three east African community intervention trials are explained by the different stages of the HIV epidemic and different sexual behaviours in the two countries when the studies were conducted. In Uganda, behaviour change and safer sexual practices had largely occurred before the study interventions were implemented. Although HIV prevalence was higher in Uganda, the proportion of men and women with multiple sexual partners was lower than in

the United Republic of Tanzania. Similarly, the proportions of men and women reporting condom use were 10 times higher in the Uganda sites than in the United Republic of Tanzania. The HIV epidemic in the latter country was rapidly expanding, fuelled by unsafe sexual behaviour and a high incidence of curable STIs. By contrast, the incidence of HIV and STIs in Uganda was lower, thus providing less opportunity for an aggressive STI control strategy to have an impact on the HIV epidemic. While such STI control strategies appear to have greatest impact in settings where there are high rates of curable STIs and an expanding HIV epidemic, STI control remains critical where the incidence is low so that the epidemic can be contained. A greater impact on further reducing HIV incidence in low-incidence settings may be achieved through other interventions, such as encouraging partner testing and disclosure, or promoting dual protection within stable relationships and among regular partners.

The interpretation of the results from the east African intervention trials is complex and the STI Team is working closely with the research groups to facilitate dissemination of their results and appropriate assessment of the programmatic implications at country level.

Strengthening capacity for microbicide research

There are few sites in developing countries with adequate clinical trial capacity to implement safety and effectiveness studies on microbicides. In collaboration with the Technical Support to Countries Team, clinical and laboratory facilities are being upgraded and staff trained in research methodology, Good Clinical Practice requirements, clinical trial design and implementation, and STI diagnostics.

The centres involved in the Phase I safety trial of 6% Cellulose Sulfate in India, Nigeria and Uganda were evaluated in 2002 with a view to expanding their capacity to implement more complex microbicide research protocols. Several new clinical sites were identified in 2002, and their interest and capacity to participate in microbicide research assessed. The Department of Obstetrics and Gynaecology, University of Addis Ababa, Addis Ababa, Ethiopia, was visited in March 2002, and a preliminary plan for staff training, and upgrading clinical and laboratory facilities was developed. Swaziland was visited in September 2002, and there is potential to build capacity at the University of Swaziland and through the Ministry of Health and Social Welfare, for microbicide and reproductive health research in the country. Two research centres in Mozambique were assessed in November 2002: the Maputo Central Hospital Department of Obstetrics and Gynaecology and the Regional Centre for Health Development.

Strengthening national capacity for microbicide research and registration

Research, development, and safety and effectiveness assessment of microbicides pose particular scientific, ethical and regulatory problems. There are important differences between the assessment and approval of products to treat conditions and those intended to prevent disease. In addition, all HIV prevention work is highly complex in ethical and social terms owing to the stigma surrounding the condition, the lack of cure and the extreme inequities between rich and poor. National Regulatory Authorities (NRAs) in many countries where new microbicidal products are likely to be most valuable do not have the capacity to oversee and assess the research and then register the product. In 2002, the Department initiated discussions with scientists, advocates and representatives from NRAs and local Institutional Review Boards (IRBs) on mechanisms and procedures to facilitate microbicide development, assessment of safety and effectiveness, and registration.

The Department, in conjunction with CONRAD and the Alliance for Microbicide Development, convened an international consultation in March 2002 in Villars-sur-Ollon, Switzerland, on the Scientific Basis for Regulatory Decisions on Microbicides. The meeting brought together 42 representatives from 16 developed and developing countries, bringing expertise from academic institutions, clinical trial centres, national and international regulatory authorities, biopharmaceutical companies, and non-profit research and advocacy organizations. The meeting identified areas of consensus on the scientific basis for proceeding systematically through the different stages of pre-clinical testing, Phase I safety trials, expanded safety studies and efficacy trials. Questions were raised regarding the progressive expansion from well-screened and low-risk volunteers involved in the Phase I safety trials, to higher-risk volunteers more typical of the intended eventual users of the products, before proceeding to full-scale efficacy trials. Bridging studies to broaden the basis for safety recommendations among intended eventual users were recommended. The meeting was unable to reach a consensus on a number of issues, including whether colposcopy was necessary in all volunteers in efficacy trials, and on the minimum standards of care required in order to implement studies in an ethical and scientifically sound manner. The meeting revealed close parallels between the scientific and regulatory considerations for HIV vaccines and those for microbicides.

As a follow-up to the March meeting, a Southern African Regional Workshop was held in Gaborone, Botswana, in November 2002, with members of NRAs and IRBs from 16 countries in the southern African region. The purpose was to disseminate the report and recommendations from the March meeting, facilitate discussions on the parallels and differences between HIV vaccines and microbicides, and identify ways in which WHO could best support and strengthen NRAs and IRBs to oversee such research. A key recommendation from the workshop was for WHO to establish a Microbicide Scientific and Ethical Advisory Committee which would be able to address the scientific and ethical concerns in microbicide safety and efficacy trials, as well as provide technical, scientific and ethical comment and advice in response to particular questions raised by NRAs.

Global distance learning network on the prevention of MTCT

In 2002, the Department convened a series of video conferences for countries to exchange information and experiences in implementing MTCT-prevention interventions, using the World Bank Global Distance Learning Network and the PMTCT Gateway, a web site where participants pursued electronic discussions and posted reading materials for exchange of information. Ten sessions were conducted, each bringing together approximately 60 participants to discuss a specific topic on MTCT prevention. There were four sessions for Asian countries (Cambodia, China, Sri Lanka, Thailand and Viet Nam), three sessions for English-speaking African countries (Ethiopia, Ghana, Malawi, Uganda and Zambia), and three sessions for French-speaking African countries (Burkina Faso, Cameroon, Côte d'Ivoire, Rwanda and Senegal) making a total of 15 countries. This work was executed as part of WHO's contribution to UNAIDS/WHO/UNICEF/World Bank Inter Agency Task Team on MTCT. Two additional sessions are planned, to be followed by an evaluation in 2003.

Annex 1a

STRATEGIC COMMITTEE ON CONTROL OF SEXUALLY TRANSMITTED AND REPRODUCTIVE TRACT INFECTIONS

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	10	71			4	29	14
Women	4	29			2	14	6
from:							
AFRO	5	36					5
AMRO	2	14					2
EMRO	1	7					1
EURO					4	29	4
SEARO	2	14					2
WPRO							

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Annex 2a

CONTROL OF SEXUALLY TRANSMITTED AND REPRODUCTIVE TRACT INFECTIONS

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	23	85	4	15			27
Women	13	48					13
from:							
AFRO	3	11					3
AMRO	2	7.5					2
EMRO							
EURO			4	15			4
SEARO	6	22					6
WPRO	12	44					12

Annex 2a (continued)

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Improving management of sexually transmitted infections

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Introduction and field evaluation of essential care practice guides

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	28	54	1	2	22	42	52
Women	12	23	1	2	10	19	23
from:							
AFRO	10	19					10
AMRO	5	10			6	12	11
EMRO	2	4					2
EURO			1	2	18	35	19
SEARO	6	12					6
WPRO	4	8					4

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	3	100					3
Women	1	33					1
from:							
AFRO	2	67					2
AMRO							
EMRO							
EURO							
SEARO	1	33					1
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	9	100					9
Women	6	67					6
from:							
AFRO	6	67					6
AMRO							
EMRO							
EURO							
SEARO	3	33					3
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	6	100					6
Women	3	50					3
from:							
AFRO	5	83					5
AMRO							
EMRO							
EURO							
SEARO	1	17					1
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	26	78			7	22	33
Women	11	33			4	12	15
from:							
AFRO	26	78					26
AMRO					2	6	2
EMRO							
EURO					5	15	5
SEARO							
WPRO							

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Annex 3

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Section 4
Preventing unsafe abortion

Preventing unsafe abortion

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INTRODUCTION

The guiding document for the Department's work on abortion is the Programme of Action adopted at the International Conference on Population and Development (ICPD) held in Cairo, Egypt, in 1994, which urges countries and organizations to address the health consequences of unsafe abortion and to ensure that, in circumstances where abortion is not restricted by law, the provision of abortion is safe. It is estimated that 46 million abortions are performed annually of which 19 million are unsafe. Unsafe abortion is defined by WHO as a procedure for terminating an unintended pregnancy either by persons lacking the necessary skills or in an environment lacking the minimal medical standards, or both. The consequences of unsafe abortion are many. It has been estimated that in addition to some 80 000 women who die each year as a consequence of unsafe abortion, a further 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 abortion prevalence and practices, to improve technologies and interventions to make abortion safer, to translate evidence into norms, tools and guidelines, and to assist in the development of programmes and policies to reduce unsafe abortion. The Department's activities address priorities identified by two consultations on abortion, held in August and September 2000, and by the 2002 meeting of the Scientific and Technical Advisory Group (STAG).

RESEARCH ACTIVITIES

Specific objectives of research

The specific objectives of research by the Programme include, but are not limited to, providing evidence on the incidence of unsafe abortion and its related morbidity and mortality; assessing safety of abortion technologies; developing evidence-based norms, tools and guidelines; and assisting countries in implementing best practices for high-quality abortion services and post-abortion care. The Department conducts research to document the global dimensions of unsafe abortion by compiling and maintaining data on the incidence of unsafe abortion and abortion-related mortality and morbidity. It also conducts research on the determinants and consequences of unsafe abortion, including access to qualified providers and post-abortion care.

Since its inception the Programme has carried out research for developing safe and effective non-surgical methods for early termination of pregnancy. This research was important for the registration, in 1988, of the first non-surgical method of early abortion, the sequential regimen of mifepristone followed, two days later, by a suitable prostaglandin. Subsequent research led to a simplified regimen, and investigated ways to shorten the duration of post-abortion bleeding. Two consultations on abortion in 2000 recommended that the Programme should develop effective, safe and acceptable misoprostol-only regimens for early first trimester as well as second trimester abortions. Two multicentre studies have been launched to address these recommendations. The benefits of routine priming of the cervix with misoprostol are also being investigated in a new study to determine whether the safety of the vacuum aspiration procedure can be improved further. Another new area of research is aimed at developing

an effective non-surgical method for a non-viable pregnancy (missed abortion).

The research generated by the Programme is used for developing norms, tools and guidelines as well as assisting countries in implementing best practices. One example of such interface is the *Technical and policy guidance* document completed in 2002.

Progress

Updating global and regional data on the incidence of unsafe abortion

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 globally and by region, new estimates of unsafe abortion became available in 2002. These data, updated every five years, provide global and regional estimates of the incidence of unsafe abortion, the ratio of unsafe abortions to 100 live births and the number of unsafe abortions per 1000 women aged 15 to 49 years, and of maternal mortality due to unsafe abortion. Overall, 19 million unsafe abortions are estimated to take place each year, corresponding to one in ten pregnancies ending in an unsafe abortion or one unsafe abortion to approximately seven live births. In Latin America and the Caribbean, the ratio of unsafe abortion is one to every three live births. Important regional differentials are found in the incidence, ratio and rate of unsafe abortion (Table 4.1). This update shows that despite a major increase in contraceptive use and in spite of

Table 4.1. Global and regional annual estimates of incidence of unsafe abortion by United Nations region, for the year 2000

	Estimated number of unsafe abortions (000s)	Incidence ratio (unsafe abortions to 100 live births)	Incidence rate (unsafe abortions per 1000 women aged 15–49)
World	19 000	14	12
More developed regions[1]	500	4	2
Less developed regions	18 500	15	15
Africa	4 200	14	22
Eastern Africa	1 700	16	29
Middle Africa	400	9	20
Northern Africa	700	15	15
Southern Africa	200	16	16
Western Africa	1 200	13	24
Asia [1]	10 500	14	11
Eastern Asia [1]	— [2]	— [2]	— [2]
South-central Asia	7 200	18	20
South-eastern Asia	2 700	23	19
Western Asia	500	10	11
Europe	500	7	3
Eastern Europe	400	14	5
Northern Europe	10	1	1
Southern Europe	100	7	3
Western Europe	— [2]	— [2]	— [2]
Latin America and Caribbean	3 700	32	26
Caribbean	110	15	11
Central America	680	20	19
South America	2 900	39	30
Oceania [1]	30	12	15

N.B. Figures may not add up to totals due to rounding.
[1] Japan, Australia and New Zealand have been excluded from the regional estimates, but are included in the total for developed countries.
[2] No estimates are shown for regions where the incidence is negligible.

the fact that unsafe abortions are entirely preventable, they continue to prevail in all developing regions.

Abortion and the Global Burden of Disease (GBD)

The Department also contributed to WHO's work on the GBD 2000, specifically, the global burden of abortion. Estimated incidence of unsafe abortion, together with unsafe abortion-related mortality and infertility, were used to estimate the global burden of disease caused by unsafe abortion in 2000. Comparisons with earlier estimates for 1990 show that the magnitude of the burden remains broadly unchanged. Mortality owing to unsafe abortion is estimated at 4 per 100 000 women of reproductive age and case fatality at 0.3 per 100 unsafe abortions. The infertility caused by unsafe abortion is estimated to be 1.4 per 1000 women of reproductive age, while the importance of the burden caused by post-abortion pelvic inflammatory disease (PID) has only recently been recognized and will be included in the final calculations for the GBD 2000. This will provide a more complete account of the worldwide health impact of unsafe abortions. The total disability-adjusted life–years (DALYs) loss due to unsafe abortion is currently estimated at over 5 million. The information on the burden of unsafe abortion is included together with other important aspects of health in the updated GBD 2000.

Fertility decline and the role of abortion

An ongoing study in Togo is assessing the role of abortion in the context of western Africa where fertility has declined but increases in contraceptive prevalence are too small to account for the change. Togo is a country where recourse to abortion is thought to be high, and the study is both documenting the incidence of abortion and investigating pathways to abortion. It includes a survey of 4500 women of reproductive age (15–49 years) to measure the prevalence of abortion and its impact on fertility levels in Lomé, Togo, and uses qualitative interviews and focus group discussions to explore the pathways to abortion among women living in Lomé. Currently, legislation in Togo permits abortion only in cases where it is performed to save the woman's life. Results are expected at the end of 2003.

Assessing the safety and efficacy of abortions performed by mid-level providers

Obtaining access to safe abortion services is a challenge for many women in developing countries facing an unwanted pregnancy. In countries 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 reasons, millions of women turn to mid-level providers or non-physicians, such as midwives, paramedics, and traditional birth attendants, who may not be clinically trained in abortion techniques. An ongoing randomized trial is investigating the safety of abortions—assessed from complications—provided by medically trained and government-certified mid-level providers compared to physicians in South Africa and Viet Nam, where first trimester abortions are currently legally performed by both physicians and non-physicians. Approximately 20 providers in four clinics and 1400 women will participate in the study in each country. Results are expected at the end of 2003.

Medical abortion clinical trials

The results of several clinical trials were published in 2002. Findings from a study testing whether repeated administration of oral misoprostol following mifepristone pretreatment improves clinical efficacy, will be published in the *British Journal of Obstetrics and Gynaecology.* Studies addressing acceptability show that many women prefer oral administration of drugs, but a previous study clearly demonstrated that 0.4 mg of oral misoprostol after pretreatment with mifepristone was not effective enough in pregnancies with gestational age longer than seven weeks (Ho PC, *British Journal of Obstetrics and Gynaecology,* 2000, 107:524–530). Side-effects and the impact of this regimen on the duration and amount of post-abortion bleeding were also evaluated, as well as women's perceptions of the treatments. 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, in 3 groups of 750 women each, with duration of amenorrhoea of: (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 worldwide. In addition to assessing efficacy and side-effects, a brief questionnaire was included in the study to collect data on women's opinions of the regimen, their assessment of whether they would feel confident using the regimen at home, and whether they would prefer home use should they be given the choice.

The complete abortion rate was 92.3% in the oral plus continued oral misoprostol group (O/O); in the vaginal-only group (V) it was 93.5%; and in the vaginal group that continued with oral misoprostol (V/O) it was 94.7%. Undetermined outcome cases were considered as failures. Among women with amenorrhoea for 57 days or more, the risk of failure of complete abortion was almost three times higher in the O/O group (RR=2.8, 95% confidence interval [CI] 1.3–5.8) and more than twice as high in the V-group (RR=2.2, 95% CI 1.0–4.7) when compared to the V/O group. Among women with shorter duration of amenorrhoea, the differences were not significant. Nausea, vomiting and diarrhoea were more frequent with oral than with vaginal misoprostol. Timing of expulsion and duration of bleeding were similar in the three groups with about 25% of the women bleeding 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 57–63 days of amenorrhoea, and

that continuing prostaglandin for one week improves the efficacy of the method significantly, but does not influence the duration of post-abortion bleeding.

Findings from several single-centre studies were also published in 2002. In connection with the study discussed above, the participating centre in Hong Kong Special Administrative Region of China (Hong Kong SAR) measured actual blood loss in the three treatment groups and found no statistically significant difference. In a separate study, the pharmacokinetics of sublingual administration of misoprostol were studied by collaborators in Hong Kong SAR; the results suggested great potential for the sublingual route to be developed into a method of medical abortion. Subsequently, a uterine contractility study was carried out in Stockholm, Sweden, comparing the sublingual and vaginal administration of misoprostol. Findings indicated that uterine contractility and uterine tonus were both significantly greater two to four hours after sublingual intake of misoprostol when compared to either vaginal or oral administration of the drug.

New projects initiated during the year

Research on men and abortion

Work is under way at the Centro de Estudios de Población, Buenos Aires, Argentina, to produce a review paper on *Men and abortion: their knowledge, attitudes, perspectives and roles*. The report will be based in part on a bibliographic review of studies and a synthesis of findings. Various topics will be analysed, including: (i) men's attitudes and their perceived roles and responsibilities toward unintended pregnancy; (ii) men's attitudes and perspectives regarding abortion including grounds for being in favour of or against abortion; (iii) the perceived psychosocial consequences for men whose partner has an abortion as well as their opinion of the consequences for their partner; (iv) men's perspectives on male involvement in abortion decision-making, on support during the abortion process (emotional, economic), and on post-abortion care, as well as on post-abortion contraceptive use; and (v) models for male involvement in abortion and post-abortion.

The review will also incorporate findings from the analysis of data from the World Values Survey describing overall patterns of attitudes towards abortion and their variation by age and sex. This analysis will evaluate the extent to which attitudes towards abortion vary across countries and identify those countries in which men and women show the greatest (and least) differences in their views on abortion. The availability of data from different points in time for selected countries will also allow examination of the extent to which attitudes towards abortion have changed over the past decades in those countries and whether men and women have experienced similar patterns of attitudinal change.

The paper will also include a critical assessment of the strengths and limitations of the studies reviewed, and the extent to which the evidence is ambiguous. On the basis of the review and the assessment, the paper will propose a strategy to address policy-relevant gaps in knowledge through research in the area of men and abortion.

Research on quality of care for post-abortion services

Although abortion is restricted by law in Argentina, health services there are beginning to address the reproductive health care needs of women with abortion complications. A new study was launched to assess the quality of post-abortion care and to evaluate a strategy for improving such care in a public hospital in Buenos Aires. Specifically, the investigators propose to assess pre- and post-intervention levels of professional competence, user satisfaction, and availability of technical resources. They will develop, implement and evaluate a model intervention that will include training health professionals in manual vacuum aspiration (MVA), pain management, diagnosis and treatment of complications, use of antibiotics, post-MVA care, post-abortion contraceptive counselling, and ethical, psychological and social aspects of the doctor-patient relationship. The issue is important for the field of reproductive health and for the field of reproductive rights. Although similar work has been done in other countries, this kind of research has not been done in Argentina, where abortion policies are restrictive. The research design and instruments build on similar work conducted in Mexico.

Non-surgical abortion with misoprostol alone

The wide availability and reasonably low price of misoprostol compared to other prostaglandin analogues have contributed to its use and to a renaissance of research into a prostaglandin-only method of pregnancy termination with this compound in countries where mifepristone has not been available. However, no systematic research had been carried out to determine the best regimen for this indication. To this end a randomized multicentre trial was launched involving 11 centres in Armenia, Cuba, Georgia, India, Mongolia and Viet Nam. The aim is to recruit 2100 pregnant women (up to 63 days of gestation) requesting legal termination of pregnancy: eligible women who wish to join the study are allocated randomly to four treatment groups. All women receive three doses of 0.8 mg of misoprostol, which will be administered either sublingually or vaginally, at intervals of 3 or 12 hours. 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 and the results should be available by the end of 2003.

Non-surgical abortion using a sequential regimen

Another study of medical abortion is comparing two doses of mifepristone, 100 mg and 200 mg, followed by 0.8 mg of vaginal misoprostol either 24 hours or 48 hours later, when used for the termination of early pregnancy in women with amenorrhoea of up to 63 days from last menstrual period.

The four regimens are to be compared with respect to the following main outcomes: effectiveness of induced complete abortion relative to the length of gestation, frequency of side-effects, and duration of bleeding. This study includes 2100 women in 14 centres in China, Hungary, Mongolia, Romania, Serbia and Montenegro, Slovenia, South Africa, Sweden, Viet Nam and Zambia. It is anticipated that the clinical phase of this study will last one year.

Routine priming of the cervix with misoprostol

A randomized, double-blind multicentre study is ongoing to test whether routine pre-operative treatment with 0.4 mg of vaginal misoprostol administered three hours prior to vacuum aspiration reduces complications, such as cervical injury, uterine perforation, severe haemorrhage, incomplete evacuation, pelvic infection, etc. This study includes a total of 5000 women up to 12 weeks of pregnancy, who are being recruited for the study in 14 centres in Armenia, China, Cuba, Hungary, India, Mongolia, Romania, Slovenia and Viet Nam. The centres estimate that recruitment of volunteers for this study will take one year.

Misoprostol-alone regimens for second trimester abortion

The two consultations on the Department's activities in the area of unsafe abortion recommended that effective regimens should also be developed for second trimester pregnancy termination. To this end, a randomized, double-blind multicentre study was launched which involves 680 pregnant women requesting legal termination of pregnancy during the second trimester of pregnancy (14–20 weeks amenorrhoea). Women are randomized to receive 0.4 mg misoprostol either vaginally or sublingually every 3 hours for up to 5 doses. Twelve centres are participating in this study from Armenia, Georgia, Hungary, India, Slovenia, South Africa, Viet Nam and Zambia. The recruitment for the study is expected to take six months and results should be available in 2003.

Sublingual/vaginal administration of misoprostol after mifepristone

Two randomized double-blind studies, one in the first trimester and the other in the second trimester, are ongoing in Hong Kong SAR to compare the efficacy, side-effects and acceptability of sublingual administration of misoprostol compared to vaginal administration after mifepristone pre-treatment. The results of these studies are expected to be available in late 2003.

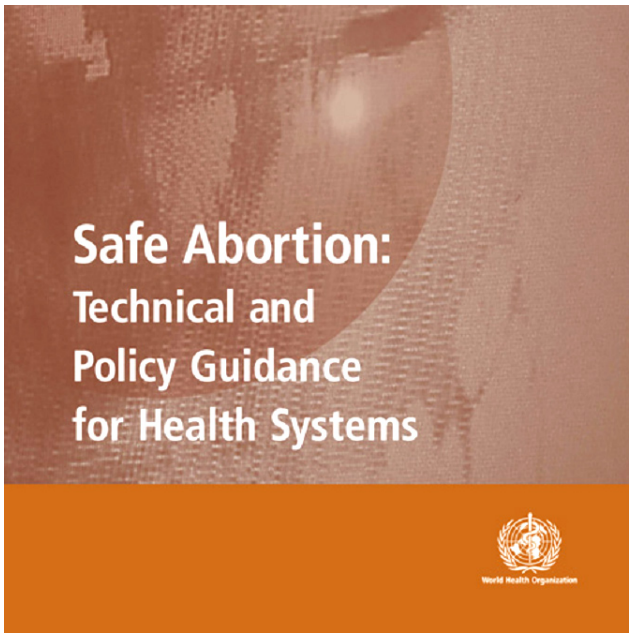
NORMS AND TOOLS

Specific objectives/targets

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

Technical and policy guidance on safe abortion

During 2002 a document entitled *Safe abortion: technical and policy guidance for health systems* was revised and finessed by a group of clinical, legal and health systems experts. The document is ready for publication and will be available in English in early 2003. Over the next year, translations into French, Russian and Spanish, and possibly Portuguese and Romanian, are plannned.



The rationale for the document is the ICPD+5 government agreement that "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 the International Conference on Population and Development.* New York, United Nations, 1999).

The document consists of four chapters covering: (i) the public health challenge of safe abortion; (ii) clinical care for women undergoing abortion; (iii) putting services in place; and (iv) legal and policy considerations. It includes a number of annexes relating to further reading, post-abortion contraception, and international agreements on abortion services. The following sections summarise the main recommendations from the document.

The public health challenge

In developing countries, the risk of death following complications from an unsafe abortion procedure is several hundred

times higher than that of an abortion performed professionally under safe conditions. Complications resulting from unsafe abortion, including infertility, contribute to serious sequelae for women's health. Since no contraceptive is 100% effective, there will continue to be unwanted pregnancies which women may seek to end by induced abortion. In almost all countries the law permits abortion to save the woman's life and in most countries abortion is allowed to preserve the physical and mental health of the woman (Figure 4.1).

For women to have rapid access to safe abortion services as provided by law, these services need to be available, provided by well-trained health personnel, supported by policies and regulations, and supported by health systems infrastructure, including equipment and supplies.

Clinical care for women undergoing abortion

Determining the length of pregnancy is a critical factor in selecting the most appropriate abortion method. Bimanual pelvic examination and recognition of other symptoms of pregnancy is usually adequate although laboratory or ultrasound testing may be used for confirmation. In areas where anaemia is prevalent, measuring haemaglobin or haematocrit levels will enable prompt response in case of complications requiring blood transfusion. Routine use of antibiotics at the time of abortion reduces the post-procedural risk of infection. Complete, accurate and easy-to-understand information about the procedure and what to expect during and afterwards must be given to the woman, as well as voluntary counselling about options available to her to help her make informed decisions.

Preferred methods for early abortion (first trimester) are: (i) manual or electric vacuum aspiration, for up to 12 completed weeks since the woman's last menstrual period, and (ii) medical methods of abortion consisting of a combination of mifepristone followed by a prostaglandin such as misoprostol or gemeprost, for up to 9 completed weeks since last menstrual period. Misoprostol is the prostaglandin of choice for most settings since it is relatively inexpensive and does not require refrigeration.

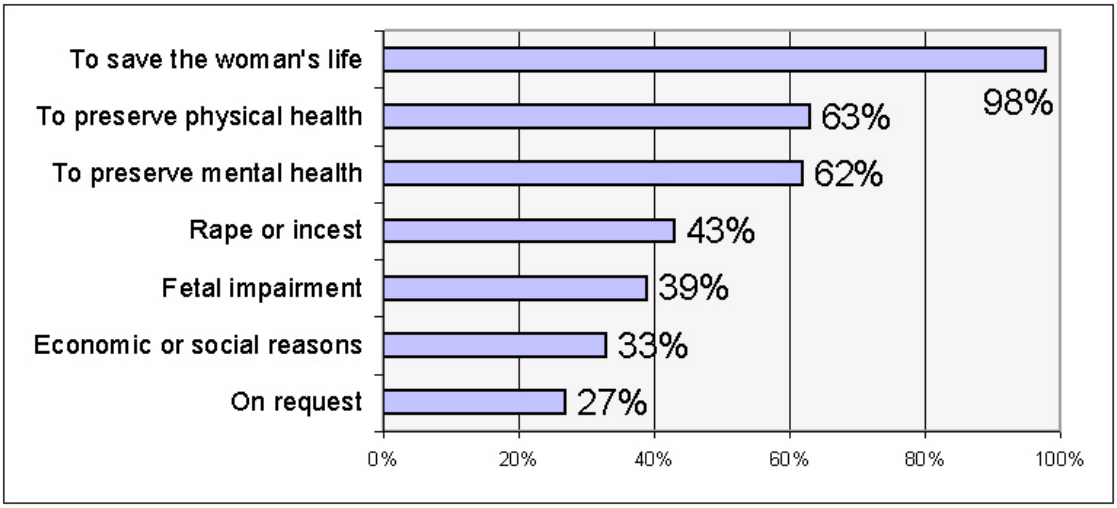
For pregnancies of more than 12 completed weeks since the woman's last menstrual period, the preferred methods are: (i) dilatation and evacuation (D&E), using vacuum aspiration and forceps; (ii) mifepristone followed by repeated doses of a prostaglandin such as misoprostol or gemeprost; and (iii) prostaglandins alone (misoprostol or gemeprost), in repeated doses.

Medication for pain management should always be offered. Universal precautions for infection control should be used, as with the care of all patients at all times, to reduce the risk of transmission of bloodborne infections including HIV. Before they leave the health care facility, all women should receive information on contraception and, for those who want them, contraceptives or referral to contraceptive services should be provided. Women should receive oral and written instructions about how to care for themselves after leaving the health care facility, about how much bleeding to expect, and about recognizing complications and how to seek help for them.

Putting services in place

Planning and managing abortion services requires consideration of a number of factors which are applicable irrespective of the circumstances under which abortion is legal, or who has responsibility for decision-making and implementation within the health system. They apply whether services are public, private or nongovernmental and include the following: (i) assessment of the current situation regarding laws and regulations, extent, level and quality of services currently provided, characteristics of users, and attitudes and knowledge of health care providers; (ii) establishment of national norms and standards governing the provision of quality

Figure 4.1. Percentages of countries by legally permitted grounds for abortion



Source: United Nations Population Division, 1999.

abortion care, including essential equipment and supplies, referral mechanisms, respect for women's informed decision-making, attention to the special needs of adolescents, and special provisions for women who have suffered rape; (iii) definition of provider skills, training, supervision and certification processes; (iv) monitoring and evaluation of services; and (v) financing.

Legal and policy considerations

As Figure 4.1 shows, in almost all countries abortion is allowed at least when there is a threat to the woman's life. The majority of national laws also allow abortion when pregnancy poses a threat to the woman's physical or mental health; many allow it when pregnancy is the result of rape or incest or when there is fetal impairment; and several allow it for socioeconomic reasons and on request by the woman. Very often, administrative barriers exist which hinder women from accessing the services to which they are legally eligible.

An enabling policy environment is needed to ensure that every woman legally eligible has ready access to high-quality abortion services. Policies should be geared to achieving positive health outcomes for women, to providing good-quality family planning information and services, and to meeting the particular needs of groups such as poor women, adolescents, rape survivors and HIV-infected women. Policies and programmes should aim to remove barriers to the timely provision of services such as lack of knowledge of the law, lengthy judicial processes for rape victims, third-party authorization or notification clauses, unnecessary conditions or procedures such as waiting periods, and excessive restrictions on the kinds of health professionals or institutions licensed to provide abortion.

New work and progress on systematic reviews of abortion

In 2002, two new Cochrane systematic reviews addressing safe abortion were published in the Cochrane Library. One of these reviews compares different surgical methods for first trimester termination of pregnancy. The review found the evidence inadequate for comparing surgical methods in terms of rare outcomes, women's satisfaction, the need for pain relief, and providers' preferences. The second review compares medical and surgical methods for first trimester termination of pregnancy. Although based on evidence from small trials, the results of this review suggest that prostaglandins alone are less effective and more painful than surgical methods. There is inadequate evidence to compare the acceptability and side-effects of the two methods. Another Cochrane review comparing medical methods for first trimester termination of pregnancy is currently under way and will be ready for publication in the Cochrane Library in 2003.

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 the introduction of post-abortion family planning. In response to the assessment, the Vietnamese Ministry of Health began a series of activities to implement the recommendations made, and included strategies for reducing recourse to abortion and for improving the quality of abortion services in its National Reproductive Health Strategy for 2001–2010, which has just been published.

In late 2001, the Ministry of Health began a project known as the Comprehensive Abortion Care (CAC) Project which is developing and testing a high-quality, client-centred abortion care model to be replicated at all levels of the health system in Viet Nam. The project is being implemented in collaboration with the Institute for the Protection of Mothers and Newborns, Hanoi and Tu Du Obstetrics and Gynaecology Hospital, Ho Chi Minh City. The 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 in 2002, WHO and Ipas supported the development of Vietnamese 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. The guidelines and service delivery protocols are being tested at the two national tertiary referral hospitals responsible for national training in reproductive health, prior to being revised and disseminated. The Programme will include training for their utilization at more peripheral levels of service delivery.

Although the new national standards and guidelines included the provision of medical abortion, the initial service delivery guidelines being tested did not include introduction of medical abortion protocols, focusing instead on improving the provision of existing surgical abortion services. The project is currently assisting in the development of service delivery protocols for the introduction of first trimester medical abortion into project activities.

Improving abortion care in Romania: policy and practice

In November 2001, the Programme assisted the Ministry of Health of 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 abor-

tion services in the public and private health care sectors. A national conference to disseminate the findings of the assessment was convened in Bucharest in April 2002 and included a wide range of stakeholders from across the country. Core members of the assessment team began implementing some of the key recommendations immediately following the conference.

The first policy recommendation addressed was the need to develop national standards and guidelines for abortion care. Staff from the Ministry of Health and Family, the National College of Physicians, and the Society of Obstetrics and Gynaecology are developing draft guidelines which will be circulated for review to a broader technical committee, as well as to the team that carried out the strategic assessment. Completed guidelines will be disseminated in a proposed dissemination conference in early 2003.

In response to other assessment recommendations, the Directorate of Maternal and Child Health recently expanded the eligibility criteria for free contraception to include not only students and the unemployed, but also all women residing in rural areas and all those undergoing abortion in the public sector. For the first time, the Ministry has earmarked its own funds for the purchase of contraceptives for eligible women. In addition, oral and injectable contraceptives were placed on the list of drugs to be subsidized by the National Health Insurance House. A related new policy now requires all obstetrics-gynaecology departments to provide safe, high-quality abortion services, including post-abortion contraception, at an affordable price which is set by the Ministry of Health and Family. Further policy outcomes of the assessment have included the signing of an agreement between the Ministry of Health and Family and the Ministry of Education for the mandatory introduction of health education in Romanian schools in 2003, as well as plans to begin an information, education and communication campaign utilizing mass media to inform women about the availability of free contraceptives, following the introduction of the new, expanded eligibility criteria.

In November 2002, the East European Institute of Reproductive Health began work on a project to introduce high-quality post-abortion family planning counselling and modern contraceptives as part of comprehensive reproductive health care. The project will run for four years and complement planned work to improve abortion care in Romania.

Members of the assessment team are currently preparing a proposal for a three-year project which will develop a model for comprehensive abortion and post-abortion care services in Romania, based on the recommendations of the assessment and the new standards and guidelines. This model will be tested at referral and district level hospital services in two regions of Romania, prior to being scaled up throughout the country. It will focus on improving the quality of existing services and will include the introduction of MVA and medical abortion.

Annex 1

SPECIALIST PANEL FOR SOCIAL SCIENCE AND OPERATIONS RESEARCH IN REPRODUCTIVE HEALTH IN 2002
AND
RESEARCH GROUP ON POST-OVULATORY METHODS OF FERTILITY REGULATION IN 2002

See Section 1 on Promoting Family Planning.

Annex 2a

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	26	100					26
Women	15	86					15
from:							
AFRO	2	8					2
AMRO							
EMRO							
EURO			20	77			20
SEARO	1	4					1
WPRO	3	12					3

Annex 2b

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Annex 2b (continued)

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	27	66	10	24	4	10	41
Women	15	37	3	7	2	5	20
from:							
AFRO	2	5					2
AMRO	2	5					2
EMRO							
EURO			10	24	4	10	14
SEARO	4	10					4
WPRO	19	46					19

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	8	47	7	41	2	12	17
Women	5	29	3	18			8
from:							
AFRO	2	12					2
AMRO	2	12			1	6	3
EMRO							
EURO			7	41	1	6	8
SEARO							
WPRO	4	24					4

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Section 5

Promoting sexual and reproductive health of adolescents

Promoting sexual and reproductive health of adolescents

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

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, socioeconomic status, region and cultural context. Addressing the needs of young people in the context of rapid and profound social, economic and political change in the developing world is undoubtedly challenging. Behaviours of young people may also change faster than societal values, a disjuncture that has implications for the development of sound policies and programmes, such as appropriate family planning services for young people. These changes have enormous implications for adolescents' education, employment, marriage and childbearing, but also for their sexual and reproductive health and behaviour.

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 much of the world. The 1994 International Conference on Population and Development (ICPD) highlighted these issues and noted that "the reproductive health needs of adolescents as a group have been largely ignored to date by existing reproductive health services" (*ICPD Programme of Action*, paragraph 7.41. New York, United Nations, 1995). 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.

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 supporting research that addresses issues relevant to policy-making and enhances the evidence base on the sexual and reproductive health situation and needs of adolescents, including intervention research on the optimal provision of health and information services. Related to this work are activities intended to strengthen research capacity and to disseminate findings. At the same time, technical and managerial tools and advocacy materials developed by the Department for reproductive health in the population at large are also tailored to address the unique needs of adolescents.

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. The focus is on behavioural research, both social science and operations, largely supported by the ongoing social science research initiative on the topic.

Progress

Trends in sexual and reproductive behaviour among young never-married women: a case study of Colombia and Peru, 1985–1999

In collaboration with staff of the University of London School of Hygiene and Tropical Medicine, London, United Kingdom, a study was completed that documented yearly trends in sexual activity, contraceptive use, and subsequent reproduc-

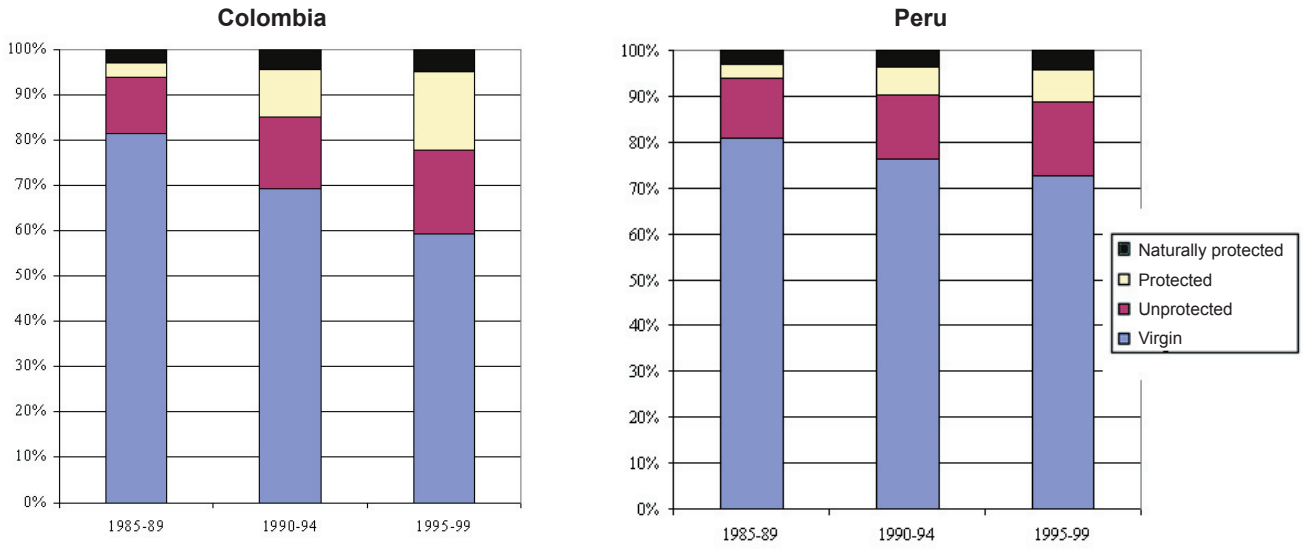
tive outcomes among never-married women aged 15–24 in Colombia and Peru. Using 'calendar' data from successive Demographic and Health Surveys (DHS), the study reveals that over the period 1985–1999, young single women in both settings became sexually active at increasingly younger ages (Figure 5.1). Contraceptive use, and especially the use of condoms, did increase (Figure 5.2), but this increase did not fully offset the rise in sexual activity. The evidence suggests, therefore, an increase in the incidence of unplanned pregnancies and abortions among young single women.

The results have three major implications for programmes and policies. First, the clear trend towards sexual activity—for many, unprotected—at early ages among adolescent females calls for programmes and policies that reinforce efforts to provide appropriate information and services to the unmarried. Second, contraceptive services and choices must be made available to youth, condoms must be promoted vigorously and made widely available, and efforts made to reduce failure associated with periodic abstinence and withdrawal. Third, a more comprehensive strategy may be warranted to address the various dimensions of young women's sexual and reproductive lives. This strategy would need to go beyond the focus on contraceptive use to address the ever-increasing number of abortions and unwanted children born out of wedlock.

Estimating unsafe abortion among young women

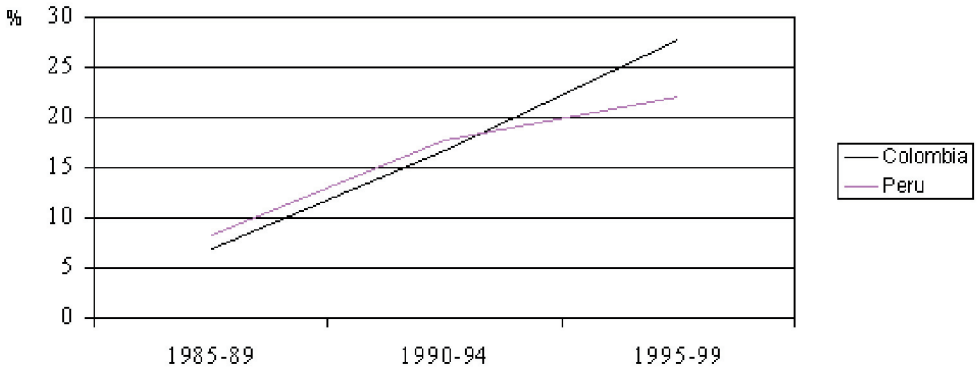
As part of the Department's work on estimating the incidence of unsafe abortion, data by age were used to estimate the magnitude of unsafe abortion among women aged 15–19 and 20–24 years. Overall, 40% of all unsafe abortions in the developing world occur among women aged 15–24 years, resulting in 7.3 million unsafe abortions in this age group each year. In Africa, nearly 59% of all unsafe abortions occur among women aged 15–24 years (Table 5.1).

Figure 5.1. Never-married women, 15–24 years, in specific exposure states, Colombia and Peru.



Source: Ali et al, forthcoming

Figure 5.2. Contraceptive protection through condom use, never-married women of 15–24 years, Colombia and Peru



Source: Ali et al, forthcoming

Table 5.1. Unsafe abortions worldwide by age group and region

Region	Age group					
	15–19 years		20–24 years		15–24 years	
	% of all unsafe abortions	No. of unsafe abortions	% of all unsafe abortions	No. of unsafe abortions	% of all unsafe abortions	No. of unsafe abortions
Developing countries	14	2 500 000	26	4 800 000	40	7 300 000
Africa	26	1 100 000	33	1 400 000	59	2 500 000
Asia	8	900 000	22	2 300 000	31	3 200 000
Latin America & Caribbean	15	500 000	29	1 100 000	44	1 600 000

Social science research initiative on adolescent sexual and reproductive health

The year 2002 witnessed the continuation, in 28 countries, of 41 research projects approved in 2001 or earlier, addressing social and behavioural aspects of adolescent sexual and reproductive health in different developing country settings. As described in earlier reports, the studies address sexual risk behaviours, their correlates and consequences, and health-seeking behaviour, quality of care and provider perspectives.

Since late 2001, 36 papers have been published, presenting results and policy implications; these have highlighted the extent, patterns and consequences of risky sexual behaviours, contraception and condom use, and abortion. They have also shed light on underlying factors that place youth at greater risk of, or protect them from, unsafe sexual and reproductive experiences. These include the roles and perspectives of parents and providers; exposure to sexuality education programmes; health-seeking behaviour and the quality of services; and gender attitudes and roles. Many studies focus on filling evidence gaps relating to the sexual and reproductive health needs of the particularly disadvantaged, such as out-of-school and migrant adolescents. Here we summarize findings from three studies addressing the particularly disadvantaged in diverse settings.

A study conducted in a slum setting in Jakarta, Indonesia, focused on young men aged 15–24, using a participatory approach and qualitative techniques. The majority of study participants had some education, but were out-of-school and unemployed. Premarital sex among young men in this setting was reported to be "*common"* and "*taken for granted*". Sexual relations with sex workers were frequently reported and often described as a group activity, usually spontaneous and largely dependent on the availability of cash. As other studies in this age group have noted, condom use was largely dismissed and a sense of invulnerability prevailed. Examples of statements recorded include: *"No condom, boys do not use condom… if you use condom, it is not sex. Sex is skin to skin. With protection it is not pleasant"* (in-depth interview, unemployed man aged 23); and *"I do not think that far…I do not bother*" (focus group discussion [FGD], unemployed group).

Neither infection nor pregnancy are necessarily perceived as likely adverse consequences of sexual relations: *"I go to the brothel… if we got a disease… it is fate… have thought about it but never got it"* (FGD, unemployed group). Infection is perceived as easily treatable: *"… One time I got a disease but taking ampicillin [antibiotics] 500, after three days recovered… just drink herbs, you won't get [sexually transmitted] disease, you can be sure of traditional herbals"* (in-depth interview, temporarily employed parking-lot attendant aged 23). Pregnancy and abortion were not uncommon, but sometimes used as a strategy for forcing parents to consent to an early marriage: *"Many [unwanted pregnancy] happen here… It happens because of the parent factor, because parents don't permit it, they just do it [sex, become pregnant]"* (FGD, unemployed group).

Several programmatic implications were recommended as a result of this study. First, misconceptions and lack of awareness about sexual risk behaviours need to be addressed in ways that are acceptable to peer networks; messages concerning condom use in particular must be reinforced. Second, study participants themselves acknowledged the need for counselling—preferably through mentoring relationships—and for opportunities to discuss and seek information and advice on sexual and reproductive health. Third, the findings suggested the need to modify current approaches to youth to address the special service delivery needs of low-income and out-of-school young men and women.

A study of the sexual risk behaviours of adolescent girls and boys in a low-income setting in New Delhi, India, also reveals risky sexual behaviours: 5% and 15% of adolescent girls and boys, respectively, reported sexual activity. As in Jakarta, many sexually active young men reported relations with sex workers, yet a considerable percentage reported relations with girls residing in the community. Study findings underscore wide gender disparities in socialization and a false confidence among parents that withholding information from adolescents and closely regulating the activities of daughters will protect them from risky sexual encounters. Findings suggest that despite strict regulation of daughters, sexual relations are not unknown: "*There are a lot of constraints on girls' movements. But they continue to meet their male friends stealthily. When parents learn of these cases they generally forcibly get them married off elsewhere after an abortion or agree to get them married to the same boy"* (adolescent girls, 17–19, slum resident); and, *"There are some cases of pregnancies among unmarried girls, we do have girls of this kind in our area. We do not know them well"* (adolescent girls, 15–17, resettlement colony).

The findings from this study highlight the need for interventions that: (i) recognize and address misperceptions held by parents; (ii) apprise parents of existing conditions and of the need to communicate with their adolescent children in order to inform them about sexual and reproductive health issues, to protect them from unsafe and unwanted sex; and (iii) convince parents of the need to focus on enhancing informed choice among adolescents rather than imposing tight regulation, because it is a more effective strategy of ensuring sexual and reproductive well-being.

The findings also suggest the need for programmes that provide extensive sexuality education for both young females and males, that facilitate communication between adolescent partners and between adolescents and their parents on sexual matters, and that seek to redress gender imbalances and double standards influencing adolescents' own autonomy and ability to exercise informed choice. Finally, programmes are needed that reorient adult gatekeepers, and particularly providers, away from traditional and judgemental attitudes to premarital sexual activity and towards the provision of services that enable safe sexual relations among young people.

A qualitative study of young migrant females to five cities in China (Beijing, Guangzhou, Guiyang, Shanghai and Taiyuan) underscores the risky sexual behaviour characterizing this population. The findings also show that there are many obstacles to negotiation with partner(s) on sexual matters as well as to the access of contraception and services. Major industrial cities in China attract a large number (between 70 and 80 million) of internal temporary or seasonal migrant workers—called "floating population"—mostly from rural areas. On short-term employment contracts and without permanent household residence, these migrants do not receive the health and welfare benefits available to registered residents. Women comprise over a third of this population, and about half of these women are under 25 years and unmarried; most work in small factories or in the service industry.

The study revealed that while premarital sex was perceived as acceptable, young female migrants deeply feared disclosure of their sexual activity status to their families at home. While they expressed concern about the social consequences of an unintended pregnancy, several obstacles inhibited them from practicing contraception. Most sexually active young women believed that family planning distribution centres were for married women only. Most had never used contraception, few knew where to obtain it, and many preferred to risk pregnancy (calling it "*just bad luck*") than the embarrassment of acquiring contraceptives and risking disclosure of their sexual activity status. Providers reported that migrant women were more likely than non-migrants to delay seeking abortion and to experience multiple abortions. They were also more likely to resort to private—usually unqualified—providers, believing that confidentiality would be better protected.

The researchers made several programmatic recommendations based on the evidence: that registration offices and employers of migrant workers should provide information to new arrivals regarding family planning and the location of services; that reproductive health services for migrants be made available in medical clinics attached to the workplace; and finally, that service delivery strategies be adapted to address the needs of migrant young women, for example through visits by urban family planning workers to migrant workplaces and residences. Findings of this study were disseminated through a WHO *Social science policy brief* and a paper in *Reproductive Health Matters* (Zheng et al., 2001).

Network activities

A network of researchers supported by the social science research initiative on adolescent sexual and reproductive health was established in 2000 to initiate a forum for the exchange of ideas and information. The network is also a means of providing technical support to researchers. Network activities include: (i) regular updating of both the synopsis of ongoing research supported by the initiative and the annotated bibliography of relevant materials; (ii) the maintenance of a limited documentation centre and facilities to provide researchers with materials they are unable to access otherwise; (iii) the provision of core instruments (FGD guidelines, in-depth interview guides and a survey questionnaire) for the study of adolescent sexual risk behaviours, that are intended for researchers to adapt to the thematic focus of their research and to the local context; and (iv) site visits to investigators in selected countries.

Dissemination

In addition to publication in peer-reviewed journals (see Annex 3), findings from several projects supported by this

research initiative have been disseminated at seminars and conferences. Highlights include:

- The International Union for the Scientific Study of Population (IUSSP) Population Conference: Southeast Asia's Population in a Changing Asian Context, Bangkok, Thailand, June 2002. A session on "Adolescent sexual and reproductive health: the new Asian scenario" was organised by the Department, and four papers by participating investigators were presented.

- The 6th Asia-Pacific Social Science and Medicine Conference, Kunming, China, October 2002. The Department sponsored five sessions at the conference, dealing with issues related to adolescent sexual and reproductive health. Eleven papers by investigators participating in the initiative were presented.

- A volume submitted for publication with syntheses of 45 major presentations and panel discussions from an international conference held at Mumbai, India in 2000, entitled Adolescent Reproductive Health: Evidence and Programme Implications for South Asia.

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

As described in previous 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 includes three phases: (i) a baseline survey of adolescents using health services, and of the quality of services offered; (ii) an intervention, informed by findings from the baseline survey, to address the information needs of adolescents, training of service providers or modification of existing services to enhance their youth-friendliness; and (iii) a post-intervention survey to evaluate the effectiveness of the intervention. The Programme facilitates and coordinates this regional initiative and provides support for research capacity strengthening, but funding for each country project is raised locally.

In Benin and Côte d'Ivoire, the survey was completed in 2000, findings were disseminated at local and national levels and interventions have been under preparation but not yet implemented because of a lack of funding. In Senegal, the evaluation has been completed and analysis is ongoing. In 2002, research activities were initiated in Cameroon and the baseline survey commenced in December. In Guinea, the evaluation phase will be initiated in early 2003.

With the Programme's collaboration, the centre in Senegal was included in the USAID-funded project FRONTIERS in Reproductive Health (along with centres in Bangladesh, Kenya and Mexico), in a study of reproductive health services for youth. Selected findings have been presented in earlier reports.

The project has also contributed to the development of tools, including a training manual for health professionals on adolescent health and development. These tools are now available for French-speaking countries.

Regional research initiative on adolescent migrants and reproductive health in the Greater Mekong region

A regional research initiative is ongoing in one major city in each of five countries of the Greater Mekong region, namely China (Yunnan Province), the Lao People's Democratic Republic, Myanmar, Thailand and Viet Nam. The objective is to assess the reproductive health needs of a growing but vulnerable and marginalized sub-population, young migrants. At the same time, the initiative aims to strengthen research capacity through intraregional networking. Using qualitative research methods, the study explores risky and health-seeking behaviours, and service and information needs.

In 2002, an investigators' meeting was held at the Institute of Population and Social Research (IPSR), Mahidol University, Bangkok, Thailand, to develop study instruments and implementation plans. Preliminary findings from Thailand are available and suggest that young migrants perceive themselves as healthy; as far as health seeking is concerned, neighbourhood pharmacies are commonly mentioned sources of treatment for minor ailments, and government hospitals are sought for delivery care or immunization of children. However, reproductive health knowledge and use of reproductive health services is limited. For example, while unmarried adolescents are aware of HIV/AIDS, they tend to lack information about sexually transmitted infections; use of government health services is limited, and condoms, if used, are more likely to be purchased from pharmacies than obtained from government facilities.

Data from all settings will become available in early 2003 and investigators will meet to discuss analysis in March at a workshop to be held in Kunming, China, and organized by the Institute of Sociology, Yunnan Academy of Social Sciences, China. Results from the initiative will be disseminated at the World Congress of the International Institute of Sociology in Beijing, China, on 7–11 July 2003.

Research on pre-adolescent girls reporting vaginal symptoms

Studies are under way in Mongolia in response to reports from providers of unusually high levels of lower genital tract infection among pre-adolescents. Symptoms may have been observed by adolescents themselves or 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 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.

Study on bone mass and hormonal contraception

An ongoing study in Durban, South Africa, explores the extent to which use of hormonal contraception at ages 16–20—a period critical for bone mass acquisition—depresses peak bone mass achieved and puts young women at greater risk of osteoporosis in later life. This is a five-year longitudinal study in young (16–20 years) and older (45–49 years) women of the impact of depot medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN) and combined oral contraceptives on bone mass density, with a comparison group of women not using any hormonal contraception. Preliminary results were presented at a meeting in September in South Africa (for further details, see the chapter on Safety and effectiveness of existing methods).

New projects initiated during the year

Social science research initiative on adolescent sexual and reproductive health

Two new projects were approved in 2002. The first, "Interactive sex education program on the Internet", provides an exciting and youth-friendly opportunity to address young people's sexual and reproductive health concerns and information needs. The study, to be undertaken in selected schools in Shanghai, China, will (i) design and implement a sex education web site for adolescents; and (ii) evaluate this intervention in terms of changes in knowledge and attitudes, and also in terms of young people's own assessments about its usefulness. The second study, "Condom use among temporary migrants in urban China", aims to understand the perspectives of young male migrants with regard to condoms: their awareness, attitudes and practices. More specifically, it will identify condom use patterns and explore constraints to condom use among young temporary migrants. Findings should help identify acceptable strategies to increase condom use among young migrants in China.

Plans for future work

Although there is increasing evidence of risky *consensual* sex among young people in developing countries, *non-consensual* sexual experiences among them have rarely been studied. Moreover, few interventions exist that are intended to protect adolescents from unwanted sexual experiences. In this context, the Programme intends to take steps, jointly with YouthNet and the Population Council, to consolidate available evidence and identify and fill research gaps in the area of non-consensual sexual experiences of young people.

The *World report on violence and health* (World Health Organization, 2002) has increased awareness of the issue of forced sexual debut among young people; similarly, an ongoing study, coordinated by WHO, of physical and sexual domestic violence experienced by women in six countries, sheds light on sexual violence experienced by young women, and raises important questions. A more dedicated investigation of their situation and needs is required. For the most part, however, while the non-consensual sexual experiences of young people are highlighted in studies of sexual violence in general, few studies focus exclusively on the experiences and particular circumstances of young people. Rape is the most extreme form of non-consensual sex, but it is not the only form that youth experience and the available evidence demonstrates the existence of unwanted touch, coerced sex through threats, deception and use of force, and sex in exchange for gifts and money in diverse sociocultural settings. Yet these issues remain poorly studied and insights into the context in which these experiences occur and the risks they pose to a healthy transition to adulthood remain limited.

To raise awareness of this neglected issue and arrive at a global consensus on concepts, ethical issues, and measurement issues and appropriate design, the Programme will collaborate with the Population Council and YouthNet in a phased initiative intended to promote dialogue and enhance the evidence base on non-consensual sexual experiences of young people. In its first phase, scheduled for late 2003, a consultative meeting is proposed that will consolidate the available evidence and raise awareness of the issue, outline outstanding gaps in evidence, identify scientifically and ethically sound research approaches to fill these gaps, and lay the foundation for evidence-based direction for programmes intended to protect young people from non-consensual sexual advances.

NORMS AND TOOLS

Specific objectives

Because adolescents are more likely than adults to experience risky outcomes and to require different approaches in terms of service and care provision, norms and tools intended to enhance the reproductive health of individuals in general must be adapted to the particular situation and needs of adolescents. These issues are highlighted in guidelines and other tools for programming and capacity building developed by the Department. Other norms and tools relating to adolescent sexual and reproductive health needs are developed by the Department of Child and Adolescent Health and Development.

Tools developed

Included in every tool developed by the Department for the promotion of reproductive health is a special section devoted to the unique needs of adolescents. For example:

- The *Pregnancy, childbirth and newborn care: a guide for essential practice*, and the ECPG for RTI/STIs, give special attention to the needs of adolescents and the special considerations that should be accorded when dealing with adolescents. Further information on these

two tools can be found in the chapters on Implementation of evidence-based programes in Section 2: Making Pregnancy Safer and in Section 3: Controlling sexually transmitted and reproductive tract infections.

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

- The Department also developed specification and procurement guidelines for the male latex condom and is working with the United Nations Population Fund (UNFPA) and the Inter Agency Task Force Team on Prevention of HIV to develop condom programming guidelines, giving special consideration to the needs and situation of adolescents.

- The training curriculum, *Transforming health systems: gender and rights in reproductive health,* provides support for programming at national level for adolescent sexual and reproductive health in several ways, including through the presentation of case examples of adolescent sexual and reproductive health issues intended to sensitize participants to address adolescent needs within their programmes and services.

- Following the publication in 2001 of *Advancing safe motherhood through human rights,* a shorter version for use by policy-makers and programme managers is now under development. This pocket guide is intended to assist national level managers address key rights issues for adolescents and other special groups.

- In January 2002, a Technical Consultation on Sexual Health was held, which addressed both adolescent and adult sexual health issues. The consultation report will be published in early 2003, together with a selection of the background papers, including one focusing particularly on healthy sexual development.

LINKS WITH THE DEPARTMENT OF CHILD AND ADOLESCENT HEALTH AND DEVELOPMENT

The Department continues to collaborate with the Department of Child and Adolescent Health and Development (CAH) in several activities. Staff members actively participate in the working groups on HIV/AIDS and young people and on adolescent pregnancy. Staff members also participated in a meeting on Monitoring & Evaluation of HIV/AIDS in Young People, jointly organized by WHO, the United Nations Children's Fund (UNICEF), and the Joint United Nations Programme on HIV/AIDS (UNAIDS), to take a significant step towards developing a guide for the monitoring and evaluation of HIV/AIDS programmes for young people. Staff members also participated in a workshop on the role of "regulation" on adolescent behaviour organized by CAH, and in a meeting on adolescent pregnancy organized by CAH to obtain the perspectives of all relevant WHO departments. They also continued to provide extensive comments and suggestions on documents produced on adolescent sexual and reproductive health issues.

Annex 1

SPECIALIST PANEL FOR SOCIAL SCIENCE AND OPERATIONS RESEARCH ON REPRODUCTIVE HEALTH IN 2002

See Section 1 on Promoting Family Planning.

Annex 2

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Annex 2 (continued)

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	53	91	4	7	1	2	58
Women	33	57	3	5	1	2	37
from:							
AFRO	11	19					11
AMRO	17	29			1	2	18
EMRO	2	3					2
EURO	2	3	4	7			6
SEARO	11	19					11
WPRO	10	17					10

Other scientists

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	9	50			9	50	18
Women	3	17			5	28	8
from:							
AFRO	2	11					2
AMRO	2	11			5	28	7
EMRO							
EURO					4	22	4
SEARO	3	17					3
WPRO	2	11					2

Annex 3

PUBLICATIONS IN 2002

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Section 6

Gender and reproductive rights in reproductive health

Gender and reproductive rights in reproductive health

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

INTRODUCTION

The International Conference on Population and Development (ICPD, Cairo, 1994) and the Fourth World Conference on Women (FWCW, Beijing, 1995) both clearly emphasized the need to promote gender equity and equality in reproductive health policies and programmes, and to promote and protect human rights. These agreements were reinforced in the five-year reviews of both conferences, held in 1999 and 2000, respectively. Among the key issues to be given greater attention following the recommendations of the reviews were: measures aimed at promoting and achieving gender equality and equity in a systematic and comprehensive manner (ICPD+5, paragraph 39); the incorporation of issues related to sexual and reproductive health 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 by ensuring that all health services and workers conform to ethical, professional and gender-sensitive standards in the delivery of women's health services, including through the establishment or strengthening of regulatory and enforcement mechanisms (Beijing+5, paragraph 107 g). In order to contribute 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;
- to support countries to ensure that reproductive programmes and policies respect, protect and fulfil human rights and promote gender equity and equality; and
- to 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.

INTEGRATING A RIGHTS-BASED APPROACH INTO SEXUAL AND 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 have a negative impact on health. This can be by 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 non-discrimination. The absence of laws and policies which protect human rights, such as those which prohibit female genital mutilation, and the lack of punishment and social condemnation of perpetrators of violence against women, have also been shown to contribute to negative health outcomes. Thus, 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. The Department is therefore working both at the country and the interna-

tional 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 improve reproductive and sexual health. The objectives of this area of work are:

- to elaborate and implement a methodology for integrating human rights into aspects of reproductive health interventions, through country pilot projects; and

- to develop evaluation mechanisms, including indicators for measuring the impact of integrating human rights.

Over the past year, the Department has continued to work on the development of a human rights framework for maternal and neonatal health, and has been defining new work in the areas of sexual health broadly and sexual and reproductive health of refugees specifically.

Progress

Health and human rights framework and prioritising tool for maternal and newborn health

The framework and tool, initially elaborated for WHO's Making Pregnancy Safer initiative, is designed to facilitate a multidisciplinary analysis of the determinants of maternal and neonatal mortality and morbidity and the interventions to address them. Organized around rights related to safe motherhood, the tool links a government's commitments to international human rights treaties, conventions and consensus document targets, to the national legal and policy environment, and health processes and outcomes associated with maternal and newborn health. It helps countries to review clearly, and appraise systematically, the range of rights, their accepted meanings, and consequent obligations in terms of government law, policy and practices. This in turn permits an identification and assessment of those laws, policies and practices that are facilitating the reduction of maternal and neonatal mortality and morbidity, and those that are hindering such a reduction. By bringing different perspectives to bear, the tool and the analysis process will result in recommended areas for action based on multidisciplinary, multistakeholder consensus on what is urgently needed to improve maternal and newborn health. Through this rights-based process and use of the tool, the Department will contribute to governments' efforts to become more accountable for their international commitments to promote and protect their citizens' rights to maternal and neonatal health care.

With the continued assistance of the Francois-Xavier Bagnoud Center for Health and Human Rights at the Harvard School of Public Health, Boston, MA, USA, the Department finalized the framework in 2002 and presented it to the Department's Scientific and Ethical Review Group (SERG) for comment. It was agreed that the more detailed tool, when further elaborated and validated, could be submitted for further review in early 2003.

The Department commissioned the Swiss Institute for Social and Preventive Medicine in Basel, Switzerland, to instrumentalize and validate the tool. The results and recommendations of the study will inform the finalization of the process and tool before it is field-tested in Mozambique in 2003. In response to the recommendations of GAP and SERG, a user's guide has been developed to explain terminology, and the purpose and intent of the data collection, analysis, and reporting sections of the tool. It also explains the participatory methodology that must accompany the tool's use at different stages of the process. The user's guide is also part of the validation study.

Critical for the implementation of such a process and tool in countries is the collaboration and partnership of government, WHO regional offices, partner agencies such as the United Nations Population Fund (UNFPA) and the United Nations Children's Fund (UNICEF), and other key partners in the field such as the Averting Maternal Death and Disability (AMDD) network coordinated by Columbia University, New York, NY, USA, and other nongovernmental organization (NGO) actors such as the Center for Reproductive Law and Policy (CRLP) and the International Planned Parenthood Federation (IPPF). In 2002, various meetings were held with these partners to share approaches to addressing maternal and perinatal mortality reduction efforts using a rights-based approach.

If the planned field test in Mozambique is successful, the Department, as recommended by GAP in 2002, plans to support the use of the tool and process in two other countries with high maternal and neonatal mortality and morbidity. The countries will be selected on the GAP-suggested criteria of: (i) government commitment to applying a human rights approach; (ii) a basic public health infrastructure being already in place; and (iii) capacity to undertake the process,

including the involvement of nongovernmental partners, especially women's health and rights groups and human rights committees.

Indicators for measuring fulfilment of rights

At its January 2002 meeting, GAP recommended that the Department continue to work on a framework for rights indicators, focusing on laws and their application, already existing reproductive health process and outcome indicators, and on finding a way to capture a state's accountability. Progress in this area has been slow, partly because priority was given to other areas of work, and partly because elaboration of "rights" indicators is being discussed at a broader, Organizational level, coordinated by the Health and Human Rights Unit in the Director-General's Office.

In the second part of 2002, an informal meeting was held with two members of the Committee for Economic, Social and Cultural Rights (for details, see below), whose covenant contains the right to the highest attainable standard of health. The committee has specifically requested WHO to elaborate indicators that can be used to monitor the right to health, as laid out in its General Comment No.14, adopted in August 2000. Discussion at this meeting clarified that a "rights" indicator may very well be a "health" indicator, but it must be tracked back to a human rights norm and can be used to hold duty-bearers to account. Such an indicator might be, for instance, the maternal mortality ratio which can be tracked back to the right to life, for which governments could be held accountable if they have not trained and equipped health services to provide women with comprehensive essential obstetric care or if no such services are available. Importantly, these health indicators which are also "rights" indicators, can be linked to the UN Millennium Development Goals.

The Department's work on the Health and Human Rights Framework (described above) will help flesh out this work on rights indicators, because it is organized in such a way that health indicators are grouped under specific rights to which they have relevance. The Department will continue to contribute to the overall development of rights indicators, with a specific contribution to sexual and reproductive health areas. A more formal meeting with health indicator and human rights experts is foreseen for 2003, for the Organization as a whole, to which the Department will substantially contribute.

Sexual health

In late 2000, WHO headquarters agreed to review definitions and work related specifically to sexual health. With the support of a grant from The Ford Foundation, the Department was able to engage all WHO regional offices in the preparatory process during 2001 and in the international Technical Consultation on Sexual Health which took place in January 2002. Preparatory work for the consultation included commissioning background papers from consultants in China, Egypt, Guinea, India, Indonesia, Jamaica, Latvia, Lebanon, Morocco, the Philippines, the Russian Federation, South Africa, Thailand, Turkey and Zimbabwe, as well as convening four regional roundtable discussions. This was done with the assistance of staff from the Pan American Health Organization in close collaboration with representatives of the World Association of Sexology.

The Technical Consultation on Sexual Health was organized in collaboration with the Departments of HIV/AIDS and of Child and Adolescent Health and Development. The meeting was attended by 60 participants from all regions of the world and from a variety of disciplinary fields (e.g. HIV epidemiology, sexuality and behaviour research, family planning and reproductive health service provision, sexology, anthropology, mental health). During the meeting, participants reviewed the burden of illness related to sexual ill-health, discussed background determinants (including legal and policy issues), shared regional, social and cultural barriers and opportunities for addressing sexual health, and began to build international consensus around new definitions. The report of the meeting, which includes the revised definitions and a selection of the background papers, will be published in early 2003.

One of the results of the consultation has been interest, in both regional offices and headquarters, and the commitment to better address sexual health and rights as a topic. The Regional Office for the Eastern Mediterranean (EMRO), for instance, is planning to sponsor a regional meeting on sexual health in 2003, while the Regional Office for the Americas (AMRO) cosponsored a meeting on the sexual health of indigenous populations in October 2002, in Venezuela.

Following the Technical Consultation, the Department's Scientific and Technical Advisory Group (STAG) recommended that sexual health be developed as an area of work for the period 2004–2009. This recommendation resulted in the convening of an international Strategic Committee on Sexual Health in early October 2002, with the purpose of setting new priorities in the area of sexual health and rights, which will form part of the overall work plan for the Department for the next three biennia. The committee consisted of representatives from all regions, from a variety of disciplinary backgrounds.

In preparation for this meeting, the Department commissioned two reviews to inform the discussion: *Integration of sexual health into reproductive health services: needs, evidence and implications* (Royal Tropical Institute of the Netherlands, Amsterdam, Netherlands); and *Searching for sex: a systematic literature review of international research related to sexuality and sexual behaviour* (La Trobe University, Melbourne, Australia). The reviews focused on previously unaddressed dimensions of sexual health and sexuality that could form the basis of the Department's future work in sexual health, as GAP has recommended in January 2002. As a result, the priorities developed by the Strategic Committee on Sexual Health reflect many unaddressed and

under-addressed issues such as the service delivery needs of sex workers, migrants and refugees, and topics such as pleasure, harmful sexual practices, and the construction of masculinity and femininity and how these affect sexual health and well-being. These reviews are currently being revised for possible publication in 2003.

Informed consent research

In 2002, the final report from a study in Mexico on informed consent procedures in sterilization services, carried out by the Mexican Institute of Social Security, with support from the Programme and technical assistance from EngenderHealth, became available. This descriptive, qualitative study was done through observations of client-provider interaction and in-depth interviews with users, providers and managers. The study examined postpartum and interval tubal occlusion for women and vasectomy for men. It found that the preoperative information given to many women undergoing postpartum sterilization was often inadequate. Generally speaking, women undergoing interval sterilization received more complete information than those accepting a postpartum procedure. Men were generally better informed than either group of women, and they tended to ask for more information before and during the counselling than did the women.

Perceptions of the significance of the informed consent form varied considerably. Providers and managers generally felt that signing the form indicated that clients had understood the procedure they were about to undergo. However, many of the women did not feel they had received adequate information and yet believed that the informed consent form constituted legal protection for themselves. To most vasectomy acceptors, signing the informed consent form implied a shared responsibility between them and the health workers.

As a result of the study findings, the Mexican Institute of Social Security is proposing to implement training of health workers to improve counselling for informed decision-making and to foster understanding of sexual and reproductive rights. They also intend to develop a protocol for counselling pregnant women about sterilization so that information given postpartum is better understood, and they will make information about the right to free and informed decision-making for clients widely available.

Following the pilot studies on informed consent in research, conducted in Brazil and Chile in 1998–1999, the Department will conduct further research in the coming year to examine the informed decision-making process. A suitable multicountry study needs to be identified, on which to "piggy-back" the study.

Sexual and reproductive health of refugees

The Department is currently exploring the possibility of expanding its work to the reproductive health and rights of migrants, including refugees. In November 2002, staff from the Department participated in an international expert meeting, organized by the International Centre for Reproductive Health, Ghent University, Ghent, Belgium, on sexual and reproductive needs and rights of women displaced by war and armed conflict. In 2003, the Department will work further with its partners on ways to improve the protection of reproductive rights of refugees and improve the reproductive health services provided.

Technical and policy guidance on safe abortion

During 2002, the Department finalized the guidance document on safe abortion, under the coordination of Gender and Reproductive Rights Group. The document will be published at the beginning of 2003. Details are given in the section on Preventing unsafe abortion.

NORMS AND TOOLS FOR ADDRESSING GENDER AND RIGHTS IN REPRODUCTIVE HEALTH

Specific objectives/targets

The Gender and Reproductive Rights Group aims to integrate gender and rights considerations throughout the Department's normative work. While the Group's guidance documents focus on the gender and human rights aspects of sexual and reproductive health, particularly as highlighted in the legal and policy environment, the Group also works with other Departmental teams to ensure that those considerations are integrated into other guidance documents. In 2002, the Group thus focused on addressing legal, policy, regulatory and practice barriers related to maternal and newborn health, and on expanding its work with the Human Rights Treaty Bodies to bring greater attention to the human rights related to sexual and reproductive health.

Norms/tools under development

Policy and rights in maternal and newborn standards of care

In order to assist colleagues within the Department to better address gender and rights issues within specific thematic areas, staff of the Gender and Reproductive Rights Group participated as part of the Making Pregnancy Safer core team on issues related to gender and rights. In 2002, the Group's contribution has focused on developing a health and human rights assessment framework and tool for reviewing legal, policy and practice related to maternal and newborn health (see above) and on reviewing and incorporating gender and rights considerations into the maternal and newborn health standards of care. Working as part of the health systems group within the Making Pregnancy Safer team, the Gender and Reproductive Rights Group has contributed a policy standard, policy recommendations for many of the clinical and other health system standards, and specific references to gender and rights issues within each standard. The stand-

ards of care are currently under review and are scheduled to be published in mid-2003.

Advancing safe motherhood through human rights: users' guide

In 2001, the Department published *Advancing safe motherhood through human rights* as an occasional paper. The purpose of the document is to explore how human rights, long established in national constitutional laws and other national laws, and international human rights treaties, can be applied to advance safe motherhood. The Document's aim is to contribute to national initiatives to promote compliance with human rights principles, and national and international dialogues on how a human rights approach to advance safe motherhood might be developed and applied. The document summarizes case law and examples of how governments can and do respect, protect and fulfil their obligation to safe motherhood. Since the document is very comprehensive, the Department has developed a summarized version (users' guide) to facilitate its use by a variety of actors. The users' guide is currently being reviewed to see whether it should be published independently or as a part of the *Making pregnancy safer planning guide* which is under development.

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

Over the past two to three years, greater emphasis has been given within WHO as a whole to integrating human rights into technical areas of work. This reflects the mandate given by the United Nations Secretary-General five years ago for human rights to be integrated as an approach across the United Nations Organization and its various agencies. Within WHO, the Health and Human Rights Unit in the Director-General's Office is coordinating, among other things, the various departments' technical contributions to the UN Human Rights Treaty Monitoring Bodies, in which the Department has been taking an active role.

All countries have ratified at least one, and sometimes several of the human rights treaties. The most well known of these treaties at the international level are: the International Covenant on Civil and Political Rights (monitored by the Human Rights Committee [HRC]); the International Covenant on Economic, Social and Cultural Rights (monitored by the Committee on Economic, Social and Cultural Rights [CESCR]); the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW); and the Convention on the Rights of the Child (CRC), both of whose monitoring committees have the same acronym as the Convention. Each of these committees meets twice or three times per year to examine between five and eight country reports which indicate the extent to which these countries are making progress (or not) in the respect, protection and fulfilment of the various human rights laid out in the covenant or convention. After examining a country's report, and those submitted by intergovernmental agencies and nongovernmental organizations, the committee makes concluding observations which are recommendations the country is expected to act upon before its next report in 3–5 years' time.

Because these treaties have the force of law, countries are legally bound to work towards implementing the recommendations of the committees. In the area of sexual and reproductive health, for instance, a concluding observation which requests a country to give greater support to ensuring access for all women to emergency obstetric care, in order to fulfil the right to health (and the right to non-discrimination on the basis of sex), will need to be taken very seriously by the country. WHO's work with the treaty bodies can therefore help the committees to understand a particular health issue in a country (by presenting sound data), and to include specific recommendations relating to that health issue in its concluding observations. These concluding observations can then be used by WHO and its partners in a country to strengthen the work that they are already carrying out—or about to carry out—on, for instance, making pregnancy safer. In other words, working with the treaty bodies provides an opportunity to use the human rights mechanisms as an additional tool for promoting and supporting country-level policies and programmes in sexual and reproductive health.

As recommended by GAP in January 2002, over the next year the Department plans to make reports to all four treaty bodies mentioned above on four or five countries per treaty body, and to work with at least one country on ensuring the implementation of the concluding observations. The Department will continue to contribute to the coordination of this work across different departments as well as with WHO Regional Offices, and an evaluation will be carried out after one year on the usefulness of the exercise.

The Department is embarking on more intensive work in this area over the next 1–2 years. In 2002, for example, a report was submitted to the HRC on the maternal health situation in the Republic of Moldova, one of the Making Pregnancy Safer spotlight countries. The Department worked with the WHO Regional Office for Europe and the country office to obtain the latest data available. The HRC included reference to deteriorating health services and the need to improve these for women's health in its concluding observations on the Republic of Moldova. These will be used by the Making Pregnancy Safer team in work with the country.

In October 2002, a human rights adviser joined the Gender and Reproductive Rights Group to work more specifically on collaboration with the treaty bodies. As a result, the Department has been working closely with the Department of Child and Adolescent Health and Development to ensure the provision of data on adolescent sexual and reproductive health in the reports to the CRC on Bangladesh, Jamaica, Morocco and Sri Lanka. As recommended by GAP, the Department has also been involved in discussing the proposed General Comment on adolescent health and development, which is likely to be finalized next year.

For the CESCR it was decided to focus particularly on those reporting countries where the improvement of reproductive and sexual health issues is especially crucial (Guatemala, Republic of Moldova, Russian Federation and Slovakia in 2002). The compiling of all these reports—which are usually limited to a maximum of five pages including recommendations—is done in close consultation with country and regional offices. The Department is also working with UNFPA on the preparation of some reports.

TECHNICAL COOPERATION WITH COUNTRIES

Training on gender and rights in reproductive health

The Department has played a key role in coordinating a multicountry, multi-institutional effort to elaborate a training curriculum to integrate gender and rights in reproductive health.

Of the five institutions which have run the course, two—the Key Centre for Women's Health in Society (Australia) and the Centre for African Studies (Kenya)—ran the course for the fourth time each in 2002. The Women's Health Project at the University of Witwatersrand (South Africa) ran its sixth course in October 2002. All three courses were well received. The Centre for the Study of State and Society (CEDES, Argentina) and the Yunnan Reproductive Health Research Association (YRHRA, China) both expect to run the course again in 2003, on completion of the translated versions of the curriculum (see below). Much of the continued work on the course was carried out with support from The Ford Foundation.

Expansion of the training to other regions

To support the further expansion of the course to other regions, the Department supported four trainers to attend the South African course in October 2002 in a training of trainers capacity: three people from the Kazakhstan School of Public Health and one from the University of Sains Malaysia. In all cases their participation was guided by trainers from the Women's Health Project with a view to their adapting and running the course in their region in the future. In particular, these two training centres have expressed interest in running a training course using the curriculum in 2003.

Training of trainers courses on gender and rights in reproductive health

Over recent years, the Department has been increasingly solicited to give technical support to shorter courses of two to five days, focusing specifically on rights, or on gender and rights. Therefore, the Department ran a three-day training of trainers workshop on the Rights Module from the curriculum to provide additional training to the five regional centres (in Argentina, Australia, China, Kenya and South Africa) that are already running the course. The aim was to train experienced trainers in running a two- to three-day module on human rights and reproductive health within their region, as well as to reinforce those centres' capacity to teach the Rights Module as part of the three-week training course. The evaluation by participants was very positive and some of those trained have already run the module in the context of the full training course.

Short courses and adaptation of key sessions for use in other courses and curricula

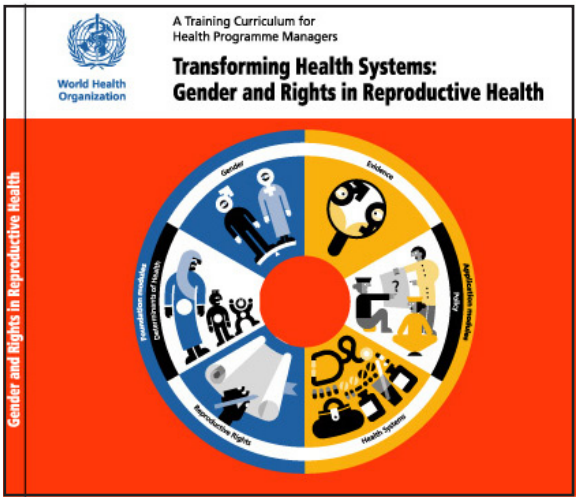
In September 2002, the Sakhi Women's Resource Centre in Trivandrum, India, which coordinates a state-level network of women's development organizations working with sexual and reproductive rights, adapted parts of the modules on Gender, Social Determinants and Policy for a two-week course on Gender, Health and Development. Part of this short course is also integrated into the Gender and Health Course of the Masters of Public Health Programme offered by Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, in Trivandrum, India, and is also going to be run in 2003.

In the field of medical education, a number of medical schools and those involved in elaborating medical curricula have approached WHO for guidance in integrating gender and rights into these curricula. Canada and India in particular are pursuing the adaptation of certain parts of the WHO training curriculum on gender and rights in reproductive health, for use in the broader curriculum. The Sree Chitra Tirunal Institute for Medical Sciences and Technology is taking the lead in a process of national sensitization for medical educators, health service managers, policy-makers and others, by designing a syllabus for a course on gender and medical education. The Department is collaborating with WHO's Department of Gender and Women's Health and the Regional Office for South-East Asia (SEARO) to give technical support to this endeavour, and to support representatives from other countries in the region to participate in an adaptation workshop to be held in July 2003.

Promotion of the training curriculum

Dissemination of the curriculum has been carried out in a targeted way through regional offices, collaborating agencies and centres and other training institutions that expressed an interest in response to a brochure published and distributed earlier in 2002. As part of the dissemination strategy, the curriculum has been promoted at several international meetings. Presentations of the curriculum were also organized at WHO headquarters and at EMRO (July 2002), the Regional Office for the Western Pacific (WPRO) (August 2002), AMRO (September 2002) and SEARO (September 2002). All these events brought regional WHO staff together with representatives of governmental organizations and NGOs, collaborating agencies, universities and medical and nursing schools.

A CD-ROM version of the curriculum in English has been prepared, and 3000 copies were available for distribution at the end of December 2002. CD-ROM versions in other languages will be prepared as the texts become available. The production of an interactive electronic version for use on the Web is being considered.



The Spanish translation of the training manual has been completed by CEDES and will be published in 2003. The Chinese translation, prepared by YRHRA, will be finalized in March 2003. Both these centres will continue to run the course in their regions in 2003. The possibility of producing a French version is being explored with several centres in Africa.

Future plans

Over the next biennium, the Department plans:

(i) to encourage and give technical support to the centres in Kazakhstan and Malaysia to run the course for countries in their region;

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

(iii) to give guidance and technical support to develop short-course adaptations for use with specific countries or organizations.

Annex 1

GENDER ADVISORY PANEL (GAP) IN 2002

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Raffaela Schiavon, The Population Council, Mexico, DF, Mexico
Angeline Faye Schrater, Florence, MA, USA
Rashidah Shuib, University of Sains Malaysia, Kelantan, Malaysia
Zhang Kaining, Yunnan Reproductive Health Research Association, Kunming, China

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	9	90			1	10	10
Women	6	60			1	10	7
from:							
AFRO	1	10					1
AMRO	3	30			1	10	4
EMRO	1	10					1
EURO							
SEARO	2	20					2
WPRO	2	20					2

Temporary advisers In 2002

Marge Berer, Reproductive Health Matters, London, United Kingdom
Borbala Koo, Society for Education on Contraception and Sexuality, Bucharest, Romania
Karen Newman, International Planned Parenthood Federation, London, United Kingdom
Wanda Nowicka, Federation for Women and Family Planning, Warsaw, Poland
Sheila Tlou, University of Botswana, Gaborone, Botswana
Makhosazana Xaba, Ipas, Johannesburg, South Africa

Annex 2

SCIENTISTS IN 2002

Korrie de Koning, Royal Tropical Institute (KIT), Amsterdam, the Netherlands
Gary Dowsett, Australian Research Centre in Sex, Health and Society, La Trobe University, Melbourne, Australia
Sofia Gruskin, François Xavier Center for Health and Human Rights, Harvard School of Public Health, Boston, MA, USA
Marian Pitts, Australian Research Centre in Sex, Health and Society, La Trobe University, Melbourne, Australia

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members					4	100	4
Women					3	75	3
from:							
AFRO							
AMRO					1	25	1
EMRO					1	25	1
EURO							
SEARO							
WPRO					2	50	2

Section 7
Technical cooperation with countries

Overview of activities—interregional activities and collaboration with regional offices

A. Ntabona, M. Mbizvo

INTRODUCTION

The Department continued to cooperate with WHO regional and country offices, governments, nongovernmental organizations (NGOs) and other partners, with the objective of addressing reproductive health needs through intraregional and national research, and through research and technical capacity strengthening.

HIGHLIGHTS OF PROGRESS IN INTERREGIONAL ACTIVITIES DURING 2002

Publication of brochures on research capacity strengthening grants

Following the recommendations made by the in-depth evaluation of research capacity strengthening by the Programme, the Department published brochures outlining key components for each research capacity strengthening grant. The brochures were complemented by a description of each grant on the Department web site. Included with each brochure are revised application and reporting forms, the grant objectives, key elements for grant award, and criteria for selection of centres and monitoring the performance of centres. Where applicable, indicators for impact and efficiency are also included.

Meeting of Regional Advisers in Reproductive Health on impact of health sector reforms

The 2002 meeting of Regional Advisers and staff of the headquarters Technical Support to Countries Team reviewed experiences and lessons learnt when implementing health reforms. Participants exchanged information and shared regional experiences, including research findings, of the impact of health sector reforms on reproductive health programmes and outcomes. They recommended that further research be conducted to establish the extent to which health sector reforms have facilitated or impeded the delivery of quality reproductive health services. There was a need to monitor the implementation of various reforms using defined process indicators.

Inter-agency workshop on Effective Partnerships for Accelerating the Implementation of Reproductive Health Programmes

The World Bank, the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF) and the Department jointly convened a workshop aimed at enhancing understanding of key reproductive health issues in the context of development modalities such as Sector-wide Approaches (SWAPs), United Nations Development Assistance Frameworks (UNDAFs) and Poverty Reduction Strategy Papers (PSRPs). The workshop reviewed strategies for accelerating the implementation of reproductive health programmes through effective partnerships. Participants agreed on defining benchmarks towards building national capacities in reproductive health and underscored the need for improving reproductive health services to serve effectively as entry points for HIV prevention and care.

Enhancing WHO and UNFPA collaboration in reproductive health

Senior technical staff from UNFPA and WHO met to outline areas of collaboration and refine modalities for such cooperation. The bilateral technical consultation preceded a high-level meeting of the executive heads of UNFPA and WHO. The meetings emphasized the need to reinforce complementarity in the implementation of activities of mutual interest and to accelerate actions towards the achievement of the

development goals of the United Nations Millennium Declaration and other international development goals and targets related to reproductive health. As part of agencies' common efforts to improve sexual and reproductive health, it was recommended that all staff in the respective agencies should articulate consistent, ethical and evidence-based messages on best practices. In addition, the meeting outlined areas of possible collaboration within the UNFPA-funded Strategic Partnership Programme, which is set to replace the Technical Advisory Specialist System at the headquarters of agencies participating in the Technical Advisory Programme.

Collaboration with WHO regional offices

Collaborative activities were undertaken with each of the WHO regional offices, in line with joint plans of action developed in 2001 or early 2002. Table 7.1 provides highlights of collaborative activities with WHO regional offices in 2002.

WHO collaborating centres in reproductive health

In 2002, there were 55 officially designated WHO Collaborating Centres for Research and Technical Cooperation in Human Reproduction/Reproductive Health and two new centres had completed the screening process for designation. In addition, there was cooperation with 26 centres which are not officially designated.

PLANNED ACTIVITIES

Meetings were held in 2002 with Family Health International (FHI), the Population Council FRONTIERS Project and other partners to plan a technical consultation in 2003 where guidelines will be drawn up for the translation of reproductive health research findings into policy and programmes.

The Department will collaborate with the United States Agency for International Development (USAID) and the Program for Applied Technology in Health (PATH) towards convening a global conference on Reaching Men to Improve Sexual and Reproductive Health for All.

The Interregional Consultation with Regional Advisers in 2003 will be based on the theme of Pregnancy in Adolescents, and will be hosted by the WHO Regional Office for the Western Pacific in Manila, Philippines.

Table 7.1. Collaboration with WHO Regional Offices, 2002

WHO Regions	Collaborative activity
Africa	• Organisation of a meeting of investigators to finalize the protocol and develop instruments for the proposed intraregional study on community and facility interventions to improve maternal health. • Organisation of the first meeting of a Regional Reproductive Health Task Force whose mandate includes, among other things, providing guidance to AFRO on issues relevant to Member States in the implementation of the region's Reproductive Health Strategy, advising on programmatic directions most likely to impact positively on service delivery, and mobilizing resources. • Collaboration in identifying centres and areas of cooperation within the proposed grants to Service Guidance Centres.
Americas	• Collaborative activities embraced the areas of improving maternal and perinatal health, introducing emergency contraception, defining programmes for male involvement, improving adolescent sexual and reproductive health, and the application of the Strategic Approach to increase access to quality reproductive health services.
Eastern Mediterranean	• Initiation of the development of a reproductive health research directory (five countries). • Continuation of the research study on adolescent reproductive health (three centres). • Organization of a workshop on ethics in reproductive health research (Oman).
Europe	• Providing support to training courses in reproductive medicine, operations research and reproductive biology.
South-East Asia and the Western Pacific	• Systematic introduction of *Essential care practice guides*.

Annex 1

PUBLICATIONS IN 2002

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. *A framework to assist countries in the development and strengthening of national and district health plans and programmes in reproductive health.* A report based on the meeting of WHO Regional Advisers in Reproductive Health, World Health Organization, Geneva, Switzerland, 21–24 August 2000 (WHO/FCH/RHR/02.2).

UNDP/UNFPA/WHO World Bank Special UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. *Programming for male involvement in reproductive health*. A report based on the meeting of WHO Regional Advisers in Reproductive Health, Regional Office for the Americas (PAHO), Washington, DC, USA, 5–7 September 2001 (WHO/FCH/RHR/02.3).

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. *Report on the in-depth review of research capacity strengthening by HRP/WHO.* Geneva, World Health Organization (WHO/FCH/RHR/02.4).

The WHO Regions of Africa and the Eastern Mediterranean

H. Bathija, D. Chikamata, A. Fahmy

INTRODUCTION

The main objective of the Department's activities in this area is to pursue the strengthening of research capacity of institutions in the WHO Regions of Africa and the Eastern Mediterranean in order 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 as follows:

1. development of subregional centres of excellence, which are capable of assisting weaker centres, especially those in least developed countries (LDCs);

2. promotion of networks through South to South and South to North links;

3. improvement of research protocol development, research management and scientific writing;

4. promotion of intraregional training;

5. stimulation of interest in sexual and reproductive health issues in LDCs, French-speaking Africa and the Eastern Mediterranean Region;

6. promotion of resource mobilization for research capability strengthening activities in the two regions;

7. strengthening of research skills in the social sciences; and

8. promotion of "targeted" research on major reproductive health problems and on the needs of LDCs.

RESEARCH ACTIVITIES

Overall research output

The nine 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 the total number of 71 studies, nine projects (13%) were implemented with support from the Programme. Twenty-six projects (37%) 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 eight projects (11%) conducted in these collaborating institutions with support from the various teams of the Department. Likewise, the institutional strengthening efforts deployed by the Programme in these regional centres have enhanced their capacities for fundraising from other international agencies, to address topics of global or local relevance: 36 projects (51%) carried out in these centres received support from international agencies other than WHO.

Some 31% of the projects were mainly in the area of epidemiology or social sciences and a similar percentage (38%) were on clinical research. Eleven projects (15%) were basic science studies and eight (11%) used operations research designs with several methodologies. All thematic areas were

studied, but the highest number of projects dealt with maternal health (21), family planning (13) and HIV/AIDS (9). Many projects were dealing with several thematic areas concurrently.

Regional research initiatives

Research on female genital mutilation (FGM)

Current work on FGM supported by the Programme focuses on the obstetric sequelae of FGM, as well as the sociocultural context of the practice. The objective of this work 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 being undertaken as a multicountry, multicentre prospective cohort study, based at maternity units and obstetrics departments in Burkina Faso, Ghana, Kenya, Nigeria, Senegal and Sudan. It aims to provide reliable information regarding the health consequences of FGM and has the primary objectives of estimating the incidence of obstetric complications among women with FGM giving birth in hospital, and evaluating 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 possible recruitment into the study. Those who volunteer 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 infants born to these women.

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

The pilot phase of the study was carried out between December 2000 and the end of February 2001. The main phase is being conducted in the same six countries as the pilot study: Burkina Faso (5 sites), Ghana (3 sites), Kenya (3 sites), Nigeria (6 sites), Senegal (13) and Sudan (3 sites). At the end of November 2002, a total of 22 440 questionnaires had been received from participating centres. Data collection for the main phase has ended in Kenya, Ghana and Nigeria and will continue in the remaining sites until March 2003. Since FGM type III is concentrated in Burkina Faso and Sudan, it was decided that centres in these countries should recruit 9000 and 6000 subjects, respectively, to ensure sufficient cases of FGM type III. The first results are expected in the second half of 2003.

Although there is growing information on the sociocultural aspects of FGM, much of it is fragmentary and obtained 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. A call for proposals for studies examining these aspects was prepared in 2001 and sent out in 2002 to more than 200 persons, groups or institutions.

The following were among the priorities highlighted in the call for proposals:

Understanding factors underlying the persistence of the practice

The determinants of marriageability; how FGM may affect directly or indirectly a woman's fertility; how childbearing is linked to the practice; and how the kinship system (type of society, lineage systems, inheritance, gender roles and identity) influence the preservation of the practice.

Understanding the decision-making process for FGM

Gender power relationship, women's status and the social organization; the power differential between the different actors involved in the FGM decision-making process; the effects of the power differentials on outcomes such as the continuation, abandonment or introduction of change in the nature of the practice.

Understanding the links between gender relations and sexual constructs, and FGM

How gender identity is constructed in relation to the practice of FGM; the social values and functions of the initiation ceremonies; the significance of the physical act of cutting and how the act of cutting influences a woman's identity and sexuality; male and female perspectives on male sexual preferences in relation to FGM.

Assessing the changes in the practice of FGM

The ways in which people reach the decision to reject or change the tradition; how people figure out how to put their decisions into practice, the support that allows them to stick to their decisions, and the extent to which they are able to share their experience with others; the implications of their decisions for their daughters' marriages, maintenance of marital unions, and impact on their own and their daughters' social and economic status; the relationship between changes in women's status and conditions and changes in the practice; the consequences of changes in the practice on individual women's and community's perceptions of women's role, identity and sexuality; and the reasons behind the adoption of FGM by non-practising communities.

A total of 30 responses were received to the call for proposals. An FGM research group was set up and met in July 2002 to review them. Nine projects were selected for further development and eventual funding. These studies are expected to start in 2003.

Operations research on improving reproductive health services for adolescents

In 2002, 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 research capacity strengthening aspects of the project, but funding for most country projects is being raised locally. The WHO Country Office for Benin funded the first phase of the study, and in Cameroon the Programme contributed to the financing of the first phase. A characteristic feature of the project is the 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 FRONTIERS Project has assumed the funding for the formative research and interventions in Senegal, while the Programme contributed financially to the evaluation phase that was completed in 2002.

Adolescent reproductive health in the Eastern Mediterranean Region

In response to the recommendations of the intercountry workshop on "Adolescents' Needs and Perspectives in Reproductive Health in the Eastern Mediterranean Region", held in Tunisia in 1999, the Department, in collaboration with the Regional Office for the Eastern Mediterranean Region (EMRO) has, since 2000, given technical support for the development of research proposals in the Islamic Republic of Iran, Oman and the Syrian Arab Republic.

These studies are in progress and explore the reproductive knowledge, attitudes and behaviour of 15–18 year old boys in Tehran, Islamic Republic of Iran, and of adolescents in secondary schools in Oman and the Syrian Arab Republic.

Operations research on community and facility interventions towards improving maternal-newborn health

The Regional Advisory Panel (RAP) for the WHO Regions of Africa and the Eastern Mediterranean agreed, in its meetings in 1998 and 1999, that a multicountry operations research study on maternal health should be initiated to examine the ways pregnant women, communities and health personnel perceive pregnancy complications and react to them. The aim was to develop appropriate strategies for action, including the use of antenatal care visits to prepare birth plans for pregnant women and explore ways of assuring skilled attendance at delivery. It had also been agreed that a special feature of the study would be to look at the role of men in maternal health care. The issue of community involvement in maternal health was identified in the February 2000 and March 2002 joint planning meetings between the Regional Office for Africa (AFRO) and WHO headquarters as one of the projects of common interest that should be developed.

In June 2002, a meeting of principal investigators was held in Geneva, Switzerland, to review a prototype protocol that had been prepared by the Department in collaboration with African researchers. At this meeting it was decided that a more detailed protocol specifically for the assessment phase should be developed. This protocol was reviewed by RAP in October 2002, and together with the overall prototype protocol that includes assessment, intervention and evaluation phases, it will be reviewed in 2003 by the Specialist Panel for Social Science and Operations Research on Reproductive Health. These protocols will be adapted to individual country needs in Ethiopia, Nigeria, South Africa and Uganda, and it is hoped the projects will start in 2003.

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

The Programme has carried out research in the area of emergency contraception to find agents that are more effective and/or have fewer side-effects than the hormonal methods used at present. 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 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 a single dose in emergency contraception up to 120 hours after unprotected intercourse, because this would simplify the treatment and increase compliance and acceptability. The project will also serve as training in clinical research carried out according to Good Clinical Practice and it will play a role in developing a network of centres that can be used for clinical research in Nigeria. Finally, the project will contribute to making emergency contraception known in parts of Nigeria where it is unknown at present and to collecting national data on the use of levonorgestrel for emergency contraception. The study will be carried out in seven family planning clinics in collaborating centres and will include 3150 women (450 for each centre). The study will be coordinated by the Centre for Reproductive Health Research in Sagamu.

Project implementation commenced with an inception meeting held on 10–13 October 2001 in Sagamu, which was attended by the principal investigator and family planning provider (nurse/midwife) from each of the seven network centres. Study materials and funds were despatched to all

study centres at the end of August 2002, allowing recruitment of volunteers to begin.

It was originally planned that the coordinating centre would receive all forms, undertake data entry and verification and conduct the data analysis. However, because of the departure of staff from the coordinating centre, it has now been agreed that all study data would be sent to the Clinical Trials and Informatics Support Unit in Geneva for data management. The Unit will assist in further capacity building of data management staff at the Sagamu Centre during the course of the project for future undertakings.

DEVELOPMENT OF HUMAN RESOURCES

Workshops and short courses

WHO-sponsored international semenology workshop

Since 1997, the Department of Obstetrics and Gynaecology in Tygerberg Hospital, Cape Town, South Africa, has organized semenology workshops for health care service providers in conjunction with WHO. The sixth WHO-sponsored semenology workshop, held in December 2002, was attended by eight participants from the University of Nairobi (Kenya), Makerere University (Uganda), University of Zambia (Zambia) and University of Pretoria and Stellenbosch (South Africa). All participants successfully completed both the theoretical and practical examinations. To date, 72 individuals have been trained and enrolled in the quality control programme for sperm morphology. The programme has allowed the establishment of satellite laboratories in various centres such as those in Kampala (Uganda), Lusaka (Zambia), Nairobi (Kenya) and Sagamu (Nigeria). Research projects in these centres such as the studies in Kenya on the potential of the primate zona pellucida as a target for contraception, have benefited. Satellite laboratories, such as the Centre for Research in Reproductive Health in Sagamu, Nigeria, have initiated local training and provided guidance to multiple individuals in the area.

Regional training course for French-speaking countries in Africa

An evaluation of more than 120 health professionals from French-speaking Africa who had taken a research methodology course organized by the Programme, suggested the need for the training of trainers who could replicate training at the national level. However, this approach has been constrained by the lack of a standardized training manual in French, among other reasons. Thus, efforts continued to develop a standardized training manual in French for research methodologies which are useful and important in studying reproductive health. The modules developed for the manual were tested in various courses during 2000 and 2001. Each module includes text, teaching aids, exercises, responses to the exercises, and handouts for the student. A working group of French-speaking experts from Africa and Europe was set up in 2002 to finalize the manual. This work will continue in 2003 since it is likely that more testing will be needed.

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.

Workshops on ethical issues in research in reproductive health

As a follow-up to the regional workshops held in Cairo (Egypt) and Kadona (Zimbabwe), the Programme supported three workshops on ethical issues in research in reproductive health in Ibadan (Nigeria), Karachi (Pakistan) and Muscat (Oman). The meeting in Karachi was organized by the National Research Institute for Fertility Care and was attended by 47 participants from research organizations in Karachi. These workshops were conducted in response to the recommendation by the Programme's Scientific and Ethical Review Group (SERG) that the Programme should organize regional workshops devoted to the principles and practice of ethics in research on human subjects in the field of human reproduction for participants from centres collaborating with the Programme. The general purpose of the workshops has been 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 infections (STIs) and HIV infection.

One regional ethics workshop is planned for French-speaking Africa for late 2003 and another for north African countries.

Regional workshop on infertility management

Since infertility is a priority issue in the WHO Regions of Africa and the Eastern Mediterranean, RAP recommended that a workshop be organized to develop a multicountry study of operational research on infertility management at the primary and secondary levels of health care. Thus a workshop on management of infertility was held in February 2002 in Nairobi, Kenya. Its objectives were to:

- define best practices and formulate solutions to the management of infertility in a limited-resource setting at both primary and secondary levels;
- 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;

- formulate a preventive strategy of infertility in the two regions.

A total of 24 participants from eight African countries (Cameroon, Democratic Republic of Congo, Ethiopia, Kenya, Nigeria, Senegal, South Africa and Uganda) and from four of the Eastern Mediterranean Region countries (Egypt, Oman, Sudan and the Syrian Arab Republic) attended. The regional offices were represented by the Regional Reproductive Health Adviser from AFRO and a consultant for EMRO. The first part of the workshop focused on sharing experience and learning from the countries in the two regions. For the second part of the workshop, the participants divided into four groups to discuss four issue areas: social aspects of infertility; prevention of infertility; management of infertility at primary and secondary health care levels; and advocacy and quality of care. The information from regional and country presentations was used in the second part of the workshop, in which discussions concentrated on development of a prevention strategy and guidelines for the management of infertility at primary and secondary levels of health care using an algorithm.

The recommendations from the workshop were as follows: (i) Services should be provided at all levels of health care for the prevention and management of STIs, unsafe abortion and traditional delivery practices and their complications, such as infertility. (ii) The use of practice guides would facilitate the improvement of quality of infertility services at the primary and secondary levels of health care. Therefore, the practice guides (algorithms) developed by colleagues in South Africa in collaboration with the Department, should be completed and field-tested. (iii) Since treatment of infertility caused by tubal damage is commonly unsuccessful, and in recognition of the limited resources available in the countries in the African and Eastern Mediterranean Regions, the development of a low-cost Assisted Reproduction Technologies (ART) protocol and establishment of low-cost ART services in a few centres in these regions should be considered.

An algorithm guide, *Prevention and management of infertility: a guide for reproductive health workers*, describing management of infertility in poor resource settings will be revised and field-tested in two centres, one in the African Region and the other in the Eastern Mediterranean Region, in 2003.

Operations research training

Recognizing the need for programmatically-focused research that complements normative and basic research, the Department, USAID, and the FRONTIERS Project signed a Memorandum of Understanding (MOU) in 2001 to collaborate in operations research (OR) activities. Improving the capacity of developing countries to conduct and utilize operations research has become an important part of this collaboration. One of the main concerns of capacity building efforts has been to institutionalize training in universities and research organizations in developing countries in order to ensure capacity to produce better-trained managers and researchers.

FRONTIERS, USAID and the Department have agreed that bringing together specialists in reproductive health research and programme management from international agencies with existing and potential training centres will contribute to improving the availability and quality of training in operations research. In turn, this will stimulate the increased use of operations research and lead to improved programme effectiveness, including quality and efficiency.

In 2002, the Programme supported 12 researchers from five collaborating centres to attend operations research training courses in Cairo (Egypt) and Dhaka (Bangladesh). Seven of the researchers selected were from the centres participating in the project "Operations research on community and facility interventions towards improving maternal-newborn health in Ethiopia, South Africa and Uganda".

A special initiative for developing an operations research training centre for French-speaking Africa was planned in collaboration with FRONTIERS and AFRO. Five institutions were first selected and invited to send in a proposal for an operations research training programme for the period 2003–2005. The selection, based on strict criteria and a site visit, ended in favour of the Centre de Recherche sur la Population et Développement (CERPOD) in Bamako (Mali). Training activities will start in 2003 and will involve 10 French-speaking countries (to be selected).

Youth training

As a consequence of the operations research projects on improving adolescent reproductive health in French-speaking countries, a youth research network was formed by the youth representatives in 2000. This network became an affiliate of the African Network for Reproductive Health Research (RESAR). In 2002, with the support of the Programme, RESAR held a research methodology training course in Abidjan (Côte d'Ivoire) that brought together young persons from eight countries. During the course the participants developed concept papers and draft protocols for four multicountry studies on themes such as "Behaviour of young people in the face of sexually transmitted infections (STIs) and HIV in rural areas", and "Sexual behaviour and use of health services by young girls who work as sex workers".

Reproductive Health Research Methodology Course in South Africa

This course has been conducted annually in the Reproductive Health Research Unit, Chris Hani Baragwanath Hospital, Johannesburg, South Africa, since 1997. The main aim of the course is to support and improve reproductive health policy and programme planning in Africa by building capacity in reproductive health research skills and intervention strategies. In 2002, the course was held on 29 July–23

August with 23 participants from eight countries. Funding was received from WHO, The Population Council, The Wellcome Trust, The Ford Foundation, the United Kingdom's Department for International Development (DFID) and the United Nations Population Fund (UNFPA).

Over the previous five years, 169 participants from 15 countries in sub-Saharan Africa have attended this course. Of these, 106 were females and 63 males. The majority of participants were from government and research institutions.

Research training grants

In 2002, six researchers were studying with funding from the Programme: one from Nigeria and one from Uganda at the London School of Tropical Medicine and Hygiene, London, United Kingdom, for a Master's course in reproductive and sexual health research; two from Côte d'Ivoire at the Free University of Brussels, Brussels, Belgium, for a course on health systems research and applied statistics; one from Nigeria at the University of Edinburgh, Edinburgh, United Kingdom, for studies in andrology; and one from Cameroon for a Master's Course in biostatistics at the University of Ibadan, Nigeria. Other grants were approved for courses to be held in 2003.

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

Since 1998, the Programme has provided support to an M.Sc. course in biostatistics at the University of Ibadan, Ibadan, Nigeria. The course is organized by the Department of Epidemiology, Medical Statistics and Environmental Health, College of Medicine, University of Ibadan. This course trains professional biostatisticians to provide statistical expertise to biomedical research groups in Africa. The Programme's support to this course includes building capacity to strengthen the academic staff and enhancing computer facilities and library resources. In the academic year 2000–2001, all eight students who had registered successfully completed the programme.

Since its inception, the course has trained 42 professional biostatisticians and epidemiologists. Of these, only five were foreign students, all others were Nigerians. However, the course now attracts students from other African countries and 10 foreign students were accepted for the fourth course held during the 2001–2002 academic year.

Training provided by the centres

Training abroad of staff from centres supported by the Programme was complemented by training programmes organized by the centres themselves for professional and technical staff from national institutions, including service providers. The nine centres receiving research capacity strengthening support (LID grants or RMGs) provided individual training to 12 staff from other institutions. Forty-five fellows participated in formal courses and 1414 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 prerequisite to their adaptation, adoption 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 way to achieve this is by means of publications in peer-reviewed journals and presentations at scientific events.

The Programme collaborated with the Francophone Regional Committee for Post-abortion Care Initiative in organizing a congress on post-abortion care in Dakar, Senegal, in March 2002. This initiative had been launched by a consortium of 12 USAID cooperating agencies. The objective of the initiative is to promote a better access to and quality of services for post-abortion care in French-speaking Africa. The congress brought together over 200 participants from 17 countries. Delegations from 12 countries prepared action plans for expansion or introduction of post-abortion care services in their respective countries at the congress.

During the reporting period, a total number of 57 research articles (42 original papers and 15 review articles) were published and 13 books or book chapters were authored by staff from the nine centres receiving research capacity strengthening support. Likewise, 46 presentations were made in national, regional or international scientific events.

SUMMARY OF COUNTRY ACTIVITIES

During 2002, the Department collaborated with 36 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 below.

OTHER ACTIVITIES

Regional directories of reproductive health

Data collection for a reproductive health research directory for the French-speaking African countries was completed in 2002 by RESAR as 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. This directory will be widely disseminated through the Internet and as a CD-ROM.

Table 7.2. Summary of country activities in the WHO Regions of Africa and Eastern Mediterranean

Country	Grants, institutions and activities
Benin	Operations research on adolescents[1] *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[1]
Burkina Faso	Obstetric sequelae of female genital mutilation (FGM)[1] - Centre Hospitalier National Yalgado Ouedraogo, Ouagadougou
Cameroon	Operations research on adolescents[1] The African Reproductive Health Research Network (RESAR): organizes research methodology courses and develops manuals for French-speaking countries[1]
Côte d'Ivoire	Operations research on adolescents[1] *LID grant 1998–2002*—National Research Cellule on Reproductive Health in the National Institute of Public Health in Abidjan, a member of RESAR: • Collaborates actively with many national agencies on issues such as validating research protocols, planning courses on reproductive health, and participated in organization of an international symposium on "Gender, population and development in Africa"
Egypt	*LID grant 1992–2002*—The Egyptian Fertility Care Society (EFCS), an affiliate of the Egyptian Medical Association. Its research network includes all university and Ministry of Health teaching hospitals: • Completed research on clinic-based assessment of incidence of reproductive tract infections in women as well as on effectiveness and side-effects of progestogen-only injectable contraceptives as perceived by users • Continued research on improving post-abortion care • Initiated a project on long-term side-effects of FGM • Conducted a 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. • Translated into Arabic and edited the textbook *The essentials of contraceptive technology—A handbook for clinic staff* (Hatcher et al., Baltimore, MD, John Hopkins University/Population Information Program, 1997) • Prepared a policy briefing and a mass media advocacy plan for efforts aiming at the eradication of FGM in Egypt • In collaboration with EMRO, provided technical assistance to Yemen for expanding the contraceptive method mix
Ethiopia	*LID grant 1990–1994. New LID grant approved for 2003–2007*—Department of Obstetrics and Gynaecology, University of Addis Ababa, Addis Ababa: • Two researchers attended operations research course[1] • Planning participation in project "Operations research on community and facility interventions towards improving maternal and newborn health"[1]
Ghana	Obstetric sequelae of FGM[1]—Rural Help Integrated, Bolgatanga
Guinea	Operations research on adolescents[1] *LID grant approved for 2003–2007*—The Reproductive Health Research Cellule (Cellule de Recherche en Santé de la Reproduction en Guinée, CERREGUI), part of RESAR

[1] Activity reported in detail elsewhere in the report.

Table 7.2. Summary of country activities in the WHO Regions of Africa and Eastern Mediterranean (continued)

Islamic Republic of Iran	*Small grant*—National Research Centre for Reproductive Health of Deputy Ministry for Research Affairs, Ministry of Health and Medical Education, Tehran Research on adolescent reproductive health: Ministry of Health[1]
Kenya	Obstetric sequelae of FGM[1]—Kenyatta National Hospital, Nairobi *Small grants*—National Centre for Research in Reproduction (NCRR) composed of 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). The Department of Obstetrics and Gynaecology, University of Nairobi, organized on behalf of the Programme the regional workshop on "Management of infertility in developing countries". Re-entry grant for research project "Production and characterization of monoclonal antibodies against BaEV and retroviral-related antigens expressed in baboon placental villous tissue", Institute of Primate Research (IPR), Nairobi
Mali	Operations research training—CERPOD: • Selected to host an operations research training programme for french-speaking countries, 2003–2005
Mozambique	*LID grant from 1989 to 1999*—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 and the centre has had an impact on the reproductive health programmes of the Ministry of Health; a number of important research activities in reproductive health utilizing a "twinning" arrangement with a counterpart department in Uppsala University, Uppsala, Sweden have taken place
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, College of Health Sciences, Ogun State University Teaching Hospital, Sagamu: • Conducts community-based research in reproductive health • Coordinates 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 Centres in Jos and Benin City planning participation in project "Operations research on community and facility interventions towards improving maternal and newborn health"[1] M.Sc. course in Biostatistics[1]—Ibadan Department of Epidemiology, Medical Statistics and Environmental Health Emergency contraception study[1]—The seven collaborating centres are the Departments of Obstetrics and Gynaecology in the university teaching hospitals in Benin City, Enugu, Ibadan, Jos, Lagos, Port Harcourt and Sagamu Support to the workshop on ethical issues in reproductive health[1], Department of Obstetrics and Gynaecology, University College Hospital, Ibadan
Oman	Support for research on adolescent reproductive health, Ministry of Health, Muscat[1] Support to the workshop on ethical issues in reproductive health held by Ministry of Health, Muscat[1]

[1] Activity reported in detail elsewhere in the report.

Table 7.2. Summary of country activities in the WHO Regions of Africa and Eastern Mediterranean (continued)

Pakistan	*Small grants*—National Research Institute of Fertility Care (NRIFC), Ministry of Population Welfare, Government of Pakistan, Karachi; Reproductive Physiology Laboratory, Department of Biological Sciences, Quaid-I-Azam University, Islamabad Support to workshop on ethical issues in reproductive health held in NRIFC, Karachi[1]
Senegal	Operations research on adolescents[1] Obstetric sequelae of FGM[1]—Université Cheick Anta Diop, Dakar *LID grant for 1999–2003*—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 Department: • Continued research on post-abortion care and on natural family planning • Organized a research methodology course and a scientific writing workshop for the Department's staff • Two researchers from the Department of Obstetrics and Gynaecology at Le Dantec Hospital, University of Dakar, Dakar attended operations research course in Cairo[1]
South Africa	*Small grant*—Reproductive Health Research Unit (RHRU), Chris Hani Baragwanath Hospital, Johannesburg Research methodology course[1]—RHRU, Johannesburg Semenology course[1]—University of Stellenbosch, Cape Town • Planning participation in "Operations research on community and facility interventions towards improving maternal and newborn health"[1]—RHRU, Durban *LID grant for 2001–2005*—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: • Objectives: to generate, implement and disseminate research-based evidence of the effectiveness of clinical and health system interventions, appropriate to the needs, customs and constraints of low-income country population; to develop the capacity of developing country health personnel in research and implementation of effective, affordable care; and to develop its research capacity through research traineeships • Focus on clinical trials designed to answer questions of relevance to reproductive health • Organized a workshop on "Practical research methods"
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; 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	Support for research on adolescent reproductive health, Ministry of Health[1]

[1] Activity reported in detail elsewhere in the report.

Table 7.2. Summary of country activities in the WHO Regions of Africa and Eastern Mediterranean (continued)

Tunisia	*LID grant for 1998–2002*—Centre for Research in Human Reproduction, National Office of Family and Population (ONFP), Tunis: • Initiated a national reproductive health research network • Held a workshop on research methodology for the research network members • Coordinates a study on the diagnosis and prevention of STIs in Morocco and Tunisia with the objective of developing a regional strategy and setting-up a regional reference laboratory for STIs • One staff member served as faculty for the international course on epidemiology and statistics held in Dakar, Senegal
Uganda	*Resource Maintenance Grant*—Department of Obstetrics and Gynaecology, 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 continuously 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 • Held a scientific writing workshop • Two researchers from the Department of Obstetrics and Gynaecology, Mulago Hospital, Kampala, attended operations research course[1] • Planning participation in project "Operations research on community and facility interventions towards improving maternal and newborn health"[1]—Department of Obstetrics and Gynaecology, Mulago Hospital, Kampala
Zambia	*Small grant*—Department of Obstetrics and Gynaecology of the University of Zambia, based in the Teaching Hospital in Lusaka : • Two researchers from the Department of Obstetrics and Gynaecology, University Teaching Hospital, Lusaka, attended operations research course[1]
Zimbabwe	*Resource Maintenance Grant*—Department of Obstetrics and Gynaecology, University of Zimbabwe, Harare: • 23 ongoing research projects and 22 publications • Developed a proposal for multicountry project on cervical cancer screening by visual inspection with acetic acid

[1] Activity reported in detail elsewhere in the report.

Informal consultation for a reproductive health research directory in the Eastern Mediterranean Region was held at EMRO in August 2001. It was attended by the country coordinators of Egypt, Islamic Republic of Iran, Lebanon, Saudi Arabia and Syrian Arab Republic, a representative of UNFPA and the WHO secretariat from EMRO and headquarters. Data collection and the follow-up activities have been hampered by the insufficiency of funds. Other funding sources have been explored in 2002 and it is hoped that the activities can be carried out in 2003.

The African Reproductive Health Research and Training Network

A feasibility study conducted in 2001 found that there was a need to establish an African Reproductive Health Research and Training Network (ARHRTN). ARHRTN will serve as an umbrella network linking, coordinating and strengthening existing reproductive health research networks for the purpose of setting regional reproductive health priorities and improving reproductive health status in Africa.

An important step towards the establishment of ARHRTN was a meeting organized by RHRU, Johannesburg, South Africa, in August 2002, where an interim steering committee of African experts in the field of reproductive health wrote a constitution and a three-year workplan. ARHRTN is seen as an important networking link for countries, networks and research institutions to scale up research across the continent and as a means of facilitating and forging links with the international reproductive health community. It is expected that ARHRTN, through its networking and knowledge

Table 7.3. Activities carried out in collaboration with other partners within the Department or other international agencies

Department Thematic Group or collaborating agency	Activity	Countries participating in the activity
Controlling STIs/RTIs	Capacity strengthening in microbicide research	Ethiopia, Nigeria and Uganda
	Expanded safety and acceptability study of 6% cellulose sulfate	Nigeria
	Multicentre study on impact of HAART on mother's health and MTCT of HIV	Burkina Faso, United Republic of Tanzania
Making Pregnancy Safer	Making Pregnancy Safer activities in spotlight countries	Ethiopia, Mauritania, Mozambique, Nigeria, Uganda and Sudan
	Use of misoprostol in the third stage of labour	Egypt, Nigeria, South Africa
	Follow-up study of children whose mothers participated in the trial on magnesium sulfate for management of pre-eclampsia (MAGPIE)	Nigeria
WHO Country Focus Initiative	Planning of Country Cooperation Strategies (CCS)	African and Eastern Mediterranean Regions
Planning and programming in collaboration with AFRO	A training initiative in evidence-based reproductive health care	African Region
Technical cooperation with countries	Participation in the evaluation of the reproductive health components of UNFPA-funded national population programmes	Sao Tome
	Strategic approach to reproductive health: Phase I, II and III	Ethiopia, South Africa, Zambia
	Anglophone Africa Regional Workshop to Disseminate Information on the WHO Strategic Approach to Improving the Quality of Care of Reproductive Health Services	English-speaking African countries

exchange activities, will facilitate the process of addressing the reproductive health research priorities of Africa. The steering committee noted that ARHRTN will provide a forum for discussions and negotiations and play a strong advocacy role. It will provide an opportunity for networks in Africa to cooperate and strengthen each other, involving all stakeholders including policy-makers in reproductive health research.

There is a need to finalize the constitution, produce a directory, elect a steering committee, engage in fund raising and link up with the African Research Forum which met in Arusha, United Republic of Tanzania, in November 2002.

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 with other international agencies are summarized in Table 7.3. Details of these activities are given in other chapters of this report.

PLANNED ACTIVITIES

Activities planned for 2003 can be summarized under the following main lines of work:

- Support and maintain institutions currently collaborating with the Department through institutional development grants to enable them to undertake research projects relevant to their identified reproductive health needs and priorities.

- Promote and further strengthen regional research networks working on key issues such as maternal health, adolescent reproductive health, FGM, infertility, cervical cancer and HIV/AIDS.

- Promote dissemination and utilization of tools developed by the Department through Service Guidance Centres.

- In collaboration with other partners, increase efforts to institutionalize operations research training in the African Region.

Annex 1

REGIONAL ADVISORY PANEL FOR THE AFRICAN AND EASTERN MEDITERRANEAN REGIONS IN 2002

Members

Asya Al-Riyami, Department of Research and Studies, Ministry of Health, Muscat, 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
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, 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
Osato Giwa-Osagie, Department of Obstetrics and Gynaecology, College of Medicine, University of Lagos, Lagos, Nigeria
Bailah Leigh, National AIDS Control Programme, Ministry of Health and Sanitation, Freetown, Sierra Leone
Boniface Nasah, Society of African Gynaecologists and Obstetricians (SAGO), Buea, Cameroon
Babatunde Osotimehin, 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 *(Chairwoman)*
Christiane Welffens-Ekra, Department of Obstetrics and Gynaecology, University Hospital Yopougon, Abidjan, Côte d'Ivoire

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	13	100					13
Women	6	46					6
from:							
AFRO	9	69					9
AMRO							
EMRO	4	31					4
EURO							
SEARO							
WPRO							

Collaborating agency scientists

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

Annex 2

SCIENTISTS COLLABORATING IN 2002

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, Maputo Central Hospital, Maputo, Mozambique
Virgile Capo-Chichi, Centre of Research in Human Reproduction and Demography, National University of Benin, Cotonou, Benin
Zvavahera Chirenje, University of Zimbabwe, Harare, Zimbabwe
Olukayode Dada, College of Health Sciences, Ogun State University, Sagamu, Nigeria
Fadel Diadhiou, University of Dakar, Dakar, Senegal
Djibril Diallo, Université Cheikh Anta Diop de Dakar, Dakar, Senegal
Osato Giwa-Osagie, College of Medicine, University of Lagos, Lagos, Nigeria
Justus Hofmeyer, University of the Witwatersrand, Effective Care Research Unit, Cecilia Makiwane and Frere Hospitals, East London, Eastern Cape, South Africa
Guyo Jaldesa, Kenyatta National Hospital Campus, College of Health Sciences, University of Nairobi, Nairobi, Kenya
Joseph Karanja, Kenyatta National Hospital Campus, College of Health Sciences, University of Nairobi, Nairobi, Kenya
Christine Kaseba, University of Zambia, Lusaka, Zambia
Daudi Langat, Institute of Primate Research, National Museums of Kenya, Nairobi, Kenya
Robert Leke, University of Yaounde 1, Faculty of Medicine and Biological Sciences, Yaoundé, Cameroon
Mairo Mandara, National Hospital for Women and Children, Abuja, Nigeria
Florence Mirembe, Makerere University, Kampala, Uganda
Jason Mwenda, Institute of Primate Research, National Museums of Kenya, Nairobi, Kenya
Kwasi Odoi-Agyarko, Rural Help Integrated, Bolgatanga, Ghana
Oladosu Ojengbede, University of Ibadan, Ibadan, Nigeria
Friday Okonofua, University of Benin Teaching Hospital, Benin City, Nigeria
Augustin Orhue, University of Benin, Benin City, Nigeria
Joseph Otubu, Jos University Teaching Hospital, University of Jos, Jos, Nigeria
James Oyieke, 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
Abdulazis Gerais, University of Khartoum, Khartoum, Sudan
Ezzeldin Hassan, The Egyptian Fertility Care Society, Cairo, Egypt
Samina Jalali, Quaid-i-Azam University, Islamabad, Pakistan
Mohamed El Fadil Saad, University of Khartoum, Khartoum, Sudan
Sami Said, 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

Annex 2 (continued)

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	38	100					38
Women	9	24					9
from:							
AFRO	30	79					30
AMRO							
EMRO	8	21					8
EURO							
SEARO							
WPRO							

The WHO Region of the Americas

E. Ezcurra

INTRODUCTION

Strengthening research capacity of institutions in the 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 2002–2003 biennium were: (i) to continue strengthening research capacity, in Programme-supported collaborating institutions in the 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 these goals:

- 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;
- increased dissemination of relevant research results to facilitate their adaptation and utilization in reproductive health programmes and services;
- improved monitoring and evaluation of supported activities; and
- increased coordination with the WHO Regional Office for the Americas (AMRO).

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

RESEARCH ACTIVITIES

The eight centres supported with research capacity strengthening grants are involved in projects which address regional and national priorities. During 2001 (the last year for which complete data are available), from the overall number of 106 studies, four projects (4%) were implemented with support from the Programme's capacity building grants: Long-term Institutional Development (LID) grants, Resource Maintenance Grants (RMGs), and Re-entry Grants. Fifty-one projects were carried out at the centres with support from national sources (48%). The participation of the regional centres in the global research effort is exemplified by the 21 projects (20%) conducted in these collaborating institutions with support from the various teams 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. During 2001, 30 projects (28%) carried out in these regional centres received support from international agencies other than WHO.

With respect to capacity developed to address research issues through different methodological approaches, it is worth noting that, in 2001, from the 106 research studies, 56 (53%) were epidemiological or social science projects, the first time ever that such projects have accounted for more than half of all those undertaken at the centres being supported.

Ongoing projects supported by LID grants include basic science work in the area of male fertility, an assessment to identify priority interventions that would improve access to and quality of family planning, maternal and neonatal health care, and social science research in the area of male involvement in reproductive health. Maternal/infant health, family planning and sexual and reproductive health of adolescents were the main thematic areas covered by projects being implemented in centres receiving RMGs.

DEVELOPMENT OF HUMAN RESOURCES

Resources for Training Grants were awarded to the Institute of Nutrition in Mexico City, Mexico, to the National Institute of Public Health, Cuernavaca, Mexico, and to the Centre of Studies of Society and Development (CEDES), Buenos Aires, Argentina, to support regional postgraduate courses in reproductive biology, in reproductive epidemiology and in the social sciences, respectively. With respect to support provided to individuals, 10 scientists from regional centres received grants in 2002 to undergo training in different areas relevant to reproductive health. Table 7.4 summarizes the overall number of training grants awarded in 2002 which were supported with funds from the regional budget. Ten fellows (seven women) received grants for short and long-term training, mostly (eight) 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 2001, the eight centres provided individual training to 112 staff from other local institutions. A total of 31 fellows participated in formal courses and 653 attended short, group-learning activities such as seminars and workshops organized by the centres receiving research capacity strengthening support.

DISSEMINATION AND UTILIZATION OF RESEARCH FINDINGS

Scientific publications

During 2001, a total number of 143 research articles (128 original papers and 15 review articles) were published and 34 books and book chapters were authored by staff from the eight centres receiving research capacity strengthening support. Likewise, 186 presentations were made in national, regional or international scientific events and 20 official reports were presented to national and international authorities and agencies. Figure 7.1 shows the distributions of publications and presentations in national/regional and international journals and meetings.

Dissemination of results from national and regional research initiatives

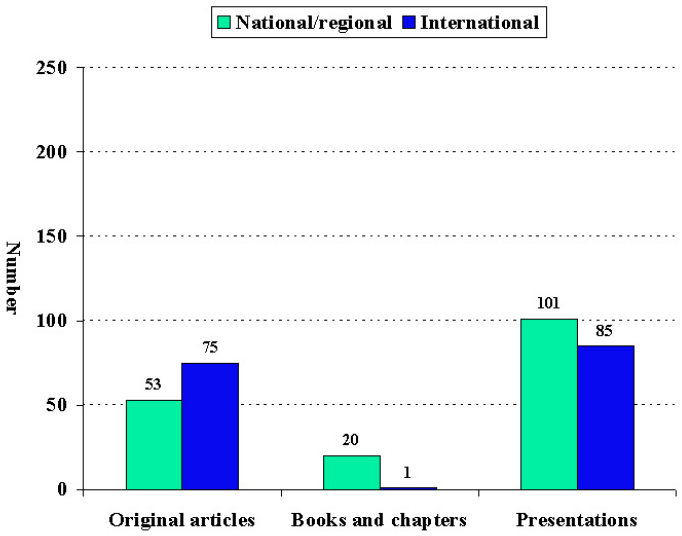
The Institute for Studies on Altitude of the Peruvian University "Cayetano Heredia" recently completed a long cycle of research capacity strengthening support. A national workshop was organized in Pachamac, Peru, on 21–23 February 2002 to discuss its contribution to research in reproductive health and the factors that determine the impact of these findings on society. The 42 participants in the workshop included researchers, health programme officers as well as representatives of nongovernmental organizations (NGOs) and other civil society groups. The main thematic areas dealt with during the workshop were maternal mortality and morbidity and neonatal health.

Of particular importance were the information dissemination activities related to the regional research initiative "Reality and beliefs in the sexual and reproductive decision-making process: men's perceptions and behaviour: a multicentre study in Argentina, Bolivia, Cuba and Peru".

Table 7.4. Research Training Grants awarded in 2002

Type of grant	Area	Number of trainees	Females	Males
M.Sc. Course	Reproductive epidemiology	1	1	
M.Sc. Course	Social sciences	1		1
M.Sc. Course	Health systems	1		1
Diploma Course	Reproductive biology	3	3	
Workshop	Programme evaluation	2	1	1
Workshop	Communication	1	1	
Course	Molecular biology	1	1	
TOTAL:		**10**	**7**	**3**

Figure 7.1. Publications and presentations in 2001



The first dissemination workshop was held in Buenos Aires, Argentina, in October 2002. For this activity, a special booklet was designed, produced and distributed. It included not only an easily understandable summary of the project's findings and of their interpretation, but also specific recommendations for policies and programmes. Oral presentations were made by the principal investigators on the results and on their policy implications, and there were extensive discussions with an audience of 106 people, including 52 scientists (researchers, representatives of professional associations, university professors), 23 health programme officers from the federal and provincial levels, 22 professionals in direct contact with the population (physicians, teachers, social workers) and nine representatives of NGOs and of international organizations and journalists. The workshop and the results of the study received press coverage: there were articles in two national newspapers and TV interviews with the project's principal investigators.

Facilitating enhanced utilization of research findings

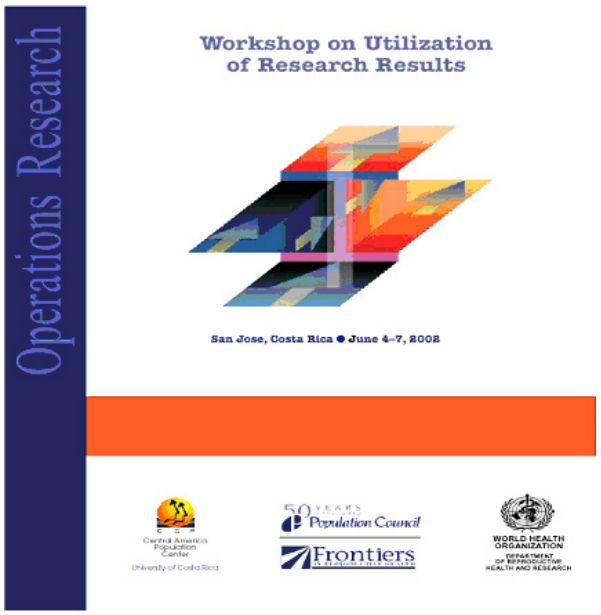
A regional workshop on utilization of research findings took place in San José, Costa Rica, 4–7 June 2002. It was funded and organized by the Population Council's FRONTIERS Project, by the Department and by the Central American Centre for Population of the University of Costa Rica, San Jose, Costa Rica. The overall objectives of the workshop were:

- to increase utilization of research results by reproductive health programmes in the Latin-American region through increasing researchers' knowledge of what constitutes programmatically relevant research, and by enhancing the ability of researchers and programme managers to work together at all stages of the research process;
- to train researchers and managers in ways to improve utilization of results prior to beginning operations research activities at the WHO Collaborating Centres in the region; and
- to identify the utilization problems most frequently encountered by participants and suggest ways to overcome these problems.

Participants came from various Latin American centres collaborating with the Department in Argentina, Brazil, Guatemala, Mexico, and Peru as well as staff from a small number of organizations in Costa Rica, El Salvador and Nicaragua. Those centres that were invited had experience in conducting biomedical, epidemiological or social science research, strong links to reproductive health service delivery programmes, and an interest in participating in future operations research activities.

Discussions revealed that very few participants included dissemination and/or utilization plans or budgets in their research proposals, and that the Department did not require these plans for funding a study. Other problems included lack of relevance of the research for programmes and absence of close working relationships with managers and policy-makers. A full report of the workshop (Figure 7.2) is available on request.

Figure 7.2. Report of regional workshop on utilization of research results, Costa Rica, June 2002



EFFECTIVE MONITORING AND EVALUATION OF REGIONAL AND COUNTRY ACTIVITIES

The recent external evaluation of the Programme's research capacity strengthening activities recommended that in-depth assessments be conducted of both achievements and the impact of capacity strengthening grants on the performance of centres being supported. The Institute for Experimental Biology and Medicine (IBYME), Buenos Aires, Argentina, is about to complete the first cycle (1998–2002) of LID grant support. A team of two Department staff members and one external consultant visited the Institute in December 2002. Important achievements were noted in the area of basic research in male fertility which is the core of the LID grant. In addition, support provided by the Department contributed to significant improvements when compared to the six-year period (1992–1997) preceding the award of the LID grant. Table 7.5 summarizes some of the main indicators of improved standing and performance.

Experiences derived from this assessment and from the well-documented self-evaluation of improved performance done by the centre and verified by the site-visit team will contribute to the development of adequate monitoring mechanisms to document the relevance and impact of research capacity strengthening activities.

INCREASED COORDINATION WITH AMRO

The Scientific and Technical Advisory Group (STAG) recommended at its February 2002 meeting that regional desks should increase coordination with their respective regional office. During the past year, eight missions were jointly undertaken by staff from the Department and from AMRO to visit centres, to interact with ministries of health and/or to participate in relevant country or regional meetings. These missions included visits to Argentina, Brazil, Costa Rica, Guatemala, Nicaragua, Paraguay and Uruguay.

The coordinator of the Regional Social Sciences Network is acting as a technical advisor to the AMRO multicentre project on promotion of men's participation in reproductive health programmes in Central America.

Finally, the Department and AMRO have initiated contacts in English-speaking Caribbean countries, in coordination with the Latin American and Caribbean Office of the Population Council, to undertake a study on providers' views and perspectives on emergency contraception in Barbados and Jamaica.

SUMMARY COUNTRY REPORTS

In 2002, the Department collaborated with 18 institutions in 10 Latin American countries: Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Guatemala, Mexico, and Peru. 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 it serves as a training and research methodology referral centre for the country and the region. Its staff have worked closely with the Ministry of Health to facilitate the utilization of research results by programmes and services.

The Centre for Population Studies (CENEP) in Buenos Aires was 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". It has developed concept papers for future initiatives on other relevant topics

Table 7.5. Some indicators of improved standing and performance, pre- and post-LID grant support. IBYME, Buenos Aires, Argentina

Indicator	1992–1997	1998–2002
Number of fellows in the Group	9	20
M.Sc. Degrees obtained by members of the Group	5	7
Ph.D. Degrees obtained by members of the Group	2	8
Courses organized at the centre	2	8
Number of staff participating as faculty in courses	10	14
Presentations in national scientific events	19	35
Presentations in international scientific events	5	32
Publications in national journals	1	5
Publications in international journals	4	18

(sexual coercion, providers' perspectives on emergency contraception).

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 organized the M.Sc. course in social sciences and is involved in several global research projects supported by thematic groups of the Department.

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 was completed in February 2002 and plans for information dissemination and utilization are expected to be implemented in 2003.

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 work undertaken on training in research methodology, on research dealing with clinical epidemiology and social science research relevant to contraceptive introduction and other aspects of women's reproductive health. In September 2002, CEMICAMP organized an international symposium on caesarean section. The centre is also implementing a Programme-supported study on counselling in family planning services.

Chile

Two institutions in Santiago continued to receive support from other thematic areas of the Department: the Institute for Mother and Child Research (IDIMI) and the Unit of Reproductive Biology and Development at the Catholic University of Chile. These centres participate in Programme-supported biomedical research on the mechanisms of action of emergency contraception preparations.

Colombia

The Centre at the University del Valle in Cali received support from the Programme 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.

Costa Rica

The Central American Population Centre of the University of Costa Rica has organized workshops on "Improving communication skills of researchers" and on "Programme evaluation", in which several fellows from Programme-supported centres in Latin America have participated. In June 2002, the Centre also hosted the regional workshop on "Utilization of research results" supported by the FRONTIERS Project and the Department.

Cuba

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

The National Institute of Endocrinology'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. Dissemination of the findings of the study on men and plans for their utilization will be undertaken in 2003.

The Institute and two obstetrics-gynaecology hospitals, members of the Network, are participating in two clinical trials concerned with improved non-surgical methods for pregnancy termination.

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. During 2002, the final report of a strategic assessment conducted to identify priority interventions that would improve access to and quality of family planning, maternal and neonatal care in Guatemala was produced, and a draft proposal for Stage II action-research based on these findings was submitted for review.

Mexico

The Department of Reproductive Biology in the National Institute of Medical Sciences and Nutrition, Mexico City, is the main recipient of Programme support in the country. The institute is actively involved with the various thematic groups of the Department and other international funding agencies. In 2002, the institute continued to receive a Basic Resources for Training Grant, to partially support its extensive participation in research training, particularly the diploma course on reproductive biology.

Another grant supports 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 10 years

from Programme-supported centres in Argentina, Chile, Cuba, Guatemala, Mexico, Panama, Peru and Venezuela.

Peru

The Programme supported two centres affiliated to the University Cayetano Heredia, 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 Faculty of Public Health 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". The study was completed and a national dissemination workshop is planned to take place in early 2003. The faculty also organized for the first time in 2002 a master's degree course in sexual and reproductive health, which was attended by national and foreign students.

PLANNED STRATEGIES

The need to develop mechanisms to conduct research capacity strengthening activities in least developed countries in the Region of the Americas was identified as being of top priority for the immediate future. At its November 2002 meeting, the Americas RAP awarded Small Grants to centres in El Salvador, Honduras and Nicaragua; this is expected to facilitate an increased interaction with scientists and groups in these countries to better explore their capacity strengthening needs so that adequate strategies are utilized to assist in their development. A site visit to Paraguay in December 2002 explored the possible implementation of the Strategic Approach in this country with support of research capacity strengthening grant.

Special emphasis will continue to be placed on the dissemination and utilization of research findings, particularly of findings resulting from national and regional research initiatives. At the same time, the regional networks will launch new initiatives on topics of relevance to countries and to the region.

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
William Fraser, Laval University, Quebec, Canada
Ana Cristina González, Santafé de Bogotá, Colombia
Sylvia Guendelman, School of Public Health, University of California, Berkely, 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

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	5	63			3	37	8
Women	3	37			1	13	4
from:							
AFRO							
AMRO	5	63			3	37	8
EMRO							
EURO							
SEARO							
WPRO							

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

PRINCIPAL INVESTIGATORS OF CENTRES IN 2002

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 Cuasnicú, Institute for Biology and Experimental Medicine (IBYME), Buenos Aires, Argentina
Luigi Devoto, Institute for Maternal and Child Health Research (IDIMI), Santiago, Chile
Oscar Díaz, National Institute of Endocrinology, Havana, Cuba
Franklin García, 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
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
María Serón-Ferré, Pontifical Catholic University, Santiago, Chile

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	17	100					17
Women	6	35					6
from:							
AFRO							
AMRO	17	100					17
EMRO							
EURO							
SEARO							
WPRO							

The WHO Regions of South-East Asia and the Western Pacific

A. Ntabona and M. Lusti-Narasimhan

INTRODUCTION

The WHO Regional Office for South-East Asia (SEARO) in New Delhi, India, covers 10 developing countries, of which five are least developed countries (LDCs). The countries of this region account for over 1.4 billion people. The WHO Regional Office for the Western Pacific (WPRO) in Manila, Philippines, includes 27 Member States and 9 territories and areas which are not responsible for the conduct of their own international relations; all participate in the work of WPRO. The total population of the countries and territories in this region is around 1.6 billion. The Regions of South-East Asia and the Western Pacific therefore comprise a very diverse population that makes up over 60% of the world's total population. This fact, combined with the very large size of the territory represented, and diverse reproductive health profiles, makes the regions especially challenging.

Since, owing to unforeseen circumstances, the meeting of the Regional Advisory Panel (RAP) was cancelled in 2001, in 2002, RAP met twice—in February and in October. At these meetings RAP recommended a strategic shift away from encouraging basic research in reproductive health to promoting regional initiatives and networking among national centres. Thus, the objectives for 2003 are to strengthen the regional initiatives through conferences, workshops and intraregional research aimed at promoting the three main priorities set for the regions, namely reducing maternal mortality, preventing unsafe abortion and controlling sexually transmitted infections (STIs) and reproductive tract infections (RTIs).

CHANGE IN FOCUS FROM BASIC RESEARCH TO REGIONAL INITIATIVES

One of the important recommendations of the 6th RAP meeting held in October 2002, was to shift focus from promoting basic research within the centres to encouraging a more regional and nationwide approach to reproductive health matters. This also implies that the future membership of the RAP advisors should include more social scientists and policy-makers.

This shift had already been enacted during the last few years with the setting-up of national networks in China, Sri Lanka and Thailand. In 2003, projects of promoting regional priorities within the context of conferences and workshops will accelerate the process. In line with these objectives, proposals for basic research from the centres have not been approved if they did not have a wider range of application. One of the most important tasks during the site visits to the centres in 2003 will be to explain the shift in focus in order to help the centres develop research proposals aimed at strengthening the priority needs of their region.

RESEARCH CAPACITY STRENGTHENING GRANTS AWARDED IN 2002

Table 7.6 shows the list of countries and names of Long-term Institutional Development (LID) grants and Resource Maintenance Grants (RMGs) recipient centres during 2002, and types of group learning activities that were proposed. There have been three Research Training Grants (RTGs) awarded to two scientists from China to study biostatistics and social sciences, respectively, and one from Mongolia

to study epidemiology. Table 7.7 shows the types of workshops that were held in the region. Owing to the fact that there was a five-month delay in holding the 5th RAP meeting from October 2001 to February 2002, there have also been delays in implementing some of the recommendations from the 2000–2001 RAP.

NATIONAL NETWORKS

Continued support was given by various parts of the Department to the national research institution networks established in China and Thailand. As stated in previous reports, these bodies play a leading role in the process of 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, the National Coordinating Board (NCB) brings together eight research institutions, namely: (1) National Research Institute for Family Planning, Beijing; (2) Shanghai Institute of Planned Parenthood Research, Shanghai; (3) Peking Union Medical College Hospital, Beijing; (4) Institute of Population Research, Beijing; (5) Tianjin Municipal Research Institute for Family Planning, Tianjin; (6) Family Planning Research Institute of Zhejiang, Hanghzou; (7) Family Planning Research Institute of Sichuan, Chengdu; (8) National Evaluation Centre for the Toxicology of Fertility Regulation Drugs, Shanghai.

The NCB helped formulate the Chinese National Reproductive Health Programme for the next decade. This programme comprises four comprehensive community-based components on (i) improving quality of contraceptive care; (ii) STI intervention; (iii) healthy baby promotion; and (iv) integrated reproductive health services in Western China. It is proposed to undertake a review of the lessons learnt from the early implementation of some of these components and identify corrective measures where necessary.

In Thailand, three university departments of obstetrics and gynaecology and seven regional hospitals have been brought together in a network that was supported until 2001 through RMGs. They have a strong working relationship with several teams in the Department and participate in global and regional research in the area of social sciences, STIs and RTIs, and maternal health, as well as on Cochrane Collaboration reviews.

REGIONAL INITIATIVES

In order to make the research capacity strengthening efforts more cost-effective and to cover a much larger population, support was given to two regional initiative programmes as follows:

- The collaborative reproductive epidemiology research project on “Patterns and predictors of caesarean section in Asia”, is a 10-country joint research programme that was prepared in mid-2000. The countries involved are Bangladesh, China, Indonesia, Mongolia, Myanmar, Nepal, Philippines, Sri Lanka, Thailand and Viet Nam. The objectives of this study are to determine the compli-

Table 7.6. Type of grants and names of country/recipient centres in 2002

Type of grant	Country	Recipient centre
Long-term Institutional Development (LID) Grants	Indonesia	Western Indonesian Reproductive Health Development Centre (WIRHDC), Faculty of Medicine, University of North Sumatra, Medan
		Reproductive Health Research Centre, Airlangga University, Surabaya
	Lao People’s Democratic Republic	Maternal and Child Health Centre, Ministry of Health, Vientiane
	Mongolia	State Research Centre on Mother and Child Health and Human Reproduction, Ulaanbaatar
	Myanmar	Department of Medical Research, Ministry of Health, Yangon
	Sri Lanka	National Coordination Committee for Research on Reproductive Health, Colombo
	Viet Nam	Hung Vuong Hospital, Ho Chi Minh City
Resource Maintenance Grants (RMGs)	China	National Coordinating Board
	India	All India Institute of Medical Sciences, New Delhi

Table 7.7. Type of workshops and names of recipient centres in 2001–2002

Country/recipient	Type of workshop
China—National Research Council	• National conference on the collaboration between China and the Department • Development and utilisation of norms, tools and guidelines • 4th International symposium on reproductive endocrinology
India—All India Institute of Medical Sciences	• Safe abortion practices • Practical training in reproductive health research methods
Indonesia—Western Indonesian Reproductive Health Development Centre	High-risk pregnancy management for midwives
Indonesia—Reproductive Health Research Centre	Primary and secondary care of infertility in Indonesia
Lao PDR—Maternal and Child Health Centre	Clinical research
Mongolia—State Research Centre on Mother and Child Health and Human Reproduction	Preparation of research proposals and data management
Viet Nam—Hung Vuong Hospital	Intervention studies

cation rates with vaginal deliveries compared to elective and emergency caesarean sections. In addition, average costs incurred by patients for the three procedures as well as predictors for elective and emergency caesarean sections for patients, obstetricians and hospitals will be estimated. Owing to a number of local constraints, five centres experienced delays in completing the first year of the study and data collection had to be extended until the end of 2002.

- The regional research initiative on adolescent migrants and reproductive health in the Greater Mekong region is a four-country joint research programme with centres in China, Lao People's Democratic Republic, Thailand and Viet Nam. This study, which began in early 2000, targeted adolescent migrant populations, members of which were interviewed in 2002 as to their motivation for migration, their knowledge and perceptions of reproductive health and their access to reproductive health services. Analysis of the results will be undertaken in 2003.

COOPERATION WITH REGIONAL OFFICES

Collaboration between the Department and WPRO has allowed implementation of a number of projects and workshops:

- A programme funded by the United Nations Population Fund (UNFPA) and executed by WHO regarding the *Medical eligibility criteria for contraception* for the 10 Pacific Island Countries took the form of a workshop in Fiji in 2002. The Governments of these nations as well as China and Indonesia requested additional training in the domains of vasectomy and intrauterine device (IUD) and Norplant insertion. WPRO will have carried out the relevant training by December 2002.

- The WHO document, *Managing complications of pregnancy and childbirth: a guide for midwives and doctors* has been translated into the languages of all six priority countries in the region: Cambodia, China, Lao People's Democratic Republic, Mongolia, Papua New Guinea, Philippines and Viet Nam. The manual is also being integrated into medical internship and residency programmes in the Philippines. WPRO's Reproductive Health Unit and the United Nations Children's Fund (UNICEF) will conduct workshops for the adaptation of the manual for the Philippines.

- Emergency obstetric care training was given to 36 participants from Cambodia, Lao People's Democratic Republic and Mongolia at the Philippines General Hospital, Manila, Philippines.

- Field-testing and pilot study of the *Pregnancy, childbirth and newborn care: a guide for essential care* will be conducted at the Fabella Hospital, a WHO collaborating centre in Manila, Philippines.

- A workshop for the Making Pregnancy Safer initiative was conducted in Beijing, China, in December 2002, which included presentations of China's associated surveillance system and software for maternal deaths, and of the experiences in Cambodia and China with maternal death audits.

- WPRO and the World Bank are evaluating the Safe Motherhood Project 1, and preparing for Project 2 in the Philippines.

- WPRO has released a national plan of action on safe motherhood for six priority countries for 2001–2005, namely Cambodia, China, Lao People's Democratic Republic, Mongolia, the Philippines and Viet Nam.

PROPOSED ACTIVITIES FOR 2003

RAP has recommended the following activities for the Regions of South-East Asia and the Western Pacific for the year 2003:

- WPRO will conduct a six-country study on the determinants of spontaneous and unsafe abortion. The initial protocol for this study has been prepared and will be submitted to the usual review process in the Department.

- A regional conference for policy-makers, research leaders and users of research findings will be held in conjunction with the 7th RAP meeting in Bangkok, Thailand, in October 2003. The conference will highlight capacity strengthening and setting research priorities for reproductive health services in the region.

- A regional workshop will be organized on adolescent reproductive health.

Annex 1

REGIONAL ADVISORY PANEL FOR ASIA AND PACIFIC IN 2002

Members

Victor 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 Hospital, Vellore, Chennai, India
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Zheng Xiao Ying, Institute of Population Research, WHO Collaborating Centre for Reproductive Health and Population Science, Peking University, Beijing, China

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	7	88			1	12	8
Women	5	63					5
from:							
AFRO							
AMRO							
EMRO							
EURO							
SEARO	5	63					5
WPRO	2	25			1	12	3

Temporary advisers

Harun Ar-Rashid, Bangladesh Medical Research Council, Mohakhali, Dhaka, Bangladesh
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Sea-Baick Lee, Planned Parenthood Federation of Korea, Yeongdeungpo, Seoul, Republic of Korea

Annex 2

HEADS OF CENTRES FOR ASIA AND PACIFIC IN 2002

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, 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, National Institute for Research in Reproductive Health, 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, Faculty of Medicine, University of Colombo, Colombo, Sri Lanka
Soe Thein, 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

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	19	100					19
Women	8	42					8
from:							
AFRO							
AMRO							
EMRO							
EURO							
SEARO	7	37					7
WPRO	12	63					12

Central and Eastern Europe, including the Newly Independent States and Central Asian Republics

A. Ntabona

INTRODUCTION

According to recent estimates, women and men in most countries in the WHO European Region enjoy relatively low reproductive health risks. However, there are striking disparities between the market economies of the west and the transitional economies of the east. Some of the common features of countries of Central and Eastern Europe (CCEE) and Newly Independent States (NIS) are: (i) relatively high numbers of births for teenage girls; (ii) a large number of repeat abortions; (iii) reliance on ineffective methods of contraception; (iv) levels of maternal deaths five times higher than in western Europe despite a universal coverage of care during pregnancy and childbirth; and (v) a potential explosion of the HIV epidemic as a result of growing numbers of sexually transmitted infections, injectable drugs use and prostitution. There is a growing concern about the overall decline in population growth owing to very low birth rates and the declining life expectancy in the east. Most countries have undertaken policy reforms aimed at improving the responsiveness and stewardship of the health systems but the effects of these measures on the effectiveness and quality of reproductive health services are still being studied.

OBJECTIVES

The main objectives of the Department in the European Region are:

- to strengthen national capacity in reproductive health research, with a particular focus on providing training opportunities for CCEE, NIS and Central Asian Republics (CAR);
- to assist the WHO Regional Office for Europe (EURO) in providing technical support to countries to implement their programmes in reproductive health.

In this regard, the major steps taken by the Department since the early 1990s include: (i) the launching of the East-West European Initiative aimed at assessing the research and service needs and identifying priorities for collaborative research and research training in reproductive health; (ii) the coordination of research and research training activities through the establishment of the WHO Scientific Working Group (1994); and (iii) the formal establishment of a Regional Advisory Panel (RAP) for the European Region in 2001.

PROGRESS

Second meeting of the Regional Advisory Panel for Europe, 29–30 May 2002, Netherlands School of Public Health (NSPH), Utrecht, Netherlands

The deliberations at this second meeting of the European RAP revolved around three major issues: (i) research and research capacity building in the region; (ii) input of RAP to the regional reproductive health programme; and (iii) other emerging issues of relevance to reproductive health in the region. As regards the regional priorities identified at the first meeting, RAP reiterated the need to bridge the gap between researchers and policy-makers, to develop models for collaboration, and to strengthen WHO's role in the collection of evidence and reliable data on reproductive health in the European Region, including evidence on the links between reproductive health and poverty.

Research development and research training

RAP was briefed on the outcome of the first operations research training course held in Romania. RAP decided that proposals prepared as part of research training will continue to be reviewed by RAP and processed through the Department's review and implementation procedures, as part of the ongoing efforts for operations research capacity strengthening in all regions. Out of seven proposals emanating from the first course, three focusing on the introduction of evidence-based medicine and best practices in the Czech Republic, the Russian Federation and Ukraine were approved with amendments and recommended to the Department for funding. RAP further recommended that the collaboration between the Department, EURO and the FRONTIERS Project should continue in order to develop and implement operations research in countries.

Programmatic issues

The WHO European Regional Strategy on Sexual and Reproductive Health had already been reviewed by RAP and was ready for publication, dissemination to Member States, professional bodies and nongovernmental organizations (NGOs). Actions recommended for the implementation of the strategy include, among others: (i) defining mechanisms for country adaptation of the strategy through multidisciplinary steering groups; and (ii) continued WHO support to national authorities for training or reorienting all stakeholders on the content of the strategy and mobilizing resources for its implementation.

Activities for the implementation of selected regional priorities are ongoing, as described below:

Making Pregnancy Safer

Continued technical support was provided for country adoption and adaptation of WHO evidence-based policies and standards for maternal and newborn care. Clinical guidelines on evidence-based medicine and appropriate use of technologies were issued, targeting specific categories of health care providers and were used in Kazakhstan, Republic of Moldova, Turkmenistan, and Uzbekistan. There are also ongoing efforts to build links between the Making Pregnancy Safer initiative and relevant regional programmes in EURO: reproductive health, HIV/MTCT/STI, health systems, and rational drug use.

Adolescent sexual and reproductive health

Major achievements in this area included: (i) the development of an interagency[1] framework for designing or expanding youth-friendly services in Europe and Central Asia; (ii) the publication of the guidelines on *Counselling skills training in adolescent sexuality and reproductive health: a facilitator's guide*, jointly with the Department of Child and Adolescent Health and Development at WHO Headquarters and the NGO "EuTEACH" (European Training in Effective Adolescent Care and Health); and (iii) the establishment of a collaborative teaching programme on adolescent health at the Multidisciplinary Unit for Adolescent Health at the Lausanne University Medical Centre, Lausanne, Switzerland. Possibilities are being explored for collaborative work with the International Planned Parenthood Federation (IPPF) for providing adolescent sexual and reproductive health education in vocational schools in the same way as in secondary schools and for developing information, education and communication (IEC) materials for out-of-school adolescents.

Gender and reproductive health

EURO has prepared a Strategic Plan for Health of Women in Europe aimed at assisting governments to achieve gender equity in health and health care. Efforts are ongoing for mainstreaming gender equity in health as an advocacy tool as well as a political and technical process to guide the necessary changes in organizational cultures, setting goals and structures as well as allocating resources.

Training in reproductive health

There is a need to undertake an inventory of training institutions that offer courses on reproductive health in the European Region. Some of these courses are specifically targeted to the developing countries but could be adapted to the needs of CCEE, NIS and CAR. The post-graduate course for training in reproductive medicine and reproductive biology being offered at the University of Geneva, Switzerland, since 1991, is a case in point.

Regional research initiatives

The Department and EURO provided support to a retrospective study that is reviewing some examples of interventions that had an influence on the reduction of maternal mortality in Europe, such as legislative and policy actions (Finland, France, Portugal, Romania); society and community actions (Republic of Moldova); actions within the health sector (Hungary, Poland, United Kingdom) and actions from, or in collaboration with, other sectors such as finance and the private sector. The report on this study will be available in 2003.

[1] Agencies involved include WHO, the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA), the United Nations Development Programme (UNDP), the United Nations Drug Control Programme (UNDCP) and the Joint United Nations Programme on HIV/AIDS (UNAIDS).

Capacity building in operations research in CCEE, NIS & CAR

This is a collaborative initiative between the Department and the FRONTIERS Project aimed at providing continued support to investigators throughout all the steps up to the reporting and dissemination of findings, with the emphasis being on bringing research into reproductive health programme management. The second course to be held in April 2003 at the Kazakhstan School of Public Health, Almaty, Kazakhstan, will be run in Russian.

PLANNED ACTIVITIES FOR 2003

Research development

Two proposals recommended by RAP for funding, focusing on maternal and perinatal health, are being reviewed with a view to initiation in 2003. The review and clearance process for projects that emerge from the second operations research course will present an added challenge because of the language barrier.

Research training

At least 14 participants, two from each of seven countries, are expected to attend the second operations research course in Kazakhstan. These will include one scientist with a track record in research and one programme manager from central or district level. The course will be facilitated by three Russian-speaking alumni from the first course, with technical support from the Department and the FRONTIERS Project.

Annual meeting of RAP

The Department, in collaboration with EURO, plans to hold the third meeting of RAP in Estonia, in August 2003.

Postgraduate course for training in reproductive medicine and reproductive biology, University of Geneva, Switzerland

Support to this course will continue in 2003.

Annex 1

REGIONAL ADVISORY PANEL FOR THE EUROPEAN REGION IN 2002

Members

Ayse Akin, Hacettepe University, Sihhiye-Ankara, Turkey
Elena Baibariana, Russian Academy of Medical Science, Moscow, Russian Federation
Mihai Horga, Ministry of Health, Bucharest, Romania
Helle Karro, University of Tartu, Estonia (*Chairperson*)
Evert Ketting, Netherlands School of Public Health, Utrecht, Netherlands
Gunta Lazdane, Family Planning Association, Riga, Latvia
Alfred Merkle, Deutsche Gesellshaft für Technische Zusammenarbeit (GTZ), Eschborn, Germany
Saule Nukusheva, School of Public Health, Almaty, Kazakhstan
Petr Velebil, Research Institute for Maternal Health, Czech Republic

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members			7	78	2	22	9
Women			5	55			5
from:							
AFRO							
AMRO							
EMRO							
EURO			7	78	2	22	9
SEARO							
WPRO							

Policy and programmatic issues

P. Fajans, M.A. Broderick[1]

INTRODUCTION

The Department's objectives in this area are to review, develop and test methodologies for the planning and implementation of reproductive health services and to assist countries in the strengthening of their reproductive health policies and programmes. Central to this work is the testing, refinement and promotion of the Strategic Approach. Although originally developed to address contraceptive introduction, the methodology has been adapted to assist countries in strategic planning on a range of reproductive health policy and programmatic issues. The Strategic Approach has three stages.

Stage I is a strategic assessment of: (i) the needs and perspectives of current and potential users; (ii) the extent of coverage, quality of care and capacity of the service delivery system; and (iii) the mix of technologies and other reproductive health interventions. The assessments use a qualitative methodology and a field-based, 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 variety of recommendations for policy and programme development emerge from such a strategic assessment. Stage II is a means of testing, on a limited scale, the recommendations for policy change or other interventions to improve access, utilization and quality of care in service delivery.

The purpose of Stage III is to disseminate and apply the findings from the Stage II action research for policy development and planning for wider implementation.

MAIN AREAS OF WORK

The main areas of work during 2002 included the dissemination of, and support for, the utilization of the Strategic Approach by countries; the adaptation of the Strategic Approach to other areas of reproductive health; and an increased focus on replication and scaling up of activities.

With regard to application of the Strategic Approach to contraceptive introduction, sufficient experience has been gained in the assessment and Stage II testing of interventions. Efforts are therefore focusing on the dissemination and promotion of use of the Strategic Approach by others, as well as the testing and synthesizing of lessons learnt 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, including HIV/AIDS, maternal and newborn health, adolescent sexual and reproductive health, abortion, and cervical cancer. The methodology is also being used to address simultaneously a broad range of issues in conducting comprehensive reproductive health strategic assessments, with an emphasis on increasing access and utilization of services by the poor and other marginalized groups.

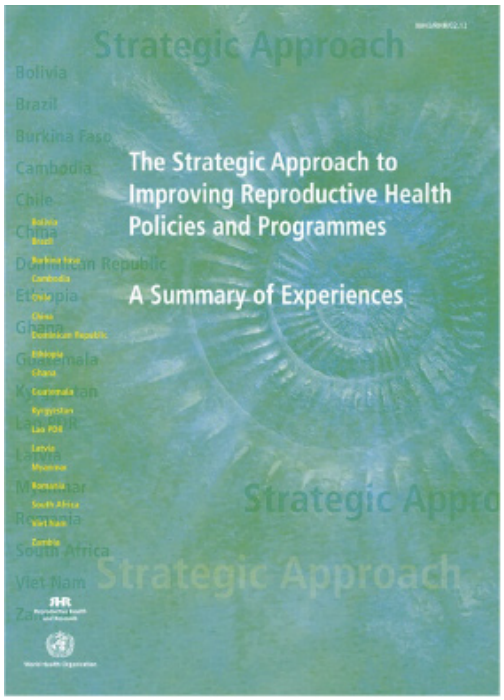
Dissemination, advocacy and capacity building

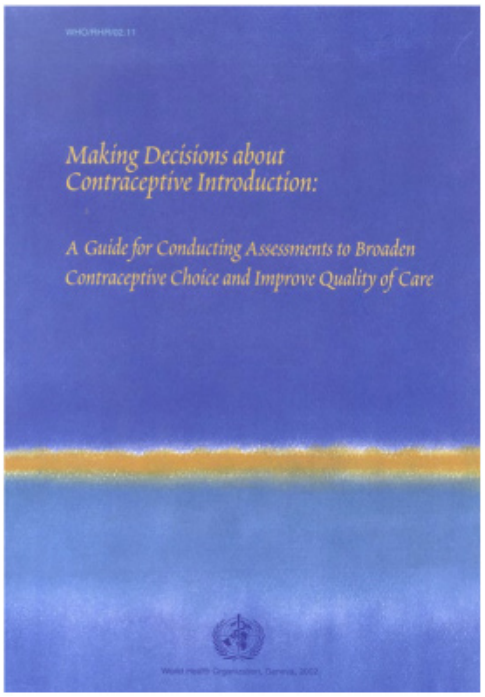
During 2002, a field guide was published entitled *Making decisions about contraceptive introduction: a guide for conducting assessments to broaden contraceptive choice and improve quality of care*. In addition, a document was published providing a summary of the framework and methodology of the approach, as well as summaries of experience with its implementation in 18 countries.

[1] Deceased September 2002.

Figure 7.3. Countries implementing the Strategic Approach (supported by the Department and by other partners)

Regional workshops to advocate for utilization of the Strategic Approach and to train national experts in implementation of strategic assessments were conducted, in collaboration with regional partners, including the International Council for the Management of Population Programmes (ICOMP) and the Population Council, Nairobi, Kenya. One workshop was held in Kunming, China, and included country teams from Cambodia, China, India, Mongolia, Pakistan, and Papua New Guinea. Another workshop held in Kenya included teams from Ghana, Kenya, Malawi, Nigeria, Uganda and United Republic of Tanzania. Participants in both workshops included senior country policy-makers and programme managers and representatives from NGOs and women's groups, as well as from the WHO Regional Offices, and Country Sup-





port Teams of the United Nations Population Fund (UNFPA). Facilitators included individuals who had participated in Strategic Approach activities in other countries in the region. A number of these country teams have initiated planning for future implementation of strategic assessments to address priority issues in their countries.

As in previous years, country experiences with implementation of the Strategic Approach have continued to be disseminated through presentations made at national and international conferences and workshops.

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 the Programme Guidance Tool, an adaptation of the Strategic Approach to address policy and programme development related to reproductive tract infections (see the chapter on Controlling sexually transmitted and reproductive tract infections). In 2002, planning for a Strategic Assessment of issues related to abortion began in Mongolia, while dissemination workshops were implemented following an assessment related to abortion and contraception in Romania, and one focusing on both maternal health and family planning in Guatemala. Planning for strategic assessments addressing maternal and newborn health has begun in Nigeria, Paraguay and Uganda, while Cuba and Nigeria also intend to use the approach to develop strategies to address adolescent sexual and reproductive health needs.

The Strategic Approach continues to be adapted by other partners as well. For example, EngenderHealth assisted Bolivia to use the methodology to address issues related to cervical cancer screening and treatment, while the Population Council, Brazil, supported an assessment of HIV prevention in six border regions of Brazil.

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 the past, strategic assessments that addressed a broader range of reproductive health concerns had been conducted in Ethiopia, Myanmar, and the Lao People's Democratic Republic. During 2002, ICOMP, in collaboration with the Population Council, Bangkok, Thailand, and the Department tested further modifications of the methodology in conducting a comprehensive reproductive health assessment focusing on access and utilization of services by the poor in Yunnan, China and began working with partners in Rajastan, India, to plan a strategic reproductive health assessment to be conducted in early 2003.

Stage III: replication and scaling-up

A conference, entitled "From Pilot Projects to Policies and Programmes: Strategies for Scaling Up Innovations in Health Service Delivery", is being planned for April 2003 to examine and synthesize knowledge about how to enhance scaling-up of service delivery research for broader policy and programme development. The conference will provide input into the development of a practical guide for policy-makers, programme managers, researchers, technical experts and donors intended to help facilitate the scaling-up of pilot projects and other service innovations.

COUNTRY EXPERIENCES IN 2002

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, and responds 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, and the reintroduction of the male condom and vaginal foaming tablets, as a means of enhancing the overall quality of youth-centred services. The project is strengthening providers' and peer educators' knowledge of all contraceptive methods, increasing youths' knowledge of family planning and STI prevention options and emphasizing dual protection. The study is funded by the United States Agency for International Development (USAID), with technical support provided by the Population Council and the Department.

Zambia

A Stage II study tested interventions to enhance contraceptive choice and quality of care in Zambia in 11 rural health centres, located in three districts in the rural Copperbelt region. The project introduced injectable contraceptives and emergency contraception, as well as offered training for providers in the provision of all available contraceptive methods and in the syndromic management of STIs. This was supported by the development of provider self-training manuals, 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 had better technical skills and provided more information to clients, resulting in a doubling of the number of new acceptors each month and a broadening of the method mix in the intervention health centres, as compared to baseline and to control sites.

During 2002, a Stage III project to replicate the strategy and the lessons learnt in all health centres in the Copperbelt region districts commenced with funding from USAID and WHO and technical support from the Population Council,

Nairobi, and the Secretariat. The project uses innovative strategies to scaling-up that support the development of districts' capacities to formulate individual implementation plans for introducing a common package of interventions, while maximizing economies of scale and the use of local expertise so as to develop sustainable programmes.

Ongoing activities in Asia

China

In 2001, the Department supported the implementation of a strategic assessment in Chongqing, China, that addressed the issue of contraceptive introduction, with an emphasis on intrauterine device (IUD) technologies available in the national family planning programme. Numerous important findings and recommendations emerged, including the need to: (i) strengthen providers' capacity to provide all contraceptive methods with improved quality of care; (ii) reduce the number of types of IUDs provided in the national programme and improve aspects of care related to both insertion and removal; (iii) strengthen the diagnosis and management of RTIs in the context of family planning health services; and (iv) review a number of the contraceptive products available with regard to either the quality of their manufacture and/or their long-term safety.

The report of the assessment was published in Chinese and English and disseminated widely, and a summary of the report was published in the *Chinese Journal of Family Planning*. Follow-up activities began in 2002 with a systematic review on the safety and efficacy of IUDs and hormonal contraceptive methods provided through the national family planning programme, with the goal of selecting a reduced number of the safest and most effective products. A proposal for a Stage II project to test a package of interventions recommended by the assessment to improve informed choice and quality of care has been developed and is undergoing review and refinement, prior to implementation in 2003.

In late 2002, the Yunnan Reproductive Health Research Association led a team representing a broad range of provincial level stakeholders in the implementation of an assessment in Yunnan Province that addressed a range of reproductive health issues. The focus was on strategies to improve access, utilization and quality of services for poor and marginalized groups, including ethnic minorities and urban migrants. The findings and recommendations of the assessment team will be presented and discussed at a dissemination workshop in early 2003 and are expected to provide important input to both provincial and national authorities who are facing challenges from the unexpected impacts of recent health reforms on access to and utilization of reproductive health services by the poor.

Myanmar

A Stage II research project is developing and testing a district-level model for improving the quality of care of family planning and other reproductive health services. Project activities include: the development of new information, education and communication (IEC) materials and activities; training for public sector basic health staff, private general practitioners, private drug shop staff, and district and community level members of a national NGO, the Myanmar Maternal and Child Welfare Association (MCWA); a community advocacy component; and efforts to strengthen the management capabilities of district-level and health centre staff related to planning, supervision and logistics. The project is being implemented in two districts with differing geographic conditions, ethnic composition and reproductive health needs.

In late 2001, a mid-project evaluation was conducted, resulting in revisions to project training materials. During 2002, refresher training was provided to health staff in the public and private sectors, including drug shop and pharmacy staff in the project districts. In addition, the provider training curricula developed by the project were utilized by the Ministry of Health in training health staff in an additional 84 districts through the UNFPA country programme. The Myanmar Medical Association provided training to private general practitioners in 25 additional districts. The IEC materials developed by the project are also being adopted by the Ministry of Health and UNFPA for use in their project districts.

Viet Nam

A Stage II study assisted the Government of Viet Nam in developing a strategy for introducing the injectable contraceptive depot-medroxyprogesterone acetate (DMPA), while at the same time strengthening the quality of family planning and reproductive health service delivery generally. This project developed training curricula for providers, improved family planning IEC materials, and trained providers and community level workers. The emphasis was on counselling and provision of balanced information, in addition to technical information on all available contraceptive methods. The project also developed approaches to strengthening management of services, including the use of supervision tools.

A Stage III project to replicate and scale-up the interventions tested initially in three provinces came to an end in 2002. The introduction of DMPA was initially implemented in 21 provinces where government or donor support for strengthening health service delivery was already available, but by the end of the project, introductory activities had expanded with government support to all but one of the nearly 60 provinces of Viet Nam. As in Stage II, the Stage III project was 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 was 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 of quality of care. This project is described in the chapter on Preventing unsafe abortion.

Ongoing activities in eastern Europe

Romania

Activities in this country focused on reducing the recourse to abortion and improving the quality of care of family planning and abortion services. They are described in the chapter on Preventing 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, in the Departments of La Paz and Santa Cruz. Interventions focused on provider training, strengthening the management of services, and the development of community participation in guiding service delivery.

Lessons learnt and materials developed through the project are now being used by the Ministry of Health in the broader introduction of DMPA, supported by the United Kingdom Department for International Development (DFID), with technical assistance provided by the Population Council, Brazil. In a related activity, the NGO Reprolatina, with funding from the Bill and Melinda Gates Foundation, is assisting the Ministry of Health in developing training capacities in the Department of Santa Cruz to support expansion and scaling-up of project activities focusing on improving quality of care.

During 2002, the Ministry of Health received support from EngenderHealth, the Pan American Health Organization (PAHO) and Reprolatina to conduct a strategic assessment of cervical cancer screening and treatment services in Bolivia. The draft report presented a broad range of recommendations to strengthen access to effective and efficient services, and identified the need for several critical studies to support improving the quality of care in these services. Follow-up activities are currently being planned.

Brazil

The Brazil Stage II project had demonstrated that expansion of reproductive choice can occur at the municipal or district 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 in twelve 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. In addition, the Strategic Approach is being utilized by the Ministry of Health to address HIV prevention and the development of STI control activities, as mentioned earlier.

Guatemala

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

Key findings and recommendations from the assessment were presented in a national dissemination workshop in 2002. A proposal for action research to test interventions to improve access to and quality of family planning and other reproductive health services was developed, reviewed and is currently being revised.

EXTERNAL QUALITY ASSESSMENTS OF REPRODUCTIVE HEALTH SERVICES

During late 2001, the Department began work on a review of the potential role of External Quality Assessments (EQAs) as a means of improving and ensuring the quality of care of reproductive health services. A consultant completed a review of the literature on the utilization of external and/or independent assessment processes for quality improvement, including accreditation, of reproductive health services. Twelve case studies of reproductive health services which had undergone an EQA process using explicit standards and indicators were subsequently undertaken to offer insight into the use and impact of EQAs from the perspectives of service providers, clients and stakeholders. A consultation was held in September 2002 with representatives from the case study sites and other experts in the field to discuss the lessons learnt. The final report will be completed in early 2003.

The work represents the first efforts of the Department in this area, and will contribute to ongoing activities to assist countries to improve the quality of reproductive health service delivery. It is also expected to be of value in efforts to advise ministries of health in setting and ensuring norms and standards, including in the context of health reforms such as decentralization, where a key role of ministries lies in monitoring and supporting adherence to standards and improving the quality of services. The Department will continue to work closely with WHO's Department of Health Service Provision to gain further understanding and experience in this area and to support a range of effective processes and tools for improving quality of care.

UNFPA/WHO/ILO-STEP/UNICEF PROJECT ON QUALITY OF CARE

The Department has continued to play a role as a partner in the UNFPA/WHO/ILO-STEP/UNICEF project "Improving the quality of sexual and reproductive health care through empowering users". The project addresses the question of whether the organization of community demand can influence the quality of reproductive health care and, if so, what mechanisms can be used to effectively increase the capacity of communities to influence the way reproductive health care is delivered?

The project is being undertaken in six countries: India, Kyrgyzstan, Mauritania, Nepal, Peru and United Republic of Tanzania. In each country, action research projects are being planned to examine the impact of different approaches, including empowerment of women's groups and development of community insurance schemes, on strengthening demand for high-quality reproductive health services. In addition, through the project, WHO will assist the Nepalese Ministry of Health to conduct a national reproductive health strategic assessment to provide input to the process of national reproductive health policy and programme development.

THE IMPACT OF HEALTH REFORMS ON REPRODUCTIVE HEALTH

In recent years, governments and international donors have designed and implemented major reforms in health systems. These health reforms have been promoted as means of improving effectiveness, efficiency, quality, equity, and financial soundness. Reforms have typically 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 pose challenges to the development of interventions to promote and ensure reproductive health. There is a need to understand better the impacts of the various types of health reforms on access to, utilization of, and quality of reproductive health services, as well as on reproductive health outcomes and on the sexual and reproductive rights of individuals. This increased understanding is a critical first step toward increasing the capacity of WHO and others to provide guidance to countries undertaking reforms of their health systems. A three-year research initiative to examine the interaction between health reforms and reproductive health was developed to begin implementation in 2003.

In the meantime, staff of the Department have been collaborating with the Women's Health Project of the University of the Witwatersrand, South Africa, on a project entitled "Sexual rights and reforms". The project is bringing together members of women's health NGOs from Africa, Asia and Latin America. It aims to strengthen understanding among activists and decision-makers of the role of health sector reform in facilitating or undermining efforts to achieve sexual and reproductive rights and health policies and programmes, as well as to identify and advocate for strategies to maximise positive outcomes with regard to sexual and reproductive health and services. The project is beginning by developing regional and global reviews of the literature and experiences on a series of key issues concerning the impact of health reforms on sexual and reproductive health and rights. The reviews will be presented and discussed at an expert consultation, with the objective of identifying knowledge gaps and developing an agenda for research and advocacy on these issues.

POVERTY AND REPRODUCTIVE HEALTH

The Department has begun to develop work documenting the relationships between poverty and reproductive health. Initial activities have focused on efforts to document the relationships between poverty and maternal and neonatal health and are described more fully in the chapter on Making pregnancy safer: implementation of evidence-based programmes.

Annex 1

SCIENTISTS IN 2002

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	8	89	1	11			9
Women	3	33					3
from:							
AFRO	1	11					1
AMRO	1	11					1
EMRO							
EURO			1	11			1
SEARO	2	22					2
WPRO	4	45					4

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	34	48	23	33	13	19	70
Women	20	29	15	21	7	10	42
from:							
AFRO	4	6					4
AMRO	14	20			9	13	23
EMRO							
EURO			23	33	4	6	27
SEARO	4	6					4
WPRO	12	17					12

Annex 2

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Section 8
Implementing best practices

Implementing best practices

M. Gülmezoglu, M. Usher-Patel, J. Villar, A. Shah

INTRODUCTION

Adoption of evidence-based practices depends on having access to appropriate tools and having the capacity to interpret, critically appraise and apply the evidence. The best way to generate relevant evidence has not changed: high-quality research protocols that are implemented and reported appropriately. However, the methods of synthesis of evidence and the way evidence is communicated to target populations are changing and the organizations that have this mandate must keep up with new developments. The synthesis of evidence through systematic reviews is acknowledged to be a prerequisite for undertaking research and deciding on policy and practice. The field is constantly developing and there is a need for methodological work to address the difficulties in systematically reviewing epidemiological studies that address different types of questions (e.g. evaluation of screening tests, prevalence of morbidities). Strategies such as the Implementing Best Practice (IBP) Initiative that support the transfer of knowledge and change in practice are also of particular importance. These strategies are often regarded as complex interventions where a series of activities are packaged together to address the different institutional, organizational and individual barriers to change with the aim of improving practices and the quality of reproductive health.

To address the issue of knowledge generation, synthesis, dissemination and implementation, the Department is working on two major projects:

(i) The WHO Programme to Map Best Reproductive Health Practices aims to generate evidence through rigorously conducted research, summarize this evidence through systematic reviews, disseminate up-to-date high-quality research evidence and build capacity in evidence-based medicine in countries in order to enable decision-makers to make the best use of this evidence.

The WHO Reproductive Health Library (RHL) is very important in the dissemination of the evidence generated/synthesized, and is recognized as the leading resource for evidence-based reproductive health care. RHL is a unique conduit for developing new ways to communicate information on a global scale.

(ii) The Department has led the development of a strategic approach—the IBP Initiative—to support the introduction, adaptation and application of evidence-based best practices in countries. This initiative involves a collaborative network of partner agencies committed to harmonizing approaches and to supporting the use of technical guidelines, materials and tools that have been developed. The strategy uses a number of innovative approaches to manage the transfer of knowledge to support the development of programmes that prompt change from within the system and foster the application of managerial and technical skills to implement best practices in order to improve the quality of reproductive health.

THE WHO PROGRAMME TO MAP BEST REPRODUCTIVE HEALTH PRACTICES

Research activities

Objectives

The overall objective of this activity is to generate evidence to 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 inter-

ventions 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 RHL is ongoing. The trial compares an active dissemination strategy through three workshops within a period of six months, to the standard form of information sharing (control group) in place in the local settings. In 2002, the workshops were conducted in 22 intervention hospitals. Baseline clinical data from 36 053 women and the Care Provider Profile survey of 813 service providers have been analysed. Two articles, one describing the study methodology and another the characteristics of the settings are currently being drafted. Collection of outcome data is ongoing in 22 hospitals in Mexico and is due to start in February 2003 in Thailand. A qualitative evaluation of staff experiences in the intervention hospitals will also be carried out in 2003.

Research synthesis

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 what is known and not known, 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. Systematic reviews on the effectiveness of practices are conducted through the Collaborative Review Groups of the Cochrane Collaboration, while those addressing other epidemiological questions are conducted independently.

Progress

In 2002, systematic reviews were conducted in all major areas of reproductive health (Table 8.1). The Department continues to work closely with Cochrane Collaborative Review Groups and Cochrane Centres, in both Cochrane systematic reviews and capacity strengthening activities, to provide technical support to reviewers. For non-Cochrane systematic reviews (e.g. screening, prevalence) the Department works closely with reviewers, providing technical support when necessary.

Dissemination of evidence-based reproductive health care information: *The WHO Reproductive Health Library* (RHL)

Figure 8.1. RHL 5 in English and Spanish

Objectives

The objective of 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 (Figure 8.1). RHL is an electronic review journal updated yearly, focusing on reproductive health problems of high priority for developing countries. Systematic reviews included in RHL are Cochrane reviews which are supplemented with commentaries and the practice implications of these reviews. The latter are prepared by researchers from developing countries or 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

In 2002, RHL No.5 was published in English and Spanish. The contents had been increased significantly from the previous issue. The highlights of RHL No. 5 include the following:

Updates: Fourteen Cochrane reviews and the corresponding commentaries and practical aspects were updated.

New reviews: Twelve new reviews were included bringing the total to 70. Three reviews that were out of date were removed.

Implementation aids: In this new section, practices for which there is strong evidence for implementation were complemented with documents to assist their adoption:

Table 8.1. Distribution of systematic reviews by topic area (2002)

Topic area	New Reviews	New Protocols published	Updated Reviews	Ongoing Reviews
Maternal and perinatal health	3	2	7	3
HIV/AIDS/STI	3	1	1	-
Fertility regulation (incl. unsafe abortion)	2	1	1	-
Total	8	4	9	3

- the manual for the implementation of the new WHO Antenatal Care model
- a video demonstrating how to perform external cephalic version
- a video programme on the need for and benefits of companionship during labour
- a Powerpoint presentation describing the Better Births Initiative.

Dissemination

RHL subscriptions exceeded 12 000 at the end of 2002 and the RHL print volume has been increasing gradually (Figure 8.2). Since the initiation of the RHL project a concrete dissemination strategy has been followed, which incorporates the following elements:

- *Subscriptions and other mail distribution*: the Departmental and WHO-Library newsletter mailing lists are used in a selective manner, encouraging all who receive a copy to subscribe in order to ensure continued access. These untargeted mailings have been reduced from approximately 6000 in 1997 to 2000 in 2002 according to the original dissemination strategy. Currently, approximately 10 000 subscriptions are individual, requested subscriptions, with the remainder being routine mailings.
- *Active dissemination*: conference presentations and WHO meetings serve the purpose of raising awareness of RHL and evidence-based medicine. RHL presentations and workshops are conducted by the Department, RHL regional editors and collaborators within the Programme's Maternal and Perinatal Health Research network. Table 8.2 shows the list of presentations/workshops coordinated by the Department. When the activities of the regional editors are included, more than 100 workshop/presentations were conducted in 2002.

The free-subscription system has substantially facilitated access to RHL in developing countries. The distribution of RHL subscriptions by WHO regions and the increase in subscriptions between 2000 and 2002 are shown in Figure 8.3. The publication of RHL in Spanish and active participation of the WHO Regional Office for the Americas and of centres collaborating with the Department have played a major role in increasing subscription in Latin America.

Figure 8.2. RHL print volume since 1997

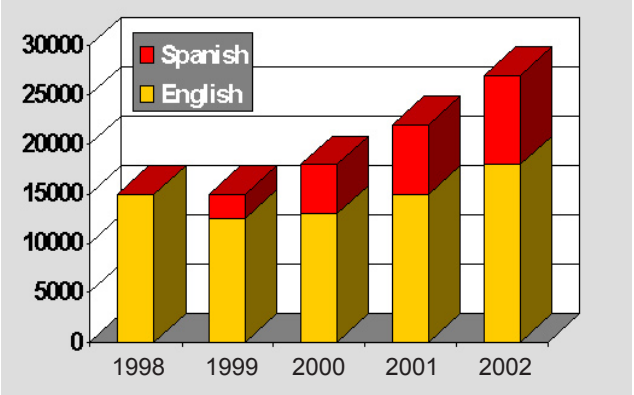


Figure 8.3. RHL subscription status (2000-2002)

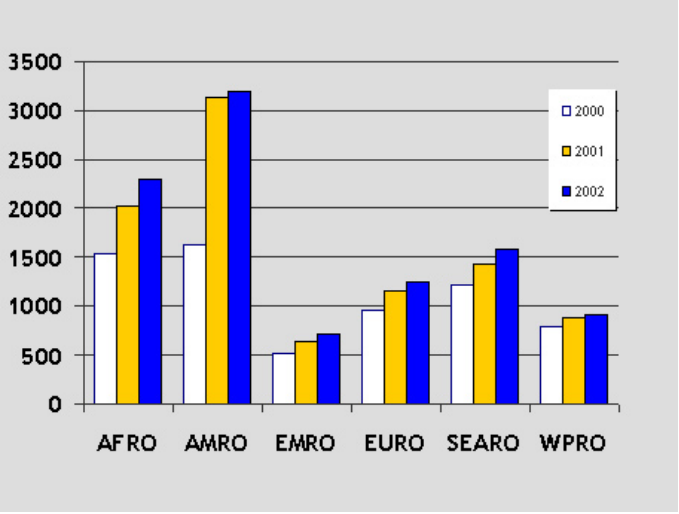


Table 8.2. RHL presentations coordinated by the Department in 2002

WHO Regions	Workshops/presentations	Attended/trained
Africa	7	316
Americas	13	2440
South-East Asia	3	250
Europe	6	203
Eastern Mediterranean	7	1000
Western Pacific	3	750
Headquarters	4	90
Total	43	5049

Translations

The experience with Spanish translations at Centro Rosarino de Estudios Perinatales (CREP) in Rosario, Argentina, meant that a system could be established that can be replicated for all translations. The use of translation-assistance software that compares documents, creates a vocabulary and ensures consistency has been helpful. The report prepared by CREP has helped the Department to determine the standards and requirements for other translations.

Work on a Chinese version in collaboration with the Shanghai Institute of Planned Parenthood Research (SIPPR), Shanghai, China, is ongoing. The translation is almost complete and it is anticipated that the Chinese version will be ready for publication by mid-2003. Efforts to raise funds and identify an institution for a French version are continuing but so far these efforts have not been successful.

Capacity building in evidence-based reproductive health care

In Africa, a training project entitled "Making evidence-based decisions in reproductive health care" was initiated jointly with the WHO Regional Office for Africa (AFRO). The South African Cochrane Centre in Cape Town, South Africa, developed a four-day training package that includes manuals for workshop facilitators and participants (Figure 8.4) and a monitoring and evaluation module. The package was pilot-tested in April 2002 and the first workshop to train facilitators took place in December 2002. In 2003, workshops will be conducted in Mozambique, Nigeria and Zambia. The training manuals will be translated into Portuguese and French. The training programme was presented at the Global Forum for Health Research conference in Arusha, United Republic of Tanzania, in November 2002.

In Latin America, support has been provided to CREP to implement a systematic RHL training and dissemination programme.

Figure 8.4. Manual for course participants

In Asia, the Thai-Cochrane Network was launched in 2002 with support from the Programme. The support specifically includes RHL training and support activities in Indonesia, the Philippines, and Viet Nam. In March 2003, an exploratory meeting to implement the training package mentioned above will be convened in New Delhi, India.

Future challenges

RHL has become a recognized source of evidence-based, up-to-date information in reproductive health. RHL is incorporated into the medical curriculum of several universities and is an important resource for postgraduate training and college membership examinations. Furthermore, the RHL trial (see above) will provide useful insights into changing professional behaviour in under-resourced settings. As RHL activities—systematic reviews and capacity building in evidence-based reproductive health care decision-making—expand and become more widely known, new challenges will emerge.

The WHO Programme to Map Best Reproductive Health Practices faces the following challenges:

- To ensure that, as recommended by the Department's Scientific and Technical Advisory Group (STAG), systematic reviews become an integral first step of all research activities undertaken by the Programme. This is already the case in maternal and perinatal research.

- To ensure that the Department's recommendations for practices and implementation are based on best available evidence from systematic reviews.

- To expand the content of RHL to cover systematic reviews of observational studies including systematic reviews of morbidities, mapping the burden of reproductive ill-health.

- To maintain and improve the quality of RHL. The number and type of documents included in RHL increase every year, with about one-third of them needing revision and updating. This increase, as well as the translations into several languages already existing, create significant management challenges. By the end of the 2002–2003 biennium, RHL will include almost 80 Cochrane reviews, accompanying commentaries and practical aspects, all of which will be updated annually. The same machinery will be running for the Spanish and Chinese versions.

- To contribute to creating a critical mass of scientists in developing countries who are knowledgeable and competent in critically appraising and 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.

- To continuously improve dissemination strategies. New innovations in dissemination and training in health include the use of satellite-aided digital broadcasting and long-distance Internet-based possibilities, among others. The challenge will be to incorporate these emerging technologies into the overall dissemination strategy.

IMPLEMENTING BEST PRACTICES

The Implementing Best Practice Initiative

Today there is a considerable body of knowledge that provides the solid evidence base for establishing internationally recognized norms and standards in reproductive health. The challenge the Department is addressing through the IBP Initiative is the complex one of how to support the management and transfer of knowledge so that it impacts changes in practice at country level. The IBP Initiative involves a collaborative network of 17 partner agencies (Annex 4). All partners work on a cost-sharing basis and are committed to minimizing duplication of effort and maximizing the use of resources to support the transfer of knowledge, and the adaptation and adoption of best practices in reproductive health at country level.

The IBP Initiative works with and expands networks of existing in-country projects and programmes of partner agencies. It does not create new materials, but promotes the use of the technical, managerial and performance improvement materials and tools that already exist. The IBP Initiative is launched through inter-country meetings involving country teams of policy-makers and programme managers. Innovative methods are used to support the transfer of information and the exchange of country experience. Managerial tools are introduced to foster leadership skills and creative thinking among key players, who are also encouraged to build on their experience to develop strategies for introducing best practices that meet their immediate programmatic needs. The IBP partners support the implementation of the plans created through a programme of mentorship and supportive follow-up.

Figure 8.5. The IBP logo

"Helping developing country health professionals capture and apply best practices in reproductive health"

Progress

IBP Consortium

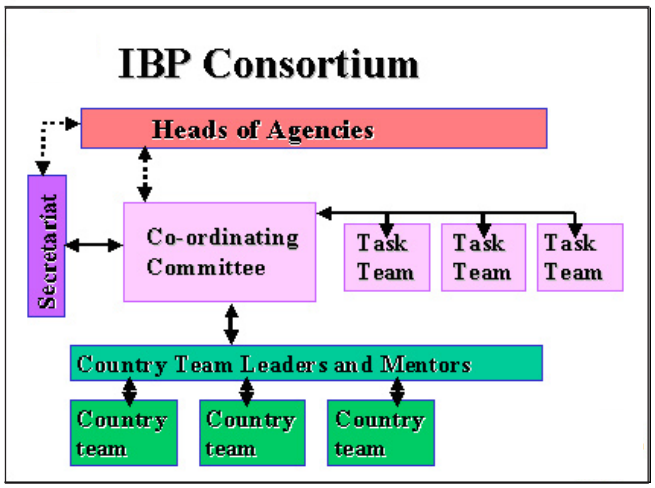
All partners have agreed to sign a Memorandum of Understanding to form the Implementing Best Practice Consortium. The Consortium will be officially launched during the IBP Intra-Country Meeting of Partners and Country Teams, due to be held in India in April 2003.

Through this Memorandum of Understanding, members of the IBP Consortium agree:

- To respect the diversity of circumstances in individual countries and work collaboratively with other members of the Consortium and local colleagues to introduce and support the implementation of culturally appropriate IBP strategies.

- To develop and maintain a style of interaction among the IBP member organizations characterized by transparency, responsiveness, inclusiveness and goodwill.

Figure 8.6. Schematic representation of the IBP Consortium



In its capacity as the secretariat of the IBP Initiative, the Department coordinates the programme of activities of the IBP Consortium. Heads of agencies delegate technical staff as members of the IBP Coordinating Committee responsible for developing the programme of activities. Each member of the Coordinating Committee leads a Task Team responsible for undertaking a specific activity within a specified timeframe that supports the programme of work. The Task Teams are currently working on: (i) an advocacy kit; (ii) revision of the IBP Tool Kit; (iii) a literature review on knowledge management; (iv) the mini university agenda for the India meeting; (v) the technology café and information exchange fair; (vi) the preparation of managerial exercises; (vii) a mentorship and follow-up programme; (viii) an evaluation framework for the IBP Initiative; (ix) an intranet-based communication and management system; and (x) financial management systems for the IBP Consortium.

Members of the IBP Coordinating Committee work directly with countries and provide a supportive follow-up programme for all activities undertaken with countries.

Programme of activities

A meeting was held with 18 representatives of partner agencies in July 2002 to review progress and prepare a programme of work for 2003–2006. All partners appreciated the effective collaboration of the IBP Initiative but recognized that its main weakness was the mentorship and supportive follow-up programme.

In accordance with previous recommendations by STAG, the IBP Initiative has been presented to and has received support from the Regional Advisory Panels, and plans are being developed to link the IBP Initiative more closely with the Strategic Approach and the dissemination of RHL.

Funding proposals for IBP Consortium

A meeting was convened in October 2002 to discuss mechanisms for generating external funding to support the current programme of work, and the inclusion of nongovernmental agencies and WHO collaborating centres from developing countries in the IBP Consortium. Task Teams were formed to prepare funding proposals and structure a transparent management system as part of the management portfolio for the Consortium.

Electronic communication and management system

As part of the management system for the IBP Consortium, the Department is working with the WHO Management Information System (WHO/MIS) group to develop an electronic communication and management system. This system will create virtual workspaces and enable the IBP partners to communicate effectively and efficiently between themselves, by storing, archiving and retrieving information, and convening online meetings. It will also facilitate communication, support the exchange of information, and support follow-up activities with country teams. The development of this system is being supported by the information technology departments of all partner agencies. WHO/MIS has prepared a detailed design specification, which is currently under review by partner agencies.

Regional and country activities

Country-specific activities with the WHO Regional Office for the Eastern Mediterranean

The IBP partners held an Inter-Country Meeting with Partners and Country Teams in Cairo, Egypt, in February 2002. A total of 152 senior managers and policy-makers attended the meeting, coming mainly from Egypt, Jordan, Lebanon, Pakistan, Palestine, Turkey and Yemen. The country teams formed as a result of the meeting have all taken action to implement the programme of work they committed to at the meeting. Supportive follow-up by partners to country teams has taken place, but it is still too limited. Corrective action is being taken and plans are being prepared to improve this component of the IBP Initiative.

Country-specific activities with the WHO Regional Office for South-East Asia (SEARO)

A team from India participated in both the Egypt and Nepal IBP inter-country meetings. They have continued to meet and work together since these meetings. Through SEARO and the Ministry of Health, Department of Health and Family Welfare, India, they requested that the IBP Initiative be launched in India. In August 2002, the Department collaborated with SEARO to lead an initial planning exercise with representatives from the ministries of health from two Indian States and six local partner agencies. One outcome of the meeting has been the formation of the IBP India Steering

Committee, which has now expanded to include 10 local partner agencies and representatives from the office of the WHO Representative and the Ministry of Health.

The IBP India Steering Committee has identified the participants, local facilitators and the information and performance improvement needs they would like the IBP Initiative to address. All partners, including members of the India Steering Committee have agreed to provide seed funding to cover administrative costs, and to fund a minimum of five participants. The meeting will involve participants from four states in India, and is due to take place in Agra, India, in April 2003. So far commitments have been made to fund 160 participants.

Future plans

During 2003, all partners will be expected to continue undertaking their agreed roles, contribute to activities on a cost-sharing basis and support the implementation of the agreed programme of work. The IBP Consortium will:

- expand, funding permitting, the partnership to include a broader representation from nongovernmental agencies and WHO collaborating centres from developing countries;
- finalize and test the management portfolio for the Consortium and seek additional funding sources;
- use the Strategic Approach (see the chapter on Policy and programmatic issues) more widely and work with teams within the Department to support the dissemination of research findings, tools and materials;
- improve the follow-up and mentorship programme in countries in which the IBP Initiative has been introduced, and monitor and report on progress;
- continue working with the IBP India Steering Committee to prepare for, undertake and follow up the IBP India Intra-Country Meeting;
- work with AFRO to introduce the IBP Initiative into selected countries in Africa; and
- publish success stories and lessons learnt, finalize the IBP Tool Kit and advocacy pack, undertake a literature review and publish a paper on knowledge management.

Annex 1

WHO PROGRAMME TO MAP BEST REPRODUCTIVE HEALTH PRACTICES

EDITORIAL GROUP OF *THE WHO REPRODUCTIVE HEALTH LIBRARY*

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Jeremy Grimshaw, Ottawa Health Research Institute, Ottawa, Canada
Justus Hofmeyr, University of the Witwatersrand, Johannesburg, South Africa
Ana Langer, The Population Council, Mexico City, Mexico
Pisake Lumbiganon, Khon Kaen University, Khon Kaen, Thailand
Suneeta Mittal, All India Institute of Medical Sciences, New Delhi, India
Manorama Purwar, Clinical Epidemiology Unit, Nagpur, India
Kenneth Schulz, Family Health International, Research Triangle Park, NC, USA
Juan Carlos Vazquez, America Arias Hospital, Havana, Cuba

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	9	82			2	18	11
Women	4	36					4
from:							
AFRO	1	9					1
AMRO	3	27			2	18	5
EMRO							
EURO							
SEARO	3	27					3
WPRO	2	18					2

Annex 2

SCIENTISTS IN 2002

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Vanchai Vatanasapt, Khon Kaen University, Khon Kaen, Thailand
Jimmy Volmink, Global Health Council, Washington, DC, USA
Godfrey Walker, United Nations Population Fund, Bratislava, Slovakia
Gijs Walraven, Medical Research Council Laboratories, Farafenni Field Station, Gambia
David Wilkinso, Adelaide University, Whyalla, Australia
Chris Williams, Oxford University, Oxford, United Kingdom
Ray Yip, United Nations Children's Fund (UNICEF), Beijing, China

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Scientists	60	72	1	1	22	27	83
Women	18	22			6	7	24
from:							
AFRO	26	31					26
AMRO	17	20			6	7	23
EMRO	3	4					3
EURO			1	1	14	17	15
SEARO	12	14					12
WPRO	2	2			2	2	4

Annex 3

PUBLICATIONS IN 2002

COCHRANE REVIEWS

[1]Brocklehurst P, Volmink J. Antiretrovirals for reducing the risk of mother-to-child transmission of HIV infection.

Kulier R, Nardin JM, Boulvain M, Peterson HB, Campana A. Techniques for the interruption of tubal patency for female sterilization.

[2]Mangesi L, Hofmeyr GJ. Early compared with delayed oral fluids and food after Caesarean section.

Say L, Kulier R, Gülmezoglu M, Campana A. Medical versus surgical methods for first trimester termination of pregnancy.

Thinkhamrop J, Hofmeyr GJ, Adetoro O, Lumbiganon P. Prophylactic antibiotic administration in pregnancy to prevent infectious morbidity and mortality.

van den Broek N, Kulier R, Gülmezoglu AM, Villar J. Vitamin A supplementation during pregnancy.

Wilkinson D. Nonoxynol-9 for preventing sexually acquired HIV infection.

Wilkinson D. Nonoxynol-9 for prevention of sexually transmitted infections.

Updated reviews

Brocklehurst P, Volmink J. Antiretrovirals for reducing the risk of mother-to-child transmission of HIV infection.

Gülmezoglu AM. Interventions for trichomoniasis in pregnancy.

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

Hofmeyr GJ. Interventions to help external cephalic version for breech presentation at term.

Hofmeyr GJ. Amnioinfusion for meconium-stained liquor in labour.

Hofmeyr GJ, Atallah AN, Duley L. Calcium supplementation during pregnancy for preventing hypertensive disorders and related problems.

Hofmeyr GJ, Gülmezoglu AM. Maternal hydration for increasing amniotic fluid volume in oligohydramnios and normal amniotic fluid volume.

Kulier R, Boulvain M, Walker D, De Candolle G, Campana A. Minilaparotomy and endoscopic techniques for tubal sterilisation.

Smaill F, Hofmeyr GJ. Antibiotic prophylaxis for Caesarean section.

Protocols

Abalos E, Carroli G. Bed rest with or without hospitalisation for hypertension during pregnancy.

Abdel-Aleem H, Vogelsong K, d'Arcangues C, Gülmezoglu AM. Treatments for irregular bleeding associated with the use of injectable progestin-only contraceptives.

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[1]This review appears again under Updated reviews because both reviews were published in 2002.
[2]This review appears again under Protocols because both reviews were published in 2002.

Annex 3 (continued)

Mangesi L, Hofmeyr GJ. Early compared with delayed oral fluids and food after Caesarean section.

OTHER PUBLICATIONS

Chalmers I, Lumbiganon P. The Cochrane Collaboration: providing research syntheses to inform health care and research. *Science Asia,* 2002 (supplement):9–14.

Gülmezoglu AM, Villar J. The WHO Reproductive Health Library (RHL). In: *Making childbirth safer through promoting evidence-based care*. Washington, DC, Global Health Council, May 2002:12–14.

Villar J, Gülmezoglu AM, Carroli G, Schulz KF, Lumbiganon P, Mittal S, Hofmeyr GJ, Langer A, Cheng L. Is it time to do away with conclusions in systematic reviews? *WHO Reproductive Health Library* (No.5), Geneva, WHO/RHR/02.1.

Annex 4

IMPLEMENTING BEST PRACTICES (IBP) INITIATIVE

PARTNER AGENCIES

1. World Health Organization/Department of Reproductive Health and Research (WHO/RHR)
2. United States Agency for International Development (USAID)
3. United Nations Population Fund (UNFPA)
4. Centre for African Family Studies (CAF)
5. EngenderHealth
6. Family Health International (FHI)
7. Georgetown University, Washington, DC, USA
8. International Planned Parenthood Federation (IPPF)
9. Innovative Technologies for Health Care Delivery/Program of International Training for Health (INTRAH/PRIME)
10. Johns Hopkins Program of International Education in Gynecology and Obstetrics (JHPIEGO)
11. Johns Hopkins University/Center for Communication Programs (JHU/CCP)
12. Management Sciences for Health (MSH) and Advance Africa Project
13. Partners in Population and Development (PPD)
14. Pathfinder International and Catalyst Project
15. Population Leadership Program
16. Program of Appropriate Technology for Health (PATH)
17. Regional Centre for Quality Health Care, Makerere University, Kampala, Uganda

Section 9
Monitoring and evaluation

Monitoring and evaluation

M. Gülmezoglu, A. Betran, L. Say

INTRODUCTION

Monitoring and evaluation work in the Department entails a series of activities that maintain and provide the means of monitoring and appraising progress towards the reduction of maternal and under-five mortality. These activities have two dimensions: (i) work towards better understanding of the extent of related morbidities and mortality; and (ii) work on the tools—"indicators"—used to monitor progress.

Improved knowledge of the magnitude/burden of leading causes of maternal and newborn morbidity and mortality is crucial in identifying needs, setting targets and allocating resources for any improvement programme and for identifying new research priorities. This information needs to be reliable and up-to-date and to be generated and summarized on the basis of a rigorous scientific methodology. In addition to the need for improved knowledge on leading morbidities such as eclampsia, haemorrhage and low birth weight, other reproductive morbidities like genital prolapse, incontinence and depression (during pregnancy or postpartum) that affect large numbers of women but have been neglected to date, require attention.

Indicators are important for the monitoring of health status locally. Unfortunately, there is a discrepancy between locally relevant indicators and those that are useful for global monitoring purposes. Global indicators obscure differences in health status within countries, and between socioeconomic groups, rural and urban populations, different age groups and minority groups. Furthermore, there is 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 to improve data collection at country level before some of the indicators can be regarded as useful. It is also important to develop tools to provide access to and training in reproductive health indicators.

EPIDEMIOLOGY OF REPRODUCTIVE ILL-HEALTH

Objectives

The overall goal is to map reproductive morbidities in a comprehensive and systematic manner. Mapping will provide evidence to help in identifying the priorities for future research on practices which prevent these morbidities, and support for the implementation of evidence-based country programmes and for advocacy. The specific objective is to calculate prevalence/incidence, case-fatality rates, sequelae and attributable fractions of pregnancy-related and reproductive morbidities, from systematic reviews of published or unpublished studies and datasets.

Progress

Maternal morbidity and mortality: a systematic review

In 2002, the protocol for the systematic review on maternal morbidity and mortality was revised and finalized. A methodology working group was convened to discuss the statistical and methodological challenges of conducting systematic reviews of observational data of incidence/prevalence. These challenges include the expected wide heterogeneity across studies with regard to study designs, population characteristics, setting characteristics, and definitions/diagnostic procedures. However, it is worthwhile and indeed crucial to face these problems in order to provide tabulations of data for the different characteristics and also to provide a standard set of definitions for important health conditions. Providing tabula-

tions for different characteristics/circumstances will be useful for future work on addressing the gap between global and locally relevant indicators.

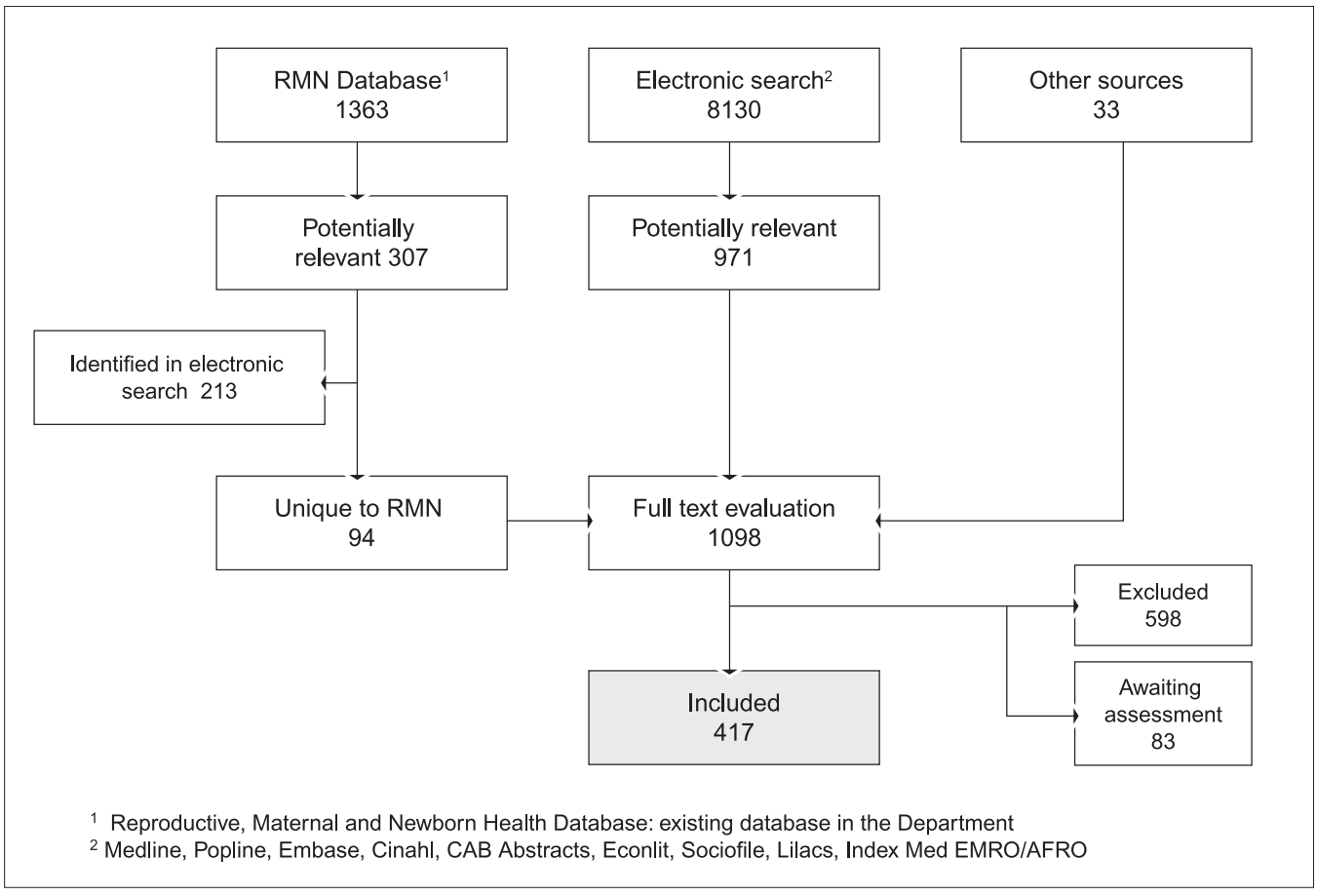
As summarized in Figure 9.1, a comprehensive search strategy was developed, tested and run for published/unpublished data from 1997. Over 8000 citations identified through the electronic search were screened by evaluating titles and/or abstracts. Of these, 971 were deemed to be potentially relevant and retrieved for full text evaluation. In addition, 1363 published/unpublished reports from 1997 have been identified from the previously compiled departmental database (Reproductive, Maternal and Newborn Health Database—RMN Database). They were appraised for inclusion in the systematic review. Out of these, 307—of which 213 were already captured in the electronic search—were considered to be potentially relevant. Figure 9.2 shows a flow diagram of the process of the reports identified through the departmental database and how it relates to other sources of data for the systematic review. Other sources including conference proceedings, reference lists, circulating documents within the Department, and Internet search engines were scanned and this provided 33 more articles.

Overall, 1098 reports were thoroughly appraised and the 417 that fulfilled the pre-determined inclusion criteria were included in the systematic review. For the year 1997, about 4.5% of all screened reports were finally included in the review. Data from the included reports were extracted on specifically designed data extraction forms. Data entry and descriptive analysis for the year 1997 was completed. The same process is being carried out for the year 1998. Data extraction, entry and detailed analysis for published/unpublished reports released until the end of 2002 are planned to be finalized by mid-2003. It is expected that for all years to be included (1997–2002), screening of around 60 000 citations will result in the inclusion of about 3000 reports. The systematic review will be updated regularly.

Skilled attendant at delivery

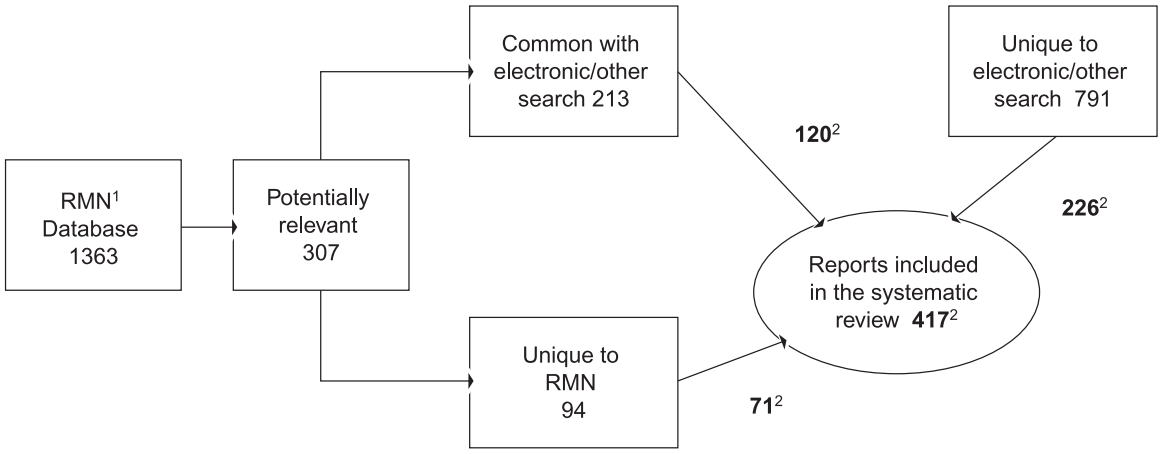
The Millennium Development Goals (MDGs) include the proportion of births attended by a skilled health worker as a key indicator for tracking progress in reducing maternal mortality. Nationally representative data available up to 2001 as well as global, regional and subregional estimates of the proportion of births attended by skilled health worker were published on the Department's web site. Regional estimates are compared with the established MDG, which states that by 2015, 90% of births should be attended by a skilled health worker. Skilled attendant estimates are updated annually and posted on the Department's web site. These estimates will be reviewed and updated in 2003. The new estimates will also be published on the Department's web site in 2003.

Figure 9.1. Identifying and processing reports from 1997 for inclusion in the systematic review



[1] Reproductive, Maternal and Newborn Health Database: existing database in the Department
[2] Medline, Popline, Embase, Cinahl, CAB Abstracts, Econlit, Sociofile, Lilacs, Index Med EMRO/AFRO

Figure 9.2. The distribution of reports from 1997 obtained from the Department's RMN Database and from electronic/other searches and included in the systematic review



[1] Reproductive, Maternal and Newborn Health Database holds 1363 articles from 1997, 973 from 1998, 455 from 1999 and 17 from 2000

[2] Figures in bold refer to reports included in the review after full-text evaluation

Systematic review on genital prolapse

The conduct of a systematic review to estimate the prevalence, associated factors and consequences of genital organ prolapse was started in 2002 and the first draft is currently being reviewed.

Antenatal care in developing countries

An analysis of levels, trends and differentials of antenatal care in developing countries using data from Demographic Health Surveys (DHS), Multiple Indicator Cluster Surveys (MICS) and Pan Arab Project for Child Development (PAPCHILD) surveys between 1990 and 2001 was carried out in 2002. The report concludes that levels of antenatal care use in developing countries have improved during the 1990s. However, there are significant disparities in access between rural and urban areas, low and high income. The impacts of wealth distribution and education appear to be among the major determinants of antenatal care use.

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 at international forums. The Department's work on mapping the epidemiology of reproductive ill-health will improve knowledge on the status of these indicators globally. The tools developed for the collection and use of these indicators will help to build capacity in countries.

Progress

A database for reproductive health indicators is under development. The main purpose of the database is to provide up-to-date information at the national, regional and global levels on the 17 global reproductive health indicators short-listed for global monitoring. In addition, this database includes five additional reproductive health and 16 socioeconomic and demographic indicators. It will be published on the WHO web site, allowing the user to search the database by country/countries or region(s) and to easily generate tables and graphs from these data. Database files have been prepared. These include the latest available data for each indicator. In 2002, the database was improved to allow the data to be entered and information displayed more precisely and consistently. It is expected that the XML version of the application will be ready for testing by May 2003.

FUTURE CHALLENGES

Challenges in the area of monitoring and evaluation can be summarized as follows:

1. *Introducing mapping of the burden of illness through systematic reviews to this public health component.* 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 and regularly updated.

These reviews will cover neglected conditions that affect large numbers of women as well as leading morbidities.

2. *Reproductive health indicators.* How the chosen indicators reflect the reproductive health status of populations remains to be demonstrated. The gap between global goals and locally relevant and operational indicators must be addressed by international agencies. It is also important to develop tools such as computer-assisted programmes to facilitate training in reproductive health indicators.

3. *Systems for global monitoring.* The systematic review mentioned above will reveal gaps in data with regard to different morbidities. The next step will be to implement systems to collect these data in a more reliable way through prospective studies. Facility-based systems in randomly selected countries in each of the WHO regions are currently being developed for routine monitoring of important health conditions and for conducting prospective research on emerging issues. Through these studies it will be possible to obtain facility-based data on morbidities that are representative of different regions. Once the system is established, it will be possible to look at those morbidities over time in order to assess trends.

Section 10
Communication, advocacy and information

Communication, advocacy and information

J. Khanna, C. Hamill, S. Kolev, J. Maurice

INTRODUCTION

The Communication, Advocacy and Information Group (CAI) 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. The Group sees the following as its 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 2002:

Progress in reproductive health research

The Department's newsletter, *Progress in reproductive health research,* has continued to serve as a key instrument for dissemination of research information to policy-makers, programme managers, scientists and the general public. Three issues of the newsletter were published in 2002. The topics covered included adolescent reproductive health, dual protection against pregnancy and sexually transmitted infections, and intrauterine devices. *Progress* continues to be translated into Chinese and is published on the Department's web site.

CD-ROM: Department of Reproductive Health and Research 2000–2001

This elegantly designed CD-ROM contains key documents on the work of the Department, including the following (the documents in bold were prepared in 2002):

1. Highlights of 2000
2. **Highlights of 2001**
3. Annual technical report 2000
4. **Annual technical report 2001**
5. **Research on reproductive health at WHO: biennial report 2000–2001**
6. **Better reproductive health—implementing the global agenda: biennial report 2000–2001**
7. **HRP Programme budget 2002–2003**
8. **RHR Programme budget 2002–2003**

In addition to the above, the CD-ROM includes the Department's biennial reports for 1998–1999 (*Reproductive health research at WHO: a new beginning: biennial report 1998–1999* and *Reproductive health programme development: implementing Cairo: biennial report 1998–1999*) and *Annual technical report 1999*. Together, these documents provide a full package of information on the work of the Department from 1998 to 2001. Some 2500 copies of the CD-ROM had been distributed by December 2002, primarily to scientists and national and international policy-makers. Print copies of all the new documents were also produced and distributed.

Safe motherhood—a newsletter of worldwide 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 worldwide activity* in 1989. In 2002, one issue of the newsletter was published, covering the topic of skilled attendance.

Other documents

Table 10.1 lists all the documents produced by the Department in 2002. A total of 23 documents (including other-language versions and promotional materials) were produced and distributed. In view of the increased acceptance of, and demand for, documents in electronic form, many new documents are now being produced on CD-ROM. In addition, in order to speed up and facilitate the availability of documents, all new information products are first published on the Department's Internet web site.

Reproductive health web site

The web site of the Department continues to expand and now houses over 3000 pages. New health topics added to the site in 2002 included:

- family planning
- best practices in reproductive health
- ethics
- gender and rights
- global monitoring and evaluation.

Work on integrating the Programme's web site into the Department's web site was completed early in 2002 and the Making Pregnancy Safer pages were also revised. Updates and additions are made to all the health topic areas as necessary during the year. All of the Department's documents are now listed on the site, either with full text online, or with instructions on how to obtain a hard copy. In addition, the Reproductive Health Home Page was given a fresh, new look.

Web statistics became available during 2002 and, as of 11 November 2002 the following had been recorded:

- The number of successful hits for the Department's web site from 1 January to 11 November was 2 490 423. More tellingly, for the same period, the number of page visits (impressions) was 1 337 482. These views were made during the course of 378 456 visits of an average length of 11 minutes and 28 seconds. Visitors are primarily routed through the United States of America (52.4%), with 24.3% of visitors from other developed countries (primarily, Western Europe and Australia) and 23.4% from the rest of the world. Since large organizations, such as the United Nations agencies and national health and civil services, use caching proxies extensively, these figures are underestimates of the true figures: WHO central web services believe that the real number of visitors to the Department's site is probably double the above. While web statistics remain at best very approximate guesses of visiting trends, the sheer size of these numbers indicates the importance of the Department's web site as a communication tool.

Dissemination of *The WHO Reproductive Health Library* (RHL) No. 5 and production of RHL No. 6

The fifth issue of RHL was published in February 2002. Later in the year, its Spanish version was also published. A total of 20 000 copies of the English version and 9000 copies of the Spanish version were produced. By December 2002, all the 20 000 copies of the English version had been distributed. A key element of the dissemination strategy adopted for RHL has been free distribution on a subscription basis. Subscriptions to RHL continue to rise rapidly. By December 2002, there were more than 12 000 addresses in the mailing list for the English version. 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. For the first time, RHL No. 5 included two training videos: one on social support during pregnancy and another on external cephalic version. During 2002, work was under way to produce RHL No. 6. Work was also started on a Chinese version of RHL.

Press releases

The Department issued two press releases in 2002. The first, in May 2002, reported the findings of the three-year study—dubbed the "MAGPIE" trial—which found that magnesium sulfate was effective in preventing pre-eclampsia and eclampsia. The second, issued in June 2002, highlighted the conclusions of a meeting of experts that nonoxynol-9 was ineffective in preventing HIV infection. Both releases generated healthy media interest.

Table 10.1. Documents produced in 2002

Electronic documents on CD-ROM

1. Department of Reproductive Health and Research 2000–2001
2. The WHO Reproductive Health Library No.5
3. Transforming health systems: gender and rights in reproductive health. A training curriculum for health programme managers

Printed documents

1. A framework to assist countries in the development and strengthening of national and district health plans and programmes in reproductive health: suggestions for programme managers
2. Programming for male involvement in reproductive health
3. Report of the In-depth Review Panel on research capacity strengthening
4. Annual technical report 2001
5. Selected practice recommendations for family planning
6. Clinical management of survivors of rape
7. Better reproductive health—implementing the global agenda: biennial report 2000 –2001
8. Reproductive health research at WHO: biennial report 2000–2001 (HRP)
9. A strategic assessment of the need for contraceptive introduction in the Chongqing municipality, China
10. Making decisions about contraceptive introduction: a guide for conducting assessments to broaden contraceptive choice and improve quality of care
11. The strategic approach to improving reproductive health policies and programmes: a summary of experiences
12. Expanding capacity for operations research in reproductive health: summary report of a consultative meeting
13. Current practices and controversies in assisted reproduction; report of a WHO meeting
14. Global action for skilled attendants for pregnant women

Language versions

1. Managing complications of pregnancy and childbirth (French)

Revised field-testing version

1. Essential care practice guide for pregnancy, childbirth and newborn care

Promotional materials

1. Highlights of achievements 1990–2001 (HRP)
2. A strategy for research capacity strengthening in developing countries. A series of five brochures on different types of grants
3. A set of six leaflets on the work of Making Pregnancy Safer (including a poster on global action for skilled attendants for pregnant women)
4. Sexual and reproductive health: publications and documents, October 2002

Strengthening the capacity for communication and information dissemination of 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 of 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 Programme's collaborating centres to publish more papers, especially in international peer-reviewed journals.

During 2002, a scientific writing workshop was conducted at the Institute for Research in Reproductive Health, Mumbai, India. A total of 20 researchers were trained. An evaluation conducted by the institute after the workshop found that a great majority of the participants had found it to be "very useful". The workshop included an observer and two participants from the FRONTIERS project of the Population Council. The Department is discussing a collaborative activity under which, using the proven model of its own workshops, the Department will help the FRONTIERS project to develop a scientific writing workshop specifically for social scientists.

A trainers' scientific writing workshop was conducted at the Department of Obstetrics and Gynaecology, All India Institute of Medical Sciences, New Delhi, India. The 20 participants in the workshop were mostly senior medical staff in the Department of Obstetrics and Gynaecology.

Workshops to improve communication skills and networking with the mass media

Researchers have the 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 January 2002, a communication workshop was conducted at the Department of Social and Preventive Medicine, University of Malaya, Kuala Lumpur, Malaysia. The workshop was attended by 22 participants, most of whom were middle-to-senior-level physicians involved in research and programme delivery in reproductive health. The participants were trained in communication strategy planning as well as in skills for communicating with the mass media. In an effort to enhance further the practical value of the communication workshops, a follow-up workshop was conducted in March 2002 to review how the participants had used their newly learned communication skills in the real world. Fifteen of the original 22 participants participated in this workshop. They presented five communications projects relevant to their work in the area of reproductive health. One project, presented by a group of six participants (including one journalist) was particularly interesting: it involved creating a new reproductive health web site for Malaysian adolescents. The presenters believed they were close to getting funding from commercial advertisers for this novel project.

Table 10.2. Respondent's rating of the newsletter in terms of interest value and usefulness of information

Question	Number of respondents	Very (%)	Quite (%)	Somewhat (%)	Not at all (%)
How interesting are the topics?	2149	58	38	3	0
How useful is the information to you?	2145	51	39	10	0
How useful is the information to your organization?	2117	43	34	11	9[1]

[1]These respondents did not belong to an organization.

Table 10.3. Respondent's profession and their rating of the interest value of the newsletter

Profession	Number (%) of respondents	Very interesting (%)	Quite interesting (%)	Somewhat interesting (%)	Not at all interesting (%)
Doctor/public	369 (17%)	52	45	3	0
Doctor/private	143 (6%)	50	46	4	0
Midwife	299 (13%)	71	26	3	0
Nurse	186 (8%)	69	27	4	0
Health worker	198 (9%)	56	40	4	0
Scientist	209 (9%)	50	45	5	0
Civil servant (government)	191 (9%)	60	37	3	0
Civil servant (international)	68 (3%)	48	48	3	0
Librarian	85 (4%)	57	35	7	1
Other	475 (21%)	57	40	3	0
Total	2223	58	39	3	0

Evaluation of information products

Safe motherhood newsletter

In 2000, the Department conducted a survey among the readers of the *Safe motherhood* newsletter. The results of this survey became available in 2002. A total of 21 215 questionnaires were mailed and 2273 responses were received. This response rate of over 10% can be regarded as more than satisfactory for a mailed questionnaire. Overall, the respondents found the newsletter to be interesting, useful and relevant to their work: out of 2127 respondents who made an overall assessment of the newsletter and its contents, 28% found it to be excellent, 55% very good, 16% good, 1% fair. Only one respondent rated it as poor. Tables 10.2 and 10.3 provide a summary of the findings.

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. Discussions were under way in 2002 to collaborate with the FRONTIERS project of the Population Council to develop a scientific writing workshop for social scientists.

PLANNED ACTIVITIES

In 2003, the Department will continue to produce its usual serial and non-serial publications, disseminate appropriate public relations material and conduct its scientific writing, communication and information management workshops. The Department intends to collaborate with the Population Council's FRONTIERS project to develop a special dedicated workshop for training social scientists in writing research papers for peer-reviewed journals; this workshop will use the training methods developed in the Programme's scientific writing workshop. The first workshop of this kind is expected to take place in Africa in 2003. Special emphasis will continue to be placed on the development of the Internet web site.

It is planned to conduct scientific writing workshops in Sri Lanka and Oman. Other activities to strengthen the communication capacity of collaborating centres will also continue.

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 Unit 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 Unit 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 Unit 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 members of the Unit provide on-the-project training in research data management and statistical analysis to staff members of centres participating in some multicentre studies or carrying out their own single-centre trials. They contribute to the development of appropriate techniques for the conduct, management and analysis of multicentre research projects in reproductive health in developing countries. They also provide local informatics support to the administrative management of the Department.

The Unit'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 Unit in 2002 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 68 research projects were supported by the Unit. The distribution of these projects by their stage of support at the end of 2002 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 with the 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.

Table 11.1. Number of studies by stage of support (December 2002)

Status of studies	Number
In the planning stage or just starting: protocol preparation, forms design, data management systems design, supplies distribution	27
Ongoing studies: data validation, data quality control, study monitoring, interim analysis	9
Final analysis: final data cleaning, preparation of final analysis	7
Statistical report drafted, manuscript in preparation, revisions and/or additions to final analysis	17
Final analysis completed	8
TOTAL	68

Implementation of GCP guidelines in research

During the year, efforts continued to formally implement WHO GCP research guidelines throughout the Programme's research activities. Work continued on the editing of the Standard Operating Procedures (SOPs). A consultant with experience in human research quality assurance and harmonization of regulatory quality assurance was contracted for this purpose. The exercise has reached an advanced stage and will be completed in early 2003.

Development of methodological tools

Staff of the Unit, in collaboration with an external consultant from the Department of Epidemiology and Biostatistics, University of Western Ontario, Ontario, Canada, have continued work on statistical issues related to cluster randomization trials. One paper was accepted for publication. The Unit provided support to users of the software, "Acluster", used for sample size determination and analysis of cluster randomization trials, which was developed by two staff members of the Unit during 1999/2000.

Staff of the Unit, in collaboration with the London School of Hygiene and Tropical Medicine, London, United Kingdom, are involved in extending the Consolidated Standards of Reporting Trials (CONSORT) guidelines to clinical trials using various designs. Work on writing a chapter on methodology of clinical trials for a textbook on clinical trials is in progress.

The WHO multicentre randomized controlled trial to evaluate the use of misoprostol in the management of the third stage of labour, completed and published in 2001, used an innovative approach for its randomization procedures. The methods of sequence generation, allocation concealment and blinding used in the trial were presented in a paper at the 23rd Annual Meeting of the Society for Clinical Trials in Arlington, VA, USA in May 2002.

Work is also ongoing on the methodology of meta-analysis of observational studies. A staff member from the Unit participated in a workshop on this theme organized by the Institut national de la santé et de la recherche médicale (INSERM), La Roche-Posay, France, in July 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

Activities in 2002 included the following highlights:

Training courses, seminars and workshops

A staff member presented a course on "Advanced methods of epidemiological analysis" as part of a training programme in epidemiological research in the University of Uruguay, Montevideo, Uruguay. Another staff member served on the faculty of a training workshop on "Advanced statistical methods in reproductive health research" at the International Institute for Population Studies in Mumbai, India. An analyst-programmer in the Unit participated in teaching a course in SAS programming in Tervuren, Belgium.

Site visits

A statistician from the Unit visited three centres in east Africa to assess their data management capabilities for participation in the new study on the impact of highly active antiretroviral therapy during pregnancy and breastfeeding on mother-to-child transmission of HIV and mother's health. The centres were the Department of Paediatrics, Faculty of Medicine, University of Nairobi, Nairobi, Kenya; the International Centre for Reproductive Health (ICRH), Mombasa, Kenya; and the Kilimanjaro Christian Medical Centre, Moshi, United Republic of Tanzania. Subsequently, two staff members from the Unit participated in the principal investigators meetings for the same study in Mombasa.

Annex 1

PUBLICATIONS IN 2002

Ali MM, Shah I, Cleland JG. Trends in reproductive behaviour among young single women in Colombia and Peru 1985–2000. *Demography* (submitted).

Cui N for the WHO Task Force on Methods for the Natural Regulation of Fertility. The impact of breast-feeding pattern on the duration of lactational amenorrhoea in Chengdu, China. *Journal of Reproduction and Contraception* (accepted).

Dada OA, Akesode FA, Olanrewaju DM, Olowu OA, Sule-Odu AO, Fakoya TA, Oluwole FA, Odunlami BV for the WHO Task Force on Methods for the Natural Regulation of Fertility. Infant feeding and lactational amenorrhea in Sagamu, Nigeria. *African Journal of Reproductive Health* (accepted).

Donner A, Piaggio G, Villar J. Meta-analyses of cluster randomization trials: power considerations. *Evaluation & the Health Professions,* 2003 (accepted).

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Hill Z, Cleland J, Ali M. Religious affiliation and extra-marital sex in Brazil. *International Family Planning Perspectives* (submitted).

Langer A, Villar J, Romero M, Nigenda G, Piaggio G, Kuchaisit C et al. Are women and providers satisfied with antenatal care? Views on a standard and a simplified, evidence-based model of care in four developing countries. *BMC Womens Health,* 2002, 19:2(1):7 (available at http://www.biomedcentral.com/1472-6874/2/7).

Lumbiganon P, Piaggio G, Villar J, Pinol A, Bakketeig L, Bergsjo P et al. for the WHO Antenatal Care Trial Research Group. The epidemiology of syphilis in pregnancy. *International Journal of STD & AIDS,* 2002, 13:486–494.

Lumbiganon P, Villar J, Piaggio G, Gülmezoglu AM, Adetoro L, Carroli G for the WHO Collaborative Group to Evaluate Misoprostol in the Management of the Third Stage of Labour. Side-effects of oral misoprostol used in the third stage of labour during the 24 hours after administration. *British Journal of Obstetrics and Gynaecology*, 2002, 109:1222–1226.

Piaggio G, Elbourne D, Schulz KF, Villar J, Pinol A, Gülmezoglu AM on behalf of the WHO Research Group. Methods for randomisation, concealment and blinding in the WHO misoprostol third stage of labour trial. *Controlled Clinical Trials,* 2002, 23(2S):39S–40S (abstract).

von Hertzen H, Honkanen H, Piaggio G, Bartfai G, Erdenetungalag R, Gemzell-Danielsson K et al. for the WHO Research Group on Post-Ovulatory Methods for Fertility Regulation. WHO multinational study of three misoprostol regimens after mifepristone for early medical abortion: I. efficacy. *British Journal of Obstetrics and Gynaecology* (submitted).

von Hertzen H, Piaggio G, Ding J, Chen J, Si S, Bártfai G et al. and the WHO Research Group on Post-ovulatory Methods of Fertility Regulation. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *The Lancet*, 2002, 360:1803–1810.

WHO Working Group on the Growth Reference Protocol and the WHO Task Force on Methods for the Natural Regulation of Fertility. Growth of healthy infants and the timing, type, and frequency of complementary foods. *American Journal of Clinical Nutrition,* 2002, 76:620–627.

Xiao, BL, von Hertzen H, Zhao H, Piaggio G. A randomised double blind comparison of two single doses of mifepristone for emergency contraception. *Human Reproduction,* 2002, 17(12):3084–3089.

Appendix 1
Staff of the Department, December 2002

Dr Paul Van Look (Director)

Office of the Director

[1] Anne ALLEMAND (Programme Assistant)
[1] Luc BERNIER (Reproduction Equipment Operator)
[1] Catherine d'ARCANGUES (Medical Officer)
[1] Barbara KAYSER (Secretary)
Craig LISSNER (Technical Officer)
[1] Michael MBIZVO (Scientist)
Bérengère NAIL (Secretary)
[1] Corinne PENHALE (Programme Assistant)
[1,2] Claire TIERNEY (Secretary)
[1] Hazel ZIAEI (Administrative Assistant)

Promoting Family Planning

[2] Kathryn CHURCH (Technical Officer)
[1] David GRIFFIN (Scientist)
[2] Sarah JOHNSON (Technical Officer)
Gloria LAMPTEY (Secretary)
[1] Lynda PASINI (Secretary)
Herbert PETERSON (Coordinator)
[1,2] Johannes SCHMIDT (Medical Officer)
[1] Lynn SELLARO (Secretary)
[1,2] Effy VAYENA (Technical Officer)
[1,2] Kirsten VOGELSONG (Scientist)

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[1,2] Rowena BONDAD (Secretary)
Luc DE BERNIS (Medical Officer)
Bocar DIALLO (Project Manager)
[1,2] Janette FERGUSON (Secretary)
[2] Helga FOGSTAD (Technical Officer)
[2] Kreeneshni GOVENDER (Secretary)
[2] Rita KABRA (Medical Officer)
[2] Catherine LEGROS (Clerk)
[2] Ornella LINCETTO (Medical Officer)
[1,2] Mario MERIALDI (Medical Officer)
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[2] Annie PORTELA (Technical Officer)
[1,2] Archana SHAH (Technical Officer)
[2] Della SHERRATT (Midwife)
[1] Jose VILLAR (Medical Officer)
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[1] Sybil DE PIETRO (Secretary)
[2] Isabelle DE VINCENZI (Medical Officer)
[2] Bidia DEPERTHES (Technical Officer)
[2] Sibongile DLUDLU (Medical Officer)
[1] Timothy FARLEY (Coordinator)
[1,2] Isaac MALONZA (Medical Officer)
[1,2] Justin MANDALA (Technical Officer)
[2] Sophie MERLET (Secretary)
[2] Charles MORRISON (On secondment)
[2] Doris MUGRDITCHIAN (Medical Officer)
Francis NDOWA (Medical Officer)
Carol PETERS (Secretary)
Theresa RYLE (Secretary)
[2] Julie SAMUELSON (Technical Officer)

Preventing Unsafe Abortion

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