

Department of Reproductive Health and Research

including

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Development and Research Training in Human Reproduction**

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Highlights

ABOUT THE DEPARTMENT

The Department of Reproductive Health and Research (RHR—referred to in this document as “the Department”) seeks to help 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 high-quality reproductive health services when needed.

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

ABOUT THE 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 debates 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.

HIGHLIGHTS

A key highlight of the Department’s work was the development of WHO’s first global strategy on reproductive health. Entitled *Reproductive health strategy to accelerate progress towards the attainment of international development goals and targets*, it was adopted by the 57th World Health Assembly in May 2004. The strategy document was produced in all WHO official languages (Arabic, Chinese, English, French, Russian and Spanish) and widely disseminated. The strategy is intended for a broad audience of policy-makers within governments, international agencies, professional associations, nongovernmental organizations and other institutions. It sets out the major discrepancies between global goals and global realities, and describes the principal barriers to progress,

noting in particular the inequities related to gender and poverty and the exposure to risk of adolescents. It also lays out a strategy for action, which is guided by principles based on international human rights. It highlights the core aspects of reproductive and sexual health services and proposes ways for countries and WHO to take innovative approaches.

PROMOTING FAMILY PLANNING

In pursuit of the goals set out in the Programme of Action of the 1994 International Conference on Population and Development (ICPD), the Department is implementing a programme of work aimed at improving the quality of family planning care globally. This includes: (i) the development and dissemination of evidence-based family planning guidelines and tools; (ii) research into users' perspectives on family planning services and technologies; and (iii) the development of improved or new methods of fertility regulation and the evaluation of the long-term safety of existing methods.

Highlights for the Department

- Two major family planning guidelines, the *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use*, were updated, published and widely disseminated.
- A new document designed to support the family planning counselling process—the *Decision-making tool for family planning clients and providers*—was finalized and local adaptations were field-tested in Indonesia, Nicaragua and South Africa. The Department also collaborated with the International Planned Parenthood Federation (IPPF) to help IPPF introduce the tool globally; IPPF is translating the tool into Bengali, Nepali and Urdu.
- Work was under way on the *Global handbook for family planning providers*, the fourth cornerstone in the Department's family planning guidance series. This guide will include comprehensive reference material on contraception for family planning providers.
- The Strategic Partnership Programme (SPP) between UNFPA and the Department is providing financial and technical support to help with the introduction and use of the Department's evidence-based guidance in countries. In 2004, seven countries (Benin, Cameroon, China, Nigeria, the United Republic of Tanzania, Turkmenistan and Zambia) submitted proposals for adoption and use of the Department's guidelines, especially in the area of family planning.

Highlights for the Programme

- A ongoing multicountry study in East and Southern Africa on the dual risks of unintended pregnancy and HIV and sexually transmitted infection (STI) has indicated that

women play an active role in negotiating condom use with their primary sexual partners and that condom use in these relationships is most likely to be related to a perception of risk of HIV or another STI rather than the desire to regulate fertility.

- A study assessed involvement of men in family planning in Turkey, highlighting the importance of including men in programmes related to contraceptive use.
- A secondary analysis of DHS¹ data on contraceptive uptake following childbirth or pregnancy termination in 19 countries found that over 50% of women delay contraception until after they regain their susceptibility to pregnancy, and 30% go on to discontinue contraceptive use within the first 12 months of adopting it. Women with no contact with skilled health personnel during pregnancy or delivery are more likely to delay adopting contraceptive use than those who are in contact with health services during pregnancy or delivery.
- A study compared the concentration in blood of levonorgestrel when the compound was administered in the form of either two 0.75 mg tablets (standard dedicated formulation for emergency contraception) or 50 mini-pills, each containing 30 µg of levonorgestrel (standard formulation for oral mini-pills). The results showed that the blood concentrations of levonorgestrel were similar for the two types of pills. In many countries, mini-pills are widely available and are inexpensive, whereas dedicated 1.5 mg pills for emergency contraception are less easily available.
- Preparations were made for the launch in early 2005 of a Phase I study of a matrix formulation of the hCG immunocontraceptive.
- A mouse model of menstruation was further developed and modified in order to replicate the changes observed in the endometrium of women using progestogen-only contraceptives.
- The Phase III study of testosterone undecanoate as a male hormonal contraceptive continued with a total of 1045 men enrolled in ten Chinese centres; data collection is expected to be completed by the end of 2005.
- The long-term follow-up of women using the copper-releasing TCU380A IUD continued. At the end of 2003, over 500 women had completed 13 years of use of the device. In 2004, the Programme made available final data on 12 and 13 years of use of the TCU380A device for submission to the US Food and Drug Administration with a view to extending further the registered lifespan of the device from the current 10 years.
- A study was completed which investigated whether sufficient antibodies could be delivered in the lumen of the

¹ Demographic and Health Surveys.

male reproductive ducts to use this approach in the development of an immunocontraceptive for male fertility regulation.

- Work began on the fifth edition of the *WHO laboratory manual for the examination of human semen and sperm-cervical mucus interaction*.
- A study on infertility, based on DHS data from 47 developing countries was published. It was estimated that over 186 million couples in developing countries, excluding China, face either primary or secondary infertility. Women who have never had a child are much more likely to be divorced or separated, and childless women are also more likely to have been married more than once.

IMPROVING MATERNAL AND PERINATAL HEALTH

Work on improving maternal and perinatal health within the Department is undertaken through the WHO Making Pregnancy Safer (MPS) initiative, which aims to contribute to the improvement of maternal and newborn health in general, and to the achievement of the Millennium Development Goals (MDGs)—especially MDGs 4 and 5²—in particular. The work undertaken to date by MPS in countries and at regional and global levels includes research, normative work, community-based interventions and advocacy.

A key objective of the Programme in this area is to widen the range of products and technology in order to help improve maternal and perinatal health especially in resource-poor settings. In this regard the Programme: evaluates the effectiveness of practices; seeks to improve the understanding of sociocultural and economic factors influencing maternal and newborn health care; reviews methodological issues related to maternal and newborn health research; conducts follow-up studies of the populations included in pregnancy-related research; stimulates basic research on outstanding obstetric and perinatal problems of global importance; and maps the magnitude of maternal ill-health.

Highlights for the Department

- At the end of 2004, the WHO Director-General announced the creation of a new Department of Making Pregnancy Safer, effective from 1 January 2005. The particular aim of this Department will be to strengthen WHO's capacity to support countries in their endeavour to improve maternal and newborn health. It is envisaged that work on strengthening the evidence base (i.e. research, normative functions and global monitoring) to ensure that WHO can provide the most updated information and guidance on maternal and newborn health will continue to be done in the Department of Reproductive Health and Research.
- A new strategy for making pregnancy safer was finalized. Based on the latest evidence-based knowledge and lessons learnt from country experiences, the strategy presents clear steps that can be taken to tackle maternal and newborn health issues effectively in order to obtain the required decreases in maternal and newborn mortality and morbidity.
- With the publication of *Pregnancy, childbirth, postpartum and newborn care—a practice guide for care at the primary health care level (PCPNC)* and *Managing newborn problems: a guide for newborn care at the referral hospital (MNP)*, work on the clinical series of guidelines under the Integrated Management of Pregnancy and Childbirth (IMPAC) came to an end. These two guidelines, together with *Managing complications in pregnancy and childbirth: a guide for midwives and doctors (MCPC)*, have been endorsed by the United Nations Children's Fund (UNICEF), UNFPA and The World Bank, The International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM). The MNP has also been endorsed by the International Pediatric Association (IPA). Regular updating of these four clinical guidelines is envisaged to ensure that they reflect the latest scientific evidence.
- In the WHO Western Pacific Region, MCPC was translated and adopted in Cambodia, China, Lao People's Democratic Republic, Mongolia and Viet Nam. With regards to PCPNC, 15 countries participated in a workshop on how to use this guide, and one country, China, already translated it. A training course on newborn care using the PCPNC was developed and conducted in Mongolia, Philippines and Viet Nam.
- The WHO Regional Office for the Americas recently completed the Spanish translation of the MNP, which will be published in 2005.
- In the WHO South-East Asia Region, printing and/or dissemination of MCPC, PCPNC and MNP to all member countries was ongoing. MCPC was translated into Bengali and widely disseminated in Bangladesh. MCPC and PCPNC were translated into the local language and disseminated in Timor Leste; PCPNC was adapted and translated into Thai and Korean. Furthermore, training manuals for essential obstetric and neonatal care based on MCPC were developed in Myanmar.
- The results of a pilot validation study of the PCPNC conducted in Brazil were used to finalize the validation study protocols of the Rapid Assessment and Management (RAM) flowchart and the Newborn Examination flowchart. Research teams were established in Sudan and Uganda to implement the validation studies. It is anticipated that the study results will be available by the end of 2005 and will be incorporated in the next edition of PCPNC.

² MDG 4: Reduce child mortality. MDG 5: Improve maternal health.

- A set of 32 *Standards for maternal and neonatal care* was finalized. These standards provide clinical and health systems recommendations to policy-makers and programme managers. They also include evidence of cost-effectiveness, feasibility, actions needed to implement them and indicators to be used in their monitoring and evaluation. An additional 12 standards, including seven health systems standards, are in an advanced state of development.
- *Kangaroo mother care—a practical guide* was translated into Albanian, Bahasa Indonesia, Bengali, French, Italian, Mongolian, Spanish and Vietnamese. A manual on essential care of the newborn was close to completion after extensive field-testing.
- The process of revision of the midwifery training modules was completed and the contents brought in line with the various WHO clinical guides. The series now includes a full module on the management of incomplete abortion and post-abortion care. The foundation module for midwives working in the community has been substantially revised to include more elements on HIV/AIDS and human rights and the community profiling section has been brought in line with the manual *Beyond the numbers: reviewing maternal deaths and complications to make pregnancy safer*.
- The WHO Regional Office for the Americas organized a meeting with countries in the region to share and discuss ways of putting into practice the recommendations in the document *WHO antenatal care randomized trial: manual for the implementation of the new model*. This document has also been published in Spanish and disseminated throughout Latin America and the Caribbean.
- Estimates of neonatal and perinatal mortality were finalized, taking into account the latest WHO/UNICEF under-five mortality estimates. Neonatal mortality accounts for 38% of under-five mortality globally.
- A document entitled *Low birthweight: country, regional and global estimates* was published. Globally, less than 40% of newborns are weighed and thus the rates are the best proxy estimated with current data.

Highlights for the Programme

- Several research projects designed to develop effective interventions were ongoing or completed in 2004. The table below lists completed, ongoing and planned projects.
- The trial of calcium supplementation for the prevention of pre-eclampsia suggested that calcium supplementation may have only a moderate protective effect on the risk of pre-eclampsia and severe pre-eclamptic conditions but that it nevertheless could contribute to reducing maternal and neonatal morbidity and mortality.
- A global effort was initiated under the title of “The WHO Global Survey for Maternal and Perinatal Health” to assess the relationship between the quantified burden of disease and services currently provided in the area

Research activities in maternal and perinatal health conducted with leading participation of the Programme (updated to 2004)

	Centres	Participants	Status
Reduction of unnecessary caesarean section	5	149 206	Published (2004)
Epidemiology of preterm delivery and intra-uterine growth restriction	4	38 319	Published (2004)
Evaluation of the <i>WHO Reproductive Health Library</i>	2	76 053	Submitted (2004)
Primary prevention of pre-eclampsia (calcium)	7	8300	Submitted (2004)
Long-term follow-up of the MAGPIE Trial ^a	19	3375	Submitted (2005)
Long-term follow-up of calcium supplementation trials	2	800	Submitted (2005)
Screening and treatment of asymptomatic bacteriuria	4	18 000	Ongoing
Primary prevention of pre-eclampsia (antioxidants)	4	4150	Ongoing
WHO Global Survey of Maternal and Perinatal Health (pilot phase)	16	150 000	Ongoing
Treatment of postpartum haemorrhage	5	1400	To be started in May 2005
Secondary prevention of pre-eclampsia (treatment of moderate hypertension)	6	2000	In preparation
Screening for pre-eclampsia with placental growth factors	7	12 000	In preparation

^a The Programme participated in these trials but was not directly responsible for their management.

of maternal and perinatal health. This will help identify the gap between interventions shown to be effective and those actually implemented in services.

CONTROLLING SEXUALLY TRANSMITTED AND REPRODUCTIVE TRACT INFECTIONS

The Department's work in the area of controlling sexually transmitted infections (STIs) and reproductive tract infections (RTIs) includes: (i) generating evidence for new and improved STI and RTI control strategies; (ii) developing guidelines and tools for establishing health policies for STI and RTI control; (iii) promoting the dissemination and utilization of the guides in regions and countries; (iv) programme planning and implementation; (v) conducting research on the prevention of mother-to-child transmission of HIV and other STIs; and (vi) advocating for, and conducting research on, the development and deployment of safe and effective microbicides.

Highlights for the Department

- Through a series of regional and global consultations, a new Global Strategy for STI Prevention and Control was finalized. This strategy is based on the best currently available scientific evidence and experience of STI control and of the fight against the HIV epidemic, accumulated at national, regional and global levels.
- An advocacy strategy summarizing the key reasons for investing in STI control and the opportunities for synergies between STI control, sexual and reproductive health and HIV prevention and care programmes was also developed.
- Within the context of the Global Strategy for STI Prevention and Control, two specific and interrelated initiatives were developed for implementation in countries and regions: (i) elimination of congenital syphilis; and (ii) control of genital ulcer disease in the general population.
- Guidelines and tools were finalized to assist programme managers in planning and implementing effective and appropriate interventions to prevent, control and manage STIs and RTIs. These include: the provisionally entitled "STI/RTI programme guidance tool"; *Sexually transmitted and other reproductive tract infections: a guide to essential practice*; *Guidelines for the management of sexually transmitted infections*; *Training modules for the management of sexually transmitted infections*. Further development continued of a new guide entitled *Comprehensive cervical cancer control: a guide to essential practice*.
- In partnership with CONRAD, the Department successfully completed the three-centre randomized double-blind Phase I study of the safety and acceptability of 6% cel-

lulose sulfate gel compared with placebo (K-Y Jelly®) among healthy women volunteers in Sagamu (Nigeria), Kampala (Uganda) and Mumbai (India). Further evaluation of cellulose sulfate for the prevention of HIV infection is now under way by CONRAD.

- In partnership with the International Partnership for Microbicides and the US Centers for Disease Control and Prevention, a consultation was held on the particular safety issues arising from development of the next generation of microbicides that contain low doses of potent antiretroviral agents.
- A high-level consultation was convened on the opportunities for linkages between family planning services and programmes to prevent mother-to-child transmission of HIV. This led to the "Glion Call to Action on Family Planning and HIV/AIDS in Women and Children". This call, made in partnership with the WHO HIV/AIDS Department and UNFPA, urges governments, parliamentarians, United Nations agencies, donors and civil society (including nongovernmental and community-based organizations) to strengthen efforts to prevent mother-to-child transmission of HIV (MTCT), including through better integration of family planning services with MTCT services.

Highlights for the Programme

- Fieldwork was completed in a project on the contraceptive effectiveness of the female condom compared with the male condom, which was assessed in volunteers from family planning clinics in Chengdu (China), Sagamu (Nigeria), Panama City (Panama) and Durban (South Africa). Overall, at six months of use, the effectiveness of the two methods in terms of pregnancy prevention was similar.
- A protocol was implemented to study the impact of highly active antiretroviral therapies (HAART) on mother-to-child transmission (MTCT) of HIV and mothers' health. This research addresses key issues of acceptability, safety and effectiveness related to MTCT prevention and the impact of a triple-combination antiretroviral prophylactic regimen on the rate of MTCT. The study is a response to the critical issue of safe breastfeeding by women who are HIV-positive and makes an explicit link between MTCT prevention and care of the HIV-positive mother and her family. The research is particularly important in the context of rapid expansion of HIV care and treatment, since it addresses and operationalizes key questions on the interface between the two programmes.

PREVENTING UNSAFE ABORTION

Unsafe abortion is entirely preventable, but continues to be practised with a high incidence (19 million), exerting a heavy

toll on women in terms of maternal deaths (68 000) and morbidity (5 million women) each year. The work on prevention of unsafe abortion is entirely undertaken by the Programme, and has five objectives: (i) mapping and generating scientifically sound evidence on unsafe abortion prevalence and practices; (ii) improving technologies and interventions to make abortion safer; (iii) translating evidence into norms; (iv) developing tools and guidelines on safe abortion practices; and (v) assisting countries to develop programmes and policies that reduce unsafe abortion and improve access to safe abortion, to the fullest extent permitted by law, and quality post-abortion care.

Highlights for the Programme

- A study in Viet Nam that assessed the safety, efficacy and client satisfaction with abortions performed by mid-level health-care providers who were not physicians found that they performed the first-trimester abortions at least as safely and effectively as physicians.
- Work following on from the national assessments conducted using the Strategic Approach³ in Mongolia, Romania, and Viet Nam addressed the provision of comprehensive abortion care, including improvement of the quality of reproductive health care in general, and the quality of abortion care in particular.
- In collaboration with the WHO Regional Office for Europe (EURO), a regional workshop was organized in Riga, Latvia, to introduce participants to the WHO guideline *Safe abortion: technical and policy guidance for health systems* and to the Strategic Approach.
- Findings became available from a study that explored the pathways to abortion in the context of restricted legal access, fertility decline and low prevalence of contraceptive use. Researchers in Lomé, Togo, interviewed 4500 women of reproductive age (15-49 years) and conducted in-depth interviews and focus group discussions with some of them. They found that, when faced with an unintended pregnancy, women in Lomé turned to abortion; 25% of sexually active women reported at least one induced abortion. The higher a married woman's level of education, socioeconomic status and the number of previous pregnancies and births, the higher was the likelihood that she would have had an abortion.
- A document entitled *The effects of contraception on obstetric outcomes* was published. This document reviews the evidence on the relationship between prevalence of contraceptive use and the incidence of induced abortion. In Bulgaria, Kazakhstan, Kyrgyzstan, Switzerland, Tunisia, Turkey and Uzbekistan, a rise in contraceptive use was associated with a decline in the incidence of induced abortion, while in Cuba, Denmark, Netherlands, the Republic of Korea, Singapore and the USA, a parallel rise in contraceptive use and the incidence of induced abortion has been witnessed. This unexpected trend is explained by the fact that family planning programmes alone cannot meet the demand for contraceptives as norms for smaller families become widespread during fertility transition. When fertility stabilizes, increased contraceptive use results in fewer induced abortions. Thus, in the long run, a rise in contraceptive use will inevitably lead to a decline in induced abortion.
- Preliminary results from a number of clinical trials, including those on the use of misoprostol-alone for first-trimester and second-trimester abortions, became available. The results suggest that efficacy was higher in the groups that took misoprostol tablets vaginally and that the 3-hour interval between doses was more efficacious than the 12-hour interval for administering three doses of 0.8 mg of misoprostol.
- An International Consensus Conference on Medical Abortion was organized and evidence-based recommendations for medical abortion services were discussed. Participants agreed on recommendations for approximately 30 practical questions related to legal issues, government registration of the drugs used for medical abortion, service delivery, pre-abortion assessment of the client, recommended regimens, and post-abortion care. Background papers and recommendations from the conference will be published in 2005.
- An application was submitted to include mifepristone combined with misoprostol for first-trimester medical abortion in the WHO Model List of Essential Medicines. A review of this application will take place in early 2005.
- *Unsafe abortion: global and regional estimates of the incidence of unsafe abortion and associated mortality in 2000*, 4th edition was published and widely disseminated. Estimates indicate that 19 million unsafe abortions take place each year, that is, approximately one in ten pregnancies end in an unsafe abortion, giving a ratio of one unsafe abortion to about seven live births. Almost all unsafe abortions take place in developing countries.
- By the end of 2004, nearly 20 000 print copies of *Safe abortion: technical and policy guidance for health systems* had been distributed or sold, and 5345 copies had been downloaded from the Programme's web site. The document is available in English, French, Polish, Portuguese, Russian and Spanish.

³ The Strategic Approach is a three-stage process to assist countries to assess reproductive health needs and priorities, test interventions to increase access to and the quality of reproductive health services, and then scale up successful models for wider implementation.

SEXUAL HEALTH

In this cross-cutting area of work, the Department's focus is on the following objectives: (i) building the evidence base for high-quality, non-discriminatory, acceptable and sustainable sexual health education and service programmes; and (ii) increasing knowledge and understanding of the social and cultural factors related to harmful sexual practices in order to develop strategies to abolish such practices.

Highlights for the Department

- Three key publications were prepared in 2004: (i) *Defining sexual health: report of the WHO Technical Consultation on Sexual Health*, held in Geneva in 2002; (ii) *A conceptual framework for programming in sexual health*; and (iii) *Integrating sexual health interventions into reproductive health services: programme experience from developing countries*. All three will be published in 2005.
- In collaboration with the WHO Department of Violence and Injury Prevention and the WHO Department of Gender, Women and Health, guidelines were published for the medical and legal care of survivors of sexual violence.
- A meeting was convened to review good practice models of community-based interventions for the eradication of female genital mutilation (FGM). The results of the meeting are informing the development of an operations research protocol of best practice in community-based efforts to eradicate FGM which will be conducted in the coming years.
- A sexual health research course was planned with the Fonds Universitaire Maurice Chalmere and the Geneva Foundation for Medical Education and Research. Entitled "From Research to Practice: Training in Research in Sexual Health", this course will run in parallel with the "Post-graduate Training in Reproductive Health" course in 2005.

Highlights for the Programme

- In collaboration with the Royal Tropical Institute of the Netherlands, the London School of Hygiene and Tropical Medicine, and the WHO Departments of Violence and Injury Prevention and of Gender, Women and Health, operations research projects were planned to review and evaluate programme delivery experiences in three sexual health programme areas: (i) expansion of counselling to address sexuality issues more effectively; (ii) detection and treatment of sexual violence; and (iii) inte-

gration of programmes for RTIs and STIs into sexual and reproductive health programmes.

- Preparatory work was completed for the first phase of a multicountry study on gender, sexuality and vaginal practices to be conducted in Indonesia, Mozambique, South Africa and Thailand.
- All pre-launch work was completed, including getting approval from the Programme's technical and ethical review committees, for a research study on the decision-making process with regard to FGM. This study is entitled "Contingency and change in the practice of FGM: dynamics and decision-making in Senegambia".

GENDER ISSUES AND REPRODUCTIVE RIGHTS IN REPRODUCTIVE HEALTH

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

Highlights for the Department

- Technical and financial support was provided for regionally adapted versions of the Gender and Rights in Reproductive Health training course in Kazakhstan and Sudan.
- The Department began the implementation of a project in Burkina Faso to adapt and translate the Gender and Rights in Reproductive Health training course into French. The course in French will be conducted as a regional course in West Africa in 2006.
- The Department reported on the sexual and reproductive health situation in seven countries reporting to the Committee on the Elimination of All Forms of Discrimination Against Women, and contributed to the reports made by the Department of Child and Adolescent Health and Development on two countries reporting to the Committee on the Rights of the Child.

Highlights for the Programme

- The Programme provided technical and financial support for the field-testing of a health and human rights tool⁴ in

⁴ This tool is entitled "Using human rights for maternal and neonatal health: a tool for strengthening laws, policies and standards of care". It is designed to help countries to use a human rights framework to identify and address legal, policy and regulatory barriers to women's access to, and use of, maternal and newborn health care services, and to the provision of quality services.

Mozambique, and planning was started for similar field tests to be conducted in Brazil and Indonesia in 2005.

PROMOTING THE SEXUAL AND REPRODUCTIVE HEALTH OF ADOLESCENTS

To help promote healthy sexual development and healthy sexual and reproductive behaviours among adolescents, the Programme generates evidence, develops guidelines and provides technical support to countries. The evidence sought through research is intended to inform policies and programmes in developing countries, while technical support activities aim to strengthen research capacity and help countries to achieve wider dissemination and use of research results.

- One or more research papers were prepared on the following topics: attitudes to sex (Myanmar, Turkey); risky sexual behaviours (Colombia, Mexico, Paraguay); dual protection against STIs and pregnancy (Indonesia); unwanted pregnancy (Bangladesh, Kenya); sexual coercion (India, Nigeria, Turkey); health-seeking behaviour (China, Nepal); quality of care of reproductive health services for adolescents (Argentina, Brazil, Lao People's Democratic Republic); and the impact of information, education, and communication interventions (China, Turkey). In addition, another 26 research papers were published or are in press.
- Four summary briefs on non-consensual sexual experiences of young people in developing countries were issued and widely distributed. In addition, a policy brief was published on perception of gender roles and sexual behaviour of Croatian adolescents.
- Technical assistance was provided to a workshop on "Adolescent reproductive health needs and rights" held in June 2004 in Baku, Azerbaijan. The participants were from Azerbaijan, Bashkortostan, Kazakhstan, Kyrgyzstan, Tatarstan, Turkey and Uzbekistan. The discussions covered the sexual and reproductive health needs of adolescents and the main challenges faced in addressing those needs in the participating countries.
- Qualitative data analysis and research methodology workshops were held to support the regional research initiative on "Adolescent migrants and reproductive health in the Greater Mekong Region". The main objective of this research is to identify the sexual and reproductive risks experienced by migrants and to describe barriers to their access to information and services for sexual and reproductive health. A related objective was to develop human resources and to share knowledge on research methodology and compare results.

TECHNICAL COOPERATION WITH COUNTRIES

Interregional activities

Within the overall objective of widening the range of products and technologies, the Programme's work in this area continued to provide support to countries by strengthening the capacities of national research institutions, and the individual researchers in them, to address the priority research issues of national and regional relevance. During 2004, special emphasis was placed on strengthening the ability of institutions, particularly those receiving long-term institutional development (LID) grants, to develop project proposals, and on improving skills of individual researchers in data analysis, writing of original research papers and dissemination of research findings. This work was further expanded by fostering linkages between research and practice, enhancing the dialogue with policy-makers, and building capacity for operations research.

- The Programme continued to pursue its long-standing strategies that have proven to be highly effective, namely the development and maintenance of institutional capacities through LID and resource maintenance grants (overall, 35 centres received such grants in 2004) and individual capacity strengthening through various training grants. Taking due account of the current funding constraints, potential new centres for institutional development were identified in Africa (one) and South-East Asia (three); respective WHO Regional and Country Offices contributed in the process of identification.
- National, regional and inter-regional networks of research and training institutions were also strengthened; mechanisms for establishing cost-effective North-South collaboration were also explored, particularly in the Asia and Western Pacific Regions.

Technical cooperation with countries—*Africa and Eastern Mediterranean*

The main objective in this area is to pursue the strengthening of research capacity of institutions in the WHO African and Eastern Mediterranean Regions 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 2004, the Programme had collaborative activities with 42 institutions or research groups in 24 countries of the WHO African and Eastern Mediterranean Regions.

- Support for research capacity strengthening was provided to ten institutions through LID grants and resource maintenance grants (RMG). The output of these institutions was as follows:
 - A total of 121 studies were carried out. The highest number of projects were in the area of maternal health, followed by family planning.

- The institutions published 30 publications in national and international journals.
 - The staff from these institutions served in 36 different advisory roles at national, regional and international level.
 - Twenty-three staff members from these institutions attended courses outside their home countries.
- Two new institutions received research capacity strengthening grants (one LID grant and one service guidance centre—SGC—grant). The SGC grant is a specific instrument for promoting and supporting the use of evidence-based recommendations through in-country dissemination and application of best practices contained in standard guidelines.
 - Support for regional research and programmatic projects was provided to two institutions.
 - Technical and financial support was given to two countries in the WHO Eastern Mediterranean Region for the process of identifying reproductive health needs.
 - Research on obstetric sequelae of female genital mutilation was completed at 28 obstetric units in Burkina Faso, Ghana, Kenya, Nigeria, Senegal and Sudan. The objective of this study was to estimate the incidence of obstetric complications among women with FGM giving birth in hospital and to evaluate the relationship between the different types of FGM and obstetric complications. Data from a total of 28 393 women were available for analysis, which is ongoing. The results will be submitted for publication in 2005.
 - The generic protocol for the operations research project entitled “Community and facility-based interventions towards improving maternal and newborn health” was approved and was transmitted to research institutions for local adaptation.
 - Four researchers received a research training grant (RTG).
 - Financial support was given to the M.Sc. course in biostatistics of the University of Ibadan, Ibadan, Nigeria.
 - Workshops and short courses were organized on various themes: research methodology, semenology, and research synthesis and systematic reviews.
 - Operations research on improving sexual and reproductive health services for adolescents continued in Benin, Cameroon, Côte d’Ivoire and Guinea, and was completed in Senegal.
 - Financial and technical support was provided to the African Task Force on Reproductive Health, to two regional networks (Africa and Eastern Mediterranean), to sub-regional networks and to professional associations for the dissemination of research results.
 - Financial and technical support for a national workshop on ethical issues in reproductive health research was provided to a centre in Nigeria.
- ### Technical cooperation with countries—Americas
- The Programme’s main objectives for the Americas Region are: (i) to continue strengthening research capacity in Programme-supported collaborating institutions by promoting and supporting the implementation of well-designed and ethically sound research projects on topics relevant to national and regional reproductive health problems; and (ii) to promote the dissemination and use of relevant research findings and evidence-based guidelines in policy-making and planning to improve reproductive health.
- During 2004, from the overall number of 119 research studies conducted at the seven centres that received major research capacity strengthening grants, 12 projects were implemented with support from the Programme (10%), 57 with support from national sources (48%), and 50 studies (42%) were funded by international agencies other than WHO.
 - A subregional research initiative on physicians’ knowledge and attitudes on emergency contraception began to be implemented in Barbados and Jamaica.
 - Twelve staff from the seven regional centres receiving research capacity strengthening support underwent training outside their home countries. The seven centres themselves ran 22 postgraduate courses in which there were 204 students; they also conducted short, group-learning activities such as seminars and workshops, which were attended by 1030 participants.
 - During 2004, institutions that received major research capacity strengthening support published 105 research articles (99 original papers and six review articles). In addition, staff in these centres authored 33 books or chapters in books.
 - Workshops on research ethics were organized in Guatemala and in Panama. More than 80 researchers, non-technical personnel and members of ethical review committees of almost all research and academic institutions in these countries active in the area of reproductive health took part in these workshops. Up to 30 participants in these workshops also participated in a training-of-trainers workshop on research ethics.
 - A grant was awarded to seven universities, three research centres and two maternity teaching hospitals in 12 countries in the Americas Region to cover the subscription fees for the Health InterNetwork Access to Research Ini-

tiative (HINARI). Between June 2003 and October 2004 these institutions recorded 81 840 log-ins to the HINARI system.

Technical cooperation with countries—*Asia and Western Pacific*

The main objectives of the Programme for the Asia and Western Pacific Regions are to collaborate with countries in these regions to enhance national capacity for conducting reproductive health research at national, regional and global levels and to promote the use of research results in policy-making and planning to improve reproductive health.

- Nine centres in the WHO South-East Asia Region and 12 centres in the WHO Western Pacific Region received research capacity strengthening grants (six LID grants and six resource maintenance grants; eight centres in China and three in Sri Lanka shared one resource maintenance grant each).
- Regional workshops were conducted as follows: operations research (20 participants from six countries) and data analysis of two regional projects (14 researchers from nine countries for a study of the “Patterns and predictors of caesarean section in Asia” and 12 participants from four countries for a study of “Adolescent migrants and reproductive health in the Greater Mekong Region”). National workshops were conducted on: epidemiology, management and laboratory diagnosis of sexually transmitted infections, and scientific writing.
- A total of 407 research projects were conducted in the 21 institutions receiving research capacity strengthening grants. Of these, 322 (79%) were funded by national authorities, 58 (14%) by the Programme and 27 (7%) by other international agencies.

Technical cooperation with countries—*Central and Eastern Europe*

All the support provided by the Programme to the WHO European Region, mainly to Central and Eastern European countries, is implemented by the WHO Regional Office for Europe. Strong emphasis remained on programmatic support, including capacity building in operations research.

- Progress made in the implementation of the initiative on operations research capacity building in Eastern Europe was assessed in the context of the overall Memorandum of Understanding between the Department of Reproductive Health and Research, the United States Agency for International Development (USAID) and the Population Council’s FRONTIERS programme.
- Aspects related to institutional capacity strengthening and mechanisms for ensuring technical assistance for the follow-up of research proposals were highlighted for

further attention in the next phases of the above-mentioned inter-agency collaboration in Europe and other regions.

Technical cooperation with countries—*Policy and programmatic issues in reproductive health*

The overall goal in this area is to build health system capacity at national and subnational levels for strategic planning, development, implementation and evaluation of appropriate interventions for the provision of high-quality sexual and reproductive health services to all people. Central to this work is the refinement of, and support to countries for, the implementation of the Strategic Approach to the WHO Reproductive Health Policy and Programme Development (the Strategic Approach)⁵.

- A draft core guide for implementing all three stages of the Strategic Approach was developed.
- Technical support and funding were provided to strategic assessments in Oman (focusing on family planning) and in Paraguay (addressing family planning and maternal health).
- Proposals were developed for strategic assessments in Nigeria (adolescent sexual and reproductive health) and Afghanistan (family planning), while Latvia, Lithuania, the Republic of Moldova, the Russian Federation and Ukraine developed strategic assessment proposals for addressing the area of fertility regulation.
- Continued support was provided to Stage II action research projects and related activities in China, Ethiopia, Kyrgyzstan, Lao People’s Democratic Republic, Mongolia, Myanmar, Nepal and Viet Nam.
- Work was under way to document the determinants of successful scaling-up of pilot interventions. This includes (i) preparation of a volume of scholarly papers on this topic; (ii) the formation of a network to promote research on and the practice of scaling-up of pilot projects; and (iii) the drafting of a practical guidance document on scaling-up of pilot projects.
- A technical consultation on the impact of health sector reform on reproductive health was held, with presentations and plenary discussions on contemporary trends in reforms, and group discussions to identify critical areas for research. The consultation concluded, among other things, that research on the process of reform is as important as studying the outcomes of reforms. The evidence base on the impact of health sector reform on reproductive health is not well developed. Evidence suggests that reproductive health services have not been valued in the priority-setting that underpins the different elements of health sector reform, or in the decentralized

⁵ See footnote 3.

structures existing in many states, and thus have disproportionately suffered from human resource constraints.

- The Programme participated in an evaluation of a World Bank-supported health reform programme in the Philippines. Baseline population and facility-based sample surveys were conducted as the first element of a case-control study design.
- Technical support was provided to a World Bank Institute course on “Public policy and the private sector in Asia” and to the “Health sector reform and reproductive health” courses in English-speaking and French-speaking countries in Africa.

Technical cooperation with countries—*Mapping and implementing best practices*

The objectives in this area are: (i) to synthesize existing research in reproductive health to strengthen the evidence base for WHO guidelines; (ii) to provide leads and rationale for further research; (iii) to disseminate research summaries in a user-friendly, relevant and accessible format; (iv) to conduct research to implement evidence-based practices; and (v) to build capacity to facilitate informed decision-making.

- In order to reconcile the discrepancies between the WHO Model List of Essential Medicines and various reproductive medicines lists, including the Department’s own guidelines, a comprehensive review of the relevant evidence was initiated.
- The cluster randomized trial to evaluate an educational outreach strategy using the *WHO Reproductive Health Library* was completed. The methodology of the trial was published in 2004 and a further two publications are currently at the submission stage.
- With experience of having established its own clinical trials register, the Programme is leading the International Clinical Trials Registry Platform within WHO. Preliminary activities initiated at the end of 2003 in collaboration with the WHO Department of Research Policy and Coordination led to international support for WHO to lead a global clinical trial registration project.

Technical cooperation with countries—*Monitoring and evaluating reproductive health*

Monitoring and evaluation activities involve monitoring of progress towards reproductive health-related goals and targets set in international conferences such as those agreed at the International Conference on Population and Development (ICPD) and the Millennium Summit. This involves provision and dissemination of timely and methodologically sound information on indicators used for this purpose.

- The systematic review of maternal morbidity and mortality was completed. The methodology of the systematic review and estimates of the prevalence of severe maternal morbidity were published. Reports on the usefulness of different electronic databases in identifying prevalence studies and on stillbirth prevalence were submitted for publication.
- A technical consultation was organized on the analysis of data for systematic reviews of observational studies.

COMMUNICATION, ADVOCACY AND INFORMATION

Key objectives of the Department in this area are: (i) to develop a strategic, proactive and cost-effective programme for the dissemination and communication of sexual and reproductive health knowledge to target audiences and stakeholders; (ii) to facilitate the transfer of reproductive health information through appropriate strategies and media, focusing on participatory communication; and (iii) to strengthen the capacity of the Programme’s collaborating centres in writing and publishing scientific papers in peer-reviewed journals, and in communicating research findings to policy-makers and the public.

- Issue No. 7 of the *WHO Reproductive Health Library* (RHL) was issued in English and Spanish and widely distributed.
- A 10-minute training video on vacuum extraction was produced for inclusion in RHL No. 8.
- Two biennial reports for 2002–2003—one for the Programme and one for the non-research component of the Department, namely Programme Development in Reproductive Health—were published and widely distributed.
- A major advocacy effort was made during the 57th World Health Assembly in May 2004. This included: (i) display of a large exhibit at the Assembly and of photographs from a photo competition entitled “River of Life”; (ii) the issuing of a set of 11 fact sheets on reproductive health; and (iii) publication of a new brochure on the Programme.
- Six scientific writing workshops were conducted in which 145 scientists were trained.

CLINICAL TRIALS AND INFORMATICS SUPPORT

This area of work undertakes statistical and data-processing tasks for the Programme’s research projects and helps to strengthen research capacity of collaborating institutions in biostatistics and data processing. The group also provides informatics support for the administration and management of the Department.

- Statistical and data processing support was provided to 32 single- and multicentre research projects.
- Analyses of data were undertaken from the 1999 Iraq Child and Maternal Mortality Survey as well as from Demographic and Health Surveys to address issues related to contraceptive use and consequences of contraceptive failure.
- A new software was developed for the analysis of menstrual bleeding patterns and for centralized data management based on Statistical Analysis System (SAS) software. A portable data management system based on Statistical Package for Social Sciences (SPSS) software for decentralized projects was also developed.

Annex 1

SCIENTIFIC AND TECHNICAL ADVISORY GROUP IN 2004

Members

Salim Abdool Karim, University of KwaZulu-Natal, Durban, South Africa (*Vice-chairman*)
 Lawrence Adeokun, Association for Reproductive and Family Health, Ibadan, Nigeria
 Yagob Y. Al-Mazrou, Assistant Deputy Minister, Ministry of Health, Riyadh, Saudi Arabia
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 Anna Glasier, NHS Lothian and University of Edinburgh, Edinburgh, UK (*Chairperson*)
 Sioban D. Harlow, University of Michigan, Ann Arbor, MI, USA
 Nasreen Huq, ActionAid Bangladesh, Dhaka, Bangladesh
 Angela Kamara, Regional Prevention of Maternal Mortality, Accra, Ghana
 Hoda Rashad, American University in Cairo, Cairo, Egypt
 Gaston Sorgho, Harvard School of Public Health, Boston, MA, USA

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	7	64			4	36	11
Women	4	36			2	18	6
<i>from:</i>							
AFRO	3	27					3
AMRO	1	9			2	18	3
EMRO	2	18					2
EURO					2	18	2
SEARO	1	9					1
WPRO							

Annex 2

SCIENTIFIC AND ETHICAL REVIEW GROUP IN 2004

Gordon Ada, John Curtin School of Medical Research, Canberra, Australia
 Abdul-Aziz Al Meshari, King Saud University, Riyadh, Saudi Arabia
 Karen Beattie, EngenderHealth, New York, NY, USA
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 Jean Cohen, Paris, France
 Kitayaporn Dwip, Mahidol University, Bangkok, Thailand
 Andrea Genazzani, Institute of Obstetrics and Gynaecology, Modena, Italy
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 Timothy Hargreave, Western General Hospital, Edinburgh, UK
 Korrie de Koning, Royal Tropical Institute, Amsterdam, Netherlands
 Fernando Larrea, National Institute of Nutrition, Mexico City, Mexico
 Ruth Macklin, Albert Einstein College of Medicine, Bronx, NY, USA
 Oscar Mateo de Acosta, National Institute of Endocrinology, Havana, Cuba
 Marvellous Mhloyi, Population Studies Centre, Harare, Zimbabwe
 Yuji Murata, Osaka University Medical School, Osaka, Japan
 Ngeow Yun Fong, University of Malaya, Kuala Lumpur, Malaysia
 Charles Ngwena, Centre for Health Systems Research and Development, University of the Free State, Bloemfontein, South Africa
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 Manee Piya-Anant, Siriraj Hospital, Bangkok, Thailand
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 John Sciarra, Northwestern University Medical School, Chicago, IL, USA
 Carmel Shalev, Gertner Institute for Health Policy, Tel Hashomer, Israel
 Carlos Simón, 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, National Population and Family Planning Commission, Beijing, China

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	13	46	1	4	14	50	28
Women	7	25	1	4	4	14	12
<i>from:</i>							
AFRO	3	11					3
AMRO	3	11			4	14	7
EMRO	1	4					1
EURO	1	4	1	4	7	25	9
SEARO	3	11					3
WPRO	2	7			3	11	5

Annex 3

TOXICOLOGY PANEL IN 2004

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Ranjit R. Chaudhury, National Institute of Immunology, New Delhi, India

Ralph Heywood, The Larches, The Lanes, Huntingdon, UK

Alex Jordan, Division of Reproductive and Urologic Drug Products, Food and Drug Administration, Rockville, MD, USA

Shirley Price, University of Surrey, Guildford, UK

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
<i>from:</i>							
AFRO							
AMRO					1	17	1
EMRO							
EURO			1	17	3	50	4
SEARO	1	17					1
WPRO							

Chapter 1

Promoting family planning

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1. INTRODUCTION

Millions of individuals and couples around the world continue to be poorly served, or not served at all, with regard to their needs for family planning. The causes of unmet need are multiple and include: (i) lack of services or commodities, or barriers to their access; (ii) poor quality of services (e.g. inappropriate client–provider interactions, substandard technical competence of providers, inadequate information, poor design and management of service delivery systems); (iii) problems related to technology (e.g. limited or inappropriate choice of available contraceptive methods, fear or experience of side-effects); and (iv) broader social issues, such as an individual's lack of knowledge, power imbalances within couples and families, and sociocultural, religious and gender barriers. In considering the family planning needs of people, it is also important to consider the needs of infertile couples and individuals who desire to have children. The Department strives to meet the family planning needs of people by focusing on meeting the following four objectives:

- 1) Increasing the availability of high-quality services.** The Department aims to improve the quality of family planning services (i.e. improving access to family planning services, choice in family planning methods and the use of informed consent) through the creation and implementation of evidence-based tools and guidelines and the evaluation of the impact of the Department's guidance. In doing so the Department employs social and behavioural science and operations research to understand the determinants of successful use of family planning services, evaluate barriers to uptake, and develop and test strategies to address these barriers. Finally, the objective also includes the development of protocols for infertility prevention, diagnosis and management.
- 2) Broadening the range of safe, effective, acceptable and affordable family planning and infertility care that is available to all women and men.** This objective seeks to improve quality through research into the safety and effectiveness of contraception, the development of new contraceptive methods, the evaluation of male and female reproductive functions to identify new targets for contraception, and the evaluation of technologies for the treatment of infertility that are suitable for resource-poor settings.
- 3) Strengthening the capacity of national health systems to ensure the availability of high-quality and sustainable family planning programmes and services in resource-poor settings.** Providing high-quality services requires the support of a strong health system. This objective seeks to develop managerial and service-delivery guidelines as well as to support countries in adapting and implementing evidence-based norms and tools. Much of the Department's work in strengthening health systems to promote reproductive health is conducted through the Implementing Best Practices Initiative, the WHO/United Nations Population Fund (UNFPA) Strategic Partnership Programme, the use of the Strategic Approach to improve quality of care and other Departmental mechanisms for providing technical support to countries. In addition, the Department contributes to the advocacy needed for international commitments to reproductive health by providing evidence on the prevalence of ill-health in this area.

- 4) **Fostering an enabling environment at the global level that is supportive of family planning.** In this area, the Department aims to monitor the reproductive health status of populations around the world with a view to generating the knowledge necessary for promoting better sexual and reproductive health.

2. OBJECTIVE: TO BROADEN THE PROVISION OF QUALITY SERVICES

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 contraception if they had access to it. However, many family planning programmes need to substantially improve the quality of care that they provide. The Department is contributing to these efforts by creating “four cornerstones” of evidence-based and consensus-driven guidance for family planning. A system has also been created to ensure that this global family planning guidance is based on the best available evidence; this is done through a continuous, systematic process that identifies, critically appraises and synthesizes new evidence as it becomes available. The creation of evidence-based guidelines and tools, while important, is insufficient to ensure that the quality of family planning services improves. The ultimate impact of the Department’s norms and tools is contingent on the development and utilization of successful strategies for implementation.

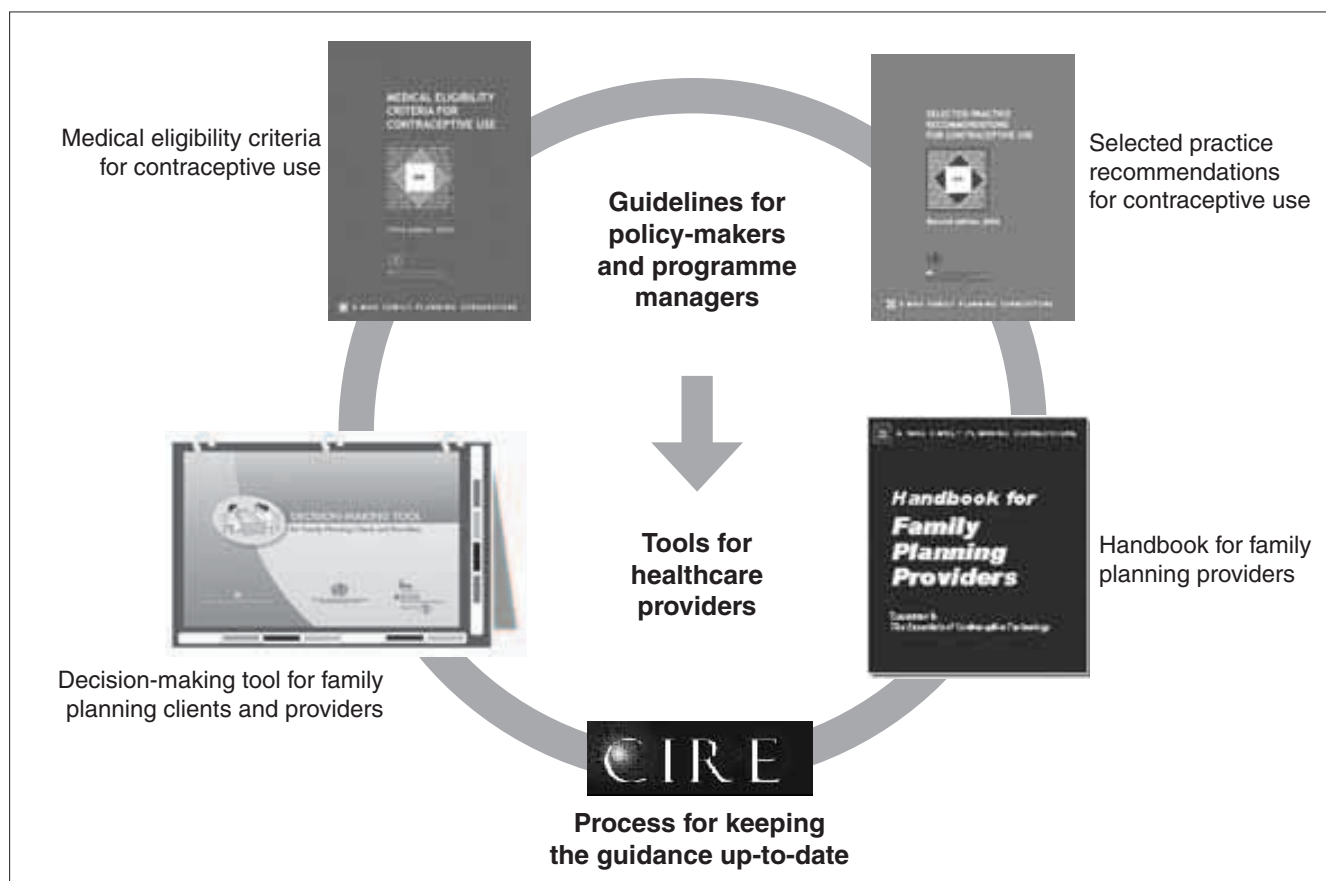
2.1 Progress

2.1.1 Family planning guidance

Medical eligibility criteria for contraceptive use and *Selected practice recommendations for contraceptive use* are the first two cornerstones of the evidence-based and consensus-based foundation of WHO’s family planning guidance (Figure 1.1). These guides are intended to be used by policy-makers, programme managers of family planning or reproductive health services and the scientific community; their aim is to make it easier to develop guidelines for service delivery, thus providing “guidance for guidelines”. *Medical eligibility criteria for contraceptive use* gives guidance on *who* can safely use various contraceptive methods. *Selected practice recommendations for contraceptive use* gives guidance on *how* to safely and effectively use contraceptive methods. Recommendations include instructions for providers on when and how to initiate contraceptive use and what to do in problem situations.

The *Decision-making tool for family planning clients and providers* and the *Handbook for family planning providers* are the third and fourth cornerstones. Their content is derived primarily from the first two guides but also includes the best evidence from social science research on how to meet the needs of family planning clients. They are intended to be used during the family planning encounter to improve the quality of care, thus providing guidance for providers and clients.

Figure 1.1. The four cornerstones of evidence-based guidance in family planning



The *Decision-making tool for family planning clients and providers* is designed to support the counselling process, while the *Handbook for family planning providers* includes reference material on contraception for family planning providers. These two tools will be accompanied by implementation and training guides.

2.1.1.1 Continuous Identification of Research Evidence

Since November 2002, WHO has used the Internet-based Continuous Identification of Research Evidence (CIRE) system to identify and critically appraise new evidence relevant to family planning guidance. CIRE operates in partnership with the Johns Hopkins Bloomberg School of Public Health's Center for Communication Programs (JHU-CCP) and the United States Centers for Disease Control and Prevention—WHO Collaborating Centre for Reproductive Health.

Together with the US Centers for Disease Control and Prevention, the Department is responsible for appraising newly identified evidence and either preparing a systematic review or updating existing systematic reviews in order to include new evidence. Systematic reviews are sent through CIRE to a group of independent experts for peer review. Peer reviewers provide recommendations to WHO on whether (i) the current recommendation remains consistent with the body of evidence and no action is needed, (ii) the current recommendation is inconsistent with the body of evidence but the inconsistency is insufficient to warrant interim guidance, or (iii) the current recommendation is strongly inconsistent with the body of evidence and interim guidance should be issued. Recommendations are then sent to the Guidelines Steering Group, which serves as the caretaker of the development and updating processes for guidelines. Based upon the results of the systematic review and peer reviewers' recommendations, the Guidelines Steering Group determines whether current WHO guidance needs to be changed. Consensus statements from peer reviewers and the Guidelines Steering Group are uploaded from CIRE onto the Department's web site. The CIRE system was used to identify evidence to update the third edition of *Medical eligibility criteria for contraceptive use* in 2003 and the second edition of *Selected practice recommendations for contraceptive use* in 2004.

2.1.1.2 Medical eligibility criteria for contraceptive use

The third edition of *Medical eligibility criteria for contraceptive use* was published in 2004, following a meeting of an Expert Working Group in October 2003. This new edition included discussions of three new contraceptive methods (the combined patch, the combined vaginal ring and etonogestrel implants) and three new topics (depressive disorders, thrombogenic mutations and the use of antiretroviral therapy) and incorporated several changes to existing recommendations for which new evidence had been identified. In particular, the Expert Working Group made several changes to the guidance on the use of the intrauterine device (IUD) by women

with sexually transmitted infections (STIs) or HIV/AIDS. These changes aim to lessen providers' concerns about offering IUDs to women in areas where HIV infection and other STIs are common. A number of international family planning organizations have already used this guidance to advocate for increased use of the IUD in these settings.

The document was published on the web in August 2004, and in the first three months was downloaded by more than 6000 users. The printed copy was disseminated to more than 9000 organizations in early 2005. It is being translated into Arabic, Chinese, French, Portuguese, Romanian, Russian and Spanish.

Since the meeting in October 2003, new evidence has been identified through the CIRE system on women who are at risk of STIs, who have thrombogenic mutations, who have endometriosis or menorrhagia and on the effect of age. This new evidence resulted in an updating of five systematic reviews. Peer reviewers' recommendations have not resulted in any changes to current guidance.

2.1.1.3 Selected practice recommendations for contraceptive use

The second edition of *Selected practice recommendations for contraceptive use* was published in 2004 following the meeting of an Expert Working Group in April 2004. The Expert Working Group comprised international family planning experts, including clinicians, epidemiologists, policy-makers, programme managers and experts in evidence identification and synthesis. The recommendations of the Expert Working Group were made in response to 33 specific questions selected by WHO based on (i) important controversies or inconsistencies in existing guidance, (ii) proposals from Expert Working Group participants and family planning organizations or agencies, and (iii) the likelihood that relevant evidence was available.

Since the first edition was published in 2002, new evidence relevant to seven of the original recommendations has been identified through the CIRE system. The Department has also added 10 new questions to the second edition. During the meeting, systematic reviews of evidence were presented on 17 topics, and the recommendations were finalized by consensus. Of the recommendations updated from the first edition, the guidance on the management of women who have missed contraceptive pills underwent the most change and was simplified considerably. This was in response to feedback received from users of the document, as well as the results of a study conducted by Family Health International that assessed women's understanding of rules regarding missed pills.

The 10 new questions added to the second edition are listed below.

- How can a woman take emergency contraceptive pills?

- Can a woman receive an advance supply of emergency contraceptive pills?
- What can a woman do to prevent nausea and vomiting when taking emergency contraceptive pills?
- How long can levonorgestrel implants be left in place?
- When can a levonorgestrel-releasing IUD be inserted?
- What can be done if a woman experiences menstrual abnormalities when using a levonorgestrel-releasing IUD?
- What should be done if a woman using a levonorgestrel-releasing IUD is diagnosed with pelvic inflammatory disease?
- What should be done if a woman using a levonorgestrel-releasing IUD is found to be pregnant?
- Should prophylactic antibiotics be provided for levonorgestrel-releasing IUD insertion?
- When can a man rely on his vasectomy for contraception?

The finalized document was posted on the Department's web site in November 2004, and the paper version will be disseminated to more than 9000 organizations in early 2005. It is being translated into Arabic, Chinese, French, Portuguese, Romanian, Russian and Spanish.

Since the April 2004 meeting, new evidence has been identified through the CIRE system about when a woman can initiate progestogen-only injections and how bleeding abnormalities resulting from implant use can be treated. This new evidence triggered an update of two existing systematic reviews. Recommendations from peer reviewers have not resulted in any changes to current guidance.

2.1.1.4 *Decision-making tool for family planning clients and providers*

The *Decision-making tool for family planning clients and providers* is unique among family planning materials in that it is designed not only to give technical information about family planning methods but also to facilitate key elements of the client-provider interaction during the provision of family planning services to adolescents, women and men; in particular it focuses on the processes of decision-making and problem-solving. This tool was reviewed, edited and finalized in 2004. A plan for production and dissemination was also elaborated in collaboration with JHU-CCP, who are co-developers of the tool.

Supporting materials, to be published on a CD-ROM, are being developed, again in collaboration with JHU-CCP. An

implementation guide is being finalized; it includes information on adapting the tool, a summary of the evidence-base for the tool and training materials. The CD-ROM will also include an electronic version of the tool, additional illustrations that can be used to adapt the tool, additional sections on methods, a demonstration video to be used to train providers as well as other, related training materials on contraception and counselling. An informational brochure on the tool is also under development. The brochure will have a much wider distribution than the paper version and will be accompanied by the CD-ROM. (See section 4.1.1 for a discussion of training and adaptation activities for the tool.)

2.1.1.5 *Handbook for family planning providers*

The Department has continued to develop the *Handbook for family planning providers* in partnership with JHU-CCP. This handbook will be the successor to the widely distributed *Essentials of contraceptive technology: a handbook for clinic staff*. The book is being developed in collaboration with more than 20 reproductive health organizations and agencies including members of the Implementing Best Practice Consortium and a number of individual international family planning experts. The handbook will incorporate guidance from *Medical eligibility criteria for contraceptive use* and *Selected practice recommendations for contraceptive use* as well as consensus recommendations from a meeting to be held in the spring of 2005. The issues to be discussed during the consensus meeting include inconsistencies or controversies in guidance and other issues identified by partner agencies. In addition, in response to evaluations from field users of *Essentials of contraceptive technology*, the new handbook will be updated to better meet their needs: several new chapters will be added and some sections will be expanded.

During 2004, writers and researchers from JHU-CCP have been working with experts from various organizations to review the guidance in *Essentials of contraceptive technology*, to identify the best available evidence and to draft text for the new handbook. Several subgroup meetings were held with partner agencies to work on key issues. In April 2004, a subgroup meeting was held to discuss contraceptive effectiveness, including how to communicate effectiveness to clients. In October 2004, a larger subgroup meeting was held at the JHU-CCP office in Baltimore, MD, USA, to develop consensus on several key issues. The results of that meeting will be presented to the larger consensus meeting in spring 2005. The handbook will be finalized and published in autumn 2005.

2.1.2 *Norms, tools and standards in andrology*

In response to a growing need for the standardization of procedures for the examination of human semen, the Programme published the first *WHO laboratory manual for the examination of human semen and sperm-cervical mucus interaction* in 1980. New editions followed in 1987, 1992 and 1999 (reprinted in 2000). These publications have been used

extensively by clinicians and researchers worldwide, with more than 6000 copies of the most recent edition distributed. The 2003 external evaluation of the Programme found strong evidence that the WHO manual is the global standard in semen analysis.

The discipline of andrology has continued to advance rapidly; progress in the development of a male contraceptive and in the treatment of male subfertility, together with concerns about the environment and putative consequences on male reproductive function, have led to increased awareness of the need for standardized measurements of all semen variables; these factors are being taken into account in planning for the fifth edition of the manual.

In 2004, the process for the revision was formally initiated: a senior editor was appointed and a working group was established; members of the working group were identified in consultation with the Programme's Research Group on Methods for the Regulation of Male Fertility. The fifth edition will be unique in that, in order to meet WHO requirements, it will provide evidence-based guidance, to the extent that this is possible. A meeting of the working group, at which draft revisions will be presented and reviewed, is scheduled for 21–24 March 2005. A proposal to seek peer review of a draft revision of the manual at the 8th International Congress of Andrology in June 2005 is under consideration. The fifth edition of the manual will be published in late 2005.

2.1.3 Users' perspectives

2.1.3.1 Quality of care in family planning services

Findings from the social science research initiative evaluating the quality of care in reproductive health services became available in 2004 and cover a range of issues. Only those related to family planning are reported here; these are comparisons of users' and providers' perspectives on the quality of family planning services in Argentina and the use of the withdrawal method by couples to prevent unintended pregnancies in Turkey.

The study in Argentina used exit interviews with clinic attendees to evaluate the quality of three public family planning clinics. Both native and immigrant clients were interviewed. The Quick Investigation of Quality, a standardized method of evaluation developed by the MEASURE Evaluation project, was used. The results highlighted attendees' dissatisfaction with non-medical aspects of the health services, such as long waiting times, poor accessibility, short consultations and poor personal treatment by staff. This study is unique because it used not only the objective standardized questionnaire but also in-depth interviews to explore discrepancies among native and immigrant attendees' concepts of quality of care that have deep sociocultural roots—i. e. users of these services assessed the quality of care based on the technical competence of the providers, their interpersonal skills and their ability to communicate information about con-

traception, but these assessments were further mediated by the cultural context. For example, immigrant women reported receiving a poorer quality of care than native women; some of the reasons for this discrepancy included the women's inability to fully understand the language in which the interaction occurred, a disjuncture between their expectations and their experience, and perceived discrimination due to their immigrant status. Findings from this study highlight the importance of considering cultural issues that may not be addressed when using standardized measures to assess health-care delivery, especially among immigrants.

A qualitative study in Turkey explored men's perspectives on withdrawal as a method of fertility regulation. The study documented the motivations and perceptions of 68 men (some of whom were users of the method and others not) regarding the use of withdrawal compared with the use of modern methods. According to current and ever-users of the method, the advantages of using withdrawal instead of a modern method are that it is easily accessible, does not require visits to health services and has no side-effects. The study results indicate that despite the reported decrease in sexual pleasure by some, men were generally motivated to use the method to limit unplanned pregnancies and take responsibility for fertility regulation. While user failure was cited as an important deterrent among men who did not choose this method, current-users reportedly believed that withdrawal was less prone to failure than modern methods. The researchers suggested that the important lessons for improving the quality of care in family planning were that accurate information on modern methods needs to be provided in a non-threatening, client-friendly environment and that couples should have access to information and services that will enable them to effectively use their method of choice, including withdrawal.

2.1.3.2 Condom use within marriage—new areas for intervention

A multicountry study in Kenya, South Africa, Uganda, the United Republic of Tanzania, Zambia and Zimbabwe on the perceptions and management of the dual risks of unintended pregnancy and infection with HIV or other sexually transmitted diseases continues to yield new information and publications. The study is groundbreaking not only in terms of the number of countries it covers, but also in terms of the comprehensiveness of the issues it addresses. It includes 6829 sexually active adults and their spouses or cohabiting partners, thereby providing a unique opportunity to match responses of partners on attitudes, motivation and behaviours. The study seeks to understand participants' perspectives on the dual risk of unintended pregnancy and STIs, and identify practical and effective strategies used by couples to cope with these risks. Of particular importance is the couples' perceptions and behaviours about their perceived risk of HIV and their use of condoms.

An analysis of data from 1245 co-resident partners from five of the six countries (Kenya, South Africa, Uganda, the

United Republic of Tanzania and Zambia) on factors affecting condom use in primary sexual relationships yielded findings that have significant implications for policies and programmes. Specifically, data were analysed to determine concordance between partners in attitudes and communication about condom use as well as perceptions of their HIV risk. Findings indicate that the majority of partners (60%) agreed that condoms are an effective method for preventing pregnancy; however, a smaller percentage (45%) agreed that the method was efficacious in preventing HIV. The study recorded a divergence of views among partners regarding the acceptability of condom use within marriage. While 25% of couples agreed that condom use was acceptable within marriage, an almost equal percentage (23%) agreed that it was not. Similarly, while 29% of couples felt it appropriate for a married woman to ask her partner to use a condom, about 20% of couples believed it was not appropriate.

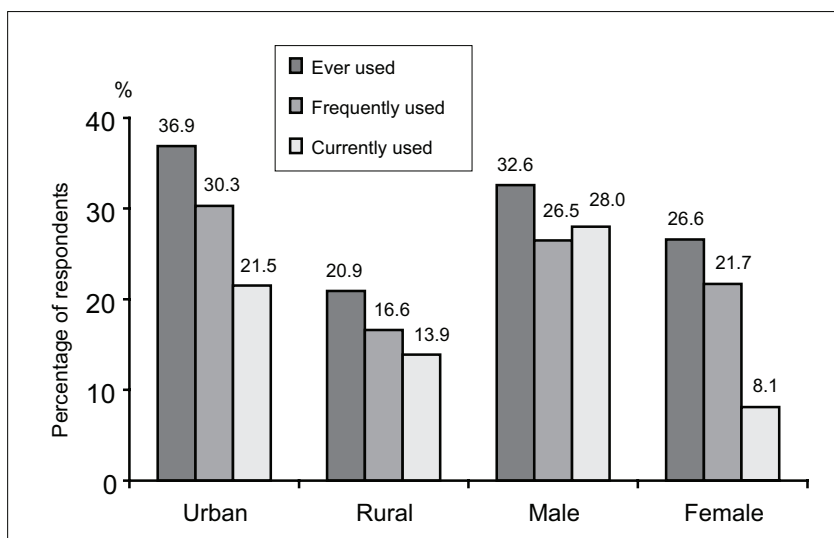
However, the most important finding is the relatively active role married women play in making decisions about using condoms—a finding that is in sharp contrast to what earlier studies have shown. When women and men were asked who had more influence over whether a condom was used, 34% of women reported that the man had more influence; 34% reported that both had influence or they were unsure who had influence; and 32% of women said that the woman had more influence. In contrast, nearly half (47%) of the men reported that influence was exerted by both partners; 34% reported that men had more influence; and 19% reported that women had the most influence. Another salient finding from this analysis indicates that condom use is more likely to be accompanied by a perception of HIV risk within couples than a motivation to space or limit births. The reported current use of condoms for preventing pregnancy and/or HIV or STIs

was more than 20% in urban areas and among men (Figure 1.2). However, the family planning function of the condom was found to be secondary to the prevention of infection.

Another part of the multicountry study focused on KwaZulu-Natal, South Africa, where 622 women and 523 men were interviewed. The perception of the risk of acquiring HIV from a spouse or cohabiting partner was fairly widespread: 37% of men believed they were at some risk of infection from their spouse or cohabiting partner compared with 57% of women. Condoms were reported to be used in marital and cohabiting unions by 14% of men and 17% of women. The odds of reporting condom use were six times higher among women who perceived themselves to be at risk of HIV infection from their spouse or cohabiting partner than among other women. This suggests that women who fear becoming infected by their husband or partner are able to initiate and sustain condom use. More than 20% of younger women, of urban respondents and of those with secondary or higher education reported that they consistently or occasionally used condoms within marital or cohabiting relationships. Within these relationships condoms were primarily used to prevent disease rather than for the dual purpose of preventing disease and pregnancy. Most women reporting that they used condoms also reported using another contraceptive method.

The findings from this study are particularly important because they indicate three potential opportunities for intervention that have not been previously considered: (i) condom use within marriage or stable relationships is growing and will continue to rise in eastern and southern Africa through the expansion of use among rural and less well educated segments of the population; (ii) women are able to and do negotiate condom use with their husband or cohabiting part-

Figure 1.2. Percentage of respondents reporting condom use, by frequency of use, place of residence and sex of respondent in Kenya, South Africa, Uganda, United Republic of Tanzania and Zambia



Source: Pullum, Cleland, Shah, 2004

ner; and (iii) individuals who perceive themselves to be at risk of contracting HIV are much more likely to use condoms with their partners.

2.1.3.3 Uptake of contraception after childbirth or pregnancy termination—implications for developing countries

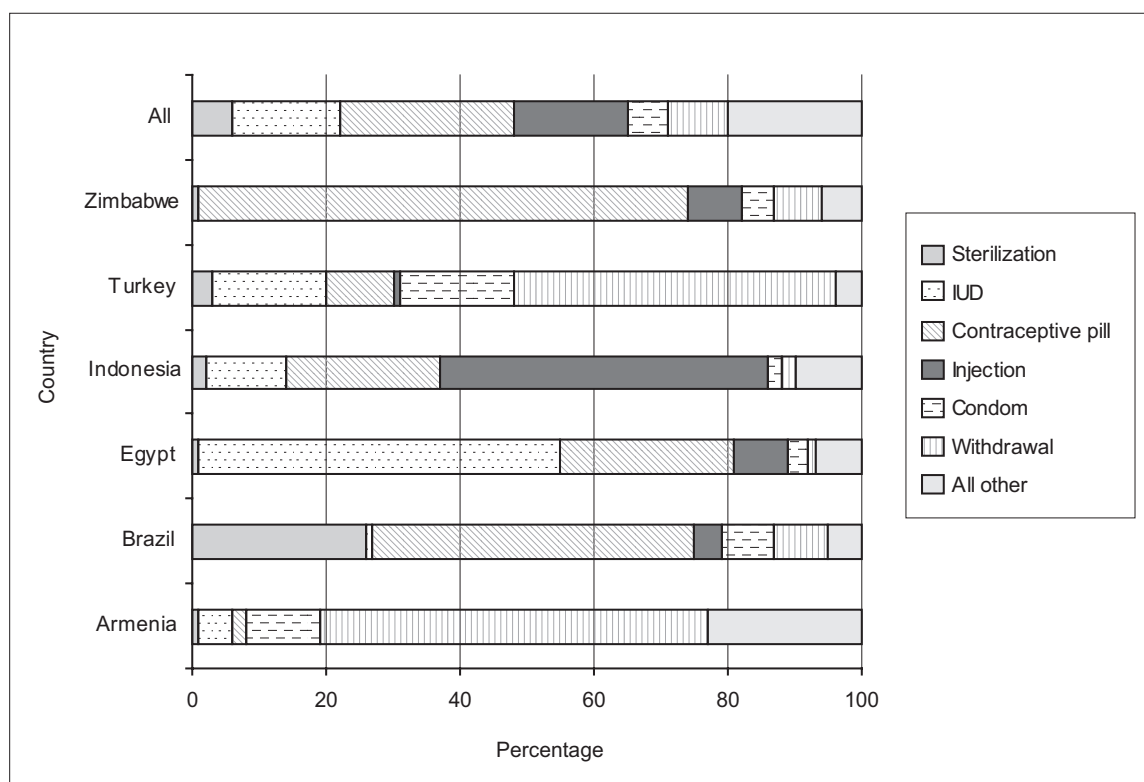
An in-depth analysis of data from 35 surveys has been undertaken to identify gaps in postpartum protection against pregnancy during the 12 months following a birth or pregnancy termination. These surveys had been conducted as part of the Demographic and Health Survey programme during 1990–2000. The analysis focused on month-by-month data on behaviour and events following a birth or pregnancy termination (due to induced abortion or miscarriage) during the five years prior to the survey in such diverse countries as Armenia, Bangladesh, Bolivia, Brazil, Colombia, the Dominican Republic, Egypt, Guatemala, Indonesia, Jordan, Kazakhstan, Kenya, Morocco, Nicaragua, Paraguay, Peru, the Philippines, Turkey and Zimbabwe. Altogether, information on 196 274 pregnancies was analysed.

The level of postpartum contraceptive uptake within a year following birth or pregnancy termination ranges from 24% in Guatemala to 36% in Bangladesh and to 74% in Colombia. The type of the first contraceptive method used varies from country to country (Figure 1.3). However, 60% of users in these countries rely on the contraceptive pill, IUD or injectable contraceptives as their first choice. One in three users

starts contracepting before the return of menses (i.e. when they are naturally protected). About 9% start using a method in the same month as they regain their fertility; and 58% delay contraceptive uptake until after they are at risk of conceiving. The timing of postpartum contraceptive uptake has an important bearing on the continuation of use (Figure 1.4). Interestingly, those who start using a method while still infertile are more likely to continue to use it in the next year (72%) than those who start to use contraception when they regain their fertility (67%) or later (64%). This holds true irrespective of the type of the method first used and may be explained by the fact that women motivated to prevent an unintended pregnancy start using contraception soon after birth or pregnancy termination and continue to use it for a prolonged period regardless of the method they choose. Overall, 30% of postpartum episodes of contraceptive use are discontinued within the first 12 months. Women who have no contact with skilled health-care personnel for antenatal care are more likely to delay contraceptive uptake than those who have access to skilled care, even when confounding factors, such as place of residence, educational level, age at conception, number of living children and desire for another child, are controlled for (Figure 1.5).

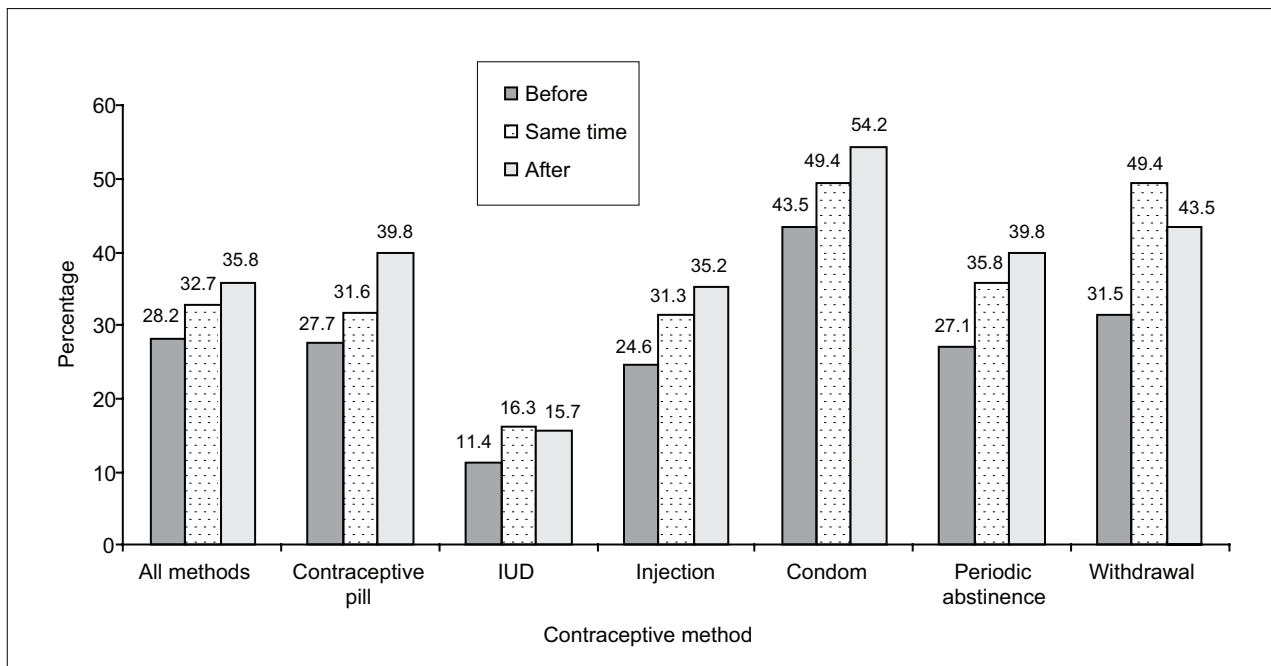
The findings have important implications for family planning and maternal and child health programmes. Postpartum family planning advice and services need to address the optimal timing of the uptake of contraception since more than 50% of new mothers delay their use of contraception until after they regain their fertility. Furthermore, those who delay

Figure 1.3. Type of contraceptive method first used after birth or pregnancy termination (%) by women in selected countries



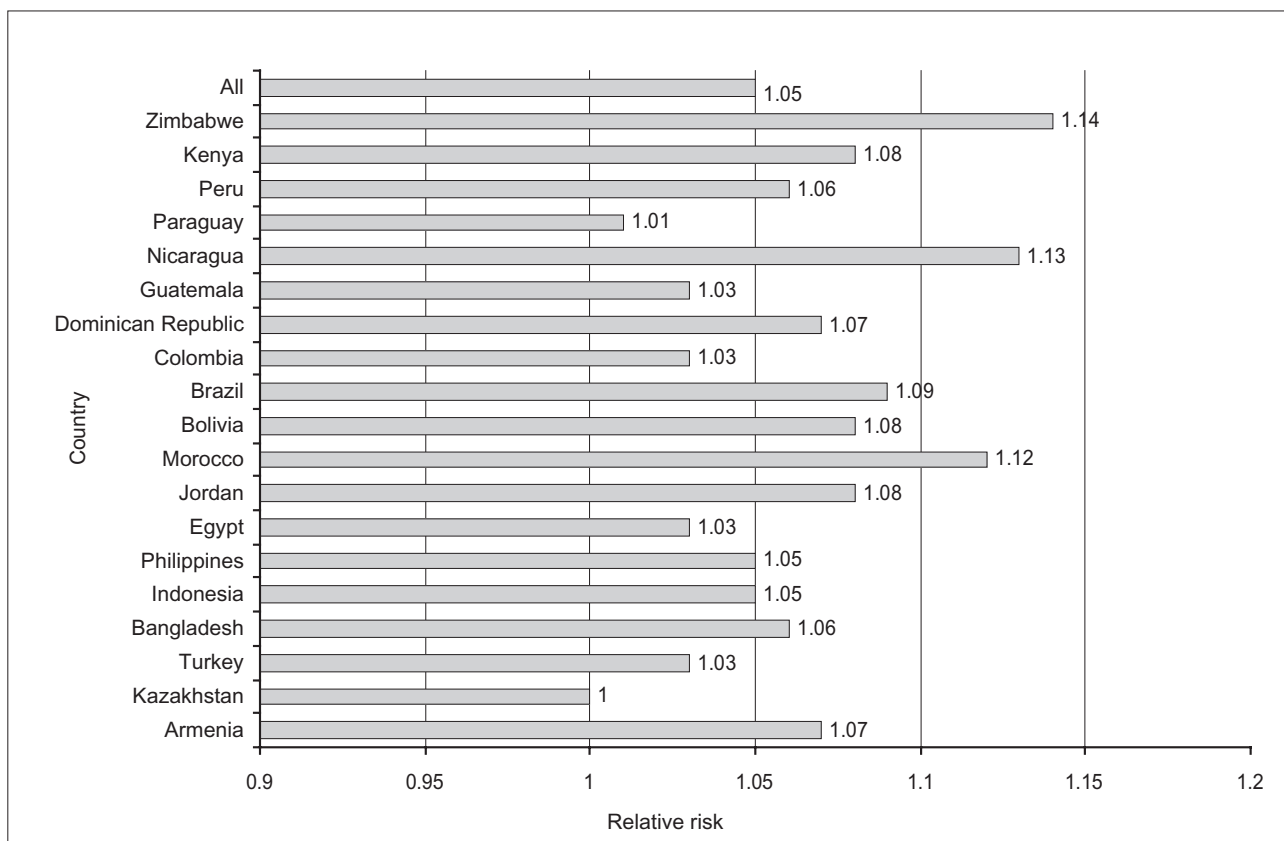
Source: Ali and Shah, 2004

Figure 1.4. Twelve-month discontinuation probabilities of using contraception per 100 episodes by time of uptake relative to postpartum return of fertility for 19 countries (see text for names of countries included)



Source: Ali and Shah, 2004

Figure 1.5. Adjusted relative risk of delaying contraceptive use after giving birth if there is no contact with skilled health-care personnel during pregnancy, by individual country and for all 19 countries



Source: Ali and Shah, 2004

uptake are also more likely to discontinue within 12 months. Thus, the provision of information on postpartum family planning during antenatal visits and at the time of delivery or pregnancy termination needs to be improved.

2.2 Planned activities

2.2.1 Monitoring evidence and keeping guidance up to date

During 2005, the CIRE system will continue to be used to ensure that WHO's family planning guidance remains up to date. As new evidence becomes available, it will be appraised and synthesized into systematic reviews for peer review. Recommendations from peer reviewers will be presented to the Guidelines Steering Group during a meeting scheduled for 2005. At this meeting, the Group will thoroughly review the new evidence and systematic reviews that have been prepared since their last meeting in April 2004. Consensus statements from peer reviewers and the Group will be posted on the Department's web site before the next meeting of the Expert Working Group. In addition, the Department encourages research to address the key unresolved issues identified by the Expert Working Group related to these recommendations.

2.2.2 Continuing development of guidelines

In 2005, the main focus of the Department in the area of norms and tools for family planning will be finalization of the *Handbook for family planning providers*. The Department will work with other departments within WHO to ensure consistency of guidance, particularly in the areas of antenatal care, STIs, dual protection and HIV. Writers and researchers at JHU-CCP will work with international agencies involved in this collaborative effort in order to finalize a draft of the handbook; this will be reviewed by all partners prior to the consensus meeting in spring 2005. The meeting will focus on outstanding issues that need addressing, and it will also develop an implementation strategy for the handbook, including encouraging adoption of the handbook by agencies, and translating and disseminating the handbook.

Finalizing supporting materials for the *Decision-making tool for family planning clients and providers* will also be a priority. These materials will include an implementation guide and training materials (see section 2.1.1.4). Translations into Chinese, Spanish and Vietnamese will be finalized, and translation into Arabic, French, Portuguese and Russian will be initiated.

The Department is collaborating with the HIV/AIDS Department on modules addressing reproductive health and HIV programming, specifically on the *Guidelines on care, treatment and support for women living with HIV/AIDS and their children in resource-constrained settings*. The Team also plans further adaptations of the *Decision-making tool for family planning clients and providers* including an adaptation

for use in settings of high HIV prevalence; this adaptation will focus on dual protection, prevention of mother-to-child transmission, voluntary counselling and testing, and contraceptive choices for HIV-positive women. An adaptation is also planned for community-based family planning providers.

2.2.3 Implementing the guidelines

By working with international partners, *Medical eligibility criteria for contraceptive use* and *Selected practice recommendations for contraceptive use* have been widely disseminated. The recommendations in *Medical eligibility criteria for contraceptive use* have been incorporated into national standards and guidelines in more than 50 countries. Since 2002, the practice recommendations have also been highly successful and the recommendations have been adopted globally. Implementation of the guidelines, however, remains an important focus for the Department. The Department is developing a process for systematically introducing the guidelines, and is contributing by developing guidance to support countries that wish to implement the guidelines. Much of this work is being done through the Strategic Partnership Programme, which is a collaboration with UNFPA that is designed to improve quality of care through the introduction and adoption of guidelines (see section 4). The Team also plans to collate the lessons learnt from applying guidelines in the field in order to support effective strategies for changing providers' practices.

2.2.4 Norms, tools and standards in andrology

In addition to revising the laboratory manual for the examination of human semen (described above in section 2.1.2), in 2005 the Department proposes to initiate revision of the *WHO manual for the standardized investigation, diagnosis and management of the infertile male* and the *Guidelines for the use of androgens in men*, if resources allow.

2.2.5 Quality of care research initiative

Two new studies on quality of care were approved from among 19 proposals and 17 concept papers received. One examines the quality and responsiveness of reproductive health services in addressing the reproductive needs of HIV-positive men and women in South Africa and the second deals with the assessment of the quality of obstetric care in rural south India.

Few studies have evaluated the reproductive health needs of HIV-positive people, and fewer studies still have focused on issues related to their desire to have children or to use contraceptives to prevent unintended pregnancy. The objective of this new study in South Africa is to improve the delivery of reproductive health services to women and men infected with HIV by gaining insight into their attitudes, beliefs and opinions as well as those of the health-care providers who are likely to play a critical role in determining their access to and the quality of these services. The research will be conducted in the periurban community of Langa in Cape Town,

South Africa. The sample will be clinic-based, and HIV-positive individuals accessing different types of care at the clinic will be recruited for the study. The study has two phases. The first phase is qualitative and will include 20 in-depth interviews and four focus group discussions with men who are HIV-positive. The second phase is quantitative. Researchers will survey 470 women and men who are HIV-positive and 70 health-care providers from Langa and the surrounding communities. The findings from the study will be shared with health-care policy-makers at the local, provincial and national levels in order to facilitate supportive policies and appropriate services for individuals living with HIV/AIDS. In addition, an intervention package that can be implemented through primary health care centres will be developed; the aim will be to use this package not only in South Africa but in other countries as well.

The second new study aims to ascertain perceptions of the quality of antenatal, delivery and emergency obstetric care and experiences among clients of these services in rural south India. The study will also explore services providers' perspectives on the quality of care.

3. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS AND TECHNOLOGIES

This objective seeks to broaden the range of safe, effective, acceptable and affordable family planning and infertility care methods available to men and women. The main focus of research includes:

- developing contraceptive methods including improved methods of emergency contraception, dual-protection methods, long-acting hormonal methods for women, long-acting nonhormonal methods for women and long-acting hormonal methods for men;
- basic science investigations to identify new targets for contraceptive research;
- epidemiological research on the safety and efficacy of existing methods of fertility regulation;
- evaluation of new technologies for treating infertility.

3.1 Progress

3.1.1 Emergency contraception

During 2004, an efficacy study of two levonorgestrel regimens was performed in Nigeria (see Chapter 9, section 2.1.11.1), and other studies continued to investigate the pharmacokinetics and tissue concentrations of levonorgestrel after oral and vaginal administration. Studies were also launched to investigate the mechanism of action of emergency contraception.

Vaginal administration of certain drugs provides an effective way to deliver the drug to the target organ. It has been shown that even small oral doses of levonorgestrel can modify cervical mucus making it impossible for sperm to penetrate or change uterine pH so that sperm that has reached the uterine cavity become nonmotile. These mechanisms can contribute to the efficacy of emergency contraception. It was hypothesized, therefore, that vaginal administration of levonorgestrel could be more effective in inducing local changes.

A randomized study was carried out to compare plasma levels and endometrial tissue concentrations after oral or vaginal administration of 1.5 mg levonorgestrel, the dose used for emergency contraception. The results showed that tissue concentrations of levonorgestrel are not related to plasma levels because orally administered levonorgestrel produced higher plasma concentrations but lower endometrial tissue concentrations; the opposite was true after vaginal administration. Also, the half-life of levonorgestrel was longer after vaginal administration (32 hours) compared with oral administration (25 hours). These data suggest that levonorgestrel pills may be administered vaginally for emergency contraception.

Although levonorgestrel is an inexpensive compound, factors such as packaging, marketing costs, and profits for manufacturers, increase the price of dedicated emergency contraceptive pills so that they are often too expensive for individual women or family planning clinics in developing countries. Providers have, therefore, asked for guidance on whether mini-pills containing levonorgestrel could be used instead of dedicated 0.75 mg or 1.5 mg tablets. To investigate the issue a study was undertaken to compare the pharmacokinetics of two tablets of 0.75 mg of levonorgestrel (1.5 mg dose) and 50 mini-pills each containing 0.03 mg of levonorgestrel (1.5 mg dose), packed in capsules for the study. The results showed that plasma concentrations were similar after oral administration of either the mini-pills or the two tablets. This suggests that mini-pills containing levonorgestrel can be used for emergency contraception.

Staff of the Programme were invited to make presentations about the use of emergency contraception at international and national conferences during 2004.

3.1.2 Methods of fertility regulation for women

The Programme has had a successful history of undertaking research to improve existing methods and develop novel methods for women to use to regulate their fertility. Most of the current work in this area is related to hormonal methods, with the exception of an injectable immunocontraceptive approach.

3.1.2.1 Immunocontraception

The development of a new method of contraception based on the production of an 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. A large number of animal studies and a limited amount of clinical experience have shown that, depending on the approach and type of preparation, such a method could provide a relatively long-acting, safe and effective type of contraception.

The research being supported by the Programme aims to develop an immunocontraceptive based on, and directed against, human chorionic gonadotrophin (hCG). The objective is to develop a long-acting, nonhormonal method of contraception that can provide approximately six months' protection after a single injection and that does not produce the endocrine and other metabolic disturbances often experienced with long-acting steroid hormone preparations that are currently on the market and under development. A preparation that is capable of meeting these requirements has been developed and consists of hCG peptide:diphtheria toxoid (DT) immunogen conjugates and a muramyl dipeptide immunostimulant incorporated in biocompatible, biodegradable inorganic matrix particles and suspended in an emulsion of water in oil formed from squalene and phosphate-buffered saline, using mannide mono-oleate as the emulsifying agent.

The results of development work supporting the clinical testing of this preparation and of studies for improving manufacturing procedures were described in the *Annual technical report 2003*. Also described in that report were the development and testing of alternative versions of the hCG immunocontraceptive consisting of totally synthetic chimeric peptides representing B-cell and T-cell epitopes of hCG and DT, respectively, and the hCG peptide:DT conjugate incorporated into an alternative delivery system consisting of biodegradable polylactide–glycolide microspheres; these formulations are still in the relatively early stages of development but could eventually be tested as second-generation products for fertility regulation and may offer promise for vaccine development generally.

A clinical trial application was submitted to the regulatory authorities in Sweden in May 2002 to carry out a Phase I study with the matrix formulation of the hCG immunocontraceptive described above. In February 2003, the Department's Scientific and Technical Advisory Group (STAG) endorsed a plan to move forward with the preparation of clinical trial supplies for the study. In January 2004, the Swedish regulatory authorities approved the application, and in February 2004, STAG agreed that the Phase I trial could be implemented if funds allowed. Funds became available at the end of 2004, and recruitment will begin in the first half of 2005.

Tests of the immunogenicity, safety and stability of the 2003 Good Manufacturing Practice batch of this material are under way. The systemic potential and local tolerance of the formulation when administered intramuscularly to rabbits has been evaluated in a 28-week study. Two groups of animals received the preparation. In the first group, animals received

an immunogen dose of 50 µg on day 1 and 25 µg on day 169 (24 weeks); the second group received 100 µg on day 1 and 50 µg on day 169. A control group received a dose of a combined injectable contraceptive (25 mg depot-medroxyprogesterone acetate and 5 mg estradiol cypionate) at 4-week intervals for the duration of the study. Clinical condition, body weight, food consumption, organ weight and macroscopic pathology were evaluated, and histopathological investigations were performed. The preparation was well tolerated, producing inflammation at the injection site but no clinical sign of reaction to treatment. With the exception of the changes observed at the injection sites, the effects produced by the injectable contraceptive were often greater.

The preparation has been shown to be stable for a period of more than two years; stability testing is continuing. Studies reported previously indicate that commercial manufacture of the preparation is feasible.

3.1.2.2 Hormonal methods

The Programme is evaluating a variety of hormonal contraceptive methods for women. Levonorgestrel butanoate, prepared in a chemical synthesis programme conducted by the United States National Institutes of Health's National Institute of Child Health and Human Development (NICHD) together with the Programme in the late 1970s and early 1980s, has been investigated as a superior alternative to depot medroxyprogesterone acetate (DMPA). There has been renewed interest in this formulation; at a meeting in November 2003, WHO, NICHD, the CONRAD programme, the Concept Foundation, and representatives of academia and industry unanimously agreed that levonorgestrel butanoate is an attractive alternative to DMPA as a three-monthly injectable contraceptive and determined to collaborate on its further development; a draft product development plan has been elaborated. In 2004, a confidentiality agreement was signed by all parties, allowing for the exchange of data and information for decision-making. The ongoing development work is being managed in a collaborative manner; CONRAD has contracted with a research laboratory to assess the formulation development work and determine the optimal method of sterilizing the steroid compound. In accordance with the requirements of WHO's legal office, a patent search has been initiated to ensure that the risk of infringement claims on this compound is negligible. When this has been verified (expected in early 2005), an agreement with Gedeon Richter Ltd., Budapest, Hungary, will be implemented in order to ensure an adequate supply of the compound for formulation work and for preclinical and clinical testing. According to the current strategy, the Programme will fund the manufacture of the product, and the CONRAD programme and NICHD will support any required preclinical work and Phase I clinical evaluation, with possible contributions from the Programme in later-stage trials.

A large proportion of the more than 20 million women using progestogen-only methods of contraception experience irregularities in vaginal bleeding. This has significant implications

for their sexual life and affects the sociocultural, economic and, for some, religious dimensions of their lives. Other than counselling, few options are available to women to help them cope with this problem.

A double-blind, randomized, placebo-controlled, multicentre 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 prolonged bleeding induced by the implantable contraceptive Norplant. Results were published at the end of 2004. Neither of the treatments had a significant beneficial effect on bleeding patterns.

A systematic review of the evidence for the efficacy of various options for treating progestogen-induced endometrial bleeding irregularities is being supported by the Programme through the Fertility Regulation Review Group of the Cochrane Collaboration. The review is under way and should be completed in early 2005.

3.1.3 Methods of male fertility regulation

The family planning community is becoming increasingly aware of the need for and public health benefits of developing positive partnerships with men. The Programme has taken a leadership role in developing male contraceptives as a step towards the goal of increased shared responsibility for contraception. A research agenda for the development of male contraceptives must identify and exploit the leads that are feasible and show the most promise, such as hormonal methods that suppress spermatogenesis and produce temporary infertility. The Programme's clinical trials are complemented by research into acceptability and behaviour.

3.1.3.1 Clinical research

The flagship trial is a Phase III study of the safety and efficacy of testosterone undecanoate. This is the world's first and only Phase III trial of a male hormonal contraceptive. The 4-year trial is evaluating the effects of a monthly injection of 500 mg testosterone undecanoate on the fertility of 1045 men at 10 centres in China. The study is progressing according to schedule (Table 1.1), and data collection will be complete by December 2005. Preliminary analysis indicated that 43 participants failed to respond adequately to the regimen. Age, height, body weight, body mass index, testes volume and semen values at baseline were not predictive of response to the regimen. To date, 304 volunteers have withdrawn or were discontinued from the trial (Table 1.2). Ten of these men were discontinued because of a rebound in sperm concentration to > 1 million/ml semen. Nine pregnancies have occurred during the study, six of these in partners of men who experienced sperm rebound and three in partners of men whose sperm concentrations remained below the threshold. The most common side-effects have included discomfort at the injection site and acne; other side-effects, reported by a few participants, have included allergy or sensitivity to the steroid preparation and severe coughing at the time of injection. These preliminary results were presented at the NICHD meeting on the future of male contraception held in Seattle, WA, USA, in September 2004 and at the international conference on men as partners in sexual and reproductive health held in Mumbai, India, in November 2004.

The Xianju Pharmaceutical Corporation, Zhejiang, China, provided the testosterone undecanoate for the Phase III trial. It is currently marketed for androgen replacement therapy in China; it is formulated at a concentration of 125 mg/ml, so a large volume (4 ml) is needed to deliver the dose required

Table 1.1. Status of 1045 volunteers enrolled in Phase III trial of testosterone undecanoate as a male contraceptive as of 30 September 2004^a

Study phase	Number of volunteers
Suppression (first six months)	0
Efficacy (24 months)	490
Recovery (\geq 12 months)	353
Follow-up completed	109
Lost to follow-up	93
Total	1 045

^a Volunteers have monthly injections of testosterone undecanoate (1000 mg at the first injection and 500 mg thereafter) and are tested for sperm suppression for six months (Suppression phase). If sperm concentrations are suppressed to \leq 1million/ml, 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 complete the Efficacy phase or who withdraw early for any reason are followed (Recovery phase) until their sperm concentrations return to levels generally considered to be fertile (20 million/ml).

Table 1.2. Reasons for early discontinuation

Reason	Number of volunteers
Lost to follow-up	93
Change in contraceptive method	45
Inadequate response	43
Missed injection	36
Side-effects	17
Other ^a	70
Total	304

^a The category of Other includes participants wishing to discontinue ($n = 20$), sperm rebound ($n = 10$) and partner becoming pregnant ($n = 9$).

for the study. In response to a request from the Programme, the company produced a pilot batch of the preparation with a higher concentration (250 mg/ml) of the steroid; such a preparation would allow the injection volume to be halved, reduce pain at the injection site and improve acceptability. A study of the pharmacokinetics of this formulation in monkeys, initiated in 2003, was completed in 2004. Results demonstrated that the new formulation does not have a pharmacokinetic profile significantly different from other formulations that are available.

At the October 2004 meeting of the Research Group on Methods for the Regulation of Male Fertility, two protocols to test this formulation were discussed. Earlier correspondence with the pharmaceutical company revealed that it is not interested in pursuing the commercial manufacture of the higher concentration formulation in the absence of financial support to conduct the required safety testing. Given the existing financial constraints and the commercial availability of a 250 mg/ml testosterone undecanoate manufactured by Schering AG, Berlin, Germany, the Research Group recommended that these proposals be given a low priority and be re-evaluated if funds become available to support development.

In 2002, a Phase II trial to evaluate the ability of an androgen–progestogen combination (testosterone undecanoate plus DMPA) to suppress spermatogenesis in Indonesian men was completed, as described previously. Data analysis and manuscript preparation are under way; the manuscript will be submitted for publication in 2005.

3.1.3.2 Behavioural and social science research

In conjunction with the clinical trial of the testosterone undecanoate plus DMPA regimen described above, a study to assess users' perspectives on the acceptability of the study regimen was completed in 2002, as described previously. A manuscript is in preparation and will be submitted for publication in 2005.

The Programme is supporting a study to pilot-test instruments to assess the acceptability of male hormonal methods of contraception as well as their effect on mood and behaviour. The study is being conducted among Italian men using testosterone undecanoate combined with the progestogen norethisterone enantate (NET-EN) as a potential contraceptive. Instruments have been developed and validated; data collection was completed in 2003, and analysis is under way. Preliminary evidence indicates that sexual behaviour and mood are not altered as a result of the regimen. It is anticipated that these instruments will be used in future clinical trials of male hormonal contraceptive methods.

3.1.4 Basic science research related to reproduction and fertility regulation

In 2004, the Programme supported three basic science initiatives related to contraceptive research and development. Topics funded included research into the physiology of implantation, the role of progestogens in endometrial breakthrough bleeding, and male reproductive physiology.

A method of fertility regulation that needs be taken on only one occasion in any menstrual cycle would be an attractive option for many individuals and couples. The utility of such a method would be greatly increased if it need not be taken regularly in every cycle but only on an as-needed basis, for example in the case of occasional, otherwise unprotected intercourse or as a back-up in the case of failure of another method, such as for example, condom breakage. A method with these attributes would also be largely free of the logistical difficulties and side-effects associated with the provision and use of many existing methods of family planning and, because of its infrequent use, should be relatively inexpensive and, therefore, affordable for women in many parts of the world.

At the end of 1998, a collaborative 5-year initiative in the area of basic research in implantation was established between the Rockefeller Foundation and the Programme. The primary

objective of this initiative is to identify promising leads for development, in eventual collaboration with industry, of novel once-a-month methods that are safe, effective, acceptable in their mode of administration and mechanism of action and that can be self-administered. The initiative has focused on (i) the implantation window in primates, at the endometrial level, (ii) the development and demise of the corpus luteum in primates, and (iii) preimplantation interactions between the embryo, uterus and corpus luteum. The work is being carried out by a network of six centres in Australia, China, Germany, India, the United Kingdom and the USA; financial support is provided by the Rockefeller Foundation and technical oversight is provided by the Programme.

The 5-year period of the initiative ended in 2003; in late 2003 the six centres were each asked to prepare a report of their activities that would be suitable for publication. A meeting of the Project Review Committee was held in August 2004. Comments were provided to the investigators, and the final manuscripts have been accepted by *Contraception* for publication in April 2005.

Because irregular bleeding is the primary reason that women discontinue using progestogen-only fertility regulation methods, there is a clear need to better understand the mechanisms of menstruation and of irregular bleeding in order to formulate appropriate treatments and develop new methods that do not cause this side-effect. A basic science project designed to provide insight into the cellular and molecular mechanisms that underlie progestogen-induced breakthrough bleeding was initiated in 2002. This is a collaborative study being conducted at two institutes in Australia. One of the laboratories is in the third year of the project; the other encountered delays in starting and is still working towards achieving its second-year objectives.

In 2004, the investigators conducted experiments in a human endometrial cell line to demonstrate that chemokines are differentially regulated by progesterone and levonorgestrel; this model is being used to explore the effects of a third progestogen, etonogestrel. The expression of eight highly abundant endometrial chemokines was examined in endometrial samples from women using Norplant and the levonorgestrel-releasing IUD; this was correlated to leukocyte populations. The results demonstrate that chemokine expression is dysregulated in progestogen-exposed endometria and generally up-regulated to levels present in endometria undergoing normal menstrual cycles during periods of peak leukocyte recruitment.

The investigators have modified a mouse model of menstruation in order to replicate the changes observed in women using progestogen-only contraceptives. In the model, decidualization is stimulated in one horn of the uterus and, 49 hours later, animals receive implants of either levonorgestrel or etonogestrel; the implants are left in place for up to 15 days. In these animals, the stimulated horn of the uterus

demonstrates a transient increase in weight by day 5, but there is no change in the unstimulated horn. Examination of the morphology of the stimulated horn revealed progressive tissue breakdown over time in animals exposed to either progestogen. Further studies analysing matrix metalloproteinases, leukocytes and chemokines are ongoing. Additional progress in this area includes the establishment of a suitable cell line for *in vitro* cellular investigation of the role of progestogens in breakthrough endometrial bleeding. Studies to analyse progesterone receptor function in three types of epithelial cells are ongoing.

During 2000–2001, the Programme issued a call for proposals for basic science activities aimed at identifying a novel target for male contraception. Four proposals have been funded; three were completed in 2003 and have been described previously. One project was completed in 2004. This study, known as “Delivery of antibodies to the male reproductive ducts to achieve immunocontraception”, investigated whether a sufficient titre of antibody could be delivered to the lumen of the male reproductive ducts to saturate a target antigen in order to achieve immunocontraception. Results indicated that low concentrations of IgG and IgA enter the rete testes and prostatic fluid of the mouse and rat. Immunization of male mice with preparations of sperm surface proteins had no effect on fertility. A manuscript describing the results is in preparation.

3.1.5 Safety of existing methods of fertility regulation

3.1.5.1 Implantable contraceptives for women

A randomized comparative study to assess the clinical performance and contraceptive efficacy of Jadelle and Implanon was initiated in seven countries at the end of 2003 (Brazil, Chile, the Dominican Republic, Hungary, Thailand, Turkey and Zimbabwe). Jadelle is a two-rod 5-year levonorgestrel implant; Implanon is a single-rod 3-year etonogestrel implant. The aim of the study is to compare the contraceptive efficacy, adverse events and discontinuation rates of the two implants over three years. A total of 2000 women will be randomly allocated to receive one of the two implants. Enrolment at each site will last approximately one year. To assess adverse events that are not related to the reproductive system, an age-matched cohort of 1000 women who have elected to use the TCU 380A intrauterine device will be enrolled in parallel to the randomized trial. This will allow for rational assessment of complaints such as dizziness, headache, skin alterations and mood changes that are associated with progestogen-only implants. Study end-points include pregnancy rates, incidence of adverse effects, reasons for discontinuation and continuation rates. Study initiation in two sites in China has been delayed due to difficulties in obtaining approval from the Chinese Food and Drug Administration for importation of the devices; it is anticipated that the study will be officially withdrawn from consideration at these sites. To reach the required sample size, the number of women recruited will be increased at other sites.

Table 1.3. Status of women participating in comparative study of implantable contraceptives, 31 October 2004

Centre	Date first implant inserted	Number of implant insertions		
		Jadelle	Implanon	IUD
Ankara, Turkey	19 September 2003	42	39	35
Bangkok, Thailand	16 June 2003	29	30	36
Campinas, Brazil	4 August 2003	78	69	8
Harare, Zimbabwe	20 August 2003	100	100	100
Santiago, Chile	25 July 2003	100	100	130
Santo Domingo, Dominican Republic	2 December 2003	100	100	100
Szeged, Hungary	21 May 2003	41	40	0
Total		490	478	409

Most sites started recruiting in the second half of 2003 (Table 1.3). About a third of enrolled women have completed one year of follow-up. A total of 300 women have been enrolled at each centre in Harare, Santiago and Santo Domingo. Investigators in Bangkok, Santiago and Santo Domingo have agreed to recruit an additional 300 women at each site in order to compensate for the loss of the sites in China. In Szeged, the recruitment of women into the IUD component of the trial has been delayed.

Fourteen serious adverse events have been reported, eight of which occurred among women using implants. None of the serious adverse events were related to study products. Women who withdrew from participation included 26 using implants and 27 using IUDs. Reasons for withdrawing from the trial included bleeding disturbances, other medical reasons, personal reasons, wishing to become pregnant and expulsion of the IUD. One woman in Ankara discontinued IUD use following admission to hospital for an ectopic pregnancy diagnosed two weeks after IUD insertion. She was thought to have been pregnant prior to insertion. Interim results will be available in mid-2005, one year after device insertion. The study is expected to be completed by 2007.

3.1.5.2 Bone mineral density and progestogen-only contraception

Worldwide more than 20 million women are estimated to be using progestogen-only contraceptives, including injectables, implants, vaginal rings, the levonorgestrel-releasing IUD and oral preparations. Concerns have been raised that progestogen-only preparations may decrease bone mineral density and thus increase subsequent risk of osteoporotic fracture. It is unclear whether decreases noted during current use of progestogen-only contraception are transient or persistent.

The Programme is supporting investigators at the Reproductive Health Research Unit, Durban, South Africa, to conduct a prospective study of the impact of progestogen-only contraception among women aged 15–19 years and 42–49 years. The younger age group covers the period of maximal bone mass acquisition, and any decrease resulting from the use of 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.

A total of 988 women were recruited between June 2000 and May 2003. Selected characteristics of the cohorts at recruitment are shown in Table 1.4. There were substantial differences in ethnicity, employment status, alcohol and caffeine consumption and smoking among the users of different types of contraceptives; these differences will have to be adjusted for in the analysis of baseline bone mass and changes over time when analysis by contraceptive method used is performed.

Women are being followed at 6-month intervals for five years, irrespective of whether they change their contraceptive method. To date 316 women have withdrawn from the study (Table 1.5). The main reasons were that they moved out of the area (50% of all withdrawals from the study) or were lost to follow-up (35%). The 28 pregnancies that occurred were in the younger cohort and consistent with the South African Demographic and Health Survey that reported that 35% of women had their first pregnancy by the age of 19 years. Eleven women died; the majority of these deaths were apparently due to AIDS and/or tuberculosis-related complications (for which information on cause of death is available). One suicide was recorded among the younger age group in 2003.

Table 1.4. Selected characteristics of study cohorts

	Initial contraceptive method chosen			
	DMPA ^a	NET-EN ^b	Combined oral contraceptive	Controls (non-users)
15–19 year olds				
Number enrolled	114	114	116	148
Mean (SD) age (years) ^c	17.8 (1.4)	17.4 (1.7)	17.8 (1.0)	17.4 (1.2)
Education (mean highest grade completed)	10.9	10.5	11.3	10.3
% currently employed	6	3	10	3
Ethnicity (% African)	94	89	57	92
% participants who consume alcohol	15	33	5	16
% participants who exercise regularly	22	27	35	22
% participants who ever consume caffeine	87	90	80	90
% current smoker	6	7	14	3
40–49 year olds				
Number enrolled	127	102	106	161
Mean (SD) age (years)	43.6 (2.7)	43.0 (2.2)	43.7 (2.5)	45.4 (2.5)
Education (mean highest grade completed)	8.4	9.8	9.9	9.0
% currently employed	44	74	72	63
Ethnicity (% African)	98	96	67	94
% participants who consume alcohol	18	15	11	18
% participants who exercise regularly	3	4	4	7
% participants who ever consume caffeine	91	82	81	88
% current smoker	5	6	6	10

^a DMPA = depot-medroxyprogesterone acetate.

^b NET-EN = norethisterone enantate.

^c SD = standard deviation.

Prompted by data from a prospective study of young DMPA users in the USA, the Food and Drug Administration (FDA) and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) in November 2004 cautioned against the use of DMPA by adolescents. The MHRA recommended that DMPA could be used by adolescents "as first-line contraception, but only after other methods have been discussed with the patient and considered to be unsuitable or unacceptable"; in advice directed at patients the FDA suggested that potential long-term users (those using DMPA for more than two years) should consider the product "only if other methods of birth control are not right for you". These cautions may be appropriate in the developed world where several contraceptive options are available and the risks associated with unplanned pregnancy are considerably lower. However, for women in resource-limited settings the cautions may reduce access to a highly effective, confi-

dential, convenient and reversible method of contraception. The results of the ongoing study in Durban are awaited, and consideration is being given to continuing follow-up of the younger cohort beyond the five years initially planned.

3.1.5.3 Long-term safety and effectiveness of copper IUDs

Up to 140 million women worldwide use IUDs for family planning. IUDs have the advantage of being long-acting and relatively easy to remove, with a rapid return to 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 using the copper-releasing TCU 380A device continues. In the period 1989–1998 a total of 5953 women had this device inserted as part of Programme-sponsored randomized trials comparing the

Table 1.5. Reasons for discontinuation

Reason	Number
Moved out of area (reported to study)	157
Lost to follow-up (no contact)	110
Pregnancy	28
Death	11
Withdrew (illness related)	4
Withdrew (personal reasons)	4
Other	2

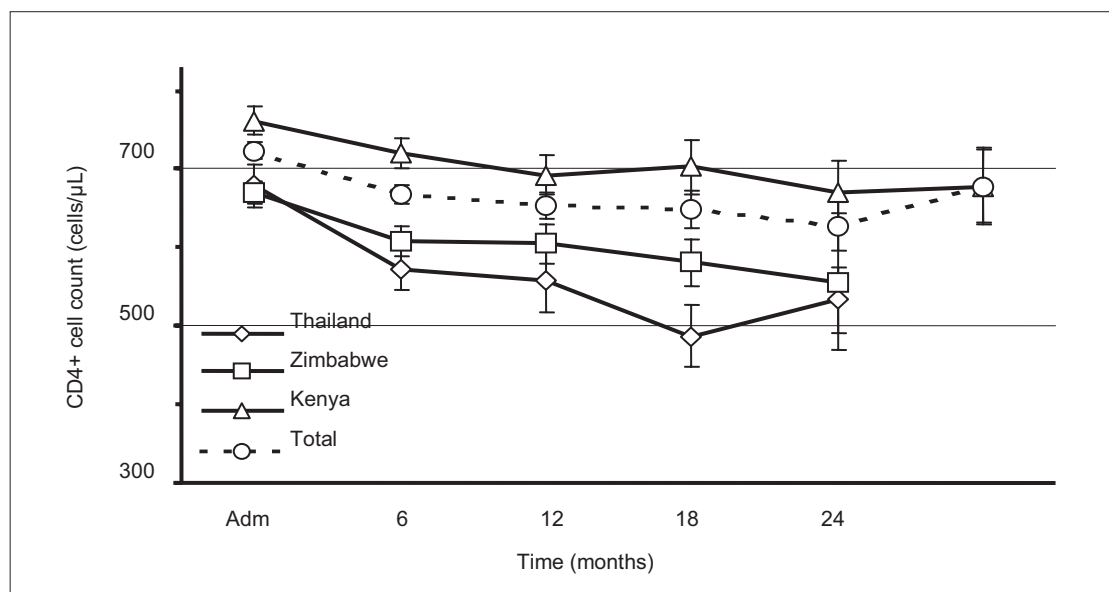
safety and effectiveness of different devices. The majority of the insertions took place in 1990–1991. Thus, the first large cohort of users completed 10 years of use at the end of 2001, and more than 500 completed 13 years of use by the end of 2003. The Programme has made available final data on 12 years of use and 13 years of use to FEI Products LLC, New York, NY, USA, to submit to the FDA in order to extend the registered lifespan of the device from the current 10 years. Total experience with the device between 10 years of use and 13 years of use was 548.6 woman-years, based on women from Armenia, China, Hungary, India, the Philippines, Slovenia, Thailand, Uzbekistan and Zambia.

3.1.5.4 HIV and steroidal contraception

To assess the impact of different contraceptive methods on the clinical course of human HIV infection, the Programme is sponsoring a multicentre study in Brazil, Kenya, Thailand and Zimbabwe. Women who are HIV positive have been invited

to participate in an observational cohort study with follow-up visits every six months for four years. Study end-points include HIV disease progression, the incidence of opportunistic infections, and changes in CD4+ cell counts and viral loads. These will be analysed according to the contraceptive method used.

Recruitment closed on 31 December 2003, by which time a total of 623 women had been enrolled: 332 in Kenya, 87 in Thailand and 204 in Zimbabwe. It was not possible to recruit women in Brazil since few patients had CD4+ cell counts of at least 500 cells/ μ L and antiretroviral therapy is available nationally for all patients. The majority of women were using hormonal contraception at enrolment (primarily DMPA in Nairobi and combined oral contraceptives in Harare); nonhormonal methods were used by 25%. Provisional data on the rates of decline in CD4+ cell count in all study participants, regardless of contraceptive method used, show a much steeper decline in Thailand and Zimbabwe than in Kenya

Figure 1.6. Decline in CD4+ cell counts (cells/ μ L) by study centre among HIV-positive women for all methods combined

(Figure 1.6), possibly reflecting the impact of different HIV subtypes. Although plans had been made in 2003 to introduce antiretroviral treatment to the cohort in a systematic manner, funding constraints have required delaying this.

Additional questions on the interactions between hormonal contraception and antiretroviral therapy are becoming more urgent as therapy becomes more widely available in resource-limited settings. Issues that need to be addressed include:

- the response to first-line antiretroviral therapy among users of different contraceptive methods;
- the acceptability and tolerance of different contraceptive methods among women starting first-line antiretroviral therapy; and
- the need for pharmacokinetic and pharmacodynamic studies of the interactions between hormonal contraceptives and antiretroviral therapy among women from developing countries.

Results from studies examining these issues will form the basis for evidence-based recommendations regarding contraceptive choices for HIV-positive women who are using antiretroviral therapy. The Programme is exploring ways of assembling larger cohorts of women in order to address these issues.

3.1.6 Infertility

Following the recommendations of STAG, the report on infertility presented in 2004 was submitted for publication as an introduction to the proceedings of the 2002 Nairobi workshop on infertility. The report, known as *The global problem of infertility: a perspective from the World Health Organization*, summarizes the Programme's contributions to the prevention and management of infertility from the early 1970s until today. In addition, the Programme supported the revision of the algorithm known as *Prevention and management of infertility: a guide for reproductive health workers*, which describes the management of infertility in resource-poor settings. The revised algorithm will be evaluated in two countries, one in the African Region and the other in the Eastern Mediterranean Region.

Developments of low-cost assisted reproductive technologies have been followed closely. A draft treatment protocol for low-cost *in vitro* fertilization was prepared by experts at the Monash Institute of Reproduction and Development in Melbourne, Australia, and is being reviewed by the International Federation of Fertility Societies. While the lack of funds has only allowed a marginal contribution of the Programme to this work, the Programme continues to follow the development of the protocol and hopes to increase its involvement at later stages, such as in the final review of the protocol as well as in its field-testing.

The Programme's collaboration with the International Committee on Monitoring Assisted Reproduction (ICMART) continued in 2004 with participation in a regional workshop on monitoring assisted reproductive technologies, which was organized by ICMART and the European Society for Human Reproduction and Embryology in Thessaloniki, Greece, in September 2004.

3.2 Planned activities

3.2.1 Methods of fertility regulation for women

A Phase I trial of the hCG immunocontraceptive will begin in early 2005 as described above.

Acceptability studies show that women need long-acting methods of contraception that do not require daily interventions and that are under the user's control. The vaginal ring is one approach that meets these needs. Most steroid hormones are absorbed efficiently through the vaginal wall and can be released from a Silastic ring. The ring can be easily inserted and replaced by the woman. 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 Population Council has developed a combined contraceptive vaginal ring releasing 150 µg of norgestrel (a progestogen) and 15 µg of ethinyl estradiol daily over the course of a year. Studies evaluating the effects of ring use on clotting factors and liver proteins demonstrated that this ring mimics a third-generation combined oral contraceptive with respect to effects on lipid factors. The Population Council will conduct further clinical evaluation of the ring, with a Phase II run-in to a Phase III trial to begin in mid-2005. The Programme is planning to provide support to one centre to take part in the Phase III trial, beginning in January 2006.

Levonorgestrel-releasing IUDs have the advantage over copper-releasing IUDs of reducing menstrual blood loss and, in time, inducing amenorrhoea in a proportion of users. This is an important consideration, particularly for populations where anaemia is prevalent, such as in developing countries. The only levonorgestrel-releasing IUD available is too expensive for most national family planning programmes, and the Programme is exploring a number of collaboration possibilities in order to develop a low-cost device.

3.2.2 Methods of male fertility regulation

The Programme has developed a Phase II protocol to evaluate the safety and contraceptive efficacy of testosterone undecanoate combined with norethisterone enantate and administered at 8-week intervals as a male hormonal contraceptive. The trial will be funded and conducted in collaboration with the CONRAD programme. In 2004, a confidentiality agreement was signed by the Programme, CONRAD and

the manufacturer as a first step in securing the study compounds. CONRAD is funding a dose-finding trial; results will be available in early 2005 and will be used to determine the dose to be evaluated in the study. A 2005 start date is anticipated.

3.2.3 Long-term safety and efficacy

The study on implantable contraceptives for women will continue, with an expected completion date in 2007. Follow-up of women participating in the trial of bone mineral density and progestogen-only contraception will continue through 2008.

The final data are being prepared for publication in 2005 of 10 years' experience with the Multiload (ML) 375 copper-releasing IUD and on seven years of use with the 20 µg levonorgestrel-releasing device, each compared with the TCu 380A in separate randomized studies.

4. OBJECTIVE: TO STRENGTHEN HEALTH MANAGEMENT AND SUPPORT SYSTEMS

Under this objective, the Department seeks to assist countries in adopting, adapting and implementing WHO guidelines.

4.1 Progress

4.1.1 Decision-making tool: adaptation and training

Following field-testing of the *Decision-making tool for family planning clients and providers*, several of the countries and agencies who aided the testing adopted the tool for use in their programmes. The Department has provided technical assistance for the adaptation and implementation process in Indonesia, Nicaragua and South Africa, and has helped the International Planned Parenthood Federation (IPPF) by providing training to introduce the tool globally.

In Indonesia, the tool was adapted by the Sustaining Technical Achievements in Reproductive Health/Family Planning programme of JHU–CCP in collaboration with the National Family Planning Coordinating Board, the Ministry of Health and other partner organizations. The tool has now been adopted as a national standard for counselling and will be undergoing pilot implementation supported by The World Bank. It will also be used as part of the quality standards kit for the private midwife programme and will be integrated into counselling training by the two largest organizations providing family planning services in Indonesia.

In Nicaragua, JHU–CCP—in collaboration with Family Health International, the Institute for Reproductive Health at Georgetown University and the Austria Cooperative—is conducting an impact evaluation of the tool in Nicaragua. The tool was first adapted through a participatory process involving the Ministry of Health, Profamilia, UNFPA, the Pan American

Health Organization and other family planning experts and agencies. The study involves 100 providers at 50 clinics, and it will provide quantitative and qualitative data on the impact of the tool on the quality of counselling, client satisfaction and method continuation.

Activities undertaken in South Africa are described in section 4.1.2.

The training draft of the tool was introduced into IPPF's quality of care programme in 2004. A global training of trainers was held in London in April 2004, and regional training sessions will be conducted to introduce the tool to family planning providers in 34 countries. IPPF is translating the tool into Bengali, Nepali and Urdu. In selected countries, the use of the tool will be monitored by IPPF Member Associations as part of their own programmes.

4.1.2 The WHO/UNFPA Strategic Partnership Programme

The Promoting Family Planning Team has been contributing to the WHO/UNFPA Strategic Partnership Programme (SPP). This programme is instrumental in the effective dissemination and utilization of the Department's evidence-based guidance.

During 2004, three of the four cornerstones of evidence-based guidance for family planning have been promoted through the partnership: *Medical eligibility criteria for contraceptive use*, *Selected practice recommendations for contraceptive use* and the *Decision-making tool for family planning clients and providers*.

The Team assisted in planning and implementing regional workshops in the African, Eastern Mediterranean, European, South-East Asian and Western Pacific Regions. As a result, staff from WHO Regional Offices, UNFPA Country Support Teams and country programmes have developed greater awareness of the Department's family planning guides and greater motivation to implement their recommendations. The workshops were conducted using a participatory approach that included interactive presentations, games and exercises on the use of the guidelines.

Action plans drafted by country teams during the workshops included practical activities for incorporating the family planning guidance into national guidelines, training and supervision. The action plans also focused on effective dissemination including the need for translation into local languages. Countries were encouraged to develop proposals for the implementation of their action plans. The following countries have submitted proposals that include a special focus on the family planning guidelines: Benin, Cameroon, China, Nigeria, the United Republic of Tanzania, Turkmenistan and Zambia.

As part of the Strategic Partnership's activities, the Team is supporting the Reproductive Health Research Unit of the

Department of Obstetrics and Gynaecology at the University of the Witwatersrand in South Africa to introduce the *Decision-making tool for family planning clients and providers*. This experience in South Africa is expected to be of benefit to the sub-Saharan African region. The project will:

- field-test the South African adaptation of the tool, pilot its implementation and scale up dissemination;
- document the in-country adaptation process so that lessons learnt can be disseminated to other countries embarking upon the process of adapting and implementing the tool.

Also as part of the Strategic Partnership's activities, the Team is supporting the East European Institute for Reproductive Health in Romania as it undertakes a survey on the attitudes and perceptions of physicians who have received copies of *Medical eligibility criteria for contraceptive use* and *Selected practice recommendations for contraceptive use*. The survey will evaluate the content and usefulness of the guides as well as their impact on the quality of services offered, and it will contribute to evaluating the impact of the dissemination, adoption and introduction of these guidelines.

4.2 Planned activities

During 2005, the Department will continue to assist in adapting guidelines. It will continue to support the Strategic Partnership's activities by:

- contributing to the planning and facilitation of a workshop planned in Cairo for the Eastern Mediterranean Region in January 2005, which will be the last in the first series of SPP regional workshops;
- providing technical support to WHO Regional Offices, UNFPA Country Support Teams and countries themselves in the implementation of action plans;
- facilitating the availability of the WHO family planning guides in various languages as required;
- providing updates on information relevant to family planning guidance to WHO Regions, UNFPA and countries;
- assisting in global activities undertaken by the Strategic Partnership's core group at WHO Headquarters in Geneva.

5. OBJECTIVE: TO FOSTER AN ENABLING ENVIRONMENT AT THE GLOBAL LEVEL THAT IS SUPPORTIVE OF FAMILY PLANNING

In working towards meeting this objective the Department aims to monitor reproductive health around the world. In 2004, the work focused on infertility.

5.1 Progress

Under this objective, the Department, in collaboration with ORC Macro, completed and published a study on infertility. The study utilizes data from 47 Demographic and Health Surveys in developing countries and provides information on levels of infertility, trends, and differentials in the inability to bear children. The level of infertility in a population has important demographic and health implications for countries and can have serious emotional consequences for people who are infertile. The study estimates that, in 2002, there were more than 186 million ever-married women of reproductive age in developing countries (excluding China) who were infertile because of primary or secondary infertility. This number represents more than one quarter of ever-married women of reproductive age (15–49 years) in these countries. However, using comparable data the study found that infertility, both primary and secondary, has declined in most countries. There is no obvious pattern to the change in levels of infertility among countries most affected by HIV.

The study also examined some of the consequences of infertility and the coping mechanisms used by couples affected by infertility. Women who were unable to have children were much more likely to be divorced or separated, and childless women were also more likely to have been married more than once. Adoption seems to be a primary means of coping with childlessness, and childless women are 15% more likely to live in a household with an adopted child than are women who have given birth. In five West African countries, more than half of childless couples live with adopted children.

5.2 Planned activities

The relationship between the level of primary and secondary infertility and the prevalence of different types of sexually transmitted infections will be examined in the coming year.

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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					
<i>from:</i>							
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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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	2	29			5	71	7
Women	1	14			3	43	4
<i>from:</i>							
AFRO							
AMRO	2	29			2	29	4
EMRO							
EURO					3	42	3
SEARO							
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	2	50	1	25	1	25	4
Women	1	25			1	25	2
<i>from:</i>							
AFRO							
AMRO							
EMRO							
EURO			1	25	1	25	2
SEARO							
WPRO	2	50					2

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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
<i>from:</i>							
AFRO							
AMRO					3	30	3
EMRO							
EURO			1	10	3	30	4
SEARO	1	10					1
WPRO					2	20	2

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

Collaborating agency scientists

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Annex 1f

RESEARCH GROUP ON METHODS FOR THE REGULATION OF MALE FERTILITY**Members**

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 Christina Wang, Harbor-University of California at Los Angeles Medical Center, Torrance, CA, USA
 Frederick Wu, University of Manchester, Manchester, UK

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	4	29			10	71	14
Women	1	7			2	14	3
<i>from:</i>							
AFRO	1	7					1
AMRO					3	21	3
EMRO							
EURO					6	43	6
SEARO	2	14					2
WPRO	1	7			1	7	2

Sub-Committee for the review of male basic science research

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Annex 2a

RESEARCH GROUP ON POST-OVULATORY METHODS FOR FERTILITY REGULATION

Scientists in 2004

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	5	83			1	17	6
Women	4	67			1	17	5
<i>from:</i>							
AFRO							
AMRO	2	33					2
EMRO							
EURO					1	17	1
SEARO							
WPRO	3	50					3

Other scientists

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	6	55	1	9	4	36	11
Women	2	18			2	18	2
<i>from:</i>							
AFRO							
AMRO	1	9			1	9	2
EMRO							
EURO			1	9	3	27	4
SEARO	2	18					2
WPRO	3	27					3

Annex 2b

RESEARCH GROUP ON IMMUNOCONTRACEPTIVES

Scientists in 2004

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	
Members					3	100	3
Women							
<i>from:</i>							
AFRO							
AMRO					3	100	3
EMRO							
EURO							
SEARO							
WPRO							

Other scientists

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

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

Annex 2c

RESEARCH GROUP ON LONG-ACTING SYSTEMIC AGENTS FOR FERTILITY REGULATION

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 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	
Members	6	75			2	25	8
Women	5	63			1	13	6
<i>from:</i>							
AFRO							
AMRO	2	25					2
EMRO	2	25					2
EURO							
SEARO	1	13					1
WPRO	1	13			2	25	3

Other scientists

Frank Álvarez, PROFAMILIA, Santo Domingo, Dominican Republic
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 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	
Members	3	50			3	50	6
Women	1	17			3	50	4
<i>from:</i>							
AFRO							
AMRO	2	33					2
EMRO	1	17					1
EURO							
SEARO							
WPRO					3	50	3

Annex 2d

WHO/ROCKEFELLER FOUNDATION INITIATIVE ON IMPLANTATION RESEARCH

Scientists in 2004

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Jayasree Sengupta, All India Institute of Medical Sciences, New Delhi, India

Stephen Smith, Rosie Maternity Hospital, Cambridge, UK

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	
Members	2	33			4	67	6
Women	1	17			1	17	2
<i>from:</i>							
AFRO							
AMRO					1	17	1
EMRO							
EURO					2	33	2
SEARO	1	17					1
WPRO	1	17			1	17	2

Annex 2e

RESEARCH GROUP ON METHODS FOR THE REGULATION OF MALE FERTILITY

Scientists in 2004

Principal investigators

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 Russell Jones, University of Newcastle, New South Wales, Australia
 Eberhard Nieschlag, Institute of Reproductive Medicine, Münster, Germany

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	1	33			2	67	3
Women							
<i>from:</i>							
AFRO							
AMRO							
EMRO							
EURO					1	33	1
SEARO							
WPRO	1	33			1	33	2

Other scientists

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 Bo Li-Wei, Henan Family Planning Research Institute, Henan, China
 Cheng Li-Fa, Henan Family Planning Research Institute, Henan, China
 Trevor Cooper, Institute of Reproductive Medicine, Münster, Germany
 David Handelsman, University of Sydney, Sydney, Australia
 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
 Liu Xiao-Zhang, Sichuan Family Planning Research Institute, Sichuan, China
 Song Shu-Xiu, Hebei Family Planning Research Institute, Hebei, China
 Tong Jian-Sun, Jiangsu Family Planning Institute, Jiangsu, China
 George Tsagareishvili, Zhordania Institute of Human Reproduction, Tbilisi, Georgia
 Wu Wei-Xiong, Family Planning Research Institute, Guangzhou, China
 Xiong Cheng-Liang, Institute of Family Planning, Tongji Medical University, Hubei, China
 Yao Kang-Shou, Zhejiang Institute of Planned Parenthood Research, Zhejiang, China
 Kathryn Yount, Emory University, Atlanta, GA, USA
 Zhao Heng, National Research Institute for Family Planning, Beijing, China
 Branko Zorn, University of Ljubljana, Ljubljana, Slovenia

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	12	63	3	16	4	21	19
Women	3	16			1	5	4
<i>from:</i>							
AFRO							
AMRO					2	11	2
EMRO							
EURO			3	16	1	5	4
SEARO							
WPRO	12	63			1	5	13

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Chapter 2

Improving maternal and perinatal health

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1. INTRODUCTION

As part of the global effort towards promoting the Safe Motherhood initiative, the Making Pregnancy Safer (MPS) initiative aims to contribute to improving the health of mothers and their newborn children and, in particular, to achieving the related Millennium Development Goals (MDGs).

The MPS initiative addresses the fifth development goal ("Improve maternal health") but is also closely linked to other goals and targets, including those of MDG number 4, which aims to reduce mortality among children aged younger than five years (38% of mortality in this age group is due to perinatal causes). Other MDGs aim to halt the spread of HIV/AIDS, to control malaria, to promote gender equality and empower women, and to eradicate extreme poverty. Public health plays a key part in socioeconomic development, and the health of mothers and their newborn children plays a key part in improving public health. It is with this in mind that WHO has decided to strengthen its support to countries' programmes that aim to improve the health of mothers and their children, and create a new department to be known as the Making Pregnancy Safer Department within the Family and Community Health Cluster. It is anticipated that this new Department, which will come into effect on 1 January 2005, will receive an enhanced budget to meet this ambitious objective. The new Department will work closely with all departments that address related issues including Reproductive Health and Research; Gender, Women and Health; Child and Adolescent Health and Development; departments focusing on infectious diseases (HIV, Roll Back Malaria); and the Department of Health Service Provision, in particular the Department's working groups on human resources for health and health systems, policy and operations. The work undertaken to date by the MPS initiative at country

level, regional level and global level, ranges from research to normative work to community-based interventions and advocacy; this will provide a solid base for the expected move into a more country-focused strategy, which has been proposed by WHO. However, key to achieving success in meeting the new Department's objectives and aspirations will be to further reinforce collaboration between all levels within WHO and with WHO's partners.

Global programmatic efforts to contribute effectively to strategies to reduce mortality and morbidity among mothers and their newborn children have been integrated with research activities by implementing a research programme that is innovative, feasible, collaborative and, most importantly, focused on research in developing countries that addresses the needs of these countries. The priorities of this research programme are to identify knowledge gaps by developing systematic reviews of screening, epidemiology and etiology of important maternal and perinatal pathological conditions. This will ensure that programmatic interventions are targeted effectively. This is the basic principle that guides the development of the research programme, in the context of which more than 450 000 mothers and infants have been studied during the past decade.

2. OBJECTIVE: TO BROADEN THE PROVISION OF QUALITY MATERNAL AND NEWBORN HEALTH SERVICES

Work in 2004 focused on completing the Integrated Management of Pregnancy and Childbirth (IMPAC) tool-set, and important progress has been made. Evaluation of the tool-set has not begun, because this activity will require a specific allocation of funds. The establishment of the "Maternal and

newborn health reference library” will provide the scientific evidence needed to revise and update the tools, in line with WHO guidance on developing guidelines.

2.1 Progress

2.1.1 Standards for maternal and neonatal care

The document *Standards for maternal and neonatal care* complements MPS’s clinical guidelines by providing clinical and health systems recommendations to policy-makers and programme managers. These are provided in the form of standardized evidence-supported statements on the cost-effectiveness and feasibility of interventions; there are also descriptions of actions that can be taken to implement the standards and indicators that can be used to monitor and evaluate each standard. Thirty-two clinical standards for maternal and neonatal care have been completed and peer-reviewed, and the evidence for them has been graded. An additional 12, including seven health-system standards, are in an advanced state of development. The ability of health-care providers to implement the interventions needed to meet the clinical standards in maternal and neonatal health depends upon the state of a number of “enabling conditions” related to the delivery of health-care services. As such, a set of seven health-system delivery standards have been developed; these were reviewed in October 2004 by representatives from WHO Regional Offices, experts in the field of health-quality improvement and standards, and managers of maternal and neonatal health-care services.

Plans have been developed and funds secured to translate the standards into three languages (French, Spanish and Portuguese), to disseminate them at regional level, to work with countries to help them prepare for a standards-setting process and to regularly update the document. This work is also supported by the United States Agency for International Development (USAID), the Australian Agency for International Development (AusAID), The World Bank and the Italian Expertise Fund.

2.1.2 Clinical guidelines

The series of complementary clinical guidelines for the Integrated Management of Pregnancy and Childbirth tool-set has been completed with publication of two clinical practice guides (*Pregnancy, childbirth, postpartum and newborn care: a guide for essential practice* and *Managing newborn problems: a guide for doctors, nurses and midwives*). These two guidelines, together with *Managing complications in pregnancy and childbirth: a guide for midwives and doctors*, have been endorsed by the United Nations Children’s Fund (UNICEF), the United Nations Population Fund (UNFPA) and The World Bank, which have all been sensitized to the need to make concerted efforts to disseminate these materials. The documents have been distributed through WHO Press. A large number of copies have been provided to various tech-

nical meetings and governments. New translations of *Managing complications in pregnancy and childbirth* have been produced in Arabic, Bengali, Cambodian, Mongolian and Vietnamese. *Managing newborn problems* is already available in English and Bahasa Indonesia. A learning package to accompany it is available from JHPIEGO, an international health organization affiliated with Johns Hopkins University.

Among the seven priority countries in the Western Pacific Region targeted by the MPS initiative, five have translated *Managing complications in pregnancy and childbirth* into their languages (Cambodia, China, Lao People’s Democratic Republic, Mongolia and Viet Nam). All seven priority countries have adapted the guide to their own country settings and adopted the guide as their national standard. Wall charts for this guide have been elaborated in Mongolia.

Maternal health programme managers in Viet Nam, 10 Pacific Island countries (the Cook Islands, the Federated States of Micronesia, Fiji, Kiribati, Nauru, Palau, Solomon Islands, Tokelau, Tuvalu, Vanuatu, Western Samoa), Mongolia, Papua New Guinea and the Philippines have had an orientation on how to use *Pregnancy, childbirth, postpartum and newborn care*; China has translated it. A training course on neonatal care using the tool’s approach to classification and decision-making has been developed and conducted in Mongolia, the Philippines and Viet Nam.

The WHO Regional Office for the Americas/Pan American Health Organization (AMRO/PAHO) completed a Spanish translation of *Managing newborn problems* which will be published in 2005.

In the South-East Asia Region, printing and/or dissemination of all three of the guides to all Member Countries is under way. *Managing complications in pregnancy and childbirth* has been translated into Bengali and widely disseminated in Bangladesh. *Managing complications in pregnancy and childbirth* and *Pregnancy, childbirth, postpartum and newborn care* have been translated into the local language and disseminated in Timor-Leste; *Pregnancy, childbirth, postpartum and newborn care* has been adapted and translated into Thai and Korean and has been disseminated in the Democratic People’s Republic of Korea and Thailand. Training manuals for essential obstetric care and neonatal care based on *Managing complications in pregnancy and childbirth* have been developed and are being used in Myanmar.

The results of a pilot validation study of *Pregnancy, childbirth, postpartum and newborn care* conducted in Brazil have been used to finalize validation study protocols of the Rapid Assessment and Management flowchart and the Newborn Examination flowchart. Research teams have been established in Sudan and Uganda to implement the validation studies. It is anticipated that results will be available by the end of 2005, and they will be incorporated into the next edition of the guide.

2.1.3 Estimates of incidence of low birth weight

The first discussions on the need to develop a strategy for prevention of low birth weight began in 2002. At the time, it was recognized that to focus only on low birth weight is limiting. In practice, the issue of concern is the need to optimize fetal development: size at birth reveals only one aspect of this process. A meeting of experts was held in November 2003 to review knowledge about the impact of earlier life events on the neonatal transition, on infant development, cognitive development and on life-long sequelae. The review suggested that a broader characterization of the outcomes of pregnancy is needed. The burden of death and disability as a result of impaired fetal development is high, particularly in developing countries, but it is also of significant concern in developed countries.

As a result of the above review, a document was developed outlining the strategic steps that would need to be taken to address the optimal development of the fetus. The document was reviewed in a biregional consultation of experts in reproductive health and nutrition with representatives from 16 countries of the WHO South-East Asia Region and the WHO Western Pacific Region where the incidence of low birth weight is the highest and thus, concerns about their effect on populations the most pressing. The experts identified region-specific issues related to fetal development as key components of a global strategy for optimizing fetal growth and development. They also defined feasible ways to implement the strategy along with other global and regional strategies (i.e. through existing systems) and identified gaps in knowledge regarding optimal fetal growth and development that could form an agenda for research. Similar consultations with other regions are planned for 2005.

Estimates of neonatal and perinatal mortality have been finalized, taking into account the latest WHO/UNICEF estimates of mortality among children younger than five years. Worldwide, 38% of mortality among under-fives is due to perinatal causes. Its contribution ranges from 25% in countries with the highest childhood mortality to 50% in industrialized countries. Stillbirth is an adverse pregnancy outcome that has not been recognized as an important public health problem although the woman concerned goes through the risk of pregnancy and childbirth without having the child she wanted. Within the next couple of years, WHO plans to publish for the first time country-level estimates of stillbirths. The document will describe in detail the methods used to derive the estimates.

Global, regional and country estimates of low birth weight, developed with UNICEF, are available in a publication that also provides details of the methods used. Globally, less than 40% of neonates are weighed at birth, and thus the rates are the best proxy that can be estimated using current data. The estimates published by WHO are being used in the World Health Report for 2005 and other publications that will appear

in conjunction with World Health Day which, in 2005, has the theme of maternal and child health.

2.1.4 Other reference guides

The development of an antenatal reference guide is in progress, and the first review meeting is planned for early 2005. The first draft of a manual on the management of obstetric fistulae was completed in December 2004.

2.1.5 Action plans for MPS initiative

Technical support has been given to priority countries to develop, implement and evaluate their plans of action for the MPS initiative. In November 2004, the WHO Regional Office for the Western Pacific organized a subregional workshop for the South Pacific on the monitoring and evaluation of maternal and child mortality. AMRO/PAHO worked to improve a maternal mortality surveillance system and to develop and support the collection of baseline data on maternal mortality in Bolivia, Brazil and Guatemala. PAHO and the Latin American Center for Perinatology and Human Development, Montevideo, Uruguay, provided technical cooperation to 15 countries to improve surveillance of maternal and perinatal mortality. In 2004, all necessary steps were taken to carry out a Reproductive Age Mortality Study in the Dominican Republic and in El Salvador in collaboration with the United States Centers for Disease Control and Prevention (CDC). Technical cooperation was provided to create systems that include the development of data-collection forms based on the "three delays" model. (The "three delays" model suggests that pregnancy-related mortality largely occurs as a result of delays in: (i) making the decision to seek appropriate medical help for an obstetric emergency, (ii) reaching an appropriate obstetrical care facility, and (iii) receiving adequate care upon reaching the facility.) AMRO/PAHO also supported staff training and software adaptation. The collaborative effort to provide emergency obstetric care, which has been conducted in various countries, has also reinforced the use of maternal mortality surveillance by including audits of maternal deaths among its key results indicators; teams participating in the collaborative effort collect data on these indicators regularly. Improvements in surveillance have also been facilitated by two tools, one technical and the other policy-related. The first is the technical *Guidelines for maternal mortality epidemiological surveillance* (published by PAHO and CDC in 1996); it has been revised by PAHO based on regional experience and the revised version will be published in 2005. The second is the policy-related tool entitled *Monitoring maternal mortality and morbidity reduction*, which was disseminated to countries starting in 2003.

2.1.6 Other tools

Kangaroo mother care: a practical guide has been translated by WHO into French and Spanish and by other countries into Albanian, Bengali, Indonesian, Italian, Mongolian and Viet-

namese. An essential newborn care manual is close to completion after revisions and field-testing.

The educational modules on safe motherhood, known collectively as the *Midwifery modules: education material for teachers of midwifery* have been revised, as reported previously, so that their guidance is in accordance with that found in *Managing complications in pregnancy and childbirth*; and they have been updated and their coverage expanded. The series now includes a full module on the management of incomplete abortion and care after an abortion. The foundation module for midwives working in the community has been substantially revised to include more elements on HIV/AIDS and human rights as well as ensuring that guidance in the community profiling section is in accordance with *Beyond the numbers: reviewing maternal deaths and complications to make pregnancy safer*. Copies on CD-ROM have been made available to countries developing educational materials and updating training programmes; CD-ROMs have been made available to Afghanistan, Nepal and Sudan to aid in their development of a curriculum for midwives. Translation into French has been completed, and the Portuguese version will be available in hard copy and on CD-ROM in the first quarter of 2005. Hard copies and CD-ROM versions will be distributed at workshops and conferences throughout 2005. The possibility of making these available on the web is being explored. The size and the sometimes complex layout need to be addressed before these versions can be published on the Internet.

AMRO/PAHO organized a meeting with representatives from countries to share and discuss implementation of the new antenatal care model in the Region. The model has been published and disseminated throughout Latin America and the Caribbean.

2.2 Planned activities

The first set of 32 clinical standards for maternal and newborn health care and seven service-delivery standards will be published in the first half of 2005 in hard copy and on a CD-ROM to accompany the 2005 World Health Report. The standards will be available on the Department's web site together with an overview explaining the evidence base and development process as well as the framework for standard-setting and monitoring that is to be used at country level. In addition, regional meetings have been planned to present the document and to help regions prepare for standard-setting and auditing at the national level. A second set of standards will be published in the second half of 2005; these will include, among others, five standards on HIV/AIDS and alternatives to breastfeeding neonates, all of which have been developed in collaboration with the relevant WHO departments.

Although much has already been done to disseminate the clinical guidelines, the Department plans to intensify the programme of translation, adaptation and dissemination through use and evaluation in collaboration with Regional Offices and partner organizations.

The maternal and newborn health reference library, which will be established in 2005 will play a key part in the development and updating of tools and guidelines. In particular, this new tool will allow revisions to *Managing complications in pregnancy and childbirth* to begin; revisions are urgently needed because this manual was first published in 2000 and is widely disseminated and used.

3. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS OR TECHNOLOGIES

The Programme supported research activities in maternal and perinatal health, which are described in this section; these are related to the objective of broadening the provision of quality maternal and newborn health services (see section 2) of the 2004–2005 Programme of Work—that is, improving maternal and perinatal health by widening the range of products or technologies. To meet this objective, activities conducted and/or planned during 2004 were aimed at improving maternal and newborn health by implementing several components:

- evaluating the effectiveness of practices;
- improving the understanding of sociocultural and economic factors influencing maternal and neonatal health care;
- reviewing methodological issues related to maternal and neonatal health research;
- conducting follow-up studies of populations included in pregnancy-related research;
- stimulating fundamental research on obstetric and perinatal problems of global importance;
- mapping the magnitude of maternal ill-health.

All these components have been developed and implemented by conducting research that is based on systematic reviews of the literature. The main research activities recently completed, under way or in preparation are listed in Table 2.1.

3.1 Progress

3.1.1 Evaluating the effectiveness of practices

3.1.1.1 Mandatory second opinion to reduce caesarean section rates

Based on the best available evidence about the effective and safe management of childbirth this randomized controlled study in Latin America was designed to evaluate the effect of establishing a policy requiring a mandatory second opinion before a non-emergency caesarean section was performed. The trial did not demonstrate a clinically relevant reduction in

rates. The main report was published in *The Lancet* in 2004. A new article reporting an analysis of information on global and regional rates of caesarean sections and correlations with indicators of the development of reproductive health-services systems has been submitted for publication.

3.1.1.2 Calcium supplementation during pregnancy to prevent pre-eclampsia

The protective effect of calcium supplementation provided during pregnancy to women with low calcium intake was evaluated in Argentina, Egypt, India, Peru, South Africa and Viet Nam. Data on 8338 pregnant women and their offspring were collected and analysed. The results of the trial suggest that calcium supplementation may have a moderately protective effect on the risk of pre-eclampsia and severe pre-eclamptic conditions and that it could help reduce maternal and neonatal morbidity and mortality. Several papers reporting the results of the main study and of ancillary studies are in press or have been submitted for publication.

3.1.1.3 Cochrane systematic reviews

The systematic review of the treatment of asymptomatic bacteriuria has been updated and was published in Issue 4 of

the 2004 Cochrane Library; it will be included in the *WHO Reproductive Health Library* in 2005.

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

3.1.2.1 Women's and providers' perceptions of quality of antenatal care

An assessment of women's and providers' perceptions of the quality of antenatal care was conducted in tandem with the trial of requiring a second opinion for caesarean section. A paper has been submitted for publication.

3.1.2.2 Economic evaluation of a rational package for antenatal care

This economic evaluation was completed in collaboration with the University of East Anglia, Norwich, United Kingdom, and the London School of Hygiene and Tropical Medicine, London, United Kingdom. The overall aim was to assess whether a new programme of antenatal care tested in the WHO Antenatal Care Trial was more cost-effective than the existing level of services, both for women using the services and for health-care providers. Results of this analysis dem-

Table 2.1. Research activities addressing maternal and perinatal health conducted with leading participation of the Programme, 2001–2005

Research topic	Number of centres	Number of participants	Status
Antenatal care	5	24 678	Published 2001
Prevention of postpartum haemorrhage	9	18 530	Published 2001
Treatment of pre-eclampsia (Magpie trial) ^a	28	10 141	Published 2002
Reduction in unnecessary caesarean sections	5	149 206	Published 2004
Epidemiology of preterm delivery and intrauterine growth restriction	4	38 319	Published 2004
Evaluation of the <i>WHO Reproductive Health Library</i>	2	76 053	Submitted 2004
Primary prevention of pre-eclampsia (calcium)	7	8 300	Submitted 2004
Long-term follow-up of the Magpie trial ^a	19	3375	Submitted 2005
Long-term follow-up of calcium supplementation trials for prevention of pre-eclampsia	2	800	Submitted 2005
Screening and treatment of asymptomatic bacteriuria	4	18 000	Ongoing
Primary prevention of pre-eclampsia (antioxidants)	4	4 150	Ongoing
WHO Global Survey of Maternal and Perinatal Health (pilot phase)	16	150 000	Ongoing
Treatment of postpartum haemorrhage	5	1 400	Starting in May 2005
Secondary prevention of pre-eclampsia (treatment of moderate hypertension)	6	2 000	In preparation
Screening for pre-eclampsia with placental growth factors	7	12 000	In preparation

^a The Programme participated in these trials but did not manage them directly.

onstrate that the main determinants of the average cost of antenatal care are staffing patterns and productivity.

3.1.3 Research methods related to maternal health

During 2004, a paper was published presenting the issues and challenges associated with performing systematic reviews of epidemiological data on maternal mortality and morbidity. This study summarizes the methodological aspects of the WHO systematic review of maternal mortality and morbidity for which more than 65 000 citations were reviewed. A second report on the strategic problems related to the publication of research results by authors from developing countries has also been published. In addition, the methodological issues that occur when comparing systematic reviews of randomized trials and large randomized trials were discussed in a chapter of a book that is in press (see Annex 3: Villar & Piaggio, 2004).

3.1.4 Follow-up studies of pregnancy-related research

A follow-up on infants born to mothers who participated in epidemiological studies is a necessary complement to any research effort aimed at evaluating the long-term outcomes of therapeutic and preventive interventions in pregnancy. Details of some of these follow-up studies are discussed below.

3.1.4.1 Effect of calcium supplementation for mothers on infant growth

Infants born to women enrolled in the calcium supplementation trial in Egypt were followed during the first year of life, and several anthropometrical measurements were taken. The results of this study show evidence that maternal calcium supplementation is associated with better infant growth during the infant's first year.

3.1.4.2 Effect of high calcium exposure in utero on blood pressure during late childhood

This is a prospective 10-year follow-up study of 600 pre-adolescent children born to women enrolled in a previously conducted randomized trial of calcium supplementation during pregnancy. No effect on blood pressure from calcium supplementation was observed during the follow-up period.

3.1.4.3 Follow-up of the Magpie trial

This is a follow-up of children born to mothers enrolled in the Magpie trial, in which magnesium sulfate was used to treat pre-eclampsia. The follow-up study aims to evaluate whether the treatment has any long-term effects on the children. Results are expected to be published by early 2005.

3.1.5 Encouraging research into worldwide obstetric problems

There are three morbidities related to pregnancy that are highly prevalent in developing countries and for which there is little knowledge of pathophysiology on which to base preventive and therapeutic interventions. These are hypertensive disorders of pregnancy, impaired fetal growth and preterm birth. Current interventions consist largely of symptomatic treatment for mothers and intensive care for preterm or growth-impaired infants. It is unlikely that morbidity and costs can be reduced without identifying effective preventive measures; to do so will require considerable efforts to implement basic science research aimed at understanding the pathophysiological process involved. The Programme is coordinating several activities aimed at clarifying the pathophysiology of these conditions.

3.1.5.1 Global Programme to Conquer Pre-eclampsia/Eclampsia

In 2002, in collaboration with a network of institutions in both developing and developed countries, the Global Programme to Conquer Pre-eclampsia/Eclampsia was launched. This is a new comprehensive research and service programme. It is based on the concepts of using systematic reviews and elucidating priority research areas. Two major systematic reviews have been published in the *Journal of Nutrition*, one on screening and treatment and the other on interventions to prevent pre-eclampsia. In addition, the first systematic review on the possible etiologies of pre-eclampsia has been published in *Obstetrics and Gynecology*. In recognition of the work done by the Programme, six investigators and staff members were invited to give a presentation at the November 2004 congress of the International Society for the Study of Hypertension in Pregnancy, the major international forum for research on pre-eclampsia and hypertensive disorders in pregnancy.

Relevant research in this area is outlined below.

- An overview of systematic reviews of randomized clinical trials has been published in *Seminars in Nephrology*; this presents the most up-to-date revision of all strategies to treat and/or prevent pre-eclampsia.
- WHO conducted a systematic review of methods used to screen for pre-eclampsia. The review assessed the usefulness of clinical, biophysical and biochemical tests in predicting whether a pregnant woman would develop pre-eclampsia. As of 2004, the conclusion is that there is no clinically useful screening test to predict the development of pre-eclampsia and that prospective, longitudinal studies are needed.
- Work on the systematic review of the etiologies of pre-eclampsia led to the drafting of four papers; one of them focused on the role of homocysteine in the pathophysiol-

ogy of pre-eclampsia and it has already been published in *Obstetrics and Gynecology*. The use of systematic reviews to evaluate mechanistic, etiological and pathophysiological hypotheses represents a novel approach to identifying promising hypotheses that warrant further research.

- A study assessed the dietary intake of calcium among 767 pregnant nulliparous women in Argentina, Colombia, Egypt, India, Mexico, South Africa and Viet Nam, and a systematic review of studies assessing calcium intake in pregnant women was completed. The results indicate that there is a need to ensure adequate calcium intake among pregnant women, particularly those in developing countries.
- In a prospective study, 12 000 pregnant women from six countries will be enrolled to determine gestational patterns of urinary placental growth factor throughout gestation and its contribution to the pathogenesis of pre-eclampsia. The study protocol is in preparation. If funds are available, the study will be implemented in 2005.

3.1.5.2 Epidemiology of the causes of preterm birth and related outcomes

In 2004, a comprehensive reanalysis of data from the WHO Antenatal Care Trial was conducted to study the epidemiology of the causes of preterm birth and their relation to outcomes in newborns. The study showed that neonatal outcomes in preterm deliveries vary according to clinical presentation, other pregnancy complications and gestational age at delivery. Preterm delivery is also associated with the baby being small for gestational age.

3.1.5.3 Studies on low birth weight and related conditions

- In 2004, data from the WHO Antenatal Care Trial were reanalysed to study the relationship between pre-eclampsia and intrauterine growth restriction. Although these conditions are often considered to be related, the results of the analysis showed that risk factors and outcomes for these conditions may be different.
- The 1995 WHO Expert Committee on Physical Status indicated there was a need for growth reference data that were suitable for international applications. Consequently, WHO implemented a multicentre study in order to develop growth charts for infants and children. An international research effort has been planned, in collaboration with several institutions, to extend the results of the child-growth study to the period of fetal life by assessing fetal growth in utero (using fetal ultrasonography) and at birth (using neonatal anthropometry). As preliminary evidence on which to base a protocol for a multinational study, data on fetal growth collected during two clinical trials were analysed in 2004 to describe and compare patterns of fetal growth in populations in Argen-

tina, Egypt, India and Peru and to relate them to growth references used in clinical practice.

- Identifying genes related to the origin and development of pre-eclampsia, preterm delivery and intrauterine growth restriction could potentially lead to novel methods for identifying women at risk, thus allowing them to be referred in a timely manner and offered appropriate care; identifying genes that play a part in these conditions may also help researchers develop new methods of preventing and treating these conditions. An international research initiative has been launched to develop a large multinational genetic disease study focusing on preterm birth, pre-eclampsia and intrauterine growth restriction.

3.1.6 Mapping the magnitude of maternal and perinatal ill-health

A global effort has been initiated to assess the relation between the quantified burden of disease and services provided in the areas of maternal and perinatal health. This study is known as the WHO Global Survey for Maternal and Perinatal Health. It will help identify the gap between interventions shown to be effective and those actually implemented. A network of randomly selected institutions and geographical areas will be created to collect focused information in order to monitor maternal and perinatal health services worldwide. This network will systematically and periodically conduct a global assessment using a simplified but specific short data-collection instrument. The preparatory phase for this survey started in 2004 in the first two regions (Latin America and Africa). The first study to be implemented under this global network is known as the Mode of Delivery and Maternal and Perinatal Outcomes study. It is under way in Africa (where the randomly selected countries are Algeria, Angola, the Democratic Republic of the Congo, Ethiopia, Kenya, Niger, Nigeria and Uganda) and in the Americas (where the randomly selected countries are Argentina, Brazil, Cuba, Ecuador, Mexico, Nicaragua, Paraguay and Peru). These countries are shown in Figure 2.1.

Data collection, with online data entry, started in both regions in September 2004 and continued for three months. Data management and data cleaning have taken place in Latin America and are under way in Africa. Preparation for implementation of the survey in other regions will begin in spring 2005. Data analysis will be conducted in summer 2005.

3.1.7 Collaborative epidemiological studies

3.1.7.1 Radiation and reproductive health: Semipalatinsk, Kazakhstan

In collaboration with the Institute of Cancer Research in London and the Scientific Research Institute for Radiation Medicine and Ecology in Kazakhstan, the Programme launched a research effort in 2001 to investigate the conse-

Figure 2.1. Countries participating in the WHO Global Survey for Maternal and Perinatal Health



quences for reproductive health of exposure to radiation in the area of Semipalatinsk in Kazakhstan. This area was a nuclear weapons testing site from 1947 to 1989; as a result, there is considerable radioactive contamination of large territories and residents have been exposed to large amounts of radiation. The study is now in its third (last) year. An investigators' meeting was held in Geneva in December 2004. Results will be presented in 2005.

3.1.7.2 Maternal and newborn mortality: Chile

During 2004, a collaboration between the Department and the Chilean Ministry of Health was started to document factors related to the significant reduction in maternal and neonatal mortality that occurred in Chile between 1990 and 2000. Data on approximately 3 000 000 pregnancies and deliveries have been collected by the Ministry of Health and are being analysed. The analysis will focus on temporal trends in mortality and on identifying interventions that have been most cost-effective in producing the observed declines in mortality.

3.1.8 From research to action

The dissemination of research results must have a high priority in order to complement the publication of study results in medical journals. Specifically designed dissemination materials (known as *From research to action*) are produced and actively distributed worldwide to facilitate the translation of research results into clinical and public health practice. Two

examples of successful dissemination strategies being used at country level as tools for effective implementation of best health-care practices are the dissemination packages for the WHO antenatal care model and for the prevention of postpartum haemorrhage; these packages include all literature published by the Department on these topics. During 2004, two new packages (*Nutrition in pregnancy: from research to action* and *Pre-eclampsia/eclampsia: from research to action*) have been added to the series.

3.1.8.1 Dissemination plans

In 2004, extensive dissemination of the results of WHO studies was achieved by giving presentations and training workshops at national and international conferences. In total, 1030 dissemination packages of *Antenatal care: from research to action*, 500 packages of *Preventing postpartum haemorrhage: from research to action* and 417 packages of *Nutrition in pregnancy: from research to action* have been distributed to medical and public health institutions in developing countries.

3.1.8.2 Implementation of the new antenatal care model and online course

The new WHO antenatal care model is at different stages of implementation in several countries; these are Argentina, Australia, Brazil, Bolivia, Chile, Cuba, the Democratic People's Republic of Korea, El Salvador, Ethiopia, Haiti, Oman, Pakistan, Spain, Syria, Thailand and Zambia. In Thailand,

it was introduced in the city of Khon Kaen, where it is being monitored and evaluated. A similar evaluation is going on in Argentina. PAHO presented the model at a conference in Quito, Ecuador, in November 2003. The conference was organized by PAHO, USAID and the MPS initiative, and it was attended by representatives of ministries of health from Latin America and the Caribbean, thus initiating a large-scale introduction of the new model.

To facilitate training and introduction at the health-care level, the new antenatal model has been translated into an online course in collaboration with the Section of General Internal Medicine, Boston University, Boston, MA, USA. The course was piloted in 2004, and 10 participants from WHO collaborating centres took part in the online classes. Because of the success of the pilot run, in April 2005, the online course will be introduced on a larger scale.

3.2 Planned activities

In 2003, the Department's Scientific and Technical Advisory Group (STAG) recommended that priority should be given to research programmes for which results are expected in the near future in order to generate positive interest from donors. In 2004, STAG acknowledged that these recommendations had been adequately followed and suggested that new centres should be included in activities and specific efforts should be made to integrate the work of the research and programmatic components of the MPS initiative. Following those recommendations, seven research activities were planned in 2004 and are at different stages of implementation or preparation. Two of them (one focusing on birth asphyxia and one on maternal and neonatal health and poverty) are being conducted in direct collaboration with the programmatic arm of the newly created MPS Department.

3.2.1 Strategies for routine screening and treatment of urinary tract infections during pregnancy

A randomized controlled trial is being implemented by collaborating centres in Argentina, the Philippines (a new centre), Thailand and Viet Nam (a new centre) to evaluate the most effective strategies for screening, diagnosing and treating urinary tract infections during pregnancy.

3.2.2 Multicentre randomized clinical trial of vitamin supplementation to prevent pre-eclampsia

The cause of pre-eclampsia is thought to be related to oxidative stress that may potentially be reversed by antioxidants (vitamins C and E). The specific aim of this multicentre randomized trial will be to determine whether giving high-risk women daily doses of 1000 mg of vitamin C and 400 IU of vitamin E beginning in the second trimester will reduce the incidence of pre-eclampsia. This will be a collaborative research effort between the Programme and the Maternal and Fetal Research Unit at Guy's, King's and St. Thomas' Medical School in London, United Kingdom.

3.2.3 Analysis of studies of calcium supplementation to prevent pre-eclampsia

This analysis will include three studies to determine the effect of calcium supplementation on (i) fetal growth and placental blood flow, (ii) biochemical markers for hypertensive disorders in pregnancy, and (iii) infant growth during the first year of life. Data collected from these studies are being analysed, and results will be available in 2005.

3.2.4 Treating mild-to-moderate hypertension during pregnancy

Treating mild-to-moderate hypertension has been proposed as a strategy to delay progression to more severe disease. Therefore, a multicentre randomized placebo-controlled trial evaluating the effectiveness of labetalol in treating moderate hypertension during pregnancy is being prepared. After participating in a competitive process, the Programme has been awarded a grant to conduct this study by the British charity the Wellbeing Foundation; the grant was awarded on the occasion of Wellbeing's 40th anniversary.

3.2.5 Birth asphyxia, neonatal mortality and morbidity

Birth asphyxia has been estimated to contribute to approximately 30% of all neonatal deaths occurring in developing countries. Because of the limited data available, and despite its magnitude, this figure is likely to underestimate the true dimensions of the problem. Epidemiological research is needed to estimate accurately the contribution of birth asphyxia to perinatal morbidity and mortality at community level. Thus, the Programme has launched a collaboration with Save the Children's Saving Newborn Lives initiative to develop and validate a diagnostic instrument for birth asphyxia that could be implemented at the community level to estimate rates of mortality and morbidity resulting from this complication in developing countries. A study protocol has been prepared and was finalized during a meeting of experts held in 2004 in Geneva.

3.2.6 Strategies to treat postpartum haemorrhage

A multicentre randomized trial is being planned to evaluate whether misoprostol has additional effects beyond that of conventional injectable drugs in women requiring additional uterotonic drugs after active management of the third stage of labour. The trial will be implemented in 2005 in centres in Argentina, Egypt, South Africa, Thailand and Viet Nam. These centres participated in a previous misoprostol trial and will implement the new study using a similar design.

3.2.7 Capacity building in the context of the global survey

Coordinating centres conducting the WHO Global Survey of Maternal and Perinatal Health in Latin America and Africa are receiving specific training in collecting and managing hospi-

tal data for epidemiological purposes. National coordinators train local hospital staff. Most centres are collaborating with the Programme for the first time.

3.3 The future

By 2003, the Programme and its network of collaborating centres had completed 90% of the maternal and perinatal health research programme approved by STAG for the period 1998–2003. A total of 122 reports were produced and published in scientific journals. The same output of projects, publications and dissemination activities is planned for the next six-year period (2004–2009). Collaborations have been extended in both developed and developing countries, and frequent invitations to meetings and requests for publications testify to the international recognition these efforts have received.

Projects for the future build on previous experience and are specifically targeted towards achieving two of WHO's major priorities: the Millennium Development Goals and the progressive decentralization of activities from the Geneva headquarters to countries that are conducting the research. The Programme has always followed a policy of decentralizing research activities, including for studies related to maternal and perinatal health; the majority of responsibility for the conduct of clinical trials and literature reviews has been assigned to researchers from institutions in developing countries. The coordinating unit in Geneva has had a leading role in producing protocols and scientific reports, coordinating research activities and, importantly, creating effective, mutually satisfactory, and therefore sustainable, collaborations between institutions in developing and developed countries.

4. OBJECTIVE: TO STRENGTHEN HEALTH MANAGEMENT

In 2004, the MPS initiative continued its efforts to identify key issues in the management of maternal and neonatal health services, to develop guidance and provide technical support in the planning and management of quality maternal and neonatal health services, and to ensure that these services are accessible to all, especially those who are poorer and underserved by health-care services.

4.1 Progress

4.1.1 *Beyond the numbers*

Beyond the numbers: reviewing maternal deaths and complications to make pregnancy safer was published and introduced to the public on 29 September 2004 in Nairobi, Kenya, where the finalized printed version and a CD-ROM of sample questionnaires were presented to a gathering of partners, policy-makers, programme managers and journalists. The launch was accompanied by a workshop designed to train experts from different WHO regions in the methods described

in *Beyond the numbers*. A global database of ongoing audits and experiences will be developed and made available on the web in 2005.

The WHO Regional Office for the Americas has been revising its manual for maternal mortality surveillance to incorporate the content and methods of *Beyond the numbers*. A global partnership of interested agencies and organizations has also been established to build on the strengths and experiences of those involved with *Beyond the numbers* and to develop a coherent global approach to maximizing the effective use of resources and skills and to avoid duplicating efforts.

In the South-East Asia Region a self-learning guide has been developed in Indonesia; it is adapted from *Beyond the numbers* and from the distance learning course on maternal and perinatal health that has been developed in and run from South Africa. Pilot-testing of methods of reviewing maternal deaths is ongoing in Bangladesh, India, Myanmar and Nepal.

Work on developing methods from *Beyond the numbers* is ongoing in 11 English-speaking countries; this work is being done in collaboration with the East, Central and Southern Africa Association of Obstetrical and Gynaecological Societies (ECSAOGS) and UNICEF. The work started with the French-speaking African countries in Bamako, Mali, in 2003 and will continue with a workshop to be held in 2005 in Cotonou, Benin, in collaboration with UNICEF, the African Society of Obstetrics and Gynaecology (SAGO) and the "Amélioration de la qualité et de l'accès aux soins obstétricaux d'urgence" project (AQUASOU). In the Western Pacific Region, facility-based reviews of maternal deaths have started in Mongolia and are supported by an expert consultant. The WHO Regional Office for Europe has conducted, with support from headquarters, a workshop involving six countries (the Republic of Moldova plus the five Central Asian Republics) to introduce the methods described in *Beyond the numbers*.

4.1.2 *Making pregnancy safer planning guide*

The *Making Pregnancy Safer planning guide* was revised in 2004 and a new version will be finalized, along with a workshop manual, in 2005. The guide is intended to assist district managers and planners in preparing for and implementing the Making Pregnancy Safer initiative. This guide will include information on health-systems issues and evidence-based interventions related to maternal and neonatal health services. It will focus on how to select the most relevant programming processes, methods and tools for each system and on how to adapt these to meet the needs found in the local context. Guidance on planning processes, including budgeting, monitoring and evaluation, will also be included.

A situation analysis framework on maternal and neonatal health, designed to be used by managers, has been developed and will be included in the planning guide. The framework focuses on key health-systems issues. It will enable

managers to identify the managerial needs of health teams and to assess capacity-building opportunities for strengthening management and leadership, especially as they relate to key maternal and neonatal health issues. Included in the framework is an overview of all WHO guidelines and tools that are or will be available shortly.

4.1.3 Guide for programme monitoring at district level

A meeting was held to advance work on a guide to monitoring district-level programmes in maternal and neonatal health; the guide is designed to meet the needs of member countries in the South-East Asia Region. A group of experts developed criteria that can be used to select indicators to allow monitoring of availability, accessibility, utilization, continuity, quality of services and selected outcomes. For the four components of maternal and neonatal health services (antenatal care, childbirth care, emergency obstetric care and postpartum care) more than 30 indicators were identified. Data for these indicators are available from routine service data, reviews of records and household surveys. The monitoring indicators were divided into three groups: core, highly recommended and optional. The proposed core indicators are:

- proportion of deliveries attended by skilled birth attendant
- availability of a functioning emergency obstetric facility in the district
- numbers and places of maternal and neonatal deaths and stillbirths.

The other indicators can be used to provide second and third layers of information, thus enriching information on the district situation. The group also identified some important issues that are in need of immediate review and guidance, such as how to monitor equity of access, how to determine the costs of maternal and neonatal services, how data can be used from surveys conducted by the Evidence and Information for Policy Cluster on maternal and child health services or activities outside the health sector (registration of births, deaths and pregnancies), and the availability of midwifery schools. A research agenda was proposed that included monitoring referrals from primary care to higher levels of care, examining the sustainability of services and postpartum care and determining how to make inferences from process indicators to outcome indicators. The agenda also included specific topics such as the use of active management during the third stage of labour and monitoring interventions in areas where there is a significant prevalence of malaria, syphilis or HIV.

4.1.4 Perinatal death review manual

A manual describing how to conduct a review of perinatal deaths and complications will be developed during 2005. It will be integrated into *Beyond the numbers*. A technical consultation was held in Geneva in September 2004 to agree

upon the content and scope of the manual as well as to develop the first outline.

4.1.5 Essential health technology package

The Making Pregnancy Safer essential health technology package is a software tool available on CD-ROM that facilitates the analysis of resources and the technologies required to deliver the key maternal and neonatal health-care interventions in the IMPAC tool-set. It builds on the *Mother–baby package: costing spreadsheet* and is being developed in collaboration with the Department of Health Systems, Policies and Operations and the WHO Collaborating Centre for Essential Technologies in Health at the Medical Research Council in South Africa. Clinical experts from all six WHO regions reviewed the clinical scenarios and the related procedures, techniques and technologies at a meeting held in November 2004 in Geneva. The resource planning and management aspects of the tool will be technically reviewed by health-care managers in the early part of 2005.

4.1.6 Human resources management

In 2004, in collaboration with the Nuffield Institute for Health at the University of Leeds, Leeds, United Kingdom, the Making Pregnancy Safer initiative developed a conceptual framework for workforce planning in maternal and neonatal health services. This framework can be used to determine:

- the likely demand for skilled care for mothers in terms of the volume and variety of care;
- the standards of care that need to be met;
- the number of hours of care by skilled birth attendants (and, later, medical skills) required to meet that demand and to meet defined standards of maternal and neonatal care.

The framework and a detailed report will be discussed with technical experts from all six WHO regions during 2005.

Using the workforce staffing framework, estimates have been developed to calculate the number of skilled birth attendants needed to obtain 95% coverage of midwifery services in developing countries. These calculations are part of the scaling-up estimates to be published in *The World Health Report 2005: making every mother and child count*. In the South-East Asia Region, a regional workshop on family planning, sexually transmitted infections and the availability of skilled attendants at birth addressed the importance of human resources and quality of services in maternal and neonatal health. In Nepal, a framework is being developed for a human resources strategy to provide maternal and neonatal health services. In India, plans have been drawn up to address the availability of skilled care during birth and to make this care more accessible.

A number of countries face shortages, maldistributions or poor deployment of front-line health-care providers with midwifery skills and thus are looking for ways to strengthen their capacity to provide midwifery care, especially at the community level. The as yet unpublished midwifery tool-kit on guidelines for strengthening midwifery, a joint publication with the International Confederation of Midwives (ICM), has been used in a number of settings to help frame the agenda, undertake a rapid assessment of a country's situation and plan activities at both regional and country levels. For example, in September 2004, the WHO Regional Office for Africa, with support from headquarters, held a workshop jointly funded with ICM for 11 English-speaking countries with high maternal mortality. Participants discussed, reviewed and developed actions to strengthen the education, regulation and practice of midwifery in their countries. The tool-kit was used as a resource during this workshop. Similar work is under way in Latin America. At country level the tool-kit has been used to identify priority areas for action in Nepal and Sudan. The tool-kit will be available for distribution in 2005.

In the Western Pacific Region, the case of the Philippines illustrates the MPS initiative's efforts to improve the skills of midwives and obstetricians. After adapting *Pregnancy, childbirth, postpartum and newborn care* to the national context and launching it with national professional associations and UN sister agencies, the Ministry of Health developed a training curriculum based on the guideline and used it to train health professionals at provincial and district levels. The "training of trainers" to improve the skills of the health personnel was conducted at Fabella Hospital in Manila and lasted for two weeks. Additionally, a course on neonatal care, based on the guide, was also introduced in the country.

In the South-East Asia Region, evaluation studies on in-service training programmes for skilled birth attendants in Indonesia and pre-service training programmes for skilled attendants in Bangladesh were conducted with the support of partners and headquarters. In Indonesia, a clinical performance development management system was introduced in selected districts, and a framework for standardization of midwifery education and services was developed in several provinces. An assessment of health facilities for maternal and neonatal services at community and referral levels was conducted in the Democratic People's Republic of Korea. Financial support was provided for training in basic and comprehensive emergency obstetric and neonatal care in Indonesia, the Democratic People's Republic of Korea and Myanmar. In Myanmar, a survey of midwifery practices in the border areas was conducted; manuals aimed at different types of health providers and focusing on post-abortion care were revised; and training in post-abortion care was given to staff who provide basic health care and to private practitioners.

In the Region of the Americas, activities during 2004 sought to improve the skills of providers attending births by providing

pre-service and in-service training and tools and by attempting to increase the number of women who have access to and utilize skilled attendants during their deliveries. Working with the Collaborative Partnership for Nursing and Midwifery, AMRO/PAHO held a series of technical consultations and training workshops focusing on the essential competencies of midwifery (Puerto Rico, 1998), management of postpartum haemorrhage and neonatal asphyxia (Trinidad and Tobago, 2004), midwifery education (Puerto Rico, 1999) and research and practice (Puerto Rico, 2004). The Latin American and Caribbean Regional Interagency Task Force for the Reduction of Maternal Mortality (see section 6.1.1), of which PAHO is the technical secretariat, held a larger technical consultation on skilled attendance at birth in Santa Cruz, Bolivia, in 2003, highlighting the need to broaden the spectrum of appropriately skilled health-care providers trained to offer prenatal, childbirth and postpartum care. Each of the 14 countries in attendance developed a strategic plan and made a public commitment to ensuring universal access to skilled attendance at birth. PAHO also provided technical support to strengthen the development of nursing and midwifery curricula in Bolivia, the Dominican Republic, Ecuador, El Salvador, Haiti and Paraguay.

Efforts have been made to strengthen the management and leadership capacity of maternal and neonatal health teams during planned regional meetings, such as the Reproductive Health Managers' meeting scheduled to be held in the WHO African Region in July 2005, the Reproductive Health Task Force meeting in Harare, Zimbabwe, scheduled for October 2005 and the meeting of the WHO/UNFPA Strategic Partnership Programme in Colombo, Sri Lanka, in August 2005.

AMRO/PAHO provided countries with technical assistance to aid them in using selected emergency obstetric care tools and also continued to support the region's perinatology collaborating centres. Additionally, with support from PAHO, UNFPA and other agencies, evaluations on the use and availability of basic and comprehensive emergency obstetric care were conducted in Bolivia, El Salvador, Honduras and Nicaragua; this led to the reorganization of obstetric and neonatal networks in all nations where the evaluations took place.

Work commenced in Mozambique on developing and applying a costing method for analysing the resource implications of using mid-level providers as a strategy to increase access to maternal and neonatal emergency care. These providers are known as assistant medical officers. Efforts are also being made to assess legal and regulatory barriers to using these providers. Ways to encourage the use of these mid-level providers are also being examined; these include factors that enhance sustainability, such as incentives and fringe benefits or the existence of a career path. This work has been conducted in collaboration with Lund University and the Karolinska Institutet in Sweden. The findings of this study will be made available in 2005.

4.1.7 Health-sector reforms and maternal and neonatal health

An extensive review of the literature on health-sector reforms in maternal and neonatal health was conducted in 2004. This review investigated changes brought about by the great number of system-level and macro-level reforms undertaken across countries and how they affected maternal and neonatal health services. The paper has been peer-reviewed and will be included in the CD-ROM accompanying the 2005 World Health Report. The MPS Department will be taking this work further in 2005 by collaborating with the Policy and Programmatic Issues Team within the Department of Reproductive Health and Research. Another paper has been commissioned by the Department to discuss public and private providers and their coverage, inequities and trends. The paper will provide an overview of evidence on coverage of maternal and neonatal health services by public services and compare this with the rising trend seen in coverage offered by private for-profit and not-for-profit providers. This paper will delineate the implications and characteristics of these trends, especially for members of poor and marginalized groups. The paper will be peer-reviewed in 2005.

The Making Pregnancy Safer web site was expanded in 2004 to include information on health-system issues as well as a link to information on maternal and newborn health and poverty (<http://www.who.int/reproductive-health/MNB/index.htm>). The intention is to have all of the IMPAC management tools and papers on this site as well as on the CD-ROM that will accompany the 2005 World Health Report.

4.2 Planned activities

A number of activities are planned to further disseminate *Beyond the numbers*. These activities include staging a national workshop in the Republic of Moldova arranged by the Regional Office for Europe, follow-up of activities initiated in the Central Asian Republics, a francophone workshop in Benin organized by the Regional Office for Africa and follow-up of activities initiated in English-speaking African countries.

The revised version of the *Making pregnancy safer planning guide* will be finalized and field-tested.

The education and training strategy for making pregnancy safer is being developed; it aims to improve the skills of midwives and obstetricians, and it will be finalized during 2005. A similar workshop to the one conducted for anglophone countries on education, regulation and practice in midwifery is planned in 2005 for francophone countries in Africa. The as yet unpublished Making Pregnancy Safer tool-kit to strengthen midwifery will be used as material for a planned three-region WHO workshop (to include the South-East Asia, Western Pacific and Eastern Mediterranean Regions) aimed at improving the regulation and licensing of skilled birth attendants. This will be a follow-up to the UNFPA meeting in

Islamabad, Pakistan, held in April 2004. An additional tool on supportive supervision is in the planning stages.

Work will begin in early 2005 on a guide to involving communities in assessing the quality of maternal and neonatal health services. Literature reviews will be used to establish a maternal and neonatal health standards package as well as standards related to community engagement and community linkages, which include community involvement in quality processes of the services.

5. OBJECTIVE: TO FOSTER A SUPPORTIVE ENVIRONMENT

The Making Pregnancy Safer initiative recognizes the important role women, their partners, families and communities can have in improving maternal and neonatal health. Key strategies and interventions have been identified, and a strategy paper was developed to support the global Making Pregnancy Safer Team in strengthening this component in regional and national strategies as well as strengthening capacities for implementation. Many of the activities in support of this objective are described below.

5.1 Progress

5.1.1 Handbook for counselling and communication

A *Handbook for counselling and communication in maternal and newborn health* will be a companion to *Pregnancy, childbirth, postpartum and newborn care*. The handbook is designed to improve the communication skills of birth attendants. During 2004, field reviews were conducted in Indonesia, the Philippines and Sudan. Reviews were also sought from experts. Additionally, a meeting was held in December to consider the outcome of the field-test and the expert review and to decide on the next steps. It is expected that the new version of the handbook will be completed in June 2005.

5.1.2 Strategy paper on working with individuals, families and communities

The strategy paper *Working with individuals, families and communities to improve maternal and newborn health* is being translated into Bengali, French, Russian and Spanish. Regions and countries are focusing more attention on this component of national strategies, and work has begun in three regions as outlined below.

A regional meeting in the Americas was held in Ecuador in 2004 with country representatives to discuss models of antenatal care including strategies to increase access and use of services during pregnancy and to improve support and care in the home and in the community. A national meeting was held in Bolivia in 2004, and a meeting is planned for January 2005 in the Dominican Republic.

A plan of work is being finalized to strengthen the capacities of the AMRO/PAHO representatives and their ministry counterparts in the 11 priority countries. This includes a proposal to develop district activities in four countries (Bolivia, El Salvador, Honduras and Paraguay) to strengthen the community component of strategies; activities will use a participatory and interactive approach that involves women and community members. The target populations for these initiatives are the rural and indigenous communities who are recognized as the most vulnerable to maternal mortality in the Latin American and Caribbean areas. This work will receive support at the national and regional levels. The Regional Office for the Americas has ensured that there will be close collaboration with the community component of the Integrated Management of Childhood Illness (IMCI) programme. An Internet community is being established to help groups discuss their experiences. In Paraguay, Stage 1 of the Strategic Approach has been completed; it assessed factors that influence maternal mortality by focusing on family planning and maternal health services as well as on links with the communities. Stage 2 implementation will be linked to the proposal mentioned above.

In the WHO European Region, a national workshop on improving family and community practices in maternal and child health was held in the Republic of Moldova. Recommendations were made about how to integrate a community component into existing national strategies; and assurances were given that coordinated efforts would be made in developing these components. A key recommendation was that a national working group should be formed to act as a coordinating structure to oversee planning, implementation, monitoring and evaluation. A first task of this group would be to elaborate a national plan that will be submitted to the parliament for approval in July 2005. Support is being provided to the Republic of Moldova through the joint efforts of IMCI and the MPS initiative. This was the first joint activity between these two programmes that focused on households and communities. Despite the fact that these initiatives use different approaches, the joint MPS-IMCI workshop was considered useful and could be used as a model for similar workshops elsewhere in the region.

In the African Region, the WHO Regional Office organized a 2-day meeting with participants from 10 English-speaking African countries to discuss a comprehensive approach to improving maternal and neonatal health. The meeting was conducted in collaboration with the Department of Health Promotion and the MPS Team from headquarters. Although many country programmes have initiated activities to increase the use of planning to ensure safe delivery and birth and to cope with emergencies during the antenatal period, to engage communities in improving the health of mothers and children, and to increase the use of services by women, participants agreed that a more strategic and coordinated approach is needed. A regional plan is being developed to strengthen capacities and to implement a comprehensive approach to health care for mothers and neonates in Angola, Burkina

Faso, Mozambique, Nigeria, and in the United Republic of Tanzania in Zanzibar. The African Region's framework for developing community interventions has been translated into French.

To strengthen the body of evidence related to individual, family and community actions for maternal and neonatal health, literature reviews as well as systematization of country experiences are planned. A protocol for a systematic review on interventions to strengthen links between communities and health services is under development.

A systematic review of barriers that prevent skilled attendants from providing community care was initiated in 2004. A protocol has been drafted for the development of a background document using the findings of a literature review on women's, families' and communities' preferences for care during pregnancy, childbirth and the postnatal period. The review focuses on the use of traditional birth attendants and the use of skilled attendants. The findings of the review will inform the debate on women's preferences for the services of a skilled attendant or for those of a traditional birth attendant in situations in which conditions of access are the same. The final review is expected to be completed later in 2005.

In the South-East Asia Region, a number of activities have been launched in the Maldives, including a video spot to promote awareness of maternal health issues and information, education and communication materials on caring for mothers and neonates. Training programmes for health-care providers on health education and promotion have also been launched as has the implementation of nationwide home-based record cards for mothers and infants. In Myanmar, information, education and communication materials on basic obstetric and neonatal care and post-abortion care have been developed, reviewed and revised.

5.2 Planned activities

A steering committee on educational approaches and interdisciplinary approaches to developing education and communication materials will be established in 2005 to guide future work in this area.

6. OBJECTIVE: TO PROMOTE SOUND NATIONAL POLICIES AND LAWS

In 2004, the MPS initiative advanced its agenda of promoting the use of skilled attendants, evidence-based practice and ensuring effective collaboration with key stakeholders to increase access to skilled care for women and neonates, especially among communities whose members may be poor or marginalized. This was achieved through policy reviews, advocacy and collaboration. The Department's MPS Team accelerated the work of gathering evidence on policies and strategies that may improve the provision of maternal and neonatal health services to poorer members of society, which

would improve outcomes and reduce poverty. Policy and advocacy work contributed significantly to the World Health Report for 2005 and to 30 reviews on poverty and maternal and neonatal health, which will provide vehicles for disseminating key messages and evidence-based policy recommendations.

6.1 Progress

6.1.1 Developing regional strategies

The Regional Office for Africa has provided the African Region with a strategy to accelerate progress. The strategy was presented to ministers of health in the African Region in September 2004. The ministers adopted a resolution applying the principles and interventions described in the strategy document and requested a yearly progress report on implementation from their respective countries. The strategy document has already been endorsed by 15 partners including UNICEF and UNFPA, and it has been adopted by 17 countries.

In the Region of the Americas, the regional strategy for reducing maternal mortality and morbidity was approved by the 26th Pan American Sanitary Conference in September 2002. It is now being implemented. This strategy is the result of significant efforts by PAHO and its partner organizations to turn the latest research, information on best practices and experience gained over more than a decade of the Safe Motherhood movement into concrete steps that countries can take to fulfil national plans and work towards achieving MDGs. This new strategy was developed with full participation of the countries in the region. A regional meeting of representatives from ministries of health was convened by PAHO and partners in Washington, DC, USA, in February 2004 in order to disseminate the strategy's key interventions, analyse advances and discuss challenges related to operationalizing the strategy at regional level and at country level.

The Interagency Strategic Consensus for Latin America and the Caribbean was launched by the Regional Interagency Task Force for the Reduction of Maternal Mortality at PAHO headquarters in February 2004; the launch was broadcast over the Internet to 15 countries, many of whom followed the broadcast with their own events to launch national policies along with the regional document. This document represents a common vision on how to address maternal deaths in order to optimize technical cooperation and collaboration within countries and among agencies.

AMRO/PAHO concentrated its efforts on supporting countries in revising and updating their national plans and policies to align them with regional strategy. Countries have also been encouraged to prioritize MDGs within their national development frameworks and programme strategies. At the time of this report, nine priority countries (Bolivia, Brazil, Colombia, Ecuador, El Salvador, Guatemala, Honduras, Panama and Paraguay) had either updated or completed their national

maternal health policies. Nicaragua launched its own version of the strategic consensus document in June 2004, espousing national and interagency commitment to skilled attendance at births and underlining its commitment to providing essential obstetric care to reduce maternal mortality. PAHO continues to provide special support to Haiti to develop and implement its strategic action plan. Over the past five years, PAHO has also supported the establishment of Inter-Agency Coordinating Committees for Safe Motherhood at country level. Ten priority countries, as well as several non-priority countries, now have active coordinating committees whose members include representatives from ministries of health and other ministries, such as education and women's affairs, social security institutes, donor agencies, international and national nongovernmental organizations, and professional organizations. In countries such as Bolivia, Brazil, the Dominican Republic, El Salvador, Haiti, Honduras, Panama and Paraguay, achievements include advocating safe motherhood as a high priority.

The Regional Interagency Task Force for the Reduction of Maternal Mortality includes PAHO, UNFPA, UNICEF, USAID, the Inter-American Development Bank, the World Bank, the Population Council and Family Care International. The task force's main objective is to reduce maternal mortality, generate consensus about strategies to reduce maternal mortality, share lessons learnt at the regional and country levels, optimize financial and technical resources at the country level and support countries in their efforts to reduce maternal mortality. The task force has also collaborated with Family Care International on a case study to highlight the experience, goals, achievements and principal functions of the task force. The case study, published by JHPIEGO, an international health organization affiliated with Johns Hopkins University, will serve as a model for documenting and systematizing practices at country and local levels throughout the region. In addition, task force members agreed by consensus that skilled attendance at birth should be an important focus of the work.

6.1.2 Strengthening policies for skilled attendance

Making pregnancy safer: the critical role of the skilled attendant is a joint statement that was published by WHO, the International Confederation of Midwives and the International Federation of Gynaecology and Obstetrics (FIGO); it was endorsed by the International Council of Nurses in 2004. This document provides an updated definition of a skilled attendant, which has been endorsed by all UN agencies and the World Bank; this endorsement is critical at a time when countries have to report the percentage of births attended by a skilled attendant. The document is especially aimed at countries in which the coverage of skilled attendants at births is less than 85%. It defines clearly who is considered to be a skilled attendant, what skills she or he should have and how she or he should be trained and supported. (The full statement is available on the web at: http://www.who.int/reproductive-health/publications/2004/skilled_attendant.pdf.)

The MPS initiative, in collaboration with the Team for Gender Issues and Reproductive Rights (see Chapter 6, section 3.3), finalized a document provisionally known as "Using human rights for maternal and neonatal health: a tool for strengthening laws, policies and standards of care". This tool will be used to assess the legal, policy and regulatory environments as they broadly relate to maternal and neonatal health. With the support of MPS regional and country advisers, the tool was field-tested in Mozambique in 2004. The review in Mozambique paid special attention to government efforts to provide quality maternal and neonatal health services, particularly to members of poor or marginalized groups. Field-testing has started in Indonesia, and Brazil has expressed interest in using the tool in connection with its national Pact for Maternal and Neonatal Health, which was launched by the President in 2004.

In addition, a review was conducted to analyse the political will for improving maternal and newborn health in 20 countries. The review sought to assess and better understand the political processes that affect countries' progress, stagnation or reversals in efforts to reduce maternal and neonatal mortality. This review was conducted as part of the activities under the Programme's maternal and neonatal health and poverty portfolio (see section 6.1.3). Evidence from this review was used in the 2005 World Health Report and will inform guidance designed to help countries put in place skilled birth attendants for every woman at the time of delivery. A workshop has been conducted in the African Region to assist countries in reviewing and revising their legal and policy environments as they relate to ensuring equitable access to skilled care.

Mapping midwifery services and other providers to produce a global midwifery services database continued in 2004. Few countries have been successful in completing the full data set. It has been difficult to obtain accurate data on the number of skilled attendants in many countries, and few countries are able to give data stratified by professional group. The greatest difficulty appears to be in obtaining the number of medical doctors who have midwifery skills and those with specialist obstetric skills. Moreover, the ability to accurately predict or plan for a skilled workforce to meet national needs to reduce maternal and neonatal mortality and morbidity appears to be lacking in most countries. The template has been useful in identifying data that could help managers of maternal and neonatal health services make evidence-based decisions related to workforce and service planning. This work is being conducted in close collaboration with other departments at headquarters, with regional and country offices, as well as with partners such as the International Confederation of Midwives, the International Council of Nurses, FIGO and relevant nongovernmental organizations.

Early in 2004, a document was developed to delineate what WHO and its partners must do to address human resources issues in order to meet the ambitious ICPD+5 target of 90% of all births being attended by skilled health-care personnel by

2015. The document is provisionally known as "90% by 2015: skilled attendants and human resources needs for achieving the MDGs for maternal and child health". This document has been used as a basis for discussions with countries, partners and donors about human resources issues associated with improving maternal and newborn health. Regional activities are highlighted below. Efforts will continue in 2005 to provide support to regions, countries and professional associations to improve access to skilled attendants as outlined in the WHO 5+5 strategy (http://www.who.int/reproductive-health/mpr/global_action.html) and the joint statement.

A draft document (known as "Human resources needed to provide a continuum of maternal–newborn health care that reaches out to all women") sets out the prospects for developing an effective workforce of skilled attendants to achieve the MDGs on maternal health and child mortality. Using estimates of coverage and existing professional skill levels, evidence on the state of the human resources available is provided as well as an indication of the care preferences of women and their families. The review is in three parts; sections are organized according to the level of skills necessary to provide care to all women and to ensure that care reaches members of poor, marginalized and isolated communities. Evidence is presented on the scale, cost and problems associated with building a workforce of skilled attendants and maximizing the use of non-physicians. The review also discusses the need for care by physicians, and evidence is presented for contexts where there are no skilled attendants, thus addressing the interim role of traditional birth attendants. The paper has been peer-reviewed and is included in the CD-ROM accompanying the 2005 World Health Report.

The MPS initiative is participating actively in the newly established in-house working group on primary care-led health systems, which is designed to strengthen collaboration between the Departments of Reproductive Health and Research, Child and Adolescent Health and Development, HIV/AIDS, Roll Back Malaria and Stop TB with those of Health Systems Policy and Operations, and Human Resources for Health to demonstrate the effectiveness of an integrated approach to improving human resources for primary care and contributing to meeting the MDGs.

6.1.3 Maternal and neonatal health and poverty

Twenty-eight comprehensive reviews of published and unpublished data on the determinants and consequences of poverty on maternal and neonatal health have been undertaken. The reviews seek to document the impact of strategies for alleviating poverty on maternal and neonatal health and survival and on social development in general. An advisory committee has been established and members of this committee were invited to participate in the technical review of the papers. The first review took place in December 2004; eight of the papers were reviewed. The remaining papers will be reviewed at technical review meetings in early 2005. A fact sheet and a poster have been developed to describe the

project. The MPS website has also been expanded to include new tools and a link to the poverty work. An overview of all of the papers can be found at http://www.who.int/making_pregnancy_safer/mdg/en/.

A global database on maternal and newborn health and poverty was developed in collaboration with the Evidence and Information for Policy Cluster. This database will form the basis for recommendations for maternal and newborn health programmes at country level. UNFPA, the World Bank, and the MDG Task Force on Poverty and Economic Development are supporting this initiative. Three review meetings have been scheduled, and this work will be published in the *Bulletin of the World Health Organization* and made available on the web.

6.1.4 Gender-based violence

Gender-based violence has been one of the focus areas of PAHO. Domestic violence and the need to improve maternal and infant health are recognized as global public health problems. The links between them, however, are not well understood. PAHO is therefore developing a research protocol to improve the understanding of the association between domestic violence and maternal and infant health. The protocol will analyse existing data from and/or propose additional quantitative and qualitative studies in Argentina, El Salvador, Guyana and Nicaragua.

6.1.5 2005 World Health Report

The Department's MPS Team made significant contributions to the development of the 2005 World Health Report. The contributions emphasize the importance of providing universal coverage of maternal and child health-care services. Many of the background papers used for the report have been mentioned above and will be included in the accompanying CD-ROM. An extensive review of options for financing maternal and child health-care services was conducted in 2004 and is included in the series of papers on the relationship between maternal and newborn health and poverty.

6.2 Planned activities

In 2005, the MPS initiative will continue to support countries and advocate for improvements in policies related to maternal and newborn health. This will be done specifically with the launch of the 2005 World Health Report and on World Health Day along with the publication of the reviews on poverty and maternal and newborn health. The Programme will use evidence-based information on what works in policy processes and content to encourage countries to review and improve their legal, policy and regulatory framework to better support important interventions. Messages will focus on how countries can ensure there is a skilled attendant at every birth, especially for members of poor and marginalized groups, by improving their human resource policies and plans, implementing quality evidence-based interventions and develop-

ing financial mechanisms to ensure universal coverage of services for all women and their newborn children. Success stories and guidance related to options for financing services will be incorporated in the *Making Pregnancy Safer planning guide*, the 2005 World Health Report and in one of the accompanying policy briefs.

In 2005, the Team for Gender Issues and Reproductive Rights will conclude field-testing of the tool known as "Using human rights to improve maternal and newborn health through a multisectoral approach for strengthening laws, policies and standards of care" in Mozambique and will follow up resulting recommendations. The Team will also complete field-testing of the tool in Brazil and Indonesia. Based on the results of the policy review done in 2004, additional analyses of selected countries will be done to further evaluate the key ingredients of policy success or failure as they relate to attempts to reduce maternal and neonatal mortality. Lessons learnt from this review will be published as a guidance document for developing countries. In addition, the Department will support and participate in a policy meeting to be held in the European Region where, among other reviews, findings from the maternal and newborn health and poverty review, and recommendations from the joint statement on skilled attendants and the 2005 World Health Report will be presented to country delegations.

The MPS Department will complete the mapping of midwifery with data from at least 50 countries.

Efforts will continue to provide support to regions, countries and professional associations to improve access to skilled attendants as outlined in the 5+5 strategy and the joint statement.

The papers on poverty and maternal and newborn health will be finalized in 2005 and provided in a CD-ROM which will accompany the 2005 World Health Report. They will also be available on the web. Plans for 2005 include the development of a full report on poverty as well as publication of a series of papers in the *Bulletin of the World Health Organization*. Additional efforts will be undertaken to promote recommendations for implementing evidence-based approaches to maternal and neonatal health interventions that target members of poor or marginalized groups.

In anticipation of the release of the 2005 World Health Report and to prepare for its follow-up, a meeting with high-level policy-makers from selected countries will take place on 7–8 March 2005 at WHO headquarters in Geneva. The objectives of the meeting are to discuss key policy messages emanating from the 2005 *World Health Report* in light of existing policies on maternal and child health, to examine the implications of these messages for the implementation of interventions and scaling-up of health systems, and to facilitate an exchange between countries on policies related to achieving universal coverage of health care for mothers and children. The expected outcomes of the meeting are the final

policy briefs for the 2005 World Health Report and a renewed commitment from participating countries to implement the recommendations of the report.

A document is being commissioned to give an historical overview of the most common models of maternal and newborn services and the relationships between the different professional groups providing these services. The terms of reference and commissioning for this paper have been completed and the paper is expected to be peer-reviewed and finalized in the early part of 2005.

7. OBJECTIVE: TO ENSURE EFFECTIVE INTERNATIONAL EFFORTS AND COLLABORATION

The work of the Department in this area covers not only clinical but also all aspects of maternal and neonatal health, from health planning and economics to health policy and the empowerment of communities. The Department has established links with other programmes working on health issues affecting mothers and neonates, such as those dealing with health systems, children's health, malaria and HIV/AIDS. Furthermore, the Department has had close working relationships with WHO Regional Offices and many WHO Country Offices, giving WHO a unique advantage in terms of building partnerships and close relationships with ministries of health around the world. The Department is working with partners, academic institutions, ministries of health and nongovernmental organizations to ensure that safe motherhood is kept high on the health and development agenda.

7.1 Progress and planned activities

7.1.1 Partnerships

The Department has continued to develop partnerships with other organizations concerned with improving maternal and newborn health. Hosting the secretariat of the Partnership for Safe Motherhood and Newborn Health at WHO's headquarters was important in this regard. The *Safe motherhood* newsletter will be produced by the Partnership in 2005. The MPS Team is also involved in different partnership task forces including those addressing advocacy, effective interventions and country support. At the same time, the director of the Department of Reproductive Health and Research is a member of the Partnership Steering Committee.

All Regional Offices have worked to develop and strengthen partnerships at the regional level, to contribute to global partnerships and to improve cross-country collaboration and information sharing. The Regional Office for Africa has attended meetings of the Steering Committee of the Partnership. The Regional Office for Europe is working closely with UNICEF in many countries including the Republic of Moldova and the Central Asian Republics.

As the result of the establishment of a new UNICEF team and a meeting held in Geneva in September 2004, UNICEF and UNFPA together with the MPS Team have renewed efforts on their joint project on skilled care. Work with Regional Offices on this project has begun with the aim of adopting the project and selecting countries where collaboration between the three agencies could be successfully strengthened with specific roles delineated for each agency.

Maternal and newborn health is a new component of a collaborative project with UNFPA that hopes to disseminate norms and guidelines produced by WHO and support their use. This work has been developed within the WHO/UNFPA Strategic Partnership Programme.

As mentioned in section 2.1, UNICEF, UNFPA and the World Bank have endorsed the guidelines in *Managing complications of pregnancy and childbirth; Pregnancy, childbirth, postpartum and newborn care; and Managing newborn problems*. WHO is active through the MPS Team in the movement led by UNFPA aimed at ending obstetric fistulae. The Team is producing a manual on fistula management with a first draft expected to be completed in early 2005.

The MPS Team is working with the European Union (EU) within the WHO-EU strategic partnership to establish, together with the Regional Office for Africa and PAHO, a project to accelerate the reduction of maternal and neonatal mortality in seven countries.

The alliance between FIGO and WHO has decided to focus its efforts on human resources. The Team is developing a collaboration with professional associations in Africa (SAGO and ECSAOGS). This work represents an important contribution towards defining the competencies of skilled birth attendants. PAHO has joined forces with FLASOG (the Latin American Federation of Obstetric and Gynaecological Societies), FEPPEN (the Pan-American Federation of Nursing Professionals), FIGO and the International Confederation of Midwives to integrate the idea of reducing maternal mortality into the daily practice of the professionals they represent.

The MPS Team is working with the Commonwealth Secretariat and the British Council to prepare meetings for ministers of health and to develop associated advocacy materials. The Team is also collaborating with the Commonwealth Secretariat to strengthen the role of chief nurses and midwives working at ministerial and policy level in contributing to policy change and in advocating for more skilled attendants. The role of nurses and midwives in providing an appropriate policy and regulatory environment to support those with midwifery skills will be especially important. The Team will participate in a workshop for senior leaders of nursing and midwifery services to be held in Sri Lanka in February 2005.

The MPS Team is collaborating with SAGO and the French government on the AQUASOU project, which aims to provide access to emergency obstetric care in francophone African countries.

Immediately prior to the International Confederation of Midwives Triennial Congress in July 2005 in Brisbane, Australia, WHO, the Confederation and other partners will present a pre-congress workshop on keeping the mother–baby dyad safe. During the congress, WHO, the Confederation and other partners will undertake a number of activities to highlight the need for skilled care, in particular for women and neonates.

The MPS web site, within the Reproductive Health and Research web site (at <http://www.who.int/reproductive-health>), is regularly updated to improve access to all IMPAC documents and information on maternal and newborn health. The number of visitors shows that the IMPAC tools are increasing in popularity.

7.1.2 Monitoring and evaluation

The MPS Team is making efforts to increase the knowledge base and understanding of key elements of health systems including laws, policies and socioeconomic, sociocultural and demographic parameters as a prerequisite to developing and implementing maternal and newborn health programmes. To this end, the Team has created the *Making Pregnancy Safer health systems country profiles* database. Profiles of health systems are being developed in order to build the foundation for monitoring progress and evaluating achievements and to facilitate comparisons within and among countries. Work has continued in collaboration with the Initiative for Maternal Mortality Programme Assessment (IMMPACT) project of the University of Aberdeen in Scotland to finalize the health-system profile template and increase the number of desk reviews, which now include Burkina Faso, Ghana and Indonesia in addition to Ethiopia, Mozambique and Nigeria. The number of countries profiled will increase in 2005, and the profiles will be available on WHO and IMMPACT web sites.

The pilot phase of CALMAT (a guide on the use of indicators for maternal and perinatal health) was completed in 2004, and included the finalization of a demonstration CD-ROM. Plans for 2005 include proceeding with further development of the guide in collaboration with the University of Aberdeen so that tools can be developed to monitor and evaluate national implementation of the Making Pregnancy Safer strategy and maternal and neonatal health programmes. A section on country implementation is an integral part of the Making Pregnancy Safer strategy, which was finalized during the first part of 2004. The MPS Team has also developed a draft monitoring framework of the initiative at global and country levels as well as a monitoring framework of WHO's functions. The finalization and implementation of these frameworks will be completed in time for the launch of the World Health Report in 2005.

The collaboration with IMMPACT has continued by means of consultations on the World Health Report and the writing of a joint review paper on the relationship between poverty and maternal and newborn health. The review paper discusses the contribution health systems make to maternal and neonatal outcomes. This paper is being published in a shortened form in the *2005 World Health Report* as "Explaining variations in maternal, neonatal and child mortality: care or context?". Ongoing discussions on health-systems data collection in IMMPACT countries are regularly held with the head of the IMMPACT health-systems group. Detailed health-systems assessments for all three IMMPACT countries (Burkina Faso, Ghana and Indonesia) have been developed jointly, and special emphasis has been put on assessing the health infrastructure that delivers care to mothers and neonates. These assessments will be posted on the web site.

In order to strengthen the support provided to countries, the MPS initiative plans to create teams of consultants at regional and subregional levels. Orientation and capacity building started in September 2004 with the launch of *Beyond the numbers*. The MPS Team is also making efforts to involve systematically national experts working at country level, especially to adapt and disseminate IMPAC tools. The MPS Team provides financial support to international conferences conducted by ICM, FIGO and SAGO. PAHO and headquarters participated in discussion panels at the FIGO meeting in Chile in November 2003.

7.1.3 Collaboration with other WHO initiatives

Within the Reproductive Health and Research Department the MPS Team contributed to the development of the reproductive health strategy adopted by the World Health Assembly in 2004, to research on HIV issues and to producing *Safe abortion: technical and policy guidance for health systems*. Support was also provided to the Reproductive Tract Infections Team to develop the congenital syphilis elimination strategy, which includes recommendations to increase the access to, and use and quality of, maternal and neonatal services as one of the main pillars of the strategy.

The Team has been working with other departments to ensure that key interventions from other programme areas are appropriately addressed within maternal and neonatal services. In particular, the Team has been working closely with the Departments of HIV/AIDS, Roll Back Malaria and Child and Adolescent Health and Development and other units within Reproductive Health and Research to ensure adequate integration of key interventions into programmes and services for mothers and neonates. The Team has become part of the HIV "3 by 5" country plans in order to ensure, *inter alia*, that activities to prevent mother-to-child transmission are well integrated into maternal health programmes. The Team is also involved in developing a cross-cluster platform for HIV activities in the Family and Community Health Cluster. In line with this effort, learning sites have been established in Mozambique and Uganda to provide guidance on

integrating service delivery for mothers and neonates in the context of HIV/AIDS. In Uganda, this work is closely linked with the implementation of guidelines from *Pregnancy, childbirth, postpartum and newborn care* and scale-up at country level to ensure involvement of stakeholders at all levels of the health-care delivery system.

Indicators for monitoring and evaluating programmes aimed at malaria in pregnancy have been pilot tested in five African countries in collaboration with Roll Back Malaria. A framework for monitoring and evaluating malaria during pregnancy at the health-facility level is being finalized. This framework will complement the document *A strategic framework for malaria prevention and control during pregnancy in the African Region* published by the Regional Office for Africa in 2004 (AFR/MAL/04/01).

The Team is working with the Departments of Essential Drugs and Medicines Policy and Essential Health Technology to harmonize their lists of essential devices and medicines for maternal and newborn health and reproductive health. The Team also works with the Department of Essential Drugs and Medicines Policy, the Programme for Appropriate Technology in Health and other partners to promote access to and use of Uniject, a device for dispensing oxytocin to prevent postpartum haemorrhage. The Team is working with the Department of Essential Health Technology, UNICEF and other partners to improve access to screening tools for anaemia, particularly the haemoglobin colour scale, and is aiding the Department of Essential Drugs and Medicines Policy in revising *The new emergency health kit 1998*, which will be republished in 2005.

7.1.4 Communication and advocacy

A final edition of the *Safe motherhood* newsletter in its present format has been published. The Partnership for Safe Motherhood and Newborn Health is taking over responsibility for the production and dissemination of this newsletter as of 2005.

The Team's strategies for communication and fund-raising are being developed and will be finalized in 2005. This strategy will work across Departments such as Reproductive Health and Research, Child and Adolescent Health and Development and the Evidence and Information for Policy Cluster and will build synergies and ensure coherence with the WHO strategy as a whole and, more particularly, with the reproductive health strategy.

The REDUCE/ALIVE advocacy tool for maternal and neonatal health was developed in Ethiopia and presented to the Parliament. The aim of the tool is to help advance newborn health within existing programmes to meet MDGs for both mothers and their children. Appreciating the magnitude of the problem of maternal and neonatal mortality, the Prime Minister instructed the Minister of Health to ensure that maternal health receives all necessary attention. The document has been translated into Amharic and is to be disseminated at

community level. The REDUCE model in Uganda has been updated to conform to REDUCE/ALIVE, and dissemination to stakeholders has started. The same tool is under development along with national advocacy plans in Ghana and Mali.

AMRO/PAHO has been providing technical support to countries and communities in order to systematically collect information about their experiences in reducing maternal mortality. The lessons learnt will be shared with countries that are working towards this goal. While country studies provide a macro-level perspective on balancing resources to achieve reductions in maternal mortality at national levels, community-based research permits micro-level insights into direct experiences in the field. PAHO plans to continue country-level case studies on maternal mortality and motherhood based on experiences in 11 priority countries. Case studies for Bolivia, Chile, Honduras, Jamaica and Peru are now complete.

Other key activities that have been used to advocate for better care for mothers and their newborn children and to work with the media include:

- launching *Beyond the numbers* in Nairobi in September 2004;
- launching *Making pregnancy safer: the critical role of the skilled attendant*;
- holding regular briefings for journalists at the United Nations office in Geneva, Switzerland;
- building long-term partnerships with the media (discussions have started with the BBC about developing radio and television programmes focusing on maternal and neonatal health);
- building long-term partnerships with stakeholders, such as the Commonwealth Secretariat, NGOs and the private sector;
- appointing Liya Kebede as Goodwill Ambassador for Maternal and Child Health;
- planning to train journalists, in conjunction with the Regional Office for Africa, about issues surrounding maternal and neonatal health.

Annex 1

RESEARCH GROUP ON MATERNAL AND PERINATAL HEALTH IN 2004

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	6	67			3	33	9
Women	2	22			2	22	4
<i>from:</i>							
AFRO	3	33					3
AMRO	3	33			1	11	4
EMRO							
EURO					2	22	2
SEARO							
WPRO							

Annex 2

MATERNAL AND PERINATAL HEALTH RESEARCH

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	32	71			13	29	45
Women	11	24			6	13	17
<i>from:</i>							
AFRO	9	20					9
AMRO	15	33			5	11	20
EMRO	2	4					2
EURO					8	18	8
SEARO	3	7					3
WPRO	3	7					3

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Chapter 3

Controlling sexually transmitted and reproductive tract infections

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1. INTRODUCTION

Sexually transmitted infections (STIs) and reproductive tract infections (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 infection with HIV. Some 340 million new cases of curable STIs are estimated to occur worldwide each year, and many millions of people become infected with incurable viral STIs annually, including an estimated five million people who become infected with HIV. WHO's role in reducing 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 of WHO's STI and RTI work with the transfer of the Sexually Transmitted Infections Unit 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) as they relate to the prevention and treatment of STIs and RTIs and their complications. The Department has identified the need to position STI control as a separate but overlapping component of a comprehensive approach to sexual and reproductive health and HIV control.

In the 1960s and 1970s, STIs were mainly considered from the point of view of their negative impact on fertility and the

stigma associated with being infected; their treatment was a component of family planning and reproductive health programmes. In the 1980s, the prevention and treatment of STIs were identified as key approaches to controlling the HIV pandemic but the focus of many HIV/AIDS programmes has turned to other issues, such as the expansion and sustainability of programmes providing antiretroviral therapies and care, overshadowing the importance of STIs. The need to maintain focus on STI control is even more critical when expansion of programmes to provide antiretroviral therapy to cover three million patients by 2005 (WHO's target as part of the 3 by 5 initiative) is a major objective of the Organization. This expansion of AIDS care must be accompanied by a complementary focus on HIV prevention, of which STI control is one of several key elements. In addition, sexual and reproductive health services offer an opportunity to provide counselling and advice on HIV prevention and to encourage men, women and adolescents to be tested for HIV.

The mandate of the Department in the area of sexually transmitted and reproductive tract infections is to promote and develop guidelines and tools to address STI and RTI policies, programme planning and implementation; establish the evidence for new and improved STI and RTI control strategies; conduct research on the prevention of mother-to-child transmission of HIV and other STIs; and advocate for, and conduct research on, the development and deployment of safe and effective microbicides. In order to fulfil this mission, the Department collaborates with a number of partners within the Organization, and with WHO Country and Regional Offices, international agencies, research networks and nongovernmental organizations (NGOs).

2. OBJECTIVE 1: TO BROADEN THE PROVISION OF QUALITY SERVICES

In order to meet the objective of increasing the availability of high-quality, culturally sensitive, gender-sensitive, non-stigmatizing services to prevent and manage STIs and RTIs and their complications and to care for those who have these infections, our work focuses on the development, adaptation and dissemination of norms and tools based on the best available evidence.

2.1 Progress

One mandate of the Department is to promote and develop guidelines and tools to aid in the effective control, prevention and management of STIs and RTIs in various settings and among different populations. The Department's STI/RTI Team clarified further the strategies for eliminating congenital syphilis and genital ulcer disease through a series of workshops held during 2004. The Team continues to produce and update guidelines and tools to support countries in developing and implementing high-quality programmes and services for STI and RTI control (Table 3.1). This work is carried out through the Department's Strategic Partnership Programme (SPP) with the United Nations Population Fund (UNFPA); the goal of the SPP is to improve the quality and coverage of services in selected partner countries by increasing the use of evidence-based tools and guidelines.

The guidelines reflect a comprehensive view of STI and RTI control that is broader than clinical management; they address population-level factors that impact on sexual and reproductive health as well as commitments made to improving reproductive health at the International Conference on Population and Development in 1994. Work has continued on the completion of guidance that was under development in 2003; further guidelines have been developed for cervical cancer control; and work on guidance for adapting generic guidelines to national or local use has also continued. Guidance focusing on specific population groups (sex workers, adolescents and prisoners) has been updated and an expanded module on counselling has been developed.

2.1.1 Guidelines for the management of STIs and training modules

Altogether, 10 000 copies of *Guidelines for the management of sexually transmitted infections* were printed initially in English, and an additional 5000 have been reprinted in response to demand. Dissemination has been effected through the normal distribution channels of WHO and UNAIDS and in response to specific requests from individuals and institutions. Additional channels used this year were the Implementing Best Practices Consortium and regional and international conferences as well as through regional consultations held as part of the WHO/UNFPA Strategic Partnership Programme. Translations into French, Portuguese and Spanish are under way or have been completed. The training modules linked

to the STI case management guidelines have been updated and an expanded module on counselling has been developed.

2.1.2 STI/RTI guide to essential practice

Sexually transmitted and other reproductive tract infections: a guide to essential practice provides a comprehensive approach to STI and RTI management that has been adapted to meet the needs of clients presenting to reproductive health facilities, who have different patterns of risk factors for, and prevalences of, STIs and RTIs than patients presenting with STI complaints or to specific STI services. The guide covers counselling, prevention, screening, case-finding and management. The development of the guide started in 2002. It was pre-field-tested in Brazil, China, Jamaica, Kenya and Latvia and reviewed by an expert group as well as by country representatives and regional offices.

The last revisions from the reviewers and from the regional workshops held within the SPP have been incorporated. The generic version is now ready and is being translated into Arabic, Chinese, French, Portuguese, Russian and Spanish. Dissemination through introduction and initial country-level planning started with regional workshops organized by the SPP in five of six WHO regions; the workshop in the Eastern Mediterranean Region is planned for 2005.

An adaptation guide has been developed to the draft stage. This guide will include the Department's generic guidance about the process of adaptation and then specify, chapter by chapter, items to be considered when adapting the STI guidelines, as well as the evidence base supporting the development of the guide.

The adaptation and introduction of the generic guide is being evaluated in Kenya in collaboration with the Population Council's FRONTIERS programme and UNFPA. This phase is aimed at developing an adapted version of the guidelines, training materials and a national-level plan for implementation in Kenya.

The following key steps have been achieved in Kenya.

- The initiative is jointly owned by the Division of Reproductive Health and the National AIDS and STD Control Programme within the Ministry of Health.
- There has been buy-in by these key national stakeholders.
- There is national agreement on adopting the guidelines.
- The STI Working Group (previously acting in an advisory capacity to the National AIDS Control Council) has been re-launched as the National RTI Working Group.
- Terms of reference for the National RTI Working Group have been developed; and it will share a joint secretariat

Table 3.1. List of WHO guidelines and tools for STI and RTI control programmes

Documents	Audience	Elements of STI/RTI control covered ^a							
		Assessment	Planning & development	Control strategies	Clinical interventions	Community interventions	Support strategies	Monitoring & evaluation	
Conceptual framework	Programme managers		X	X	X	X X	X X	X X	
<i>RTI/STI programme guidance tool</i>	Programme managers	X X	X X						
<i>STI.PAC: a framework and tools for implementing STI prevention and care</i>	Programme managers	X	X	X	X	X	X	X	
<i>Guidelines for the management of sexually transmitted infections</i>	Programme managers; health-care providers				X X		X X		
<i>Sexually transmitted and other reproductive tract infections: a guide to essential practice</i>	Health-care providers			X X	X X	X	X		
<i>Sexually transmitted and other reproductive tract infections: a pocket guide for essential practice</i>	Health-care providers			X	X X		X X		
Adaptation guidelines	Health-care providers								
Syndrome management training	Programme managers; health-care providers			X	X X		X X		
<i>The male latex condom: specification and guidelines for condom procurement</i>	Management; procurement officers	X					X	X X	
Documents from WHO departments other than Reproductive Health and Research									
<i>Laboratory diagnosis of sexually transmitted diseases</i>	Clinical and medical microbiologists							X X	
<i>Guidelines for sexually transmitted infections surveillance</i>	Ministries of health; programme managers; surveillance officers	X							X X
<i>Initiating second-generation HIV surveillance systems: practical guidelines</i>	Programme managers; surveillance officers	X							X X
<i>Managing drug supply</i>	Programme managers	X					X		X X
<i>National AIDS programmes: a guide to monitoring and evaluation</i>	Surveillance officers; programme managers	X							X X
<i>Estimation of the incidence and prevalence of sexually transmitted infections</i>	Surveillance officers; programme managers	X							X

^a X indicates that the issue is addressed; XX indicates that the issue is treated in-depth.

with the Division of Reproductive Health and the National AIDS and STD Control Programme.

- Task teams have been set up to address issues around integration, service delivery, training, adaptation, supervision, monitoring and evaluation, and communication.
- Agreement has been reached on plans and timelines for the task teams.
- A proposal is under development for a second phase that will test the adapted guidelines in rural and urban demonstration settings prior to wide-scale implementation.
- Documentation of the process has been undertaken.

2.1.3 Strategic Partnership Programme

WHO and its partners are actively engaged in using research to identify possible solutions to sexual and reproductive ill-health and to supporting countries in their efforts to provide quality services that respond to people's needs. Generating research-based evidence culminates in the production of consensus-driven normative guides for implementation of best practices at country level. However, country-level implementation is often not systematic. Evidence suggests that there is a gap between the knowledge generated and the application of this knowledge in practice. Therefore, the Strategic Partnership Programme between UNFPA and the Department has been initiated to promote the introduction, adaptation and adoption of practice guides developed by WHO that are designed to promote sexual and reproductive health at national and subnational levels. The normative and scientific functions of WHO are complemented by UNFPA's network of Country Support Teams and links with implementing partners. The SPP offers a unique opportunity to strengthen the technical links between guideline development and actual utilization.

The primary objectives of the SPP are to systematically introduce to countries practice guides that have been developed to improve the quality of sexual and reproductive health services and to enhance country-level, regional-level and headquarters-level linkages and collaborative networks to promote harmonized messages on adopting the best practices for improving reproductive health.

2.1.3.1 Progress

Initial work within SPP related to STIs and RTIs and to family planning guidelines. The workshops were conducted with WHO Regional Office staff, UNFPA Country Support Teams, WHO and UNFPA country officers as well as national programme officers responsible for STIs and reproductive health. The guidelines (and primary changes in revised versions) were introduced, and small-group work allowed participants to gain familiarity with the new guidelines and

revised sections. A plan of action for adaptation and use in each country was developed during each workshop. Upon receipt of finalized proposed plans of action, approval was given to approximately 10 countries; these countries will be given more intensive focus and will receive financial and technical assistance consistent with their needs and plans. A situation analysis is one of the first steps of the process in all countries. An instrument has been developed to support this work and assist in monitoring and evaluating it.

The STI guidelines were also introduced to participants at the launch of the Implementing Best Practices Initiative in Uganda in June 2004. Funds from the SPP will provide partial support to the operations research that is being undertaken with the FRONTIERS programme and the Department, as described above in section 2.1.2.

2.1.4 Cervical cancer

The development of *Comprehensive cervical cancer control: a guide for essential practice* was initiated in 2003 by the Department and the WHO Cancer Control Programme in partnership with the Alliance for Cervical Cancer Prevention (ACCP), the International Atomic Energy Agency and the WHO International Agency for Research on Cancer (IARC).

The cervical cancer guide has taken the health-care provider's perspective; each chapter includes specific activities to be implemented at different levels of health care (community, primary health care, district or regional hospital, central or referral hospital). The procedure sheets included as annexes to the guide can be used separately as job aids. The guide covers anatomy and physiology, prevention, counselling and health education, screening, treatment of pre-invasive disease, treatment of invasive disease and palliative care.

A draft version of the guide was sent for external review in June 2004 to approximately 50 experts including partners in the initiative, the International Federation of Gynaecology and Obstetrics, the International Gynecologic Cancer Society, NGOs involved in cervical cancer control in developing countries, country representatives and other international experts. Proposed changes were reviewed during the core group meeting in September 2004, and the revised draft will be available for pre-field-testing in early 2005.

Additional work done by the Department in 2004 in relation to cervical cancer includes the following projects.

- *Cervical cancer prevention in developing countries* was published. This is a review of screening and programme strategies developed in collaboration with ACCP and published as an occasional paper. It provides practical information for programme managers and policy-makers on launching or improving screening programmes for cervical cancer.

- The report of a consultation held by the Department and the WHO Cancer Control Programme has been published as *Cervical cancer screening in developing countries*. This report documents the discussions and findings from the consultation and addresses (i) the programmatic research necessary to improve programme efficiency, (ii) visual inspection with acetic acid as an alternative approach to cytology screening in low-income countries, and (iii) the use of human papillomavirus (HPV) tests in cervical cancer screening programmes and their possible role in middle-income countries.
- The Department was also involved in the review and subsequent endorsement of the ACCP document *Planning and implementing cervical cancer prevention and control programs: a guide for managers*. This generic manual responds to the challenge of moving from policy to organizing, implementing and monitoring newly developed programmes or improving existing cervical cancer prevention and control programmes. It complements WHO's managerial guidelines on national cancer control plans and WHO publications on the evidence for cervical cancer screening in developing countries as well as the IARC monograph on cervical cancer screening and the forthcoming WHO guide on essential practice in cervical cancer prevention and management for health-care providers (*Comprehensive cervical cancer control: a guide for essential practice*). The ACCP manual is part of a comprehensive resource package using current evidence and encompassing policy, clinical practice and service delivery to improve cervical cancer control. It is available in English, French and Spanish.

2.1.5 STI services for adolescents, sex workers and prisoners

2.1.5.1 Adolescents

Collaborative work with the Department of Child and Adolescent Health and Development (CAH) together with the German Agency for Technical Cooperation (GTZ) has produced *Sexually transmitted infections among adolescents: the need for adequate health services*. This document reviews the literature on experiences in providing services for STIs to adolescents. It was commissioned by GTZ to clarify the advantages and disadvantages of different options for service delivery for detecting and treating STIs. It summarizes both published and unpublished reports of programmes' experiences worldwide, including public and NGO health services that are adolescent-friendly, reproductive health clinics and multi-purpose centres for young people, school-based or linked services and community-based and private sector services. The document has now been finalized and it is ready for publication with the support of GTZ.

Sexually transmitted infections: issues in adolescent health and development (from the WHO Discussion Papers on Adolescence series) has been published. It was jointly prepared

by CAH and the Department. This document covers adolescent-specific issues around STIs including HIV infection, the risks of STIs and HIV among adolescents, and how to tailor diagnosis and management to the needs of adolescents. Additionally, it explores the potential to influence behaviour and treatment-seeking practices at the outset of young people's sexual and reproductive lives.

2.1.5.2 Sex workers and prisoners

Owing to resource constraints the work on guidelines on STI prevention and management for sex workers and prisoners has not commenced. However, GTZ and WHO, in collaboration with networks of sex workers around the world, launched the first ever online tool-kit aimed at helping sex workers protect themselves and their clients from infection with HIV and other STIs (*World Health Organization sex work toolkit*, available at <http://www.who.int/hiv/toolkit/sw>). The tool-kit is intended to be used by programme managers, field workers and peer educators who work with female, male and transgender sex workers. It is a collection of more than 130 documents, manuals, reports and research studies examining interventions with sex workers.

2.1.6 Congenital syphilis elimination

In June 2004, the *Bulletin of the World Health Organization* published a theme issue devoted to maternal and congenital syphilis; it included seven commissioned articles and an editorial. The articles reviewed policies and programmes for preventing congenital syphilis, presented case studies of antenatal syphilis control programmes, discussed recommendations for preventing congenital syphilis, and reviewed the pathophysiology and treatment of maternal syphilis.

A systematic review of policies devoted to maternal and congenital syphilis control has been completed; it compares approaches taken by 13 selected countries that cover a range of geographical, socioeconomic and epidemiological conditions. The report served as a background paper for a meeting held in Geneva on 2–3 December 2004 (the technical consultation on the strategy for the global elimination of congenital syphilis) and forms part of the evidence base for the strategy (see section 6.1.4). A non-technical advocacy document aimed at convincing decision-makers, policy-makers and donors to invest in programmes to eliminate congenital syphilis is under development together with an advocacy plan and fund-raising strategy.

2.1.7 Genital ulcer disease: control and eradication

A consultation was held in Geneva in early November 2004 to consider issues related to the control of ulcerative STIs. It was noted that a number of STI-prevention and HIV-prevention programmes have documented reductions in STI prevalence including the rapid control of genital ulcer disease and virtual disappearance of chancroid. Several of these countries—including Cambodia, Kenya, South Africa

and Thailand—have also shown an impact on HIV prevalence at the population level. The control of genital ulcer disease—defined as a reduction in prevalence of curable ulcerative diseases—was considered to be feasible and to have significant benefits including slowing the transmission of HIV. Recommendations for initial control activities have been identified. A strategy for genital ulcer disease control and eradication will be developed (see section 2.2.6 below).

Control of infectious syphilis, already a priority in several regions, will aid in the control of congenital syphilis and its high morbidity and mortality. Strategies to control syphilis and chancroid largely overlap and include the use of interventions targeted towards networks of commercial sex workers, the strengthening of STI services, the use of syphilis screening in antenatal and delivery services, and the development or improvement of surveillance. These strategies, therefore, should become the core components of programmes to control genital ulcer disease, and control should be pursued as a specific initiative within the broad context of STI control and HIV-prevention interventions.

2.2 Planned activities

Following directly from the work undertaken by the Department in 2004 on broadening the provision of quality services, future activities will include the further development, testing and dissemination of guidelines and assisting countries in strengthening and improving their programmes.

2.2.1 Guidelines for the management of sexually transmitted infections

The French, Spanish and Portuguese translations of the *Guidelines for the management of sexually transmitted infections* and training modules in French and Spanish will be printed and distributed in 2005.

2.2.2 STI/RTI guide to essential practice

Sexually transmitted and other reproductive tract infections: a guide to essential practice will be introduced to more countries and adapted to country programmes through the Strategic Partnership Programme (SPP), the Implementing Best Practice Initiative and other WHO channels. Evaluation of the adaptation process will continue in Kenya, and support will be sought to implement the guidelines nationally from June 2005 and to conduct operational research to assess the costs and effectiveness of the guide in two sites. Bangladesh, Bolivia, Brazil and Kyrgyzstan have expressed interest in introducing the guidelines into their national programmes. The pocket guide, a companion to the guide to essential practice, will be developed and tested in 2005, and the adaptation guide will be revised as it is used in the first set of countries that introduce the guide.

2.2.3 Cervical cancer guidelines

The new draft of *Comprehensive cervical cancer control: a guide for essential practice* will be reviewed by the core group before being sent to countries for pre-field-testing. The first months of 2005 have been dedicated to the pre-field-testing process; this will be discussed during the annual Technical Advisory Group (TAG) meeting in March 2005. A generic guideline will be produced after this meeting.

The rest of the year will be devoted to developing the adaptation guide, which will provide information on key items required for country implementation (e.g. prevalence of cervical cancer, existing programme guidelines, resources and services for cervical cancer control). The remainder of 2005 will also be spent publishing, translating and introducing the essential practice guide.

A comprehensive package, including the essential practice guide, *Planning and implementing cervical cancer prevention and control programs: a manual for managers* and *Cervical cancer screening in developing countries* is being prepared for introduction and testing through the SPP.

2.2.4 STI services for adolescents, sex workers and prisoners

Guides for programme managers will be developed for both of the documents that discuss caring for adolescents. These will highlight best practices in providing services and information for adolescents; there will be special emphasis on STI prevention and care.

2.2.5 Eliminating congenital syphilis

The systematic review of policies to control maternal and congenital syphilis will be submitted to *Health Policy and Planning*. The advocacy strategy to ensure international support for the initiative will be further developed during 2005.

2.2.6 Genital ulcer disease: control and eradication

Key planned activities for the next two years include:

- mapping rates of curable genital ulcer disease and chancroid using national surveillance data to identify countries where these rates are high and where initial implementation activities would be beneficial;
- selecting between one and four countries that would benefit from direct technical support to design, implement and evaluate efforts to control genital ulcer disease. Discussions with a mix of countries with high and falling prevalence rates of genital ulcer disease would permit development of strategies for initial control and chancroid eradication phases;

- using in-country experience to develop generic strategy, policy and programmatic tools for genital ulcer disease control and related surveillance and to define appropriate control and elimination or eradication targets for syphilis and chancroid based on data and experience from initial activities;
- providing support to the STI Diagnostics Initiative to expand work on rapid diagnostics for syphilis and chancroid;
- by building on the service-delivery mechanisms of initiatives to control genital ulcer disease, developing strategies to target infection with herpes simplex virus type 2 (HSV-2), which are the subject of ongoing research.

Funding requests for this initial work plan include an outline of scale-up activities beyond the second year.

3. OBJECTIVE 2: TO WIDEN THE RANGE OF PRODUCTS AND TECHNOLOGIES

This overall objective highlights the need to broaden the range of safe, effective, acceptable and affordable methods to prevent and manage sexually transmitted, reproductive tract and vertically transmitted infections. Specifically, work to meet this objective focuses on developing chemical and mechanical barriers to STI transmission, on testing the safety and effectiveness of highly active antiretroviral therapy in preventing mother-to-child transmission of HIV, and on completing epidemiological studies of STIs and RTIs.

3.1 Progress

3.1.1 Microbicides

Vaginal microbicides are urgently needed to prevent the transmission of HIV and other STIs, especially for women who have few alternative methods of protection. As yet there are no microbicides available for general use. Five new microbicide products are undergoing Phase II or Phase III clinical evaluation. To increase the possibility of finding a safe and effective microbicide, it is essential to accelerate the development of promising new leads and to support clinical research into novel products.

3.1.1.1 Objective and rationale

WHO, in collaboration with the CONRAD programme and other agencies, is facilitating research and development of safe, effective and affordable microbicides for use in developing countries.

3.1.1.2 6% cellulose sulfate vaginal gel

In collaboration with CONRAD, an expanded safety and acceptability study of 6% cellulose sulfate gel was completed

in Mumbai, India, Kampala, Uganda, and Sagamu, Nigeria, in 2003. Cellulose sulfate gel was shown to be as safe and as well tolerated as K-Y Jelly. The final study report was submitted to the United States Food and Drug Administration in March 2004, and a manuscript is in preparation. As a result of this and other studies of cellulose sulfate gel, the CONRAD programme is implementing two Phase III effectiveness trials of the gel in multiple countries.

3.1.1.3 10% polystyrene sulfonate

Polystyrene sulfonate is a non-cytotoxic compound with antifertility and antimicrobial effects *in vitro*. In non-clinical studies, it has been shown to have high activity against HIV, HSV-2, human papilloma virus (HPV), and gonococci, and moderate activity against chlamydia. Initial safety studies of 10% polystyrene sulfonate have been conducted in the USA, and the product has been shown to be less irritating to the genital epithelium than nonoxynol-9-based products. To supplement safety trials by CONRAD in Belgium and India, the Programme has prepared a protocol for an expanded safety and acceptability study to be conducted at several sites in Africa. However, studies of 10% polystyrene sulfonate were put on hold due to adverse toxicological findings. A thorough review of toxicology data has since been conducted by CONRAD and other partners and the product has been cleared for further clinical development. WHO and CONRAD are discussing further development strategies for polystyrene sulfonate in view of other similar products that are currently in Phase II or Phase III effectiveness studies.

3.1.1.4 Safety of antiretroviral-containing microbicides

A new generation of microbicial products with potential for greater effectiveness than products entering Phase III trials is under development. They are antiretroviral (ARV) agents (e.g. TMC-120 and UC-781) with poor systemic absorption that are applied in the vagina to inhibit local viral replication. Such products pose safety concerns beyond those of products currently undergoing clinical testing, particularly the potential to select for resistant virus if used by someone with an established HIV infection as well as the potential transmission of resistant virus among the population. A technical consultation meeting was held in Geneva on 7–8 September 2004 to review implications of the possible selection of drug-resistant virus and the types of safety studies needed to address these issues. The consultation was held in collaboration with the United States Centers for Disease Control and Prevention and the International Partnership for Microbicides. Key conclusions from the meeting are outlined below.

- ARV-containing microbicides will most likely select for resistant HIV virus if the products are used by women with established HIV infection or incident HIV infection. Although the clinical significance of this phenomenon is unknown, there is a possibility that it could compromise the use of non-nucleoside reverse transcriptase inhibi-

tors for AIDS therapy among women exposed to such products intravaginally.

- There are no special safety tests required for this new class of products other than the usual preclinical and clinical safety tests performed for other microbicides.
- ARV-containing microbicides are initially likely to be prescription-only products administered to HIV-seronegative women. The additional infrastructure needed to conduct HIV testing for women requiring these microbicides will markedly limit access to these products.

3.1.2 Female condoms

The female condom provides an additional 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 cooperation, or less cooperation, from her male partner. WHO's research into female condoms addresses whether the protection they provide against pregnancy and STIs is equivalent to that provided by male condoms.

3.1.2.1 Condoms for pregnancy prevention

A study was conducted to evaluate the contraceptive effectiveness of the female condom in comparison with the male latex condom among a population of women seeking contraceptive counselling or supplies in health facilities and family planning clinics in Chengdu, China, Durban, South Africa, Panama City, Panama, and Sagamu, Nigeria. Women aged between 18 and 39 years (inclusive) were enrolled in the study and provided with male or female condoms according to their choice of method (about 500 women in each group); women were frequency-matched for age in 5-year bands to ensure a similar age distribution between the two groups. Women were scheduled for monthly follow-up visits for six months and for visits once every two months thereafter until 12 months. The study end-points were pregnancy or the use of emergency contraception following non-use of condoms or perceived condom failure.

The study started in August 2002 and was completed in July 2004. An interim analysis of data registered as of August 2004 was conducted. Study groups were defined as "male condom" for women whose partners exclusively used male condoms for the entire study period or "female condom" for women who exclusively used female condoms. A woman was classified as "mixed condom use" if she had switched condom types at one or more follow-up visits. Altogether, 960 women participated in the project. During the first six months of the study, 393 women reported that they depended exclusively on their partners to use male condoms as their main method of contraception and 455 women used only female condoms. A total of 112 women used both types of condoms.

Table 3.2 displays the pregnancy rates and discontinuation rates (for reasons other than pregnancy) by condom type, site and overall. In Chengdu and Sagamu the cumulative 6-month probabilities of pregnancy varied from between 2% and 3% in both groups exclusively using male or female condoms; in Chengdu, however, the proportion of women discontinuing use of a particular type of condom for reasons other than pregnancy at the end of the first six months was 15 times higher among women who used female condoms than among those who depended on their partners to use male condoms (15% versus 0.8%). In Panama, the 6-month life-table pregnancy rate was significantly higher (more than three times) among women whose partners used male condoms than among women using female condoms, although the number of pregnancies was too small to allow definitive conclusions to be drawn. There were no pregnancies reported in Durban in either group for the first six months; this could be explained by the high discontinuation rates observed in both groups.

The overall 6-month life-table probabilities of pregnancy with use of either the male or female condom were not significantly different. However, 6-month probabilities of discontinuation for reasons other than pregnancy were significantly higher among women whose partners used the male condom; this was mainly attributable to the high drop-out rate of participants in Durban whose partners were using the male condom.

Table 3.2. Pregnancy and discontinuation rates by pattern of condom use in four countries

Pattern of condom use	Number of women	Time in study (woman-years)	Number of pregnancies	Cumulative 6-month pregnancy rate (95% confidence interval)	Cumulative 6-month discontinuation rate for reasons other than pregnancy (95% confidence interval)
Male condom	393	215.7	10	2.92 (0.90–4.94)	35.13 (30.19–40.07)
Female condom	455	283.6	8	1.80 (0.48–3.13)	19.31 (15.43–23.19)
Mixed use	112	90.4	0		0
Total	960	589.7	18		

3.1.2.2 Condoms for STI prevention

Biological markers are an extremely sensitive method of assessing whether condoms prevent exposure to semen or STIs during intercourse. Post-coital levels of prostate specific antigen have been used to compare the efficacy of male and female condoms to prevent exposure to semen. WHO has extended this concept to detect whether any exposure to sexually transmitted pathogens occurs following intercourse with an infected partner.

A study is being planned that will include sex workers from the Hillbrow area of Johannesburg, South Africa. The sex workers will take vaginal swabs before and after intercourse, and the used condom will be assessed for the presence of STIs in the ejaculate. A pilot project to assess the acceptability and practicality of the study was completed in 2004.

A preparatory study used the detection of STIs to assess the performance of self-collected vaginal swabs kept at room temperature for four days in a DNA–RNA stabilizer and compared these with speculum-assisted clinician-collected swabs. A total of 773 female STI patients who provided self-collected vaginal swabs were recruited into the study. One swab was placed into a dry plastic tube, and the second one was put for four days in a covered tube containing DNA/RNA Protect transport fluid. After the self-collected swabs had been taken, the study clinician collected vaginal and cervical swabs using a speculum. These were sent to the laboratory on dry ice where they were analysed using polymerase chain reaction amplification within five hours of collection. *Chlamydia trachomatis* was detected in 19.7% of women, *Neisseria gonorrhoeae* in 19.4% and *Trichomonas vaginalis* in 39.8%. More than half of the women (65%) had at least one STI. Using the clinician-collected swabs as the reference, the sensitivity of the self-collected vaginal swabs for *C. trachomatis* was 100%; specificity was 99.7%; positive predictive value was 99.3%; and negative predictive value was 100%. For *N. gonorrhoeae* the sensitivity was 100%; the specificity was 99.7%; the positive predictive value was 99.3% and negative predictive value was 100%. For *T. vaginalis* sensitivity was 86.6%; specificity was 99.6%; the positive predictive value was 99.4% and negative predictive value was 90.5%. The acceptability of self-collected swabs was high among women in the study.

Information from this study will be used to plan the study assessing and comparing the efficacy of male and female condoms to prevent exposure to sexually transmitted pathogens.

3.1.3 Preventing mother-to-child transmission of HIV

Interventions to prevent mother-to-child transmission of HIV have been increasing rapidly over the past six years in developing countries. The first programmes were based on a short course of zidovudine but were rapidly superseded by the single-dose nevirapine regimen for mother and infant follow-

ing publication of the results of HIVNET 012 study in 1999. The simplicity and practicality of this regimen had many programmatic advantages, but its effectiveness is lower than more intensive regimens.

Antiretroviral treatment programmes are rapidly expanding in developing countries, providing an opportunity to treat women with advanced disease in addition to reducing the risk that they will pass the virus on to their infants. Due to side-effects of the antiretroviral regimens and the uncertainty about long-term adverse effects, treatment is started only when women are severely immunocompromised. However, it is unclear whether and when to start combination antiretroviral treatment in pregnant women who do not yet require treatment for their own health: the substantial reduction in viral load is expected to reduce the risk of transmission during late pregnancy, delivery and breastfeeding, yet this comes at the cost of side-effects and difficulties in adherence.

Replacement feeding is recommended to HIV-infected women when it is acceptable, feasible, affordable, safe and sustainable. In many developing countries where HIV is prevalent, it is rare for all of these conditions to be met. Combination antiretroviral treatment continued through the breastfeeding period has the potential to reduce the risk of transmission to low levels, thus allowing mothers with HIV infection to breastfeed safely. This reduces the stigma associated with replacement feeding and provides optimal nutrition and immunological benefits to the infant.

3.1.3.1 Objectives and rationale

The goal of the Kesho Bora project is to optimize the use of antiretrovirals during pregnancy to preserve the health of the mother, minimize side-effects and reduce the risk of mother-to-child transmission.

The Kesho Bora project (“A better future” in Swahili) is a cohort study of pregnant women who are infected with HIV and who have been identified during late pregnancy; they are offered antiretroviral treatment or prophylaxis according to the stage of their disease and CD4+ count. Women who require treatment for their own disease (because they are symptomatic or have CD4+ count < 200 cells/mm³) are offered triple-combination antiretroviral treatment that is continued as long as required for their own health. Women with early stage disease (CD4+ count > 500 cells/mm³) are offered a short-course regimen during the last month of pregnancy. Women with intermediate-stage disease are enrolled in a nested randomized controlled trial comparing triple-combination antiretroviral treatment started late in pregnancy and continued for a maximum of six months during breastfeeding with a short-course prophylaxis regimen. All infants in the cohort study and the nested trial receive a single dose of nevirapine within 72 hours of birth. All women and their infants will be followed for two years, with regular monitoring of their health status, including CD4+ cell count assessment. Women whose health deteriorates such that they require

treatment (they become symptomatic or their CD4+ count falls below 200 cells/mm³) will be offered antiretroviral treatment that will be continued for as long as necessary.

Although the project is primarily embedded within antenatal and obstetric services at the participating sites, strong linkages are being developed with other maternal and child health services and with family planning and reproductive health services. An important challenge is to ensure good integration with rapidly expanding antiretroviral treatment programmes so that the woman's close household and family members also receive HIV counselling and testing, advice on HIV prevention, information on where and when to seek care for any HIV-related disease, and can access treatment when required.

The primary end-points of the prospective cohort study and the nested randomized controlled trial are:

- HIV-free infant survival at six weeks and 12 months;
- AIDS-free survival among mothers 12 months postpartum; and
- incidence of severe adverse events in mothers.

3.1.3.2 Progress

The Kesho Bora project brought together a consortium of international partners with a view not only to develop and implement the project, but also to ensure its timely completion. In addition to the Programme, partners include the United States Centers for Disease Control and Prevention; the United States National Institutes of Health, National Institute of Child Health and Human Development; Agence Nationale de Recherches sur le SIDA (ANRS), Paris, France; the International Centre for Reproductive Health, Ghent, Belgium; Laboratoire de bactériologie-virologie, University of Montpellier, Montpellier, France; Institut de Recherche pour le Développement, Paris, France; and the Centre de Recherche Cultures, Santé, Sociétés, Université d'Aix-Marseille, Marseille, France. The project is being implemented at three sites initially (Bobo-Dioulasso, Burkina Faso, with support from ANRS; Mombasa, Kenya, with support from WHO and the Belgian Government; and Nairobi, Kenya, with support from the United States Centers for Disease Control and Prevention and the National Institutes of Health).

Study instruments (case-report forms, standard operating procedures, manual of operations, laboratory procedures) were developed and pilot-tested during 2004. Information sheets and consent forms are being translated into local languages, and all materials have been translated into French for the project site in Bobo-Dioulasso.

A comprehensive training course was organized for the study teams, covering information on HIV infection in general and prevention of mother-to-child transmission of HIV in

particular. The latter component included training in how to strengthen antenatal care and counselling services for infant feeding as well as antiretroviral treatment of HIV-infected women. The course also covered nutrition counselling and anthropometry, good clinical and laboratory practices, and research procedures.

Despite difficulties in purchasing supplies, the first three sites are about to start recruiting the first volunteers into the study cohort. The central purchase of supplies has been a challenge throughout 2004. For example, the successive cancellation of pre-qualification of all of the generic suppliers of the zidovudine–lamivudine (ZDV-3TC) combination from the WHO-approved list led to cancellation of antiretroviral orders. In addition, between the initial offer of infant formula from a WHO- and UNICEF-approved supplier and the order placement, the supplier decided to discontinue manufacturing the formula. An alternative supplier who can meet WHO criteria has now been identified.

Three additional sites (Durban, South Africa, Kigali, Rwanda, and Moshi, United Republic of Tanzania) have been identified and are being prepared to start the second phase of recruitment in mid-2005, subject to availability of funding. Funding the coordination of the study at WHO also remains a challenge.

3.1.4 STI surveillance and special studies on burden and etiology

The lack of data regarding the magnitude of STIs and etiologic profiles limits the effectiveness and efficiency of prevention and care programmes and services. In the South-East Asia and Western Pacific Regions there is a particular need to increase the capacity to perform this type of study.

The Programme provides technical and financial support to enhance the capacity of researchers to develop and conduct studies on STIs and RTIs, primarily in reproductive health settings, such as family planning clinics, general gynaecological service settings and antenatal care settings.

3.1.4.1 Prevalence of STIs and RTIs in reproductive health settings

In general, the need for assessment of laboratory capacity was addressed through a visit to five study sites by external technical consultants in 2004 (Medan and Surabaya in Indonesia, Mongolia, Myanmar and Viet Nam); these visits included workshops on laboratory diagnostics. The capacity of the various laboratories was considered adequate to undertake the proposed studies, since they had all increased their capacity during the previous two years.

A total of seven protocols and studies were launched to assess the etiology and prevalence of STIs and RTIs in facilities that provide reproductive health services and in the community.

- A study on the prevalence of reproductive tract infections at family planning clinics at the Central Women's Hospital, Yangon, Myanmar, obtained renewal of local ethical clearance and has begun; most specimens will be collected during 2005.
- A study on the prevalence of STIs and RTIs among antenatal clinic patients in two central hospitals in Vientiane, Lao People's Democratic Republic, has been completed; specimens were analysed by polymerase chain reaction in Thailand. The investigators are completing the manuscript.
- The team conducting the community-based cluster study on the prevalence of lower genital tract infections among rural women in Sichuan province, China, completed field-survey work between March 2003 and June 2004. The final total sample size is 2000. Data management and analysis are under way.
- In Indonesia, two studies to assess the prevalence of reproductive tract and sexually transmitted infections among university attendees are about to begin.
- Investigators taking part in a third study in Medan, Indonesia, have as their primary objective the assessment of the burden of STIs among antenatal attendees; they are finalizing the protocol for submission to the Programme's review process.
- In Mongolia, despite a national policy of antenatal syphilis screening, reported rates of maternal syphilis continue to increase, with 43 new cases of congenital syphilis in 2000. A protocol has been developed to compare the effectiveness of a strategy in which clients will be tested and treated if necessary at a single antenatal care visit versus the standard practice, which requires at least three visits before treatment. If proven feasible and effective, the study results will be disseminated to pivotal health policy-makers to influence the development of more suitable policies and programmes.
- In Myanmar, the case-control study to assess the association between STIs and other risk factors and ectopic pregnancy has required extensive technical assistance to develop a clearer and more scientifically appropriate protocol. A laboratory expert visited this site to clarify issues related to diagnostics. It is anticipated that the study will be submitted for approval to the Programme during 2005.

3.1.5 Incidence of and risk factors for pelvic infection after induced abortion

The multicentre nested case-control study on the incidence of and risk factors for post-abortion pelvic infection entered the recruitment phase during 2004; women have been recruited at 10 of the 14 main study sites. The project is embedded in

a randomized double-blind trial evaluating the effect of vaginal administration of 400 µg of misoprostol prior to vacuum aspiration on the incidence of complications in women seeking termination before 12 completed weeks of pregnancy. Six sites have completed enrolment, and four sites have shipped specimens to the reference laboratory at the Prince Leopold Institute of Tropical Medicine in Antwerp. The incidence of post-abortion upper genital tract infection will be obtained from follow-up during the randomized controlled trial, while the risk factors for post-abortion pelvic infections resulting from pre-existing STIs or RTIs will be assessed in the nested study.

It is anticipated that the remaining study sites will complete enrolment during 2005 and send specimens to the laboratory in Belgium. Specimens from cases and matched controls will be tested once data have been reviewed in Geneva and cases identified.

4. OBJECTIVE 3: TO STRENGTHEN HEALTH MANAGEMENT AND SUPPORT SYSTEMS

Activities within this objective aim to strengthen the capacity of national health systems to improve the quality and sustainability of culture- and gender-sensitive programmes with a view to preventing RTIs and STIs, including HIV, and their complications.

4.1 Progress

4.1.1 Models for integration: RTI/STI programme guidance tool

The *RTI/STI programme guidance tool* is an adaptation of the Strategic Approach to introducing contraceptive technology (*Making decisions about contraceptive introduction: a guide for conducting assessments to broaden contraceptive choice and improve quality of care*) that is appropriate to the problems of RTI and STI control and management.

The tool is an action-oriented process that enables decision-makers to set goals and directions for policy and to prioritize interventions for addressing the problem of reproductive tract and sexually transmitted infections. It comprises two sets of documents. The first includes seven modules that outline the steps needed to implement the tool nationally or subnationally; it also provides a step-by-step guide to the assessment phase, which results in the identification of strategic recommendations. The second set of documents, "The PGT country experiences" (not yet published), includes three modules that detail the experiences of Brazil, Ghana and Latvia in implementing the guide during a 4-year period.

4.1.2 Implementation of the RTI/STI programme guidance tool

Teams in Brazil, Ghana and Latvia are implementing recommendations made during the process in their countries. In Brazil, the recommendations were implemented in the state of Fortaleza, and the Ministry of Health is discussing the possibility of extending implementation to other states. Implementation of the tool in two provinces in China demonstrated the value of the creation by the Ministry of Health and the National Population and Family Planning Commission of a common policy and strategy addressing RTI and STI control. Implementation of the recommendations in the two provinces will continue through 2005.

In Kosovo, the process described within the tool continued with the completion of field assessment follow-up work and the writing of the assessment report; this report was then distributed to key stakeholders and shared at a dissemination workshop. Although the workshop was supported by external technical advisors, the recommendations proposed were not prioritized at that time, so prioritization has continued with the core group taking the lead role. In parallel, WHO in Kosovo has supported the development of an STI surveillance system. Once the recommendations have been prioritized, further support requirements from the Department will be identified.

4.1.3 Capacity strengthening for research on microbicides

Lack of clinical trial capacity in developing countries may delay implementation of Phase III effectiveness trials of promising new microbicides. Expanding the research capacity of WHO collaborating centres to conduct high-quality research into microbicides and reproductive health is a priority for the Programme. The Programme is building research capacity for microbicides and their development in Ethiopia, India, Kenya, Mozambique, Nigeria and Uganda.

4.1.3.1 Research methods, Good Clinical Practice and research ethics courses

To strengthen the capacity of institutions to conduct research on microbicides, the Programme, in collaboration with the National Institute for Research in Reproductive Health, Mumbai, India, conducted a research methods course from 22 June–2 July 2004. The objectives of the course were to improve the knowledge of participants of the principles and practice of epidemiology, to improve their skills in developing and implementing research protocols, to offer training in research ethics and Good Clinical Practice guidelines, and to foster partnerships among WHO collaborating centres involved in microbicide research. Twenty-four middle-level scientists from WHO collaborating centres in Ethiopia, India, Kenya, Nigeria, Swaziland and Uganda participated. Family Health International staff facilitated the training in Good Clinical

Practice and research ethics using standardized training modules.

4.1.3.2 Institutional strengthening activities

The Programme provided funds for the renovation and procurement of basic equipment for expanded research facilities at the Department of Obstetrics and Gynaecology, Makerere University, Mulago Hospital in Kampala, Uganda. The Department's clinic and laboratory facilities have been upgraded in readiness for a Phase III effectiveness trial that will be conducted at the site as part of the WHO–CONRAD collaboration on microbicides. A proposal to expand and upgrade research facilities at the Centre for Research in Reproductive Health, Sagamu, Nigeria, is under review. Similar institutional strengthening activities will be considered for collaborating centres in Ethiopia, Kenya and Mozambique.

4.2 Planned activities

4.2.1 STI/RTI programme guidance tool

Further technical support will be given to Kosovo to implement priorities that emerged from the Stage 1 assessment using the tool.

4.2.2 Strategic Partnership Programme

A global meeting took place in February 2005 to assess the progress made within the SPP in 2004 and to plan partnership work for the remainder of 2005 and for 2006.

Plans call for providing technical support in 2005 to UNFPA's Country Support Teams and officers, as needed, for the adaptation and implementation of the technical guidelines. Activities are planned in Benin, Cameroon, China, Indonesia, Nigeria, the United Republic of Tanzania, Turkmenistan, Vanuatu, Viet Nam and Zambia. Further translations and printing of guidelines will also be supported, including printing of a large number of copies of the English version of *Sexually transmitted and other reproductive tract infections: a guide to essential practice*. Specific adaptation guidance for the essential practice guide will be finalized as well.

A regional workshop will take place in early 2005 in Cairo, Egypt, on family planning and maternal care, and it is anticipated that further activities related to STI control will be supported in the Eastern Mediterranean Region in 2005.

5. OBJECTIVE 5: TO PROMOTE SOUND NATIONAL POLICIES AND LAWS

To support this objective the Department aims to ensure an enabling environment at the national level that is supportive of non-stigmatizing, culturally sensitive and gender-sensitive STI and RTI programmes, policies, laws and initiatives.

5.1 Progress

5.1.1 Microbicides

Because microbicides represent a new class of products, there is no established regulatory pathway for licensure. Product developers need clear regulatory guidance on what is required for novel products to be approved. Regulatory bottlenecks, which include a lack of regulatory capacity in many developing countries, may delay the rapid availability of microbicides in communities ravaged by HIV. Developing countries urgently require support to develop effective regulatory mechanisms for microbicides.

In recognition of these hurdles, WHO and its partners convened two separate meetings, one in Switzerland and the other in Botswana; they took as their theme the scientific basis for regulatory decisions on microbicides, addressed in Villars-sur-Ollon, Switzerland, 3–6 March 2002, and the scientific guidance for regulation of the research and development of microbicides and HIV vaccines, addressed in Gaborone, Botswana 18–20 November 2002. These meetings developed working documents on the regulatory requirements for guiding microbicide research and development from discovery through to human trials and on to approval and licensure.

A third meeting, addressing the regulatory pathways for microbicides in Asia, was held in New Delhi, India, on 7–9 November 2004 in collaboration with the Indian Council of Medical Research. The meeting brought together 80 participants from countries in the region including Cambodia, China, India, Indonesia, Myanmar and Thailand. It provided a forum for national drug regulators, scientists, advocates and community leaders to review national drug regulatory processes and to discuss regulatory requirements for development, preclinical and clinical research, and licensure of microbicides in Asia. Key points from the meeting included highlighting:

- the urgent need for the microbicide field to demonstrate efficacy among products currently undergoing Phase IIB or Phase III evaluation. Study designs must be optimized to increase the chance of showing product effectiveness;
- the importance and essential nature of community mobilization and involvement to support microbicide research in order for studies to be successfully implemented;
- the fact that there are similarities in regulatory frameworks and processes between countries in Asia. However, regulatory capacity varies widely among countries according to drug discovery and/or manufacturing capability within a country. Responsibility for certifying product quality, safety and efficacy lies with the regulatory authority of the country of manufacture;

- the balance of risks and benefits for microbicides. This differs among countries, and decisions on whether to license products will depend on the local context. Countries need to be supported to make independent risk–benefit assessments of novel products, such as microbicides, despite having limited technical expertise in examining registration dossiers;
- the harmonization of national drug regulatory mechanisms that is under way in countries that are members of the Association of Southeast Asia Nations.

5.1.2 STI networks of excellence

The process for the establishment of STI networks of excellence in the Eastern Mediterranean Region has been deferred as a result of administrative changes in that region. A meeting with the new HIV/STI Regional Adviser took place in December 2004 during which technical networks for STI prevention and care were discussed, among other issues. In the African Region, terms of reference for a consultant have been drawn up to organize the launch of the network and the assignment of tasks to the network.

5.1.3 Public–private partnerships

Representatives from the private health-sector were involved in a meeting held to discuss improving access to the drugs needed to treat STIs; the meeting was held in Harare, Zimbabwe, in October 2004. The key issue under discussion was the potential for a common procurement agency to supply the needs of both the public and the private sectors. This method of procurement would translate into more affordable drugs for patients, particularly in the private sector. In many countries the majority of patients with STIs seek care from the private sector where drugs are more easily available but prohibitively expensive.

A pilot project for joint procurement was successful in Zimbabwe but was not scaled-up due to a shortage of foreign currency. Currently, the procurement agency that took part in the pilot project has prioritized procurement for the needs of the public sector.

5.1.4 Scientific basis for antiretrovirals used to prevent mother-to-child transmission

The Department collaborates with the HIV/AIDS Department, the Child and Adolescent Health and Development Department and the Making Pregnancy Safer initiative to support work on preventing mother-to-child transmission (PMTCT) of HIV. The Department is the focal point for technical and scientific issues related to this prevention and supports the publication of the monthly *PMTCT intelligence report* (available from http://www.who.int/reproductive-health/rtis/MTCT/monthly_publications/listing_mtct_reports.htm). These reports are compiled by members of the Bordeaux Working Group, which regularly surveys publications related

to the prevention of mother-to-child transmission. The report also covers abstracts presented at international conferences and includes a brief summary and comments prepared by the group that help place the publications surveyed in context. The reports are widely disseminated to policy-makers, public health officials, advocates and scientists as an information service. Each monthly report contains an average of nine or 10 references to recent important publications related to PMTCT. The Department has been supporting this activity since 2001 and is seeking additional sponsors working in the area of programmes and policy-making to prevent mother-to-child transmission to partner the initiative. Plans are being made to extend the reports to cover developments in HIV care in developing countries because this area is rapidly expanding.

With the rapid expansion in the availability of antiretroviral care in resource-limited settings there has been a need to reassess WHO's recommendations and guidance on the selection of drugs used for preventing mother-to-child transmission. In February 2004, the Department, in collaboration with the HIV/AIDS Department, convened a technical consultation to review new developments in preventing mother-to-child transmission and HIV care since the last guidance was issued by WHO in 2000. Those guidelines were reassessed in the context of the rapid expansion of antiretroviral treatment programmes that are using simplified, standardized regimens. In addition, considerable experience in implementing programmes to prevent mother-to-child transmission of HIV in resource-constrained settings has accumulated since 2000 as well as further evidence on the safety and effectiveness of various antiretroviral regimens.

The recommendations from the technical consultation were published in *Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants* (available from <http://www.who.int/reproductive-health/rtis/docs/arvdrugsguidelines.pdf>), which was released at the XV International AIDS Conference in Bangkok in July 2004. The report summarizes existing evidence on the use of antiretroviral drugs for preventing mother-to-child transmission and makes recommendations on the choice of regimens in the context of the expanding access to antiretroviral treatment. The recommendations complement revised guidelines on antiretroviral treatment that have been issued in support of the 3 by 5 Initiative.

In the light of the scientific evidence and accumulated programmatic experience, the participants at the technical consultation recommended specific antiretroviral regimens for different clinical situations. The guidelines described above were based on those recommendations and on expert opinion where evidence was lacking. Key recommendations include:

- Women who need antiretroviral treatment for their own health should receive it in accordance with WHO guidelines on treatment. The use of antiretroviral treatment during pregnancy, when indicated, substantially benefits

the health of the woman and decreases the risk of HIV transmission to the infant.

- Pregnant women who are infected with HIV but who do not have indications for antiretroviral treatment, or do not have access to treatment, should be offered antiretroviral prophylaxis to prevent mother-to-child transmission using one of several regimens known to be safe and effective:
 - zidovudine from 28 weeks of pregnancy plus single-dose nevirapine during labour, and single-dose nevirapine plus one-week of zidovudine for the infant. This regimen is highly efficacious, as is initiating zidovudine later in pregnancy;
 - alternative regimens based on zidovudine alone, short-course zidovudine plus lamivudine or single-dose nevirapine alone are also recommended.
- Although expanding access to programmes to prevent transmission presents many challenges, and single-dose maternal and infant nevirapine is the simplest regimen to deliver, programmes should consider introducing more complex regimens where possible. The expansion of programmes to prevent transmission using single-dose nevirapine should not be hindered while necessary improvements in health systems are taking place to enable more complex regimens to be delivered.

WHO will regularly review the evidence base for these guidelines and will issue updated recommendations when warranted by new information. In this rapidly changing field, it was anticipated that new scientific information would be presented at the 12th Conference on Retroviruses and Opportunistic Infections in February 2005, and thus several recommendations may need to be reconsidered.

5.2 Planned activities

5.2.1 Microbicides

The reports from previous regulatory meetings will be disseminated to policy-makers, product developers (including research institutions) and advocates, and additional meetings with representatives of national drug regulatory authorities in West Africa and Latin America will be held in 2005 to sensitize them to regulatory issues on microbicides. Work will continue with the European Medicines Evaluation Agency to develop mechanisms for supporting regulatory authorities with limited resources to obtain impartial expert advice on registration dossiers.

5.2.2 STI networks of excellence

There are plans to train members of the networks and assign them operational research tasks in order to build capacity to provide technical support to countries.

6. OBJECTIVE 6: TO ENSURE EFFECTIVE INTERNATIONAL EFFORTS AND COLLABORATION

The focus of the Department's work to meet this objective is to ensure and improve access to drugs for the treatment of STIs, to develop and implement the Global Strategy for STI Prevention and Control, to develop and implement the strategy for eliminating congenital syphilis, and to ensure suitable integration and the development of linkages between reproductive health and HIV programmes.

6.1 Progress

6.1.1 Inputs into the WHO Model List of Essential Medicines

In developing countries, access (especially through the public sector services) to modern drugs for the treatment of STIs remains a problem: the high cost of drugs (even of the generic ones) renders them unaffordable to poor people, and unreliable government financing and procurement arrangements lead to frequent interruptions in the supply of vital drugs. One way of ensuring more reliable government financing and supply arrangements for these drugs is to have them included in each country's national list of essential medicines. Hence, the Department is working towards having most, if not all, drugs for the treatment of STIs included in the WHO Model List of Essential Medicines.

A proposal to include cefixime in the WHO Model List of Essential Medicines for the treatment of uncomplicated anogenital infections caused by *Neisseria gonorrhoeae* has been completed and submitted to the WHO Expert Committee of the Department of Essential Drugs and Medicines Policy. Cefixime is highly efficacious in a single oral dose, it is safe and has limited side-effects. It is well suited for the management of STIs, especially in settings where compliance and follow-up may be problems—e.g. during pregnancy.

In addition, a statement has been prepared in support of retaining spectinomycin in the WHO Model List of Essential Medicines. This drug is recommended in the WHO *Guidelines for the management of sexually transmitted infections* as one of the first-line treatment options for uncomplicated anogenital gonococcal infection, disseminated gonococcal infection, adult gonococcal conjunctivitis and pelvic inflammatory disease. It is recommended as second-line treatment for neonatal conjunctivitis and as one of the options for prophylaxis in infants born to mothers with gonococcal infection.

The WHO Collaborating Centre for Sexually Transmitted Infections in Sydney, New South Wales, Australia, monitors gonococcal antimicrobial resistance and is a member of the WHO Gonococcal Antimicrobial Surveillance Programme. When consulted about the proposed deletion of spectinomycin, the response was that retention of spectinomycin on any list for gonococcal treatment should be supported because

data from the Western Pacific Region show that treatment options for gonorrhoea are shrinking. Quinolones are, generally, no longer effective in many countries in the Region, leaving only third-generation cephalosporins for use, along with spectinomycin. The WHO Collaborating Centre has indicated that spectinomycin is used quite widely in China and Japan (*Sexually Transmitted Infections* 2004;80:105–7), where ceftriaxone and spectinomycin are the recommended treatments for gonorrhoea. The most recent reports from the WHO Collaborating Centre are available on its web site (<http://www.cda.gov.au/pubs/annlrpt/gonoanrep.htm>).

6.1.2 Consultation on improving access to drugs for treating STIs

In October 2004, the Department, in collaboration with the WHO Regional Office for Africa, convened a consultation in Harare, Zimbabwe, aimed at improving access to drugs for the treatment of STIs. The meeting was attended by 27 participants from 16 countries in the WHO African Region. International partners who participated included: the Population Council, the United States Centers for Disease Control and Prevention, the West Africa NGO Projet Appui à la Lutte Contre le SIDA en Afrique de L'Ouest (Projet SIDA 3), and the Canadian Centre de Coopération internationale en Santé et Développement. The private medical sector in Zimbabwe was also represented. The specific objectives of the consultation were: (i) to review issues related to access to STI drugs in general; (ii) to identify appropriate short-term and long-term strategies for improving and scaling-up access to STI drugs in the region; and (iii) to define the links between access to STI drugs and access to antiretroviral therapy for HIV.

The recommendations from this meeting were that:

- governments should ensure the inclusion of appropriate, quality drugs for STI treatment on their essential medicines lists and commit to their sustainable procurement, availability and distribution;
- governments and other stakeholders should encourage public–private partnerships to ensure access to drugs for STI treatment among all sectors of the community;
- to ensure community involvement, governments should support the effective participation of the community at all levels of health-care delivery and put in place effective information packages, delivery of services and monitoring of the drug-management system;
- in order to minimize costs, governments and national procurement agencies should explore mechanisms for bulk purchasing of drugs for treating STIs;
- international agencies should provide technical assistance to countries on quality assurance, distribution and control of drugs in all sectors.

6.1.3 Global strategy for STI prevention and control

In 2004, a working draft of a document entitled “Global strategy for STI prevention and control” was produced following a comprehensive consultative process undertaken at regional and global levels. Two regional consultations were held—one in the WHO South-East Asia Region (in Colombo, Sri Lanka, August 2004) and the other in the WHO African Region (Harare, Zimbabwe, October 2004). For the other WHO Regions, a global consultation was held in Geneva on 15–18 November 2004; this was attended by STI experts, international partners, country representatives and WHO Regional Office staff.

The regional consultations helped to bring out regional peculiarities and the need for local adaptation of the strategy. The WHO South-East Asia Region has the second highest HIV burden in the world, and has the highest number of sexually transmitted infections (Figure 3.1 and Figure 3.2). These are strong indications that STI control is of major importance in this Region because STIs are likely to fuel the HIV epidemic to proportions that may exceed the situation in sub-Saharan Africa. Furthermore, studies in the Region seem to indicate a higher prevalence of STIs among men having sex with men, female and transgender sex workers (includes, among others, transsexuals (pre-, post-surgery), transvestites, cross-dressers, persons with ambiguous genitalia, persons who have chosen to adopt ambiguous social genders, and persons who have chosen a lifestyle without any social gender). Therefore, targeted interventions for STIs, including, for example, 100% condom use strategies, should be priority interventions for most countries in the Region. Following the

success of the 100% condom use intervention in Thailand, other countries with a similar pattern of STI and HIV infection have implemented the strategy with good results. A brothel-based 100% condom-use strategy in Cambodia brought about a reduction in STIs among sex workers between 1996 and 2001 (Figure 3.3).

The development of the “Global strategy for STI prevention and control” has taken into account regional epidemiological variations and the success of different interventions; the strategy seeks to recommend a mix of interventions that best respond to a particular setting in order to produce the maximum impact on STI incidence and prevalence. It also highlights the importance of the link between STIs and HIV transmission and STIs and sexual and reproductive health. During the Geneva consultation participants expressed considerable support for the strategy (both the overall concept and the technical elements) and provided ideas on how best to communicate the need to invest in STI prevention and control. Prevention and control are cost-effective interventions that prevent HIV transmission, reduce the pressure for HIV to spread through the general population and improve reproductive health and reproductive outcomes; they also provide a tool to monitor the potentially adverse impact of the increasing availability of antiretroviral treatment on sexual behaviour. The challenge for the Department is to ensure sufficient support for investments in STI control within WHO and to help countries implement effective programmes, despite competing pressures from other health priorities. It is hoped that the global strategy will spark renewed interest in strengthening HIV prevention despite competition for resources to support the expansion of antiretroviral care.

Figure 3.1. Estimated number of people living with HIV/AIDS by WHO Region, 2003

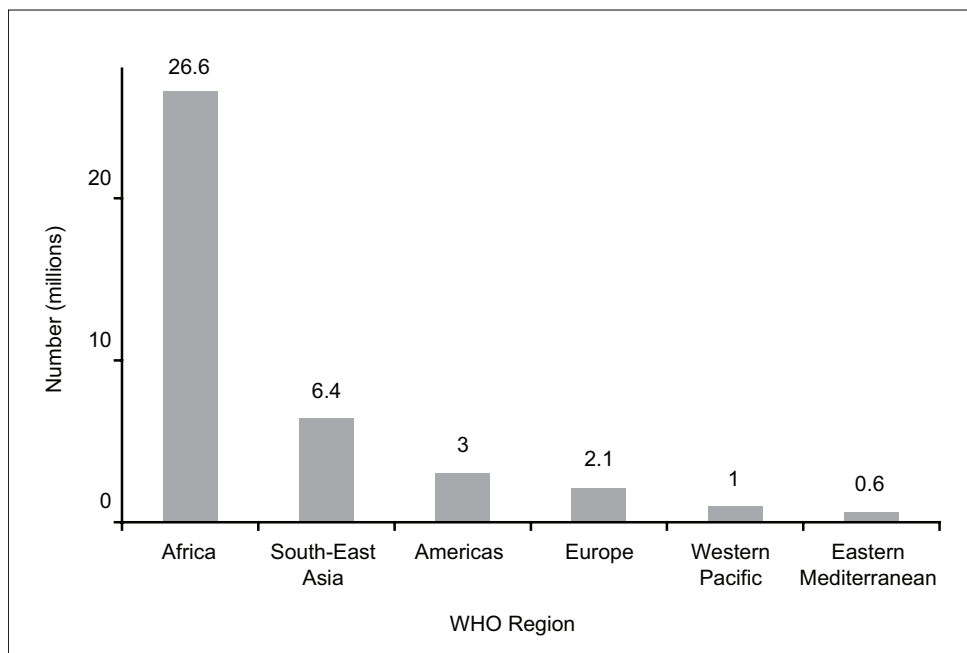


Figure 3.2. Burden of HIV and sexually transmitted infections (STIs) in sub-Saharan Africa and South and South-East Asia

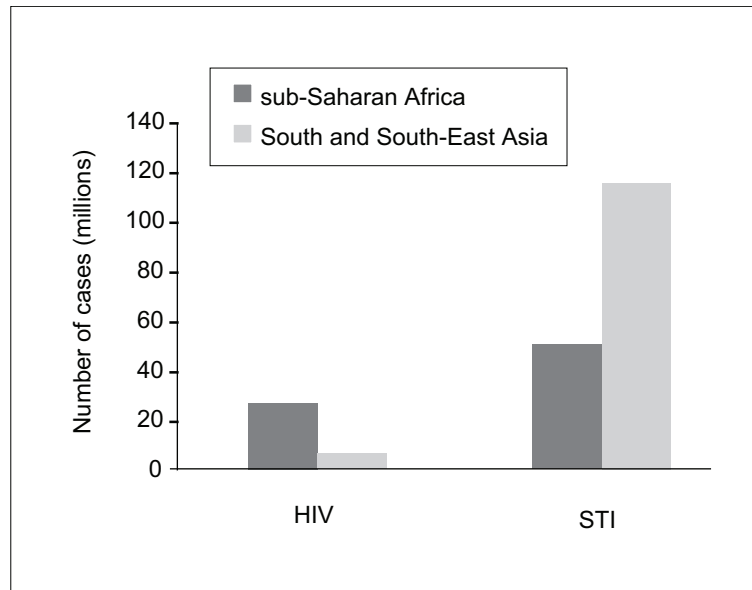
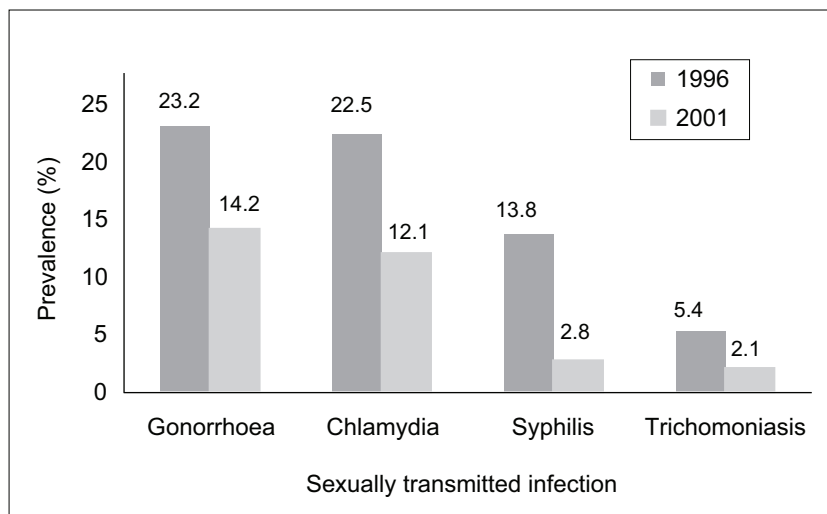


Figure 3.3. Impact of 100% condom-use strategy among brothel-based sex workers on sexually transmitted infections, Cambodia, 1996–2001



6.1.4 Strategy for the global elimination of congenital syphilis

Following recommendations from the Department's Scientific and Technical Advisory Group in 2003 to advance the strategy aimed at eliminating congenital syphilis, a draft strategy and advocacy document was developed internally in advance of a technical consultation on the subject, which was convened in Geneva on 1–2 December 2004.

The participants at the technical consultation recommended that, while the long-term goal of eliminating congenital syphilis globally should remain, a more achievable intermediate goal would be to reduce the incidence of congenital syphilis by 90% in at least four countries by 2009. Which indicators to

use for monitoring and evaluating the implementation of the strategy are still under discussion, as are the indicators to be used for surveillance purposes. Similarly, agreement still needs to be obtained on screening strategies. Different algorithms will be proposed and these will need to be adapted to the local context.

There was strong consensus that the elimination of congenital syphilis must be integrated with other reproductive health and STI programmes and initiatives. These include the Making Pregnancy Safer initiative, mother-and-child health programmes, programmes for preventing mother-to-child transmission of HIV, and the "Global strategy for STI prevention and control". In addition, the elimination of congenital syphilis cannot be achieved without controlling syphi-

lis among the general population, and the strategy must be implemented, therefore, in partnership with strategies to control genital ulcer disease, when appropriate.

The four pillars of the agreed strategy are:

- to develop political commitment and advocacy;
- to increase and improve access to maternal and neonatal health services;
- to screen and treat pregnant women according to prevalence and resources;
- to monitor and evaluate the implementation and effectiveness of the strategy.

One opportunity to support implementation of the global strategy to eliminate congenital syphilis is a European Union call for research proposals. In June 2004, a letter of intention was prepared for the European Union by the Department in collaboration with the London School of Hygiene and Tropical Medicine, London, UK; this aimed at field-testing the strategy in four countries using policy analysis and strategic approach methods. Four countries were identified following consultation with WHO Regional Offices. In order to respond to the anticipated call, the views and links among potential stakeholders involved in the proposal were discussed and established.

The objectives of the research proposal were: (i) to gain an appreciation of the policy and economic constraints and opportunities related to the widespread introduction of antenatal syphilis control programmes in the public sector in selected countries, (ii) to understand barriers and opportunities to antenatal syphilis control programmes from the perspective of health-care providers, pregnant women and communities, (iii) to develop a political strategy for introducing antenatal syphilis control in target countries, and (iv) to evaluate the implementation and impact of the strategy.

It was agreed that representatives from ministries of health in each country should participate at an early stage of the project's development. In view of the geographical limitation of the call, an initial proposal involving selected African countries, Bolivia and Cambodia was submitted. Similar proposals would be formulated for submission to future calls; these will involve the Russian Federation, Eastern Europe including the Newly Independent States, and Central Asian Republics.

6.1.5 Facilitating linkages between reproductive health and HIV programmes

The rapid expansion of care and treatment programmes for people living with HIV and AIDS has provided new opportunities and resources to build bridges across distinct programme areas and ensure suitable integration and linkages.

One particular building block is the link between family planning services and programmes to prevent mother-to-child transmission of HIV. These programmes have increased their extent and coverage substantially over the past six years, yet have focused on late pregnancy and the immediate postpartum period. Little attempt has been made to ensure proper links and integration with the prevention of unwanted pregnancy in women known to be infected with HIV, despite models showing that pregnancy prevention in this group can more easily reduce the number of infected infants than more intensive programmes to prevent mother-to-child transmission. In order to promote and advocate for more interest and investment in this critical link, the Department together with the HIV/AIDS Department and UNFPA convened a high-level consultation with scientists, programme managers, policy-makers and advocates from developing and developed countries in May 2004 in Glion, Switzerland. Following a review of the evidence supporting the value of the link, the practical constraints of making the link and examples of several successful links, the meeting concluded with the *Glion call to action on family planning and HIV/AIDS in women and children* and a declaration of commitment to link more closely family planning and programmes aimed at preventing mother-to-child transmission.

The call to action has been widely disseminated and promoted at international forums by both WHO and UNFPA, and it is being used to advocate for and implement improved prevention and family planning programmes.

6.2 Planned activities

6.2.1 Inputs into the WHO Model List of Essential Medicines

A total of eight drugs recommended in the *Guidelines for the management of sexually transmitted infections* do not appear on the WHO Model List of Essential Medicines. Proposals for the inclusion of these drugs will continue to be submitted to the Department of Essential Drugs and Medicines Policy to address this discrepancy.

6.2.2 Consultation for improving access to drug treatment for STIs

Technical support will be provided, ideally primarily through STI technical networks, to incorporate access to drugs for treating STIs into the antiretroviral access initiatives, including the 3 by 5 initiative. In addition, WHO's Regional Office for Africa will explore methods of assisting countries in identifying and establishing sustainable funding to improve access to drugs for STI treatment.

6.2.3 Global strategy for STI prevention and control

The "Global strategy for STI prevention and control" will be presented to the WHO Executive Board in January 2006 and

to the World Health Assembly in May 2006. This strategy will form the basis for the development of regional strategies.

A shorter draft advocacy document is being reviewed and will be available prior to the presentation of the strategy to the Executive Board. The document will be widely distributed, and an advocacy campaign will take place for fund-raising purposes and to raise the profile of STIs as a public health problem.

6.2.4 Strategy for the global elimination of congenital syphilis

An advocacy plan is being developed, including activities to build consensus within WHO on the strategy for the global elimination of congenital syphilis, and the development of fund-raising strategies will be the main activity for 2005.

The strategy for eliminating congenital syphilis is being reviewed by the Department's Scientific and Technical Advisory Group for the global elimination of congenital syphilis and additional external reviewers. Their comments will be included in the strategy and coordinated activities between regions, countries and international partners will be developed.

6.2.5 Facilitating linkages between reproductive health and HIV programmes

During the course of the year, examples of linkages between family planning services and programmes to prevent mother-to-child transmission of HIV and other STIs will be documented. Work is under way in China on this issue and will be continued and evaluated.

Annex 1a

GLOBAL CONSULTATION ON THE DEVELOPMENT OF THE GLOBAL STRATEGY FOR PREVENTION AND CONTROL OF SEXUALLY TRANSMITTED INFECTIONS

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	7	44	3	19	6	37	16
Women	3	19	2	12	1	6	6
<i>from:</i>							
AFRO							
AMRO	2	12			2	12	4
EMRO	2	12					2
EURO			3	19	4	25	7
SEARO							
WPRO	3	19					3

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Annex 1b

AFRO REGIONAL CONSULTATION ON THE DEVELOPMENT OF THE GLOBAL STRATEGY FOR PREVENTION AND CONTROL OF SEXUALLY TRANSMITTED INFECTIONS AND CONSULTATION ON IMPROVING ACCESS TO DRUGS FOR THE TREATMENT OF SEXUALLY TRANSMITTED INFECTIONS

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	10	34	2	7	17	59	29
Women	3	10	2	7	10	34	19
<i>from:</i>							
AFRO	5	17					5
AMRO	2	7			10	34	12
EMRO							
EURO			2	7	7	24	9
SEARO	1	3					1
WPRO	2	7					2

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	14	52	1	4	12	44	27
Women	5	19	1	4	4	15	10
<i>from:</i>							
AFRO	5	19					5
AMRO	2	7			6	22	8
EMRO							
EURO	1	4	1	4	5	19	7
SEARO	4	15					4
WPRO	2	7			1	4	3

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	3	50			3	50	6
Women	2	33					2
<i>from:</i>							
AFRO	3	50					3
AMRO					1	17	1
EMRO							
EURO					2	33	2
SEARO							
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	8	100					8
Women	2	25					2
<i>from:</i>							
AFRO	8	100					8
AMRO							
EMRO							
EURO							
SEARO							
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	2	20			8	80	10
Women	1	10			5	50	6
<i>from:</i>							
AFRO	2	20					2
AMRO							
EMRO							
EURO					8	80	8
SEARO							
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	8	73			3	27	11
Women	4	36			1	9	5
<i>from:</i>							
AFRO	8	73					8
AMRO							
EMRO							
EURO					3	27	3
SEARO							
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	3	100					3
Women	1	33					1
<i>from:</i>							
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	
Members	10	100					10
Women	7	70					7
<i>from:</i>							
AFRO	6	60					6
AMRO							
EMRO							
EURO							
SEARO	4	40					4
WPRO							

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	7	58	4	33	1	8	12
Women	6	50	1	8			7
<i>from:</i>							
AFRO							
AMRO	1	8					1
EMRO							
EURO			4	33	1	8	5
SEARO	1	8					1
WPRO	5	42					5

Annex 3

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Chapter 4

Preventing unsafe abortion

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1. INTRODUCTION

Preventing unsafe abortion continues to be an important public health priority. There are an estimated 19 million unsafe abortions performed each year, resulting in the deaths of 68 000 women worldwide. An additional five million women suffer temporary or permanent disability because of complications from unsafe abortion. The UN Millennium Development Goal (MDG) 5 aiming “to improve maternal health” requires that morbidity and mortality associated with unsafe abortion be addressed: unsafe abortions are entirely preventable. The persistence of unmet need for family planning, user-failure or method-failure associated with different methods of contraception, a lack of information about contraception, and restricted access to safe induced abortions are factors that contribute to the relatively high incidence of unsafe abortion in developing countries.

Unsafe abortion is defined by WHO as a procedure for terminating an unwanted pregnancy either by persons lacking the necessary skills or undertaken in an environment lacking minimal medical standards, or both. The International Conference on Population and Development’s Programme of Action urges countries and organizations “to deal with the health impact of unsafe abortion as a major public-health concern” and to ensure that, in circumstances where abortion is not against the law, the provision of abortion is safe. The Programme’s work on preventing unsafe abortion responds to these recommendations. The overall strategy is to map and to generate scientifically sound evidence on the prevalence of unsafe abortion 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 that reduce the incidence of unsafe abortion and improve access to safe abortion and

high-quality post-abortion care. This work forms an integral part of WHO’s efforts to improve reproductive health and to reduce maternal morbidity and mortality. WHO’s first global strategy on reproductive health, adopted by the 57th World Health Assembly in May 2004, notes that “[as] a preventable cause of maternal mortality and morbidity, unsafe abortion must be dealt with as part of the Millennium Development Goal on improving maternal health and other international development goals and targets.” The Programme’s work in this area is organised around six main objectives; notable progress was made in 2004 on five of these, as discussed below.

2. OBJECTIVE: TO BROADEN THE PROVISION OF QUALITY SERVICES

The Programme supports research and activities that (i) evaluate interventions, (ii) seek to understand the socio-cultural and service barriers to eliminating unsafe abortion, (iii) assess reproductive health services generally and the quality of abortion services in particular, and (iv) develop evidence-based norms, tools and guidelines with the objective of expanding access to safe abortion services.

2.1 Progress

The Programme’s activities addressing this objective are described below.

2.1.1 Assessing abortions performed by mid-level providers

Restrictive abortion legislation impedes access to safe induced abortion in many countries. Even in countries where legislation permits early termination of pregnancy, access to

safe abortion services is often restricted because of limited resources, including a lack of trained personnel. Some countries have trained mid-level reproductive health-care providers (i.e. non-physicians) to perform induced abortions in an effort to improve access to safe abortions. To date there has not been an assessment in developing countries that compares the safety of first-trimester abortions performed by mid-level providers to those performed by physicians.

To address this evidence gap and to inform policy-makers, the Programme launched studies in South Africa and Viet Nam to test the hypothesis that the rate of abortion complications among women having first-trimester abortions by manual vacuum aspiration (MVA) performed by trained mid-level abortion providers was the same as the rate from abortions performed by physicians. A second objective of the study was to assess the quality of abortion care provided by mid-level providers compared with that provided by physicians. The study was conducted in Marie Stopes International clinics in South Africa and Viet Nam using a randomized controlled trial design. Women who agreed to participate in the study and to be randomly assigned either to a physician or to a mid-level provider (pre-determined by a random-number algorithm) were included in the study.

The findings from Viet Nam became available in 2004. In Viet Nam, mid-level providers include nurses, midwives and assistant doctors, but the study compared only midwives and one assistant doctor with physicians. The sample included 1734 women aged 18 years and older seeking a first-trimester abortion in four clinics located in four provinces. Table 4.1 shows the number and type of complications by type of abortion provider. There were no significant differences in the rates of complications occurring among women attended by mid-level providers and those attended by physicians.

The study also measured the quality of abortion care from the women's perspective (Table 4.2) and through observation (Table 4.3). All women receiving care from a physician or a mid-level provider were asked six specific questions related to the quality of care they had received. Six obstetrician–gynaecologists from the National Hospital of Obstetrics and Gynaecology in Hanoi observed a total of 60 procedures performed by physicians and 62 performed by mid-level providers. The study found that mid-level providers performed early abortions and provided abortion care at least as adequately as physicians. The only significant differences reported by women were a slightly lower tendency for mid-level providers to give a post-procedure explanation of pos-

Table 4.1. Number (%) of women with complications from first-trimester abortion, by type of provider and type of complication, Viet Nam, 2003

Indicators	Number (%) procedures performed by physician (n = 812)	Number (%) procedures performed by mid-level provider (n = 824)
Number of women with:		
Verified complications	10 (1.2)	10 (1.2)
Immediate complications		
Reaction to anaesthesia	1 (0.1)	0
Delayed complications		
Retained products	8 (1.0)	9 (1.1)
Infection	1 (0.1)	1 (0.1)
Number of women reporting symptoms at follow-up:^a	57 (7.0)	51 (6.2)
Abnormal bleeding problem	29 (3.6)	19 (2.3)
Abnormal vaginal discharge	20 (2.5)	18 (2.2)
Persistent pain or cramps	9 (1.1)	12 (1.5)
Raised temperature	4 (0.5)	5 (0.6)
Sickness, nausea, vomiting	4 (0.5)	4 (0.5)
Distribution of symptoms reported by women at follow-up:		
One symptom	51 (89.5)	45 (88.2)
Two symptoms	4 (7.0)	5 (9.8)
Three or more symptoms	2 (3.5)	1 (2.0)

^a Six women in each group had more than one symptom.

sible complications or provide counselling on contraception. By contrast, observers found that significantly more mid-level providers (98%) washed their hands before the examination than did physicians (90%) and that more mid-level providers examined uterine size and position before the procedure and changed gloves after the examination.

In sum, this study found no discernable or significant differences in the rates of overall or major complications from first-trimester abortions performed by physicians or by mid-level

providers in Viet Nam. These results should, however, be interpreted in the context of the study. The physicians and mid-level providers performing the abortions were well trained and had had several years of experience performing MVA abortions; they worked in a well-organized clinic environment; and the women receiving abortions were generally well educated. Nevertheless, this study suggests that in Viet Nam mid-level health-care providers who are given appropriate training and who work in a supportive clinic environment, can provide first-trimester MVA abortions as safely as physicians.

Table 4.2. Number (%) of women reporting on quality of abortion care, by type of provider, Viet Nam, 2003

Indicators	Number (%) of women reporting on physician provider (n = 812)	Number (%) of women reporting on mid-level provider (n = 824)
Pre-procedure explanation	789 (97.2)	806 (97.8)
Explanation during procedure	769 (94.7)	790 (95.9)
Opportunity to ask questions	789 (97.2)	790 (95.9)
Adequate management of pain	768 (94.6)	774 (93.9)
Post-procedure explanation of complications*	800 (98.5)	796 (96.6)
Counselling on contraceptive use*	790 (97.3)	786 (95.4)

*P < 0.05.

Table 4.3. Number (%) of procedures for which quality of care indicators were observed, by type of provider, Viet Nam, 2003

Indicators	Physician provider (n = 60)		Mid-level provider (n = 62)	
Washed hands before examination*	54	(90.0)	61	(98.4)
Examined uterine size and position before procedure	53	(88.3)	60	(96.8)
Changed gloves after examination	51	(86.4)	59	(95.2)
Put a clean cloth underneath client on the procedure table	58	(96.7)	59	(95.2)
Swabbed vulva	59	(98.3)	62	(100.0)
Swabbed vagina	60	(100.0)	62	(100.0)
Measured uterine height with cannula	60	(100.0)	61	(98.4)
Used no-touch technique	60	(100.0)	62	(100.0)
Moved cannula to empty the uterus	53	(88.3)	55	(88.7)
Stopped evacuation when procedure complete	60	(100.0)	62	(100.0)
Examined aspirated tissue	59	(98.3)	62	(100.0)
Cleaned the table after the procedure	53	(88.3)	52	(83.9)
Performed post-abortion abdominal examination	27	(45.0)	33	(53.2)
Discussed warning signs of complications	56	(93.3)	59	(96.7)

*P < 0.05.

2.1.2 The role of abortion in fertility decline

The findings from a study that examined the role of abortion in fertility decline became available in 2004. The study was conducted in Togo, but the phenomenon studied is typical of western Africa more generally; fertility has declined in this region, but increases in contraceptive prevalence are too small to fully explain the drop. The exact legal status of abortion in Togo remains unclear. Abortion is legally permitted on the grounds of "saving the life of the woman". Official interpretations of the law generally permit abortion on the grounds of "preserving physical or mental health" and in cases of rape, incest or fetal impairment. The decision to interrupt a pregnancy is made by the physician and requires the permission of the family of the pregnant woman. The intervention may take place up until the third month of pregnancy.

The study was a reproductive health survey of 4500 women of reproductive age (15–49 years); and also included in-depth interviews and focus group discussions that explored the pathways to induced abortion among women living in Lomé, Togo. The findings reveal that women in Lomé turn to abortion when faced with an unintended pregnancy: 25% of sexually active women reported having had at least one induced abortion. The likelihood that a married woman will have an abortion increases with age at marriage, level of education, economic status and the number of previous pregnancies and births. Recourse to abortion is especially high among young unmarried women aged 15–24 years. Altogether 39% of young women who had been pregnant at least once reported having had a clandestine induced abortion and of these 66% reported they had had complications (including haemorrhage and infection) following the abortion. The reasons young women gave for seeking abortion included avoiding the scandal of being a single mother (32%), having been raped (27%), not knowing who was the father of the child (21%) and others, such as wanting to stay in school or economic reasons (20%). Increasing the level of effective contraceptive use among women in Lomé would reduce the level of unintended pregnancy and the need for induced abortion. Clarification and dissemination of information about the circumstances under which abortion is legally permitted in Togo is urgently required.

The Programme has published *The effects of contraception on obstetric outcomes*; this document includes a review of the evidence on the relationship between the prevalence of contraceptive use and the incidence of induced abortion. In Bulgaria, Kazakhstan, Kyrgyzstan, Switzerland, Tunisia, Turkey and Uzbekistan a rise in contraceptive use is associated with a decline in the incidence of induced abortion, while in Cuba, Denmark, the Netherlands, the Republic of Korea, Singapore and the USA parallel rises in contraceptive use and in the incidence of induced abortion have occurred. This latter trend is explained by the fact that family planning programmes alone cannot meet the demand for contraceptives as norms for smaller families become widespread during fertility transition (the move from high fertility to low fertility).

When fertility rates stabilize, increased contraceptive use results in fewer induced abortions. Thus, in the long run, a rise in contraceptive use will inevitably lead to a decline in induced abortion.

2.1.3 The impact of induced abortion on uptake and continuation of contraceptive use: Armenia

In contexts where induced abortion is legally available on demand, unintended pregnancies that result from ineffective contraception are generally terminated. It remains unclear, however, whether the failure of the method, the failure of the user and/or the experience of an induced abortion has an impact on the post-abortion choice of contraceptive method and continuation of method use. Post-abortion contraceptive counselling is considered successful if a more effective method of contraception is adopted and the incidence of repeat abortion is reduced.

The fertility regulation trajectory in Armenia is characterized by a complicated nexus between abortion and contraception, with a high prevalence of contraceptive use (61%) accompanied by a high incidence of induced abortion (60% of pregnancies). Most contraceptive users, however, rely on traditional methods; withdrawal alone accounts for 51% of all current contraceptive use by Armenian couples. Abortion is legally available on demand and has traditionally been a commonly used method of fertility regulation. It is generally performed by trained physicians in either public or private facilities; the cost of an abortion in public clinics or hospitals is low. However, poor sanitary conditions, shortages of equipment and overcrowded facilities contribute to serious post-abortion complications. A paper using the detailed histories of contraceptive use collected during the 2000 Demographic and Health Survey in Armenia examined whether the experience of contraceptive failure and induced abortion led women to adopt a more effective contraceptive method (Ali & Shah, 2004).

Of the 4124 pregnancies reported to have occurred during the 5 years preceding the survey, 60% were terminated. Many contraceptive users (40%) had stopped using their contraceptive method within 12 months of initiation. The analysis of method-specific failure rates suggests that within 12 months of method initiation, a failure had occurred in one quarter of the episodes of periodic abstinence and almost one third of those of withdrawal. The majority of aborted conceptions (88%) resulted from method failure or user failure rather than from non-use or discontinuation of a contraceptive method.

The majority of women (70%) adopted a contraceptive method (usually withdrawal) within 12 months of having had an abortion. Another 17% reported conceiving within 12 months of having had an abortion, and the remaining 13% were at risk of pregnancy since they had not been using a method during the 12 months following an abortion. Post-abortion contraceptive choices were dominated by withdrawal (65%); condoms were the second most popular choice (11%), followed

by periodic abstinence (9%), the intrauterine device (8%) and other modern methods, such as the contraceptive pill, injection or female sterilization.

By the third month post-abortion, 65% of women who had terminated pregnancies that resulted from non-use of contraception were still not using contraception (Figure 4.1) while an additional 13% of women had become pregnant again. The majority of women who had used the traditional methods of withdrawal and periodic abstinence (86%) and then experienced a failure and terminated the pregnancy, returned to using a traditional method; as many as 76% of women who experienced failure while using a modern method and terminated the pregnancy, started using a modern method again. Previous use of a modern method was the strongest predictor of its subsequent use. Adjusting for background characteristics (such as place of residence, years of schooling, age and number of living children), the odds of adopting any modern method post-abortion were 13.5 times higher among those who had used modern methods before having an abortion compared with those who had used no contraception. Pre-abortion use of traditional methods was associated with lower odds (0.55) of adopting modern methods post-abortion. Another important predictor of post-abortion use of modern methods was older age.

The experience of method failure or user failure and abortion in Armenia did not significantly modify contraceptive behaviour following abortion. Contraceptive method uptake in Armenia is skewed towards withdrawal, and there is no apparent impact of its failure on the subsequent adoption of effective modern methods. A shift towards the use of modern methods of contraception is urgently needed to address the high level of unintended pregnancies and abortions that result from ineffective contraception in Armenia. Information on the consistent and correct use of withdrawal is also required to reduce failure rates. The Armenian study recommended the following policy and programmatic interventions:

- strengthen services to provide information and contraception at the time of abortion to promote the use of contraception post-abortion;
- increase the uptake of modern effective methods. This remains a challenge for the national family planning programme and it needs to be addressed on an urgent basis to break the cycle of method failure, unintended pregnancy, induced abortion and use of ineffective methods;
- provide information on the correct and consistent use of all contraceptive methods.

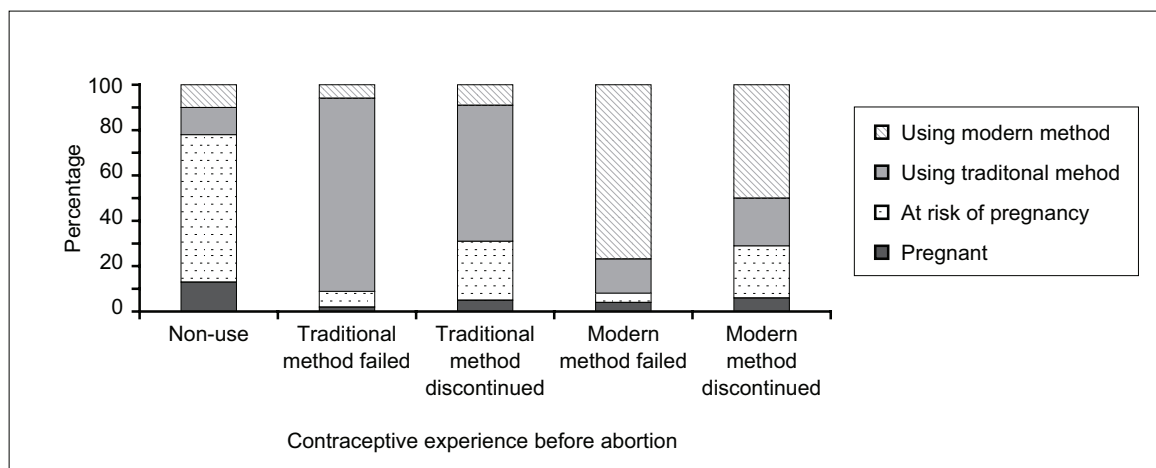
2.1.4 Assessing and improving abortion care

National strategic assessments of abortion-related issues have been previously undertaken in Viet Nam, Romania and Mongolia. These assessments, involving key stakeholders, identified gaps in services and the actions required to improve both the quality of reproductive health care generally and the quality of abortion care in particular.

2.1.4.1 Viet Nam

The Vietnamese Ministry of Health is working to implement the recommendations of the assessment. The Ministry launched the Comprehensive Abortion Care project during 2002–2003 to improve the quality of abortion services at two national reproductive health training centres (Tu Du Hospital in Ho Chi Minh City and the National Hospital of Obstetrics and Gynaecology in Hanoi). The Comprehensive Abortion Care project has been expanded to the provincial level via implementation of training and performance-improvement activities at four hospitals in two provinces. Scaling-up continues and, in 2004, under the guidance of provincial-level teams, the interventions were implemented in four district-level and eight commune-level health facilities in the same two provinces (Hai Phong and Dong Nai).

Figure 4.1. Percentage of women using contraception, pregnant or at risk of becoming pregnant at 3-months post-abortion, Armenia, 2000



Abortion care project activities to introduce medical methods of abortion for early abortion began in April 2004 with the training of 90 abortion providers from the central and provincial project sites. Women seeking abortions at any of these four sites are now offered the option of either medical methods or vacuum aspiration for early abortion. The abortion care project, at the request of the Ministry of Health, also provided an advanced training-of-trainers course to refresh trainers' clinical and training skills. The Ministry of Health funded this activity to further its goal of scaling-up the project's interventions, including the provision of medical abortion. In light of the project's success in Viet Nam, Ipas has organized study tours for policy-makers and abortion providers from Cambodia, India and Nepal. The participants visit project sites to learn how quality abortion services can be implemented in low-resource settings. A formal evaluation of the project is scheduled for 2005.

2.1.4.2 Romania

The Romanian Ministry of Health and Family is also working to implement the recommendations generated by the assessment. The Ministry has promulgated national standards and guidelines for abortion care and developed a proposal (not yet completely funded) for a 3-year project to test a model of comprehensive abortion and post-abortion care. In the meantime, the Government is giving priority to expanding contraceptive services at the primary health-care level, especially in rural areas. Funds have been earmarked for the purchase of contraceptives, which are provided free of charge to poor women and to women who undergo an abortion at a public health unit. The Government has launched an information and education campaign to communicate to women about the availability of free contraceptives, and the national health insurance board has included oral and injectable contraceptives on its list of reimbursable drugs.

The Romanian Government is also taking action that is directly related to abortion services. The Ministry of Health and Family has set a maximum fee for providing abortions, so that cost will not limit women's access to abortion services. The Romanian Parliament approved the Reproductive Health Law in 2004, which mandates the provision of quality abortion care, the availability of medical abortion and the routine use of vacuum aspiration rather than dilatation and curettage. All public hospital obstetrics and gynaecology departments must ensure that they offer safe high-quality abortion services and must provide counselling and post-abortion contraception. The Eastern European Institute for Reproductive Health has initiated a service-delivery research project on post-abortion contraception with funding from the United States Agency for International Development. The Institute, with technical support from the Programme, will soon begin testing an intervention in Romania that provides work-based reproductive health services to people working in factories; these services provide both contraceptives and counselling about reproductive health. The Ministry of Health and Family has signed an agreement with the Ministry

of Education and Research making it mandatory for health education (including education on reproductive health) to be taught in Romanian schools.

2.1.4.3 Mongolia

The Programme assisted the Mongolian Ministry of Health with its national strategic assessment of abortion-related issues in May 2003. The assessment identified appropriate policy, programme and research interventions needed to reduce the rate of unintended pregnancies and to improve the quality of abortion services in both the public and private health-care sectors. A workshop to disseminate the results of the assessment was held in September 2003. A funding proposal was developed and submitted to WHO and other donors including the German Agency for Technical Cooperation (also known as GTZ), the Japan International Corporation of Welfare Services, the United Nations Population Fund and the Mongolian Open Society Institute. The Public Health Institute and the State Research Centre for Maternal and Child Health and Human Reproduction (MCHRC) have been awarded grants to support the development, testing and scaling-up of comprehensive abortion care in Mongolia.

The project began in 2004 with the development and review of draft national technical standards and policy guidelines for safe abortion care. A baseline survey was conducted, and services and provider capacity at MCHRC in Ulaanbaatar were assessed. The survey highlighted the need for infrastructure upgrades and also identified training needs to be met in order to provide quality comprehensive abortion services. A training of trainers in comprehensive abortion care, including manual vacuum aspiration for first-trimester termination of pregnancy and post-abortion contraceptive counselling and provision, was conducted in November 2004.

The Ministry is working on registering and procuring mifepristone and misoprostol for first-trimester and second-trimester abortions. A follow-up in-service training session, including training in medical abortion, is tentatively scheduled for early 2005, but is contingent upon successful registration of mifepristone.

2.1.5 Guidelines on removing barriers to safe abortion services

WHO, in response to numerous requests for advice, published *Safe abortion: technical and policy guidance for health systems* in 2003. The Programme subsequently received requests for technical support from a number of countries and from WHO Regional Offices seeking to implement the policies in the document. In June 2004, a regional workshop, organized in collaboration with the WHO Regional Office for Europe and with Ipas, was held in Riga, Latvia. Five-person teams from Latvia, Lithuania, the Republic of Moldova, the Russian Federation and Ukraine attended the workshop. The teams were made up of representatives from the ministries

of health, from professional associations of obstetricians and gynaecologists, from national reproductive health institutes and from non-governmental organizations. The purpose of the meeting was to introduce participants to the guidance document and to the Strategic Approach, a tool that countries can use to implement WHO recommendations. The workshop also helped participants develop proposals for strategic assessments of the quality of abortion care and/or related reproductive health services.

All of the country teams expressed an urgent need to strengthen policies and programmes related to contraception and abortion. They presented an overview of data. Their research results document barriers to access to contraception, high rates of induced abortion, poor quality of care in abortion-related services and lack of post-abortion counselling on contraceptives. The participants were enthusiastic about implementing WHO's recommendations and developed draft proposals for conducting a strategic assessment of fertility regulation services in their countries. After returning home, they held discussions with other key stakeholders and each reached agreement on their country's desire to move forward with the implementation of a strategic assessment. They submitted proposals for strategic assessments to the Programme for review and approval by the Specialist Panel for Country Programme Development. The Programme has funding available to support one or two strategic assessments and is seeking additional funds to support assessments in all five countries.

Nearly 20 000 copies of the guidance document had been distributed or sold by the end of 2004. In addition, 5345 copies of the document have been downloaded from the Programme's web site. The document is available in English, French, Polish, Portuguese, Russian and Spanish. The Russian version was translated, published and disseminated by the Regional Office for Europe, and the Spanish version was translated and published by the Pan American Health Organization, both with financial support from the Programme. In December 2004, the French version was presented during a workshop at the 8th Congress of the Société Africaine des Gynécologues et Obstétriciens in Cotonou, Benin, and several hundred copies were distributed.

2.2 Planned activities

2.2.1 Publication, dissemination and follow-up of the study on abortions performed by mid-level providers

A paper comparing the results of the study conducted in South Africa and Viet Nam that looked at the safety, efficacy and quality of abortions performed by mid-level providers will be published in 2005 along with papers presenting results from individual countries. The results will be disseminated nationally in the two participating countries. Contingent upon the availability of funds, the study will be implemented in public hospitals in South Africa and Viet Nam or replicated in clinics in another country (for example, Nepal or Zambia).

2.2.2 Assessing and improving abortion care

The Comprehensive Abortion Care activities in Viet Nam will be formally evaluated with technical assistance from the Programme. In Romania, a project that has technical support from the Programme will test interventions to provide reproductive health services to factory workers. A strategic assessment of the quality of abortion care will be undertaken in the Republic of Moldova and, contingent upon the availability of funds, in one or more of the following four countries: Latvia, Lithuania, the Russian Federation or Ukraine.

The Programme together with WHO's Regional Office for South-East Asia, will also hold a regional meeting (in late May 2005) involving participants from the Region's 11 countries. The aim of the meeting will be to disseminate the guidance on safe abortions. The meeting will focus on the details of the clinical, service-delivery and policy aspects, and will support elaboration of plans by country teams for implementing the guidance at the national and subnational levels, as appropriate.

2.2.3 New projects

Two new projects will be implemented in 2005. The first project, "Unsafe termination of pregnancy: a comparative analysis of choices and opportunities in Kenya", will describe the sociocultural context of women seeking abortion, both safe and unsafe, and explain how it influences their choices and opportunities within a restricted setting. The objectives are to (i) describe the women's experiences of induced abortion and post-abortion care, (ii) understand the decision-making process for terminating a pregnancy, and (iii) document the sociocultural factors that facilitate or inhibit women's choices and opportunities for seeking either safe or unsafe abortions.

The second project, "The strategic assessment of post-abortion care in China", seeks to provide baseline diagnostic information on the quality of post-abortion care in typical health-service settings. The study objectives include (i) assessing the availability of equipments and supplies at different levels of the health-delivery system, (ii) documenting providers' and clients' perspectives on the quality of post-abortion care, and (iii) comparing the quality of post-abortion care in public health clinics with that in private clinics.

3. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS OR TECHNOLOGIES

Improving abortion technologies and expanding the choice of safe and effective methods of abortion are critical to reducing the incidence of unsafe abortion. The Programme's research has already contributed to the development of medical (non-surgical) methods for the termination of early pregnancy, which are preferred by many women. Research has also shown that the dose of mifepristone (the more expensive

of the two compounds used for medical abortion) can be decreased and that vaginal administration of misoprostol is more effective and better tolerated than oral administration.

Ongoing research will help identify ways to reduce the duration of post-abortion bleeding after medical abortion and will further simplify and improve regimens, including developing misoprostol-only regimens; it will assess the benefits of routine priming of the cervix prior to vacuum aspiration in order to reduce complications; and it will aim to identify the best treatment for a non-viable pregnancy.

3.1 Progress

3.1.1 Development of misoprostol-only regimens for non-surgical abortion

The sequential mifepristone-misoprostol regimen to induce early abortion has been used in a few countries for more than 10 years. However, women in most parts of the world do not have access to this procedure; cost, commercial issues and the political climate hinder the availability of mifepristone even in countries where abortion services are available. A technical consultation on abortion held in 2000 recommended that the Programme develop effective, safe and acceptable misoprostol-only regimens for both first-trimester and second-trimester abortions. Other prostaglandins were tested about 20 years ago and were found to be expensive, cumbersome to use and unacceptable for early abortion, but there has been no systematic research undertaken on the development of misoprostol-only regimens. The Programme sought evidence on the proper dose of the drug, on the optimal interval between repeat doses, on the most effective route of administering the drug and on the acceptability of misoprostol-only regimens.

The Programme organized two randomized multinational trials to test the efficacy and safety of misoprostol-only regimens: one focused on abortions during the first trimester and the other on abortions during the second trimester. The first-trimester study compared the effectiveness of up to three 0.8 mg doses of misoprostol administered either vaginally or sublingually at either 3-hour or 12-hour intervals. Eleven centres in Armenia, Cuba, Georgia, India, Mongolia and Viet Nam participated in the trial. The investigators recruited 2068 pregnant women (up to 63 days' gestation) who had requested legal termination of pregnancy. The four regimens were compared with respect to their effectiveness for inducing complete abortion, the time required to abort, the acceptability of the regimens and the occurrence of side-effects.

The results of an interim analysis of 1559 participants (conducted after completion of the clinical phase of the study) were presented at the meeting of the Research Group on Post-ovulatory Methods of Fertility Regulation in May 2004. The results suggest that efficacy was higher among women in the groups that used the tablets vaginally and that the 3-hour interval between doses was more efficacious than the

12-hour interval. The final analysis will be carried out during summer 2005 and, if these results hold up, they will have significant implications for non-surgical abortion practices. Currently, relatively long intervals (often 24 hours) are used between doses of misoprostol administered to induce abortion in the first trimester. However, preliminary results suggest that the 3-hour interval not only improves efficacy but that it significantly reduces the time to abortion; most of the women to whom the drug was administered at 3-hour intervals aborted during the day of treatment. Side-effects such as vomiting and diarrhoea were more common among women who took misoprostol sublingually. A large percentage of women in all four of the groups (87–94%) reported that they were either highly satisfied or satisfied with the method; satisfaction rates were somewhat higher in the groups that used the tablets vaginally.

The second-trimester study involved 681 women who had requested legal termination of pregnancy at 14–20 weeks' gestation. Clinicians from various countries collaborating with the Programme on the trials requested that a study be done to look at improving the procedures for second-trimester abortions. The study was carried out in nine centres in Armenia, Georgia, Hungary, India, Slovenia, South Africa and Viet Nam. Women requesting termination of pregnancy in the second trimester received up to five doses of 0.4 mg of misoprostol, administered either vaginally or sublingually, at intervals of three hours. The results of an interim analysis of 607 women performed in May 2004 suggest that vaginal administration had higher efficacy. The results show no significant difference in the occurrence of side-effects between vaginal and sublingual administration. When asked about the method of administering the drug, most women preferred sublingual administration (60–70%). Most of the centres participating in the study indicated that the regimens tested produced better results than the regimens they were using (intra-amniotic or extra-amniotic injection of hypertonic agents, ethacridine lactate or prostaglandins), and five centres indicated that they have already changed their second-trimester regimen to that used in the study.

3.1.2 Non-surgical abortion using a sequential regimen

Research has shown that the pharmacokinetics of mifepristone are similar for doses ranging from 100 mg to 800 mg. Tablets of mifepristone are generally sold in packages of three 200 mg tablets, and the registered dose is 600 mg. Earlier research by the Programme demonstrated that 200 mg is sufficient in the sequential regimen to induce abortion, and many clinicians follow the regimen recommended by these research results. In an effort to further reduce unnecessary costs, the Programme launched a study of first-trimester abortion comparing 100 mg doses of mifepristone with 200 mg doses. Shanghai Hualian Pharmaceuticals in China supplied the 100 mg tablets for the research. This randomized trial includes women up to 63 days from their last menstrual period and also tests two different time intervals between

administration of mifepristone and vaginal administration of 0.8 mg misoprostol (24 hours and 48 hours).

The four regimens will be compared to determine their effectiveness in inducing complete abortion relative to the length of gestation, the frequency of side-effects and the duration of bleeding. The project included 2184 women and the clinical phase of the trial was completed at the end of 2004 in 13 centres in China, Hungary, India, Mongolia, Romania, Serbia and Montenegro, Slovenia, South Africa and Viet Nam. If the study demonstrates similar efficacy among all study groups, the recommended dose of mifepristone can be reduced to 100 mg, and the interval between administration of mifepristone and misoprostol can be reduced to 24 hours. These changes will reduce the cost of medical abortion and shorten the length of the procedure.

3.1.3 Routine priming of the cervix with misoprostol

Vacuum aspiration is generally safe when performed by trained providers but complications (cervical injury, uterine perforation, severe haemorrhage, incomplete evacuation, pelvic infection) may occur. WHO recommends that cervical preparation prior to abortion by vacuum aspiration be considered for women under the age of 18 years, for nulliparous women with gestations of ≤ 9 weeks and for all women with gestations of ≤ 12 weeks. Despite the advantages of cervical preparation, this recommendation has not been put into practice in many settings because it increases the cost of and time needed for abortion. When misoprostol became available, the Programme first tested its effects on priming the cervix in small trials and, in October 2002, launched a large randomized, double-blind multicentre trial to test whether routine preoperative treatment with 0.4 mg misoprostol administered vaginally three hours prior to vacuum aspiration to all women at ≤ 12 weeks' gestation would reduce the prevalence of complications.

The study is nearing completion; as of early December 2004, out of a target sample size of 4984 women, a total of 4063 women had been included in the study at 14 centres in Armenia, China, Cuba, Hungary, India, Mongolia, Romania, Slovenia and Viet Nam. The results are expected in late 2005. If the results show a reduction in the prevalence of complications, then WHO's recommendations would need to be revised to reflect the benefits of using misoprostol—a drug that is cheap and easy to administer—for all women at ≤ 12 weeks' gestation.

There is little information on the prevalence of sexually transmitted infections among women seeking abortion or on infection rates following the procedure. To address these issues, a nested study was added to the main study to investigate the prevalence of sexually transmitted infections among women seeking an abortion. Some of the study centres give prophylactic antibiotics to all women; the study will evaluate the benefit of this practice and whether it should be generally recommended.

3.2 New projects initiated and planned

The protocols for three multicountry trials were approved in 2003: (i) a randomized study evaluating methods for reducing post-abortion bleeding after medical abortion, (ii) a comparison of two doses and two routes of administration of misoprostol after pretreatment with mifepristone for early termination of pregnancy, and (iii) a comparison of medical and surgical methods to evacuate the uterus in women who have a non-viable pregnancy of ≤ 12 weeks' gestation. Initiation of the studies will require reaching an agreement with a pharmaceutical company that is willing to collaborate with the Programme and is prepared to set a preferential price for mifepristone and misoprostol sold to the public sector in developing countries after registration of the drugs in these countries. The Programme is collaborating with the Concept Foundation to find a pharmaceutical company that meets these criteria and is willing to supply the medicines for these studies.

The Programme's staff drafted several protocols for testing various drug combinations to improve non-surgical procedures for termination of early pregnancy. The aim was to induce abortion with a single administration of medicine and to reduce the duration of bleeding. In its review the Programme's Toxicology Panel recommended that toxicology studies be carried out before the proposed combinations of medicines are used in clinical trials. These studies could not be performed due to a lack of funds. The protocols were thus given to the Programme's collaborators, and they are now conducting clinical trials of these combinations in China, the Hong Kong Special Administrative Region of China, Sweden and Switzerland.

In 2005, in addition to launching the three multinational trials noted above, the final analysis of four of the projects mentioned above (the two misoprostol trials, the study on cervical priming, and the study testing 100 mg versus 200 mg of mifepristone administered at 24-hour versus 48-hour intervals between mifepristone and misoprostol) will be completed, and papers will be drafted. Findings from these trials are anticipated to have major implications for medical abortion procedures and services.

4. OBJECTIVE: TO STRENGTHEN HEALTH MANAGEMENT AND SUPPORT SYSTEMS

This objective addresses the provision of critical information for national policies and programmes, including listing safe abortion drugs in the WHO Model List of Essential Medicines, developing training curricula using an ethical and legal framework and documenting the cost and cost-effectiveness of providing different methods of abortion by type of provider.

4.1 Progress

The progress of activities under this objective was constrained by a lack of funding. Only two activities (inclusion of safe abortion drugs on the WHO Model List of Essential Medicines and training curricula using an ethical and legal framework for providing safe abortion) were given high priority. An application was submitted for mifepristone combined with misoprostol to be included for first-trimester medical abortion (up to 63 days from the last menstrual period) in the WHO Model List of Essential Medicines. The application is being processed and its review by the Expert Committee is scheduled for early 2005.

5. OBJECTIVE: TO PROMOTE SOUND NATIONAL POLICIES AND LAWS

The aims of this objective are to assist with the development of sound national policies and laws, and to ensure that they are based on an up-to-date and in-depth understanding of how they affect the safety of women having abortions. The Programme's contribution consists in generating, collating and synthesizing evidence on the incidence of unsafe abortion and its determinants and consequences.

5.1 Progress

5.1.1 *Global and regional estimates of the incidence of unsafe abortion and associated mortality in 2000: fourth edition*

The report providing global and regional estimates of the incidence of unsafe abortion and associated mortality was published. Overall, 19 million unsafe abortions are estimated to occur each year, resulting in the deaths of 68 000 women. A paper on the distribution of unsafe abortion by age and another on levels of contraceptive use, fertility and unsafe abortion by region are in press.

The work for the Global Burden of Disease project on ill-health resulting from unsafe abortion has been completed and a working paper is available on the WHO website (<http://www3.who.int/whosis/burden>). Global and regional estimates of abortion mortality and disability-adjusted life years are also available in this report. However, in the tables published in WHO's annual *World Health Report*, all maternal conditions, including unsafe abortion, are grouped together in one category.

5.1.2 *Consensus conference on medical abortion*

The WHO guideline *Safe abortion: technical and policy guidance for health systems* contains a chapter on medical abortion. This chapter describes medical methods and their use. Service providers, however, need additional detailed evidence-based guidance on various issues related to medical abortion. There is also a need to harmonize the recom-

mended regimens and the clinical practices used, since these vary among countries and hospitals.

An international consensus conference on medical abortion was organized by the Programme, from 1–5 November 2004, at the Rockefeller Foundation's Bellagio Study and Conference Centre in Italy. Prior to the conference, participants reviewed the evidence for recommended regimens and prepared background papers on topics relevant to the discussions. These papers will be submitted for publication in a peer-reviewed journal. Participants identified approximately 30 practical questions related to legal issues, government registration of drugs used for medical abortion, service delivery, pre-abortion assessment of the client, recommended regimens and post-abortion care. Answers to these questions, and recommendations based on the answers, were drafted during the conference. Conference participants strongly recommended that this information be published as soon as possible to improve the availability of high-quality medical abortion services. A publication similar to WHO's *Selected practice recommendations for contraceptive use* was proposed. It is clear that the mifepristone-misoprostol regimen is preferable but it is also important to provide guidance on the misoprostol-only regimen for early first-trimester abortions. It was, therefore, proposed that the document should also contain the main findings of the Programme's misoprostol-only trials.

5.1.3 *Technical support*

Technical assistance was provided for the implementation and evaluation of a study on unwanted pregnancies and post-abortion complications in Pakistan, undertaken by the Population Council's office in Pakistan. The study revealed that about 890 000 induced abortions occur each year in Pakistan, and 197 000 women are estimated to be treated annually at public health facilities for complications resulting from unsafe induced abortion. Results were disseminated in a meeting attended by government officials, providers and representatives of national professional associations and international organizations. Recommendations to improve contraceptive uptake, continuation of use of contraceptives and post-abortion care were outlined. Senior government officials considered that addressing the high incidence of unsafe induced abortions and the resulting complications should be a high priority.

5.2 Planned activities

Activities planned for 2005 include (i) updating information on the incidence of unsafe abortion and related mortality, (ii) publishing papers presented at the international consensus conference on medical abortion, and (iii) developing selected practical recommendations for medical abortion. In addition, the Programme will be working with the Alan Guttmacher Institute to update global estimates of abortions (both legal and illegal).

6. OBJECTIVE: TO ENSURE EFFECTIVE INTERNATIONAL EFFORTS AND COLLABORATION

This objective seeks to create an enabling legal and policy environment through the use of evidence-based advocacy and action that aims to eliminate unsafe abortions. The Programme collaborates with the United Nations human rights treaty bodies and provides scientific advice to assist in the development of appropriate programmes and policies.

6.1 Progress

6.1.1 Collaboration with UN human rights treaty bodies

The Programme organized a technical consultation with the UN Human Rights Committee to discuss technical and policy guidance on safe abortion and post-abortion care in the context of the International Covenant on Civil and Political Rights. Further details are available in the report by the Gender and Reproductive Rights Team (see Chapter 6)

6.1.2 Collaboration with the International Consortium for Medical Abortion

The Programme collaborates with the International Consortium for Medical Abortion. In October 2004, the Programme participated in an international conference, organized by the Consortium and held in Johannesburg, South Africa; the conference was an international forum on policies, programmes and services as they relate to medical abortion. More than 100 physicians, nurses, representatives of ministries of health, as well as human rights and women's rights advocates, and researchers attended. The discussions and conclusions noted that the one major stumbling block to accessing

medical abortion was that mifepristone and misoprostol are unavailable in a number of countries. In places where these drugs have been registered, the price of mifepristone makes medical abortion unaffordable for many women. The meeting recommended that effective misoprostol-only regimens should be developed, information on these regimens should be made widely available and efforts should be pursued to make the combined regimen less expensive.

6.1.3 Collaboration with the Concept Foundation

One of the major obstacles to accessing medical abortion is the lack of availability of the required drugs, especially mifepristone. The price of mifepristone in many countries where it is registered is prohibitive; thus national health services are unable to offer it. The Programme is working with the Concept Foundation to identify pharmaceutical companies willing to collaborate in the effort to improve access to medical abortion. The plan is to use data from the Programme's trials to obtain government registration of the regimen and to develop an agreement with the companies so that in developing countries where the regimen is registered it is available at an affordable preferential price for purchase by the public sector.

6.2 Planned activities

In 2005, collaboration with UN human rights treaty bodies, the International Consortium for Medical Abortion and the Concept Foundation will continue. It is anticipated that registration dossiers will be compiled using results from the Programme's trials to register the combined regimens in selected countries. In addition, working with the Concept Foundation, the preferential price for the medical abortion regimen for the public sector in developing countries will be negotiated.

Annex 1a

SPECIALIST PANEL FOR SOCIAL SCIENCE AND OPERATIONS RESEARCH IN REPRODUCTIVE HEALTH

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See Annex 1 of "Promoting Family Planning"

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	2	50	1	25	1	25	4
Women	1	25			1	25	2
<i>from:</i>							
AFRO							
AMRO							
EMRO							
EURO			1	25	1	25	2
SEARO							
WPRO	2	50					2

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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	
Members	37	71	10	19	5	10	52
Women	20	38	4	8	2	4	26
<i>from:</i>							
AFRO	4	8					4
AMRO	3	6			2	4	5
EMRO							
EURO			10	19	3	6	13
SEARO	5	10					5
WPRO	25	48					25

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	27	53	9	18	15	29	51
Women	17	33	7	14	9	18	33
<i>from:</i>							
AFRO	3	6					3
AMRO	6	12			7	14	13
EMRO	2	4					2
EURO			9	18	6	12	15
SEARO	3	6					3
WPRO	14	27			1	2	15

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Chapter 5

Sexual health

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1. INTRODUCTION

Sexual health has always been closely linked with reproductive health, particularly since the International Conference on Population and Development in 1994, which defined reproductive health as incorporating sexual health. However, recently, this conceptualization has been challenged with the increasing acceptance of sexual health as a broader and more encompassing field than reproductive health. Rather than being a component, sexual health should in fact be seen as a necessary underlying condition for reproductive health, while at the same time being relevant throughout the lifespan and not only during the reproductive years.

The achievement of sexual and reproductive health necessitates that people have the right and power to exercise control over their sexual and reproductive lives and have access to related health services. While these rights, and the ability to exercise them, constitute important values in themselves, they are also preconditions for well-being and development. The neglect and denial of sexual and reproductive health and related rights are at the root of many health-related problems around the world, such as sexually transmitted infections (STIs) and reproductive tract infections (RTIs), HIV infection, unintended pregnancy and unsafe abortion, infertility, sexual dysfunction, violence related to gender and sexuality, mental health and well-being related to sexuality, the impact of physical disabilities and chronic illnesses on sexual health, and female genital mutilation and other harmful sexual practices.

These issues go far beyond medical concerns. Indeed, one of the most significant developments of the past decade has been the acknowledgement of the complex social, economic and political forces that influence people's vulnerability to sexual ill-health. In light of this understanding, it is evident

that efforts to change the behaviour of individuals or groups are unlikely to be successful in improving sexual health if carried out in isolation. Underlying forms of exclusion and inequality—in particular poverty, gender inequalities and unequal access to education and health care—also have to be addressed.

The linkages between sexual and reproductive health problems and people's ability to have a safe and satisfying sexual life require that a wider spectrum of health-care needs are recognized and provided for. Determining the best ways of addressing sexuality and some specific sexual health issues in the public health-care system, such as sexual violence or dysfunction, remains a challenge. Sexual health concerns are often dealt with by the private sector because few resources are publicly available. As a result, there is little evidence on how sexuality and sexual health interventions (other than HIV or STI prevention and treatment) have been specifically implemented and scaled-up in different countries. This may be because in resource-constrained settings dealing with sexuality, and even many aspects of sexual health, often appears to be a luxury despite its fundamental relevance for sexual and reproductive health. Without such evidence, few recommendations can be made about how to programme sexual health interventions in an integrated manner at country level.

The Department's emerging area of work in sexual health gives priority to building the evidence base in order to develop programmes that address sexuality and sexual health effectively and holistically and to increase the understanding of the meaning, context and effects of harmful sexual practices in order to help eradicate them. This necessitates rethinking of what it is that constitutes evidence: the complex nature of sexuality and sexual relations means that classical models

of evidence generation (systematic reviews, meta-analyses, randomized controlled trials, etc.) may not apply, and therefore alternative models of looking at programmatic experiences and best practice may need to be constructed. It also requires expanding the scope of enquiry to non-health-sector interventions (e.g. community-based or school-based interventions or programmes, legal reform, or use of media) that may contribute to or facilitate changes in the delivery of health services or in the actions that the health service may be able to take to improve the sexual health and well-being of individuals and couples.

2. OBJECTIVE: TO BROADEN THE PROVISION OF QUALITY SERVICES

It is recognized that there is an insufficient evidence base from which to make broad programmatic recommendations that address sexuality and sexual health. Cultural and contextual specificities are often cited as the reason good practice in one country is not necessarily transferable to another country or region. The Department seeks to investigate, in collaboration with partners, alternative models of generating evidence on sensitive topics related to sexuality and sexual health. The results of these efforts will assist in building the evidence base for better programming and delivery of sexual and reproductive health-care services. The Department will also invest in the training of a new team of sexual health researchers that will contribute to increasing the breadth and scope of the evidence base through their research initiatives in developing countries.

2.1 Progress and planned activities

In 2004, to conduct evidence-generation projects, partnerships were established with the Department of Injuries and Violence Prevention and the Department of Gender, Women and Health, as well as with international institutions, such as the Royal Tropical Institute (KIT) of the Netherlands and the London School of Hygiene and Tropical Medicine (LSHTM). These partnerships and collaborative activities will form the basis of the work on programmatic guidance in sexual health in the coming years.

2.1.1 Generating evidence to promote sexual health

The Department has developed an innovative plan to generate new evidence in sexual health programming using modified systematic reviews and rapid assessment or evaluation methods to identify potential evidence of good or best practices in two key programme areas: counselling that addresses sexuality (sometimes called sexuality counselling), and detection and treatment of victims of sexual violence. In 2004, partnerships were forged and strengthened in order to begin operations research in 2005. KIT will conduct research on counselling that addresses sexuality. The Department, in collaboration with experts from LSHTM, the Department of Gender, Women and Health, and the Department of Injuries

and Violence Prevention will conduct operations research on sexual violence interventions. This evidence-gathering will be guided by a research advisory group of experts on systematic reviews and from each of the disciplines under investigation.

The two operations-research initiatives will have similar methods, protocols and instruments for rapid assessments. The research on sexuality counselling will begin in early 2005, and the research on sexual violence will commence approximately six months later. It is anticipated that both protocols will be presented for technical and ethical review by the Programme in the fall of 2005.

2.1.2 Sexual health documents series

The report of the WHO Technical Consultation on Sexual Health held in 2002 in Geneva, *Defining sexual health*, and a review of programmes' experiences in integrating sexual health, *Integrating sexual health interventions into reproductive health services: programme experience from developing countries*, have been finalized and will be published in 2005. A third document, *A conceptual framework for programming in sexual health*, provides a basis for understanding and developing programmes that include sexuality and sexual health more directly in primary and reproductive health-care settings. These documents are the first in a series that will offer guidance on programming in sexual health.

The new series will be guided by an internal committee that will establish criteria for the selection of appropriate publications for inclusion in the series in consultation with the Department's Documents Committee.

2.1.3 Sexual health research course

Over the past 11 years, the Department, in collaboration with the University of Geneva, Geneva, Switzerland, has run a reproductive health research course for scientists from current and potential collaborating research centres. In 2004, the Programme, in collaboration with the Fonds Universitaire Maurice Chalmou of the University of Geneva and the Geneva Foundation for Medical Education and Research, developed a sexual health research course that will run in parallel and in conjunction with the Programme's post-graduate training course in reproductive health. The aim of the new course is to broaden the perspective of researchers who are conducting biomedical, epidemiological, operations or social science research in areas related to sexual health, such as STIs and HIV, by teaching them about the need for more qualitative and quantitative research studies that capture both the determinants and effects of sexual practice and health status. The course also aims to teach researchers from developing countries representing a variety of disciplines how to use and interpret qualitative and quantitative data to improve their research objectives. This pilot course will target researchers from research centres in developing countries in order to begin building the capacity to conduct

qualitative and quantitative research studies in sexual health in the coming years.

Twelve scientists from developing countries will be attending the course, which will run for six weeks in February–March 2005 at WHO in Geneva. Sponsorship is provided by the Geneva Foundation for Medical Education and Research, the Department, and the Ford Foundation, Indonesia. Lecturers are drawn from the Department; the Departments of HIV/AIDS and Gender, Women and Health; the London School of Hygiene and Tropical Medicine; the Kinsey Institute for Research in Sex, Gender and Reproduction at the Indiana University, Bloomington, IN, USA; the University of Lausanne, Lausanne, Switzerland; and from the scientific community in Geneva.

3. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS OR TECHNOLOGIES

In recent years there has been an increased recognition of the impact of pharmaceutical agents, alternative medicines and health treatments on sexual well-being and sexual function. Due to resource constraints, low-priority activities related to studying the impact of treatment for cancer, heart disease and diabetes on sexual function have not been undertaken.

3.1 Progress and planned activities

Work in this area was limited to completion of the *Guidelines for the use of androgens in men*, which is described below. Because sexual health is a new field of work in the Department, the sexual health-specific activities that the Department was already undertaking were moved to this new programme area. The work described below was one such product. As stated above, work in this area remains important but it is currently beyond the financial scope of the Department. However, the Department continues to monitor developments in the field concerned with the promulgation of technologies and their positive and negative effects on sexual health and well-being.

3.1.1 Guidelines for the use of androgens in men

In 1992, the Programme published *Guidelines for the use of androgens in men*. This document summarized the biological effects of androgens and the risks and benefits of exogenous androgen administration. It also made recommendations for selection and surveillance of hypogonadal men and male volunteers participating in trials involving the use of androgen preparations.

At the time these guidelines were published, the Programme was one of the few supporters of investigations into male contraception and was actively developing new androgen preparations for male contraception. The Programme therefore saw a need to provide guidelines for assessing the

efficacy, safety and reversibility of new experimental androgen-containing male contraceptives.

During the past decade, the Programme has completed several trials of testosterone-containing male contraceptives and continues to support research into these contraceptives in China and other developing countries. At the same time, a multitude of new androgenic preparations has been developed; male contraception has attracted the interest of the pharmaceutical industry; the combined use of androgens and gestagens has become the preferred experimental model for more rapid onset and greater efficacy in suppressing spermatogenesis; and a better understanding of androgen deficiency is developing.

Thus, in 2003, a meeting of an editorial board was held, and the group determined that it would be appropriate to update the guidelines in order to provide researchers and clinicians with an up-to-date perspective on the potential risks and benefits of androgens and combined androgen–gestagen regimens for male contraception; the group also decided to revise recommendations for experimental surveillance of participants taking part in male hormonal contraception protocols. These proposed guidelines will also be of benefit to regulatory agencies and national ethical review bodies that are involved in reviewing research proposals looking into male hormonal contraception.

In 2004, the concept of revising the guidelines was reviewed and approved by the Department's Documents Committee, and work has been under way to identify and contact authors for various chapters. A meeting will be held to review the proposed revisions in late 2005 or early 2006, as resources allow.

4. OBJECTIVE: TO STRENGTHEN HEALTH MANAGEMENT AND SUPPORT SYSTEMS

Understanding and strengthening the health system to deliver high-quality, non-discriminatory sexual health interventions or to better address sexuality within existing sexual and reproductive health services has been identified as an important area of work for the Department. It is anticipated that work in this area will evolve out of the operations research being conducted under the objective of broadening the provision of quality services (see section 2.1.1) in subsequent years. In the period under review, therefore, only one activity has been undertaken.

4.1 Progress

In recent years, the Department's Scientific and Technical Advisory Group has reiterated the importance of assessing the quality of, and working to improve, the training on sexuality for health professionals, particularly mid-level providers. Given that resources are limited, the Department has thus far focused on joining existing initiatives in this important

area. As resources allow, the Department plans to increase its work on the development of curricula for health workers that addresses gender, sexuality and rights as they relate to reproductive and sexual health, in collaboration with other departments and partners.

4.1.1 Develop and strengthen training on human sexuality for health workers

The Department has lent its support to the International Society for Sexual and Impotence Research to conduct an international review of medical school curricula to assess whether and how human sexuality is being taught to general practitioners. The results of the review will inform the development of a project to elaborate new medical curricula in order to strengthen both pre-service and in-service training for a variety of health-care workers. Studies have shown that sexuality and sexual health needs are most often addressed (when they are addressed) by front-line health workers, such as nurses, counsellors and midwives. The Department therefore will focus future efforts on improving pre-service and in-service training for these groups. In addition, given the gender disparities in sexual health problems, and the direct and indirect links to issues such as sexual violence, the Department will focus its efforts on developing a curriculum that builds on and adapts the gender and rights course (known as *Transforming health systems: gender and rights in reproductive health*) in collaboration with the Department of Gender, Women and Health. The future development of this project will, however, depend on the availability of additional resources.

5. OBJECTIVE: TO FOSTER A SUPPORTIVE ENVIRONMENT

The Department is committed to developing a better understanding of sexual practices that may be or are harmful to women's physical and mental health or that contribute to existing gender disparities. To develop this understanding, the Department has received significant support from the European Union for its work on female genital mutilation, and from a variety of national and regional partners and collaborating organizations, such as the Ford Foundation and UNAIDS, to support this portfolio of work.

5.1 Progress and planned activities

Research initiatives in the area of female genital mutilation and other harmful sexual practices began in 2003 and are scheduled to continue through 2006. The aim of this work is to better understand the determinants and meanings of these practices for those who engage in them and to strengthen our messages and other efforts aimed at eradicating any practices that may be harmful or that contribute to furthering gender inequalities between men and women.

5.1.1 Research on female genital mutilation and sexuality

The Department is planning to implement a study to investigate the relationship between female genital mutilation and sexuality. A closed call for concept papers has been developed and will be sent to selected researchers. The researchers have been selected as the result of an open call by the Population Council for research results on female genital mutilation and sexuality. The concept papers will be reviewed by a technical group, and appropriate researchers or institutions to conduct the study will be identified. Once approved by the Department, research will likely begin in mid-to-late 2005.

5.1.2 Research on female genital mutilation and decision-making processes

A research study on the decision-making process around female genital mutilation has been developed. The study, called "Contingency and change in the practice of female genital mutilation: dynamics and decision-making in Senegambia", represents a pioneering effort to integrate theoretical models of behaviour change in order to develop a comprehensive understanding of the process of decision-making surrounding female genital mutilation. The research will be conducted in two Senegalese and two Gambian communities. It will be conducted in two phases: the first will be qualitative and the second quantitative. Data collection for the first phase of the study started this year.

5.1.3 Operations research on community interventions to eradicate female genital mutilation

As a preparatory activity, a consultative meeting on community-based interventions and programmes took place in Bamako, Mali, from 30 November–3 December 2004. It was attended by representatives of organizations who have implemented community-based interventions to abolish the practice of female genital mutilation. The main objectives of the meeting were to identify the determinants of best practices with regard to community-based interventions and to provide guidance for the development of an operations research protocol. Following the meeting, a study protocol is being developed and will be submitted for review by the Department's technical and ethical review committees in early 2005. Data collection is expected to start in 2005.

5.1.4 Research on harmful sexual practices

In 2004, the Department developed a multicountry study on gender, sexuality and vaginal practices (the GSVP study) that will investigate the gendered meanings of a variety of vaginal practices and investigate women's perceptions of the importance and/or impact of these practices on their sexual life, their health and their sense of cleanliness. It will be conducted in Indonesia, Mozambique, South Africa and Thailand, and it will involve about 100 women and men in total in

each country. The qualitative first phase of the project will be followed by a quantitative prevalence survey at each study site. In all four countries, sites with high prevalences of STIs and HIV have been chosen so the findings can be translated to STI and HIV programmes.

The protocol was developed collaboratively by researchers from the four countries and regional research coordinators in a research design workshop held in Jakarta in May 2004. Funds have been secured for the qualitative first phase for all four countries.

In early 2005, regional research planning and training will take place in Indonesia for Thai and Indonesian researchers and in South Africa for Mozambican and South African researchers. These trainings will be followed by the data collection phase of the project after approval of the research protocol by the Scientific and Ethical Review Group and the WHO Ethical Review Committee. Assuming approval is received and data collection commences soon thereafter, a meeting will be held to share national research results before the end of 2005. At this meeting, survey instruments for the second phase of the project will be finalized.

5.1.5 Guidelines for medical–legal care for victims of sexual violence

In 2004, the Department, in collaboration with the Department of Injuries and Violence Prevention and the Department of Gender, Women and Health, the United Nations High Commissioner for Refugees, the United Nations Population Fund and the International Committee of the Red Cross, revised *Clinical management of survivors of rape*, which was originally published in 2001. This guide has been updated to include the most recent technical information on the various aspects of care in emergency settings for people who have been sexually abused. The new publication will be available at the beginning of 2005.

6. OBJECTIVE: TO ENSURE EFFECTIVE INTERNATIONAL EFFORTS AND COLLABORATION

Given the focus of the Department on building the evidence base for sexual health programming, activities under this objective aim to build an understanding and acceptance of programme guidance that will be provided by the Department in future in selected regions. In the past year, particular attention was given to developing a better understanding of sexual health issues in Muslim countries and to providing training on these issues. The focus, therefore, of regional collaboration has been limited to the South-East Asian, Eastern Mediterranean and, to a lesser extent, the African Regions.

6.1 Progress and planned activities

The promotion of sexual health in a variety of country and regional contexts remains a challenge. The Department is

committed to assisting countries in understanding the constraints on sexuality and sexual health and seizing opportunities to promote a positive and healthy approach to sexuality and sexual health issues within health-care settings. The Department therefore tries to support local and regional initiatives that seek to advance these aims by providing technical assistance, as resources permit.

6.1.1 Support for national and regional strategies and programmes

In 2004, the Department was associated with, and in some cases supported, regional activities related to sexual health and human rights. Support for a regional meeting (the African congress for sexual health and rights) held in Johannesburg, South Africa, on 25–28 February 2004, was offered to help create an African network for sexual health research. Technical support was provided to a regional training workshop on sexual health and human rights in Jakarta, Indonesia, (23–26 September 2004) that specifically dealt with sexuality and human rights in Muslim societies in South-east Asia and could be used as a model for similar training in other Muslim countries. The Department also participated in a meeting held to advance the knowledge of the psychosexual effects of female genital mutilation. This meeting was convened by the Population Council in Alexandria, Egypt, on 10–12 October 2004. The purpose of the meeting was to review research on female genital mutilation and sexuality and discuss ways in which research on sexuality could be undertaken in Muslim societies.

Discussions are under way to assist in adapting a training course on sexuality and sexual health, run previously in Indonesia (see above), for the Eastern Mediterranean Region. The Department has discussed with the Islamic Republic of Iran and partner organizations in Turkey and Indonesia the way to best adapt the course for Iranian and other regional religious and cultural contexts. A mission will be planned in 2005 to follow up on these discussions as resources allow.

6.1.2 Developing rights indicators related to sexual and reproductive health

In 2004, the Department did not elaborate work on sexual health indicators because this was judged to be a lower priority and resources were lacking. Work on the development of sexual health indicators, however, remains an intention and future priority of the Department, and it will be pursued as funds allow.

6.1.3 Review and promotion of strategies and programmes related to human rights and sexual health

The Department did not work specifically on issues related to human rights and sexual health in 2004. Sexual rights were however defined and described in forthcoming publications of the new document series resulting from the 2002 WHO

Technical Consultation on Sexual Health (see section 2.1.2). In addition, rights issues will also be addressed in the review of evidence for sexual health programmes, described in section 2.1. In the future, as resources allow, the Department hopes to increase its work on human rights as they affect access to, and use of, sexual and reproductive health services. In particular, the Department wishes to investigate legal and policy barriers to integrating sexual and reproductive health services with HIV services.

6.1.4 Sexual health and the global burden of disease

As mentioned in section 2.1, the Department is working on modifying systematic reviews on two issues related to sexual health. The result of this work and other activities described above will provide the foundation for a possible future review to estimate the global burden of disease due to sexual ill-health. Further planning on this activity will be done depending on the results of these ongoing activities.

Annex 1

SCIENTISTS IN 2004

Principal investigators and partnering scientists

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 Ninuk Widyantoro, Women's Health Foundation, Jakarta, Indonesia

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	7	54			6	46	13
Women	6	46			4	31	10
<i>from:</i>							
AFRO	4	31					4
AMRO					1	8	1
EMRO							
EURO	1	8			4	31	5
SEARO	2	15					2
WPRO					1	8	1

Chapter 6

Gender issues and reproductive rights

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1. INTRODUCTION

The Programme of Action of the International Conference on Population and Development (ICPD) held in Cairo, Egypt, in 1994 and the Platform for Action of the Fourth World Conference on Women (Beijing) held in 1995 both clearly emphasized the need for promoting gender equity and equality in reproductive health policies and programmes, as well as emphasizing the promotion and protection of human rights. These agreements were reinforced in the 5-year reviews of both conferences (ICPD+5 and Beijing+5), held in 1999 and 2000, respectively. Among the key issues to be given greater attention 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 of 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 the establishing or strengthening of regulatory and enforcement mechanisms (Beijing+5, paragraph 107g). The Gender and Reproductive Rights Team helps to ensure that the Department's work explicitly contributes to these goals, and it carries out a number of specific projects to promote gender equity and reproductive rights.

2. OBJECTIVE: TO BROADEN THE PROVISION OF QUALITY SERVICES

This area of work concerns ensuring that the provision of sexual and reproductive health services contributes to reducing gender inequities and promotes gender equality. Violence

against women—or gender-based violence—is one clear manifestation of gender inequality, and has a complex and significant impact on women's sexual and reproductive health. Equipping health-service providers with tools and skills to treat appropriately women who are suffering violence would be an important contribution that would both improve the quality of reproductive health services and also confront this fundamental gender issue.

2.1 Progress

The one product in this area—"Guidelines on violence against women in pregnancy"—was given medium priority in the "Medium-term Programme of Work for 2004–2009". Although this is considered by many to be a critical area for the Department to pursue, it was given lower priority against the demands of providing support to ongoing activities because it is new. As soon as additional funding is available this product will be pursued jointly with the Department of Gender, Women and Health.

3. OBJECTIVE: TO STRENGTHEN HEALTH MANAGEMENT AND SUPPORT SYSTEMS

The objective in this area of work is to contribute to equipping health-programme managers with the analytical tools and skills needed to integrate the promotion of gender equity, equality and reproductive rights into their reproductive health policies and programmes. The work involves providing continued support to expand and adapt the WHO training course on gender and rights in reproductive health and the field-testing of a health and human rights tool in three countries. (The health and human rights tool also contributes towards meeting the aims of Objective 5—the promotion of sound national policies and laws.)

3.1 Progress in training programmes on gender and rights

In 2004, while continuing to provide assistance to the regional centres running the course (in Argentina, Australia, China and Kenya), the Department also provided technical assistance to two new centres to enable them to run the course (Kazakhstan and Sudan). In addition, the Department has developed a project with the University of Geneva to run a 2-week subregional training course in 2006 that will be specifically adapted for francophone African countries.

3.1.1 Kazakhstan and Central Asia

In October 2004, the Kazakhstan School of Public Health, a WHO Collaborating Centre for the region, ran a 2-week adapted regional course on gender and rights in reproductive health for 23 participants from Central Asia (Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan and Uzbekistan), including mid-level health managers from ministries of health and nongovernmental partners. The course was facilitated by a team of trainers from the School of Public Health and a trainer from Kyrgyzstan. Organized with the financial support of the Open Society Institute and in collaboration with the WHO Regional Office for Europe, this course falls under Kazakhstan's broader national reproductive health strategy, which was adopted in 2003. The Department assisted the School of Public Health with the regional adaptation of the course, and the Russian version of the curriculum will be finalized and published in 2005. The overall evaluation of the course indicated that all participants felt they had gained important analytical skills that they would use to apply a gender and rights analysis in their work. Many expressed the need to build training capacity on gender and rights in other countries in Central Asia.

3.1.2 Sudan and countries of the Eastern Mediterranean Region

The Institute for Women, Gender and Development Studies at Al Ahfad University for Women in Omdurman, Sudan, organized a 2-week training course for 25 people from Afghanistan and Sudan at the end of November 2004. The course was facilitated by a team of trainers from the University. It was organized with the financial and technical support of the Department and in collaboration with WHO country and regional offices.

As part of the preparatory process, the Department organized an adaptation workshop for trainers from the University at the end of March 2004. The aim was to provide course trainers with an opportunity to practise facilitating and teaching, to decide on the relevance of case studies and select new, regionally relevant material. As a result, an adapted version of the curriculum was produced for the 2-week course.

3.1.3 Burkina Faso and francophone Africa

The Department is collaborating with the Graduate Institute of Development Studies (IUED) in Geneva, Switzerland, to produce a regionally adapted French-language manual on gender and rights in reproductive health, based on the WHO curriculum. The adapted manual will incorporate results from research to be conducted by IUED, and it will be used to run the first 2-week French version of the subregional training course, which will be held in Burkina Faso in 2006. The local partners involved in the project are the Centre International de Formation en Recherche-Action and the Centre de Recherche en Santé de Nouna in Burkina Faso. As part of the preparatory phase, the Department will organize an adaptation workshop to be hosted at IUED in 2005 that will involve trainers from these centres. This work is supported financially by the Geneva International Academic Network.

3.2 Training programmes: planned activities

During 2005, in addition to working on the adaptation workshop with trainers from Burkina Faso, at the request of WHO's Regional Office for the Western Pacific, the Department will adapt the curriculum to a one-week training course focusing specifically on maternal and neonatal health, to be run in the Western Pacific Region during the second half of the year. A training-of-trainers workshop will be conducted in the South-East Asia Region in order to increase the number of trainers from different centres in the Region who can run the course. Technical assistance will continue to be given to those centres already running the course, if requested, and the overall evaluation will be started.

In 2004, the Scientific and Technical Advisory Group (STAG) "encouraged the dissemination of the highly successful curriculum to professional societies, reproductive health service providers and into medical schools, working through the Regional Advisory Panels". In line with this recommendation, the Department will work with the Department of Gender, Women and Health to support specific initiatives to bring elements of the course into the curricula of medical schools.

3.2.1 Evaluation of impact of training courses

Both the Department's Gender Advisory Panel and STAG have indicated that there is a need to document a measurable impact arising from the courses. Thus, an evaluation method has been developed to assess the impact of the courses both on participants and on institutions running the course. The evaluation will be conducted in 2005 using a questionnaire at all centres that have run the course; the questionnaire will also be distributed to selected participants in each region. The results of an analysis of the questionnaires will be presented at a regional evaluation workshop with the five regional training centres that have been running the course, to be held in 2006.

3.3 Health and human rights tool: progress and planned activities

During the year under review, the health and human rights tool has been further revised and refined, and a field test was initiated in Mozambique. Plans for field tests in Brazil and Indonesia have been set in place. The tool (*Using human rights for maternal and neonatal health: a tool for strengthening laws, policies and standards of care*) is designed to help countries use a human rights framework to identify and address legal, policy and regulatory barriers to women gaining access to, and using, maternal and newborn health-care services. Using a human rights framework complements public health approaches by enabling (i) a systematic application of human rights principles—such as non-discrimination, participation and accountability—to policies and programming, and (ii) an examination of laws and policies to ensure they are supportive of, rather than a barrier to, maternal and newborn health, as well as being in line with a government's human rights obligations.

After a review meeting with external experts in February 2004, considerable revisions were made to the tool in preparation for the field test in Mozambique. This began with an orientation workshop held in March 2004. Data compilation was carried out from May to October, and a preliminary data analysis workshop was held in October. The report of the analysis will be presented to a final stakeholders' meeting before the end of June, 2005. Initial results of the field test in Mozambique have been incorporated into the revised instrument, the user's guide, and the question and indicator guide, to be used for subsequent field tests in Brazil and Indonesia. A guide to monitoring and evaluation is also being developed as a result of this initial experience, and it will be used in the other field-test sites. The stakeholder analysis workshop will identify areas where WHO can provide further technical assistance and support.

In response to the interest shown by the Indonesian Medical Association to field-test the tool, the Department entered into discussions with the Ministry of Health and other possible stakeholders in Indonesia. The tool was presented to, and its uses discussed with, a wide variety of potential stakeholders, including the Ministry of Health, the Ministry of Justice and Human Rights, the Ministry of Women's Empowerment, the national Family Planning and Reproductive Health Board, professional associations (obstetricians, gynaecologists, nurses, midwives, paediatricians), research institutions, nongovernmental organizations, UN agencies and selected donors. The Ministry of Health was extremely supportive of conducting the field test, and it agreed to begin the test in August 2005, at both the national and subnational levels.

The tool will also be field-tested in Brazil at national and subnational levels. Introduction of the tool to the Ministry of Health and other potential partners in 2003 in Recife led to an invitation from the Government to begin planning for a field test in 2004–2005 (after the Mozambique field test was

under way). Department staff presented the tool to the Pan American Health Organization in Brazil in October 2004. A follow-up briefing for the Ministry of Health and partners was undertaken in December to prepare the timetable of the field test to be started in June 2005.

In 2004, STAG "encouraged the [Department] to look more explicitly at how the human rights movement mediated government provision of treatment in relation to HIV, and to consider whether a similar action could occur in relation to obstetric care to reduce maternal mortality". It should be noted that work on the health and human rights tool is one way in which human rights can be brought to bear favourably on maternal health, especially by intergovernmental agencies such as WHO. This process engages various actors, including the human rights movement.

4. OBJECTIVE: TO PROMOTE SOUND NATIONAL POLICIES AND LAWS

The work carried out under this objective aims to help governments ensure that their sexual and reproductive health policies and laws are grounded in human rights, including the right to non-discrimination on the basis of sex, which should thus promote gender equality.

4.1 Progress

As mentioned above, work carried out on the health and human rights tool (section 3.3) contributes directly to this objective. In addition, during 2004, the Department undertook detailed policy analyses of maternal health programmes in selected countries.

4.1.1 Legal and policy analyses

The Department conducted a review analysing "political will" at national level for improving maternal and newborn health as part of the maternal and newborn health and poverty project of the Making Pregnancy Safer Team (Chapter 2, section 6.1.3). Evidence from 20 countries was reviewed to assess the political processes that affect progress, contribute to stagnation or effect reversals in countries' efforts to reduce maternal and neonatal mortality. A secondary analysis of selected countries was carried out to assess whether specific attention to non-discrimination, accountability and participation contributed to the sustainability of political will over time. Evidence from this review was used in the World Health Report 2005 and will inform the development of further guidance to countries on how to create political will to improve maternal and newborn health.

This review complements existing work done by other organizations that are assessing laws relating to sexual and reproductive health in different regions. This work is a contribution to STAG's recommendation in 2004 when they "requested the [Department] to consider the feasibility of producing a

document comparing legal barriers to sexual and reproductive health in different countries". Additional work in this area is planned for 2005 related to the impact of abortion laws on women's health.

4.2 Planned activities

Building on the work already carried out related to maternal and neonatal health and to the provision of safe abortion, the Department will further its work in the legal and policy domains, particularly focusing on topics related to people with HIV/AIDS.

4.2.1 Legal and policy guidance and analysis

In 2005, the Department will seek to publish in peer-reviewed journals the theoretical framework of the health and human rights tool and the policy review paper on political will.

4.2.2 Reproductive choices for women and men living with HIV

It is estimated that more than 38 million people worldwide are now living with HIV, but many of them do not know that they are infected. The widespread introduction of affordable antiretroviral treatment is expected to reduce the fear, stigma and discrimination surrounding HIV and AIDS, and it is anticipated that the demand for HIV testing and counselling will increase. As more people become aware of their HIV status, the need to ensure good-quality prevention, treatment and care through sexual and reproductive health services will become a high priority.

WHO is developing a series of guidance documents on different aspects of the care, treatment and support of women with HIV and their children living in resource-constrained settings. One of these, *Sexual and reproductive health of women with HIV: guidelines on care, treatment and support for women living with HIV/AIDS and their children in resource-constrained settings*, outlines the clinical and management recommendations related to family planning; care during pregnancy, childbirth and the postpartum period; the prevention of mother-to-child-transmission of HIV infection; the prevention and treatment of reproductive tract infections; and the management of other sexual and reproductive health problems. This document is being produced jointly by the HIV/AIDS Department and the Reproductive Health and Research Department, together with the United Nations Population Fund (UNFPA). It will be published in 2005.

Nonetheless, there is a lack of clear policy and programmatic guidance at the global level on measures needed to ensure that women and men living with HIV are able to realize their reproductive goals. During 2005, the Department, together with its major partners, will develop this policy and programmatic guidance through a consultative process with a variety of key actors, including organizations of people living with HIV, policy-makers, health-programme managers, the donor community and other concerned agencies.

5. OBJECTIVE: TO ENSURE EFFECTIVE INTERNATIONAL EFFORTS AND COLLABORATION

Activities under this objective seek to promote and protect human rights and gender equality in sexual and reproductive health policies at the international level.

5.1 Progress

Work in this area focused on ensuring the adoption of the WHO *Reproductive health strategy to accelerate progress towards the attainment of international development goals and targets* by the World Health Assembly (WHA) in May 2004 and continued through interaction with international human rights treaty bodies as a major international mechanism for monitoring the protection of human rights related to sexual and reproductive health at country level.

5.1.1 Adoption and implementation of the reproductive health strategy

The Department has developed a strategy for accelerating the attainment of the international development goals and targets (including the Millennium Development Goals) related to reproductive health. The strategy was requested by a resolution of the World Health Assembly (WHA) in 2002. After extensive consultation in the regions and internationally, the draft strategy was adopted by the WHA at its meeting in May 2004 through a resolution sponsored by more than 30 countries. The strategy outlines the key areas of action for countries as well as for WHO.

Following the WHA resolution, the Department disseminated the strategy to all its partners and made it available on the web in six languages. In October 2004, a user-friendly version of the strategy was published in English and French. The strategy has been introduced and promoted in many international and regional forums and is being used as the framework to guide the development of both national reproductive health strategies and thematic strategies, such as those on making pregnancy safer and on the prevention and control of sexually transmitted infections.

5.1.2 Human rights treaty monitoring bodies

During 2004, the Department continued to prepare reports on the sexual and reproductive health situation in selected countries, reporting to the various human rights treaty monitoring bodies. Reports were made to the United Nations Committee on the Elimination of Discrimination Against Women (CEDAW) on the situation in Bangladesh, Ethiopia, Nepal and Nigeria; and preliminary reports were issued on Algeria, Gabon and Turkey. Information on the situation in Brazil and Nigeria was contributed to reports to the United Nations Committee on the Rights of the Child (CRC).

The compiling of all these reports—which are usually about 10–15 pages including questions and recommendations—is done in close consultation with country and regional offices.

The Department also works closely with the Department of Child and Adolescent Health and Development, the Department of Gender, Women and Health and the HIV/AIDS Department, and consults with UNFPA in preparing the reports.

The Department organized two technical consultations with treaty monitoring bodies. One was organized with CEDAW and focused on the use of reproductive health and rights indicators to monitor and implement the Convention on the Elimination of All Forms of Discrimination Against Women. The second consultation was organized with the Human Rights Committee that oversees implementation of the International Covenant on Civil and Political Rights (ICCPR); this focused on offering technical and policy guidance on providing safe abortion and post-abortion care in the context of the ICCPR. Both consultations were appreciated by the committees. Technical presentations on WHO's role in the treaty monitoring process were made at various WHO regional meetings.

The Department contributed to a common statement submitted by the United Nations Development Fund for Women (UNIFEM), the United Nations Children's Fund (UNICEF), UNFPA and WHO on Article 2 of the Convention on the Elimination of All Forms of Discrimination Against Women, for which CEDAW is elaborating a general recommendation.

5.2 Planned activities

5.2.1 Reproductive health strategy

In 2005, the Department will continue to disseminate the WHO Reproductive Health Strategy and seek to promote the framework for action in all relevant national, regional and international gatherings. During the year, the first progress report for the Executive Board (due in January 2006) and WHA (due in May 2006) will be prepared.

5.2.2 Human rights treaty monitoring bodies

In collaboration with WHO's Regional Office for South-East Asia and the Department of Child and Adolescent Health and Development, the Department is organizing a meeting for WHO's reproductive health managers, the reproductive health advisers of ministries of health and representatives of ministries of women's affairs from each Member State in the Region. The objectives of this meeting are to improve understanding of the UN treaty monitoring system, paying special attention to CEDAW and the CRC. It is expected that the workshop will lead to concrete plans for country-level involvement in preparing reports and implementing concluding recommendations from CEDAW, CRC and other committees.

During 2005, the Department will work closely with WHO offices in selected countries to prepare reports on sexual and reproductive health to be presented to CEDAW and other committees and to ensure that a plan is made for implementing concluding recommendations.

The Department will continue to work closely with all treaty monitoring bodies and the Office of the United Nations High Commissioner for Human Rights. In 2005, further seminars will be conducted with monitoring bodies to improve their understanding of sexual and reproductive health as a key to the fulfilment of human rights.

Annex 1

GENDER ADVISORY PANEL (GAP) IN 2004

Members

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	10	83	1	8	1	8	12
Women	7	58	1	8	1	8	9
<i>from:</i>							
AFRO	2	17					2
AMRO	3	25					3
EMRO	1	8					1
EURO			1	8	1	8	2
SEARO	2	17					2
WPRO	2	17					2

Annex 2

SCIENTISTS IN 2004

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Chapter 7

Promoting the sexual and reproductive health of adolescents

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1. INTRODUCTION

The sexual and reproductive health needs of adolescents present an important public health challenge, given that neglecting these needs may expose adolescents to health risks that have important consequences for their lives. The Programme of Action adopted at the International Conference on Population and Development in 1994 noted that “the reproductive health needs of adolescents as a group have been largely ignored to date by existing reproductive health services”. The sexual and reproductive health needs of adolescents differ from those of adults and remain poorly understood and inadequately served by existing health services in much of the world. The Programme addresses existing research gaps with the aim of promoting healthy sexual and reproductive development, maturation and behaviour in this underserved population; the Programme also seeks to increase the opportunities for adolescents to enter into equitable and responsible sexual relationships. The Programme supports research that has high relevance to policy and programmatic development including the testing of interventions aimed at providing optimal health and information services. The Department addresses the special needs of adolescents in all of its technical and managerial tools and advocacy materials.

2. OBJECTIVE: TO BROADEN THE PROVISION OF QUALITY SERVICES

Evidence from many countries suggests that younger age at first sexual experience, later age at marriage and the rising incidence of premarital sex have all increased the exposure of adolescents to the health risks associated with unsafe sex. In some countries, the increase in the level of premarital

sex has been much greater than the rise in contraceptive use. Adolescents, in general, are not well informed about sex, contraception, sexually transmitted infections (STIs) or HIV. They often lack access to information and services that address their needs. As a result, they are often misinformed about sexual and reproductive matters. Adolescent women, in particular, are ill-equipped to negotiate safe sex with their partners. Misinformation and misperceptions, combined with social and cultural barriers to services, expose adolescents to greater risks than adults of STIs and HIV infection, unintended pregnancy and unsafe abortion. Research supported by the Programme identifies knowledge gaps and ascertains the perspectives and preferences of adolescents on sexual and reproductive health services. This information is used to inform programmes for adolescents’ sexual and reproductive health, to broaden the provision of quality services, and to increase access to services by those who are most in need.

2.1 Progress

In 2004, 26 papers were published or were in press, and results from several other projects became available. For the sake of brevity, results from only a few studies are reported below.

2.1.1 Unintended pregnancy, abortion and decision-making

A research project in the South Nyanza region of Kenya examined possible explanations for poor pregnancy outcomes (abortion, stillbirth and premature delivery) observed in the study population (Table 7.1). The study found that about one in five of the adolescent girls aged 12–19 years who were surveyed had ever been pregnant: 30% of urban adolescents had been pregnant, as had 16% of rural adoles-

cents. About 92% of the pregnancies had ended in a live birth (either premature or full term) while the remaining 8% ended in an abortion or stillbirth. Pregnancies occurring outside of marriage were significantly more likely to end in abortion or stillbirth than those within marriage.

The study also found an unusually high rate of premature deliveries (about half of all live births).

A striking finding was the strong association between the desire for a pregnancy and premature delivery: unintended pregnancies were highly likely to result in a premature birth. One possible explanation for the high incidence of premature births may be adolescent girls' attempts at unsafe, risky and often unsuccessful induced abortion. The findings suggest the need for interventions designed to address the risk of premature deliveries, especially for unintended pregnancies. To formulate the most effective interventions and to broaden the provision of quality services, programmes need to take cultural practices into account and provide any special care required for premature deliveries occurring among adolescent mothers.

The results of a project supported in Bangladesh were presented at the 2004 meeting of the Population Association of America as *Worried lives: poverty, gender and reproductive health for adolescent women in a slum in Dhaka, Bangladesh*. The study focused on the reproductive health needs of married adolescents aged 10–19 years (Table 7.1). Survey data revealed that 72% of respondents reported being coerced into childbearing soon after marriage. The positive advantages for a married adolescent of producing a child reportedly included greater social acceptance, increased security in the marriage and greater decision-making power in the household.

However, in the slum where the research took place, there is tension between income generation and the value placed on producing children. Married adolescents are expected to raise income for the family, yet bearing a child generally ends a woman's income-generating capability at the same time as it increases the household's need for additional income to support another family member. The competition for limited resources encourages household members to pressure married adolescent women to terminate their pregnancies. The

study found that 20% of respondents had been coerced into terminating their first pregnancy by husbands, fathers-in-law and/or mothers-in-law. The findings suggest that married adolescents' reproductive lives are controlled and manipulated by others. The investigator concluded that unequal gender and power relations, combined with structural, political and economic inequalities, force many poor married adolescent females to go along with decisions made by others that adversely affect their reproductive health and violate their reproductive rights and choices. They do so to gain advantages under conditions of extreme poverty and limited options. In such a context, services need to ensure that the reproductive choices of young women are respected.

2.1.2 Non-consensual sexual experiences and their implications

WHO defines sexual violence as "any sexual act, attempt to obtain a sexual act, unwanted sexual comments or advances, or acts of traffic, or otherwise, directed against a person's sexuality using coercion, by any person regardless of their relationship to the victim, in any setting including but not limited to home and work". Coercive sex encompasses a continuum of behaviours that violate the human rights of the victim. Non-consensual sex has been found to present serious public health consequences including transmission of STIs, unintended pregnancy, adverse pregnancy outcomes (miscarriage and low-birth-weight infants) and depression; it is increasingly associated with HIV infection.

Attitudes, norms and experiences of sexual coercion among young people in Ibadan, Nigeria reports the findings of a study intended to understand the contexts in which non-consensual sexual activities occur and to assess the consequences of coercion among victims aged 15–19 years (Table 7.2). The data revealed that a significant number of girls had experienced non-consensual sex: 15% had experienced forced penetrative sex; over 27% had experienced attempts to force sex; and 44% reported being touched sexually against their wishes. Some females, and an even greater number of males, condoned forced sex when a male had spent a lot of money on a girl. Some justified forced sex on the grounds that young males have "uncontrollable sexual urges" and that female victims "are to blame for inviting the incident". Both female and male respondents agreed that

Table 7.1. Background information on studies of unintended pregnancy and abortion in Bangladesh and Kenya

Country	Primary research focus	Study design	Sample design	Age range and sex of respondents
Kenya	Pregnancy outcomes	Survey of 269 females; in-depth interviews with 39 females	Household survey of 1247 adolescent women in 32 clusters or communities	Females aged 12–19 years
Bangladesh	Pregnancy and abortion	Survey of 153 females; in-depth interviews with 50; case studies of eight females	Ethnographic and social survey with purposive selection of respondents	Married females aged 10–19 years

once a girl agrees to be someone's girlfriend "she should be available for sex".

The study also found that in this cultural context, rape is used as a "weapon of punishment to teach an unwilling female a lesson". The data from eight in-depth interviews with female rape victims revealed that rape victims suffer in silence: six of eight victims had not disclosed the event to anyone primarily because they were ashamed, afraid of being stigmatized and of being blamed for provoking the incident.

The data also suggest a weak shift towards attitudes that view gender equality positively, as evidenced by a majority of females and some males acknowledging that the sexual coercion of girls is unacceptable.

Males and females both reported positive outcomes from participation in a workshop that was conducted as part of the study; they reported becoming sensitized to the unacceptability of all forms of coercive behaviour, and there was a shift in females' attitudes away from the belief that victims are to blame. Positive feedback was given by females indicating that the workshop had empowered them with skills to prevent coercive behaviour and to deal with perpetrators. Many males made commitments to refrain from perpetrating forced sex. The findings suggest the need for gender-sensitive interventions that target both females and males and promote respect for women's rights and choices. There is a need for public awareness programmes, run through the media or other sources, to address the stigma associated with rape in Nigeria. Services that respond to the specific needs of victims are also needed to help with advocacy, legal assistance and care and support of victims.

Sexual abuse and mental health in adolescents: exploring the role of parental relationships investigates the hypothesis that the quality of an adolescent's relationship with his or her parents influences the association between exposure to coercive sex and the risk of adverse psychosocial health outcomes. The study was conducted in Goa, India, and surveyed students in secondary high school (aged 14–21 years). The study focused on three variables: coercive sex, psychosocial outcomes and relationships with parents

(Table 7.2). Experiences of sexual coercion were common with about one in three students reporting sexual abuse and 6% reporting being forced to have sex. The results suggest that in terms of negative psychosocial outcomes boys and girls are equally affected. The findings further suggest that the association between coercive sex and adverse psychosocial outcomes is influenced by an adolescent's relationship with his or her parents. This finding was much more significant for girls: a good relationship with both parents entirely attenuated the negative impact of coercive sex on psychosocial outcomes. The investigators concluded that the quality of an adolescent's relationship with his or her parents is an important variable in studying the risk of coercive sex and the impact of coercive sex on adolescent psychosocial health. The findings suggest that interventions to improve reproductive health among adolescents should include components to improve adolescents' communication skills with their parents and to educate parents about healthy communication with adolescents.

2.1.3 Services for vulnerable populations

The first phase of the Mekong Delta Research Initiative, which looks at adolescent migrants and their reproductive health, consisted of a multicountry research project undertaken in one major city in each of four countries: China, the Lao People's Democratic Republic, Thailand and Viet Nam. In this region, youths aged 15–24 years often migrate from rural areas to urban areas to look for work. The migrants often face sexual and reproductive health risks, but lack information about them and have poor access to services. The main objective of this research was to identify the sexual and reproductive risks migrants experience and to describe barriers preventing them from obtaining information and services on reproductive health. A related objective was to develop human resources and to share knowledge on research methods between the participating countries and to compare results.

The findings show that male adolescents in all four countries have greater sexual freedom than females but female adolescents' sexual behaviour is restricted by conventional norms, which safeguard them to some extent from sexual and repro-

Table 7.2. Background information on studies of non-consensual sexual experiences

Country	Primary research focus	Study design	Sample design	Age range and sex of participants
Nigeria	Non-consensual sex and its consequences	Four narrative workshops involving 77 male and female students; survey of 1025 participants; in-depth interviews with eight rape victims	Secondary school students from five schools; apprentices from 80 businesses; rape victims identified from survey interviews	Males and females aged 15–19 years
India	Exposure to sexual coercion, psychosocial health outcomes	Survey of 811 students	Purposive selection of higher secondary schools with both urban and rural students	Males and females aged 14–21 years

ductive health risks. However, the project identified a distinct period of risk during the engagement period. It is acceptable for them to have sexual relations during this period but the woman is expected not to become pregnant until after marriage. This suggests that the engagement period is the time during which reproductive health interventions, including HIV prevention, are most critically needed. The inaccessibility of accurate reproductive health information and inadequate services for unmarried adolescents is exacerbated by adolescent migrants' perceptions that they are not at risk and do not need reproductive health information or services, as well as by social norms that discourage unmarried people—especially women—from learning about sex or contraceptive methods. A further barrier is the lack of confidentiality at public hospitals; this discourages adolescent migrants from seeking care. Instead, migrants generally buy medicine at drugstores. Factors that influence the health-seeking behaviour of migrant youths aged 15–24 years include the convenience, cost and confidentiality of the services; whether they have health insurance coverage; how familiar they are with health services; and the provider's skills. The investigators concluded that the use of existing services would increase if they were made more convenient, affordable and confidential and if providers were trained to deal with the sexual and reproductive health concerns of migrant adolescents.

2.2 Planned activities

2.2.1 Policy communication and dissemination workshop

A policy communication and dissemination workshop for the Mekong Delta Research Initiative will take place during

24–27 January 2005. The workshop will include presentation, discussion and synthesis of findings from the studies conducted in the four countries; plans for the intervention phase of the project will also be developed.

2.2.2 Research on non-consensual sexual experiences in developing countries

The consultative meeting on the non-consensual sexual experiences of young people in developing countries, organized in September 2003 jointly with the Population Council's office in India and Family Health International's YouthNet programme, identified a number of research gaps in policy and programme interventions. A background paper was subsequently developed and presented to the Specialist Panel for Social Science and Operations Research on Reproductive Health. Staff from the Department of Gender, Women and Health participated in the discussions and in prioritizing topics for research.

2.2.3 New research projects

Three new research projects have been approved for implementation in early 2005. These include (i) a study of reproductive health risks among unmarried Tibetan youth in Sichuan province, China, (ii) a study in Nigeria examining child fosterage and trafficking for domestic work and the implications for reproductive health, and (iii) interventions to prevent violence among secondary school students in Ibadan, Nigeria.

Table 7.3. Background information on studies of family planning provision for adolescents and youths in Nepal and China

Country	Primary research focus	Study design	Sample design	Age range and sex of participants
China	Impact of youth-friendly reproductive health services	Quasi-experimental with one intervention site and one control site in suburban Shanghai; baseline survey, intervention and post-intervention survey	Towns purposively selected to have comparable social, cultural, economic and demographic characteristics; 1220 respondents from intervention area and 1007 from control area	Unmarried males and females aged 15–24 years
China	Attitudes of family planning providers on providing services to adolescents	Survey of 1927 family planning providers; focus group discussions with 123 family planning workers and community-based distributors of contraceptive services	8 purposively selected sites using convenience sampling of providers and distributors	Male and female providers and distributors aged 30–50 years
Nepal	Perception of illness and health-seeking behaviours	Focused ethnographic study of 2000 unmarried female respondents	Purposive selection of four ethnic groups with equal numbers of respondents from urban and rural areas	Unmarried females aged 14–19 years

3. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS OR TECHNOLOGIES

Existing evidence from many countries suggests that adolescents have limited access to sexual and reproductive health services, products and technologies, and their access to contraceptives is especially limited. The Programme builds research capacity in developing countries and in countries in transition and supports the testing of interventions aimed at broadening the range and increasing the use of products and technologies.

3.1 Progress

3.1.1 Progestogen-only contraception and bone mineral density

A 5-year prospective study is taking place in Durban, South Africa, investigating the impact of progestogen-only contraceptives on bone mineral density in adolescent and premenopausal women. Analysis of the data is under way, and results are expected in 2005. (Further details can be found in Chapter 1, section 3.1.5.2.)

3.1.2 Assessing pilot intervention programmes and scaling-up

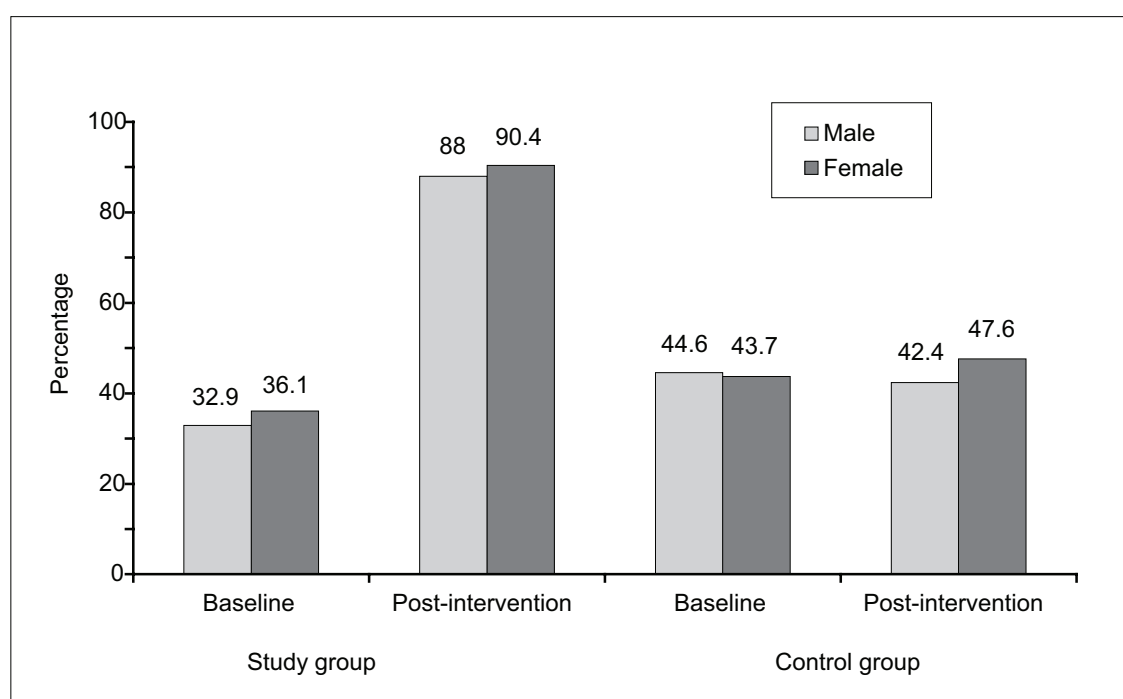
A project in China evaluated the effectiveness of a youth-friendly intervention aimed at promoting safe-sex behaviour (the use of contraception and condoms) among sexually active unmarried youths aged 15–24 years in Shanghai (Table 7.3). The intervention was aimed at unmarried youths

in one town in Songjiang district, Shanghai; it was intended to build awareness of, and to offer counselling and services related to, sexuality and reproduction. Awareness-building activities included disseminating educational materials, using instructional videos, giving lectures and conducting small-group activities. Counselling activities included setting up a youth-health counselling centre with a full-time counsellor and providing access to relevant publications. Activities designed to enhance access to services included distributing contraceptives and pregnancy tests free of charge through local family planning units. The control site, another town in the same district, that was comparable to the intervention site in terms of social, cultural, economic and demographic characteristics, continued to provide routine information and services. A baseline survey was followed by an intervention programme that ran for about 20 months (May 2000–December 2001); this was followed by a post-intervention survey.

The study results indicated that, other things being equal, participants in the intervention group were 15 times more likely to use contraceptives at the onset of intercourse than those in the control group. Regular contraceptive use among sexually active youths (males and females) in the intervention area rose from 34% to 89% between the baseline and post-intervention surveys, as compared with a rise from 44% to 45% in the control area. Results by sex and study site are shown in Figure 7.1.

Initial reported condom use among sexually active youths was high in both the intervention and control areas. It became nearly universal (more than 97%) in the intervention area and also increased in the control area, but not to the same extent (Figure 7.2).

Figure 7.1. Percentage reporting regular contraceptive use by sex and study site, Shanghai, China



These findings strongly support the hypothesis that a multifaceted intervention programme providing information and skills as well as counselling and services enhanced contraceptive practice and condom use among unmarried female and male youth in suburban Shanghai; it also increased safe-sex behaviours. To examine whether the effect would continue after the end of the project, a supplementary study was conducted in the same areas about two years later. An interim analysis shows mixed results with regard to the sustainability of the impact of the interventions. The interventions had long-term effects on increasing participants' knowledge of sex and reproductive health and reducing the number of unintended pregnancies, but it had only a limited long-term effect on regular contraceptive use and no effect on attitudes towards premarital sex. Results from the in-depth analysis are expected in 2005.

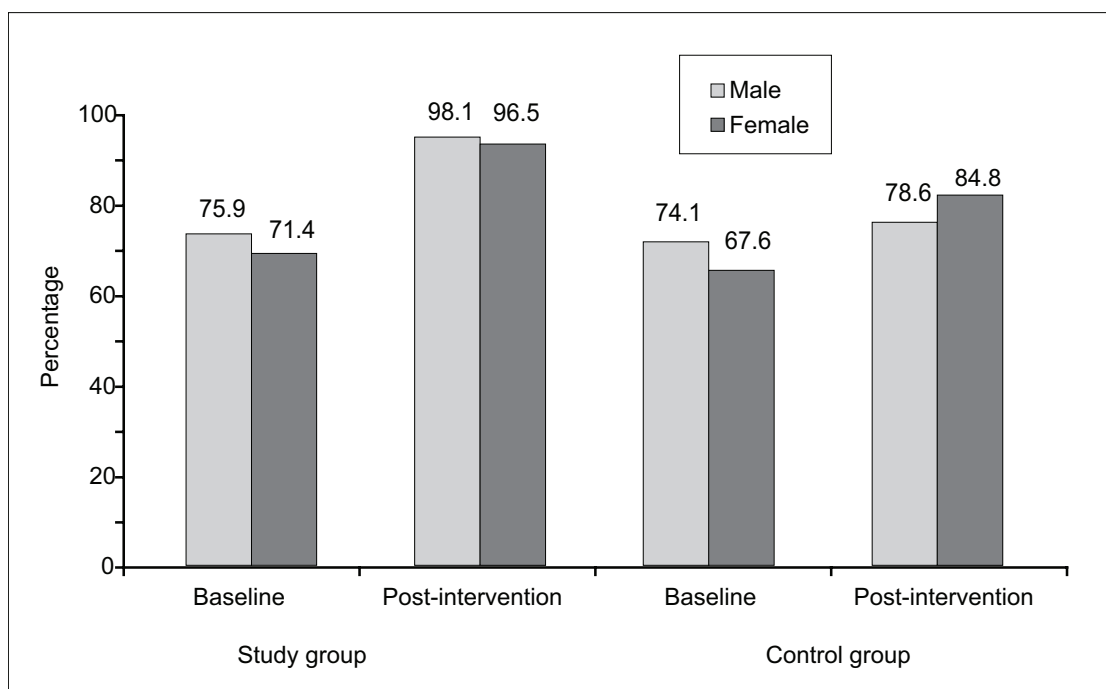
The results of a second Chinese study conducted in eight sites are described in *Do family-planning workers in China support provision of sexual and reproductive health services to unmarried young people?* This paper was published in the *Bulletin of the World Health Organization* in 2004 (Tu et al., 2004). It is based on a study of family-planning service providers and looks at the provision of sexual and reproductive health services to unmarried young people aged 18–24 years (Table 7.3). Family planning workers were overwhelmingly positive about the need to provide unmarried young people with information about sexual health and about the need for government agencies to provide information and education. However, about two thirds of the respondents qualified their willingness to provide contraceptives to unmarried young people by requiring that clients be aged 18 or older; and only

about a quarter agreed that contraceptive services should be provided to those in senior high school. The attitudes of family-planning workers pose a significant obstacle to improving access to information and services needed to encourage young unmarried people in China to adopt safe-sex practices. The authors recommended that training programmes for family-planning workers should address this issue.

A project in Nepal explored the perceived sexual and reproductive health problems, explanations of the causes of these problems, care-seeking behaviour and constraints on care-seeking among unmarried rural adolescent girls aged 14–19 years. The study combined focused ethnographic methods with a quantitative survey to elicit information from rural adolescent girls in four different ethnic communities (Table 7.3). The findings suggest that adolescent girls in rural areas are poorly informed about reproductive health issues. They are most familiar with a range of menstrual problems and symptoms of reproductive and urinary tract infections. However, they hold misperceptions about the etiology and attribute symptoms to diet or witches' spells. They prefer sources of care outside the formal health system, such as home remedies and traditional faith healers, and seek formal medical care only if problems persist and are severe. The authors recommended that culturally appropriate health interventions should take into account the needs of individual ethnic groups to raise awareness, dispel misperceptions and provide counselling and reproductive health services.

As has been described in previous annual reports, an operations research project to evaluate and improve reproductive health services for adolescents has been ongoing in five

Figure 7.2. Percentage reporting condom use by sex and study site, Shanghai, China



French-speaking sub-Saharan countries. The project has three phases: (i) a baseline survey of adolescents who are using health services and of the quality of services offered; (ii) an intervention to address the information needs of adolescents, to train service providers, or to modify existing services to enhance their youth-friendliness; and (iii) a post-intervention survey to evaluate the effectiveness of the intervention.

The status of the research project in five of the countries is summarized below.

- The Senegal and Guinea projects are complete and final reports are available.
- The Côte d'Ivoire project has been halted due to political instability.
- The Benin project continues to seek funds to implement the intervention activities.
- The Cameroon project is entering the intervention stage.

The evaluation of the project in Guinea highlighted the need for greater coordination between all organizations providing sexual and reproductive health services to adolescents. The project coordinators are planning meetings and other activities for 2005 to move the coordination efforts forward.

The Cameroon project used the results of the baseline study to plan the interventions. Youth-friendly services will be established in two locations and compared with existing services in two similar locations. The project plans to actively involve adolescents in establishing, administering and evaluating the two centres. The intervention phase, set to begin in 2005, will last 24 months. A series of activities including collecting statistical data, holding regular meetings, making site-visits and developing evaluation reports will inform the post-intervention analysis of the project.

3.1.3 Building research capacity in developing countries and countries in transition

The Programme maintains a documentation centre and a web site that hosts material on the sexual and reproductive health of adolescents and which is available for public distribution. Materials and information are routinely circulated electronically among investigators participating in the research initiative and other interested researchers. In addition, technical assistance is provided through training workshops in research methods, site-visits and by reviewing drafts of papers and providing suggestions on analysing and interpreting data.

In June 2004, a workshop was held in Baku, Azerbaijan with the objectives of (i) discussing the importance of adolescent sexual and reproductive health and the rights of adolescents, (ii) assessing the sexual and reproductive health needs of adolescents in participating countries, (iii) identifying knowledge gaps and appropriate interventions, and (iv) developing a plan for future joint adolescent reproductive health projects or studies. Working groups produced reports that set forth the major sexual and reproductive health problems, needs and risks of adolescents including STIs and HIV/AIDS, early sexual experience and young age at pregnancy and delivery. The main challenges reported were the dearth of laws protecting reproductive health and rights, the absence of youth-friendly services, the limited number of service providers specially trained in adolescent care, the lack of statistical data on adolescents and the absence of coordination among different sectors working within adolescent health. Possible solutions that were suggested included establishing youth-friendly services, making contraceptives available to adolescents, providing confidential services, preparing educational programmes for students at all educational levels (from kindergarten to college), training service providers and preparing individual educational manuals for parents, teachers and adolescents.

Programme staff also participate in an international course on adolescents' sexual and reproductive health, organized each year by the International Children's Centre at Bilkent University, Ankara, Turkey, and in a training course run by the Royal Tropical Institute, Amsterdam, the Netherlands. Information related to the sexual and reproductive health of adolescents in participating countries is reviewed during these courses. Participants are also included in the Programme's network of researchers who routinely receive materials and information on events.

3.2 Planned activities

3.2.1 Publication and dissemination

In 2005, results from a number of studies, including the study on progestogen-only contraception and bone mineral density in South Africa and the study on the long-term impact of interventions in Shanghai, China, are expected. These results will be of considerable importance for policies, programmes and future research.

3.2.2 Strengthening research capacity in developing countries

The network of researchers will continue to receive relevant material and information. The Programme will continue to provide technical assistance to courses offered by the International Children's Centre, Ankara, Turkey, and the Royal Tropical Institute, Amsterdam, the Netherlands.

4. OBJECTIVE: TO PROMOTE SOUND NATIONAL POLICIES AND LAWS

Many developing countries have no national policies or laws protecting the reproductive health or rights of adolescents, and service norms and standards of care for adolescents' sexual and reproductive health are generally lacking. The absence of such policies, laws and standards of care may undermine the ability of service providers to adequately address adolescents' needs and may serve as barriers to access. The Programme promotes norms and standards of care through its guidelines and, in collaboration with other agencies and other WHO departments, works to promote sound national policies and laws.

4.1 Progress

4.1.1 Guidelines, norms and tools

The Programme's guidelines include information on issues related to adolescents' sexual and reproductive health. For example, *Medical eligibility criteria for contraceptive use* provides guidance on the use of contraceptive methods by women of different age groups, including women younger than 18 years. The guidelines for adolescent contraceptive users indicate that they can safely use most hormonal contraceptive methods or intrauterine devices (IUDs). However, it warns that progestogen-only injectable contraceptives should not be considered a first choice for women younger than 18 years of age because of the contraceptive's effect on bone mineral density, which may have a long-term impact. It also warns that women younger than 20 years of age may require special follow-up when using the IUD, given concerns about the risk of expulsion due to nulliparity and the risk of STIs among younger age groups. The guidelines also recommend caution when younger users request sterilization since evidence shows that up to 20% of women sterilized at a young age later regret this decision; additionally, men who undergo vasectomy at a young age are more likely to have the procedure reversed than those who undergo vasectomy at older ages.

The *Decision-making tool for family planning clients and providers* also offers guidance on contraceptive use for younger clients. The tool helps family planning providers counsel their clients and aids them in choosing the contraceptive method that best suits their situation and needs. The tool itself and the counselling model it promotes are youth-friendly and client-oriented. It encourages providers to use basic terminology to explain complex medical facts, and it also contains many useful pictures and diagrams that are especially helpful for younger clients. The tool also contains a special page of information about counselling younger clients (those who are aged < 20 years), and it encourages providers to explore the concerns and needs of this particularly vulnerable population. The tool's counselling appendices contain information that is useful for educating adolescent family planning clients about basic reproductive biology and the menstrual cycle.

4.1.2 Promoting sound national policies and programmes through collaboration

The Programme promotes sound national policies and programmes on the sexual and reproductive health of adolescents through its collaboration with other major international programmes, such as Family Health International's YouthNet and the Population Council's FRONTIERS programme. The Programme promotes evidence-based policies and programmes through joint publications and by participating in advisory committee meetings. The Programme also actively collaborates with the Department of Child and Adolescent Health and Development in promoting evidence-based policies and in providing technical support to countries for programme development.

4.1.3 National dissemination and policy discussions

A national seminar was held in Ankara, Turkey, in April 2004 to disseminate findings from the Programme-supported study on adolescent sexual and reproductive health and their implications for national policies and programmes. The seminar was attended by senior officials from the Ministry of Health and the Ministry of Education, parliamentarians and programme managers. Participants developed a list of recommendations and concluded a plan of action aimed at improving the sexual health of adolescents in Turkey. At the conclusion of the study, the investigators established youth-friendly services at the study sites.

A project in Croatia led to the development of an interactive web site addressing adolescents' sexual and reproductive health needs and produced a number of publications. Several meetings were held to mobilize support for the provision of information and services. A policy brief (*How do perceptions of gender roles shape the sexual behaviour of Croatian adolescents?*) was issued and widely distributed. In light of the findings from the project, it was recommended that school-based education programmes for adolescent sexual health should be established. These programmes should emphasize communication with parents and peers, and question stereotypical gender-based sexual expectations, and include information on negotiating safe sex with partners.

4.2 Planned activities

4.2.1 Synthesis and dissemination of results

A number of studies are now complete. Future activities will prioritize the synthesis and dissemination of research results. This work is in progress on studies from Latin America.

4.2.2 Collaboration

A meeting is planned to disseminate the results of studies supported by the Programme and those supported by the Population Council's FRONTIERS programme. Collaboration on the publication and dissemination of results with Family

Health International's YouthNet is under way, and collaboration with the Department of Child and Adolescent Health and Development is maintained on a regular basis.

Annex 1

SPECIALIST PANEL FOR SOCIAL SCIENCE AND OPERATIONS RESEARCH IN REPRODUCTIVE HEALTH

Members and Collaborating agency scientists

See Annex 1 of Section 1 "Promoting Family Planning"

Annex 2

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	54	93	4	7			58
Women	36	62	3	5			39
from:							
AFRO	10	17					10
AMRO	16	28					16
EMRO	3	5					3
EURO	2	3	4	7			6
SEARO	12	21					12
WPRO	11	19					11

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 Shireen Jejeebhoy, Population Council, New Delhi, India
 Marwan Khawaja, American University of Beirut, Beirut, Lebanon
 Naohiro Ogawa, Nihon University, Tokyo, Japan
 Zhang Kaining, Institute for Health Sciences, Kunming Medical College, Kunming, China

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

Annex 3

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Chapter 8

Technical cooperation with countries: interregional activities

M. Mbizvo, A. Ntabona

1. INTRODUCTION

The mission of the Technical Cooperation with Countries Team is to assist countries in enhancing their capacity to develop and implement research and programmatic activities at national and regional levels in order to improve the reproductive health status of their population. The cross-cutting nature of the Team's work is organized into three major areas.

- **National research capacity strengthening:** This is an important component of the Department's work, with long-established mechanisms for (i) assisting developing countries in identifying areas where research is required to address reproductive health needs and (ii) strengthening the capabilities of institutions and individual researchers in these countries to address priority research needs of national and regional relevance. Work related to this area falls under the departmental objective aimed at widening the range of products and technologies. The reports on activities carried out in 2004 in different geographical areas are provided in separate sections below (Chapters 9, 10, 11, 12).
- **Policy and programmatic issues:** The main focus of this area is to support countries in conducting national-level planning and programming activities using the WHO *Strategic approach to improving quality of care in reproductive health services*. This method emphasizes the use of a participatory process to obtain input from a wide range of stakeholders to identify, test and expand in a phased manner innovations designed to increase access to and improve the quality of care in the deliv-

ery of sexual and reproductive health services. Recently, work in this area has been expanded to include developing an evidence base on the effects of health sector reform on reproductive health programmes and outcomes; it also includes the provision of technical support to countries engaged in reform processes. Overall, this area contributes to the departmental objectives aimed at strengthening health management and support systems (Objective 3) and promoting sound national policies and laws in favour of reproductive health (Objective 5). The report on activities carried out in 2004 on policy and programmatic issues is provided under Chapter 13.

- **Mapping and implementing best practices:** The aim of this area is to provide a sound foundation for the Department's commitment to work on knowledge-management issues to improve access to and the utilization of evidence-based practices at country level; the work also aims to build strong partnerships for harmonizing approaches and using cost-sharing mechanisms to more effectively expand the introduction, adaptation and scaling-up of best practices to improve delivery of sexual and reproductive health services at country level. Activities related to this area fall under the departmental objective of strengthening health management and support systems of reproductive health programmes in countries (Objective 3) and are reported under Chapter 14.

The work reported in this Chapter concerns the set of activities that were carried out at the interregional level with collaborating institutions and partners in support of the three major areas of cooperation mentioned above. They contributed to the objectives of the Department as detailed below.

2. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS AND TECHNOLOGIES

Work in this area included the Department's participation in the global review of officially designated WHO Collaborating Centres; work with partners was also done to strengthen the involvement of national research institutions in programmatic support activities in order to facilitate the translation of research findings into policy actions and policy development.

2.1 Progress

2.1.1 Network of Collaborating Centres

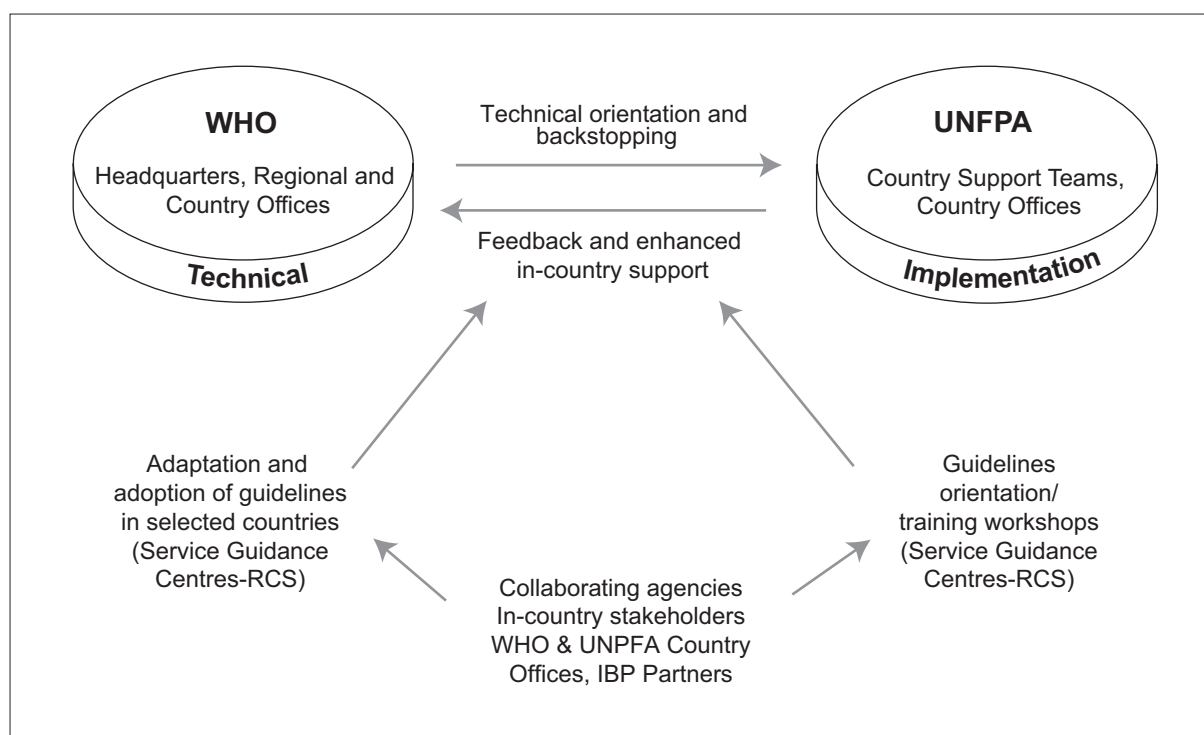
Efforts have been ongoing at the global level since 2003 to overhaul the global network of WHO Collaborating Centres because it had been reported that up to one third of such institutions had neither renewed their designation status nor reported on their activities for many years. In order to address the situation, all centres were asked to regularize their designation status as soon as possible and by no later than 15 April 2004. As a result, all the institutions collaborating with the Department whose designation period had lapsed were requested to apply for re-designation. They submitted their proposed or revised terms of reference and a 4-year work plan to be reviewed and forwarded to the respective regional screening committees for further review and endorsement. The final outcome of this exercise is as follows:

- Forty-two Collaborating Centres are up-to-date and/or have had their official designation status renewed.
- Nine institutions had their designation status discontinued (two in the African Region, three in the European Region, two in the South-East Asia Region, and two in the Western Pacific Region).
- Two institutions working on the prevention and control of sexually transmitted infections (Clinical Research Unit, London School of Hygiene and Tropical Medicine, London, United Kingdom) and on research synthesis (Effective Care Research Unit, University of the Witwatersrand/University of Fort Hare, East London, South Africa) have applied for new designation in 2004, and their applications are under review.

2.1.2 Turning research into practice

The Department collaborated with partners to develop a tool-kit using selected case studies. The tool-kit outlines a conceptual framework and elaborates pathways for enhancing the utilization of research findings to inform policy-making and the use of evidence-based interventions. This tool-kit was a response to the request for a guidance tool made at a symposium arranged by the Department for policy-makers, programme managers and heads of research centres that were receiving research capacity-strengthening grants from the Programme. Additional case studies and experience are being collected to widen the base for informing the process of research utilization.

Figure 8.1. Schematic representation of the WHO/UNFPA Strategic Partnership Programme



2.2 Planned Activities

These include:

- continuing to support Collaborating Centres in the designation or re-designation process, including site-visits;
- enhancing collaboration and information-sharing among centres and facilitating joint activities on issues of common interest;
- developing further the “turning research into practice” tool-kit.

3. OBJECTIVE: TO STRENGTHEN HEALTH MANAGEMENT AND SUPPORT SYSTEMS

The activities carried out in 2004 under this objective enabled the Team, through their respective regional desks, to strengthen effective collaboration with other departmental teams to provide coherent support to countries for the adoption and adaptation of evidence-based guidelines and to improve service-delivery practices in sexual and reproductive health.

3.1 Progress

3.1.1 The WHO/United Nations Population Fund Strategic Partnership Programme

Pursuant to its previous function as Headquarters’ tier for the United Nations Population Fund (UNFPA) Technical Advisory Programme, the Department’s work on the WHO/UNFPA Strategic Partnership Programme (SPP) is aimed at supporting the introduction and utilization of evidence-based guidelines to improve sexual and reproductive health. This Partnership supports the Department’s commitment to enhancing linkages between the creation of evidence-based tools and the implementation of recommended practices to improve programmes and the delivery of services. More specifically, the objectives of the SPP are:

- to introduce systematically selected practice guides to improve sexual and reproductive health, initially in the areas of family planning and sexually transmitted infections (STIs) and reproductive tract infections (RTIs);
- to support the dissemination, adaptation and adoption of guidelines within countries;
- to strengthen technical capacity by providing orientation on new guidance, knowledge sharing and providing technical assistance to peers or colleagues (backstopping) in sexual and reproductive health, including maternal health.

3.1.1.1 Global workshop

A global workshop was convened in February 2004 for staff from WHO Headquarters and Regional Offices as well as staff from UNFPA Headquarters and Country Support Teams, with the objectives of providing an orientation to the SPP, outlining a plan of work, introducing selected guidelines and updating participants on technical developments in the areas of SPP’s focus. New guidelines were introduced for family planning, STIs/RTIs and maternal health. Participants were also made aware of the ongoing work on gender and reproductive rights issues, the promotion of sexual and reproductive health within the context of the Millennium Development Goals, the relationships with national poverty reduction strategy papers, sector-wide approaches to national health development plans, the *WHO Reproductive Health Library* and the Health Metrics Network. The workshop reviewed barriers to and opportunities for dissemination and utilization of reproductive health guidelines and manuals, and participants developed regional action plans for project implementation, monitoring and evaluation.

3.1.1.2 Regional workshops

Five regional workshops were conducted with the objectives of:

- reviewing countries’ situations in terms of policies, practices, guidelines, relevant epidemiological data and indicators;
- identifying needs in sexual and reproductive health, in particular family planning and the management of STIs and RTIs;
- familiarizing participants with WHO and partners’ evidence-based guidelines on family planning and STIs and RTIs;
- developing action plans for in-country adaptation and/or adoption of the guidelines;
- identifying technical assistance needs for countries in implementing their action plans.

Forty countries participated in the regional workshops, and each country-team outlined an action plan for introducing and utilizing guidelines. The main features and lessons learnt from the four regional workshops are summarized in Table 8.1.

3.1.1.3 Countries on which focus will be intensified

Fourteen countries have been identified as candidates preferred for intensified focus following submission of proposals developed after the workshops. This will entail implementation of activities to introduce the guidelines and selection and monitoring of specific indicators to assess how the guidelines are being used (Figure 8.2).

Table 8.1. Synopsis of WHO/UNFPA Strategic Partnership Programme's regional workshops held in 2004

Region (location, date)	Countries participating and profile of attendees	Lessons learnt
Europe (Issy Kul, Kyrgyzstan, 25–29 May 2004)	Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Uzbekistan <ul style="list-style-type: none"> • Programme Officers from UNFPA Country Offices • Lead specialists in obstetrics and gynaecology • Lead specialists in dermatovenereology • Representatives from local USAID mission and cooperating agencies 	<ul style="list-style-type: none"> • National family planning guidelines already developed in Kazakhstan need updating; other countries are ready to adapt the generic WHO guidelines • Proposal made to incorporate WHO guidelines in pre-service and post-graduate training curricula • Meeting provided an opportunity for cross-country review of strengths and barriers in the use of guidelines on family planning and STI management • Strong potential for use of WHO guidelines for developing web-based interactive training materials for physicians in Russian
South-East Asia (Colombo, Sri Lanka, 2–5 August 2004)	Bangladesh, Bhutan, India, Indonesia, Myanmar, Nepal, Sri Lanka, Thailand <ul style="list-style-type: none"> • Programme Officers from UNFPA Country Offices • National reproductive health programme managers • Representatives from International Planned Parenthood Federation and Family Planning Association, Sri Lanka 	<ul style="list-style-type: none"> • Attendance of skilled health-care providers during birth was added as an additional area of focus for the workshop • Meeting highlighted the major role that professional societies play in several countries and the flexibility required for needs-based design of family planning programmes in countries • Emphasized role of the private sector and of social marketing in ensuring commodity security • Stressed the importance of local issues in the adaptation of guides for essential practice and STI guidelines (e.g. men having sex with men as a special group, consistency of recommendations in <i>Medical eligibility criteria for contraceptive use</i> and <i>Sexually transmitted and other reproductive tract infections: a guide to essential practice</i>), religious barriers to the dual protection concept)
Western Pacific (Phnom Penh, Cambodia 23–27 August 2004)	Cambodia, China, Lao People's Democratic Republic, Malaysia, Mongolia, the Philippines <ul style="list-style-type: none"> • UNFPA Programme Officers • National programme managers for reproductive health and STIs • Representatives from Japan International Cooperation Agency, International Planned Parenthood Federation 	<ul style="list-style-type: none"> • Need to update and revise developing national guidelines • Strong interest in adopting the <i>Decision-making tool for family planning clients and providers</i> • Strong interest in STI/RTI guidelines and many suggestions made about the content • Emphasized the potential for enhanced collaboration between family planning and STI programmes and for collaboration among countries with different levels of development within the region • Strong potential for enhanced participation of partners in the country adaptation/adoption processes and mobilization of additional resources

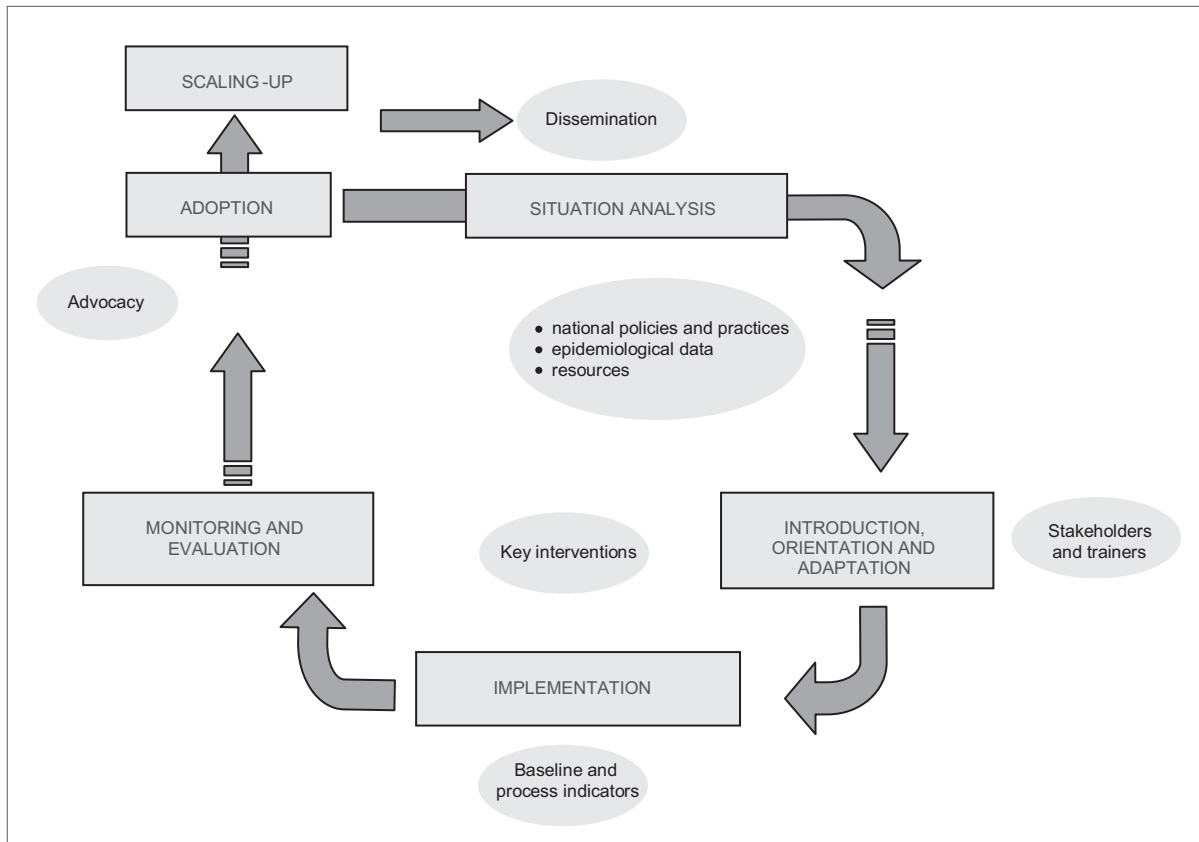
Region (location, date)	Countries participating and profile of attendees	Lessons learnt
Africa (Dar es Salaam, United Republic of Tanzania, 20–24 September 2004)	Benin, Cameroon, Mozambique, Nigeria, Rwanda, South Africa, United Republic of Tanzania, Zambia, Zimbabwe <ul style="list-style-type: none"> • Programme Officers from UNFPA Country Offices • Programme Officers from WHO Country Offices • National programme managers in reproductive health and STI control • Representatives from USAID cooperating agencies 	<ul style="list-style-type: none"> • Revised guidelines in French and Portuguese are not available. This is a major constraint on local utilization • National guidelines based on previous guidance are available in many countries, some of them have been updated • Similar workshops planned in countries for local buy-in should take into account competing demands on policy-makers for HIV-related activities • In addition to the guidance included in the guidelines for essential practice, more specific guidance on a framework for integrating STI prevention and care into primary health-care settings is required • Critical issues of logistics for both family planning and STI products were also stressed (e.g. lack of reagents for syphilis screening in pregnant women, drug procurement)

3.2 Planned activities

Activities undertaken in countries where there is intensified focus include:

- holding national workshops to review and revise national guidelines to incorporate policies and practices recommended in the WHO guidelines;
- holding national and subnational meetings of stakeholders to introduce WHO guidelines and develop an operational framework for integrating the guidelines into activities within the local context, including identifying the most effective channel for introducing best practices;
- developing training manuals to introduce best practices;
- mapping use of evidence-based manuals, including availability, through situation analysis;
- developing advocacy tools that incorporate practices from recently introduced guidelines;
- working with partners to support the process of implementation of guidelines and their distribution to the service-delivery levels;
- using various instruments to assess the effective utilization of the guidelines.

Figure 8.2. Schematic representation of process used during systematic introduction of guidelines in countries benefiting from intensified focus



Chapter 9

Technical cooperation with countries: Africa and the Eastern Mediterranean Regions

H. Bathija, D. Chikamata, A. Fahmy

1. INTRODUCTION

The main objective of the Technical Cooperation with Countries Team is to pursue the strengthening of research capacity among institutions in the African and Eastern Mediterranean Regions in order to enhance their potential to implement reproductive health research relevant to national and regional needs and to facilitate their participation in global research efforts. The strategy continues to focus on the strengthening of selected institutions and the stimulation of interest in reproductive health research in various countries.

2. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS AND TECHNOLOGIES

It is within the context of ensuring that countries have adequate capacity to develop and carry out the research and programme development activities required to implement the Programme of Action adopted at the International Conference on Population and Development that the Team continued and intensified its support of countries in their efforts to strengthen national research capacity. There was a particular emphasis on fostering action-oriented research as well as cooperation between the Programme, Regional Offices and countries. Various mechanisms were used to identify and support potential new collaborating institutions in the least developed countries. Efforts were made to consolidate the gains from previous investments in strengthening the capacities of institutions and the skills of individual researchers or networks; this includes the development of capacities

for operations research. In addition, special attention was given to increasing the opportunities for dialogue with policy-makers, programme managers and other stakeholders as a means to enhance the dissemination of research findings and their translation into practices.

2.1. Progress

2.1.1 Identifying reproductive health research needs and priorities

Support was given to two countries in the Eastern Mediterranean Region to identify their reproductive health needs: Afghanistan and Oman. The work in Oman on birth spacing is reported under Chapter 13, section 2.1.4.1.

The Ministry of Health of Afghanistan requested assistance from the Department to develop a national high-quality family planning programme. A team from the Department undertook a mission to Kabul in June 2004, and subsequently the Ministry of Health submitted a proposal for Stage 1 of the Strategic Approach (a situation analysis). However, due to the security situation in the country it has not yet been possible to start the fieldwork. Nevertheless, the Department has provided technical support to the Ministry of Health in various ways, such as by supporting the participation of Afghan nationals in the Department-sponsored course on gender and reproductive rights in Khartoum, Sudan, and by using video conferencing and dispatching a large amount of the Department's publications.

2.1.2 Support to regional networks

2.1.2.1 The African Reproductive Health Research and Training Network

The African Reproductive Health Research and Training Network, established in 2002, is a regional umbrella network linking, coordinating and strengthening existing reproductive health research networks for the purpose of improving reproductive health in Africa. Membership is open to African institutions and individuals involved in research and research-training activities in reproductive health. The network is affiliated with the African Health Research Forum. The Secretariat of the network is based at the Reproductive Health Research Unit, University of the Witwatersrand, Johannesburg, South Africa.

In 2004, activities (postponed from 2003) included updating the research directory of the network, holding fund-raising and networking activities, holding a meeting of the interim steering committee, developing an information leaflet and other materials as well as finalizing the constitution. The final draft of the constitution will be reviewed at the steering committee meeting in January 2005.

2.1.2.2 Network in the Eastern Mediterranean Region

With the support of the Programme, the Regional Office for the Eastern Mediterranean Region has created a network for reproductive health research. This network aims to facilitate the exchange of information and research-related experiences in the field of reproductive health both between and within countries. The network's web site became functional in 2004 and is available at <http://www.emro.who.int/rhrn/>.

2.1.3 Awarding research capacity-strengthening grants and planning to strengthen capacity

2.1.3.1 Malawi

In collaboration with WHO Regional and Country offices, the Centre for Reproductive Health (part of the Departments of Community Health and Obstetrics and Gynaecology at the College of Medicine of the University of Malawi) was identified as a potential recipient for a research capacity-strengthening grant to support the national reproductive health priority programmes of the Ministry of Health. These programmes include safe motherhood; adolescent sexual and reproductive health; family planning; prevention and management of sexually transmitted infections (STIs), reproductive tract infections (RTIs) and HIV/AIDS; early detection and management of cervical cancer; elimination of harmful practices; and reducing domestic violence. The Long-term Institutional Development (LID) grant application, together with the institutional profile and 5-year plan of work, was reviewed and approved by the Regional Advisory Panel.

2.1.3.2 Kenya

The Department of Obstetrics and Gynaecology at the University of Nairobi was awarded a Service Guidance Centre grant to promote and support the utilization of evidence-based recommendations contained in standard guidelines through in-country dissemination and the application of best practices. In 2004, the Programme provided support to the centre to expand the use of the *WHO Reproductive Health Library* to all provincial hospitals and to introduce the new WHO antenatal care model at the Kenyatta National Hospital.

2.1.4 Developing institutional research capacities through workshops and training

2.1.4.1 Research synthesis and systematic reviews workshop, South Africa

The third annual research methods course, run by the Effective Care Research Unit of the University of the Witwatersrand in Johannesburg was held in July 2004. The emphasis of the course is on giving researchers the knowledge and practical skills to allow them to carry out clinical randomized controlled trials and to complete a Cochrane systematic review. Participants attended the course from Cameroon, Democratic Republic of Congo, Egypt, Pakistan, South Africa, Uganda and Zimbabwe.

Several participants from previous courses have already completed protocols or reviews, and 10 have had their reviews published in the Cochrane Library.

2.1.4.2 International semenology workshop, South Africa

In 2004, a 5-day practical workshop designed to cover the evaluation of human semen, as described in the *WHO laboratory manual for the examination of human semen and sperm-cervical mucus interaction* (1999), was organized by the Department of Obstetrics and Gynaecology of Stellenbosch University, Tygerberg Hospital, Cape Town, South Africa. Nine participants from research centres in the African and Eastern Mediterranean Regions attended. All participants were trained individually and received daily feedback on their performance. At the completion of the workshop, all participants underwent theoretical and practical examinations.

The Continuous Quality Control Programme for the evaluation of sperm morphology, which is organized by Tygerberg Hospital, has been extremely successful and has led to the establishment of satellite laboratories in the region. A long-distance teaching programme allows individuals to communicate with a reference laboratory, for example by using e-mail. Altogether, 86 individuals have been trained and enrolled in the quality control programme. Data from the project have been used to develop a unique statistical model to enable laboratory directors to distinguish the performance of individual laboratory technicians.

2.1.4.3 Course on research methods in sexual and reproductive health and HIV, South Africa

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. The course was organized by the Reproductive Health Research Unit at Chris Hani Baragwanath Hospital in Soweto, Johannesburg.

In 2004, 22 participants from eight countries in sub-Saharan Africa attended the course. To date, 212 participants from 17 countries in sub-Saharan Africa have attended. Of these, 128 were women and 84 were men. The majority of participants were reproductive health advisers, project managers, medical officers and nurse–midwives from governmental organizations, nongovernmental organizations and research institutions.

2.1.4.4 M.Sc. course in biostatistics, Nigeria

Since 1998, the Programme has provided support to an M.Sc. course in biostatistics that is organized by the Department of Epidemiology, Medical Statistics and the Environment at the University of Ibadan, Nigeria. This course aims at training professional biostatisticians to provide expert advice to biomedical research groups in Africa. The Programme's support for this course includes building capacity to enhance the skills of the academic staff and strengthening computer facilities and library resources. Seventeen students were enrolled during the 2003–2004 academic year. Three of these were foreign students: one each from Cameroon, Ghana and Kenya.

Since its inception, the biostatistics programme has trained 75 professional biostatisticians and epidemiologists. Of these, 11 were from outside Nigeria. An in-depth appraisal of the course will be conducted in 2005.

2.1.5 Enhancing capacities for operations research

A special initiative to develop an operations research training centre for francophone Africa was planned in 2002 in collaboration with the Population Council's FRONTIERS programme and with the WHO Regional Office for Africa. The Centre de Recherche sur la Population et le Développement, within the Institut du Sahel in Bamako, Mali, was selected to become the training centre for francophone countries.

The first orientation workshop took place in September 2003 in Bamako. This was followed by two training and protocol-development workshops (May and November 2004). The teams from different countries included programme managers, service providers and researchers. Each team chose a theme that was a priority for their country and developed a proposal for operations research (titles are given in Table 9.1). These proposals are under review, and possible sources of funding are being identified; funding will hopefully come from the country or regional level.

2.1.6 Improving ethical standards in reproductive health research

As a follow-up to the regional workshop on ethical issues in reproductive health research held in Kadoma, Zimbabwe in 2000, a 5-day national workshop was organized by the Department of Obstetrics and Gynaecology at the University of Ibadan, Nigeria, in October 2004. This was attended by 31 participants from research institutions and tertiary hospitals. The Programme also used other means to promote ethical standards in reproductive health research including offering sessions as part of operations research training workshops described above, offering sessions at the Congress of the African Society of Obstetricians and Gynaecologists and initiating collaboration with the Networking for Ethics on Biomedical Research in Africa.

2.1.7 Strengthening institutional research capacities

2.1.7.1 Overall research output

The 10 centres supported with LID grants or Resource Maintenance Capital grants are involved in projects that address regional and national reproductive health priorities. Out of a total of 121 studies, more than 50% were clinical research projects. All thematic areas were studied, but the highest number of projects focused on maternal health and family planning. Many projects dealt with several thematic areas at one time.

2.1.7.2 Training provided by the centres

Staff from centres supported by the Programme were sent abroad for training and the centres themselves organized extensive training programmes for professional and technical staff from national institutions, including service providers. The 10 centres receiving support to strengthen research capacity provided individual training to 154 staff from other institutions. A total of 23 fellows participated in formal courses and 2564 people attended short-course group-learning activities, such as seminars and workshops organized by these centres. A total of 1670 people were trained in Tunisia, where the Centre for Research in Human Reproduction was integrated into the International Training Centre in Reproductive Health in 2004.

2.1.7.3 Summary of country activities

During 2004, the Department's Technical Cooperation with Countries Team collaborated with 42 institutions or research groups in 24 countries in the African and Eastern Mediterranean Regions. A brief description of the main developments at country level follows in Table 9.1.

Table 9.1. Outline of support and activities administered by Technical Cooperation with Countries Team by country, 2004

Country	Support and activities
Afghanistan	Preparatory activities relating to the strategic assessment for family planning ^a Preparatory activities relating to training in gender and reproductive rights ^a
Benin	Operations research on adolescents ^a Team (including representatives from the Ministry of Health, research institutions and WHO Country Office) participated in operations research training initiative ^a Developed a proposal to prevent infections in the maternity ward of the Central Hospital of Département de Ouémé The Centre for Research in Human Reproduction and Demography of the Department of Obstetrics and Gynaecology, University of Benin, Cotonou, has initiated a project known as "The health and psychosocial consequences of severe (near-miss) obstetric morbidity in Benin" Priority country for the WHO/UNFPA Strategic Partnership Programme
Burkina Faso	Team (including representatives from the Ministry of Health, research institutions and WHO Country Office) participated in the operations research training initiative ^a Developed proposal on reducing rates of early removal of Norplant in Kossodo, Ouagadougou Centre Hospitalier National Yalgado Ouedraogo, Ouagadougou, continued study of obstetric sequelae of female genital mutilation
Cameroon	Operations research on adolescents ^a Member of African Reproductive Health Research Network (RESAR) Priority country for the WHO/UNFPA Strategic Partnership Programme
Chad	Team (including representatives from the Ministry of Health, research institutions and WHO Country Office) participated in operations research training initiative ^a Developed proposal to examine the reduction in maternal deaths due to eclampsia in two referral hospitals in N'Djamena
Côte d'Ivoire	Operations research on adolescents ^a LID ^b grant awarded to National Research Cellule on Reproductive Health at the National Institute of Public Health in Abidjan Member of African Reproductive Health Research Network
Egypt	Resource Maintenance Grant awarded to but not executed by Egyptian Fertility Care Society, an affiliate of the Egyptian Medical Association and its research network (includes all University and Ministry of Health teaching hospitals)
Ethiopia	New LID grant approved for 2003–2007 to the Reproductive Health Research Unit, Department of Obstetrics and Gynaecology, University of Addis Ababa, Addis Ababa Preparations in progress to participate in microbicide research
Ghana	WHO Representative requested support for Department of Obstetrics and Gynaecology, Korle-Bu Hospital to establish a collaborating centre; site-visit planned for February 2005 Rural Help Integrated, Bolgatanga, participated in study on obstetric sequelae of female genital mutilation ^a
Guinea	Operations research on adolescents ^a LID grant approved for 2003–2007 for Reproductive Health Research Cellule (Cellule de Recherche en Santé de la Reproduction en Guinée), part of the African Reproductive Health Research Network Interventions phase of study to examine the impact of the use of the partogram on the reduction of labour complications in rural health centres in the administrative region of Kankan in Guinea was planned after the dissemination seminar

^a Additional details of this activity are reported elsewhere in this chapter.^b LID = Long-term Institutional Development grant.

Table 9.1. Outline of support and activities administered by Technical Cooperation with Countries Team by country, 2004
(continued)

Country	Support and activities
Iran (Islamic Republic of)	Small grant awarded to but not executed by the National Research Centre for Reproductive Health of the Deputy Ministry for Research Affairs, Ministry of Health and Medical Education, Tehran Research on adolescent reproductive health ^a
Kenya	Kenyatta National Hospital, Nairobi, participated in study of obstetric sequelae of female genital mutilation ^a Small grants awarded to but not executed by the National Centre for Research in Reproduction, Nairobi The Department of Obstetrics and Gynaecology, University of Nairobi, Nairobi, is a new recipient of a Service Guidance Centre grant The above Department published proceedings of the 2002 regional workshop on the management of infertility in developing countries Re-entry grant awarded to Institute of Primate Research, Nairobi One student is pursuing M.Sc. degree studying the production and characterization of monoclonal antibodies against baboon endogenous virus and retroviral-related antigens expressed in baboon placental villous tissue at Institute of Primate Research, Nairobi
Malawi	New LID grant awarded for 2005–2009 to Centre for Reproductive Health, College of Medicine, University of Malawi, Zomba
Mali	Centre for Research on Population and Development organized operations research training programme for francophone countries, 2003–2005 ^a Team (including representatives from the Ministry of Health, research institutions and WHO Country Office) participated in operations research training initiative ^a and developed proposals to increase the number of births attended by a skilled person in two areas (communes) in the district of Bamako and a proposal to increase prevalence of contraceptive use among adolescents and young people in Bamako
Mauritania	Team (including representatives from the Ministry of Health, research institutions and WHO Country Office) participated in the operations research training initiative ^a Developed proposal to increase the use of family planning and birth spacing in Nouakchott
Niger	Team (including representatives from the Ministry of Health, research institutions and WHO Country Office) participated in the operations research training initiative ^a Developed proposal to improve management of obstetric emergencies in the Maternity Hospital of Maradi
Nigeria	Participating in study of obstetric sequelae of female genital mutilation ^a at the National Hospital for Women and Children, Abuja, and University of Benin City Hospital, Benin City Small grants awarded to but not executed by: 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 Directors of Nigerian centres made presentations at the scientific workshop at the Regional Advisory Panel meeting in 2004 Priority country for the WHO/UNFPA Strategic Partnership Programme Centre for Research in Reproductive Health, Sagamu, continues to develop clinical and laboratory facilities for research activities

^a Additional details of this activity are reported elsewhere in this chapter.^b LID = Long-term Institutional Development grant.

Table 9.1. Outline of support and activities administered by Technical Cooperation with Countries Team by country, 2004
(continued)

Country	Support and activities
Nigeria (continued)	Centres in Jos and Benin City planning to participate in project A 25194 (operations research on community and facility interventions to improve maternal health) Fifth year of support for M.Sc. course in Biostatistics, Department of Epidemiology, Medical Statistics and Environmental Health, Ibadan, 2004; due for in-depth evaluation in 2005 ^a Emergency contraception study under way ^a
Oman	Implementation of the Strategic Approach to birth spacing programme ^a Technical support provided to Ministry of Health for development of proposal on the integrated management of maternal and child health
Pakistan	Small grants awarded to but not executed by National Research Institute of Fertility Care, Ministry of Population Welfare, Government of Pakistan, Karachi; Reproductive Physiology Laboratory, Department of Biological Sciences, Quaid-i-Azam University, Islamabad
Senegal	Participating in operations research on adolescents ^a Université Cheikh Anta Diop, Dakar, coordinating study of obstetric sequelae of female genital mutilation ^a LID grant awarded to Department of Obstetrics and Gynaecology, Le Dantec Hospital, University of Dakar, Dakar, and the International Centre for Training and Research in Reproductive Health, which is attached to the Department International Centre for Training and Research in Reproductive Health is coordinating regional activities on post-abortion care Team (including representatives from the Ministry of Health, research institutions and WHO Country Office) participated in the operations research training initiative ^a and developed proposal to increase the recruitment of new family planning acceptors through involvement of non-family planning service providers in districts of Gossas and Kaolack
South Africa	Small grant awarded to but not executed by Reproductive Health Research Unit, Chris Hani Baragwanath Hospital, Soweto, Johannesburg Research methods course organized by the Unit in Johannesburg ^a Semenology course and quality control programme ^a organized by University of Stellenbosch, Cape Town Reproductive Health Research Unit, Durban, planning to participate in operations research on community and facility interventions to improve maternal health LID grant awarded for 2001–2005 to Effective Care Research Unit, University of the Witwatersrand, University of Fort Hare and Department of Health, Eastern Cape Province Priority country for the WHO/UNFPA Strategic Partnership Programme
Sudan	Resource Maintenance Grant awarded to Department of Obstetrics and Gynaecology, University of Khartoum, Khartoum University of Khartoum, Khartoum, is coordinating study of obstetric sequelae of female genital mutilation ^a School of Family Science, Ahfad University for Women, Omdurman, organized the course on gender and rights in reproductive health
Syrian Arab Republic	Support for research on adolescent reproductive health, Ministry of Health ^a
Tunisia	Resource Maintenance Grant awarded to but not executed by Centre for Research in Human Reproduction, Tunis, part of the National Office of Family and Population, for a project on the diagnosis and management of high-risk pregnancies

^a Additional details of this activity are reported elsewhere in this chapter.^b LID = Long-term Institutional Development grant.

Table 9.1. Outline of support and activities administered by Technical Cooperation with Countries Team by country, 2004
(continued)

Country	Support and activities
Uganda	Resource Maintenance Grant awarded to the Human Reproduction Research Unit, Department of Obstetrics and Gynaecology, Makerere University, Kampala The above Unit participated in launch of the Implementing Best Practices initiative in East Africa The above Unit plans to participate in project studying operations research on community and facility interventions to improve maternal health
United Republic of Tanzania	LID grant awarded for 2003–2007 to Kilimanjaro Reproductive Health Research Centre at the Kilimanjaro Christian Medical Centre, Moshi The above Research Centre participated in launch of the Implementing Best Practices initiative in East Africa Priority country for the WHO/UNFPA Strategic Partnership Programme
Zambia	Small grant awarded to Department of Obstetrics and Gynaecology, University of Zambia, which is based in the Teaching Hospital in Lusaka Conducted <i>The WHO Reproductive Health Library</i> training-of-trainers workshop Staff member received Research Training Grant to attend reproductive health course in Geneva Participated in launch of the Implementing Best Practices initiative in East Africa Priority country for the WHO/UNFPA Strategic Partnership Programme
Zimbabwe	Resource Maintenance Grant awarded to Department of Obstetrics and Gynaecology, University of Zimbabwe, Harare Priority country for the WHO/UNFPA Strategic Partnership Programme

^a Additional details of this activity are reported elsewhere in this chapter.

^b LID = Long-term Institutional Development grant.

2.1.8 Strengthening skills and abilities of individuals

In 2004, four researchers completed their studies under a grant from the Programme: a researcher from Nigeria was trained in polymerase chain reaction in the Molecular Diagnostic Laboratory, University of the Witwatersrand, Johannesburg, South Africa; a researcher from Ethiopia completed a Master's degree course in reproductive and sexual health research at the London School of Hygiene and Tropical Medicine, London, England; a researcher from Zambia attended a course on reproductive health research methods at the Foundation for Medical Education and Research, Geneva, Switzerland; a researcher from Côte d'Ivoire completed the Master's degree course on health systems research at the Free University, Brussels, Belgium. Her thesis discussed the integration of family planning into school and university health services in Abidjan.

2.1.9 Enhancing the dissemination and utilization of research

2.1.9.1 Regional congresses and conferences

In 2004, the Programme supported researchers from collaborating institutions in Cameroon, Egypt, Guinea, Nigeria,

Senegal, South Africa, Uganda and the United Republic of Tanzania so they could make presentations at four international events (the East, Central and Southern African Obstetrical and Gynaecological Societies conference in Kampala, Uganda; the Reproductive Health Priorities Conference, Sun City, South Africa; a conference on men as partners in Mumbai, India; and the congress of the African Society of Obstetricians and Gynaecologists in Cotonou, Benin). The scientific papers presented were based on the results of projects that had received support from the Programme.

2.1.9.2 Partogram study in Guinea

The results of a study examining the impact of the use of partograms on reducing labour complications were presented in a series of dissemination seminars organized in November 2004 in Guinea. The Cellule de Recherche en Santé de la Reproduction en Guinée had carried out this research under a LID grant. The researchers reviewed obstetrical records, observed deliveries and conducted in-depth interviews with health-service staff; they also reviewed completed partograms. The results showed that partograms were poorly utilized, and the researchers identified several underlying reasons for this.

Recommendations made at the dissemination seminars included revising national standards, norms and guidelines during the second phase of the study in order to strengthen the overall system of reproductive health care and, more specifically, recommendations were made that informative, participatory supervision of health personnel should occur in the Kankan region, where the study took place.

2.1.10 Regional research and programmatic initiatives

2.1.10.1 Obstetric sequelae of female genital mutilation

Women presenting for delivery at 28 obstetric units in Burkina Faso, Ghana, Kenya, Nigeria, Senegal and Sudan from November 2001 through to March 2003 were included in a study designed to estimate the incidence of obstetric complications among women giving birth in hospital who had undergone female genital mutilation and to compare this incidence with women who had not had genital mutilation; the study also sought to evaluate the relationship between different types of genital mutilation and obstetric complications. Data from a total of 28 393 women were available for analysis; 7171 (25.3%) without genital mutilation, 6856 (24.1%) with type I mutilation, 7771 (27.4%) with type II mutilation and 6595 (23.2%) with type III mutilation.

Obstetric complications among study participants included, for instance, 1970 (6.9%) deliveries complicated by postpartum blood loss \geq 500 ml; additionally 1400 (4.9%) infants were stillborn or died in the immediate postnatal period. Analysis of the relationship between different types of genital mutilation and obstetric complications is continuing.

A meeting of principal investigators and external experts held in Geneva in November 2004 emphasized the importance of this study for programmatic and policy actions in efforts to encourage abandonment of the practice of female genital mutilation.

2.1.10.2 Management of infertility

The Regional Advisory Panel for the African and Eastern Mediterranean Regions has, at its previous meetings, requested that the Programme address the issue of infertility as a reproductive health problem, despite the fact that it is not a priority topic for many donor agencies. In 2004, the Programme supported publication of the proceedings of the regional workshop on the management of infertility for the African and Eastern Mediterranean Regions, which was held in Nairobi, Kenya, in February 2002. The Programme has contributed a chapter entitled "The global problem of infertility: a perspective from the World Health Organization". The report summarizes the Programme's contributions to preventing and managing infertility from the early 1970s until the present.

In addition, the Programme supported the revision of the algorithm known as the "Prevention and management of infertility: a guide for reproductive health workers", which describes the management of infertility in resource-poor settings. The revised algorithm will be evaluated in two countries, one in the African Region and the other in the Eastern Mediterranean Region.

2.1.10.3 Cervical cancer screening by visual inspection with acetic acid

As a follow-up to the 2003 workshop on cervical cancer screening using visual inspection with acetic acid, project coordinators from Nigeria, Uganda, the United Republic of Tanzania and Zambia submitted draft proposals to the Regional Office for Africa and to Headquarters. The main purpose of the demonstration projects is to explore ways to introduce cervical cancer screening by visual inspection with acetic acid into existing reproductive health services at district hospitals. Based on these proposals, a generic proposal is being developed in collaboration with the African Population and Health Research Centre, Nairobi, Kenya. A meeting of project coordinators will take place in March 2005 in Nairobi.

2.1.10.4 Operations research on improving reproductive health services for adolescents

In 2004, the operations research project to evaluate and improve sexual and reproductive health services for adolescents continued in francophone sub-Saharan countries. More details on this project are given in the chapter on Promoting the sexual and reproductive health of adolescents (see Chapter 7, section 3.1.2).

2.1.10.5 Operations research on community and facility interventions to improve maternal and neonatal health

This study proposes to test an intervention for improving the health of mothers and neonates by identifying and utilizing community-based and health-facility-based interventions that involve pregnant women, their partners, their families, community leaders, health-care providers and policy-makers in making it easier for pregnant women to obtain health care. The study will be conducted in Ethiopia, Nigeria, Uganda and South Africa. The study will include three phases: a pre-intervention assessment, an intervention and an evaluation. The impact of interventions at community level and at the health-facility level will be evaluated by comparing pre-intervention and post-intervention indicators.

It is anticipated that the first phase of the study will begin in at least two centres in 2005, depending on the availability of funds.

2.1.11 Other research

2.1.11.1 Study comparing two regimens of levonorgestrel in emergency contraception, Nigeria

The objective of this randomized double-blind project is to compare the efficacy and side-effects of two different levonorgestrel regimens, one administered in two doses of 0.75 mg with a 24-hour interval and the other administered in one dose of 1.5 mg.

If the single-dose regimen proves to be effective it would simplify treatment and increase compliance and acceptability. The project is also being used to train researchers in good clinical practices and to develop a network of seven clinical research centres in Nigeria.

Recruitment of 3150 subjects was completed in December 2004, and data management and analysis will begin in April 2005.

2.1.11.2 Project to evaluate highly active antiretroviral treatment on mother-to-child transmission of HIV and the mother's health

The Kilimanjaro Reproductive Health Research Centre at the Kilimanjaro Christian Medical Centre in Moshi, Tanzania, is a new LID grant recipient.

It submitted a request for partial funding to cover the costs of building research capacity for a study looking at how to optimize the use of antiretrovirals during pregnancy to preserve the health of the mother, minimize side-effects and reduce the risk of mother-to-child transmission of HIV. The study is known as the "Kesho Bora" project, which means "A better future" in Swahili.

The project is mainly being funded by the RTIs/STIs Team (see Chapter 3, section 3.1.3.1). During this period of reporting, three members of the research team received training in good clinical practice. Patient recruitment will begin in 2005.

2.1.12 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 9.2. Details of these activities are given in other chapters of this report.

2.2 Planned activities

Activities planned for 2005 can be summarized under the following main lines of work:

- promote and further strengthen regional research networks working on key issues, such as maternal health, adolescent sexual and reproductive health, female genital mutilation, infertility, cervical cancer and HIV/AIDS;
- promote the dissemination and utilization of tools developed by the Department through the WHO/UNFPA Strategic Partnership Programme and the Implementing Best Practices initiative with collaborating centres;
- in collaboration with other partners, continue and increase efforts to institutionalize training in operations research in francophone African countries;
- through institutional development grants, support and maintain institutions currently collaborating with the Department to enable them to undertake research projects relevant to their identified reproductive health needs and priorities;
- in collaboration with the Department for Health Action in Crisis and other partners, continue to develop approaches for assisting countries in crisis.

Table 9.2. Summary of collaborative activities on programmatic issues

Department's thematic area or collaborating agency	Activity	Countries participating
Promoting family planning	Multicentre clinical trial of two implantable contraceptives for women (Jadelle and Implanon)	Zimbabwe
Making pregnancy safer	Making Pregnancy Safer initiative	Africa and Eastern Mediterranean Regions
	Use of misoprostol during third stage of labour	Egypt, Nigeria, South Africa
	Follow-up study of children whose mothers participated in the trial of magnesium sulfate for management of pre-eclampsia (Magpie)	Nigeria (Ibadan and Sagamu)
	Essential care practice guide validation study	Sudan, Uganda
	WHO Global Survey of Maternal and Perinatal Health (ongoing)	Algeria, Angola, Democratic Republic of Congo, Ethiopia, Kenya, Niger, Nigeria, Uganda
	Perinatal and neonatal mortality database	South Africa
Controlling STIs/RTIs	Capacity strengthening in microbicide research	Ethiopia, Nigeria, Uganda
	Expanded safety and acceptability study of 6% cellulose sulfate	Nigeria
	Multicentre study on impact of highly active antiretroviral treatment on mother's health and mother-to-child transmission of HIV	Burkina Faso, Kenya, Tanzania
Policy and programmatic issues	Co-facilitation of the World Bank Institute Programme in West Africa, including preparation and delivery of regional course on reproductive health and health reforms	Benin, Kenya
	Strategic Approach to reproductive health (Stages 1, 2 and 3)	Ethiopia, Nigeria, Oman, South Africa, Zambia
Implementing Best Practices initiative	Launch of initiative in Africa, June 2004, Entebbe, Uganda	Countries of intensified focus—Angola, Ethiopia, Kenya, Mozambique, Nigeria, South Africa, Uganda, United Republic of Tanzania and Zambia
WHO's Department for Health Action in Crises	Collaboration on various activities relating to reproductive health in countries in crisis	Afghanistan, Democratic Republic of Congo, Iraq, Liberia
Planning and programming in collaboration with Regional Office for Africa	A training initiative in evidence-based reproductive health care	African Region
WHO/UNFPA Strategic Partnership Programme	Regional workshop for Africa in September 2004 in Dar es Salaam, United Republic of Tanzania; activities on dissemination and utilization of guidelines; five proposals approved to start activities in 2005	Benin, Cameroon, Mozambique, Nigeria, Rwanda, South Africa, United Republic of Tanzania, Zambia, Zimbabwe
	Regional workshop for Eastern Mediterranean Region postponed from 2004 to January 2005 in Cairo, Egypt	Afghanistan, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Morocco, Pakistan, Somalia, Sudan, Syrian Arab Republic, Yemen

Annex 1

REGIONAL ADVISORY PANEL FOR THE AFRICAN AND EASTERN MEDITERRANEAN REGIONS IN 2004

Members

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	11	100					11
Women	6	55					6
<i>from:</i>							
AFRO	7	64					7
AMRO							
EMRO	4	36					4
EURO							
SEARO							
WPRO							

Collaborating agency scientists

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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	
Members	45	100					45
Women	9	20					9
<i>from:</i>							
AFRO	37	82					37
AMRO							
EMRO	8	18					8
EURO							
SEARO							
WPRO							

Chapter 10

Technical cooperation with countries: Americas Region

E. Ezcurra

1. INTRODUCTION

Strengthening the 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.

2. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS AND TECHNOLOGIES

The main goals established by the Regional Advisory Panel for the 2004–2005 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 and ethically sound research projects on topics relevant to national and regional reproductive health problems, and (ii) to promote the dissemination and utilization of relevant research findings and evidence-based guidelines.

The fundamental strategies selected for attaining these goals were:

- implementation of regional and national reproductive health research, and participation of strengthened institutions in the global research effort;
- development and strengthening of human resources;
- capacity building in research ethics at the national level;
- increased dissemination of relevant research results and evidence-based guidelines to facilitate their adaptation

and utilization in reproductive health programmes and services.

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

2.1 Progress

2.1.1 Research activities

The seven centres supported with research capacity-strengthening grants are involved in projects that address regional and national priorities. During 2004, out of 119 studies overall, 12 projects (10%) were implemented with support from the Programme's capacity-building grants or were funded by other thematic groups in the Department. A total of 57 projects were carried out at centres with support from national sources (48%), and 50 projects (42%) received support from international agencies other than WHO.

Ongoing projects supported by grants to build research capacity include basic science work in the area of male fertility, an assessment to identify priority interventions that could improve access to and the quality of family planning services, maternal and neonatal health care, and social science research in the area of male involvement in reproductive health. A subregional research initiative on physicians' knowledge of and attitudes towards emergency contraception began implementation in Barbados and in Jamaica.

Three hospitals located in Central America and associated with the Latin American Centre for Perinatology and Human Development (CLAP) in Montevideo, Uruguay, received small grants to initiate the building-up of basic research infrastructure.

2.1.2 Development of human resources

Courses Workshops Seminar (CWS) grants were awarded to the National Institute of Nutrition in Mexico City, Mexico, to support regional postgraduate courses in reproductive biology; to the National Institute of Public Health in Cuernavaca, Mexico, to support regional postgraduate education in reproductive epidemiology; and to the Centre for the Study of the State and Society (CEDES) in Buenos Aires, Argentina, to support regional postgraduate courses in the social sciences. With respect to support provided to individuals, 12 scientists from regional centres received grants in 2004 to undergo training in different areas relevant to reproductive health. Table 10.1 summarizes the overall number of grants awarded for training that were supported with funds from the Programme. Of the 12 fellows who received grants for short-term and long-term training, eight (67%) were women. Nine (75%) of the fellows studied at centres located in Latin America.

Altogether, 23 young scientists from the Programme's worldwide network of collaborating institutions applied for the first special research training grant jointly funded by the Programme and the Canadian Strategic Training Initiative in Research in the Reproductive Health Sciences. The competitive selection process concluded with the award of a grant to a fellow from the WHO Collaborating Centre in Human Reproduction, Havana, Cuba, who is currently studying for his M.Sc. degree at the University of Ottawa, Canada.

Staff from the seven centres receiving research capacity strengthening support were sent abroad for training and the centres themselves organized extensive training programmes for professional and technical staff from national institutions, including service providers. These seven centres implemented 22 postgraduate courses in which there were 204 participants, and other short-term group-learning activities, such as seminars and workshops, which were attended by 1030 participants.

2.1.3 Capacity building in research ethics at national level

The Regional Advisory Panel for the Americas recognized the need to offer appropriate training in research ethics for all personnel conducting research involving human participants and animals. It has also recognized that research ethics training is urgently needed for ethics committee members of collaborating institutions in Latin America and the Caribbean as is the strengthening of the appropriate operation of such committees.

A joint initiative to address these issues has been developed by the Office of International Research Ethics of Family Health International (FHI) and the Programme. The main objective of this initiative is to assist in the process of enhancing research ethics capabilities, both at the level of training of individual researchers as well as that of conducting the ethical review process by institutional committees. The initiative also includes the active collaboration of local staff of the Regional Bioethics Unit of the WHO Regional Office for the Americas (AMRO/PAHO) and of collaborating institutions and scientists from countries where the programme is implemented.

The research ethics training of local research staff and ethics committee members (stage 1) is based on the *Research ethics training curriculum* developed by FHI. This curriculum is a practical educational tool that provides up-to-date and standardized basic training on the ethics of research involving humans. It is widely used as a resource by national and international organizations. Up to 50 local research staff, including non-medical and non-scientific staff, can be trained in a 1-day workshop that uses participatory adult education techniques. In addition, a group of 15 staff, selected from those participating in the previously mentioned workshop, are chosen to take part in a special training-of-trainers workshop that also lasts one full day. This training is based on the training-of-trainers curriculum, also developed by FHI.

Table 10.1. Grants awarded for training in 2004, Region of the Americas

Type of course	Area	Sex of recipient		Total
		Female	Male	
M.Sc.	Perinatal epidemiology		1	1
M.Sc.	Gender, sexuality and reproductive health	1		1
Diploma	Reproductive biology	1	1	2
Short course	Molecular biology	2		2
Practical training	Reproductive biology	3	1	4
Workshop	Communication	1	1	2
Total		8	4	12

The second stage of the programme includes selecting one or two local ethics committees and assisting them in upgrading their operation. This stage includes a needs assessment or baseline information survey of the selected committees. The basis for the assessment is the document *Surveying and evaluating ethical review practices*, developed by the Special Programme for Research and Training in Tropical Diseases. Using this document, a team of up to three observers works on-site with the committee during three days to review its practices and make recommendations to strengthen its operation. The Programme and FHI's Office of International Research Ethics are expected to provide continuous technical support to these committees and to monitor their progress. One year after completing the workshops and initiating support to local ethics committees, a similar assessment to that conducted at baseline will be carried out to evaluate the impact of the programme.

In 2004, Stage 1 training workshops were organized in Guatemala and in Panama. A total of more than 80 people participated; they included investigators, non-scientific personnel and members of ethical review committees of almost all research and academic institutions in these countries that are active in the area of reproductive health. Of these participants, around 30 fellows participated in the training-of-trainers workshops so they could replicate the content of the workshop among other investigators and ethics committee members. Two ethics committees from the most prominent research and academic institutions in their countries were selected to take part in the second stage of the project, to be implemented in July 2005. A survey to assess the possible multiplier effect of the training-of-trainers workshop was conducted in December 2004; it is expected that results will be available in 2005.

2.1.4 Dissemination and utilization of research findings and evidence-based guidelines

2.1.4.1 Scientific publications

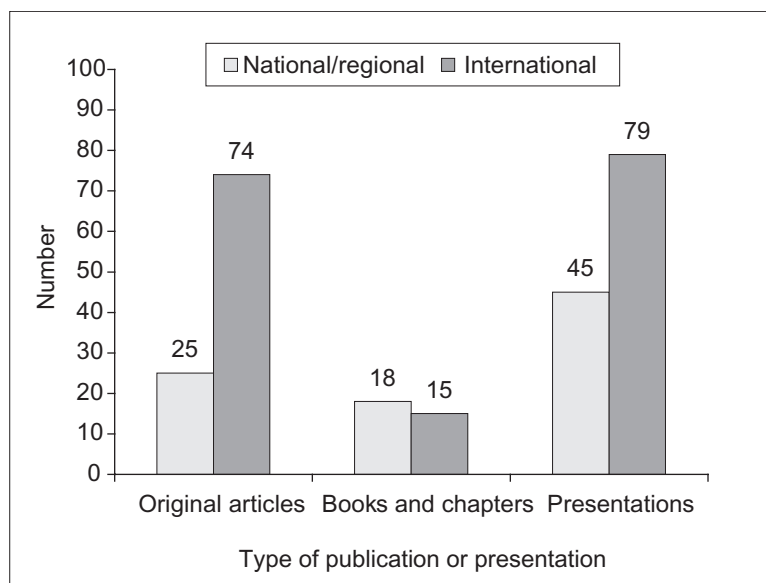
During 2004, a total of 105 research articles (99 original papers and six review articles) were published, and 33 books and book chapters were authored by staff from the seven centres receiving research capacity strengthening support. Furthermore, 124 presentations were made at national, regional or international scientific events, and 17 official reports were presented to national and international authorities and agencies. Figure 10.1 shows the distribution of presentations at national or regional meetings and publications in journals.

2.1.4.2 Promoting utilization of research findings and evidence-based guidelines

Information dissemination activities of local results of a regional research initiative (known as "Reality and beliefs in the sexual and reproductive decision-making process: men's perceptions and behaviour") were conducted in Bolivia and in Peru to promote their utilization by programmes and services.

For these activities, country teams designed, produced and distributed a special booklet that included not only an easily understandable summary of the project's findings and an interpretation of the findings but also specific recommendations for policies and programmes. The principal investigators made oral presentations of the results and discussed their policy implications, and these implications were extensively discussed with several audiences. In Peru, three workshops were held: in Chiclayo, in Iquitos and in Lima. An audience of more than 100 people attended these workshops, including scientists, representatives of professional associations,

Figure 10.1. Publications and presentations in the Region of the Americas, 2004



university professors, health-programme officers, other professionals in direct contact with the population (physicians, teachers, social workers), representatives of nongovernmental organizations and journalists.

In Bolivia, the results of the study were shared with a large audience attending the First National Meeting on Studies in Masculinities held in La Paz and co-sponsored by several national and international agencies, such as the Ministry of Health and Sports, the Vice-Ministry of Women's Affairs, the Swedish Ecumenical Action, the United Nations Development Fund for Women (UNIFEM), the United Nations Population Fund (UNFPA) and AMRO/PAHO.

Of particular importance was the implementation of the first stages of the WHO/UNFPA Strategic Partnership Programme (SPP) in Honduras, Paraguay and Peru. This programme focuses on the systematic introduction of evidence-based guidelines to improve sexual and reproductive health. During 2004, site-visits were made to these three countries to meet with relevant ministry of health authorities and other key stakeholders to plan the launch of the programme in 2005. Special efforts were deployed to undertake technical revision of the Spanish version of four different guidelines (two in family planning and two in sexually transmitted infections) so they would be available for country-level activities in 2005.

As part of this programme, representatives of UNFPA, PAHO, WHO and collaborating institutions, scientists, nongovernmental organizations and representatives from MERCOSUR (a common market of South American countries) and associated countries met in Rio de Janeiro, Brazil, in December 2004 in order to plan a subregional workshop that will bring together policy-makers and researchers. At this meeting a statement was drafted highlighting the importance of programmes and services utilizing research findings and evidence-based guidelines. This statement was presented to and endorsed at the meeting of the health ministers of MERCOSUR and associated countries held in Petropolis, Brazil, on 3 December 2004.

2.1.4.3 Facilitating access to scientific literature

The Health InterNetwork, launched by the Secretary-General of the United Nations in September 2000 and led by the World Health Organization, was created to bridge the "digital divide" in health and ensure that relevant information—and the technologies to deliver it—is widely available and effectively used by health personnel, including health professionals, researchers, scientists and policy-makers. As the first phase of making vital health content available, the Health InterNetwork developed the Health InterNetwork Access to Research Initiative (HINARI), which provides a vast online library that includes more than 2000 scientific journals.

Subscription to services offered by HINARI is free of charge for institutions in a large number of the least developed countries (those with per capita gross national product < US\$ 1000). Institutions in countries with per capita gross

national product between US\$ 1000 and US\$ 3000 pay a fee of US\$1000 per year per institution.

In the Region of the Americas, institutions from 12 countries are eligible to use HINARI if they pay the US\$ 1000 subscription fee. These are: Bolivia, Colombia, Costa Rica, Cuba, the Dominican Republic, Ecuador, El Salvador, Guatemala, Jamaica, Panama, Paraguay and Peru. It was considered to be a worthwhile investment to allocate a grant of US\$ 12 000 to cover the subscription fee for at least one institution in each of these countries, be it a Programme-collaborating institution or one selected in coordination with the local WHO Country Office. During 2004, HINARI fees were covered for seven universities, three research centres and two maternity teaching hospitals located, one each in one of the 12 eligible countries.

In order to assess the level of utilization of this service by the institutions being sponsored, data was retrieved from the library at WHO Headquarters on the number of times each institution logged-on to the system from June 2003 to October 2004. In addition, a survey of these institutions was made to explore a variety of issues including, for example, the type of user, the purpose of logging-on to the system, and the main difficulties experienced. The quantitative data showed that there had been a total of 81 840 log-ons to the system, ranging from 0 to 57 181 in individual institutions. In each of five libraries the number of log-ons was ≤ 100 ; in four the number of log-ons ranged from 101 to 5000; and in three university libraries there were $> 5 000$ log-ons. All 12 institutions replied to the survey. The results showed that the most typical user was a professional belonging to the same institution, logging-on to the system in search of information to support his/her research projects and academic tasks. Nevertheless, in some institutions, the main users logging-on to the system were university students. There was unanimous praise for the opportunities that HINARI provides for professionals in developing countries to remain up to date on scientific and medical issues. In turn, many libraries reported that the main drawback of the system was the lack of full online access to some of the most important scientific and medical journals due to regulations built into the agreement established between the publishers and WHO. A more detailed analysis of the results of the survey will be undertaken in 2005.

2.1.5 Summary country reports

During 2004, the Department's Technical Cooperation with Countries Team collaborated with 22 institutions or research groups in 17 countries in the Americas Region. A brief description of the main developments at country level is summarized in Table 10.2.

2.1.6 Thematic-group activities in the region

Institutions from several countries in the Americas Region collaborate actively with almost all of the Department's thematic groups. Table 10.3 provides a summary of this collaboration.

Table 10.2. Support and activities provided by the Technical Cooperation with Countries Team, by country, 2004

Country	Centre, type of support and main activities
Argentina	Centre for Perinatal Studies (CREP), Rosario
	Resource Maintenance Capital grant: the Centre conducts research in the areas of maternal and infant health, adolescent health and reproductive health epidemiology. It serves as a training and research methodology referral centre for the country and the region. Its staff have worked closely with Ministry of Health authorities to facilitate the utilization of research results by programmes and services.
	Centre for Population Studies (CENEP), Buenos Aires
	Long-term Institutional Development grant: CENEP is the coordinator of the regional social sciences network, which had 518 members at the end of 2004. The centre is actively involved in providing scientific advice to the multicentre research project studying the involvement of men in reproductive health in Central America [supported by PAHO/WHO/German Agency for Technical Cooperation (GTZ)], and it is preparing a comparative analysis of the six countries' survey data.
	Institute for Biology and Experimental Medicine (IBYME), Buenos Aires
Argentina	Long-term Institutional Development grant: IBYME continues to undertake basic sciences research in the field of male fertility.
	Centre for the Study of the State and Society (CEDES), Buenos Aires
	Courses Workshops Seminar grant: CEDES organizes the M.Sc. course in social sciences. It is involved in several global research projects supported by thematic groups of the Department. It also acts as regional conduit for the implementation of the gender and rights curriculum.
Barbados	Team of researchers from the Ministry of Health and the University of West Indies, Bridgetown
	Grant for subregional research initiative: the researchers are studying providers' knowledge of and attitudes towards emergency contraception.
Bolivia	Centre for Social Research, Appropriate Technology and Training (CISTAC), La Paz
	Grant for information dissemination activities of regional multicentre study on male involvement in reproductive health.
Chile	Institute of Maternal and Child Health Research (IDIMI), Santiago
	Unit of Reproductive Biology and Development, Catholic University of Chile, Santiago
	These two institutions continued to receive support from other thematic areas of the Department, mainly to participate in Programme-supported biomedical research on the mechanisms of action of emergency contraceptives.
Colombia	University Hospital, University del Valle, Cali
	The centre received support from the Programme and completed the follow-up study of children born to mothers who took part in the Magpie Trial, coordinated by Oxford University, Oxford, England, that evaluated the use of magnesium sulfate for the treatment of eclampsia.
Costa Rica	Central American Population Centre, University of Costa Rica, San Jose
	Small grant: the centre organized workshops on improving the communication skills of researchers, in which several staff members from Programme-supported centres in Latin America have participated.

Table 10.2. Support and activities provided by the Technical Cooperation with Countries Team, by country, 2004 (*continued*)

Country	Centre, type of support and main activities
Cuba	National Coordinating Network for Research in Human Reproduction, Havana Resource Maintenance Capital grant: the centre has prepared a plan aimed at disseminating and utilizing the findings of the study on men's perceptions and behaviour in respect of decision-making processes affecting sexual and reproductive health; the centre is also active in global research in the fields of adolescent reproductive health, improved non-surgical methods for pregnancy termination and on maternal and perinatal health.
El Salvador	National Maternity Hospital, San Salvador Small grant: as one of CLAP's associated centres in Central America, the hospital received for the first time a small grant to assist in building basic research infrastructure.
Guatemala	Guatemalan Epidemiologic Research Centre in Reproductive and Family Health, Guatemala City Small grant: the centre received a small grant to assist in the organization of the national research ethics workshops.
Honduras	San Felipe General Hospital, Tegucigalpa Small grant: as one of CLAP's associated centres in Central America, the hospital received for the first time a small grant to assist in building basic research infrastructure.
Jamaica	Team of researchers from the Ministry of Health and the University of West Indies, Kingston Grant for subregional research initiative: grant was awarded to assist implementation of a study on providers' knowledge of and attitudes towards emergency contraception.
Mexico	National Institute of Nutrition and Medical Sciences, Mexico City Courses Workshops Seminar grant: the institute organizes the diploma course in reproductive biology and collaborates with several of the Department's thematic groups examining research implementation and guideline development. National Institute of Public Health, Cuernavaca Courses Workshops Seminar grant: the institute organizes the M.Sc. course in reproductive epidemiology.
Nicaragua	Berta Calderon Hospital, Managua Small grant: as one of CLAP's associated centres in Central America, the hospital received for the first time a small grant to assist in building basic research infrastructure.
Panama	Centre for Research in Human Reproduction, Panama City Small grant: the centre received a small grant to assist in organizing national workshops on research ethics.
Paraguay	Several groups coordinated by the Ministry of Health, Asunción Considerable advances, including the completion of fieldwork, were made as part of the implementation of the Strategic Approach to assessing factors contributing to maternal mortality.
Peru	Faculty of Public Health, Peruvian University Cayetano Heredia, Lima Small grant: national and regional workshops were organized to disseminate local results of the regional social science research initiative looking at men's perceptions and behaviour in respect of decision-making processes affecting sexual and reproductive health. The faculty also organized, for the second time, the Master's degree course in gender, sexuality and reproductive health, which was attended by national and foreign students.

Table 10.3. Countries collaborating with the Programme's Department's thematic groups

Department's thematic area or collaborating agency	Activity	Countries participating
Promoting family planning	Multicentre clinical trial on two implantable contraceptives for women: Jadelle and Implanon	Brazil, Chile, Dominican Republic
	Phases I and II field-testing of the <i>Decision-making tool for family planning clients and providers</i>	Mexico, Trinidad and Tobago
	Studies on mechanism of action of emergency contraceptives	Chile
	Study on HIV and use of steroid contraception	Brazil
Making pregnancy safer	Follow-up study of children whose mothers participated in the trial of magnesium sulfate for management of pre-eclampsia (Magpie trial)	Argentina, Colombia, Cuba
	Randomized double-blind controlled trial of calcium supplementation during pregnancy for preventing pre-eclampsia	Argentina, Peru
	Implementation of the WHO Global Survey of Maternal and Perinatal Health	Argentina, Brazil, Cuba, Ecuador, Mexico, Nicaragua, Paraguay, Peru
	Introduction of new WHO antenatal care model	Argentina, Brazil, Bolivia, Cuba, El Salvador, Haiti
	Randomized controlled trial evaluating strategies for routine screening and treatment of urinary tract infections during pregnancy	Argentina
	Validation studies of the "rapid assessment" chart and "newborn examination chart" of <i>Pregnancy, childbirth, postpartum and newborn care: a guide for essential practice</i>	Brazil
Controlling STIs/RTIs	Study on contraceptive effectiveness of female condoms	Panama
	Field-testing of programme guidance tool	Brazil
Preventing unsafe abortion	Randomized study of routine priming of the cervix with misoprostol prior to vacuum aspiration	Cuba
	Efficacy and safety of non-surgical abortion with misoprostol	Cuba
Promoting the sexual and reproductive health of adolescents	Participation in social sciences research initiative on adolescent sexual and reproductive health	Argentina, Brazil, Chile, Colombia, Cuba, Mexico, Paraguay, Peru
Gender and rights issues	Regional implementation of workshops and country-level adaptation of gender and rights curriculum	Argentina
Policy and programmatic issues	Strategic Approach to reproductive health: stages 1–3	Bolivia, Brazil, Chile, Guatemala, Paraguay
Implementing Best Practices initiative	Randomized controlled trial to evaluate evidence-based practices available in the <i>WHO Reproductive Health Library</i>	Mexico

2.2 Planned activities

2.2.1 Research capacity-strengthening activities

2.2.1.1 Strengthening institutional research capacity

One strategy that was identified as a top priority for the immediate future was the need to develop mechanisms to conduct research capacity strengthening activities in least developed countries in the Americas. Small grants awarded in 2004 to centres in El Salvador, Honduras and Nicaragua could be considered the first step in the process of identifying new institutions or groups in these countries that eventually could become recipients of research capacity strengthening grants. The same applies to the groups participating in the strategic activities being implemented in Paraguay.

If funding becomes available in 2005, a call for applications for a Competitive Intra-regional Research grant could be launched on a topic relevant to regional needs. The implementation of the WHO/UNFPA Strategic Partnership Programme also requires the identification and awarding of grants to at least two institutions from the Region that could act as Service Guidance Centres.

2.2.1.2 Strengthening human resources for research

Rather than awarding new research training grants, in 2005 emphasis will be put on assisting the completion of the training cycle of fellows from institutions in the Region who have received research training grants from the Programme. This will mainly be done through the active pursuit of Re-Entry grant submissions and approvals. Supporting researchers to take part in communication workshops is considered an essential part of the effort to foster a closer dialogue between researchers and policy-makers in order to facilitate the increased utilization of relevant research findings. Grants for short-term and long-term research training could be awarded if additional funds became available, with priority given to intra-regional training.

2.2.2 Capacity building in research ethics at national level

The joint initiative between Family Health International and the Programme to develop knowledge, skills and abilities in research ethics among investigators, non-scientific personnel and members of ethics review committees will continue in 2005. There are plans to hold Stage 2 activities in Guatemala and in Panama and Stage 1 workshops in Paraguay and in Peru. There is also a plan to carry out a survey of ethics committees as a follow-up to the study conducted in the region in 1998.

2.2.3 Utilization of research findings and evidence-based guidelines

A subregional workshop held to bring together researchers and reproductive health programme officers from MERCOSUR and associated countries will be held in Montevideo, Uruguay, in April 2005; it will be jointly sponsored by the Programme, PAHO and UNFPA. This event is expected to facilitate the utilization of the valuable research findings produced by Programme-supported centres in these countries as well as the adaptation, adoption and utilization of evidence-based guidelines promoted by the WHO/UNFPA Strategic Partnership Programme and also the Programme's gender and rights curriculum.

Special attention will be placed on ensuring appropriate implementation at country level of the national Strategic Partnership Programmes of work, particularly in the three countries selected take part in the initial phase, i.e. Honduras, Paraguay and Peru. If additional funds are available it is likely that some Strategic Partnership Programme activities will be undertaken in Brazil and Guatemala, particularly in the area of sexually transmitted infections.

Annex 1

REGIONAL ADVISORY PANEL FOR THE AMERICAS REGION IN 2004

Members

Carlos Cáceres, REDESS Jóvenes, Lima, Peru
 Stella Campo, Hospital de Niños, Buenos Aires, Argentina
 William Fraser, Laval University, Quebec, Canada
 Ana C. González, Santafé de Bogotá, Colombia
 Sylvia Guendelman, School of Public Health, University of California, Berkeley, CA, USA
 Luis Rosero Bixby, Universidad de Costa Rica, San José, 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	62			3	38	8
Women	3	38			1	13	4
<i>from:</i>							
AFRO							
AMRO	5	62			3	38	8
EMRO							
EURO							
SEARO							
WPRO							

Collaborating agency scientists

Luis Bahamondes, Latin American Programme for Research and Research Training in Human Reproduction, Mexico City, Mexico
 Sandra García, Population Council, Mexico City, Mexico
 Roberto Rivera, Family Health International, Research Triangle Park, NC, USA

Annex 2

PRINCIPAL INVESTIGATORS IN 2004

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 Gonzáles, Peruvian University Cayetano Heredia (UPCH), 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, Pontificia Universidad Católica de Chile, Santiago, Chile

	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	17	100					17
Women	6	35					6
<i>from:</i>							
AFRO							
AMRO	17	100					17
EMRO							
EURO							
SEARO							
WPRO							

Chapter 11

Technical cooperation with countries: South-East Asia and the Western Pacific Regions

K. Ba-Thike

1. INTRODUCTION

Strengthening the research capacity of institutions in the South-East Asia and Western Pacific Regions was undertaken to enhance their potential to implement reproductive health research relevant to national and regional needs and to facilitate their participation in global research efforts. Building research capacity also contributes to each country's ability to carry out the research and programme development activities required to address their national reproductive health needs, thus contributing to the attainment of the Millennium Development Goals.

2. OBJECTIVE: WIDENING THE RANGE OF PRODUCTS OR TECHNOLOGIES

Priority areas of work for the South-East Asia and Western Pacific Regions (identified by countries and endorsed by the Regional Advisory Panel) include maternal and neonatal health and family planning, adolescent sexual and reproductive health, reproductive tract infections (RTIs), sexually transmitted infections (STIs) and prevention of unsafe abortion. With regard to the type of research and other activities, the Regional Advisory Panel had recommended that, in the context of capacity-building, the Programme should (i) shift its emphasis from biomedical research to operations or programmatic research, (ii) combine research capacity-building with the conduct of research, and (iii) promote networking, utilizing the expertise of mature centres.

2.1 Progress

In order to consolidate the research capacities that have been built over the years, the Programme helped centres to strengthen their human resources and infrastructure as necessary so that they could undertake research in priority areas of reproductive health through the grants awarded to research capacity-strengthening.

2.1.1 Research capacity-strengthening activities

2.1.1.1 Strengthening institutional research capacity

Nine centres in the South-East Asia Region and 12 centres in the Western Pacific Region received grants from the Programme. An overview of the main country-level activities follows.

China

Eight centres received a Resource Maintenance Capital grant, awarded through the National Coordinating Board of China. Table 11.1 summarizes ongoing research and new features in these centres. The first seven centres in Table 11.1 are officially designated WHO Collaborating Centres.

The programme of work carried out by the eight centres is complementary and contributes to the research and programmatic priorities of China. The mandate of the research institutes in family planning has expanded from family planning to social science and service-related studies on reproductive health more broadly; the Institute of Population Research in Beijing focuses predominantly on the critical relationships between population, environment and reproductive health.

Table 11.1. Ongoing research and new features in centres in China

Centre	Research and new features
Institute of Population Research, Peking University, Beijing	Research: key issues related to the economy in transition of the People's Republic of China, health and the environment
Department of Obstetrics and Gynaecology, Peking Union Medical College Hospital, Beijing	The WHO Collaborating Centre status of the Reproductive Endocrinology and Infertility Division was extended to the Department of Obstetrics and Gynaecology. The Department coordinates the National Programme on Prenatal Screening for Fetal Chromosomal Abnormalities and Neural Tube Defects Research: basic and clinical research on long-term, low-dose hormone replacement therapy for postmenopausal women
National Research Institute of Family Planning, Beijing	Research: 20 projects, of which 10 are Programme-sponsored multicentre trials on male hormonal contraception, emergency contraception and post-ovulatory fertility regulation, intrauterine devices (IUDs), and incidence and risk factors for pelvic inflammatory disease following induced abortion A new centre, the Social Medical Centre, conducts research on the quality of care in family planning programmes in mid-western China and cross-border studies on reproductive health issues and HIV/AIDS
Tianjin Municipal Research Institute for Family Planning, Tianjin	Research: emergency contraception, vaginal microbicides, prevalence of RTIs and STIs, and cervical cancer screening; also studying the sexual and reproductive health of middle-school students Programme-supported research: long-term follow-up of IUD users
Sichuan Family Planning Research Institute, Chengdu	Research: 16 projects, of which seven are supported by the Programme studying long-term follow-up of IUD use, long-acting male hormonal contraception, contraceptive effectiveness of female and male condoms, prevalence of lower genital tract infection in rural women in Sichuan province, and effects of long-term androgen administration on the prostate
Family Planning Research Institute of Zhejiang, Hangzhou	Research: reproductive biology, transdermal drug-delivery systems for postmenopausal hormone replacement therapy, and family planning and RTI service delivery
Shanghai Institute of Planned Parenthood Research, Shanghai	Research: 71 projects, of which 16 were initiated in 2004; basic and clinical research on contraception, quality of reproductive health services, HIV prevention and reproductive health advocacy, and community-based sexual and reproductive health services for unmarried young people Department of Epidemiology and Social Science Research has set up a new branch of molecular epidemiology
National Evaluation Centre for the Toxicology of Fertility Regulation Drugs, Shanghai	Research: establishment of toxicology assessment techniques and assessment of the reproductive and genetic toxicology of fertility-regulation drugs; 14 ongoing projects

India

Three WHO Collaborating Centres in India received Resource Maintenance Capital grants.

- National Institute for Research in Reproductive Health, Mumbai: the research agenda of the Institute has expanded from fertility regulation to infertility, prevention of STIs and RTIs, making pregnancy safer, and the management of menopausal symptoms. There were 61 ongoing projects in 2004 including three multicentre

studies for which the Programme provided funding and technical support. Ten articles were published in international journals in 2004.

- All India Institute of Medical Sciences, New Delhi: the research programme focuses on the development of post-ovulatory methods of fertility control, male methods of fertility regulation, and reproductive physiology. A total of 46 projects were ongoing in 2004, including two supported by the Programme. The Institute collaborates with the Ministry of Health and Family Welfare and the Indian

Council of Medical Research in formulating national policies for introducing emergency contraception and medical abortion.

- Postgraduate Institute for Medical Education and Research, Chandigarh: the Department of Obstetrics and Gynaecology at the Institute is a training centre for the use of assisted reproduction techniques and the management of high-risk pregnancy. Some of the 19 ongoing studies are looking at the association between methylene-tetrahydrofolate gene polymorphism with intrauterine growth retardation and recurrent spontaneous abortion, different treatments for polycystic ovary syndrome, and herbal products for RTI treatment.

Countries receiving research capacity-strengthening grants

Table 11.2 summarizes the progress of research projects in centres that are receiving their first or second cycle of research capacity-strengthening grants. Participation in regional research initiatives is reported in section 2.1.1.2.

2.1.1.2 Strengthening of human resources for research

Several regional and national workshops were conducted to strengthen the capacity of human resources for research. At least 50% of participants at the regional workshops were women.

Workshop on operations research

Twenty participants from China, Indonesia, Mongolia, Myanmar, Thailand and Viet Nam participated in a workshop on conducting operations research in the areas of reproductive health and HIV. The workshop was organized by the Insti-

tute for Population and Social Research, Mahidol University, Thailand, the Population Council's FRONTIERS project and the Programme. The objectives of the workshop were to train multidisciplinary country teams on the use and conduct of operations research to address priority issues in reproductive health and HIV and to develop operations research proposals for possible future funding.

Data analysis workshops for regional projects

Researchers from the four countries participating in the regional initiative on adolescent migrants and reproductive health in the Greater Mekong Region took part in a data analysis workshop in Bangkok in January 2004. They were from the Maternal and Child Health Centre, Vientiane, Lao People's Democratic Republic; the Hung Vuong Hospital, Ho Chi Minh City, Viet Nam; the Institute for Population and Social Research, Nakhon Pathom, Thailand; and the Institute of Sociology, Kunming, China. This workshop allowed participating countries to exchange their findings and develop plans for analysing data and writing reports.

Fourteen researchers from the following institutes (Box 11.1) participated in a data analysis workshop in Hat Yai, Thailand, in October 2004 for the multicountry study known as "Collaborative reproductive epidemiology research: patterns and predictors of caesarean section in Asia".

Scientific writing workshops

Scientific writing workshops were conducted by the Programme in two countries. Altogether 28 researchers from the Departments of Medical Research under the Ministry of Health in Lower Myanmar, Middle Myanmar and Upper Myanmar participated in a workshop held in Yangon, Myanmar, and 28 obstetricians and gynaecologists participated in

Box 11.1. Institutes participating in the data analysis workshop

- Bangladesh Institute of Research for Promotion of Essential and Reproductive Health and Technologies, Dhaka, Bangladesh
- Family Planning Research Institute of Sichuan, Chengdu, China
- Western Indonesia Reproductive Health Development Centre, University of North Sumatra, Medan, Indonesia
- Andalas University, Padang, Sumatra, Indonesia
- State Research Centre for Maternal and Child Health and Human Reproduction, Ulaanbaatar, Mongolia
- Department of Medical Research, Lower Myanmar, Yangon, Myanmar
- Department of Community Medicine and Family Health, Institute of Medicine, Tribhuvan University, Kathmandu, Nepal
- University of Kelaniya, Ragama, Sri Lanka
- Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand
- Prince of Songkla University, Hat Yai, Thailand
- National Hospital of Obstetrics and Gynaecology, Hanoi, Viet Nam
- Hung Vuong Hospital, Ho Chi Minh City, Viet Nam

Table 11.2. Progress of research projects at institutions receiving research capacity-strengthening grants

Country and institutions	Grants and progress of research
Indonesia	
Western Indonesia Reproductive Health Development Centre, Faculty of Medicine, University of North Sumatra, Medan	First cycle of LID ^a grant: data collection has been completed on a study entitled "Emergency obstetric care in North Sumatra Province" (initiated in 2003)
Reproductive Health Research Centre, Airlangga University, Surabaya	Second cycle of LID grant: lower genital tract chlamydial infections among female adolescents in Surabaya; prevalence of <i>Chlamydia trachomatis</i> urethral infection in male university students in Surabaya (initiated in 2004)
Lao People's Democratic Republic	
Maternal and Child Health Centre, Ministry of Health, Vientiane	Second cycle of LID grant: used for report writing on prevalence of RTIs in antenatal clinic patients in two central hospitals in Vientiane
Mongolia	
State Research Centre for Maternal and Child Health and Human Reproduction (MCHR), Ulaanbaatar	Second cycle of LID grant: used for analysis of data on the clinical aspects of vaginal discharge among prepubescent girls visiting the outpatient clinic of MCHR, and mothers' knowledge, perceptions and health-seeking behaviour related to their pre-pubertal daughters' vaginal discharge
	Research looking at unmet needs for infertility services in Ulaanbaatar (initiated in 2004)
	Participation in multicentre trials coordinated by the Programme (see section 2.1.1.2)
	Model clinic for comprehensive abortion care is being set up at MCHR as a pilot project following the strategic assessment of abortion services
Myanmar	
Department of Medical Research, Lower Myanmar, Yangon	Second cycle of LID grant: looking at social and behavioural dimensions of STIs among adolescent clinic attendees; prevalence of RTIs at the family planning clinic at Central Women's Hospital, Yangon (initiated in 2004)
Sri Lanka	
National Coordination Committee for Research on Reproductive Health, Colombo (task forces based in Universities of Colombo, Peradeniya and Ruhuna)	Resource Maintenance Capital grant: 16 projects ongoing at the University of Colombo, five funded by international agencies; eight research projects at the University of Ruhuna, four on male infertility
Viet Nam	
National Hospital of Obstetrics and Gynaecology, Hanoi	Resource Maintenance Capital grant: participation in multicentre trials coordinated by the Programme (see section 2.1.1.2)
Hung Vuong Hospital, Ho Chi Minh City	Second cycle of LID grant: participation in multicentre trials coordinated by the Programme (see section 2.1.1.2)

^a LID = Long-term Institutional Development grant.

a similar workshop held at the Myanmar Medical Association. Another workshop was conducted in Colombo, Sri Lanka, for 19 researchers and obstetricians and gynaecologists.

Other training activities

An STI epidemiology, management and laboratory diagnosis workshop was held in Ulaanbaatar, Mongolia. A total of 32 participants attended including clinicians, epidemiologists and microbiologists from central and provincial government institutions and laboratories.

Postgraduate research training in reproductive health was organized by Fudan University, Shanghai, China; the Geneva Foundation for Medical Education and Research; the Programme; and the International Association for Maternal and Neonatal Health. Seventeen participants from seven provinces in China attended the 2-week course.

Short-term training grants were awarded to a researcher from Myanmar studying STI laboratory diagnosis techniques at the University of Malaya, Kuala Lumpur, Malaysia, and a Sri Lankan researcher looking into genetic screening for male infertility at the Westphalia Wilhelm University, Münster, Germany. Technical assistance was provided to research trainees to finalize their Re-Entry grants through electronic communication with several centres and through consultant visits in Indonesia, Lao People's Democratic Republic and Myanmar.

A researcher from the University of Colombo participated in a workshop on the legal and ethical aspects of international collaborative research organized by WHO's Regional Office for South-East Asia.

A total of 67 national workshops were conducted, eight of which were supported by the Programme. Most of the training activities focused on research methods; others covered thematic areas and programme-related issues. A workshop on evidence-based reproductive health care was conducted in Sri Lanka using the *WHO Reproductive Health Library*, version 7.

2.1.1.3 Monitoring and evaluation

As recommended in the Programme's 1990–2002 external evaluation, there was more direct involvement in monitoring and evaluation by Regional Advisory Panel members, Reproductive Health Advisers from WHO Regional Offices and staff of WHO Country Offices.

Four centres that had received two cycles of LID grants were evaluated. These centres were Airlangga University, Surabaya, Indonesia; the State Research Centre for Maternal and Child Health and Human Reproduction, Ulaanbaatar, Mongolia; the Department of Medical Research, Yangon, Myanmar; and Hung Vuong Hospital, Ho Chi Minh City, Viet Nam.

Self-evaluation of performance by the centres was verified by site-visits. A summary of the findings follows.

Training grants in epidemiology, statistics and social sciences have created a critical mass of researchers. An increasing number of research projects have been conducted over the years, including Programme-coordinated multicentre studies. The four centres have attained the status of national reference centres for human reproduction. Research results have been widely disseminated and used in the development of reproductive health policy and programmes. It was recommended that Resource Maintenance Capital grants should be awarded to assist centres in maintaining the research resources and capacity to respond to national and global research needs.

Evaluation of the centres indicated that although the objectives of the original LID applications had been achieved, implementation of a research programme was often affected by (i) turnover of trained staff who moved to other government departments or to the private sector, (ii) changes in the heads of centres, affecting leadership in research and communication with the Programme, and (iii) the various commitments by researchers who are clinicians or university faculty members, leading to limited availability of time for research.

Monitoring of four WHO Collaborating Centres in Beijing and Tianjin, China, and centres in Vientiane, Lao People's Democratic Republic, and Hanoi, Viet Nam, was conducted. Meetings were held with the National Coordinating Board, China, and the National Coordinating Committee, Sri Lanka. Future collaboration, and technical and financial support for research, were discussed. Since several centres are conducting or preparing proposals for STI and RTI studies, quality assurance site-visits of participating laboratories were conducted.

2.1.1.4 Identifying new institutions for research capacity strengthening

The Ministry of Health, Cambodia, identified the National Institute for Public Health, Phnom Penh, to receive support for research capacity-strengthening activities.

The Department of Medical Research, Upper Myanmar, was assessed as a possible recipient of a LID grant. The proposed collaboration with the Programme will extend to the relevant departments of the Institute of Medicine, Mandalay, Myanmar.

The National Coordination Committee for Research on Reproductive Health, Sri Lanka, requested that the University of Kelaniya and the University of Sri Jayawardenepura, be considered for research capacity-strengthening grants and that support to the task force based at the University of Jaffna be revitalized.

2.1.2 Research activities

2.1.2.1 Research output

The research output of the 21 centres included the following topics: the provision of quality maternal health services, including emergency obstetric care; the safety and efficacy of contraceptives; prevalence studies on STIs and RTIs; the safety and acceptability of methods of abortion and post-abortion care; adolescent sexual and reproductive health issues, including sexual risk-taking and health-seeking behaviours.

In 2004, out of a total of 407 projects, 322 were supported by national authorities (Figure 11.1).

Seven studies were initiated during 2003–2004 through support from LID grants, Resource Maintenance Capital grants or Re-Entry grants. In addition to the five studies mentioned in Table 11.2, two other Re-Entry grants were funded: one on the identification of the function of monoclonal nonspecific suppressor factor beta at implantation (Shanghai Institute of Planned Parenthood Research, Shanghai, China) and the other on the identification and characterization of cDNA clones coding for sperm-specific antigen (National Institute for Research in Reproductive Health, Mumbai, India).

2.1.2.2 Regional projects

Programme-supported regional projects have the objectives of (i) initiating joint research projects in several countries, (ii) developing human resources in these countries through training workshops and participation in research, and (iii) disseminating research findings through regional and in-country seminars.

Adolescent sexual and reproductive health

Analysis of the behaviour and perceptions of adolescent migrants at the study sites in Bangkok, Thailand; Ho Chi Minh City, Viet Nam; Kunming, China; and Vientiane, Lao People’s Democratic Republic led to the identification of indicators of sexual risks for both male and female adolescents as well as to deficiencies in sexual and reproductive health information and services that programme managers will need to address.

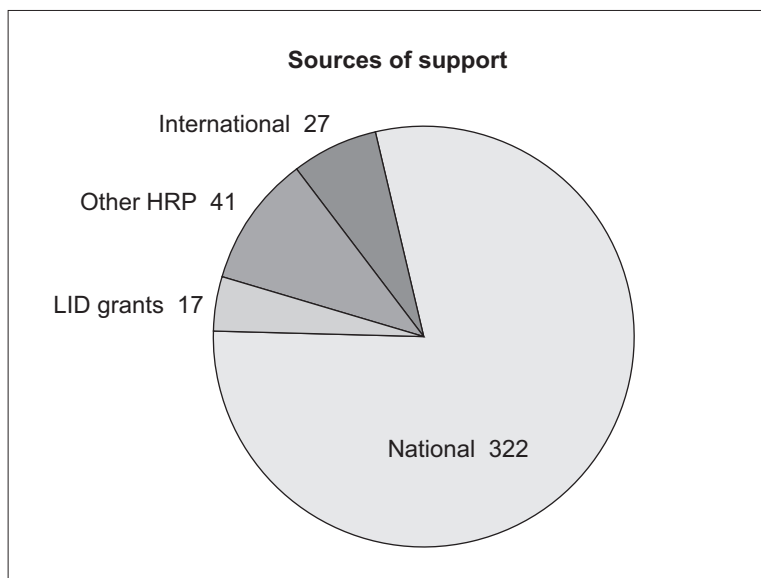
Making pregnancy safer

Preliminary data from the study known as “Collaborative reproductive epidemiology research: patterns and predictors of caesarean section in Asia” have determined the caesarean section rate and compared complication rates among mothers giving birth by vaginal delivery, elective caesarean section and emergency caesarean section in each of the collaborating centres. The researchers have also determined average costs incurred by patients who have a normal delivery, elective caesarean section and emergency caesarean section. They have also identified predictors for elective and emergency caesarean section among social variables associated with the clients, the obstetrician and the hospital.

STIs and RTIs

Prevalence studies of STIs and RTIs were initiated or are ongoing in Surabaya, Indonesia; Ulaanbaatar, Mongolia; Vientiane, Lao People’s Democratic Republic; and Yangon, Myanmar. The findings of these studies will assist in the syndromic management of STIs and RTIs, while the laboratory diagnostic capabilities of institutions are being strengthened through the process.

Figure 11.1 Number of research studies carried out by 21 centres and sources of support



2.1.2.3 Multicentre studies

Two centres in Viet Nam and one in Thailand participated in multicentre studies on the use of vitamins C and E to prevent pre-eclampsia, the prevention of postpartum haemorrhage, and screening for and treatment of urinary tract infections during pregnancy. Projects on long-acting hormonal contraception for men were conducted in two centres in China, while long-term follow-up studies of IUDs continued in China and Thailand. Institutions in China, Mongolia and Viet Nam acted as study sites for research on the safety of abortions provided by mid-level service providers, the use of different regimens for medical abortion and the provision of comprehensive abortion care (Chapter 4, section 2.1.1).

2.1.3 Dissemination and utilization of research results

During 2004, a total of 367 research articles (328 original research and 39 review articles) were published, as well as seven books and 26 book chapters authored by staff from 21 centres receiving capacity-strengthening grants. A total of 155 presentations were made at international, regional or national seminars and conferences (Figure 11.2).

Other activities undertaken included the organization of a national dissemination workshop by the National Coordinating Board, China, on the systematic review of commonly used hormonal contraceptives and IUDs. The results of studies on post-ovulatory methods of fertility regulation have informed policy-making and planning by the Ministry of Health in Viet Nam, which has approved the nationwide provision of comprehensive abortion care.

The National Hospital of Obstetrics and Gynaecology, Hanoi, Viet Nam, held two workshops to disseminate research find-

ings on the reproductive health of youth and adolescents. Researchers presented findings from a nationwide survey on Vietnamese youth and on the sexual and reproductive health counselling and services available to youths and adolescents.

Scientists from research institutions are members of advisory bodies for population and reproductive health and serve as a critical link in ensuring that research findings are utilized and applied in service programmes.

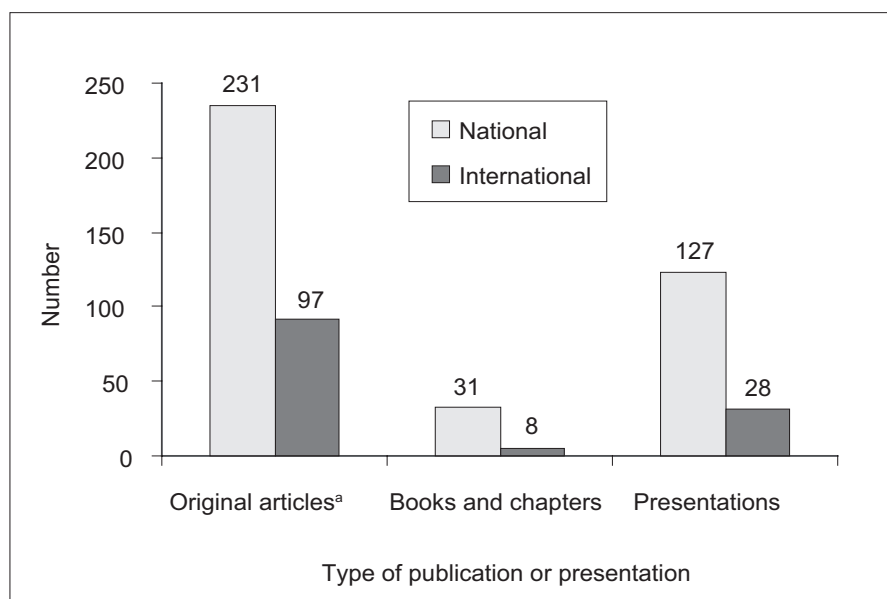
2.1.4 Reproductive health programmes

Support to reproductive health programmes in the South-East Asia and Western Pacific Regions was achieved through the implementation of the WHO/UNFPA Strategic Partnership Programme. Regional workshops were conducted to familiarize participants with WHO's evidence-based guidelines on family planning and STIs and RTIs and to develop country-specific action plans for their adaptation (Chapter 3, section 2.1.3).

Assistance was provided to the Regional Office for South-East Asia to follow up on the implementation of the review of maternal deaths in Myanmar. Recommendations were made to ensure a comprehensive review whereby the facility-based review would include near-misses, and a multidisciplinary panel of experts will be formed at national level to review the reports on maternal deaths.

With the WHO Regional Reproductive Health Adviser, the Maternity Waiting Home project in Lao People's Democratic Republic was reviewed and linkages established with the community component of research to improve the quality of care (Stage 2 of the Strategic Approach). Assistance

Figure 11.2. Publications and presentations in 2004



^a Excludes review articles (39).

was provided through desk reviews to the UNFPA Country Office in Lao People's Democratic Republic on the reproductive health policy that will form the framework for reproductive health programmes for the next five years; assistance was also provided to the WHO Country Office in the Democratic People's Republic of Korea on the reproductive health assessments that will inform assistance to the country from UNFPA and WHO.

2.1.5 Partnerships and networking

With the Programme acting as a catalyst, collaboration between the National Population and Family Planning Commission and Ministry of Health in China was strengthened for implementation of evidence-based guidelines on STIs, RTIs and family planning. The Ministry of Health, the National Population and Family Planning Commission, the Programme and the WHO Country Office organized a national seminar on implementation of the programme guidance tool on STIs and RTIs in Shenzhen and Yunnan provinces (see Chapter 3, section 4.1.1).

Coordinated by a Regional Advisory Panel member from Viet Nam, a number of hospitals are collaborating through a research and training network. These hospitals are the National Hospital of Obstetrics and Gynaecology and the Hanoi Obstetric and Gynaecology Hospital, Hanoi, and the Tu Du and Hung Vuong Hospitals, Ho Chi Minh City. The two hospitals from Hanoi, Hung Vuong Hospital, and the Mother and Child Health and Family Planning Centre in Ho Chi Minh City will jointly conduct an operations research project on post-abortion counselling.

A Regional Advisory Panel member and the WHO Country Office have initiated discussions on establishing networks among University-based research institutions in Indonesia.

For several years, the Programme has supported researchers' training in Thailand at the Epidemiology Unit, Prince of Songkla University, Hat Yai, and the Department of Obstetrics and Gynaecology, Khon Kaen University, Khon Kaen. Starting in 2005, the two institutes are waiving 50% of their tuition fees for trainees supported by the Programme.

Linkages for mentoring were established between the University of Ruhuna, Galle, Sri Lanka, and the Westphalia Wilhelm University, Münster, Germany.

2.2 Planned activities

2.2.1 Research capacity-strengthening activities

2.2.1.1 Strengthening institutional research capacity

To consolidate the progress made in strengthening institutional capacity for reproductive health research, Resource Maintenance Capital grants will be awarded to centres that have received two cycles of LID grants. Some of the "less

mature" centres will need technical assistance to sustain the momentum of the research programme.

2.2.1.2 Strengthening of human resources for research

The Programme will continue to support regional workshops as a modality for building research capacity because they also achieve the additional objectives of utilizing the expertise of mature centres and creating networks. Efforts to strengthen capacity for operations research will be focused on countries in the south Asia subregion through collaborative efforts with the Population Council's FRONTIERS project. Regional workshops devoted to the principles and practice of ethics in reproductive health research involving human participants will be organized for new institutions identified for research capacity-strengthening grants.

Assistance will continue to be provided for national training workshops on research methods and scientific writing in order to sustain human resources for research. Short-term and long-term research training in different fields will be given in institutions both within and outside the Regions, depending on the identified needs of the centres.

2.2.2 Dissemination of research findings

A dissemination seminar on the findings of national, regional and multicentre studies conducted in Viet Nam in collaboration with the Programme will be held in March 2005 in conjunction with the eighth Regional Advisory Panel meeting in Ho Chi Minh City.

2.2.3 Responding to regional priority issues

Support will be provided to identify regional priorities for reproductive health research, develop training and research networks, and disseminate and utilize research results. The in-country implementation of the WHO/UNFPA Strategic Partnership Programme will contribute to improving the quality of care in reproductive health programmes through the implementation of evidence-based guidelines on family planning, STIs, RTIs and maternal health.

2.2.4 Partnerships and networking

Regional and national networking will be promoted and strengthened in research training and by developing joint research programmes between mature and less-mature centres. Support will be provided for national-level planning and programming for reproductive health in collaboration with other agencies and partners.

Annex 1

REGIONAL ADVISORY PANEL FOR ASIA AND PACIFIC IN 2004

Members

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 Matthews Mathai, Christian Medical College Hospital, Vellore, Chennai, India
 Than Than Tin, Central Women's Hospital, Yangon, Myanmar
 Benchayoddyimnarn-Attig, Institute for Population and Social Research, Mahidol University, Nakhon Pathom, Thailand
 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
<i>from:</i>							
AFRO							
AMRO							
EMRO							
EURO							
SEARO	4	50					4
WPRO	3	38			1	12	4

Temporary advisers

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Annex 2

HEADS OF CENTRES FOR ASIA AND PACIFIC IN 2004

China

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 Djafar Siddik, Western Indonesia Reproductive Health Development Centre, Medan

Lao People's Democratic Republic

Bouavanh Sensathith, Maternal and Child Health Centre, Ministry of Public Health, Vientiane

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	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
<i>from:</i>							
AFRO							
AMRO							
EMRO							
EURO							
SEARO	7	37					7
WPRO	12	63					12

Chapter 12

Technical cooperation with countries: Central and Eastern Europe

A. Ntabona

1. INTRODUCTION

As has been the case in the past, all of the support provided by the Technical Cooperation with Countries Team to the European Region, mainly to Central and Eastern European countries, was implemented through and by the WHO Regional Office for Europe. Pursuant to the decision of the Programme's Policy and Coordination Committee that Programme strategies for strengthening research capacity should not be applied to countries in the European Region, emphasis continued to be put on providing programmatic support including capacity building for operational research.

2. OBJECTIVE: TO WIDEN THE RANGE OF PRODUCTS AND TECHNOLOGIES

To the extent possible, work in this area addresses one of the conclusions of the Programme's External Evaluation Team that:

Countries in Eastern Europe and the Newly Independent States (NIS) have specific reproductive health research needs that may not be met by Programme outputs. Still informants from Eastern Europe viewed research on medical abortion, emergency contraception, the *Medical eligibility criteria for contraceptive use* and monthly injectables useful for their countries. There is need to adapt the presentation of information to the specific needs and expectations of these countries and to translate materials into local languages.

2.1 Progress

2.1.1 Capacity-building for operations research (collaboration with FRONTIERS)

The initiative on building capacity for operations research in Central and Eastern Europe has been implemented under the Memorandum of Understanding between the Department, the United States Agency for International Development and the FRONTIERS Programme of the Population Council. The objective of the Memorandum is to make use of each partner's strengths and comparative advantages to improve reproductive health in developing countries. The collaboration is based on mutual recognition of and commitment to the role that operations research plays in obtaining evidence required for programme improvement.

In March 2004, an overall assessment was carried out to review the achievements made under this agreement with the intention of documenting the lessons learnt from nearly five years of involvement in collaborative activities. As has been reported over the past three years, most of the work on strengthening capacity in operations research during the period under review was indeed targeted to countries in Central and Eastern Europe. This included the first training course in operations research methods, held in Romania in September 2001, followed by a training-of-trainers workshop (March 2003) for five Russian-speakers identified at the course as potential instructors; a first training course for Russian-speaking countries was then held in November 2003 in Kazakhstan for participants from the Central Asian Republics.

In view of the findings of this assessment, and for the sake of efficiency, it was deemed unnecessary to undertake a formal evaluation of this same initiative as requested by the European Regional Advisory Panel at its 2003 meeting (Tallinn, Estonia, August 2003). It was suggested that the Programme, and the Regional Office for Europe as the implementer, should, when planning future courses, take into account the recommendations emanating from the March 2004 assessment. These recommendations were as follows:

Joint capacity building efforts should be strategic. There is potential for these activities [training courses, RHR review process and funding of relevant proposals] to be implemented too broadly to allow intensive institutional strengthening and follow-up of research activities (Recommendation 8).

Partners should develop a system to ensure follow-up of proposals which are developed in capacity building workshops through the WHO's review process and to ensure technical assistance during implementation (Recommendation 10).

More discussion and further guidance will be sought from the Regional Advisory Panel on the future of operations research in Eastern Europe and in the Central Asian Republics at their upcoming meeting (21–22 April 2005, Ankara, Turkey) before implementing the second operations research course for Russian-speaking countries, which is tentatively planned for the fourth quarter of 2005.

2.1.2 Other collaborative activities with the Regional Office

Technical support was provided to the Regional Office for Europe for the meeting that occurs every two years of representatives from ministries of health in countries that are implementing the regional programmes of the Family and Community Health Cluster (Making Pregnancy Safer, Child and Adolescent Health, and Women's Health). The countries involved were Albania, Armenia, Belarus, Kazakhstan, Kyrgyzstan, the Republic of Moldova, Romania, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan.

The meeting, attended by more than 60 country participants and partner agencies, provided an opportunity for a comprehensive briefing on the strategies as well as on the evidence-based interventions and tools being promoted at global and

regional levels in these areas. The pivotal role that the ministries of health should play in improving coordination among partners working in these areas was also emphasized. From the discussions, the following questions emerged that require further attention from the Programme and the Regional Office for Europe, with input from the Regional Advisory Panel as appropriate.

- What approaches to the provision of technical support to countries would be more practical in the areas of policy assessment, programme review and the development of national strategies within the European context?
- Is there a need for more appropriate modalities to be used to apply the global strategies presented at the meeting that are designed to support the development of comprehensive and integrated reproductive health programmes in countries (with special focus on countries implementing biennial cooperative activities)? Would the ongoing capacity strengthening in operations research and other programmatic activities supported by the Department contribute significantly to these efforts?
- How best could the Department support the adaptation of WHO generic guidelines and tools and improve the availability of materials in local and regional languages, especially Russian ?

2.2 Planned activities

Plans for 2005 include:

- providing ongoing technical support to Regional and Country Offices embarking on the strategic assessment of reproductive health priorities in selected countries of the Region (see Chapter 13);
- strengthening the capacity of the Regional Advisory Panel to monitor the progress of reproductive health research and programme development (to be discussed at the fourth meeting of the Regional Advisory Panel in April 2005, Ankara, Turkey);
- continuing to support systems and operations research through individual and institutional capacity strengthening. (A second operations research training course for Russian-speaking countries is tentatively planned for September 2005 at a venue to be determined).

Annex 1

REGIONAL ADVISORY PANEL FOR THE EUROPEAN REGION IN 2004

Members

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	1	12	5	62	2	25	8
Women			3	24			3
<i>from:</i>							
AFRO							
AMRO							
EMRO							
EURO	1	12	5	63	2	25	8
SEARO							
WPRO							

Chapter 13

Technical cooperation with countries: policy and programmatic issues

P. Fajans and D. Huntington

1. INTRODUCTION

The work of the Policy and Programmatic Issues group focuses on two objectives of the Department, namely, to strengthen health management and support systems (Objective 3) and to foster sound national health laws and policies (Objective 5). Under Objective 3 the group seeks to build health system capacity at national and subnational levels for strategic planning, development, implementation and evaluation of appropriate interventions for the provision of high-quality sexual and reproductive health services to all people. Central to this work is the continued refining of the Strategic Approach to improving quality of care in reproductive health services and supporting countries in the implementation of the approach. The goals of the group under Objective 5 are to foster sound national health policies and reforms that positively impact on sexual and reproductive health and related rights and contribute to country initiatives to alleviate poverty. Work under this objective includes implementing a research initiative to investigate the impact of health reforms on reproductive health, as well as providing technical advice to countries undertaking reforms.

2. OBJECTIVE: TO STRENGTHEN HEALTH MANAGEMENT AND SUPPORT SYSTEMS

The Strategic Approach is a three-stage method that can be used to assist countries in strengthening reproductive health policies and programmes. Stage 1 is an assessment, based on a systems framework, 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. These assessments use qualitative methods and

a field-based participatory approach, involving programme managers, service providers, researchers and others having an interest in improving reproductive health, including women's and youth organizations.

A variety of recommendations emerge from a strategic assessment. Stage 2 is a means of testing, on a limited scale, the recommendations for policy change or other interventions to improve access, utilization and the quality of care in service delivery. The purpose of Stage 3 is to apply the findings from the Stage 2 action research to policy development and to the scaling-up of interventions for wider impact. The Strategic Approach has been used by 23 countries to address a variety of different reproductive health issues (Figure 13.1). In six of these, the process has been used two or more times to address additional issues.

2.1 Strategic Approach activities at the global level in 2004

In response to the Scientific and Technical Advisory Group's guidance over the past few years, the main areas of work on the Strategic Approach during 2004 included dissemination of the approach and support for utilization of the strategy by countries, adaptation and refinement of the Strategic Approach to address a range of areas in reproductive health, and an increased focus on Stage 3 scaling-up of activities.

2.1.1. Dissemination, advocacy and capacity building

Work continued on a new core document that will provide an overview of the underlying philosophy and framework of the Strategic Approach in addition to giving generic guidance on implementation of all three stages of the approach. Moreover, a shorter advocacy and information document,

intended for policy-makers and programme managers, was also developed, responding to their need for a more succinct overview of the method.

In previous years, regional workshops to introduce national teams to the Strategic Approach and to discuss and advocate for its implementation were conducted in collaboration with WHO Regional Offices and nongovernmental organization (NGO) partners in Latin America, Asia and Africa. A similar workshop for countries in the European Region was implemented in Riga, Latvia, on 1–4 June 2004, focusing on the use of the Strategic Approach as a means of taking action to implement *Safe abortion: technical and policy guidance for health systems* (see also Chapter 4).

2.1.2 Adapting and refining the Strategic Approach

The adaptation and use of the Strategic Approach to address a broad range of reproductive health issues has continued. A strategic assessment addressing community-level issues in family planning and maternal health took place in Paraguay, and a proposal was submitted from Nigeria for a strategic assessment to aid in revising strategies to provide sexual and reproductive health services for adolescents. Five proposals for assessments addressing contraception and abortion were submitted from countries attending the Riga workshop.

The Programme, in collaboration with the International Council on Management of Population Programmes (ICOMP) and the Population Council's office in Bangkok, Thailand, continued efforts to test further refinements of the method to support comprehensive assessments of reproductive health services, focusing especially on access and utilization of services by poorer members of communities. A strategic assessment was conducted in Rajasthan, India (section 2.1.4.2), similar to that conducted the previous year in Yunnan, China. Individuals who had either led or provided technical assistance to these assessments met to discuss the lessons learnt concerning new approaches that had been tried during the implementation of the two assessments. These approaches included developing mechanisms for determining and setting priorities among the strategic issues to be addressed as well as for prioritizing recommendations that come out of such assessments, addressing the necessary technical updates required for members of interdisciplinary teams conducting the fieldwork, and making additional efforts to link the assessment recommendations to action in cases in which team members represent a broad range of reproductive health constituencies.

2.1.3 Stage 3: replication and scaling-up

Work continued to focus on expanding knowledge concerning the determinants of successful scaling-up for broader policy and programme development of service-delivery innovations

Figure 13.1. Countries implementing the Strategic Approach (supported by WHO and by other partners)



from pilot projects. The Rockefeller Foundation supported a team residency in Bellagio, Italy, to work with authors of the 10 papers presented at an earlier conference on this topic (see the 2003 *Annual technical report*). The background framework paper and 10 country case-studies highlight lessons learnt about scaling-up in countries implementing the Strategic Approach, as well as from the scaling-up of other projects in China and Ghana; they will be published in a WHO volume intended to provide input to policy-makers and donors. At the original conference, participants had suggested forming a new network (to be called "ExpandNet"); this would bring together policy-makers, programme managers, researchers and technical experts to share experiences, allow developing countries to provide technical support to one another, and promote research to better understand how to successfully scale-up reproductive health interventions. During 2004, a proposal to fund initial activities was developed jointly with the University of Michigan, Ann Arbor, MI, USA, and received funding from the MacArthur Foundation. One of the first activities under this project is the development of a practical guidance document on scaling-up for policy-makers, programme managers and donors. Drafting has begun, and field-testing of a draft is expected to take place in 2005.

2.1.4 Country experiences during 2004

2.1.4.1 Progress and planned activities in Africa and the Middle East

Implementation of activities continued in Ethiopia and Zambia, with technical support from the Population Council. In Ethiopia, the 2-year action research project designed to expand young people's access to male and female condoms and emergency contraception came to an end. Based on the project's success, the Ethiopian Ministry of Health registered Postinor-2, and developed a project to introduce and scale-up emergency contraception in family planning services in Ethiopia's five most populated regions. The project will also introduce training on emergency contraception in Ethiopia's three leading public medical schools and teaching hospitals.

The Ethiopian reproductive health strategic assessment highlighted the need for the development of a national reproductive health policy. Although the Ministry of Health had planned this as one of the first activities after the assessment, implementation was delayed until late 2004–early 2005 when a draft national policy was developed utilizing a participatory process.

In Zambia, a Stage 3 project, known as Pilots to Regional Programmes (PRP), has been scaling-up the innovative strategies tested during the action research phase to strengthen family planning and other reproductive health services in the Copperbelt Region. During 2004, all districts conducted rapid assessments to develop detailed action plans for implementing the project's interventions. The PRP project has subsequently provided technical and financial

support to implement their plans, which have focused on provider training, community outreach and providing necessary supplies and equipment. Districts have adopted different approaches to meeting community needs. For example, one district introduced a mobile service with providers qualified to insert intrauterine devices (IUDs) at six neighbouring health-care facilities. Others have focused on training community-based workers to provide information on the "standard days" method of natural family planning, which was introduced by the project; demand for this method is growing fastest in the rural Copperbelt Region. Districts are forging new partnerships and cost-sharing agreements, pooling financial and other resources to conduct joint training and waiving fees for clients referred from other districts. The project has also introduced depot medroxyprogesterone acetate (DMPA) and emergency contraception, as part of the project's "minimal method mix", in participating health centres.

According to national services statistics, contraceptive prevalence in the project districts is now among the highest in rural Zambia, with many women having access to methods and services previously available only in urban settings. The project's ability to respond to regional differences and local needs has prompted requests from Zambia's Central Board of Health and the donor community to scale-up project interventions nationally.

In Oman, the Ministry of Health led a strategic assessment to develop approaches to improve the quality of care in its birth-spacing programme. The Sultanate remains a traditional society, despite significant socioeconomic development. Contraceptive prevalence is around 25%, and of new acceptors, 56% are of parity five or more. To address the sociocultural barriers around birth spacing, the assessment recommended that other government sectors and NGOs be given greater responsibility for implementing the programme. It was proposed that a pilot study be initiated to build the capacity of communities and civil-society groups to participate in implementing the programme. In order to improve the access to, and the quality of, services the pilot project will also address recommendations to train midwives to provide birth-spacing services and counselling to fill the access gap caused by the shortage of female doctors in rural areas. The pilot project will also work to reintroduce the IUD, using this reintroduction as a means to improve the quality of care offered with all methods provided by the programme. Information and education on birth spacing need to be increased and made more accessible, and the role of the media should be expanded. Finally, the team suggested that issues of reproductive health and birth spacing should be integrated within the curricula of schools and universities.

The Ministry of Health in Afghanistan has submitted a proposal for support from the Programme to conduct a similar strategic assessment of their family planning and related reproductive health services.

2.1.4.2 Progress and planned activities in Asia

An earlier strategic assessment in Chongqing, China, focused on contraceptive introduction, with an emphasis on IUD technologies available in the national programme, and the quality of care more generally offered by family planning services. Numerous findings and recommendations emerged, including the need to (i) strengthen providers' capacity to provide all contraceptive methods and improve the quality of care and the ability of patients to make an informed choice, (ii) reduce the number of different types of IUDs provided by the programme and improve aspects of care related to both insertion and removal, and (iii) review the contraceptive products available with regard to their efficacy, the quality of their manufacture and their long-term safety.

Follow-up activities included systematic reviews of data on the safety and efficacy of IUDs and hormonal contraceptive methods provided through the national programme. The results of these systematic reviews were presented to national policy-makers at a workshop in early 2004. Following this presentation and subsequent further consultations, the National Population and Family Planning Commission has decided that the national programme will no longer provide both the once-a-month oral hormonal contraceptive and the "Visiting pill number 53" (which contains anordrin). Further discussions are continuing concerning the various IUDs and the other "visiting pills", which are characterized by unnecessarily high doses of levonorgestrel. Discussions are continuing concerning the implementation of a research study to test the use of lower, safer doses of levonorgestrel as an emergency contraceptive as well as randomized controlled trials comparing the efficacy of the more recent Chinese copper-bearing IUDs (which, unlike their older versions, contain higher quantities of copper) with the TCU 380A and the Multiload 375.

In late 2002, the Yunnan Reproductive Health and Research Association led a strategic assessment in Yunnan Province that addressed a range of reproductive health issues, with a focus on developing strategies to improve access to, utilization of and the quality of services for members of poor and marginalized groups, including those living in remote areas, ethnic minorities in the border areas and urban migrants. Based on the assessment's recommendations, several follow-up activities have been developed.

A project funded by the United States Agency for International Development (USAID) is addressing the prevention of sexually transmitted infections and HIV/AIDS among rural cross-border migrants. In addition, a proposal for a project that will develop and implement a model for the provision of high-quality reproductive health services for urban migrants is expected to begin in 2005, with joint funding from the Kunming local government, the Programme and the Ford Foundation. Technical support for the activities in Yunnan are being provided by ICOMP and the Population Council's office in Bangkok, Thailand.

In India, the Government of Rajasthan requested assistance in implementing a strategic assessment of comprehensive reproductive health issues, in part to provide input to the formulation of strategies for their World Bank-supported reproductive health and health reform projects. In 2004, a comprehensive reproductive health strategic assessment, with a focus on access to and utilization of quality services by the poor, was conducted by a team representing a broad range of stakeholders in Rajasthan, with technical support from the NGOs ICOMP and Swaasthya, the WHO India Country Office and the Programme. Although the socioeconomic situation has changed considerably over the past decade in Rajasthan, reproductive health indicators lag behind those of other states in India, and progress in strengthening reproductive health services has been slow. The assessment team observed a broad range of challenges and weaknesses in the provision of services, resulting in poor access to and low utilization of reproductive health services, particularly among members of poorer communities. The team formulated a comprehensive set of recommendations for strengthening services to better meet the needs of the population as a whole as well as for providing more equitable access to quality care.

These recommendations focused on several major themes. The first was the need to revise the way in which services were organized and planned, moving from a norm-based model to one based on district and local needs, with particular attention devoted to the issue of human resources; large obstacles to access and quality are the result of problems with staffing facilities and motivating providers at all levels. Particular attention needs to be given to improving the functionality of health subcentres, including offering refresher training for auxiliary nurse-midwives as well as strengthening linkages with communities, local self-help groups and local government institutions in order to better support the nurse-midwives and increase demand for services. There is a need to improve quality of care at all levels of the service-delivery system, but the team highlighted the need to ensure access and coverage for a range of underutilized technologies and services, such as basic and comprehensive emergency obstetric care, birth-spacing methods including IUDs and condoms, vasectomy, and manual vacuum aspiration and medical abortion services. In addition, the team emphasized the importance of institutionalizing a comprehensive adolescent sexual and reproductive health programme. Adolescents are a large segment of the poor with special needs, and this effort will require collaborative action with a number of government sectors. The private sector is playing an ever-larger role in providing reproductive health services in Rajasthan, and it will be important that the public sector seeks and develops increased public-private partnerships if the needs of communities are to be met.

The assessment team is developing proposals for two pilot projects. The first will bring together a major NGO and several government sectors to develop a comprehensive programme for adolescent sexual and reproductive health. The

second will implement a demonstration project to address human-resource issues in the context of district planning and a package of interventions to provide essential technologies in the context of improving the quality of care.

In the Lao People's Democratic Republic, a Stage 2 research project to explore how reproductive health outreach services can be strengthened is being integrated within the WHO Maternal Waiting Homes project, which is implementing activities in rural districts. A baseline survey was conducted in 2004, and intervention activities will commence in 2005.

Policy and programmatic interventions in response to the prior strategic assessment of issues related to abortion are under way in Mongolia and are described in Chapter 4, section 2.1.4.3.

In Myanmar, an ongoing research project has been developing and testing a district-level model for improving the quality of care offered by family planning and other reproductive health services, as described in previous Annual Technical Reports. The final activity of the project, conducted in 2004, was the development and implementation of a management training programme in reproductive health for district-level health staff. Following an assessment of management needs and existing staff skills, training modules were developed by ICOMP, and subsequently, health teams from five districts were trained in management skills, with a focus on the development and implementation of district-level reproductive health action plans that are able to respond to local conditions. Based on the success of the training, it is envisaged that the modules will be used to train health staff in all districts supported by the reproductive health project that is funded by the United Nations Population Fund (UNFPA).

In Viet Nam, the Programme assisted the Government in developing a strategy for introducing the injectable contraceptive DMPA, while at the same time strengthening the quality of family planning services for all methods of contraception. Interventions were subsequently replicated in selected districts and communes in all provinces. During 2004, expansion continued, with Government funding, and covered all districts and the majority of communes. In addition, the Ministry of Health also began scaling-up the action research project to improve the quality of abortion services. This activity is described in Chapter 4, section 2.1.4.1.

2.1.4.3 Progress and planned activities in Eastern Europe

Activities in Eastern Europe are focusing on increasing access to and utilization of contraception, and improving the quality of care of abortion services. In Romania, follow-up activities to a strategic assessment are focusing on policy actions to improve access to contraception as well as testing a model of comprehensive abortion care. A demonstration project examining the feasibility and cost of providing reproductive health services for female factory workers will start in early 2005. Following the Riga workshop, propos-

als for strategic assessments focusing on fertility regulation have been developed in Latvia, Lithuania, the Republic of Moldova, the Russian Federation and Ukraine. The assessment in Moldova will take place in early 2005; the others are contingent upon identification of financial support.

2.1.4.4 Progress and planned activities in Latin America

Activities continued in Bolivia, Brazil and Chile, building upon previous implementation of the Strategic Approach to expand contraceptive choice and improve the quality of care in family planning and related reproductive health services. This work has been led by the Reprolatina Project, a partnership between the NGO Reprolatina, the University of Michigan, and the Population Council's Brazil office. In Bolivia, scaling-up of the introduction of DMPA, in the context of strengthening the quality of care available for all methods of contraception, is continuing with support from the United Kingdom's Department for International Development. This expansion has received technical support from the three training and educational centres established locally by the Reprolatina Project.

In Chile, the Reprolatina Project has collaborated with the Ministry of Health to create three regional reproductive health training centres to support municipalities in strengthening the quality of their reproductive health services. In addition, a vasectomy programme based on the model developed in the Stage 2 project in Brazil, is now being tested in an additional municipality prior to broader expansion.

In Brazil, the Reprolatina Project continues to develop regional training centres and expand interventions to support quality reproductive health services in additional municipalities throughout the country. In addition, interventions to support adolescent sexual and reproductive health that were developed during Stage 2 research activities have been expanded to three additional municipalities, and the web site for adolescents that addresses sexual and reproductive health issues, which was established during the project, receives an average of almost 800 hits per day. The Brazilian Ministry of Health would like support from Reprolatina and the Programme to implement a national strategic assessment of adolescent sexual and reproductive health needs to support programme development.

In Paraguay, a team led by the Ministry of Health undertook a strategic assessment of issues related to maternal and neonatal health and family planning, focusing on the community level, with technical support from Reprolatina, the Programme and the Pan American Health Organization. The team found there were significant weaknesses in the provision of quality family planning services, resulting in an inability to meet the needs and demands of community members. Weaknesses were also noted in the quality of maternal health care, with the costs of emergency obstetric care constituting a major barrier to utilization; a lack of referral in emergencies was noted to be a persistent problem. Shortages of trained per-

sonnel, a dramatic lack of supplies for emergency obstetric care as well as for family planning, and a lack of technical supervision and coordination all contributed to the low quality of reproductive health services. Following a dissemination workshop in 2005, an action research project will develop and test interventions to strengthen organizational capacity and training in order to improve the quality of these services.

2.2 Project on quality of care

The Programme continues to be a partner in the project addressing the organization of community demand to influence the quality of reproductive health care. The Programme is a joint partner in this project with UNFPA, the United Nations Children's Fund (UNICEF) and the International Labour Organization's Strategies and Tools against Social Exclusion and Poverty project. The Programme provides technical assistance to activities in Kyrgyzstan and Nepal.

In Kyrgyzstan, a pilot study in nine villages from two districts was completed and evaluated in 2004. The evaluation showed that organizing community-based groups had been extremely successful. This organizing included using social mobilization and developing educational materials and training programmes for both health-care providers and communities. Most providers are now aware of the law on reproductive rights and are expanding access to reproductive health services to all community members. Maternal health and family planning services are being provided free of charge; and in those villages without a doctor, medical personnel are now visiting to provide regular consultations. The second phase of the project is being expanded to other villages in the same regions with support from the United Nations Foundation.

In Nepal, following a district-based strategic assessment, the project has assisted the Government in developing a national strategy for improving the quality of care offered by reproductive health services. A pilot intervention study began in five villages in the Saptari district, with the support of two national NGOs. Intervention activities include offering training on reproductive health, gender and rights, as well as in communication skills for both community members and health-care providers. Baseline surveys have been conducted, and training in participatory learning and action has resulted in each community developing a plan of action, which is being implemented. The project will be evaluated in 2005, and a proposal for replication and expansion, in collaboration with the German Agency for Technical Cooperation (GTZ), has been approved by the United Nations Foundation.

3. OBJECTIVE: TO PROMOTE SOUND NATIONAL LAWS AND POLICIES

3.1 Research on the impact of health reforms on reproductive health: progress and planned activities

Ongoing and planned activities addressing this objective are related to the Programme's initiative on investigating the impact of health reforms on reproductive health. In recent years, health reforms have been implemented as means of increasing the effectiveness, efficiency, quality, equity and financial soundness of health systems. Reforms typically have involved significant changes in the financing, payments, organization and regulation of health systems. There is a need to better understand the impact that various types of health reforms have on access to, utilization of and the quality of reproductive health services as well as their impact on outcomes. This increased understanding is critical in order to provide guidance to countries undertaking reforms.

The Programme's new initiative will contribute to the evidence base on the impact that health sector reforms have on the access to and use of reproductive health services. A research programme is being developed that will utilize both descriptive and prospective controlled designs to produce results that are generalizable to international discourse on health policy and have specific application to country-level programmes. In some settings, research will be embedded within existing or newly launched reform programmes, assisting governments and donors in developing systems for monitoring and evaluation. In all cases, the evaluative research will examine the extent to which efficiencies, quality, equity, client responsiveness and sustainability of reproductive health services have been achieved by a single reform or set of reforms. Partnerships, both internal and external to WHO, will be critical to this initiative. Technical support will also be provided to develop the knowledge and capacity of WHO staff and their national counterparts about mechanisms, such as Sector-Wide Approaches (SWAs) and Poverty Reduction Strategy Papers (PRSPs), for increasing the harmonization of aid and its effectiveness.

The collaboration between the Programme and the Initiative for Sexual and Reproductive Rights in Health Reforms of the Women's Health Project, University of the Witwatersrand, South Africa, continued this year. The Initiative's secretariat met to finalize a global literature review of evidence on the impact of health reforms on sexual and reproductive health and to discuss follow-on case-studies and activities related to capacity building for advocacy. An overview of the findings of the global literature review was presented at the technical consultation described below. Collaboration with the Women's Health Project will continue to ensure that there is coordination with the planned case-study research activities.

One of the first major undertakings of the Programme's health-sector reform initiative was the organization of a high-

level technical consultation held in late 2004. Conducted in collaboration with the Evidence and Information for Policy Cluster, the meeting assembled approximately 70 leaders from the fields of health-sector reform and reproductive health from academic institutions in Europe, the USA and developing countries; donors, including the World Bank, the United Kingdom's Department for International Development, the Dutch Foreign Office, GTZ, the Swedish International Development Cooperation Agency and USAID; representatives from 10 governments in developing countries and local and international NGOs; and representatives from UNFPA and the International Labour Organization. A series of discussion panels constructed around 10 background papers explored contemporary trends in reforms relating to the following topics:

- financing and payment
- private sector and public policy
- organization and decentralization
- human resource development
- equity and its measurement
- existing evidence on the effects of reform on reproductive health.

Three round-table discussions focused on learning about the effects of health sector reforms on other Millennium Development Goals (MDGs), sustainable financing and the role of health information systems; the discussion also focused on identifying evidence gaps for use in framing a broad research agenda. A summary report of this meeting is being prepared, and publication of an edited volume of papers is under discussion with the authors. All papers are available on the meeting's web site (<http://www.who.int/reproductive-health/tcc/meeting.html>).

The key points that emerged from discussions are summarized below.

- Research on the process of reform is as important as studying effects related to output and outcome. Two examples illustrate this point: (i) financing reforms related to resource mobilization in decentralized settings require new public management roles and targeted action by civil-society groups to ensure that the pooling of resources values reproductive health services; (ii) public-private partnerships necessitate not only the development of administrative skills related to contracting for services but also the assurance that quality standards in, and equity of access to, private reproductive health services are met.
- The existing evidence base on the impact of health sector reform on reproductive health is not well developed, but

the literature shows mixed effects. For example, social insurance and prepayment schemes have been shown to improve access and are linked to positive reproductive health outcomes. However, the weight of the existing evidence suggests that reproductive health services have not been valued during the priority-setting process that underpins different elements of health sector reform, nor have they been valued in the decentralized structures existing in many states. Thus they have disproportionately suffered from human resource constraints.

- The study of reform requires deconstructing and isolating particular reform activities to better measure a programme's operations and using designs that demonstrate attribution of effects and causality. Gaining access to reform programmes will be achieved through partnerships. These will require researchers to be provided with immediately relevant evaluative findings that will contribute to improving a reform's operations.

The advisory function of the Programme's health reform initiative continued during 2004. The Programme provided technical support to the World Bank Institute's courses on health sector reform and reproductive health in anglophone and francophone Africa. A Programme staff member served as a resource person for the World Bank Institute's workshop in Singapore (Public policy and the private health sector in Asia: enhancing the contribution of private service providers to the MDGs). The concepts, analytic approaches and case studies presented during this workshop highlighted the important part played by the private sector in Asia and the generally slow reaction to its growth by governments across the region. Governance and public sector management issues are cross-cutting influences on the implementation of policy reforms in response to private sector growth, confounding and complicating what is in fact a highly dynamic, market-driven field. The establishment of different forums and mechanisms for two-way communication between public-sector and private-sector actors was emphasized as being a key to success in developing effective public policy. There is clearly a role for international agencies, such as WHO, to play in facilitating such a dialogue. The development of capacity for monitoring and evaluation processes that track and assess the effectiveness of public policy on the private sector is a priority in many regions, including Asia.

Programme staff also provided technical support to the World Bank and the Philippine Department of Health's Women's Health and Safe Motherhood project preparation team, and was responsible for designing the monitoring and evaluation component of this loan. The impact evaluation component features a controlled, time-series study design that collects baseline, midterm and end-of-project measures on key output and outcome indicators at project and non-project comparison sites. The baseline survey began in December 2004, and preliminary reports are anticipated to be available by March 2005. The Programme will also assist the Department of Health in developing study protocols for conducting

investigations into innovative features of the project that are not adequately captured in the overall evaluation of impact. For example, the project has developed effective and sustainable financing mechanisms for targeting maternal and family planning patients who are poor and for sexual and reproductive health services that reach out to adolescents .

Another example of support provided by the Programme is in Egypt. The Egyptian Health Sector Reform Programme pilot phase (1998–2004) focused on developing primary health care in a Family Health Project that modelled several basic reform principles, including performance-based provider payment mechanisms and facility accreditation systems, to improve the quality of care; integrated provider networks to increase access and referral; and created the Family Health Funds to separate financing from provision. The Programme was asked by the Egyptian Ministry of Health and Population to participate in an evaluation of the pilot phase through a collaborative arrangement between WHO, the European Commission and the Ministry. Following this evaluation, the Ministry will begin to scale-up the Family Health Project from its coverage of one million people to approximately 16 million.

The December 2003 high-level consultation between UNFPA and WHO called upon both institutions to collaborate in health sector SWAps, specifically by advocating for adequate investment in reproductive health. A second high-level consultation held in June 2004 recognized the progress that had been made and identified the continued importance of making complementary efforts to bring sexual and reproductive health issues into the mainstream of national and international planning processes, including SWAps, PRSPs, and reporting on MDGs. This consultation called for an increase in capacity-building activities. In response, a working group was created to produce a strategic framework for implementing this strategy. The Programme chairs this working group, which is composed of staff from four departments from three different WHO clusters as well as UNFPA staff. A technical consultation was held in September 2004 and resulted in the development of a strategic framework and, subsequently, a plan for implementing an integrated series of capacity-building activities in the thematic areas of knowledge management, research, training and in-country technical support. Activities will begin during 2005.

Annex 1

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	10	91	1	9			11
Women	6	54					6
<i>from:</i>							
AFRO	1	9					1
AMRO	1	9					1
EMRO	1	9					1
EURO			1	9			1
SEARO	4	36					4
WPRO	3	27					3

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	26	54	12	25	10	21	48
Women	14	29	7	15	6	12	27
<i>from:</i>							
AFRO	5	10					5
AMRO	6	12			8	17	14
EMRO	3	6					3
EURO			11	23	2	4	13
SEARO	4	8					4
WPRO	9	19					9

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Chapter 14

Mapping and implementing best reproductive health practices

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1. INTRODUCTION

“Research should begin and end with systematic reviews”
Sir Iain Chalmers, 2004

Science is cumulative. New research should be initiated on the basis of what is known, and interpretation of the findings of primary research should be made after considering existing evidence. Since 1997, the Department has conducted systematic reviews to synthesize research and has disseminated these worldwide to ensure that health-care workers have access to relevant up-to-date information. The systematic reviews conducted or facilitated by the Department are included in the *WHO Reproductive Health Library* (RHL), and efforts are made to update these as new evidence becomes available.

The challenge faced to improve the quality of reproductive health is not only to produce evidence-based guidelines and programmatic tools, but also to address the inequities in access to and the application of knowledge. Evidence confirms that many health-care workers still lack the up-to-date evidence-based information they need to make informed policy and programmatic decisions and provide effective health care. It is this knowledge-to-practice gap that the Implementing Best Practices (IBP) initiative is committed to closing. The IBP partners aim to reduce duplication of effort, harmonize approaches within their own agencies and develop strategies that enable them to work individually, in groups or collectively with countries to improve access to, and adaptation and use of information to improve the quality of reproductive health. What should be done is often known but it is not easily translated into policy and practice. Strategies exist and have been reviewed extensively, but the evidence base for guiding the selection and implementation

of those strategies is weak. Some strategies, such as audit and feedback and educational outreach, seem promising but there is clearly scope for more primary research on using these approaches in the reproductive health field.

“Providing access to reliable health information for health workers in developing countries is potentially the single most cost-effective and achievable strategy for sustainable improvement to health care.”

Pakenham-Walsh N, Priestley C, Smith R.
BMJ 1997, 314:90

2. CORE OBJECTIVE: TO INCREASE ACCESS TO THE EVIDENCE BASE IN REPRODUCTIVE HEALTH

2.1 Progress

2.1.1 Research synthesis

In order to reconcile the discrepancies between the WHO Model List of Essential Medicines and various reproductive health lists, including the Department's guidelines, a comprehensive review of the relevant evidence was initiated. In the first phase of this project, discrepancies were identified and the relevant evidence was discussed at a technical meeting. The Geneva Foundation for Medical Education and Research and BMJ Knowledge, part of the BMJ Publishing Group, are collaborating with the Department to make new submissions to the essential medicines list and clarify issues related to the evidence base of reproductive medicines in order to strengthen the evidence for the essential medicines list and WHO's practice guidelines (Table 14.1).

Table 14.1. Summary of the Department's work on the essential medicines list to strengthen the evidence base for reproductive medicines

Topic	Type of work ^a	Objective	Partner institution
Betamimetics for acute tocolysis	Evidence summary	Salbutamol to be retained	BMJ Knowledge ^b
Antihypertensives (labetalol)	Evidence summary	Assess whether labetalol requires separate entry	BMJ Knowledge
Uterotonics (ergometrine)	Evidence summary	Retain in the list	BMJ Knowledge
Uterotonics (prostaglandins for treatment of postpartum haemorrhage)	Evidence summary	To provide information to the Expert Committee as requested	BMJ Knowledge
Nifedipine as a tocolytic for the treatment of preterm labour	Full submission	To be added to the essential medicines list	BMJ Knowledge
Low-dose misoprostol for labour induction	Full submission	To be added to the essential medicines list	BMJ Knowledge
Clotrimazole for candidiasis	Full submission	To be added to the essential medicines list	BMJ Knowledge
Anaemia treatments in pregnancy	Update systematic review	Decide whether to retain iron dextrane	BMJ Knowledge
Levonorgestrel-releasing intrauterine system	Full submission	To be added to the essential medicines list	GFMER ^c
Combined injectable contraceptives	Full submission	To be added to the essential medicines list	GFMER
Implantable contraceptives	Full submission	To be added to the essential medicines list	GFMER
Mifepristone + misoprostol for medical abortion	Full submission	To be added to the essential medicines list	GFMER
Uniject system for oxytocin after delivery	Evidence summary	To provide information to the Expert Committee as requested	PATH ^d

^a Evidence summaries are 1–2 page documents; the term "Full submission" refers to the summary of evidence under the 13 headings requested by the Department of Essential Drugs and Medicines Policy.

^b BMJ Knowledge is part of the BMJ Publishing Group.

^c GFMER = Geneva Foundation for Medical Education and Research.

^d PATH = Program for Appropriate Technology in Health.

The Department contributed to the *World report on knowledge for better health* and to a special issue of the *Bulletin of the World Health Organization* with articles or chapters on research synthesis.

As more reviews are completed it becomes more important to keep reviews updated. The Department continues to work closely with Cochrane Review Groups and Cochrane Centres. In 2004, core support was provided to the Cochrane Pregnancy and Childbirth Group and the Cochrane Fertility Regulation Group. Several Cochrane reviews were published or updated in 2004.

2.1.2 Research

The know–do gap and its effects on the quality of care is well recognized. A randomized controlled trial conducted

in Mexico and Thailand to evaluate a programme promoting evidence-based medicine using RHL aimed to address this issue by providing training in using good-quality information as well as providing access to good-quality information. The objective was to improve both medical and non-medical practices related to pregnancy and childbirth. The results of the trial did not indicate a consistent clinically and statistically important change in the use of evidence-based obstetric practices after three educational workshops. The method of the trial has been published; manuscripts reporting the main results and the use of magnesium sulfate in the two participating countries have been submitted for publication.

A technical meeting held to discuss various strategies for implementing evidence-based practices using RHL was convened in January 2004. The report of this meeting is in press. Participants suggested that audit, feedback and accreditation

were promising strategies and, given the paucity of evidence in this field, highlighted the need for more rigorous research.

2.1.3. Dissemination: the WHO Reproductive Health Library

The Internet version of the library was launched in October 2004 with a new interface. This interface is aimed at improving access to the documents through the implementation of a simple search function and the introduction of “containers” or “packages” where topics are grouped and introduced by short synopses giving the main findings with relevant pictures (Figure 14.1). As before, both the online version and the CD-ROM are freely available in developing countries. The printed editions of the library have gradually increased over the years, and the current estimation at the end of 2004 is that there are 13 500 subscribers. A total of 34 000 copies of both the English-language and Spanish-language versions were produced and distributed in 2004. The subscribers list has been updated, and the use of bulk mailings to collaborating institutions is monitored closely. In Peru, more than 600 copies of the library were distributed through training workshops.

The content increased with the addition of 12 Cochrane reviews, bringing the total number of reviews to 88. Another 12 reviews included in the previous year were updated (Figure 14.2).

The translation of the Spanish version is ongoing, and the first Chinese version of RHL (version 5) was released on the Internet in 2004 (Figure 14.3).

2.1.4 Capacity strengthening

The training programme developed in 2003 on evidence-based decision-making for policy-makers and practitioners was successfully implemented in Kenya, Nigeria and Zambia. An important part of the success was due to the joint support from the WHO Regional Office for Africa, for the workshops in Nigeria and Zambia, and from the German Agency for Technical Cooperation (GTZ), for the workshop in Kenya. On the basis of feedback from these workshops, the manuals were revised and updated at the end of 2004.

2.1.5 Global clinical trials registry

The *Mapping best reproductive health practices* initiative took the lead in WHO's activities in prospective trial registration. Following the setting-up of the Programme's trials register and through the activities of the Programme, the WHO Ethics Review Committee adopted the unique numbering scheme for ongoing randomized controlled trials (<http://www.controlled-trials.com/isrctn>), making its use compulsory for all WHO-supported trials. The Department's trials received their unique numbers in April 2004. Subsequently, several editorials and consultations—including the Ministerial Summit on Health Research held in Mexico—expressed the wish of the international community for WHO to take the lead in address-

Figure 14.1. New interface of the WHO Reproductive Health Library



Figure 14.2. Number of Cochrane reviews included in the *WHO Reproductive Health Library* since 1997

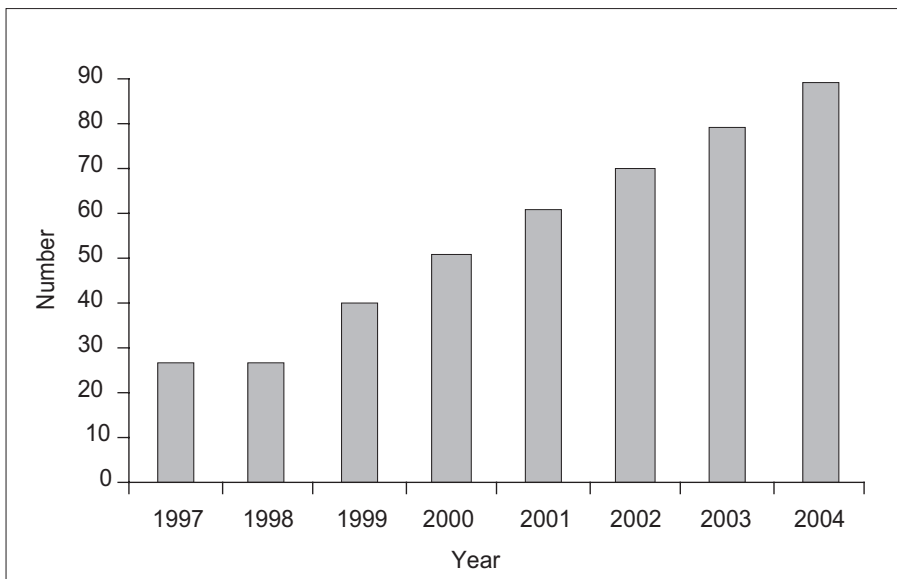


Figure 14.3. The Chinese-language interface of the *WHO Reproductive Health Library*



ing the scientific and ethical needs of clinical trial registration globally. Within WHO, the Programme has taken the lead in these activities, in collaboration with the Department of Research Policy and Cooperation.

3. OBJECTIVE: TO STRENGTHEN HEALTH MANAGEMENT AND SUPPORT SYSTEMS

The Implementing Best Practices initiative seeks to find innovative ways of working with countries to support their translation of knowledge into practice in resource-constrained settings. To change practice requires sustained input, and the IBP initiative has been developing a systematic process to increase in-country capacity to access, interpret and critically

appraise evidence as well as apply not only evidence-based practices but also managerial training and performance improvement practices that have been proven to be effective. The aim is to use meetings, mentorships, supportive follow-up and electronic communication to shorten learning curves and build on experience to facilitate the adaptation and use of information to overcome institutional and organizational barriers to change and to implement practices that will improve reproductive health.

3.1 Progress

3.1.1 Knowledge sharing using electronic communication systems

The IBP initiative has researched, developed, pilot-tested and launched the IBP Electronic Communication System (ECS). The ECS is not a list server but a unique system that is accessed through e-mail and has direct links to virtual web-based workspaces. The system has many easy-to-use functions designed to encourage the development of knowledge-sharing discussion fora and communities of practice. The ECS provides access to country-led and regionally-led projects and communities of practice and systems to support the transfer and exchange of information; most importantly, however, it provides people with an environment in which they can collaborate to achieve common aims.

3.1.2 Use of the electronic communication system

The communication system was pilot-tested in May–June 2004 in Ethiopia, Kenya and Uganda, from different locations, including Internet cafés located in rural areas of Ethiopia. Easy-start guides and management guidelines were tested and revised.

The communication system was introduced to 300 participants from 13 countries attending the launch of IBP in Africa, in Uganda in June 2004; it is being introduced to IBP partners and the four IBP teams in India. Within the Department, the system is being used by a number of groups, such as Regional Advisory Panels, the Partnership for Safe Motherhood and Newborn Health and IBP Partners. The communication system has a large global library and more than 1000 registered users; 40 communities have been established, of which 25 are active and 15 are receiving and responding to information that is being put onto the system at regular intervals.

3.1.3 Further development of the system

The technology is available to share with all interested parties in order to avoid reinventing similar systems and to encourage investment in further enhancement of the system. Departments within WHO are using this technology through the Evidence and Information for Policy Cluster and the Department of Knowledge Management and Sharing. Additionally, the Programme has signed a Memorandum of Understanding with the Johns Hopkins University's Bloomberg School of Public Health Info Project to jointly host the communication system. Technical enhancements to the system by either party will benefit both parties. The management of the system for IBP activities will remain at WHO's Headquarters. A joint programme of work has been prepared in collaboration with a cross-organizational task team involving all members of the IBP Consortium.

An IBP web site was designed and launched during 2004 (<http://www.ibpinitiative.org>). This web site is the gateway to the electronic communication system and the homepages and libraries of all partners.

3.2 IBP Consortium

3.2.1 IBP strategy development 2004–2007

Two new partners have joined the IBP Consortium: the Population Council and the International Council on Management of Population Programmes, Malaysia. The California-based Public Health Institute's Population Leadership Program, in collaboration with the IBP secretariat, has supported a process to review IBP strategy and prepare a strategic plan for 2005–2007. A midterm review of the IBP initiative's 2004–2006 programme of work and of the mentorship and follow-up programme was undertaken to highlight achievements and lessons learnt. Partners attended an IBP strategy meeting in May 2004 and formulated a revised strategy for 2005–2007. They will meet in January 2005 to prepare a programme of work that identifies how each partner will contribute to taking the strategy into action in countries and by participating in various task teams.

3.2.2 IBP task teams

As well as working with countries, IBP partners work in teams to develop specific techniques and tools that enhance knowledge-sharing activities.

- Johns Hopkins University's Information and Knowledge for Optimal Health Project (known as the Info project) leads a team focused on developing both the branding style for the IBP initiative and a set of advocacy materials. Short briefing papers and a brochure have been published on the IBP initiative and the IBP Electronic Communication System.
- Management Sciences for Health has led a team focused on the development of a CD-ROM tool-kit designed to inform policy-makers and programme managers about the resources and tools produced by this Department and the partners in the IBP Consortium.
- Other partners, including Family Health International, JHPIEGO (an international health organization affiliated with Johns Hopkins University), Pathfinder International and IntraHealth International, have led the development of a number of interactive knowledge-sharing activities, such as the Mini-University, Technology Café and Information Exchange Bazaars. These methods are used during IBP launches and by member organizations during their own meetings to engage participants in activities that foster the sharing of experience and improve access to and the use of published and/or electronic technical and programmatic tools. These events are proving popular and the teams have been requested to prepare "How to" guides.
- An Evaluation Task Team led by the Centre for Development and Population Activities has also been formed to develop methods for evaluating different models of knowledge sharing and collaborative learning.
- An IBP Newsletter summarizing recent activities and achievements is published bimonthly.

3.3 Regional and country-based IBP activities

3.3.1 IBP launch: South-East Asia and Africa

The IBP initiative was launched in Africa at a meeting held in Entebbe, Uganda, in June 2004. The launch was prepared in collaboration with country teams of representatives from the Ministry of Health, the United Nations Population Fund (UNFPA), WHO Country Offices, research institutions, professional bodies and partner-country offices, from Ethiopia, Kenya, Uganda, the United Republic of Tanzania and Zambia. The five country teams were joined by smaller teams from priority countries of the WHO/UNFPA Strategic Partnership Programme (SPP), namely Angola, the Democratic Republic of Congo, Ghana, Mozambique, Nigeria, Rwanda and South

Africa. Activities were undertaken on a cost-sharing basis, and more than 300 senior health-care officials attended. The theme of the meeting was "Repositioning reproductive health in Africa: linking challenges with best practices." As a result of the many knowledge-sharing activities undertaken, country teams prepared action plans focused on applying the knowledge shared to improve key performance goals. Implementation is being supported through an IBP partner-led mentorship and follow-up programme. Evaluations of the meeting were very positive, and the feedback provided by the participants will help shape future events.

The initiative has also collaborated with and supported regional meetings convened by the SPP and applied the principle of "piggybacking" IBP knowledge-sharing approaches onto country and regional meetings held by individual partner agencies.

3.3.2 IBP mentorship and follow-up programme

The IBP initiative was launched in four states in India in September 2003, and a mentorship and follow-up programme in each state has been maintained for more than a year. The Ministry of Health's Department of Family Welfare remains engaged in the Initiative's activities. The local IBP India Steering Committee has continued to meet every three months to review and report on progress. The Electronic Communication System has been launched, and statewide training programmes are scheduled. Each state has reported that it is making progress in achieving the markers of achievement detailed in their action plans. There are some excellent stories of local achievements and innovations that give support to taking evidence into practice.

The WHO Regional Office for South-East Asia, the IBP India Steering Committee and IBP Secretariat are supporting a series of visits to interview members of IBP State Teams to record their activities, challenges, success stories, innovations and lessons learnt; they will also identify their future information requirements in the areas of family planning and the prevention and care of sexually transmitted infections (STIs). These stories will be published as part of the commitment of IBP partners to support local knowledge-sharing processes.

The mentorship and follow-up programme has started with IBP teams in Africa and has been reinforced by the SPP. Immediately after the IBP launch, the Minister of Health in Kenya initiated a programme to reposition family planning in Kenya and requested that JHPIEGO take the lead on this initiative. Teams from Benin, Cameroon, Nigeria, South Africa, the United Republic of Tanzania and Zambia have met to review their activity plans and produce proposals to support updating local family planning and STI prevention and care guidelines; writing and dissemination of the guidelines have been funded through the SPP.

4. PLANNED ACTIVITIES

4.1 Mapping best practices

- Research synthesis activities to map best reproductive practices are expected to continue. In 2005, the work will focus on revising some existing systematic reviews in order to update the evidence base presented in the *WHO Reproductive Health Library* and other guidance documents from the Department.
- Two applications for grants to look at implementation research have been submitted and are awaiting approval. One was submitted to the United States National Institutes of Health jointly with the University of California, San Francisco, CA, USA for a project to increase the use of active management of the third stage of labour in 16 Turkish hospitals. The second was submitted jointly with a consortium of partners led by the Norwegian Knowledge Centre for the Health Services to the European Union for a project to improve understanding of the determinants of utilization of services and quality of care in Africa and Latin America. Household surveys to assess service access and utilization dynamics, and evaluation of simple facility-based audit techniques will form the initial components of this project.
- User surveys will be carried out to improve the focus of dissemination of the *WHO Reproductive Health Library*. A survey of all members of the Royal Thai College of Obstetricians and Gynaecologists is planned, as is a survey of all RHL recipients in the city of Rosario, Argentina. Also in 2005, the new-look RHL will be launched on CD-ROM and the Internet. With the launch of the Internet version it will be possible to add new documents to the library throughout the year. RHL will be included in searches on Bireme (Biblioteca Virtual em Saúde), SHARingpoint.net, Google Scholar and Scopus. The latter two are important initiatives competing with the Science Citation Index for impact factors.
- Manuals for the training programme, known as "Evidence-based decision-making in reproductive health", will be printed and implemented within the SPP framework in the countries of intensified focus in 2005.
- The initiative on the global clinical trials registry, included in the Mexico agenda for health research, will be presented to the Executive Board of WHO and the World Health Assembly in 2005. This work will be conducted in collaboration with the Department of Research Policy and Cooperation.

4.2 Implementing best practices

IBP partners will work collaboratively with regional and country teams to achieve the objectives outlined below.

- Work will be extended in the field of knowledge management and the use of electronic systems of communication to improve the access to and use of research findings, evidence-based technical guidelines and proven effective managerial, training and performance-improvement practices by:
 - undertaking a literature review to identify barriers to accessing information especially among health-care providers in the public and private sectors and among their clients;
 - establishing systems for initiating, maintaining and supporting communities of practice to encourage the transfer and exchange of information, experience, success stories and innovations within and between countries;
 - establishing and testing mechanisms, such as open learning, web-based learning and the synthesis of information to improve access to and utilization of research findings and information on effective practices.
- Methods to evaluate different models of knowledge sharing and application will be established so that they can be applied through regional and country meetings and programmes.
- The mentorship and follow-up programmes will continue to be developed in order to support in-country activities through technical support (backstopping) to diffuse knowledge-sharing and application approaches to district-level managers.
- Collaborative links with programmes within the Department and WHO that are focused on supporting research practice will continue to be forged. These links will involve the SPP, WHO/RHR Collaborating Centres and the Evidence and Information for Policy Cluster, for knowledge management and sharing activities.

Annex 1

WHO PROGRAMME TO MAP BEST REPRODUCTIVE HEALTH PRACTICES

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	6	86			1	14	7
Women	3	43					3
<i>from:</i>							
AFRO	1	14					1
AMRO	2	29			1	14	3
EMRO							
EURO							
SEARO	2	29					2
WPRO	1	14					1

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	Developing countries		Countries in transition		Developed countries		Totals
	Number	% of total	Number	% of total	Number	% of total	
Members	66	69	1	1	28	29	95
Women	22	23			7	7	29
<i>from:</i>							
AFRO	28	29					28
AMRO	19	20			7	7	26
EMRO	3	3					3
EURO	1	1	1	1	17	18	19
SEARO	13	14					13
WPRO	4	4			2	2	6

Annex 3

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Chapter 15

Monitoring and evaluating reproductive health

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1. INTRODUCTION

Reproductive health has been central to several international conferences on development since the 1990s. The Millennium Summit in 2000 set eight development goals, three of which are related to reproductive health. Millennium Development Goals (MDGs) 4 and 5, which talk about improving maternal health and reducing mortality among children younger than five years, are directly related to the Department's work. In addition, the International Conference on Population and Development's goal of ensuring universal access to reproductive health remains central to the achievement of the MDGs. The Department's work focuses on data collection and synthesis at the global level, and it provides guidance for both international agencies and national governments with regard to the status of reproductive ill-health. An emerging issue in monitoring reproductive health indicators is the increasing inequality between advantaged and disadvantaged groups within both developed and developing countries. The challenge is to measure and evaluate these inequalities and to understand their likely causes in order to address them.

2. CORE OBJECTIVE: TO MAP THE BURDEN OF REPRODUCTIVE ILL-HEALTH

Up-to-date information on reproductive morbidities and mortality is needed to inform policies and programmes targeted towards improving reproductive health. As with other areas of health care, systematic reviews of all existing research evidence are required to facilitate informed decision-making. The methods used to conduct and report systematic reviews of prevalence studies are not well developed. The Department's work in this area contributes to the development of the methods as well as the knowledge base.

2.1 Progress

2.1.1 Maternal mortality and morbidity: systematic review

The primary objective of the systematic review is to obtain estimates of the worldwide prevalence and incidence of maternal morbidity and mortality. The systematic review followed an a priori protocol and involved a comprehensive search strategy. An instrument designed to capture study-level characteristics—such as design, population and setting, as well as the reported definitions and diagnostic procedures used for conditions—was used for data extraction. An article describing the methodological issues of the systematic review was published in June 2004 in *BMC Medical Research Methodology* (an electronic resource). Another, which addresses the search strategy, has been submitted for publication.

Overall, more than 60 000 citations were screened by evaluating titles and/or abstracts, and 2580 were included in the review, providing 6540 datasets for morbidity outcomes and 1380 for mortality outcomes (Figure 15.1).

A technical consultation was held in May 2004 to discuss the methodological issues that arise when analysing data for a range of conditions. It was agreed that for the systematic review, there would be two broad categories in terms of analytical approach. Some morbidities would be more amenable to meta-analysis, but for others the approach would be primarily descriptive. The decision about which analytical approach to use would be driven by the heterogeneity in study design, location of data collection, and quality issues.

The report on the prevalence of severe acute maternal morbidity ("near misses") was published in 2004. This was a descriptive presentation of data stratified according to differ-

ent definitions and settings. Results show that in resource-poor settings, 4–8% of pregnant women who deliver in hospitals experience severe morbidity when case-identification is based on specific diseases. This rate is around 1% when organ failure is considered as the criterion. In settings in more developed countries the rates are around 1% using disease-specific criteria and 0.4% with organ-system based criteria.

An article on the prevalence of stillbirth has been submitted for publication. The analytical method was different for this topic. A meta-analysis was performed and heterogeneity was investigated using meta-regression techniques. Figure 15.2 shows an example of a graphical representation of country-specific prevalence rates of stillbirth for the region of Africa.

Overall, the results suggest that stillbirth prevalence at the community level is typically less than 1% in more-developed parts of the world and could exceed 3% in less-developed regions. Pooled prevalence rates show variation across subgroup categories of studies. Rates (per 100) are higher in studies conducted in settings in less-developed countries when compared with settings in more-developed countries (1.17 versus 0.50) and in studies of inadequate quality when compared with those of adequate quality (1.12 versus 0.66). Subnational studies had higher stillbirths rates when compared with national-level reports (1.38 versus 0.68), when all stillbirths were reported compared with only late stillbirths (more than 28 weeks' gestation or more than 1000 g birth weight) (0.95 versus 0.63), when studies were published in a language other than English when compared with English (0.91 versus 0.59) and when published as journal articles as compared with non-journal publications (1.37 versus 0.67).

Meta-regression analysis showed the development status of the study setting to be a strong predictor of stillbirth prevalence. The quality of a study appeared to be another significant predictor, independent of development status, with prevalence rates being lower in studies of higher quality. These results provide an empirical basis for the different rates observed in different studies, and highlight the fact that stillbirth is a major burden in all settings regardless of development status.

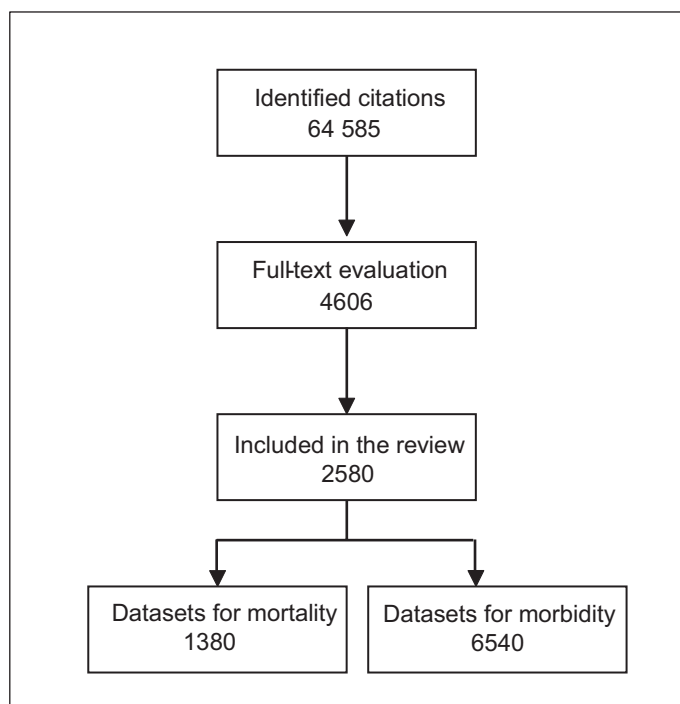
Reports are being prepared for other topics included in the systematic review of maternal mortality and morbidity. By mid-2005, reports will be ready for the following conditions:

- maternal mortality
- postpartum haemorrhage
- abortion complications
- causes of maternal deaths
- uterine rupture
- obstructed labour.

2.1.2 Systematic reviews on genital prolapse and chronic pelvic pain

Two systematic reviews designed to estimate the prevalence, associated factors and consequences of genital organ prolapse and chronic pelvic pain, initiated with partner institutions, are under way. These will be completed in 2005.

Figure 15.1. Flow diagram of the process of the systematic review



2.2 Planned activities

Several issues that emerged from the systematic review of maternal morbidity and mortality will be followed up during 2005. They are outlined below.

- Technical meetings to establish standards on the definitions of conditions and reporting of such studies are planned..
- An article will be written discussing methodological issues and describing the use of meta-analytical methods, including meta-regression, in systematic reviews of prevalence studies.
- The systematic review will be updated regularly through a more focused search strategy for maternal mortality and stillbirth to provide the information base for developing 5-yearly estimates for these indicators.

3. OBJECTIVE: TO ENSURE EFFECTIVE INTERNATIONAL EFFORTS AND COLLABORATION

Reliable estimates of relevant indicators at global, regional and national levels are needed to monitor progress towards internationally agreed goals, including the MDGs. Target 6 of Goal 5 aims at reducing by three quarters, between 1990 and 2015, the maternal mortality ratio. The Department, together with the United Nations Children’s Fund (UNICEF) and the United Nations Population Fund (UNFPA) is engaged in developing, every five years, maternal mortality estimates for the global level, regional level and country level. The proportion of births that are attended by skilled health personnel has also been included as a key indicator of maternal mortality within the MDG framework. The Department has updated

global, regional and country-level estimates of this indicator annually since 2000.

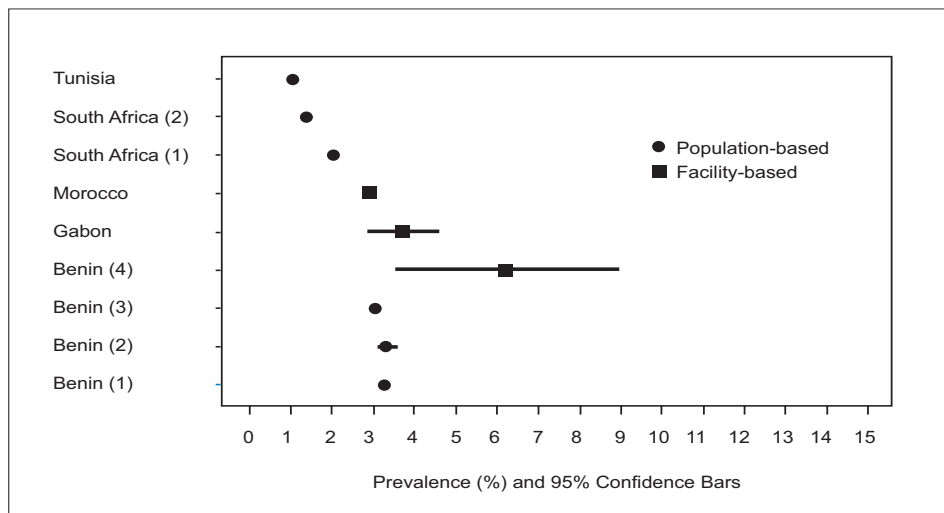
Although governments attending the International Conference on Population and Development in 1994 committed themselves to providing universal access to reproductive health by 2015, measuring and monitoring access to services has been problematic due to the lack of agreed indicators. A technical meeting was organized by the Department and UNFPA in December 2003 to define a set of indicators to be used for this purpose. An emerging issue from the meeting was the evidence that inequalities among population subgroups are increasing, and it was recommended that attention be paid to evaluating equity of access.

3.1 Progress

3.1.1 Global estimates

- The document reporting on maternal mortality estimates for 2000 was published in October 2004. The number of maternal deaths in 2000 occurring worldwide is estimated to be 529 000, 95% of which occurred in Africa and Asia. Less than 1% occurred in more developed countries. Women living in sub-Saharan Africa have a one in 16 life-time risk of dying in pregnancy or childbirth; this risk is one in 2800 for women living in more developed regions.
- The global, regional and country-level estimates of the presence of skilled attendants at birth were updated in 2004 and are available on the Department’s web site (http://www.who.int/reproductive-health/global_monitoring).
- Estimates for neonatal and perinatal mortality and stillbirth for the year 2000 have been generated and will

Figure 15.2. Stillbirth prevalence: Africa. (Numbers in parentheses refer to different studies from the same country.)



be available through the Department's web site in early 2005.

- Global and regional estimates of the incidence of unsafe abortion and associated mortality for the year 2000 were developed and published in 2004.

3.1.2 Reproductive health indicator tools

3.1.2.1 Reproductive health indicators database

The *Reproductive health indicators database* presents information on indicators developed by the Department as well as units from other international agencies. Country-level information on 17 reproductive health indicators selected for global monitoring, four additional reproductive health indicators and 17 socioeconomic and demographic indicators are available through the database (http://www.who.int/reproductive-health/global_monitoring/RHRxmls/RHRmainpage.htm).

The database allows the user to generate tables with a selected number of countries or regions and their indicators and to send a report for a chosen country or region via e-mail (Figure 15.3).

3.1.2.2 Guidelines for generating, interpreting and analysing reproductive health indicators for global monitoring

Guidelines for the generation, interpretation and analysis of national reproductive health indicators for global monitoring is intended to be used by national public health administrators and health programme managers. It aims to assist them in collecting data for the 17 agreed indicators for the global monitoring of reproductive health. The document is in press.

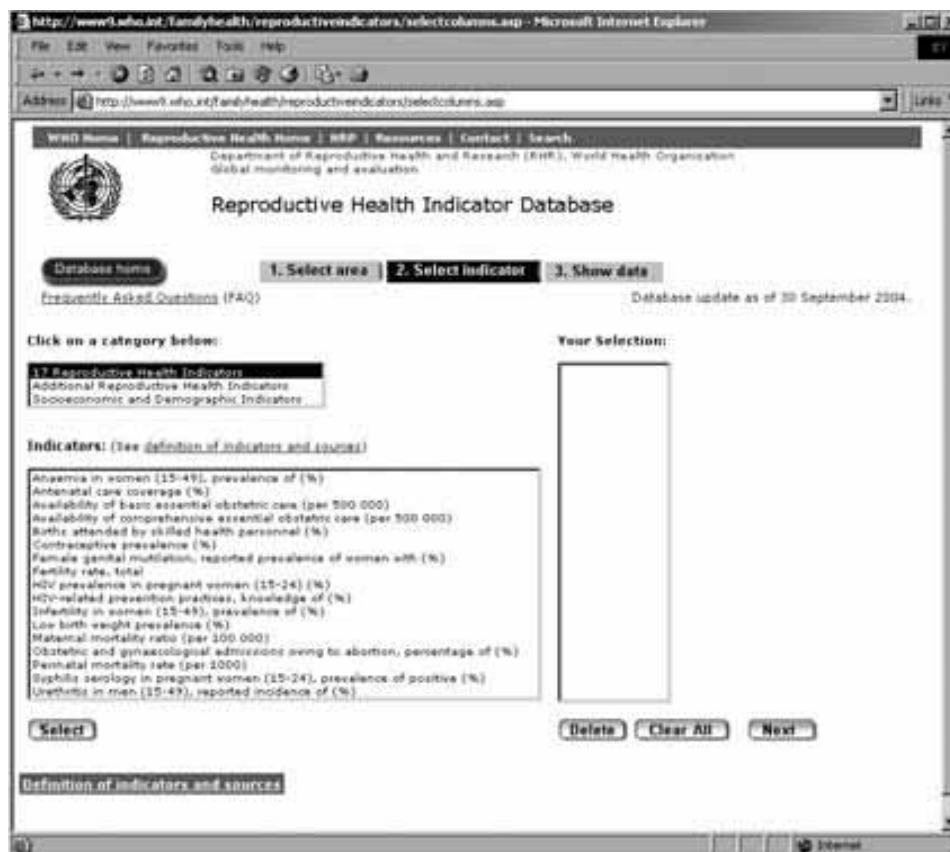
3.1.3 Access to reproductive health services

The summary report from the meeting between WHO and UNFPA on measuring access to reproductive health services was published and endorsed at a high-level meeting between the two agency heads in June 2004. The full meeting report was published in late 2004.

Four reproductive health indicators were recommended as measures of the use of reproductive health services. These indicators were chosen to reflect different areas of reproductive health and to include both women and men:

- percentage of births attended by skilled health personnel
- contraceptive prevalence, stratified by method and age
- knowledge of HIV-related prevention practices, stratified by age and sex

Figure 15.3. The reproductive health indicators database allows users to generate tailor-made tables of information



- percentage of men reporting they have had treatment for urethritis.

In response to a recommendation from the meeting, the Department initiated a research project that aims to investigate and explain inequalities among population subgroups with regard to the set of indicators listed above. The study protocol was approved by the Specialist Panel on Epidemiological Research, and the data collection instruments are being developed. The set-up for fieldwork is complete for South Africa, where the first phase of the study will be conducted. Depending on the availability of funds, the study will also be conducted in Mexico and Turkey.

3.1.4 Strategic review committee for monitoring and evaluating reproductive health

The Department will establish in 2005 a strategic committee to discuss, advise on and oversee activities for monitoring and evaluation. The aim is to provide guidance on activities in general and to ensure the scientific quality of the products, including the provision of scientifically robust estimates. Representation of a range of relevant disciplines and regions will be ensured in selecting members for the committee.

3.2 Planned activities

The work for the 2005 global estimates for maternal mortality and stillbirth will be initiated during the second half of 2005 following the analysis of the maternal mortality dataset from the systematic review.

The estimates for the presence of skilled attendants at birth will continue to be updated annually. Starting in 2005, estimates of antenatal care coverage at country, regional and global levels will be provided annually. The *Reproductive health indicators database* will be updated twice a year.

It is envisaged that the first phase of the study on measuring the equity of access to reproductive health services will be initiated in May 2005 in South Africa.

Chapter 16

Communication, advocacy and information

J. Khanna, C. Hamill, S. Kolev, J. Maurice

1. INTRODUCTION

The Communication, Advocacy and Information group aims to facilitate access to reproductive health information—both within and outside the Department—in support of WHO's mandate and objectives to improve reproductive health worldwide. The main objectives are:

- 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 information through appropriate strategies and media, focusing on participatory communication;
- to initiate, develop and manage a research programme to evaluate the impact of dissemination activities and to strengthen dissemination and communication strategies;
- to strengthen the capacity of the Department's collaborating centres in writing and publishing scientific papers in peer-reviewed journals and communicating research findings to policy-makers and the public; and
- to initiate advocacy and public relations interventions.

2. DEVELOP A PROGRAMME FOR DISSEMINATING AND COMMUNICATING REPRODUCTIVE HEALTH KNOWLEDGE

The Department produces a variety of serial and non-serial documents and information materials, all of which aim to develop a strategic, proactive and cost-effective programme for disseminating and communicating reproductive health knowledge to target audiences and stakeholders.

2.1 Progress

The following publications and documents were produced and distributed in 2004.

2.1.1 Progress in reproductive health research

The Programme's newsletter, *Progress in reproductive health research*, continues to serve as an important instrument for the dissemination of research information to policy-makers, programme managers, scientists and the general public. Three issues of the newsletter were published in 2004, covering cervical cancer prevention and new research in family planning and sexual health. The newsletter is also translated into Chinese and is published on the Department's web site.

2.1.2 Biennial reports 2002–2003

The Department published two biennial reports: (i) *Research on reproductive health at WHO—pushing the frontiers of knowledge: biennial report 2002–2003* and (ii) *Improving reproductive health—a global imperative: biennial report 2002–2003*. The former is the biennial report of the Programme, and the latter covers the work of the non-research component of the Department, namely Programme Development in Reproductive Health (PDRH). Some 6000 copies of the report of the Programme and 2500 copies of the PDRH report were distributed.

2.1.3 Publications and web site: CD-ROM

Along with the Department's *Annual Technical Report 2003*, this CD-ROM contains other key documents on the work of the Department, including the entire contents of the Department's web site as of 10 June 2004. Some 2500 copies of the CD-ROM had been distributed by December 2004, primarily to scientists and national and international policy-makers. In addition, print copies of the *Annual technical report 2003* were also produced and distributed.

2.1.4 *Safe motherhood newsletter*

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 2004, one issue of the newsletter was published (“Healthy mothers, healthy babies”).

2.1.5 *Other information materials*

A total of 50 different information materials (including versions in languages other than English and promotional materials) were produced and distributed appropriately (see Box 16.1).

2.1.6 *Video—Vacuum extraction: the technique*

To help train physicians in evidenced-based techniques of delivery using vacuum extraction, a new video was produced by the Department. This 10-minute video will be included in issue No. 8 (2005) of the *WHO Reproductive Health Library*.

2.2 Planned activities

In 2005, the Department will continue to produce and disseminate its usual serial and non-serial reports, publications and public relations materials. Two more training videos—one on breech delivery and another on active management during the third stage of labour—will be produced in 2005.

3. FACILITATE THE TRANSFER OF HEALTH INFORMATION USING APPROPRIATE STRATEGIES AND MEDIA

In order to facilitate the transfer of reproductive health information using appropriate strategies and media that focus on participatory communication, the Department publishes the majority of its information material on its web site, publishes selected materials in electronic format and undertakes mass media-related activities.

3.1 Progress

3.1.1 *Reproductive health web site*

The Department’s web site continues to be updated and to expand. In November 2004, it housed more than 5000 files and ranked in the top three health topic sites within WHO in terms of the number of visitors and the amount of information downloaded from it. From 1 January to 22 November 2004, more than one million user sessions were recorded on the Department’s site. A total of 645 000 documents were downloaded during the same period, putting the web site at the forefront of information distribution.

Twice during the year, the web site was made available on CD-ROM allowing those with poor or no access to the Internet to have all information materials from the Department available in a searchable electronic form; this format continues to be popular.

During 2004, the reproductive health home page was given a fresh look, as were the Programme pages. Notable new topics added to the site include pages on “Technical cooperation with countries” and “Programme management”. In addition, a new database of reproductive health indicators went online, providing national data on a range of indicators (see Chapter 15, section 3.1.2.1). The web was also used to host a global photo competition entitled “River of life” on the theme of sexual and reproductive health. Prize-winning entries were displayed at the 2004 World Health Assembly, and a number of selected photographs have been used in the Department’s publications.

The reproductive health home page has been translated into French. Pages on family planning, maternal and newborn health, sexually transmitted and reproductive tract infections, and abortion have also been prepared in French; these pages introduce the information available on the site and point users towards additional materials in French.

3.1.2 *The WHO Reproductive Health Library: issues 7 and 8*

Issue number 7 of the electronic journal (on CD-ROM) the *WHO Reproductive Health Library* (RHL) was published in 2004. In September, a Spanish version was also published. A total of 24 000 copies of the English version and 10 000 copies of the Spanish version (in CD-ROM format) were produced. By December 2004, all 34 000 copies had been distributed. Subscriptions to RHL continue to rise, and by December 2004, there were more than 13 000 addresses on the mailing list for the English and Spanish versions. During 2004, work was under way to produce issue number 8, and plans have been made to produce an Internet version of the library (see also Chapter 14, section 2.1.3).

3.1.3 *Mass media-related activities*

With partial funding from the Department, the Television Trust for the Environment—an international not-for-profit organization working globally and locally to raise awareness of environmental, development, and health and human rights issues through the media—produced a series on the Millennium Development Goals. The fifth programme in the series (“Staying alive”) focused on maternal mortality. It profiled Rina, a girl living in Bangladesh, who, after nearly dying during childbirth when she was aged 14 years, now works to promote safer pregnancies in her village. The programme was aired six times on BBC World in February 2004.

Box 16.1. Information materials produced in 2004

Newsletters

1. *Progress in reproductive health research* (three issues)
2. *Safe motherhood* (one issue)

Electronic documents on CD-ROM

3. *WHO Reproductive Health Library*, No. 7
4. Publications and web site 2004 (including the *Annual technical report 2003*)
5. HRP Policy and Coordination Committee, 2004: presentation and poster session
6. *Beyond the numbers: reviewing maternal deaths and complications to make pregnancy safer* (CD-ROM version)

Printed documents

7. *Annual technical report 2003*
8. *Research on reproductive health at WHO—pushing the frontiers of knowledge: biennial report 2002–2003*
9. *Improving reproductive health—a global imperative: biennial report 2002–2003*
10. *Improving sexual and reproductive health through research—an investment in the future*
11. *Measuring access to reproductive health services. Summary report of a WHO/UNFPA technical consultation, 2–3 December 2003*
12. *Beyond the numbers: reviewing maternal deaths and complications to make pregnancy safer*
13. *Medical eligibility criteria for contraceptive use*. Third edition
14. *Selected practice recommendations for contraceptive use*. Second edition
15. *Pregnancy, childbirth, postpartum and newborn care: a guide for essential practice*
16. *Sixteenth meeting of the Policy and Coordination Committee (PCC): 30 June–1 July 2003, Geneva, Switzerland*
17. *Reproductive health strategy to accelerate progress towards the attainment of international development goals and targets*
18. *Sexually transmitted and other reproductive tract infections: a guide to essential practice*
19. *The effects of contraception on obstetric outcomes*
20. *Maternal mortality in 2000: estimates developed by WHO, UNICEF and UNFPA*
21. *Cervical cancer screening in developing countries: report of a WHO consultation*
22. *Unsafe abortion: global and regional estimates of the incidence of unsafe abortion and associated mortality in 2000*. Fourth edition
23. *Making Pregnancy Safer: the critical role of the skilled attendant. A joint statement by WHO, ICM and FIGO*
24. *The male latex condom: specification and guidelines for condom procurement*
25. *Manual for the standardization of colposcopy for the evaluation of vaginal products: update 2004*
26. *Pre-eclampsia—eclampsia: from research to action*
27. *How do perceptions of gender roles shape the sexual behaviour of Croatian adolescents?* (Social Science Policy Briefs) Reprints
28. *Global action for skilled attendants for pregnant women* (revised reprint)
29. *Social science methods for research on reproductive health*
30. *Guidelines for the management of sexually transmitted infections*

Versions in languages other than English

31. *Santé sexuelle et génésique — l'essentiel*
32. *Améliorer la santé génésique par la recherche — un investissement pour l'avenir*
33. *Au-delà des nombres. Examiner les morts maternelles et les complications pour réduire les risques liés à la grossesse*
34. *Prise en charge des complications de la grossesse et de l'accouchement: guide destiné à la sage-femme et au médecin* (revised version)
35. *Método madre canguro: guía práctica*
36. *La méthode "mère kangourou": guide pratique*

37. *Avortement médicalisé: directives techniques et stratégiques à l'intention des systèmes de santé*
38. *Reunión Consultiva Técnica OMS/CONRAD sobre el nonoxynol-9*
39. Santé de la mère et du nouveau-né aujourd'hui (poster)
40. *Santé génésique: projet de stratégie pour accélérer les progrès en vue de la réalisation des objectifs et cibles du développement international*
41. *Évaluation externe 1990–2002: résumé d'orientation*

Promotional materials

42. Highlights of 2003
43. Sexual and reproductive health—the facts (a set of fact sheets)
44. Sexual and reproductive health: publications and documents, October 2004
45. Maternal and newborn health today (poster)
46. Bookmark to promote the Department's web site
47. World Health Day—7 April 2005, "Make Every Mother and Child Count"; a toolkit for organizers of activities

Video

48. Vacuum extraction: the technique

In the lead up to World Health Day on 7 April 2005, six mothers-to-be living in different countries of the world shared their experiences of pregnancy and childbirth through a new WHO web feature called "Great expectations". This feature is available on the WHO web site at http://www.who.int/features/2004/great_expectations/en/. From the fifth month of pregnancy until their babies are six weeks old, these women will describe how their pregnancy is progressing and, after the babies are born, they will tell readers about their childbirth experience and how their baby is growing. The feature will continue in the months leading up to World Health Day 2005 (7 April 2005), which will highlight issues of maternal and child health. The six women are from Bolivia, Egypt, Ethiopia, India, the Lao People's Democratic Republic and the United Kingdom.

Beyond the numbers: reviewing maternal deaths and complications to make pregnancy safer, a new publication, was launched in Nairobi, Kenya, on 29 September 2004 and a press release was issued. Before the launch two pre-event media briefings were organized, one in Geneva and another in Nairobi. The launch was attended by representatives of the Partnership for Safe Motherhood and Newborn Health, the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF), Save the Children and Family Care International. A press release and an information package were produced and sent to news organizations and journalists worldwide. The launch received wide coverage: a total of 52 pieces of reporting were collected from newspapers and news agencies in Chinese, English, French, Portuguese and Spanish.

Other press releases were titled (i) "Far more women getting antenatal care—study finds 20% jump: opportunity to reach women with key health services" (30 March 2004), (ii) World Health Assembly adopts first global strategy on reproductive health and resolution on the family and health" (22 May 2004), and (iii) "WHO publishes new guidelines on preventing mother-to-child transmission of HIV" (14 July 2004).

3.2 Planned activities

In 2005, the Department will continue to strengthen its web site and its media-related activities.

4. DEVELOP RESEARCH PROGRAMME TO EVALUATE IMPACT OF DISSEMINATION AND TO STRENGTHEN DISSEMINATION AND COMMUNICATION

4.1 Progress

4.1.1 Readers' survey of the Annual Technical Report 2003

In order to understand how useful the annual technical reports of the Department are to readers and whether they prefer to receive the reports in electronic or paper format, a survey was conducted among the readers of the *Annual technical report 2003*. Results of this survey will be available in 2005.

4.2 Planned activities

In 2005, the Department will plan and conduct one or more readers' surveys of other information materials.

5. STRENGTHEN THE CAPACITY OF COLLABORATING CENTRES IN WRITING AND PUBLISHING SCIENTIFIC PAPERS

The Programme's scientific writing workshops aim to teach the skills involved in writing a scientific research paper and seek to encourage scientists in the Programme's Collaborating Centres to publish more papers, especially in internationally read peer-reviewed journals. To this end, the Programme aims to strengthen the capacity of Collaborating Centres to ensure that researchers are well trained in scientific writing and able to communicate their findings to policy-makers and the public.

5.1 Progress

5.1.1 Scientific writing workshops

In 2004, a total of six workshops were conducted. Two of these (in Cairo, Egypt, and Khon Kaen, Thailand) were for social scientists and four were for biomedical scientists (two in Yangon, Myanmar, and one each in Colombo, Sri Lanka, and Pattaya, Thailand). The workshop in Cairo was conducted in collaboration with the Population Council's FRONTIERS programme. A total of 145 researchers were trained during these workshops.

A short training session on writing project proposals and research papers was conducted as part of the postgraduate training course in reproductive medicine and reproductive biology at the WHO Collaborating Centre in Geneva, Switzerland. It was attended by 32 participants.

5.2 Planned activities

In view of the continuing huge demand for training in scientific writing and communication skills, in 2005 the Department plans to conduct workshops in China, Myanmar, Pakistan, Sri Lanka and Viet Nam. Plans are also under way to add to the scientific writing workshop an additional training component on ethics in research.

Chapter 17

Clinical trials and informatics support

G. Piaggio, M. Ali, A. Peregoudov, S. Landoulsi

1. INTRODUCTION

The Clinical Trials and Informatics Support unit provides technical support in statistics and data processing to the Programme and the Department for Reproductive Health and Research more generally.

It has three main objectives:

- to provide technical support to research activities. This includes statistical advice on the review and development of research protocols and responsibility for the data management and analysis of single-centre and multicentre studies carried out by the Programme;
- to support institution-strengthening activities in statistics and data processing and to conduct workshops and training courses in these areas for scientists from collaborating institutions;
- to provide informatics support to the Department.

2. OBJECTIVE: TO PROVIDE TECHNICAL SUPPORT TO RESEARCH ACTIVITIES

The aim is to provide high-quality and efficient statistical and data-processing support to all research conducted by the Programme, while adhering to good clinical practice guidelines.

2.1 Progress

2.1.1 Support to research projects

A total of 32 research projects were supported by the unit. The distribution of these projects by their stage of support at the end of 2004 is shown in Table 17.1 and by area of work

in Table 17.2. Support included providing technical advice on the development and review of protocols and statistical design, as well as assistance with project organization, data processing, monitoring, statistical analysis, preparation of statistical reports and participation in the writing of scientific papers.

Support was also given to project managers by advising them on biostatistical and data-processing aspects of protocols that had been submitted to them for funding; site-visits to centres were also undertaken in order to assess facilities for data management.

In addition, further statistical analysis was conducted for at least five studies (on breastfeeding, antenatal care and intra-uterine devices) that had already been completed.

2.1.2 Support for the analysis of health surveys

Further analysis of the 1999 survey on child and maternal mortality in Iraq is being undertaken. Analyses of Demographic and Health Survey data are conducted to address issues related to contraceptive use and the consequences of contraceptive failure.

2.1.3 Development of methodological tools

Collaboration continued on developing guidelines for reporting clinical trial results with the CONSORT (Consolidated Standards of Reporting Trials) group, in particular for equivalence trials. Work is continuing on developing methods to analyse contraceptive failure due to competing causes and on the meta-analysis of observational studies.

2.1.4 Development of software

Software that can be used to analyse menstrual bleeding patterns (known as AMBP) was distributed to collaborating

Table 17.1. Number of studies by stage of support, December 2004

Stage of study	Number of studies
Planning stage	7
Recruitment ongoing	7
Recruitment finished, data-cleaning ongoing	7
Final analysis ongoing, manuscript in preparation	11
Total	32

Table 17.2. Number of studies by area of work, December 2004

Area of study	Number of studies
Promoting family planning	6
Making pregnancy safer	5
Controlling sexually transmitted and reproductive tract infections	10
Preventing unsafe abortion	9
Monitoring and evaluation	1
Technical cooperation with countries	1
Total	32

centres for testing. A system for centralized data management was developed based on optical character recognition and SAS software. For decentralized data management, the portable data management system known as DMS/3 was tested in-house and improved.

2.1.5 Implementation of good clinical practice guidelines in research

Adherence of the unit's staff to the revised standard operating procedures that were completed in 2003 was discussed and evaluated. Modifications to the operating procedures are being introduced as a result of new data management software, technological changes and decentralization of some of the unit's functions for some projects.

2.2 Planned activities

Support will continue as described under section 2.1. In addition, an external evaluation of the procedures used in the unit will be conducted in 2005 to assess their efficiency and quality and to propose cost-effective ways of improving data-management procedures, speeding up data flow and the resolution of queries and shortening the lag time between study onset and publication of results.

In the area of software development, the two data management systems developed by the unit will be tested. The portable data management system (DMS/3) will be tested in two centres in Kenya and one in Burkina Faso. Decentralized

data management will be tested as part of the Kesho Bora study on the impact of highly active antiretroviral treatment on mother-to-child transmission of HIV (see Chapter 3, section 3.1.3.2).

3. OBJECTIVE: TO PROVIDE SUPPORT TO INSTITUTION-STRENGTHENING ACTIVITIES

The aim is to strengthen the statistical and data-processing capabilities of selected institutions in developing countries in order to support their research work.

3.1 Progress

Highlights of activities during 2004 are summarized below.

3.1.1 Site-visits

On-site training of staff at collaborating centres participating in international multicentre trials has continued. A centre in Harare, Zimbabwe, was visited to review data problems that arose during a comparative study of two implantable contraceptives for women. Site-visits were conducted for training in preparation for the introduction of decentralized data management; site-visits were also conducted to aid in supervising data collection, managing data queries, assessing data quality and monitoring the study's progress. A centre in Mombasa, Kenya, was visited to train data managers for the Kesho Bora study.

3.1.2 Training courses, seminars and workshops

- Lectures were given at the 14th postgraduate course for training in reproductive health in February 2004 organized by the Geneva Foundation for Medical Education and Research, the Programme, the Department of Reproductive Health and Research and the International Association for Maternal and Neonatal Health; the course was attended by 34 participants.
- A course on Stata software was taught at the National Institute for Research in Reproductive Health as part of the WHO reproductive health research methods course in Mumbai, India.
- A staff member from the unit participated in a workshop organized by the WHO Office for Iraq, in Amman, Jordan, to discuss further analysis of data from the 1999 survey of child and maternal mortality.
- Another staff member taught a course on the design of clinical trials at the University of Uruguay in Montevideo, Uruguay.

3.2 Planned activities

Support will continue according to demand from different areas of work.

Annex 1

PUBLICATIONS AND SOFTWARE DEVELOPED IN 2004

Publications

Ali MM, Cleland JG. Sexual and reproductive behaviour among single women aged 15–24 in eight Latin American countries: a comparative analysis. *Social Science and Medicine* (in press).

Ali MM, Cleland JG, Shah IG. Response to Raymond and Trussell. *Bulletin of the World Health Organization* (in press; letter to the editor).

Ali MM, Cleland JG, Shah IH. Condom use within marriage: a neglected HIV intervention. *Bulletin of the World Health Organization*, 2004, 82:180–186.

Che Y, Cleland JG, Ali MM. Periodic abstinence in developing countries: an assessment of failure rates and consequences. *Contraception*, 2004, 69:15–21.

Cleland JG, Ali MM. Reproductive consequences of contraceptive failure in nineteen developing countries. *Obstetrics and Gynecology*, 2004, 104:314–320.

D’Arcangues C et al. on behalf of the Study Group on Progestogen-induced Vaginal Bleeding Disturbances. Effectiveness of vitamin E and low-dose aspirin, alone or in combination, on Norplant-induced prolonged bleeding. *Contraception*, 2004, 70:451–462.

Gülmezoglu AM et al. WHO systematic review of maternal mortality and morbidity: methodological issues and challenges. *BiomedCentral Medical Research Methodology*, 2004, 4:16.

Gülmezoglu AM et al. Cluster randomized trial of an active, multifaceted educational intervention to change obstetric practices (submitted).

Hill ZE, Cleland JG, Ali MM. Religious affiliation and extra-marital sex in Brazil. *International Family Planning Perspectives*, 2004, 30:20–26.

Honkanen H 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. II: Side-effects and women’s perceptions. *British Journal of Obstetrics and Gynaecology*, 2004, 111:715–725.

Lumbiganon P et al., for the Antenatal Care Trial Research Group. Risk based approach in selecting haemoglobin cut-off levels for the diagnosis of anaemia in pregnancy (submitted).

Piaggio G. Contraceptive research. In: Machin D, Day S, Green S, eds. *Textbook of clinical trials*. Chichester, John Wiley and Sons, 2004:315–336.

Piaggio G, Elbourne D, Altman D, for the CONSORT Group. CONSORT: extension to equivalence trials (submitted).

Stephenson JM et al. Pupil-led sex education in England (RIPPLE study): cluster-randomized intervention trial. *Lancet*, 2004, 364:338–346.

Villar J et al. Heterogeneity of perinatal outcomes in the preterm delivery syndrome. *Obstetrics and Gynecology*, 2004, 104:78–87.

Software developed

Pinol A. Analysis of menstrual bleeding patterns (AMBP), version 1.1, February 2004.

Pinol A. Data Management System, DMS/3 Portable, version 1.7, September 2004.

Appendix 1

Staff of the Department, December 2004

Paul Van Look, Director

Programme Management

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 Luc Bernier, Reproduction Equipment Operator¹
 Catherine d'Arcangues, Coordinator¹
 Barbara Kayser, Secretary
 Craig Lissner, Technical Officer
 Manjula Lusti-Narasimhan, Technical Officer²
 Michael Mbizvo, Coordinator
 Bérengère Nail, Secretary
 Corinne Penhale, Administrative Assistant¹
 Lihong Su, Technical Assistant¹
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