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Final Report

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INTRODUCTION

The Population Council Programmatic Cooperative Agreement CCP-A-00-94-00013 began 30 September 1994 and ended 30 September 2000. It supported several important Population Council efforts, mainly in the Contraceptive Development program and the Expanding Contraceptive Choice (ECC) project. The Contraceptive Development program develops, evaluates, and brings to market new and better products for family planning and prevention of sexually transmitted infections. The Expanding Contraceptive Choice project works to expand the number of contraceptive methods available by appropriately introducing or reintroducing methods into service-delivery settings.

About 7 percent of agreement funds supported study of the effect of improved service delivery on family planning use, maternal and child health, and prevention of sexually transmitted infections (STIs) in Ghana (the Navrongo project); the examination of selected topics regarding adolescents; and demographic analysis.

USAID missions contributed about 17 percent of agreement funding. Most of this was for capacity-building and technical assistance programs in Bangladesh; the Peru mission provided funds for a small gender study. Under the ECC project, activities were supported to different degrees by the Brazil, Senegal, Zambia, India, Kenya, Mexico, Tanzania, Nicaragua, and Honduras missions; and the Navrongo project was assisted by funding from the Ghana mission.

In addition, USAID's Africa Bureau initiated over a million dollars in funding for operations research on integrating STI prevention into service delivery in Africa; and the Health and Nutrition Office provided funding for a pilot microbicide study.

Very small amounts of funding went to a 1995 donor workshop; and travel for Reproductive Health program staff to participate in international meetings.

This document serves as the final report on work under the agreement. A new Population Council Programmatic Cooperative Agreement, HRN-A-00-99-00010, began on 13 August 1999 and will continue its efforts through 31 August 2004. The major programs of work supported by CCP-A-00-94-00013 continue to be supported by the current Programmatic Cooperative Agreement.

It is expected that an appendix to this document, listing all publications and other written works produced under the agreement, will be issued before the end of the year 2001.

October 2001

CONTRACEPTIVE DEVELOPMENT

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CONTRACEPTIVE DEVELOPMENT

Work conducted at the Population Council's Center for Biomedical Research (CBR) under USAID Programmatic Cooperative Agreement CCP-A-00-94-00013 covered the period 30 September 1994-30 September 2000. This critical support to the Council's Contraceptive Development program enabled us to make excellent progress in the contraceptive projects under development.

The broad objectives of the Contraceptive Development program are: to increase the number of contraceptives that are registered for use in family planning programs; to complete the development of new contraceptives and other reproductive health products with specific advantages over existing methods; and to identify new leads that can be developed into safe and effective contraceptive methods for men and women. Greatest emphasis is given to contraceptives that are especially suited for distribution to family planning programs in developing countries and that meet the needs of special user groups whose requirements have not been adequately addressed in the past.

The greatest potential for achieving the objectives outlined above lies in engaging commercial partners for the mass manufacture of individual methods, and a good indicator of our success to date is the extent to which the Council's products have been found to be acceptable by industry. As widespread use of products developed by the Council continues, we favor the licensing of our products to world-leading companies in reproductive medicine. In this endeavor, the track record of the Council is excellent. Norplant[®] and Jadelle[®] are licensed to Wyeth-Ayerst for the Americas and Western Europe, and to Leiras-Schering for the rest of the world; the TCu 380A to Ortho for North America; and Mirena[®] to Leiras-Schering worldwide. Recently, the Council concluded a licensing agreement with Schering AG to develop, manufacture, and market the synthetic androgen MENT[™] for contraception and hormone replacement therapy (HRT). A licensing agreement is also in effect with Orion Corporation for the development of transdermal gels containing the synthetic progestin Nestorone[®] (NES) for contraception and HRT. Under this cooperative agreement, USAID provided significant support for studies on methods containing MENT and NES. Data from these studies were instrumental in concluding the licensing agreements with Schering and Orion. USAID funding was also vital to the completion of the Phase 2 trials of the contraceptive ring releasing NES and ethinylestradiol (EE). Data from these studies led to the dose and usage schedule for the pivotal Phase 3 trial planned for initiation during 2002, which will form the basis for registration of the device with the US Food and Drug Administration (FDA).

The clinical studies of the program are conducted by our clinical network, the International Committee for Contraception Research (ICCR). The ICCR consists of investigators from several countries who serve as consultants in the clinical evaluation of potential methods. The clinics are selected for their commitment to reproductive health and their ability to perform Phase 1 and 2 studies. The clinics are rigorously monitored and over the years have developed skills, competencies, and a superb understanding of the product development process that go far beyond those of a classic clinical network. ICCR members work closely with CBR staff in New York in the design of delivery systems, prototypes, and clinical protocols for the products under development.

The development of contraceptives from the prototype stage through Phase 2 testing of new methods requires modern laboratory facilities that are compliant with Good Laboratory Practices and Good Manufacturing Practices. USAID provided significant support for the renovation of laboratories at the Council's Center for Biomedical Research under this cooperative agreement. The laboratories had not been renovated since 1975, and the need to modernize the facilities was readily apparent. Construction began in

September 1998. Contraceptive Development staff moved into their new laboratories in August 1999 and renovations were completed on all three floors in October 2000.

During the 1994–2000 period, USAID supported the development of the following methods for women: subdermal implants, contraceptive rings, transdermal delivery systems, and microbicides. Methods for men that benefited from USAID support include subdermal implants, transdermal delivery systems, and an immunocontraceptive.

Norplant and Jadelle

Work on subdermal implants for women during the cooperative agreement period included the completion of clinical trials of Norplant and Jadelle. The Norplant studies were required by the FDA to increase the precision of the data used for the labeling of the soft-tubing levonorgestrel-releasing implants. A regulatory submission requesting approval of Norplant for a seven-year period was prepared for the FDA. For the seven-year period, the pregnancy rate for women using these implants is 2 per 100, equivalent to sterilization. A regulatory submission of Jadelle for a five-year period was also prepared for the FDA. The five-year cumulative pregnancy rate for Jadelle is 1.1 per 100, identical with that of Norplant for the five-year period. In addition, Jadelle has proven to be easier for health care workers to insert and remove than Norplant.

The Postmarketing Surveillance Study of Norplant, carried out in collaboration with the World Health Organization and Family Health International, was completed during the period. This study was designed to identify events of public health importance among 8,000 women using Norplant and an equal number of controls, and to determine the relative risk of such events to implant users as compared with the controls. Results showed that major illness among women using these implants is similar in incidence to the morbidity experienced by women using nonhormonal methods of contraception.

Nestorone Implant

The attractiveness of an implant containing NES is that this steroid does not affect serum lipoprotein patterns, carbohydrate metabolism, or liver proteins. In addition, because it is not active when administered orally as a result of a high rate of first-pass hepatic metabolism, NES may be appropriate as a contraceptive for lactating women. A Phase 2 dose-finding study was completed in which 120 women used an NES implant for two years. While the 100 µg/day dose was selected for further development, one pregnancy occurred in month 24 of use. Accordingly, the implant was reformulated to give a margin of safety of at least three to six months beyond its expected life of two years. This reformulated implant is longer (4.5 cm), has a smaller diameter, and contains a higher drug load than the 4-cm formulation, enabling it to release more NES than the earlier implant. A two-year Phase 2 clinical trial of the reformulated implant commenced, and initial results are very encouraging.

A study was conducted to correlate the *in vivo-in vitro* release rates of NES from implants. A two-year study was also concluded of a single implant releasing 100 µg/day in lactating women, with lactating users of intrauterine devices as controls. Infant growth and health parameters were similar in the two groups. The data from the study confirm our expectations that the NES implant will provide long-term contraceptive protection to nursing women without adversely affecting the health or growth of the infant. A study was undertaken to determine the volume of uterine bleeding in subjects using progestin-only methods (Norplant, NES implants releasing 100 and 150 µg/day, and NES rings releasing 100 µg/day). All methods under study

manifested marked diminution in the volume of blood loss as compared with the volume lost in control cycles. In addition, a dose-finding study of higher-dose implants in women with endometriosis was carried out to yield pharmacokinetic data from women who might benefit from treatment with the implants. The majority of subjects reported relief of their endometriosis-related pain from the treatment. Market approval for the original silicone tube NES implants was received in Brazil in early 1998. This implant lasts for six months and while the indication for which it was approved is endometriosis, it can also be used as a contraceptive.

Contraceptive Rings

The development of contraceptive rings was a major research activity during the period. This device is a sustained-release drug delivery system for women desiring a low-cost, user-controlled steroid hormonal contraceptive method. The ring can also deliver other therapeutic agents for female reproductive health care. Initially, efforts were focused on the development of a ring containing norethindrone acetate and ethinylestradiol (NET Ac/EE). Phase 2 studies evaluating the effectiveness of this one-year ring as a contraceptive were successful, and the findings of these studies were published in peer-reviewed journals.

Concurrent with these studies, we explored the possibility of developing rings using a progestin with a better safety profile. One approach was to develop a ring containing NES and EE. Early Phase 2 trials of NES/EE rings lasting for one year indicated that women on the two doses studied maintained progesterone levels known to block ovulation, and both dosage forms gave good cycle control. To further refine the dose and usage schedule for commercialization of the ring, we conducted two additional Phase 2 studies. A one-year study in five clinics with rings of three NES/EE ratios (200/15, 150/20, and 150/15 μg per day) was completed. Excellent bleeding patterns, ovulation inhibition, subject compliance and continuation resulted, with the 150/15 μg dose selected for further development. A second trial of the NES/EE ring was conducted to determine whether removing the ring and keeping it out for an interval shorter than the standard one week would provide acceptable menstrual patterns and ovulation inhibition. Results indicated no change from the standard practice. A third study is very close to completion, in which a woman keeps the ring in place until she begins her menstrual bleeding, at which time she removes the ring for four days and then replaces it until the next "bleeding signal." Since the ring is out for only four days, a much shorter period than the standard schedule, the dosage of both NES and EE can be reduced. Data from the three studies described are being used to plan the large, pivotal Phase 3 study that will form the basis for the filing of a new drug application with the FDA.

Because NES is inactive when taken orally, a ring releasing NES alone was seen as a potentially appropriate method for lactating women. In a study of the ring used continuously in lactating women, the ring performed well and was well accepted by the women, although unpredictable bleeding patterns resulted. In addition, while a dose-finding study examining the performance of three doses of NES rings indicated good ovulation inhibition at all doses during correct use, irregular bleeding patterns were also observed at all doses and were a frequent reason for discontinuation. In an effort to resolve this side effect, it was decided to add estradiol to the ring formulation. Accordingly, a six-month study was carried out comparing menstrual patterns in subjects using rings delivering either 50 μg of NES or 100 μg of NES plus 180 μg of estradiol. Bleeding patterns were not significantly different from those associated with the earlier formulations, and the NES/estradiol ring lead was dropped.

Transdermal Delivery of Nestorone

Transdermal delivery of steroids will provide a reversible method of female contraception that is under the user's control. NES is uniquely adaptable to transdermal delivery because of its high potency and its ability to penetrate the skin. Our initial efforts to develop gel formulations to deliver NES were stymied in late 1994 when some of the preparations used in the formulations previously tested became unavailable. Council staff prepared a new formulation that gave excellent results *in vitro*, and clinical trials with this preparation were completed with excellent results. However, feedback from clinic personnel and patients indicated that the formulation was slightly "sticky" to the touch and that it took too long to dry on the skin. A faster-drying, more cosmetically appealing gel was formulated and, following acceptability, pharmacokinetics, and bioavailability studies, this gel was entered into a dose-finding study. Data from the study indicated that incidences of ovulation decreased with increasing concentrations of NES. The NES doses studied were 0.3, 0.6, and 1.2 mg of NES per day; maximum blood concentrations of NES were attained between four and eight hours following gel application. Further studies have demonstrated that: (1) the drug disappears from the skin shortly after gel application; (2) the size of the zone of gel application (50, 100 or 200 cm²) did not influence blood concentrations of NES; and (3) following NES gel application, blood concentrations of the steroid were higher when the gel was applied in a relatively high humidity environment, compared to one of relatively low humidity.

Efforts to develop transdermal patches containing NES showed initial promise when a joint development agreement was signed with a company to develop patch formulations of NES alone and in combination with estradiol. Extensive staff resources were dedicated to this effort; while the two-and-a-half-year collaboration was fruitful, the company was purchased by a pharmaceutical house that had no interest in developing female reproductive health products. Hence, the joint development agreement was terminated, and a search commenced to identify a new partner for development. This effort has borne fruit in the months since the end of the cooperative agreement.

Nestorone, Not Method-specific

Council scientists conducted pharmacology and toxicology studies required by regulatory agencies for all methods containing NES in order to complete the safety profile of this steroid before introduction. The potential of NES as a mutagen was investigated and in three different tests was found to be nonmutagenic. A study to investigate the potential of NES to induce cytochrome p450 enzymes in cultured human hepatocytes was carried out to evaluate drug interaction in the body. A genotoxicity study of NES was conducted; NES was found to be nongenotoxic in three different tests. A local toxicology study of NES vaginal rings was also conducted, and the rings were found to cause no toxic effects in the animals tested. A 24-month carcinogenicity study of NES in rats is continuing. In addition, USAID supported radioimmunoassay of clinical blood samples from the studies of NES methods described in this report.

Subdermal Implants for Men

Contraceptive choices for men are limited to condoms, vasectomy, withdrawal, and abstinence. The development of long-acting, reversible methods for men would represent a valuable addition. The effort to develop subdermal implants for men represents our lead project in this area. We initially focused on two approaches. Laboratory studies suggested that a gonadotropin-releasing hormone (GnRH) analog (a peptide) plus an androgen might be an effective hormonal contraceptive for men. In collaboration with an industrial partner, we developed two separate implants for this system: an implant releasing the GnRH

analog and another for the androgen. Implant administration of GnRH analogs appeared to suppress the release of GnRH-dependent pituitary hormones and, consequently, sperm and testosterone production. Clinical trial results indicated, however, that while the method was effective as a treatment for prostate cancer patients, follicle-stimulating hormone (FSH) was not sufficiently suppressed to be effective for contraceptive use. Consequently, this lead was closed and all rights for future development of the peptide implant were transferred to our industrial partner.

The androgen MENT has several advantages over the currently used androgens. When used in appropriate doses, it maintains potency and libido but is less stimulatory to the prostate than testosterone, thus avoiding the possibility of prostate hypertrophy. Studies revealed that MENT acetate (MENT Ac) diffuses more quickly from implants than MENT. Accordingly, implants made for dose-finding studies were fabricated using the MENT Ac formulation. A four-week clinical study of MENT Ac implants in normal men showed that this method of MENT administration was highly effective in suppressing gonadotropins, which control sperm production. A six-week study using MENT Ac implants in hypogonadal men showed MENT to be superior to testosterone enanthate injections, the standard treatment for hormone replacement therapy. In order to conduct long-term studies of this method, we undertook animal toxicology studies to ensure long-term safety. Following completion of the animal toxicology studies, the effects of one, two, or four implants on spermatogenesis were studied in normal men. This study yielded data indicating that the use of four implants resulted in azoospermia in most of the men. Although it was originally planned as a six-month study, some subjects agreed to remain in the trial for nine and 12 months, as the implants appeared to release enough drug to maintain a contraceptive effect for longer than six months. In a second study, hypogonadal men are using either one or two implants as hormonal replacement therapy for six months. This study is continuing, but preliminary results are also encouraging. Toward the end of the cooperative agreement period, a licensing agreement was signed with Schering AG to develop, manufacture, and market MENT for contraception and HRT. Schering has indicated its support of the Council's future plans to develop MENT implants.

Transdermal Delivery of MENT

After finding that MENT is permeable through animal skin *in vitro* at a rate three times that of NES, we undertook laboratory studies to optimize the formulation for transdermal delivery of MENT. A bioavailability study was conducted in three clinics to determine serum levels of MENT on days one and seven following seven consecutive daily single applications of 1.0 ml MENT gel (containing 8 mg of MENT); testosterone and gonadotropins were also measured. An additional objective was to ascertain how soon MENT was cleared from the systemic circulation following the last gel application. Results indicated that the gel delivering MENT gave maximal blood levels of the steroid approximately four hours after administration, with higher concentrations on day seven rather than day one. Gonadotropins were suppressed by 57 percent compare to baseline values. Testosterone was also suppressed, by about 52 percent compared to baseline values. Data from the study indicated that MENT was cleared from the systemic circulation within 72 hours of the last gel application. These results indicate that the transdermal approach to MENT delivery is viable for contraceptive and HRT indications. Future development of this approach will depend on the Council's interaction with its commercial partner, Schering AG.

MENT, Not Method-specific

Council scientists conducted pharmacology and toxicology studies required by regulatory agencies for all methods containing MENT. These studies are necessary for completing the safety profile of this steroid

before introduction. A six-month chronic toxicity study was conducted in rats, and a one-year chronic toxicity study was carried out in monkeys. No serious toxicity was observed in either species. Mutagenicity studies were also conducted; in three different tests, MENT was found to be nonmutagenic. In addition, USAID supported radioimmunoassay of clinical blood samples from the studies of MENT methods described in this report.

Gonadatropin-releasing Hormone Immunocontraceptive

Council scientists have developed an immunocontraceptive for men based upon eliciting antibodies that neutralize the biological effects of GnRH, thus suppressing gonadotropic hormones, testosterone, and sperm production. A clinical trial of the prototype formulation in prostate cancer patients showed no adverse effects in men who received the standard three-injection protocol. Before permitting a clinical trial in normal men, the FDA required that a new investigational new drug application be filed. This task was completed, and a clinical trial was initiated in which 20 normal men were immunized with the gonadotropin-releasing hormone–tetanus toxoid conjugate (GnRH-TT) immunocontraceptive formulation. While all subjects have completed the study, the final data are undergoing analysis. Some subjects responded immediately to immunization, exhibiting high anti-GnRH titers, suppression of testosterone, luteinizing hormone, and FSH, and suppression of spermatogenesis. Other subjects were late responders, showing some effect of immunization, while still others did not respond to immunization. The underlying reasons for this variation are not clear, and a decision will be taken as to future plans on this project following a review of the final data from the recently concluded clinical study, and consultation with experts in immunology in general and GnRH in particular.

Conclusion

USAID support to the Council's Contraceptive Development program under Programmatic Cooperative Agreement CCP-A-00-94-00013 was instrumental to the progress attained from 1994 to 2000 in the methods described here. Significant advances were seen in most of the projects under development; in cases where methods did not work out in the manner planned, leads were dropped or re-evaluations took place to determine future strategies. Because the commercialization of these products holds the greatest potential for achieving our goals, it is noteworthy that USAID support of the Council's contraceptive development efforts led to a more enhanced interaction with industry than existed before 1994: of the methods listed in this report, all but two involve interaction with a commercial partner.

EXPANDING CONTRACEPTIVE CHOICE

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Over the past decade, the Population Council, working internationally in diverse health care settings, has made major contributions to reproductive health knowledge. Since the mid-1980s, the Council has engaged in a variety of programs to expand contraceptive choice through appropriate technology introduction. The first program focused exclusively on introducing the fertility-regulation technologies developed by the Council—the Copper T 380A intrauterine device (IUD) and Norplant® contraceptive implants. In 1992, the program expanded to include other appropriate contraceptive technologies, not only those developed by the Council.

Based on lessons learned from contraceptive introduction efforts as well as the recommendations from the International Conference on Population and Development (ICPD), in particular placing individuals' family planning needs within a reproductive health context, the program entered a new phase in 1994. Renamed Expanding Contraceptive Choice (ECC) to reflect these changes, the focus shifted from the introduction of single technologies to a broader assessment of how a range of contraceptive options could influence the adoption, use, and continuity of family planning across the reproductive life span of individual women.

ECC began to approach the introduction of a variety of suitable technologies in a more holistic way. ECC addresses the broader issues of method mix, service systems capacity, user perspectives, and programmatic feasibility.

Overview

Program Aims and Staffing

Since 1994, the ECC project has sought to broaden the range and availability of contraceptive options for women and men and to improve the quality of care (QOC) associated with the provision of contraceptive services. The overall objective was to develop and implement effective mechanisms for introducing within national family planning programs a range of contraceptive technologies that were safe, acceptable to users, programmatically feasible, and that expanded choice in ways consistent with individuals' reproductive health goals.

The support provided by USAID allowed for a systematic approach to the introduction of contraceptive technologies. The program combined technical assistance, provider training, and policy dialogues to improve the availability of, access to, and quality of contraceptive services within a reproductive health framework. Program staff worked closely with policymakers; service providers, managers, and planners; medical and nursing educators and trainers; and women's groups to improve both the contraceptive options of clients and the technical competence of providers. In addition, the program's objectives were furthered by activities funded by USAID field missions, carried out in collaboration with national and regional ministries of health (MOHs).

The work was implemented by regionally based medical associates and social scientists. The West and Central Africa (WCA) region was staffed by medical associate Penda N'Diaye in Dakar, Senegal; the East and Southern Africa (ESA) region was staffed by medical associate Davy Chikamata, social scientist John Skibiak, and project coordinator Lucy Abubaker (1994–98), based in Nairobi, Kenya; the South and East Asia (SEA) region was staffed by social scientist Sandhya Joshi (1997–99) and medical consultant Rohit Bhatt (1996–98), based in Baroda, India. Dr. Bhatt's participation was supported entirely by funding

provided by the USAID/India field mission. Activities in Latin America and the Caribbean (LAC) were overseen by medical associates Juan Díaz and Anibal Faundes (1994–95) in Campinas, Brazil.

In New York, staff provided administrative oversight and served as liaisons with USAID/Washington. Andrew Fisher served as the International Programs Division's director of family planning, with responsibility for the ECC project from February 1995 through July 1997. Martha Brady served as associate director from October 1994 through July 1997. She was named director in August 1997 and served in this position through December 1999. Suellen Miller became director in January 2000, overseeing end-of-project activities and continuing as director under the follow-on Programmatic Cooperative Agreement. The director in New York was assisted by a program manager—Elizabeth Westley in 1994–95, Valerie Moulay-Omar in 1996–97, Ellin Kao in 1998–99, and Barry Ravitch during end-of-project activities in 2000 and continuing under the follow-on agreement.

Multidisciplinary Approach

ECC's unique multidisciplinary approach to the introduction of contraceptive technologies enabled program staff to work on several components simultaneously, coupling clinical and social science expertise, thereby enhancing program capacity to apply lessons learned to diverse project settings. The scope of work encompassed such key areas as quality of care; improving the policy environment; furthering USAID's Initiative to Maximize Access and Quality (MAQ); assessing the impact of interventions on the use of new methods; conducting training and contraceptive technology updates (CTUs); using the Internet to allow for rapid updating of knowledge; introducing and evaluating both Norplant implants and the injectable Depo-Provera[®] in new settings; assessing barrier methods (male and female condom, diaphragm) in specific settings; introducing emergency contraception (EC) and the various methods of EC provision; collaborating with the World Bank, the United Nations Development Program (UNDP), the United Nations Population Fund (UNFPA), and the World Health Organization (WHO) in the development and implementation of a conceptual framework/strategy for expanding family planning options; and working with other USAID-funded cooperating agencies and other US and international nongovernmental organizations (NGOs).

Summary of Selected Program Activities

Development and Implementation of an Expanding Contraceptive Choice Framework

The ECC project took a holistic and systematic approach to broadening contraceptive choice. To accomplish this, ECC staff, working with and serving on the WHO Task Force on Research on Introduction and Transfer of Technologies for Fertility Regulation, developed the Strategic Approach to Improving the Quality of Reproductive Health Services (*Contraceptive Introduction Reconsidered: A Review and Conceptual Framework*^a). The framework provides national health systems with a three-stage process for decisionmaking on contraceptive introduction. Stage I is an overall assessment of user and service-delivery needs, program policies, and the identification of potential program constraints. Stage II is the design and implementation of research to examine issues affecting services. Stage III focuses on the application of research results to decisionmaking and scaling-up of interventions. This methodology not only involved but *required* the support of stakeholders, including health care service-delivery agencies; women's health advocacy group members and leaders; health care providers; community leaders and community members;

^a Published by the UNDP/UNFPA/WHO/World Bank Special Program of Research, Development & Research Training in Human Reproduction, Geneva, 1994.

men as husbands, sexual partners, and service users; and marginalized populations, such as commercial sex workers and adolescents.

Quality-of-Care Projects Under the WHO Framework

USAID provided support to ECC's contraceptive intervention projects once appropriate and thorough needs assessments were conducted in accordance with the WHO Strategic Approach. In Brazil, the successful implementation of the Strategic Approach in one demonstration municipality and subsequent expansion into three additional municipalities prompted other states to request technical assistance. ECC developed a strategy for further expansion into additional municipalities, identified potential sites, recruited partners, and secured funding for a larger-scale expansion and replication study. In collaboration with the University of Michigan School of Public Health's Department of Health Behavior & Health Education and Reprolatina, a Brazilian NGO, ECC received a five-year grant from the Bill & Melinda Gates Foundation to expand and replicate the WHO Strategic Approach in six municipalities in the first year and implement sustainability strategies. One innovative aspect of this project is an Internet communications system using O'Reilly® WebBoard™ software that will enable interfacility communications on contraceptive technologies and QOC issues.

Influencing the Policy Environment Through Technical Assistance and Dissemination

Another important component of ECC's activities was to improve the policy environment for expanding contraceptive choice. Program staff provided technical assistance to USAID and UNFPA country missions, MOHs, and professional organizations on fertility-regulation methods, QOC, and technology introduction and reintroduction strategies.

Program staff participated in national and international conferences and workshops that informed the policy arena. Examples at the policy level include ECC's support to the Margaret Sanger Center International for a workshop on EC in Malawi for southern African policymakers. The purpose was to assist these policymakers in formulating guidelines for EC within their countries. Another example is a series of workshops, seminars, and lectures conducted in Gujarat State, India for governmental administrators, NGOs, women's groups, physicians, and social scientists to reduce barriers to contraceptive method availability and choice.

ECC also supported and participated in gatherings of regional professional societies, including the conferences in West Africa of the Society for African Gynecologists and Obstetricians (SAGO) and the Society of Women and AIDS in Africa (SWAA), and of the Latin American Association of Researchers in Human Reproduction (ALIRH). ECC also provided support for a symposium at the International Congress of the Society for the Advancement of Contraception on implant technologies and delivery systems for hormonal contraception. This symposium also offered an opportunity to discuss the MAQ Initiative with providers from the LAC region.

Contraceptive technology updates and reproductive health guidelines. Globally, ECC has conducted CTUs for providers, policymakers, program planners, donors, and other family planning and reproductive health professionals in Brazil, India, Kenya, Tanzania, and Zambia. In Brazil, CTUs on IUDs, surgical contraception, barrier methods, and fertility awareness were conducted to assist the MOH in revising their national guidelines. To assess the effect of guidelines on service delivery in Kenya, ECC collaborated with Family Health International (FHI) and JHPIEGO to assess whether formal training of providers on issues

contained within the revised national reproductive health guidelines improved provider knowledge, attitudes, and practices, thereby reducing medical barriers to contraception.

Grassroots-level policy activities. ECC also worked closely with women's and adolescents' community-based groups and other grassroots groups in numerous countries. One example was India, where ECC conducted workshops, seminars, and lectures for women's groups, providers, and policymakers to sensitize them to current issues in contraception and family planning in order to reduce barriers to method availability and choice. Another was a workshop on the role of implants and barrier methods in the family planning program in Brazil. With additional support from the Brazilian Federation of Gynecology and Obstetrics Societies (FEBRASGO) and a national network of feminist groups—represented by the organizations S.O.S. Corpo from Recife and the Feminist Sexuality and Health Collective of Sao Paulo—the goal of the meeting was to address concerns about new and current contraceptive technologies and to elicit suggestions on the most effective ways to introduce Jadelle® implants when they become available. This workshop laid the groundwork for introducing the new technology in a positive fashion that may potentially avoid the mistrust that occurred when Norplant was introduced in Brazil.

Contraceptive Technology Introduction/Reintroduction and Expanding Choice

Although there was little practical progress in new contraceptive method development, ECC worked on the introduction of the female condom and a new use for hormonal pills as postcoital contraception, in both the Yuzpe regimen and as a dedicated product. An older method that had declined in use, the three-month contraceptive injection Depo-Provera, was made more widely available, and older barrier methods such as the male condom and the diaphragm were reintroduced in some projects. Progress was made toward reducing medical requirements and eliminating some of the unnecessary medical contraindications to the use of hormonal methods and IUDs.

Barrier methods. ECC continued to work to integrate male and female barrier methods into national family planning programs. Not only did we look at the unique program requirements necessary for the proper introduction of barrier methods, but we also examined user perspectives and documented niche populations whose needs matched specific method characteristics.

In Brazil, ECC conducted a study to explore the effectiveness of using the diaphragm continuously without spermicide as compared to the conventional method of diaphragm use. After the first year, pregnancy rates with continuous use were only slightly higher than with traditional use (10.0 per 100 women versus 6.6 per 100 women), an increase that was not statistically significant. The study results demonstrated that, for these participants, the continuous-use model could be as effective as traditional use.

In Colombia, ECC began a study to assess the acceptability, service-delivery requirements, and use effectiveness of the diaphragm. However, the study was halted when the US government denied narcotics certification to Colombia, making it illegal to continue using federal funds there.

Studying the acceptability of the female condom has become more urgent because of the continuing high transmission rates of HIV and sexually transmitted infections (STIs) among women in developing countries. There is a critical need to ensure that female-initiated and female-controlled barrier methods are introduced into family planning programs and into women's hands. At the Population Council, ECC served as a resource for technical and social/behavioral information on the female condom and its acceptability among varied groups and subgroups. ECC staff introduced the female condom and/or studied acceptability

among different groups in Brazil, Burkina Faso, and Senegal, and have added female condoms to the method mix in Ethiopia and Zambia. In studies in Brazil and Senegal, acceptance of the female condom was low among many family planning clients; this low use was attributed to male partners' objections. In both countries, acceptability was higher among female commercial sex workers (CSWs). Both among CSWs and other family planning clients, cost was cited as a major obstacle to continued use.

In the Burkina Faso study, ECC used a peer-educator, community-based approach to introduce the female condom. Male and female adolescents were recruited, along with their sexual partners, to participate in a longitudinal study of knowledge, attitudes, and practices. The preliminary results demonstrate a strong positive association between participants' satisfaction with the method and their satisfaction with counseling about the method. Not surprisingly, the findings reveal a strong association between overall dissatisfaction with the female condom (including complaints of such problems as slippage and pain) and participants' dissatisfaction with the method-specific counseling they received. As in the previously cited studies, the Burkina participants stated that cost was a major barrier to ongoing use.

Norplant. ECC continued to introduce Norplant into national family planning programs. To improve accessibility and to lower cost, ECC examined the feasibility of nonphysicians as providers of Norplant services. In Kenya, ECC conducted a pre-training needs assessment and then trained nurses to provide Norplant services. Post-training, the nurses were found to be competent to provide counseling and Norplant insertions. In Tanzania, a similar study demonstrated that, with proper training, paramedical staff could become proficient in providing Norplant services.

In Ethiopia and Senegal evaluations were planned, in collaboration with the MOHs, for the national Norplant programs, and the Senegal evaluation began implementation. In both projects, large-scale, costly situation analyses (SAs) will be avoided by using more cost-effective, Norplant-focused data-collection activities based on a modified form of existing SA tools. Activities will be concluded for these projects under the follow-on cooperative agreement.

A Norplant demonstration project was conducted in Zambia between August 1996 and June 1999. Working with the MOH, ECC introduced Norplant in 16 service-delivery sites along the "line of rail" (Kabwe, Kitwe, Ndola, Livingstone, and Lusaka) and trained 72 service providers (47 in face-to-face training sessions and 25 on-the-job). The providers developed and maintained a registry system that documented that 4,478 women had received Norplant by the end of the project.

In Mexico, a study was conducted to assess the continuation rates of Norplant when introduced as part of postabortion family planning services. At the time of the study's completion at one-year follow-up, continuation rates exceeded 90 percent.

Depo-Provera. A study of Depo-Provera introduction within a context of QOC and enhanced choice was carried out in rural regions of the Copperbelt Province in Zambia. The study was a collaboration between the MOH, CARE, WHO, ECC, and the Zambia Family Planning Services Project. Phase One of the study comprised a baseline SA; an intervention of Depo-Provera introduction; provision of information, education, and communication (IEC) materials; strengthening of service delivery; and training. Results of Phase One demonstrated increases in new acceptors of all methods, including Depo-Provera. Phase Two will be completed in 2001, under the follow-on cooperative agreement.

A study is ongoing in India to test the feasibility of having private practitioners provide injectable services. ECC, in collaboration with EngenderHealth (formerly AVSC International), the Population Council's Frontiers in Reproductive Health program, and DKT International, introduced Depo-Provera to private medical practitioners in urban Gujarat state. Initial results indicated that training private practitioners and providing subsidized rates on Depo-Provera did not affect overall use of all methods and has not yet had a positive association with enhanced choice. Activities supported by this cooperative agreement were completed during fall 2000, and the project continues under the USAID-funded FRONTIERS program. Final results of the ECC component will be available during 2001.

To improve the quality of Depo-Provera provision in Nicaragua, ECC staff conducted training needs assessments at 71 service-delivery points in seven regions; findings of this study were used to improve the overall quality of counseling and services, including the development and implementation of improved methods for client follow-up.

In Zambia, Depo-Provera and Norplant were introduced experimentally in urban clinics in Lusaka as part of the Impact Studies program.

Emergency contraception introduction. Emergency contraception is an adaptation of older technologies for postcoital contraception. The use of either combined oral contraceptives (the Yuzpe regimen) or progestins (levonorgestrel in a dedicated product, or levonorgestrel or norgestrel in progestin-only contraceptive regimens) has required assessments of both providers and users to discover their knowledge, attitudes, biases, and fears, in order to develop appropriate interventions for EC introduction. In Brazil, ECC provided leadership in the registration of a dedicated product (Postinor) and, in collaboration with the Pacific Institute for Women's Health and the AIDS Prevention Studies Nucleus (NEPAIDS), conducted training workshops on EC for NGOs throughout the country. Leaders of grassroots women's organizations, in collaboration with workshop leaders, developed appropriate IEC materials to take back to their constituents to improve their knowledge and use of this new product.

ECC, as a member of the Consortium for Emergency Contraception, sponsored the creation of an EC Web site in Mexico to support the consortium's efforts to increase the available channels of EC dissemination. The Web site is equipped with software that tracks first-time and repeat visitors to the site. In addition, an e-mail address on the site allows visitors to request additional information and provide feedback. The Web site content may also be used for informational purposes throughout Spanish-speaking Latin America. Additionally, in Zambia staff conducted a study to determine adolescents' preferences for the provision of information on and dispensing of EC. On the basis of the findings, ECC plans to design a study to expand the access of adolescents to EC within the country.

In southern Africa, ECC supported a regional EC conference hosted by the Margaret Sanger Center International. In India, ECC collaborated with the Third World Center for Women's Studies (TINNARI), the Mahatma Gandhi Memorial Medical College Department of Medicine, and the National Institute of Applied Human Research and Development to conduct a survey of policymakers, service providers, family planning clients, and adolescents to identify factors that would increase access to EC. The findings of this study demonstrated that most of the participants surveyed did not know about EC. However, once informed and their myths and fears allayed, most participants favored the introduction of EC into the health system and favored distribution by physicians and paramedical personnel.

Postabortion Care: A New Area for Contraceptive Counseling and Choices

A commitment by the Population Council to work in the area of postabortion family planning and care (PAC) was an important contribution to the improvement of reproductive health in Latin America. In a study in Bolivia with the Unidad Nacional de Atencion a la Mujer y el Nino (a unit within the MOH), ECC helped to train physicians and other health care workers in all aspects of PAC, including postabortion family planning counseling, service provision, method provision/prescription/referral, and follow-up services. In a study in Mexico, Norplant was introduced into postabortion family planning services at four hospitals in Mexico City.

Initiative to Maximize Access and Quality (MAQ)

To ensure improvements in QOC and access to care, the ECC project has worked to further USAID's MAQ Initiative: to engage in dialogue with health ministries, assist them in identifying barriers or weaknesses in existing family planning guidelines and policies, and work with them to ensure that barriers to quality and access are overcome. Martha Brady represented ECC on three MAQ subgroups: Technical Guidance and Competence; Client-Provider Interaction; and Policy, Advocacy, Communication, and Education. ECC was also instrumental in planning regional MAQ conferences, in particular a collaboration with the Center for Training and Research in Reproductive Health (CEFOREP), a Senegalese NGO, to host a large-scale regional conference in Dakar in 1999. This meeting brought together MOHs and related governmental agencies, NGOs, researchers, providers, and other stakeholders from the francophone region of Africa (and Haiti), and interested parties from cooperating agencies involved in the MAQ Initiative to discuss effective ways to implement policies, norms, and protocols into reproductive health services. As a result of the enthusiasm generated by the 1999 conference, ECC played an instrumental role in the establishment of the francophone MAQ subcommittee, which was launched at a meeting hosted by the ECC WCA medical associate in Dakar, Senegal, in July 2000. (Funding was provided by the follow-on cooperative agreement.) The subcommittee developed the mandate of integrating HIV/STIs into family planning services. In keeping with this mandate, ECC has committed itself to expanding its dual methods and barrier methods activities within the francophone Africa region as its contribution to the subcommittee's work.

Impact Studies

Through the initiative of Anrudh Jain, the Council's International Programs Division director for policy and regional programs, QOC impact studies were developed and implemented with ECC staff and support in Senegal and Zambia. In Senegal, the study was implemented by the National Family Planning Program (PNPF) and the Ministry of Health and Social Action (MOHSA). This study was cofunded by the Council's USAID-supported Africa OR/TA Project II, ECC, and The Rockefeller Foundation. It tested the hypothesis that interventions to improve the quality of services (through upgrading infrastructure, expanding the range of services, training providers, and improving management information systems) would improve clients' perception of quality, and increase continuation rates and new acceptors in ten service-delivery points with over 1,200 new family planning acceptors. Final results of the study are pending.

In Zambia, the impact study began in six clinics in urban Lusaka that had approximately 2,500 new family planning users. The collaborators were the Central Statistical Office and the Lusaka Urban District Health Management Team. The project examined how the addition of Depo-Provera and Norplant to the method mix would affect quality and continuation rates. This study was implemented in two phases. Phase One examined six clinics—two clinics added Norplant and Depo-Provera to their method mix, two clinics added

only Depo-Provera, and two (the control clinics) added no new methods. A client-flow analysis and a SA were conducted during Phase One. In Phase Two (funded under the follow-on cooperative agreement), an endline SA and follow-up interviews will be conducted to assess changes over time.

Dissemination

Staff Contributions

ECC project staff have made numerous contributions to the literature on reproductive health, family planning, and contraceptive technologies through published works and papers presented at regional and international meetings and conferences. Below are highlights of ECC staff contributions. A full bibliography of publications, presentations, and trainings conducted by staff will be included in an upcoming appendix to this report.

Juan Díaz authored or coauthored 25 articles that were published in 11 peer-reviewed journals. He presented policy papers and research findings at three international ALIRH congresses, a National Congress of Public Health Research (Mexico), and an annual meeting of the American Public Health Association (APHA). He also contributed chapters to the 1998 and 1999 editions of the *Yearbook of Obstetrics, Gynecology, and Women's Health*. Dr. Díaz's most recently published articles based on findings from ECC studies include "Expanding contraceptive choice: Findings from Brazil" in *Studies in Family Planning*, and "Emergency contraception: Knowledge, attitudes and practices among Brazilian obstetrician-gynecologists" in *International Family Planning Perspectives* (with Loren Galvão).

John Skibiak was a major contributing author on two WHO/USAID-funded needs assessments—one on contraceptive introduction in Zambia (published in 1995; technical assistance provided by Davy Chikamata) and one on reproductive health in Ethiopia (published in 1999). He also coauthored a *Situation Analysis of the Family Planning Service Delivery Systems in Antananarivo and Fianarantsoa Provinces* as part of a collaboration with the Africa OR/TA Project II and the Madagascar MOH. Dr. Skibiak's work on the needs assessments and on emergency contraception studies in sub-Saharan Africa has been presented at numerous conferences and symposia sponsored by national MOHs and at an APHA annual meeting.

Davy Chikamata has authored and coauthored three articles in peer-reviewed journals and has presented ECC study findings at two APHA annual meetings, an annual meeting of the Population Association of America (PAA), a meeting of the Kenya Obstetrical and Gynecological Society, and two presentations at the regional ICPD+5 meeting held in 1999 in Johannesburg. A paper highlighting initial findings from the Zambia impact study (entitled "Dual needs: Contraceptive and infection protection in Lusaka, Zambia")—originally presented at PAA's 1999 annual meeting and published as a working paper for regional distribution by the Zambian Central Statistical Office—was submitted to *International Family Planning Perspectives* in 2000.

Penda N'Diaye participated in the writing of the WHO/USAID-funded *Qualitative Assessment of Reproductive Health Needs in Burkina Faso* (in collaboration with John Skibiak) and coauthored a report on the constraints and barriers affecting adolescents' access to family planning services in Senegal. Andrew Fisher, in collaboration with staff from the Council's Asia/Near East OR/TA Project, published "An assessment of Norplant removal in Indonesia" in *Studies in Family Planning*.

Jadelle Monograph

With funding provided by ECC, Irving Sivin and Harold Nash, colleagues from the Council's Center for Biomedical Research, have collaborated with Sandra Waldman from the Council's Public Information Office to produce a manuscript on the development of the Jadelle two-rod implant. The manuscript is currently under review and is expected to be published in 2002.

Other Dissemination Efforts

The ECC project began to use the Internet to disseminate information on contraception and reproductive health in LAC. In Brazil, the source book *Essentials of Contraceptive Technology* was translated into Portuguese and put on an interactive Web site accessible to policymakers, physicians, and providers. Besides allowing access to the basic *Essentials* information, the Web site also provides a forum for questions and on-line discussions. In Mexico, ECC collaborated with the Population Council Mexico office's media campaign on emergency contraception to establish an Internet Web site to provide information and current news, including links to other EC resources in Spanish.

ECC staff have held dissemination workshops and presented papers at regional, national, and international congresses. In Zambia, a national dissemination workshop was held to launch the national family planning guidelines and standards. In Kenya, a workshop was held for all stakeholders to disseminate the results of training nurses to provide Norplant. ECC-related activities have also appeared in *Population Briefs*, a quarterly research newsletter of the Population Council—"Expanding contraceptive choice: Findings from Zambia" in vol. 2, no. 2.

Collaboration with Other Reproductive Health Organizations

ECC has worked in several countries with the WHO Task Force on Research on Introduction and Transfer of Technologies for Fertility Regulation. ECC has been a key contributor to the implementation and refinement of the strategic approach to contraceptive introduction, which assesses country-level contraceptive needs within a reproductive health framework. This approach has provided a logical structure for assessing the feasibility of introducing specific contraceptive technologies given the social, cultural, and service-delivery contexts of specific communities. ECC played a critical role in the evolution and implementation of all stages of this strategy in such countries as Bolivia, Brazil, Burkina Faso, Ethiopia, and Zambia.

ECC staff also provided knowledge and expertise through their membership and/or participation in various working groups, consortiums, and other agencies. For example, Juan Díaz and John Skibiak represented ECC on the Consortium for Emergency Contraception and the American Society for Emergency Contraception, both of which promote wider availability of dedicated EC products. Dr. Díaz has also been active with the Inter-American Development Bank and co-organized their 1999 International Meeting on Reproductive Health and Health Reform in LAC. Penda N'Diaye is involved with the Senegal chapter of SWAA as well as the Senegal branch of SAGO. During 1999, Davy Chikamata served as chairman of the medical committee for Ipas and was a member of the Kenyan MOH/FHI-sponsored group of stakeholders developing strategies to introduce the female condom nationwide. Martha Brady was involved with a working group of the UNFPA Global Initiative on Reproductive Health Commodity Management. Suellen Miller now sits on the UNFPA Committee on Contraceptive Commodities Security.

ECC provided input to the contraceptive development process at the Council's Center for Biomedical Research, and participated in meetings of the International Committee for Contraception Research. In particular, program staff played key roles in technology-specific issues related to Norplant. Medical associates also provided technical expertise to developing-country family planning programs, collaborating organizations, and donors on reproductive health topics such as contraceptive technology introduction, expansion of method mix, expanding the concept of informed choice, and product registration, training, and service-delivery considerations with respect to these technologies. New York-based program staff were involved in setting program priorities and providing management expertise to the program.

ECC staff also served on key working groups of USAID and WHO. In particular, Martha Brady served as a member of USAID-sponsored interagency working groups on Norplant and the female condom. John Skibiak and Juan Díaz served as members of the WHO task force on contraceptive introduction. Martha Brady served in an advisory role to this task force.

The ECC project has a long history of collaboration with the Population Council's operations research programs as well as its impact studies and reproductive health programs. ECC staff frequently contribute their clinical expertise to the development and modification of situation analysis instruments, and to the service-delivery, infection prevention, technical competence, and quality components of several studies implemented by their Council colleagues.

Conclusions

The ECC project has made significant contributions to enhancing contraceptive options and choices and to improving the quality of contraceptive services. ECC has introduced and evaluated a range of contraceptive technologies in all regions of the developing world. ECC's work contributes to the knowledge base on ways to introduce specific and appropriate technologies. ECC staff document lessons learned from these introductions in order to develop priorities for future reproductive health and contraceptive introduction activities. The results of this work have led to enhanced understanding, improved ability to set priorities, and greater capacity for implementation of expanded contraceptive choice programs.

ECC's research, interventions, policy dialogues, and technical assistance activities have enhanced the knowledge of users, providers, policymakers, and donors on particular services, techniques, strategies, and practices. The program has also enabled individuals to learn about, acquire, and effectively use new and/or newly introduced technologies. ECC has studied not only the knowledge, attitudes, and practices of users and providers but also the social conditions that influence a user's ability to make informed choices and a provider's ability to effectively counsel clients to make such choices.

ECC has worked extensively to facilitate the introduction of a range of hormonal, barrier, long- and short-term, and dual methods with attention to the safety and quality of those technologies within country-specific service-delivery systems. ECC has used the opportunity of introducing new methods to the method mix to make improvements in the overall quality of family planning services. ECC has integrated the lessons learned about how family and gender structures affect contraceptive decisionmaking and use into its efforts, past and present. Wherever possible, ECC has incorporated this information into policies, practices, interventions, and research associated with expanding contraceptive choices. ECC's continuing work to increase contraceptive choice using introduction/reintroduction of existing technologies and applying the various lessons learned have laid a secure foundation for our ongoing efforts under the follow-on Programmatic Cooperative Agreement HRN-A-00-99-00010.

POLICY RESEARCH

UNDERSTANDING AND MEETING THE NEEDS OF ADOLESCENTS

Adolescents represent our collective demographic and economic future. The experiences of the teenage and young adult years set the boundaries of what is possible later in life. Moreover, there is a growing recognition, based in part on research undertaken at the Population Council, that a substantial fraction of future population growth stems from the early age at childbearing. Thus, the transitional period between childhood and adulthood is particularly worthy of our interest and resources, notwithstanding its frequent neglect by researchers and policymakers alike.

Despite numerous recent publications on adolescent reproductive behavior, several gaps in our understanding of adolescent experience restrict our ability to develop policy recommendations designed to support successful transitions. For example, because past studies have focused on girls, we know little about the experiences of adolescent boys and what implications their experiences might have for the timing of reproductive events.

To fill these gaps, we have designed a research program to increase our knowledge about the lives of adolescents in a range of settings and to maximize the accuracy of the data collected on adolescents. The program has two broad objectives: (1) to document patterns and trends in the incidence and timing of key events during an adolescent's transition to adulthood, including sexual initiation, school leaving, formal employment, marriage, first and subsequent births, and their interrelationships; and (2) to advance knowledge about the key external factors affecting the timing of these events, including the quality and accessibility of primary and postprimary schooling opportunities, the availability of work opportunities and their content in terms of training and capacity-building, and the reproductive health service environment. The ultimate goal is to identify policy interventions that will delay marriage and childbearing sufficiently to create conditions in which more successful transitions to adulthood can occur.

To capture a diversity of experience within and between countries, several in-depth country studies have been undertaken and partially funded by USAID, including research in Bangladesh, Egypt, Kenya, and South Africa. This report focuses on studies that produced results during the period of cooperative agreement funding, which ended in September 1999. Ongoing studies partially funded under this agreement, for which results were not yet available by that date, are not discussed here because of the brevity of this document. These include the panel study of adolescents in South Africa, which did not conclude fieldwork until the end of October 1999; and the national survey of preparatory schools in Egypt, for which analysis did not begin until the end of 1999. Support for the study of adolescents in South Africa continues under the follow-on Programmatic Cooperative Agreement HRN-A-00-99-00010.

Transitions to Marriage and Adulthood in Bangladesh

The first phase of the research, a comprehensive review of studies on transitions to adulthood in Bangladesh, revealed how little is known about the subject of adolescence in the country. While several datasets such as the Demographic and Health Surveys (DHS), the Household Expenditure Surveys, and the Labor Force Surveys, can lend themselves to analysis pertinent to adolescents, they have not been used for this purpose. Although a review and extensive reanalysis of these datasets were planned to provide a comprehensive assessment of the situation of adolescents, this review could not be completed for publication because some of the national datasets are not in the public domain and are not readily accessible. The matter of data access is still being pursued.

The absence of a substantial input on adolescents can have detrimental consequences for population policy. A recent seminar on population policy in Bangladesh was described as focusing on the health of adult women and children and on the situation of the elderly. This inattention to adolescents is at least in part attributable to the lack of comprehensive data. As a response to our inability to conduct a full analysis of existing data, we made plans to conduct a survey on adolescents in early 2001.

Some important findings that have emerged out of the review of data are noted and will set the stage for future work:

Age misreporting. Bangladesh has a pattern of severe age misreporting that can hinder analysis of trends in marriage, rates of education, and labor force participation. Misreporting of age is particularly relevant for the adolescent years, and sensitivity analysis indicates that finer subdivisions within the adolescent years, although desirable for understanding the lives of young people, will probably be misleading.

Narrowing of the gender gap in education in the 1990s. There is conclusive evidence of a narrowing of the gender gap in school enrollment rates that once favored boys. The reduction of the gender gap is simultaneously attributable to rising enrollment of girls and stagnant enrollment for boys. Education trends are particularly dynamic in rural areas and stagnant in urban areas. Reductions in both the gender gap and the urban-rural gap may be attributable to programs that have been introduced to benefit previously disadvantaged groups. Some of these programs have been introduced only in rural areas, such as the food-for-education scheme and the female secondary school scholarship scheme.

Trend toward later age at marriage for girls. While later age at marriage is attributable to positive forces such as rising education and labor force opportunities that motivate girls to delay marriage, there is some evidence that it may also be due to increasing dowry demands that force families to wait as they accumulate the resources necessary for their daughter's dowry.

Adolescent mobility. Our review of age patterns of migration from the Matlab area, which is known for its accurate vital registration data, suggests that migration from rural to urban areas is an important aspect of transitions to adulthood. Migration rates peak at adolescence or soon after. The high mobility undertaken for reasons of marriage and work has implications for adolescents themselves and for families that depend on their income.

Reproductive behavior. A large proportion of adolescents are sexually active within formal marriages. While there is some concern that rising workforce participation and migration may increase rates of premarital sexual behavior, no substantiation of such a trend is apparent in the data we reviewed.

Adolescent Livelihoods in Egypt

Egypt's liberalization policies and greater global integration have far-reaching implications for the society as a whole. Much is being written on the impact of globalization and structural change for national employment patterns, but there is little information on how these changes affect young people. This is especially true with regard to livelihood opportunities for young women. This project seeks a better understanding of the range of options and work roles available to young people. Special attention has been given to the situation of young women's work within the context of contemporary reforms and structural adjustment in Egypt. In addition to exploring the opportunities for young women (aged 15-24), a second aim is to understand how participation in livelihood activities affects girls' ability to improve their status in

their families and communities and expand their future income and employment options. This study identified gaps in policies and programs and pointed to economic growth areas that could enhance opportunities for young women.

Labor force survey data collected in 1998, analyzed in conjunction with a similar nationally representative study conducted in 1988, offered insights and generated hypotheses to be explored in the qualitative studies. Preliminary analyses from the two components of the study were completed by September 1999 and presented at a meeting on youth livelihoods held in Cairo in October 1999 under the auspices of the Population Council. Two publications are under review.

The results indicate that school attendance has increased sharply for girls and boys in Egypt, leading to a reduction in labor force participation for young people. Unemployment is higher among girls than among boys, but girls with less education have more success in getting work than girls with greater educational achievement.

Evidence suggests that the two sectors responsible for dynamic growth in the labor market are manufacturing and finance, while the contribution of agriculture has declined. Despite large investments in privatization, the government still seems to be the primary employer in Egypt.

Although a significant proportion of adolescent girls work before marriage, a considerably higher proportion would like to work if suitable opportunities were available. This disparity results in high levels of unemployment among young girls.

Little urban growth has occurred in Egypt in the past decade, and most rural young people appear to remain in rural areas, leading to an increase in the demand for jobs in such areas. Nonagricultural jobs have grown differentially within the country, with the highest growth occurring in rural lower Egypt.

In general, informal-sector employment seems to be increasing, and work conditions in terms of permanence of jobs and availability of social and medical insurance are worsening.

The Social Context of Female Circumcision in Egypt

Using data from a nationally representative survey of adolescents conducted by the Population Council in 1997, in collaboration with the Social Research Center of the American University in Cairo, the Alexandria High Institute of Public Health, and the Assiut University Faculty of Medicine, we investigated the prevalence and social correlates of circumcision among girls aged 10–19, the circumstances surrounding the procedure, and the attitudes of young people toward it. Because all women in the DHS and similar surveys are married, it has not been possible until now to estimate national prevalence levels for single women — especially for younger girls, whose experience reflects emerging trends in the society. Data analysis was completed during 1999, and a paper, originally presented at the 1999 Annual Meeting of the Population Association of America, was subsequently submitted to *Social Science and Medicine*.

While the vast majority of Egyptian adolescents are circumcised, a life table analysis indicates that girls today are at least 10 percentage points less likely to undergo circumcision than were their mothers (84 percent vs. 97 percent). While rates of circumcision may have begun to fall prior to the time when the current cohort of girls were at risk, the data hint at a temporal association between the decline and the 1994 International Conference on Population and Development in Cairo, a time when the campaign against

circumcision gained momentum. Even among circumcised girls, support for the practice is by no means universal, with 14 percent saying that the procedure is unnecessary and a further 28 percent expressing ambivalence. A multivariate analysis indicates that girls who have been or are currently in school, who live in urban governorates, and who are older are more likely to believe that circumcision is not obligatory. When the analysis includes boys as well as uncircumcised girls, a large gender gap emerges, with boys considerably more supportive of the practice than are their female counterparts.

The Links Between School Experiences and Reproductive Behavior in Kenya

Using data from nearly 600 adolescents and the schools they attended in three districts in Kenya, this study explored whether certain aspects of the school environment affect the likelihood of early and unprotected sex. Our analysis of the data indicated that, although neither the school nor the home influences whether boys engage in premarital sex, for girls a school characterized by girl-friendly teachers and a gender-neutral atmosphere, and a home containing female role models and the support of two parents, reduce the risk of premarital sex. On the other hand, girls are more likely to engage in premarital sex if they attend schools where considerable pressure to have sex is reported. The school environment also appears to have an impact on whether or not sexually active boys choose to use contraceptives. A gender-neutral environment leads to greater contraceptive use among boys, as do schools where students have greater knowledge of reproduction. Finally, even if certain school characteristics significantly affect the risk of premarital sex for girls, the results suggest that pregnancy is not the primary reason why girls leave school early. Findings from this study were presented at the 1999 Annual Meeting of the Population Association of America. A paper is being revised for submission to *Studies in Family Planning*.

Qualitative Analysis of Adolescent Childbearing and Marriage in South Africa

In this study, focus group discussions were conducted in urban and rural areas to understand the determinants of early pregnancy and the risks and opportunities young mothers and fathers face as they assume adult responsibilities. Data analysis on this study was completed during 1999, and the resulting paper has been accepted for publication in *Studies in Family Planning* in 2001.

The findings show that the opportunity young parents have to return to school after the birth of a child is strongly associated with a long delay before the birth of a second child. For boys as well, staying in school is perceived to be the key to employment, while fathering a child may mean leaving school to support the child. Many focus group participants stated that they take precautions to avoid young parenthood; others reported facing pressure to deny paternity so that they can stay in school. Education is also closely associated with brideprice practices. Because more highly educated daughters command higher bridewealth payments, parents have an incentive to keep daughters in school.

Our results suggest that the babies born to young parents are extremely vulnerable both socially and economically. Because the baby is usually born premaritally and subsequent marriage between the child's parents is uncommon, the support and maintenance of the child are subject to paternal recognition and commitment. The presence of the baby also generally means a lower brideprice for a future marriage. For this reason, the existence of the child is sometimes kept secret from prospective grooms in order to maintain higher bridewealth.

TRANSITIONS IN REPRODUCTIVE BEHAVIOR IN THE DEVELOPING WORLD

The various components of this program use demographic analysis and modeling to provide new insights into controversial issues regarding the future course of the transition in fertility and contraceptive use in the developing world, and document the implications of these findings for family planning programs and population policy. The program began during Year Five of the agreement (October 1998–September 1999) and continues under the follow-on Programmatic Cooperative Agreement HRN-A-00-99-00010. During Year Five, the objective was to enhance understanding of the complementary role of contraception and induced abortion at different stages in the fertility transition.

Since the 1960s the proportion of couples practicing contraception has risen rapidly, particularly in the developing world, and the mix of methods is now dominated by modern methods. Despite these trends, the incidence of unintended pregnancy remains high, mainly because the number of children desired has declined. Annually about 132 million births occur in the world and out of this total, one in four (34 million) is estimated to be unintended. In addition, an estimated 46 million abortions take place annually, bringing the total number of unintended pregnancies (excluding miscarriages) to about 80 million per year. In other words, there are almost as many unintended as intended pregnancies each year. Worldwide the proportion of unintended pregnancies ending in abortion is estimated at 58 percent, but there are large variations among regions, from a high of 90 percent in Eastern Europe to a low of 39 percent in Africa.

This study examined the potential role of further increases in contraceptive prevalence and effectiveness in reducing abortion rates. The model used in this analysis links the abortion rate to its direct determinants, which include the couple's reproductive preferences, the prevalence and effectiveness of contraceptive practice to implement these preferences, and the probability of an abortion to avoid unintended births when contraception fails or is not used.

An assessment of the tradeoff between contraception and abortion yielded estimates of the decline in the total abortion rate that would result from an illustrative increase of 10 percentage points in contraceptive prevalence. This effect varies among societies, primarily because the tendency to use abortion after an unintended pregnancy varies. For example, in a population with an abortion probability of 0.5, a 10 percent increase in prevalence would avert approximately 0.45 abortions per woman, assuming contraception is 95 percent effective. If all unintended pregnancies were aborted, this effect would be three times larger.

Eliminating all unintended pregnancies and subsequent abortions would require a rise in contraceptive prevalence to the level at which all fecund women who do not wish to become pregnant practice 100 percent effective contraception. A procedure is provided for estimating this "perfect" level of contraceptive prevalence. For example, in Kazakhstan, which has a relatively high total abortion rate of 1.75 per woman, the model estimates that eliminating all unintended pregnancies and subsequent abortions would require an increase in contraceptive prevalence of 9 percentage points, as well as an increase in contraceptive effectiveness of 3 percentage points. The main implication of this analysis is that modest increases in contraceptive prevalence and effectiveness can produce large reductions in abortion rates.

This study, coauthored with Charles F. Westoff, was published under the title "The potential role of contraception in reducing abortion" in the September 2000 issue of *Studies in Family Planning*.

**FAMILY PLANNING
AND RELATED HEALTH SERVICES**

EXPERIMENTAL FAMILY PLANNING STUDIES IN RURAL AFRICAN SETTINGS

Questions on how to address the reproductive and community health needs of poor African populations have been the subject of policy debate for the past three decades. Although these debates can best be resolved with experimental studies, few experiments have met the qualifications of rigorous study designs. Demographic experiments require capacities for monitoring fertility and mortality dynamics in large populations, variance in interventions with appropriate factorial controls, and policy and administrative support for maintaining experimental operations and applying results. These conditions are rarely met in settings where experimental research is needed most. Methodological compromises typically constrain the use of results for resolving policy debates.

This report summarizes achievements, during the period 1995–99, of the Community Health and Family Planning (CHFP) project of the Navrongo Health Research Center (NHRC) in the rural impoverished Kassena-Nankana District of northern Ghana. Experimental activities were contracted to the NHRC under the Population Council's Africa OR/TA Project II, with additional technical assistance funded by the Programmatic Cooperative Agreement until April 1998, when funding for the NHRC was shifted to this agreement.

The CHFP project has been designed to conform to the highest standards for factorial service-delivery experiments. By linking CHFP research operations with other NHRC health research requiring demographic surveillance, it has been possible to determine the precise magnitude and timing of project impact. Over the study period, a large-scale factorial experiment has been launched, design requirements have been addressed, and a framework for policy development in collaboration with the Ministry of Health (MOH) has been established.

Two aspects of the ongoing debate in particular are the subject of scrutiny by the CHFP project. First, before the CHFP project, no systematic evidence had established that reproductive change can be induced and sustained by service-delivery programs in rural pretransitional settings. While there is evidence of fertility transition in East and Southern Africa and in the cities of coastal West Africa, as yet there is no definitive evidence that family planning programs have caused this decline. Several studies have demonstrated that contraceptive use is enhanced by village-based services, but contraceptive services often appeal to women who are abstaining from sexual relations. Because the substitution of contraception for abstinence has little or no fertility impact, it is uncertain whether successful community-based distribution projects have an impact on fertility.

Second, there is considerable debate in the health policy community about the potential impact of volunteer health services. Although various regional programs, such as the Bamako Initiative, have been proposed by the international donor community, these programs remain untested in practical field trials. No study to date has established that low-cost community health programs can induce a health transition. The question in Ghana is whether volunteer services do more harm than good, and whether community health programs require the investment of expensive personnel, infrastructure, and equipment for the provision of community-based care.

The Navrongo experiment takes two approaches to the delivery of primary health care and family services. The first, known as the *zurugelu* (togetherness) approach, derives from the proposition that the cultural resources of African society, frequently overlooked by programs, are potentially powerful mechanisms for managing operations. The institutions of chieftaincy, lineage, networking, religion, marriage, and family-

building are often cited as representing traditional forces constraining the introduction of family planning. The CHFP project turns this argument on end by forming a strategic partnership with traditional social institutions. In this approach, the institutions that govern daily lives can also structure community ownership of health and family planning programs.

The second approach of the experiment concerns conventional service resources of the MOH. In Ghana and throughout Africa, considerable investment has been made in maternal and child health care clinics that are overstaffed, underused, and ineffective in meeting the needs of the rural poor. There is a need, therefore, to establish feasible means of reorienting existing MOH staff to village services and relocating community paramedics to village-based facilities.

The two domains of the Navrongo experiment can be implemented independently, jointly, or not at all, implying a four-cell factorial design. In the study period, a comprehensive demographic surveillance system was developed for monitoring demographic impact, and a panel survey system was developed to monitor contraceptive use, reproductive health, and the social impact of the project.

Launching the Community Health and Family Planning Project

Specific operational elements of the CHFP project were unknown at the time the experimental design was established. To develop the strategic design, leaders in three communities were approached and asked to convene committees to comment on the design of the project. Focus group studies were conducted to gauge needs in these communities, and constraints on the likelihood of program success were carefully assessed. This first phase of the project took place from April 1994 to July 1995 and resulted in a comprehensive community-evaluated pilot trial.

Lessons learned from this initial phase have been the subject of several influential national policy conferences:

- *Feasibility of operational change.* Relocating community health nurses (CHNs) to village sites was shown to be both feasible and cost-effective. Communities constructed traditional dwelling units and supported the work of community health officers.
- *Feasibility of involving volunteers.* Developing the *zurugelu* system was welcomed by communities.
- *The essential role of health services.* Promoting family planning without a strong focus on health care would not be acceptable in study areas.
- *Male involvement.* Men express concerns about family planning that are best resolved with open discussion, outreach to men's groups, and participation of chiefs and elders in community education activities.
- *Women's family planning concerns and needs.* Women want services provided under conditions of strict confidentiality. As a result, they prefer injectable contraception over other methods.
- *Project impact.* Pilot results were consistent with the hypothesis that CHFP project services would increase contraceptive use and improve immunization coverage.

Monitoring the Four-cell Experiment

In 1996 the CHFP project was scaled-up to a district-wide initiative with geographic zones corresponding to a four-cell experimental design as follows:

Cell I (Treatment Area I). In Cell I, clinical services and staff were upgraded, but CHNs retained their clinic affiliation and roles. Village leaders were oriented to the program, village peer leaders were recruited and trained, and volunteers provided services. Supervisors were trained in community organizational work.

Cell II (Treatment Area II). Clinical services and staff were upgraded as in Cell I, but the community cadre was not developed. Cell II addressed concerns in the MOH that existing CHNs are currently not used efficiently in subdistrict clinics. In this cell, CHNs were relocated from the clinics and stationed full-time in the communities. This change in the residence of CHNs required community liaison, but the scheme was managed and implemented by the MOH.

Cell III (Treatment Area III). Clinical services and staff were upgraded as in the other treatment cells. In addition, the strategy in Cell III combined those of Cells I and II by having CHNs resident in communities where intensive efforts were also directed to organizing traditional leadership of the program. If the program of CHN outreach and volunteerism can be simultaneously mobilized, Cell III is the most intense experimental area.

Cell IV (Comparison Area I). Clinical services and technical skills were upgraded, but there were no CHN activities outside the clinic; CHNs continued their regular outreach services.

Since all clinical services throughout Kassena-Nankana District were upgraded, a “pure control” cell (Cell V) was established as well. This cell was located outside the district, and in it the MOH’s usual primary health care/family planning strategy continued.

By 1998 significant fertility differentials were apparent across the four experimental cells; by 2000 initial effects on childhood mortality were evident. Cells testing the *zurugelu* approach to community health mobilization have experienced no impact on fertility or mortality; no experimental cell has seen an impact on mortality in the first year of life. Findings suggest that placing a CHN in the village increases immunization coverage, and this in turn has reduced childhood mortality. Extensive censoring of observation, however, prevented definitive mortality research in the reporting period. By 1997 fertility had declined by 17 percent in the combined cell relative to unexposed areas, supporting the hypothesis of project impact. In 1998 this effect was dissipated by the appearance of fertility decline in all study areas, including the comparison area. By 1999 fertility differences returned, suggesting that the initial impact of the project will be about 15 percent, or a reduction in the total fertility rate of 0.9 births in the combined cell. A small and significant fertility effect was observed in the first year of the project in the *zurugelu* cell. This transitory impact is due to the fact that discontinuation rates are high in the absence of CHN outreach. Results thus indicate that impact arises from combining mobilization of the traditional *zurugelu* male leadership system with mobilization of the CHN outreach system.

Findings of the pilot phase of the project and preliminary experimental results have been presented at conferences of MOH regional medical directors and in a National Health Forum of all district directors of medical services in Ghana. At a 1998 conference, the MOH adopted the Navrongo combined cell as a model for replication in all other regions of Ghana. A program of national conferences, site visits, and replication projects has been instituted in each of the ten regions of Ghana and a national secretariat has been created, the Community-based Health Planning and Services (CHPS) initiative. The goal of the new program is to use the Navrongo experiment as a means of decentralizing health care, adapting programs to local circumstances, and improving health equity.

The CHFP project has thus become a success story even before it has completed its planned period of observation. It is demonstrating that both high fertility and mortality can be reduced in an impoverished traditional environment, and that findings from a successful project can be used to guide national policy and program development.

Rationale for Sustaining Navrongo Project Activities

The Navrongo experiment was launched to test the hypothesis that fertility transition can be induced and sustained by a reproductive health and family planning program. Past investment in developing and monitoring the Navrongo experiment will not be fulfilled if the project is ended prematurely. Reproductive change has been initiated by the comprehensive CHFP service program, but whether or not this change will result in a fertility transition remains unknown. Observed shifts in reproductive preferences in Navrongo are consistent with the view that a fertility transition will eventually occur, but since the full nature of reproductive change has yet to become manifest, the hypothesis underlying the project remains incompletely tested.

The Navrongo experiment also has an ongoing child survival research agenda. Testing the impact of project interventions requires observation of cohorts of children exposed to the experiment as they go through early childhood. Early results suggest that experimental strategies have an impact on child survival. Since findings may have major implications for health policy in the region, it is important to develop statistically robust estimates of project impact.

A factorial experiment on eradication of female genital cutting was launched by the NHRC in 2000 under the follow-on Programmatic Cooperative Agreement. Observing the results of this experiment requires continuing the scaling-up of the intervention program and longitudinal survey research, as specified in the project protocol. The Navrongo female genital cutting experiment is the first study in Africa of strategies for effecting social change in this traditional practice.

HIV/MICROBICIDES ACTIVITIES

The Population Council has embarked on a major effort to develop vaginal products that will prevent women from contracting sexually transmitted infections (STIs), particularly HIV. Our objective is to develop one or more microbicides that will be widely available, stable in tropical climates, and affordable to even the world's poorest women. Funding from USAID under this agreement during the period August 1998–September 1999 supported the pilot study of the Population Council's lead candidate microbicide Carraguard™ as well as a study of the Micralax® applicator in South Africa. USAID also supported technical assistance from Family Health International (FHI) on protocol and site development, study staff training, and onsite monitoring. After September 1999 USAID continued funding of microbicides activities at the Council under the follow-on Programmatic Cooperative Agreement HRN-A-00-99-00010.

In September 1998 a three-day training workshop was held in Durban, South Africa, and was followed by several site visits by Population Council staff to prepare the study staff for enrolling participants in the Carraguard trial. Approval to conduct the expanded safety study of Carraguard was received from the South African Medicines Control Council in January 1999. However, because of problems manufacturing Carraguard, the pilot study had to be postponed.

While working to resolve the Carraguard manufacturing problems, we conducted a study of the Micralax applicator to be used in the trial. This was an excellent opportunity for study staff to pilot-test the forms and procedures to be used in the expanded safety trial. Nearly two-thirds of the women enrolled reported liking the applicator and gel as a package either very much or somewhat. No one claimed to dislike the study product (gel and applicator), either strongly or even somewhat. In March 2000 preliminary data from this study were presented as a poster at Microbicides 2000 in Washington, DC. A paper describing the findings is forthcoming in the journal *AIDS*.

In July 1999 we received US Food and Drug Administration approval to conduct a pilot study to assess expanded safety and preliminary effectiveness of Carraguard in preventing HIV transmission. This approval, coupled with the successful manufacture of the first large batch of Carraguard, allowed the study to get under way. In September 1999 we held a second training workshop, and in October 1999 both sites began screening and enrolling women into the pilot phase of this randomized, double-blind, placebo-controlled trial.

The pilot study was critical for helping to evaluate the forms and procedures before scaling-up into the full expanded safety study. Twenty-seven women completed two months of gel use, an indication that recruiting and retaining this cohort would be feasible. Based on the preliminary safety data, which showed no problems, scale-up and recruitment into the main expanded safety study began in June 2000 (under non-USAID funding).

In the follow-on Programmatic Cooperative Agreement, USAID continued funding for technical assistance from FHI, for a safety study of Carraguard among HIV-positive women, and for development at the Council's Center for Biomedical Research of a microbicide/spermicide containing lignosulfonic acid.

AFRICA: INTEGRATION OF STI/STD AND HIV/AIDS ACTIVITIES INTO FAMILY PLANNING AND REPRODUCTIVE HEALTH PROGRAMS

One of the key programmatic issues that came out of the 1994 International Conference on Population and Development was the promotion of a more comprehensive and integrated approach to reproductive health service delivery. In sub-Saharan Africa the integration of information and services for the prevention of sexually transmitted infections (STIs) into existing maternal and child health and family planning (MCH/FP) programs has received tremendous attention because of the AIDS epidemic. In late 1994 the Population Council's Africa OR/TA Project II was asked to undertake a program of operations research that would improve understanding of the practical implications of integrated service delivery so that better practices could be documented and communicated to policymakers, program managers, and donors. Funding support was provided through the Programmatic Cooperative Agreement from USAID's Africa Bureau until 30 September 2000 and continues through field support directly to the Council's Frontiers in Reproductive Health program.

No formal objectives were set for the activities. Because the research was exploratory and innovative, progress was periodically reviewed and support was continued (and still continues) because of the important lessons learned. It is important to note that the majority of the funding was assigned to support senior researcher Ndugga Maggwa, although funds were also used to partially support research and dissemination activities. The comingling of funds from the Programmatic Cooperative Agreement with those of the Africa OR/TA Project II and the FRONTIERS program has meant that far more has been achieved than would have been without this joint funding arrangement. In addition, REDSO/ESA has provided both financial and technical support.

Brief descriptions of the major activities supported through this funding follow.

Descriptive Case Studies

A series of case studies provided a better understanding of the concept of integration, particularly in clinic settings. This activity was undertaken in collaboration with Pathfinder International and REDSO/ESA, and case studies of integrated projects were completed in Botswana, Kenya (2), and Uganda. The results of this activity led to the development of a framework for describing integration and provided many lessons about the strengths and weaknesses of different approaches to integrating STI prevention into MCH/FP services. The individual case studies and a synthesis of the overall lessons learned have been widely disseminated at the national, regional, and international levels.

Development of a Module for Inclusion in the Situation Analysis Approach

A module was developed that enables the quality and functioning of integrated services to be assessed. Items that allow integration to be routinely described and evaluated were added to the standard data collection instruments used in situation analysis studies in several African countries. In addition, in Botswana a rapid assessment tool was developed and tested for use during routine supervisory visits. The results of these assessments were presented in the country-specific situation analysis reports, and a synthesis of findings from five countries was published in the Population Council's monograph "Clinic-based Family Planning and Reproductive Health Services in Africa: Findings from Situation Analysis Studies."

Testing Improved Approaches to Integrating STI Detection and Treatment Among Family Planning and Antenatal Clients

Following the wide-scale promotion of the syndromic approach for detecting and treating STIs, evidence emerged that the algorithms used for managing vaginal discharge may not be effective if used to diagnose and treat sexually transmitted cervical infections. Prospective studies using quasi-experimental designs and laboratory testing for STI prevalence were undertaken in Kenya and Zimbabwe to evaluate the effectiveness of this approach as well as a version that included risk assessment. The findings confirmed that both the basic approach and the one that included risk assessment were ineffective among women attending for family planning or antenatal care. The results continue to be widely disseminated at all levels and are being used within these and other countries in the region, and by USAID and the World Health Organization (WHO) globally, to reassess policy guidelines on managing vaginal discharge and STIs.

Case Studies on Integration of Syphilis Screening in Antenatal Care

Detecting and managing syphilis in pregnancy is a particularly important form of service integration because it is already proven to be effective and cost-effective. Despite this, very few countries have introduced properly designed and managed integrated services for pregnant women. To promote this better practice, FRONTIERS is collaborating with WHO and the Joint United Nations Program on HIV/AIDS (UNAIDS) to undertake case studies in Bolivia, Kenya, and South Africa that document examples of this type of integration. Programmatic Cooperative Agreement funds have been used to cosupport the Kenya case study, to provide technical assistance to the South Africa case study, and to work with WHO to produce a publishable paper that will advocate greater attention to this approach.

Widespread Communication and Use of Findings

Because STI prevention is such an important strategy within the context of the AIDS epidemic, the results from these activities have been widely requested. Written reports have been published and distributed and presentations have been made at international and national conferences as well as to small meetings of donor personnel (e.g., staff of USAID, the Department for International Development [DfID], and WHO). To date, over 25 presentations have been made. Population Council staff are also being called upon to provide technical assistance to WHO and to national organizations in assessing and redirecting their integration strategies.

In Kenya, the study findings contributed to a section on integration that has been included in the revised service provider guidelines and standards. The findings also brought to the attention of policymakers the fact that existing policies prohibited nurses who had been trained in the syndromic approach from prescribing the required medications. As a result, legislation was enacted to revise the prescribing laws.

In Botswana, the findings from the studies were used to identify program needs more accurately and led to the revision of the training program for nurses. Also, findings were used by the MCH/FP unit to develop performance indicators for its programs and to revise its client record forms to facilitate more comprehensive client management and record keeping.

In Zimbabwe, a training module for the integration of family planning and STI services was developed and is now part of the curriculum for the national sexually transmitted disease management training program. WHO has also used this module for training in other countries of Africa and the Middle East. In addition,

the study findings helped the Zimbabwe National Family Planning Council and the USAID mission to recognize the need to move STI services out of the clinic, as well as to target men using community-based approaches. As a result, the community-based program has been revised to include reaching men with STI services and promoting voluntary counseling and testing for HIV.

Although funding has finished through the Programmatic Cooperative Agreement, this program of operations research and dissemination will continue through financial support to FRONTIERS. We are continuing dissemination efforts internationally, regionally, and at the individual country level. In the near future, we hope to expand our efforts in francophone West Africa. We intend also to continue activities in Kenya, South Africa, Uganda, and possibly Mozambique and Zimbabwe. In addition, we are communicating results through a number of international and regional organizations—notably the Commonwealth Regional Health Secretariat, the Regional Center for Quality of Health Care, and WHO. This work will be funded through a continuation of Africa Bureau support, REDSO/ESA field support, core funding, and South Africa field support.

Many issues remain regarding the integration of STI/HIV services and existing MCH/FP services for which more empirical evidence is needed, in particular the ability of integrated programs to reach nontraditional audiences (i.e., adolescents of both sexes, and men in general). There is much rhetoric about the importance of reaching young people and men, and although the rationale is clear intuitively, there is a lack of strong empirical evidence of the feasibility, impact, and cost of doing so. Research on these topics must be followed by strong dissemination efforts to ensure that the correct messages are communicated to those responsible for program development and funding.

BANGLADESH: STRENGTHENING POPULATION POLICY AND RESEARCH CAPACITY

USAID/Bangladesh provided funds to the Programmatic Cooperative Agreement during May 1995–July 1997 to strengthen the research capacity of professionals in Bangladesh by undertaking policy-relevant research in collaboration with local institutions. The Population Council conducted five research studies in collaboration with several local and international organizations, including Associates for Community and Population Research (ACPR); AVSC International; International Center for Diarrhoeal Disease Research, Bangladesh (ICDDR,B); Marie Stopes Clinic Society (MSCS); National Institute of Population Research and Training (NIPORT); and Research Evaluation Association for Development (READ). Much of this research was pioneering in nature. The following sections describe each study and its policy implications.

Strengthening STI Services for Men: An Urban Clinic–Based Program

This study was conducted in collaboration with MSCS in two urban-based clinics in Dhaka. As part of the intervention research, a client health record form was developed and computerized. The information recorded included current complaint, previous medical history, clinical diagnosis, sexual history, and partner management in the cases of clients with sexually transmitted infections (STIs). The Council worked with MSCS to increase the knowledge and skills of clinic staff to help them better serve STI clients. While it is difficult to make generalizations from the data collected, they have important policy implications for any organization working to start a clinic for men:

- An effective male STI intervention will have to target all age groups, employment categories, and education levels.
- Personal contact appears to be an effective approach for reaching men who seek STI services. The field coordinators of MSCS were very effective in reaching men in factories, slums, and the bus station, particularly when they began to use the information, education, and communication materials created for the intervention research.
- Most men try to conceal exposure history, even when it is determined that they are infected with an STI and even when service providers are technically skilled. Thus, exposure history cannot be the only screening criteria. Service providers must acquire extensive training in order for them to elicit complete client information.
- Male STI interventions should be coupled with general health services and other sexual health services, as 50 percent of the STI diagnoses came from these two client categories.
- STI services for men require a two-pronged approach: (1) intensive efforts to educate men about risks; and (2) training for providers on sexuality and management of STI cases.

Findings from this study helped the Council develop an operations research project on male involvement under the Asia/Near East OR/TA Project.

Opportunities for Integrating RTI/STI Services into MCH/FP Programs

The Council collaborated with AVSC International in Bangladesh to conduct a study in Dhaka District that identified current reproductive tract infection (RTI) and STI services and interventions in 45 maternal and child health and family planning (MCH/FP) service-delivery points associated with the government of Bangladesh and nongovernmental organizations (NGOs). Data were collected in several ways: Clients were interviewed prior to services, services were observed, facilities were inventoried, and interviews and focus group discussions were conducted with both clinic- and field-based service providers. Important policy implications are:

- Women recognize the problems associated with RTIs and expect services from the service-delivery points. Their health-seeking behavior for MCH/FP services provides an opportunity to address RTIs. Providers must be proactive in making effective use of these opportunities. As such, providers must change their attitudes and improve their skills in dealing with clients who have RTIs.
- The basic building blocks for effective RTI services already exist. Service-delivery protocols can be revised so that each contact is used as an opportunity to provide better services and client-provider contact can be maximized.
- Competency-based supervision and support is required to ensure quality of services.
- Existing training programs can be used to orient providers on the link between RTIs and other reproductive health services.

Traditional Family Planning in Bangladesh

The Population Council and NIPORT conducted this study in collaboration with ICDDR,B's Maternal and Child Health and Family Planning Extension Project (Rural). ACPR undertook the field study, which attempted to determine whether information about basic reproductive physiology (e.g., characteristics of the menstrual cycle, timing of ovulation, and at-risk period) should be disseminated through the family planning program. While doing so would provide women and men with information that they could use to more effectively employ traditional family planning, it would also benefit users of other temporary methods by informing them of the times during the cycle when intercourse would be particularly risky in case of method failure or unavailability of contraceptive supplies. The study findings were published in *Studies in Family Planning*.

Study of Adolescents: Dynamics of Perception, Attitude, Knowledge, and Use of Reproductive Health Care

This study, conducted by READ and the Population Council, assessed the knowledge, attitudes, and practices of sexual and reproductive health of married and unmarried adolescents aged 15–19. The study's objective was to identify the gaps where interventions may be needed to improve reproductive health. Both qualitative (focus group discussion and in-depth interview) and quantitative (semistructured questionnaire) methods were used to collect data from 2,100 adolescents. Where appropriate, husbands, guardians, service providers, and community leaders were also interviewed. The topics studied included primary health care, sexuality, ideal age at marriage, reproductive health care, family planning, women's empowerment, violence against women, smoking, and drug addiction. Some of the policy implications are:

- The MCH component of the national program should target adolescent mothers as a high-risk group with special needs. Adolescent mothers need education and information on immunizations, breastfeeding, and use of family planning, as well as on access to quality care during delivery.
- A large gap exists between the actual and desired ages at marriage and first birth for both unmarried and married adolescents. Viable social and economic options must be created to enable young women to fulfill their marriage and fertility goals.
- The low level of knowledge on all health issues—and reproductive health and sexuality in particular—indicates that systematic education on these issues is required. The challenge is determining how and where to reach adolescents—in culturally sensitive ways—in order to increase their knowledge. Use of formal and nonformal education, as well as of mass media, must be explored.

The study was pioneering in nature and documented for the first time that many adolescents are engaging in risky behavior at very young ages. The study findings were used to design a global project on adolescents under the Council's Frontiers in Reproductive Health program.

Increasing Financial Sustainability of Family Planning Service Delivery in Bangladesh

While the national family planning program in Bangladesh has been successful, the contraceptive prevalence rate will have to reach 68 percent in order to achieve replacement levels of fertility by the target date of 2005 (up from 49 percent in 1996). More resources will be needed to sustain and strengthen the program in the future. There is growing concern that resources available for funding the program will be increasingly inadequate to cover its costs. Therefore, program managers must find additional resources as well as more cost-effective ways of delivering services. This study examined the feasibility of increasing the financial sustainability of the national program by reducing its net costs. The study sampled a total of 2,590 oral pill and injectable users from both high- and low-performing areas of rural Bangladesh, and from the slum populace of Dhaka City.

The study found that setting differential prices for family planning services can encourage couples to seek services outside the home; the percentage encouraged to go out will depend on the actual differential in prices. The reduction in the burden on fieldworkers that this implies, however, must be balanced against the increased burden on clinics. Also, while there is potential for cost recovery without sacrificing equity, the current NGO experience shows that deferred payment by couples for family planning supplies may neither be the most efficient nor most cost-effective strategy for achieving this goal. A simpler, administratively less burdensome alternative is clearly needed.

BANGLADESH: SUPPORT TO THE RURAL EXTENSION PROJECT, ICDDR,B

With funds provided by USAID/Bangladesh, the Programmatic Cooperative Agreement supported the Maternal and Child Health and Family Planning Extension Project (Rural) of the International Center for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) during the period May 1995–July 1997.

The Rural Extension Project—a collaborative effort of the ICDDR,B and Bangladesh's Ministry of Health and Family Welfare (MOHFW)—sought to improve the effectiveness and efficiency of maternal and child health and family planning (MCH/FP) programs in rural areas. In 1982 the project began as an attempt to translate research findings from the ICDDR,B field site in Matlab into policy changes in the national MCH/FP program. The Population Council provided support to ICDDR,B by seconding professional staff (project directors, associate project directors, operations research scientists, and postdoctoral fellows) to conduct research and evaluation activities. In addition, the Council provided project directors with research guidance and feedback, as well as significant administrative support, consultants, and fellows from its offices in New York and Delhi.

The project developed and tested innovative interventions at its field sites; a number of these interventions have greatly influenced the policy decisions of the MOHFW. Based on project recommendations, the government of Bangladesh recruited 10,000 additional fieldworkers, which has led to a more favorable worker–client ratio. The project contributed to various components of the national health and family planning program's management information system, including fieldworker registers, client screening checklists, and monitoring tools for frontline supervisors. It also helped local managers better organize logistics and management through the provision of drug and dietary supplement kits and transport fees for paramedics attending satellite clinics. The success of the project's injectable contraceptive intervention led to its phased-in expansion nationwide. Similarly, the combined satellite clinic and Expanded Program on Immunization intervention has also been implemented nationwide. Favorable results of the emergency obstetric care (EOC) intervention have led to the government's decision to scale-up the intervention nationwide.

In addition to the impact that the operations research has had on policies of the MOHFW, the project has also influenced the program activities of many nongovernmental organizations, which have adopted several service strategies that were first tested by the project (e.g., the use of cluster spots and doorstep administration of injectables). The project has also helped to shape the mandate of the USAID-funded National Integrated Population and Health Program and the government's Health and Population Sector Strategy by introducing the Essential Service Package, testing alternative service-delivery strategies to move service delivery from the doorstep to fixed sites, operationalizing comprehensive EOC services at the community level, and increasing the emphasis on providing services in low-performing areas.

PERU: MEN AS PARTNERS IN HEALTH: A COMPLEMENTARY QUANTITATIVE STUDY

USAID/Peru directed a small amount of field support into the Programmatic Cooperative Agreement to fund a questionnaire-based quantitative study of men as partners in health that was carried out during the period July 1998–June 1999. The study followed up a prior qualitative study that was funded by USAID/Peru Purchase Order 527-O-00-97-00435.

The study surveyed indigenous rural communities both in the high-altitude sierra department of Huancavelica and in the Amazon jungle department of San Martin. Interviews were conducted with 515 males and 584 females, and the results were triangulated with the findings of the qualitative study.

Study activities encompassed the research, data analysis, preparation of a final report in Spanish, and presentation of basic findings at the Second Summer Workshop of the Population Council/Lima on 20 March 2000. Workshop participants were opinion leaders in the social and health sciences in Peru.

The study found that males are dominant in the household and women generally yield in disagreements, although any decision is viewed as being that of the couple. Women subordinate themselves to men for varying reasons, however. In the sierra, women think that subordination fosters harmony in the family and in the community. In the Amazon jungle, women yield out of fear of male violence or abandonment. The study also found that male and female children are equally valued. Sierra families expect male children to economically support parents in old age, and in the Amazon jungle female children are expected to provide emotional support in old age. Only one-third of sierra women think that, once married, they must postpone having their first child; most believe they should have one child immediately and then postpone having others. Domestic violence is prevalent: 75 percent of the interviewees had heard of cases of violence, generally against women and children. Violence directed by women against children was also prevalent.

The Council's Lima office is in the process of editing the workshop proceedings and a summary of the study findings for publication. A draft is expected to be ready for submission by 30 December 2001.

DONOR WORKSHOP ON IMPLEMENTING REPRODUCTIVE HEALTH PROGRAMS

The Population Council, in collaboration with the London School of Hygiene and Tropical Medicine, served as the Secretariat for the Donor Workshop on Implementing Reproductive Health Programs, held in New York, 12–14 June 1995. The workshop facilitated discussion of technical and implementation issues in reproductive health and promoted a better understanding of the strategies that would most effectively contribute to improving reproductive health and advancing the Cairo Program of Action. The workshop brought together technical experts, policymakers, and representatives from bilateral and multilateral donor agencies as well as several private foundations. The agenda consisted of presentations and discussions on the key components of reproductive health, developing-country experiences, and donor perspectives. Seven technical presentations addressed key areas of reproductive health, and country case studies were presented by program leaders from Bangladesh, Ghana, and Mexico. A workshop report was produced by the London School of Hygiene and Tropical Medicine for dissemination to the meeting participants and to a broader group of colleagues in the donor and reproductive health communities.

PARTICIPATION IN MEETINGS AND WORKSHOPS CONCERNING THE INTEGRATION OF FAMILY PLANNING AND REPRODUCTIVE HEALTH SERVICES

This project provided support during 1995–97 for staff from the Population Council's Robert H. Ebert Program on Critical Issues in Reproductive Health to travel to and participate in nearly 30 national and international meetings, workshops, and other forums that focused on implementing a broad approach to reproductive health and family planning. The meetings were sponsored by USAID, cooperating agencies, other international institutions, and the Council's regional programs. With this support, Council staff met the goal of *sharing new concepts, making presentations, providing expertise, developing collaborative networks, and disseminating research findings and other relevant information—all with the aim of informing policy discussions and changing practices toward improving the quality of family planning and reproductive health services.*

Since the Ebert program's inception in 1988, program staff pioneered the concept of a reproductive health approach within family planning programs. Over the years, program staff developed a body of expertise, research experience, and literature that made it one of the early sources of ideas and information on how to promote and improve reproductive and sexual health. In the years following the 1994 International Conference on Population and Development in Cairo and the Fourth World Conference on Women in Beijing in 1995, Ebert program staff were increasingly called on to provide information, expertise, and technical assistance on how to put into practice the concepts raised at these conferences and integrate them into a reproductive health approach to family planning programs and services. Council reproductive health staff who participated in meetings supported by these funds include Christa Coggins, Charlotte Ellertson, Nicole Haberland, Elizabeth McGrory, Nancy Sloan, Karen Stein, Elizabeth Westley, and Beverly Winikoff.

The collaboration of Council reproductive health staff with colleagues at these forums has contributed to enhanced understanding of the concepts of reproductive health, increased collaboration among individual colleagues and international institutions, wider exploration of approaches to services that are more responsive to meeting women's and couples' needs, appreciation of the need to strengthen dissemination efforts at local and international levels, and recognition of the responsibility of agencies to integrate reproductive health into their thinking, program planning, and services. Through these efforts, in conjunction with the work of colleagues at other organizations, many of the topics and concepts Council staff originally brought to the debate, such as quality of care, have now become central elements of a reproductive health approach to health policy and services. The concept of a reproductive health-based framework as a basis for improved services is firmly in place on the international family planning and reproductive health agenda, enabling work to move ahead on fully implementing changes in health policy and practices.