

Population Council Program III
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Summary
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GLOSSARY

Population Council Program III (PCP3). USAID Cooperative Agreement HRN-A-00-99-00010 with the Population Council.

Activity. Sometimes also referred to as a project. Each program consists of one or more activities.

Division. The Population Council is organized into several divisions. Program activities are carried out in three of these divisions, the Center for Biomedical Research (CBR), the International Programs Division (IPD), and the Policy Research Division (PRD). CBR conducts biomedical research, IPD conducts international programs, and PRD conducts policy research.

Population Council Product Development (PCPD). USAID Cooperative Agreement GPO-A-00-04-00019 with the Population Council (July 2004–June 2009). Selected product development work under the PCP3 received continued USAID funding under the PCPD.

Program. One of several bodies of work funded by the PCP3; divided into activities.

Results framework. An outline provided by USAID to categorize the USAID strategic objectives to which work funded by the PCP3 will contribute, and to list the intermediate results leading to the strategic objectives.

Year One. 13 August 1999–31 August 2000, the first program year of the Population Council Program III cooperative agreement.

Year Two. 1 September 2000–31 August 2001, the second program year of the Population Council Program III cooperative agreement (overlaps with Year Three because of USAID-mandated change).

Year Three. 1 July 2001–30 June 2002, the third program year of the Population Council Program III cooperative agreement (overlaps with Year Two because of USAID-mandated change).

Year Four. 1 July 2002–30 June 2003, the fourth program year of the Population Council Program III cooperative agreement.

Year Five. 1 July 2003–30 June 2004, the fifth program year of the Population Council Program III cooperative agreement.

Year Six. 1 July 2004–31 August 2005, the sixth program year of the Population Council Program III cooperative agreement (consists of 14 months).

INTRODUCTION

The purpose of the Population Council Program III (PCP3) was to develop, evaluate, and bring to market new and better products for family planning and for prevention of sexually transmitted HIV/AIDS and other infections, as well as conduct demographic and social science research that was highly relevant to USAID programs and policy.

Contraceptive Development

The PCP3 supported work on a number of new contraceptive methods in the product pipeline. For women, these included a vaginal ring releasing the Council's synthetic progestin Nestorone[®] (NES) in combination with ethynylestradiol (EE); pharmacology and toxicology studies to complete the safety profile for all methods utilizing NES; a second-generation subdermal implant releasing NES; and a vaginal ring releasing a potent progesterone receptor modulator. The PCP3 also supported post-marketing activities on Norplant[®] and Jadelle[®] implants. For men, the PCP3 supported the development of a subdermal implant system releasing the synthetic androgen MENT; safety studies of MENT; and a novel antispermatogenic approach utilizing a product originally developed as an anti-cancer agent.

Microbicides Program

Under the PCP3, the Population Council continued research on microbicides. The PCP3 supported the development of the Population Council's lead microbicide Carraguard[®] from funding technical assistance from Family Health International to the Council's Phase 2 expanded safety trial, to supporting a Phase 1 safety study among HIV-positive women and men, to major support for the mounting of a Phase 3 efficacy trial, all in South Africa. The PCP3 also supported development work on a contraceptive microbicide and on a second-generation non-contraceptive microbicide.

New Technologies and Strategies for RTI Interventions

A program of research to effectively diagnose and treat curable sexually transmitted infections, as well as improve efforts to prevent new infections, arose out of the work of the Microbicides Program, in the exploration of ways to facilitate and enhance microbicide clinical trials. Under the PCP3, the Council evaluated new technologies, including self-sampling techniques for STI sample collection and the use of rapid point-of-care diagnostics. Both new technologies were explored for home-based versus clinic-based use. Council researchers also documented partner notification strategies and prevalence of key infections as well as worked to improve reporting of sexual risk behaviors. This work generated useful information to improve public health systems and to reduce RTIs, as well as serving its original purpose in relation to HIV/STI prevention clinical trials. The process of implementing this program of work was effectively used to increase research capacity among local counterparts.

Expanding Contraceptive Choice

The Population Council's Expanding Contraceptive Choice (ECC) program worked to improve the reproductive health of women and men in developing countries by expanding their contraceptive choices and their options for preventing sexually transmitted infections (STIs), including HIV infection. The program aimed to increase the availability, accessibility, and use of safe, effective, and acceptable contraceptive and dual-protection technologies (methods that prevent both pregnancy

and STIs); and it sought to introduce (or reintroduce) these technologies in ways that were programmatically feasible and sustainable and were consistent with individuals' reproductive health goals. ECC staff worked with women's advocacy and health groups at community, regional, and national levels to increase individuals' informed choices within both health care and alternative service delivery systems. The program was guided by WHO's Strategic Approach to Contraceptive Introduction, a three-stage strategy designed to help policymakers and health professionals address the complex issues surrounding the introduction of contraceptive methods, including client preferences, service delivery system capabilities, provider competence, and sustainability.

Experimental Family Planning Studies in Rural Africa

An experimental study launched in northern Ghana by the Navrongo Health Research Center to assess the fertility and child-survival impact of alternative community health and family planning service strategies in rural traditional social settings was sustained for an additional six years under the PCP3. The study had already begun to demonstrate an impact on fertility decline in treatment areas, and under the PCP3 the full impact of the design and its operational components were observed. It was found that posting nurses to communities reduced childhood mortality rates by half, and adding community mobilization strategies and volunteer outreach to this approach led to a 15 percent reduction in fertility. When a replication project in the Volta Region demonstrated that the Navrongo service model could be transferred to a nonresearch setting, the Government of Ghana adopted the Navrongo approach as the health component of its national poverty-reduction strategy. In 1999, the Community-based Health Planning and Services (CHPS) initiative was launched to accelerate implementation of this policy. By mid-2005, CHPS was fully operational in 20 districts and under development in nearly every other district of Ghana. Analysis of successive phases of the Ghana program development process demonstrates feasible means of improving national access to reproductive and child health services.

Understanding and Meeting the Needs of Adolescents

The Population Council's program of research on transitions to adulthood in developing countries seeks to better understand adolescents' lives and to identify, design, and test various interventions to increase opportunities and reduce risks for adolescents, particularly girls. The ultimate goal is to allow adolescents to emerge as reproductively healthy adults with productive skills that will permit them to be full participants in work, family, and community life. The PCP3 partially supported research on adolescents in five countries: Three activities assessed the impact of new programs designed to affect the timing of marriage and childbearing and improve adolescent reproductive health, in order to identify policy interventions that will delay marriage and childbearing sufficiently to create the space in which more "successful" transitions to adulthood can occur, and at the same time contribute to filling that space with investments in improved capacities. The other two activities assessed a new technique designed to improve the accuracy of the data collected on adolescent sexual and reproductive behavior.

Transitions in Reproductive Behavior in the Developing World: Key Policy Issues

Over the past three decades, a revolution in reproductive behavior has swept through most of the developing world. Contraceptive use, once rare, is now widespread. The average number of births per woman has fallen by half—from six or more to nearly three. This program carried out four studies which shed light on several key issues related to the prospects for future trends in fertility and contraceptive use, including the future trend in the demand for contraception for the world and

its major geographic regions; the accuracy and significance of the “birth dearth” hypothesis; and the impact of family planning programs on differentials in contraceptive use and fertility within developing countries.

Urban Studies

The Nairobi Urban Health and Poverty Project (NUHPP) is a project of the Council-affiliated African Population and Health Research Centre intended to address the need for systematic research and experimental interventions focusing on problems of the urban poor. The PCP3 supported a needs assessment in 2002 in the four slum settlements in Nairobi, Kenya where the NUHPP project was slated. Later, the PCP3 supported research in Ouagadougou on urban malaria control.

Other Mission- and Core-Funded Initiatives

Several other activities which fit within USAID’s results framework for the PCP3 were supported by the agreement. These activities were undertaken by Population Council researchers not on the staff of the other programs, and were therefore administratively separated into the groups “Mission-Funded Initiatives” and “Core-Funded Initiatives.” Almost all of these activities took place in the field, with most funded by mission field support.

**USAID RESULTS FRAMEWORK
for
POPULATION COUNCIL PROGRAM III**

SO 1 To expand the range and optimize the use and availability of safe, effective and acceptable technologies for the prevention of pregnancy and STIs/HIV.

IR 1.1 Improved and new contraceptive and reproductive health technologies developed, evaluated and approved.

- SR 1.1.a Improved biological knowledge base for understanding, prioritizing and applying new or existing technologies.
- SR 1.1.b Prototype technologies developed and tested.
- SR 1.1.c FDA and/or host country approval obtained.
- SR 1.1.d Private sector partnerships established.

IR 1.2 Use of contraceptive and reproductive health technologies optimized and expanded.

- SR 1.2.a Expanded knowledge of client acceptability, use dynamics, provider perspectives, and risks and benefits of technologies.
- SR 1.2.b Products, tools, technologies and knowledge transferred in a form that can be received, utilized and sustained; products introduced.
- SR 1.2.c Improved understanding of service delivery strengths and weaknesses as related to expanding technologies.
- SR 1.2.d Effective linkages created between reproductive health technologies and development of other health technologies.

IR 1.3 Microbicides and microbicides/spermicides developed, evaluated and approved.

- SR 1.3.a Improved biological knowledge base for understanding, prioritizing, and applying new or existing technologies.
- SR 1.3.b New and improved methodologies, tools and technologies for management training, IEC, policy, data collection, and evaluation developed and tested.
- SR 1.3.c Prototype technologies developed and tested.
- SR 1.3.d FDA and/or host country approval obtained.

SO 2 Improved policy environment and increased global resources for family planning and reproductive health programs.

IR 2.1 Policy reform and program planning decisions at all levels are informed by timely and accurate data.

- SR 2.1.a National and operational policies relating to family planning and reproductive health formulated, disseminated, and implemented, and barriers to service availability removed.
- SR 2.1.b Inappropriate barriers to information and services for special populations are removed.

SO 3 Innovative service delivery strategies developed, evaluated and, where appropriate, expanded to the national level.

IR 3.1 New and improved strategies developed, tested and evaluated.

- SR 3.1.a Innovative service delivery strategies developed and evaluated and existing strategies improved.
- SR 3.1.b Policy reform and program planning decisions at all levels are informed by timely and accurate data.
- SR 3.1.c Enhanced understanding of issues contributing to change of reproductive intention and behavior.

Contraceptive Development

USAID provided major funding for the Contraceptive Development program under the Population Council Program III (PCP3) cooperative agreement. These funds supported work on a number of new methods in the product pipeline. For women, this included a vaginal ring releasing the synthetic progestin Nestorone® (NES) in combination with ethynylestradiol (EE); pharmacology and toxicology studies to complete the safety profile for all methods utilizing NES; a second-generation implant releasing NES; and a vaginal ring releasing a potent progesterone receptor modulator. They also supported post-marketing activities on Norplant® and Jadelle® implants. For men, the PCP3 supported the development of a subdermal implant system releasing the synthetic androgen MENT; safety studies of MENT; and a novel antispermatogenic approach utilizing a product originally developed as an anti-cancer agent.

Female methods

A Phase 2 study completed in Year Three (2002) investigated the effect of various doses of NES/EE rings when used on a bleeding signal regimen, where the ring was left in continuously until menstruation commenced, following which the ring was removed for four days and then reinserted whether bleeding had ceased or not. Following completion of the bleeding signal study, the decision was taken to develop a ring that releases NES/EE in a dose of 150/15 µg/day on a three-weeks-in, one-week-out usage schedule. Three studies were carried out to complete the safety profile of the NES/EE ring. A review of the data from the three studies took place at the April 2004 meeting of the International Committee on Contraception Research; the data confirmed that the NES/EE ring was safe for further development and entry into a pivotal Phase 3 trial for registration. Negotiations were undertaken with potential contract manufacturers for the NES/EE ring, since in order to register the ring with the FDA, a large-scale Phase 3 study must be carried out with rings made using the mass-manufacturing method. A contract manufacturer, QPharma of Malmö, Sweden, was identified to make the rings. Technology transfer, validation of the manufacturing process, and planning for the mass manufacture of the rings—a very difficult and time-consuming series of processes—were carried out. Further development of the NES/EE ring continues under the Population Council Product Development cooperative agreement.

Various preclinical pharmacology and toxicology studies of NES were undertaken. These studies indicated that NES is not carcinogenic, has neither mineralocorticoid nor anti-mineralocorticoid activity, does not cause local toxicity, and is non-genotoxic. They also indicate that use of NES does not lead to interactions with other drugs, and that NES is significantly more antiestrogenic than two other progestins evaluated as comparators.

An implant releasing NES was tested in a clinical trial. NES is not active orally as a result of a high rate of first-pass hepatic metabolism, a feature that makes the NES implant ideal for lactating women. Although initial results of this trial were favorable, three pregnancies occurred at months 18, 21, and 24 of implant use. Accordingly, the decision was made to close out the trial. Efforts to interest a partner in the commercialization of this approach for lactating women are ongoing.

The PCP3 supported preclinical work and a Phase 1 study of a vaginal ring releasing CDB-2914, a progesterone receptor modulator. Rings were manufactured and *in vitro* release rate studies indicated that the molecule was readily absorbed into the blood stream and ovulation was suppressed in some women. Data from the Phase 1 study suggested that a significant increase in the dose delivered per day would result

in a continuous, bleed-free method of contraception. Subsequent studies of the approach were funded from sources other than USAID.

In an effort to expand the cost effectiveness of the Norplant implant, Council staff focused on extending the use-life of this implant system from five to seven years of contraceptive effectiveness. Data was analyzed and submitted to the U.S. Food and Drug Administration (FDA), which deemed the submission “approvable,” while at the same time requesting additional information from the Council and the manufacturer. The Council’s effort to extend the use-life to seven years continues with funding under the Population Council Product Development cooperative agreement.

A similar effort was mounted in support of Jadelle. Clinical trials of this highly effective implant system, completed during 1999, strongly supported a claim of effectiveness beyond the approved three years of use. The data from these studies were collected, processed, assembled, and submitted to the FDA in September 2000; Jadelle was approved for five years of use in women on November 22, 2002, significantly enhancing the cost effectiveness of this method.

Male methods

For men, the Council’s lead product was an implant releasing the synthetic androgen MENT. A multicenter dose-finding study was concluded, with subjects responding in a dose-dependent fashion. To enhance the antispermatogenic response, implants were reformulated and a study was carried out to compare MENT alone with three groups of various MENT-plus-levonorgestrel dose combinations. Subjects in all groups at each of the three participating clinics showed suppression of testosterone. Sperm suppression was uneven, however, and there were wide inter-clinic variations. As the trial was designed to be truncated at six months of use if less than 70% of subjects achieved azoospermia (the absence of sperm in semen), the decision was taken to close out the study. A series of toxicology and pharmacology studies of MENT were carried out to establish the safety profile of MENT. These indicated that MENT is neither toxic nor genotoxic, and that MENT supports bone and muscle growth without overstimulating the prostate.

Analogues of lonidamine, a drug originally developed to treat cancer, were found to have potent antispermatogenic effects *in vivo*. A series of toxicity and genotoxicity studies of AF-2364, one of the lonidamine analogues, showed no chromosomal damage or other toxic effects in animals treated with the compound at the doses tested. Preliminary pharmacokinetic studies were also conducted to investigate the clearance of AF-2364. Findings indicated that the drug was detectable within one hour of oral administration, and was then rapidly cleared from the systemic circulation. It was virtually undetectable within 24–48 hours, indicating that it is rapidly absorbed through the gastrointestinal tract. AF-2364 was not detected in the cerebrospinal fluid or brain extracts of rats treated with the molecule, suggesting that the compound does not cross the blood-brain barrier.

Microbicides Program

With significant support from the US Agency for International Development (USAID), the Population Council has been at the forefront of an international movement to develop vaginal microbicides—female-initiated products that would kill, inactivate, or block HIV and other sexually transmitted infections. The Population Council’s Microbicide Product Research and Development Program is a collaborative effort of two of the Council’s research divisions: the Center for Biomedical Research and the International Programs Division. For over 15 years, the Microbicides Program has included a broad spectrum of activities necessary for developing, testing, and producing microbicides, including basic research, product development, clinical trials, behavioral studies, and public education.

Under the Population Council Program III (PCP3), USAID provided \$300,000 over the first two years to support ongoing technical assistance from Family Health International to the Phase 2 expanded safety trial in South Africa of Carraguard®, the Population Council’s lead microbicide, as well as seed money to begin a Phase 1 safety study of Carraguard among HIV-positive women in South Africa. The dramatic increase in funding to over \$3 million a year in Years Three and Four and almost \$7 million in Year Five of the agreement allowed a significant expansion of the Microbicides Program, enabling completion of the Phase 1 safety study among HIV-positive individuals, mounting of a Phase 3 efficacy trial of Carraguard, and development work on a contraceptive microbicide and on a second-generation non-contraceptive microbicide.

Phase 3 Efficacy Trial of Carraguard

The greatest achievement was beginning the Phase 3 efficacy trial of Carraguard, currently ongoing at three sites in South Africa: Gugulethu, implemented by the University of Cape Town; Soshanguve, implemented by the University of Limpopo/Medunsa Campus; and Isipingo, implemented by the South African Medical Research Council (MRC). As this trial is one of the first microbicide Phase 3 efficacy trials of a novel product, its initiation in March 2004 was a major event, with several important milestones along the way.

PCP3 funding enabled the creation of two research centers, the Empilsweni Centre for Wellness Studies in Gugulethu and the Setshaba Research Centre in Soshanguve. These two state-of-the-art clinics are enrolling more than 4,000 women (over 2,000 per site), a ten-fold increase over Phase 2 capacity. The PCP3 also supported the first six months of the scale-up process at the MRC site in Isipingo. In addition to increasing physical capacity with substantial renovations, Phase 3 preparation and scale-up at the study sites included hiring staff (approximately 35 people at each site) and training them in Good Clinical Practice (GCP), developing on-site laboratories, producing a recruitment video and study booklet to educate potential study participants, and establishing relationships with the local communities. As of August 31, 2005, 4,361 women had been enrolled in the trial, surpassing the expected enrollment rate of 50%.

Another major achievement was completing the procedural scale-up for gel manufacturing for the Phase 3 trial at Clean Chemical Sweden (CCS), including all required documentation for the Chemistry, Manufacturing, and Control (CMC) file, required by regulatory authorities. The successful scale-up at CCS has enabled continuous gel production to keep pace with study needs. Headway was also made in documenting Carraguard’s stability, another important aspect of the regulatory file, particularly to enable

registration of Carraguard as an over-the-counter product. Under the PCP3, it was determined that Carraguard is stable for at least two years. (Stability testing to establish a five-year stability profile continues under the follow-on Population Council Product Development cooperative agreement [PCPD].)

The management of the Phase 3 trial also features several important accomplishments. The Council is the first microbicides trial sponsor to develop a biological marker to test for applicator usage. This test can determine if applicators were actually inserted in the vagina, information that will enable a much better sense of adherence than that gained from interviews only. This technology has been applauded by the U.S. Food and Drug Administration, and other sponsors have approached the Council about using the applicator test in their future trials. In addition, a bar code system was introduced to track used and unused applicators. The bar code system has been extremely helpful for product management, both in terms of product accountability as well as to determine if gel has been shared between participants. The Council also instituted the DataFax system for data management. This system allows us to keep data entry up-to-date, and functions reliably in places such as South Africa where access to the Internet is unreliable. In addition to being a valuable tool for the Carraguard Phase 3 trial, DataFax has increased capacity at the Council for other clinical trials.

In addition to the main trial outcome — determining if Carraguard reduces risk of HIV transmission in women — special aspects of the trial are also being studied. An evaluation of the informed consent process began in Gugulethu and Soshanguve, to assess whether the video has an impact on comprehension and willingness to participate. The evaluation will be completed under the PCPD agreement. Also in Soshanguve, a study co-funded by the PCP3 and the Hewlett and MacArthur Foundations began, which aims to explore the referral network for HIV-positive women to determine if women identified as HIV-positive at screening are using the services and, if so, whether or not the services meet their needs.

The Phase 3 efficacy trial of Carraguard will continue through 2007, supported by USAID under the PCPD and by the Bill & Melinda Gates Foundation. The wealth of data from this trial will be important for future microbicide trials at the Council, and for the microbicides field as a whole.

Phase 1 Safety Study among HIV-positive Women and Men in Durban

A second achievement on the clinical front was completion of a randomized, controlled, partially-blinded Phase 1 safety trial of Carraguard among HIV-positive men and women, implemented by the MRC in collaboration with the US Centers for Disease Control and Prevention (CDC). Ensuring the safety of a candidate microbicide among HIV-positive individuals is critical, as many men and women may not know their HIV status before using such a product. Carraguard was shown to be safe among this population, when compared with the placebo methyl cellulose or a no gel control arm. In addition to the primary outcome measures of safety (signs and symptoms of local irritation), Council researchers are also analyzing data from cervical-vaginal lavage samples to determine whether Carraguard has any impact on genital shedding of HIV, as well as data from the use of two novel techniques developed by Clyde Hart's laboratory at the CDC which will allow investigation of infectious virus within the lavage. These data will have broader implications than for microbicide studies alone, as scientists try to better understand genital shedding of HIV and how to measure it effectively. In addition to showing that Carraguard is safe, the study marked the first collaboration for a clinical trial between the Population Council and the MRC, paving the way for the MRC's participation in the Phase 3 efficacy trial.

PC-815: A second-generation microbicide

Second-generation microbicide products are hoped to be even more effective than Carraguard. In laboratory testing, PC-815 — a combination of Carraguard and MIV-150, an anti-retroviral — demonstrated effectiveness against a range of sub-types of HIV-1, and activity against HIV-1 and HIV-2 both in the presence and in the absence of seminal fluid. Development of PC-815 continues under the PCPD agreement.

CARRA/NES : A contraceptive microbicide

Though some women may need a non-contraceptive microbicide, a product is also needed that provides dual protection for both disease and pregnancy. CARRA/NES combines Carraguard with the hormonal contraceptive Nestorone, and it is being developed for use as an “on-demand dual protection” method. One of the greatest challenges has been developing a formulation that ensures optimal release and diffusion of Nestorone within the Carraguard gel formulation. Under the PCP3, considerable progress in pre-clinical work was made, including demonstration of even release drug kinetic profiles in *in vitro* and *in vivo* studies, and establishment of a six-month stability profile.

Basic research on HIV-transmission: Dendritic cells

During Year Five, the PCP3 agreement supported scientist Melissa Pope’s studies on the function of dendritic cells in HIV transmission, as well as research to document the capacity of carrageenan and zinc-carrageenan to block virus captured by dendritic cells. *In vitro* studies showed that these formulations had no overt impact on dendritic cell biology, as well as preliminary evidence that they could limit dendritic cell to T-cell spread of HIV infection.

USAID’s support of the Council’s Microbicides Program has enabled accomplishment of a range of groundbreaking activities in basic research, product development, and clinical trials. In addition to directly supporting our work, funding from USAID led to successful fundraising from other donors, including the Bill & Melinda Gates Foundation and the Swedish International Development Cooperation Agency. We look forward to a continued collaboration with USAID through the PCPD agreement, and to continue to move the microbicide product development field forward.

New Technologies and Strategies for RTI Interventions

Non-HIV reproductive tract infections (RTIs) constitute the second major cause of disease burden (after maternal-related causes) in young adult women in resource poor countries. An estimated 340 million curable sexually transmitted infections (STIs) and 6 million new HIV infections occur annually. Curable STIs such as gonorrhea and chlamydia, when not treated properly, can lead to serious sequelae such as pelvic inflammatory disease and infertility. Furthermore, a broad array of RTIs have been shown to increase susceptibility to HIV and HIV infectiousness. Effectively diagnosing and treating curable sexually transmitted infections, as well as enhancing efforts to prevent new infections, are therefore critical public health endeavors. The Population Council, with support from USAID under the Population Council Program III (PCP3), has made a number of important inroads toward these ends through evaluation of new technologies, including self-sampling techniques for STI sample collection and the use of rapid point-of-care diagnostics. Both new technologies have been explored for home-based versus clinic-based use. Council researchers also have been actively documenting partner notification strategies and prevalence of key infections as well as working to improve reporting of sexual risk behaviors. All of this work has served the dual purpose of generating useful information to improve public health systems and to reduce RTIs, as well as exploring ways to facilitate and enhance HIV/STI prevention clinical trials. Additionally the process of implementing this program of work has been effectively used to increase research capacity among local counterparts.

Self-sampling for reproductive tract infections

Several previous studies have shown that self-collection of vaginal swabs or tampons is a valid way of collecting specimens for diagnosis of a variety of reproductive tract infections. Self-sampling techniques may significantly aid in efforts to reach underserved populations that need improved diagnosis and treatment, particularly populations with elevated prevalence of asymptomatic RTI. Additionally, such self-collection is a potentially useful tool in field trials for HIV/STI prevention, in which women are asked to undergo frequent testing for RTIs. Until now, these self-collection techniques had not been adequately tested in resource-poor settings, and had not been used to diagnose multiple pathogens.

In preparation for the large-scale trial of the Council's lead candidate microbicide Carraguard®, the Population Council, in collaboration with the University of Cape Town (UCT), implemented a study in Gugulethu, South Africa to test the feasibility, validity, and acceptability of self-sampling techniques. Self-sampling with both tampons and swabs resulted in satisfactory validity for gonorrhea, chlamydia, bacterial vaginosis, and yeasts, and with swabs only for high-risk human papillomavirus types, though not for trichomoniasis, diagnosed by culture. Both self-sampling methods were found to be feasible and as acceptable as speculum examination. Researchers concluded that self-sampling should be further explored for RTI screening strategies in resource poor settings, as well as for use within HIV/STI prevention trials.

A second study, also in collaboration with UCT, was undertaken in Gugulethu to explore the use of self-sampling at home. Simultaneously, a sister study was implemented in Brazil, in collaboration with the Centro de Estudos Augusto Leopoldo Ayrosa Galvão Research Center (CEALAG). Preliminary results from both studies found that women generally found self-sampling to be acceptable and easy, either at the clinic or at home. The studies showed that home-based self-sampling for RTIs was acceptable and feasible and should be further explored as an option within these communities.

Rapid point-of-care testing

The World Health Organization recommends syndromic management of STIs in areas where laboratory diagnosis is not feasible due to costs and/or available technology. However, syndromic management of infections often fails to diagnose asymptomatic clients, especially among women, who have been demonstrated to make up as much as 50% of STI cases. Additionally, syndromic management often results in over-treatment of clients, notably women diagnosed with “abnormal discharge.”

Rapid point-of-care testing, where specimens are collected and tested in a short time, is a potentially effective method for improving diagnostic validity at a lower cost than current gold standard laboratory tests, while still providing same-day treatment, as syndromic management. As part of the studies in Brazil and South Africa to explore home sampling, introduction of a rapid Optical Immunoassay test for gonorrhea and chlamydia in a clinic setting, as well as an easy-to-administer litmus-type test for trichomoniasis for use at home and at the clinic was tested for feasibility. Preliminary results from both studies found that it was feasible and acceptable for both women and providers to use rapid tests in both clinic and home settings, although they also suggest that the OIA CT and GC tests, which require significant time and training, did not perform very well.

Home-based versus clinic-based RTI screening

Studies suggest that home-based screening may encourage RTI testing and treatment among young people, by virtue of convenience, privacy and avoiding the stigma of clinic attendance. A second generation of studies tested the hypothesis that home-based screening would increase the number of women screened for RTIs in Brazil and South Africa. Preliminary results from both studies suggest that slightly more women responded to the home-based initiative than clinic-based screening, although this difference was not statistically significant. While home-based screening is a viable alternative to clinic-based screening, additional efforts are needed to attain improved compliance with screening initiatives.

Partner notification strategies

Effectively treating a woman for an STI without treating her partner(s) often leads to re-infection. Partner notification and treatment is an essential component of STI care, but is often difficult to implement effectively. In the second generation of self-sampling studies, we explored the use of patient-delivered medication (in which a woman with an infection brought the treatment to her partner[s]). It was found that introducing this option was a viable option in both study locations and resulted in a high proportion of partners being treated. Brazilian and South African collaborators on this study plan to publish these findings with commentary in local medical journals to begin the process of strengthening their respective health ministries’ guidelines on partner notification and treatment.

Prevalence of infections

This body of work provided important data on the prevalence of the sexually-transmitted infections bacterial vaginosis, yeasts, trichomoniasis, Chlamydia, gonorrhoea, and human papillomavirus (HPV) in the study communities. An alarmingly high rate of high-risk human papillomavirus (HPV) was found in Gugulethu, South Africa (36%), and analysis of the types of HPV found on self-obtained vaginal swabs versus clinician-obtained endocervical swabs is being performed in late 2005. Prevalence data from this study was used as background information for the Phase 3 trial of Carraguard undertaken in the same community. In Brazil, stored specimens were tested and typed for HPV, as little is known about the prevalence of specific HPV types in this community. Additionally, these specimens were tested for *mycoplasma genitalium*, for which little to no data currently exists in Brazil. These results will be available in late 2005.

Improving reporting of sensitive behaviors

Understanding the relationship between sexual behavior and the prevalence of STIs and HIV is imperative for designing effective interventions that maximize STI/HIV prevention and minimize re-infection. If risky sexual practices and partnering are under-reported in face-to-face interviews, or if condom use is exaggerated, the ability to design and evaluate interventions to prevent STIs/HIV is greatly hindered. Additionally, accurate reporting of these types of behaviors in the context of an HIV/STI prevention trial is critical to being able to interpret trial results.

As part of the Council's work to improve reporting and documentation of sensitive sexual behaviors (further reported in the summary for the program "Understanding and Meeting the Needs of Adolescents"), a randomized sub-study to look at the use of audio computer-assisted self-interviewing (ACASI) compared with face-to-face interviewing was included in the Brazil study, with the added benefit of having biological markers of STI infections to act as external validation for any differentials found in reporting. Preliminary results from the study indicate higher rates of reporting of almost all sensitive behaviors in the ACASI arm. The converse was also true in that socially acceptable or "positive" behaviors, such as having previously had a pelvic exam, had higher levels of reporting in the face-to-face arm. Analysis comparing interview methods in predictive models of sexually transmitted infections has yet to be completed, as has the analysis of the consistency of reporting between two points in time. Nevertheless, the initial results are promising and suggest that the greater confidentiality and privacy afforded by ACASI lead to greater reporting of sensitive behaviors than traditional modes of interviewing.

Capacity building

To sustain and promote changes in health systems requires strengthening in-country capacity for relevant research and advocacy. As such, Council staff have actively and successfully sought opportunities for capacity building during the implementation of this program.

In South Africa, a researcher from the University of Cape Town, with additional support from the Gates Foundation, participated in the University of San Francisco's Center for AIDS Prevention Studies (CAPS) Program, in which she developed the protocol for the home-based versus clinic-based screening study in South Africa with joint mentoring from Council staff. For this study, UCT staff took the lead in designing the questionnaires, with technical assistance and feedback from Council staff. Additionally, UCT staff expressed an interest in taking over the data management function for the second study and were therefore trained and implemented data management successfully for this study. This study also functioned as a "trial run" for the new study facility, which was built for the larger Phase 3 Carraguard study.

The Brazil study was the first international collaboration for the local partner organization. Staff were trained in designing and administering budgets for subawards, maintaining good clinical practices, and designing and upholding standard operating procedures. These collaborators are now actively seeking to establish a research group in São Paulo and are writing proposals for new projects. Additionally, members of the staff were trained in the technical aspects of the computer interviewing software program during the design of the baseline questionnaire, and were then able to tailor the program themselves to administer the follow-up questionnaire, enabling them to use the ACASI method again in any new studies they design.

In both studies, since no commercial kits are currently available for trichomoniasis polymerase chain reaction (PCR), local laboratories calibrated and designed in-house PCR capability for trichomoniasis. Our

collaborator in Brazil has since offered the use of this low-cost test to staff within his hospital more broadly. Additionally, in Brazil, lab staff received training in the use of the Roche COBAS Amplicor system for diagnosis of gonorrhea and chlamydia, although the renting of this equipment was not sustainable after the study ended.

Finally, staff from both UCT and CEALAG attended and presented at a number of local and international conferences and meetings, including the International Society for Sexually Transmitted Diseases Research meetings (ISSTD) in 2003 and 2005, Microbicides 2004, the South African AIDS Conference, the International Conference on Chemotherapy, the 6th Brazilian Epidemiology Conference, and an in-house investigators meeting in New York.

Dissemination activities

In addition to dissemination by local partner staff, results were also disseminated at an Alliance for Microbicide Development Meeting in Washington, DC in January 2005; “Hormonal Contraception and HIV Transmission: Links? Mechanisms? Implications,” at Gynuity Health Projects, New York Academy of Sciences, May 2005; the International Center for AIDS Care and Treatment, Columbia University; and will be disseminated at the American Public Health Association meeting later this year. Additionally an abstract has been submitted to the Population Association of America. A publication on the feasibility, acceptability, and validity of self-sampling in South Africa is currently under review by a journal, and additional articles are anticipated to be submitted in the next few months. The Brazil team is organizing a meeting with local stakeholders in early 2006 to disseminate the many findings from this study, and are writing publications to be submitted to Brazilian peer-reviewed medical journals. The South African team is currently focusing on disseminating the findings on partner-delivered medications to key officials.

In conclusion, Council staff and their collaborators in South Africa and Brazil, through USAID’s generous support of the program New Technologies and Strategies for RTI Interventions, have made significant contributions to research and programs aimed at reducing RTIs, including HIV, worldwide.

Expanding Contraceptive Choice & ECC-related Mission-Funded Initiatives

The Population Council's Expanding Contraceptive Choice (ECC) program worked to improve the reproductive health of women and men in developing countries by expanding their contraceptive choices and their options for preventing sexually transmitted infections (STIs), including HIV infection. The program aimed to increase the availability, accessibility, and use of safe, effective, and acceptable contraceptive and dual-protection technologies (methods that prevent both pregnancy and STIs); and it sought to introduce (or reintroduce) these technologies in ways that were programmatically feasible and sustainable and were consistent with individuals' reproductive health goals. ECC staff worked with women's advocacy and health groups at community, regional, and national levels to increase individuals' informed choices within both health care and alternative service delivery systems. The program was guided by WHO's Strategic Approach to Contraceptive Introduction, a three-stage strategy designed to help policymakers and health professionals address the complex issues surrounding the introduction of contraceptive methods, including client preferences, service delivery system capabilities, provider competence, and sustainability.

The ECC program was staffed by a director in New York, and technical staff in each of three regions: in Nairobi and Lusaka for the East and Southern Africa region, in Dakar for the West and Central Africa Region, and in Sao Paulo for the Latin America and the Caribbean region.

USAID supported the ECC program with a mix of core and field support funds through Year Three of the Population Council Program III, with funded projects persisting to completion. Several projects in Zambia and Brazil that were begun under the ECC program but required renewed funding were sustained forward by the USAID missions. USAID/Zambia and USAID/Brazil also initiated new projects in collaboration with their regional Council colleagues during Years Four through Six, funded entirely by field support.

This section includes all projects completed either under the ECC program, or under subsequent mission-funded initiatives that arose from the working relationship between the USAID mission and former ECC regional Council staff. It is divided into three sections, one for each region's body of work under the PCP3.

East and Southern Africa Region

Work under the Population Council Program III (PCP3) in East and Southern Africa began as part of the Council's Expanding Contraceptive Choice (ECC) program, supported by a combination of core and field support funds. After USAID/Washington discontinued funding for the ECC program, activities in the region nevertheless continued: The strong working relationship between regional Population Council staff and the USAID mission in Zambia allowed for the fruition of the major "From Pilots to Regional Program" (PRP) project, and two new research projects, on dual protection and on emergency contraception.

The major achievements in the region during the six years of funding through the PCP3 cooperative agreement are summarized below.

Formulated and field tested a sustainable, cost-effective model for scaling up health care interventions originally introduced on a pilot basis.

The last ten years have seen a concerted effort by the development community to identify the successes of past health interventions, heighten awareness of them, and maximize their impact through some form of replication or scaling-up. While each step in this process has generated unique sets of problems and challenges, it is the last that has been particularly problematic, in large part because so few models exist to guide and inform the scaling-up process in any systematic manner. The PRP project has contributed significantly to filling this critical gap.

Born out of the need to expand a series of successful pilot interventions in Zambia's Copperbelt Province, the PRP Initiative developed into a flexible, innovative, and sustainable framework to guide the scaling-up of pilot interventions generally. Designed around a series of logical stages and conceptual objectives, the model applies a systematic approach for recognizing and responding to the tensions inherent in any scaling-up effort. These include conflicts between quality and quantity; expansion and local relevance; and higher costs and increased benefits.

In the past three years, the PRP Initiative has successfully increased both contraceptive choice and prevalence; it has introduced innovative, cost-effective strategies to train health care providers; and it has forged new linkages between the health sector and the communities it serves. But perhaps even more importantly, it has set in motion a scaling-up process that promises to endure well beyond the end of USAID funding. In 2004, the Zambia Ministry of Health selected the PRP framework as its model, or best practice, for scaling up reproductive health services over the coming decade. Already joint efforts are underway by the Population Council and Ministry of Health (with WHO funding) to document lessons learned, disseminate best practices nationally, and develop a proposal for submission to key bilateral and multilateral donors. Meanwhile, at the local level, the Copperbelt Provincial Health Office (PHO) has already taken over responsibility for sustaining the scaling-up of its own PRP-inspired interventions. Using resources from its existing budget allocations, the PHO is supporting key district staff to sustain key initiatives in the areas of broad method choice, provider training, and joint-district planning.

Demonstrated how the introduction of new contraceptive technologies can strengthen the quality of reproductive health (RH) services generally.

Though the impetus for introducing any new technology typically derives from some property of the technology itself — its utility, effectiveness, or responsiveness to client needs — our work under the PCP3 has shown how the introductory process can serve as a valuable tool for bringing about changes in the content and quality of RH programs and services. Because technology transfer impacts on virtually every aspect of the service delivery system, the introductory process serves as an effective tool for setting in motion a host of service-related changes. In East Africa, for example, efforts to expand contraceptive choice have been pivotal in simultaneously reinforcing provider skills and knowledge, strengthening supply and logistics systems, and empowering clients to assume a greater role in decision making towards both their health care system and fertility regulation. Nowhere has this “ripple effect” been more evident than in Zambia, where the PRP Initiative brought about fundamental changes in the service delivery system. And more recently, the Council’s work to re-introduce emergency contraception (EC) in Zambia’s Copperbelt has shown how contraceptive introduction can serve as a conduit for strengthening a whole host of support services (law enforcement, medical, psychosocial and legal) for victims of rape and sexual violence.

In Ethiopia, efforts to introduce EC served as a catalyst for broad-based changes at the service delivery level. It prompted our partner, the local International Planned Parenthood Federation affiliate Family Guidance Association of Ethiopia, to review its policies and procedures over the selection and use of peer providers. Other changes were the introduction of new approaches to disseminate information about young people’s RH needs; a heightened awareness of the importance of dual protection and condom use, reinforced through new messages and counseling linking EC and condom use; and the introduction of new service delivery systems designed to track dual protection at the community and service delivery level.

Established the technical expertise and professional credibility required to found *ECafrique*, the Africa Forum on Emergency Contraception.

In 2003, the Nairobi office of the Population Council established a bilingual, international network of health care professionals seeking to mainstream quality emergency contraception services in Africa. Called *ECafrique*, the network is today a respected, independent force for building the knowledge base and institutional framework needed to introduce, deliver, and mainstream quality emergency contraception services.

Though the immediate catalyst for *ECafrique* was grants from the Hewlett and Compton Foundations, the network itself would not have been possible without the legacy of EC-related research carried out under the PCP3. Our USAID-funded work in Zambia, for example, is noteworthy for having pioneered the study of advance provision of EC pills; of the challenges of transitioning from the Yuzpe to a progestin-only regimen; and of the obstacles to introducing EC into both public and private settings. Through the support of the PCP3, the Population Council and Ethiopia’s IPPF affiliate were the first in Africa to systematically repackage combined oral contraceptives for emergency use, and to package EC with the male condom. Worldwide recognition of this work played a pivotal role in garnering the support of partner organizations internationally, including in well over three-quarters of all countries in sub-Saharan Africa. It has also made *ECafrique* a credible entity in the eyes of the international donor community. Today, many of the interventions initially begun as pilot studies under the PCP3 are being scaled up with non-USAID funding, either through *ECafrique* or directly to implementing organizations. contraceptive method mix.

Made possible the re-introduction of DMPA and natural family planning into Zambia's national contraceptive method mix.

Though the process of contraceptive introduction can often strengthen service delivery systems in ways that extend far beyond the immediate properties of the contraceptive technology itself, there are many instances where the significance of introductory efforts does hinge on the ability of that technology to address the distinctive contraceptive needs of key population groups. In Zambia, two such technologies fell into this category: injectable contraception, specifically DMPA, and natural family planning (NFP), particularly the standard days method (SDM).

Though profoundly different in many respects, the status of these methods within Zambia's contraceptive method mix was, five years ago, quite comparable. Opposition towards DMPA, though initially motivated by political and historic concerns, was entrenched among senior staff in the Ministry of Health. As a result, despite considerable demand for the method among users and providers, it remained virtually nonexistent in the public sector. In the case of natural family planning, opposition came from the other end of the spectrum, from lower-level health care providers encouraged to believe that provision of NFP was too complex. In both instances, resistance to these methods meant that the contraceptive needs of a huge sector of the population, particularly the nearly 60 percent of the country who live in rural areas, were not being met.

One of the greatest achievements of the PRP Initiative was to have brought down the many barriers that had, for years, prevented any mainstreaming of injectable contraception and NFP. Through a combination of evidence-based data, innovative efforts at service provision, and sheer persistence, the Council's work under the PCP3 and the preceding PCP cooperative agreement succeeded in bringing about a complete reversal of attitudes towards the two methods. Thanks to the support of USAID and the active involvement of the Copperbelt Provincial Health Office, the year 2005 brought to a close a process that had begun in the mid-1990s, with the launch of a pilot study under the previous PCP Agreement co-funded by WHO. In this year DMPA received regulatory approval by Zambia's Pharmacy and Poisons Board, and SDM was incorporated within the national RH guidelines. In the eyes of the Ministry of Health, the USAID mission, and the RH community generally, credit for incorporation of these methods in the national contraceptive method mix rested squarely with the PRP Initiative and its preceding pilot study.

West and Central Africa Region

Expanding Contraceptive Choice (ECC) program objectives in the West and Central Africa (WCA) region were implemented by staff in Dakar, Senegal with direction, assistance, and support from New York–based program staff. The program worked in partnership with regional governmental and nongovernmental organization (NGO) partners to promote the use of evidence-based recommendations for improving the quality of family planning services, and to promote further appropriate research, with a focus on research leading to expanded contraceptive options, particularly for underutilized technologies with perhaps the best potential to address users' unmet needs for family planning and for dual protection from both pregnancy and sexually transmitted infections (STIs).

In Senegal, research was conducted in collaboration with the Ministry of Health, Hygiene, and Prevention's (MOH) Division of Reproductive Health to evaluate the quality of Norplant® contraceptive implant services offered under the national family planning program, and to determine the feasibility of and strategies for scaling up the method, and the potential role of newer generation implant technologies such as Jadelle®. A retrospective cross-sectional study was conducted over two phases.

The study found that Norplant, despite its associated side effects and provider-dependent nature, was highly appreciated by some users, and suggests that the method has great potential to continue to address the large unmet need for birth spacing and birth limiting in Senegal, including for clients with no previous contraceptive experience. The study also suggested the need to address gaps in monitoring, tracking, and following up time-dependent methods such as implants. Research findings were instrumental in generating discussions among stakeholders about the needs of clients, providers, and the community for better quality family planning information and counseling. Recommendations offered by stakeholders at the July 2002 dissemination meeting hosted by the Population Council and the MOH included the need for improved client follow-up mechanisms and broad support for making Norplant more widely available and accessible.

ECC was also effective on the executive board of the Francophone Maximizing Access and Quality (MAQ) Subcommittee as a research and technical support partner. The subcommittee was established in 2000 to develop MAQ activities in west and central Africa with a focus on integrating STI services into reproductive health protocols in the region. ECC worked in collaboration with subcommittee colleagues to assess the extent in four countries of STI prevention information in reproductive health protocols and to conduct formative research. While most of the countries had incorporated some information about STIs into their protocols, many protocols were incomplete and did not specify how to offer STI services in the context of providing general reproductive health, family planning, and postabortion services. The partnering CAs then surveyed reproductive health providers in the four countries to assess their familiarity with the STI components of protocols; how they incorporated these components into their practice; and how they felt the protocols could be improved through more comprehensive integration of STI services. Findings were disseminated in-country and regionally in 2002.

Latin American and the Caribbean Region

Work under the Population Council Program III (PCP3) in the Latin America and the Caribbean (LAC) region began as part of the Council's Expanding Contraceptive Choice (ECC) program, supported by a combination of core and field support funds. The ECC program sought to broaden the range and availability of contraceptive options for women and men and to improve the quality of care associated with the provision of contraceptive services. The 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. Activities were executed in Brazil, Bolivia, Guatemala, Honduras, and the Dominican Republic, continuing the ECC program of work supported by the previous PCP agreement during 1994–2000. After USAID/Washington discontinued funding for the ECC program, the Council's HIV/AIDS work in Brazil and neighboring countries nevertheless continued. The strong working relationship between Population Council/Brazil staff and USAID/Brazil allowed for the Council's continuing participation in implementing the "strategic approach" to HIV/AIDS services introduction in the Brazil borders region.

Technical Assistance

Much of the ECC program's attention in the LAC region was focused on dissemination activities and providing technical support to health ministries.

Bolivia

Under the PCP3, the ECC program continued providing technical assistance to the Ministry of Health (MOH) for improving family planning programs in Bolivia, focusing on the improvement of quality of care in reproductive health services. In 2001, the Population Council developed a project to expand the implementation of quality of care provided by family planning services in Bolivia. This technical assistance resulted in a very successful project supported by the U.K. Department for International Development and administered by the United Nations Population Fund, which was adopted as an official program by the MOH.

Brazil

Under the PCP3, the ECC program translated *The Essentials of Contraceptive Technology*, a manual on contraceptive technology for family planning providers, from English to Portuguese. The Portuguese version was prepared and published by the USAID-funded Population Information Program of the Center for Communications Programs at the Johns Hopkins School of Public Health, in collaboration with the World Health Organization (WHO) and several other agencies. This translation was widely distributed throughout the country. The ECC program then used the translated material to create a Web site on contraceptive technology for family planning providers that was successfully used by physicians, nurses, and other professionals throughout the country. The Council maintained this Web site for two years, after which the site continued under the direction of Reprolatina, a Brazilian non-governmental organization (NGO).

During 2001 and 2002, the Population Council was an important contributor, collaborating with the Brazil MOH, in adapting the material to establish a plan for national norms in family planning. The plan was published in a manual by the Brazilian Federation of Societies of Obstetrics and Gynecology.

Dominican Republic and Guatemala

The Population Council gave technical assistance to the WHO and the local MOHs in the design and implementation of strategic assessments of issues in reproductive health, with an emphasis in maternal mortality, in the Dominican Republic and Guatemala. The study in the Dominican Republic was integral in shaping the design of the USAID/Brazil country strategy in reproductive health.

Strategic Approach to HIV/AIDS Services Introduction in Brazil's Border Region

In 2001, the USAID Mission in Brazil asked the Population Council to undertake an assessment of the HIV/AIDS epidemic in border areas of the country. In close collaboration with the National STD and AIDS Program of the MOH, the Council prepared an assessment of the situation in six border areas, from Oiapoque, on the border with French Guyana, to Uruguaiana, on the border with Argentina.

This study, co-financed by USAID field support and the Brazil MOH, showed the epidemic was worse in the border areas than in big urban centers, and identified areas for further research. The results were disseminated in a large meeting, with the participation of a wide array of stakeholders from the MOH, NGOs, and donors. The Population Council prepared the final report of the study, which the MOH published and distributed widely, both nationally and internationally.

The study's identification of a series of problems in the border regions prompted USAID and the MOH to create a consortium for HIV/AIDS activities in Brazil, to implement a strategic plan for action research in those areas, with the Population Council designing the research.

Following USAID/Brazil's mandate, the Council also implemented a study in the southern border cities of Foz do Iguaçu and Uruguaiana called "Targeting Truck Drivers for STI/HIV/AIDS Prevention, Testing, and Treatment." The study showed that international truck drivers constitute a population that has very limited access to health services, and that they have urgent health needs in addition to those regarding STI/HIV/AIDS. The pre-intervention assessment showed that, with the exception of the Paraguayans, the prevalence of condom use is very high. The intervention consisted of offering information, counseling, and testing for STI/HIV and other preventable diseases within the Customs area. Results on prevalence showed that HIV has a very low prevalence in this group (less than 0.5%), and the prevalence of syphilis was also below the expected rate. The intervention was extremely well accepted, and truck drivers using the services were very happy to have the service because they have no access to services otherwise.

The results of this study were widely disseminated and met with great interest by other institutions that work in the development of HIV/AIDS service projects. The project gained additional visibility after receiving a visit from two U.S. senators and the U.S. ambassador. Accounts of the senators' visits were posted on the USAID/Brazil and U.S. Embassy Web sites.

Additional work undertaken in Brazil included a study in Corumbá, near the border with Bolivia. This study, "Improving the Quality of STI/HIV/AIDS Prevention," was aimed at improving the quality of STI/HIV/AIDS services for vulnerable populations. The study of more than 400 vulnerable people revealed a high STI prevalence but a low HIV prevalence. The most important result was increased access to STI/HIV/AIDS services. The health secretary, understanding the importance of providing these services, is taking measures to sustain their availability after the end of the project.

Conclusion

Projects undertaken by the Population Council in the Latin America and the Caribbean region under the PCP3 were quite successful. Population Council/Brazil was integral in the dissemination of essential reproductive health information and the provision of technical assistance to the Bolivian, Brazilian, and Guatemalan Ministries of Health. In Brazil, the MOH continues to work with Population Council/Brazil, both through the USAID-funded Horizons Program, and under its own funding.

Experimental Family Planning Studies in Rural Africa

The Population Council's Experimental Family Planning Studies in Rural Africa program had two major components: the Community Health and Family Planning project (CHFP) and the Community-based Health Planning and Services initiative (CHPS) in Ghana. The CHFP tested innovative strategies for health and family planning service delivery in rural areas of the country; CHPS is a nationwide service-delivery strategy modeled on the CHFP.

The Community Health and Family Planning Project

The impact of family planning programs on fertility in rural Africa has been debated in the policy literature for three decades; a more recent debate surrounds the question of whether expanding access to health services will improve child survival. To help resolve these issues, the Navrongo Health Research Centre (NHRC) in northern Ghana, under a subagreement with the Council, launched the CHFP—a field experiment testing the relative demographic impact of four approaches to providing primary health care and family planning services in the rural, traditional district surrounding the town of Navrongo. The CHFP began as a pilot project in 1994; it was scaled up to a district-wide trial in 1996.

Results of the experiment show that posting nurses to community locations reduced childhood mortality rates by over half in three years, and accelerated attainment of the childhood survival Millennium Development Goal (MDG) in the study areas to six years. Adding community mobilization strategies and volunteer outreach to this approach led to a 15 percent reduction in fertility, representing a decline of one birth in total fertility. Incremental costs added \$1.92 per capita to the \$6.80 per capita primary health care budget. The results demonstrate that low-cost community health and family planning services can have an impact on both fertility and mortality even under conditions of extreme poverty. Posting nurses to community locations where they provide basic curative and preventive care substantially reduces childhood mortality, accelerating attainment of child survival MDGs. Community volunteer approaches, however, have no such impact, challenging the child survival value of international investment in volunteer-based health programs. The results also demonstrated that extending access to contraceptive supplies alone fails to address the social costs of fertility regulation, a key goal of the 1994 Cairo Conference on Population and Development (ICPD). Effective deployment of volunteers and community mobilization strategies offsets the social constraints to contraceptive-method adoption. While volunteers had no impact on child survival, their role was crucial to achieving fertility impact. Navrongo research thus demonstrates that affordable and sustainable means of combining nurse services with volunteer action can accelerate attainment of both the ICPD and MDG agendas.

In 1998, also under a subagreement with the Council, the NHRC launched a five-year experimental project testing the effect of mobilizing communities to reduce the practice of female genital cutting (FGC). This project revealed ways in which traditional social institutions support the practice of FGC, pointing to potentially promising strategies for community-based interventions.

The Community-Based Health Planning and Services Initiative

When a replication project in the Volta Region demonstrated that the Navrongo service model could be transferred to a nonresearch setting, the Ghana Ministry of Health (MOH) adopted the CHFP as a model

for reforming community health and family planning services at a national level. In 1999 the MOH launched CHPS to accelerate implementation of the new health policy. By mid-2005, CHPS was fully operational in 20 districts and under development in nearly every other district of Ghana.

CHPS comprises national consensus-building mechanisms, a liaison program that arranges training opportunities for health management teams from regions where there is interest in CHPS, and a field program that develops CHPS demonstration capabilities in lead districts. Analysis of successive phases of the Ghana program development process demonstrates that national policy and programs in Ghana can be reformed successfully by scaling up experimental projects—an approach that may work in other African settings as well.

The CHFP Dissemination Unit, based at the NHRC, links CHPS to the CHFP, providing information, consultation, and training services that bridge the programs. The unit worked to promote effective implementation of CHPS and fostered communication aiming to improve health and family planning services in Ghana.

The Council's contribution to CHPS under the PCP3 focused on three areas: (1) systematic documentation of CHPS implementation, including its pace and barriers to progress; (2) technical assistance to develop a CHPS Secretariat to oversee the initiative; and (3) technical assistance to specific CHPS implementation and monitoring/evaluation activities.

A Population Council Policy Research Division working paper fully describing the CHFP project and the CHPS initiative may be found in Appendix 1.

Understanding and Meeting the Needs of Adolescents

The Population Council's program of research on transitions to adulthood in developing countries seeks to better understand adolescents' lives and to identify, design, and test various interventions to increase opportunities and reduce risks for adolescents, particularly girls. The ultimate goal is to allow adolescents to emerge as reproductively healthy adults with productive skills that will permit them to be full participants in work, family, and community life. USAID through the Population Council Program III partially supported research on adolescents in Bangladesh, India, Kenya, Malawi and South Africa.

Evaluation of Interventions

The projects in Bangladesh, India, and South Africa assess the impact of new programs designed to affect the timing of marriage and childbearing and improve adolescent reproductive health. The objective is to identify policy interventions that will delay marriage and childbearing sufficiently to create the space in which more "successful" transitions to adulthood can occur, and at the same time contribute to filling that space with investments in improved capacities.

Bangladesh. This project studied the impact of two large-scale interventions, in order to explore how adolescents can improve control over decisions that are consequential to their lives, such as schooling and marriage.

The first study assessed the impact of educational incentive schemes introduced in 1994 for children and adolescent girls. Data from 2000 and 2001 confirmed that school enrolment increased more for girls than for boys, but also indicated that the risk of dropping out of school remained strongly differentiated by gender and class. Boys in poor households are more likely to drop out than boys in non-poor households, and all girls face similar and high risks of dropping out because of marriage. The study also found that while school programs are successful at encouraging unmarried girls to remain in school and increase the mobility of girls in general, marriage continues to take place at early ages. Girls continue in school until they marry but do not necessarily delay marriage for school. In addition, dowry payments are a menacing concern for parents, and early marriage is encouraged by perceptions that older girls will require higher dowries.

The second study evaluated an intervention program, which applied lessons learned from the previous 2000 study in three rural districts. The intervention provides adolescent girls who are recent school graduates with life-skills and livelihood training; subsequently, some girls are linked with existing savings and credit facilities; and entrepreneurship development and internship opportunities in the local communities are supported.

A baseline survey was conducted in 2001 in 90 villages and a follow-up survey was conducted in 2003 in 68 of the villages. The study showed that programs designed to give adolescent girls access to public spaces of their own, life-skills and reproductive health training, and livelihood training can have far-reaching effects; these programs encourage increased schooling, increased income and work, and delayed marriage. The study also documented who among the rural residents are most likely to join and maintain program membership. Although programs are more likely to be used by more educated households, this selectivity is compensated because these programs appeared to be taken up with most enthusiasm in the poorest and least educated district.

While the intervention encouraged delayed marriage, it did not specifically discourage dowry payment. A negative finding of the study is that most of those who delayed marriage appear to have paid higher dowry. Families of girls perceive and believe paying dowry is a strategy to ensure the well-being of their daughters, despite the fact that those who marry without dowry are found to suffer less abuse and enjoy more leisure during the early years of marriage.

Several important policy decisions have been influenced by the study. First, a national adolescent survey is underway to identify vulnerable areas and populations. Second, the Population Council is working with implementing agencies to incorporate strategies to address the question of dowry into programs to empower adolescent girls. Third, new programs are being developed to provide age- and need-appropriate interventions to improve livelihood opportunities.

India. This project contributed to the evaluation component of an intervention study in which the Population Council, in collaboration with CARE India, tested the feasibility and impact of adding four additional components to a reproductive health project in urban slum areas of Allahabad, Uttar Pradesh: (1) counseling about savings formation and livelihoods; (2) training in vocational skills; (3) assistance in opening savings accounts; and (4) follow-up support. Using a quasi-experimental pre- and post-test design that contrasted the experimental group with a comparison group of adolescents, the project investigated whether the intervention (1) increased girls' physical mobility and contact with individuals outside the family; (2) enhanced girls' skills development and sustained use of these skills; (3) altered work aspirations of girls and encouraged more progressive gender role norms; (4) reduced gender differentials in time use; and (5) increased girls' reproductive health knowledge.

Analysis of the 2003 endline data in combination with the 2001 baseline data indicated that although the livelihoods program was acceptable to parents and feasible to implement, the project had only a minimal impact on the behavior and attitudes of adolescent girls in the experimental slums. The greatest changes between the baseline and the endline surveys were found in those outcomes that most closely reflected the content of the intervention. Girls in the intervention group were significantly more likely to have knowledge of safe spaces, be a member of a group, score higher on the social skills index, be informed about reproductive health, and spend time on leisure activities than the matched control respondents. No effect was found on gender role attitudes, mobility, self-esteem, work expectations, time use, or labor market work, likely because of the short duration of the intervention, as well as the limited number of times that groups convened. Those designing future livelihood interventions with adolescent girls are advised to extend the period of time spent on group formation, negotiation and social skills, and vocational skill development.

South Africa. This project supported some of the research personnel for a longitudinal study of youth conducted in KwaZulu-Natal, South Africa, the province hardest hit by the HIV/AIDS epidemic. Wave 1 was fielded in 1999; wave 2 in 2001. The project included interviews with young people and their parents; community surveys examining infrastructure, services, and safety; and interviews with secondary school principals to assess the extent of coverage of the government-mandated school-based life-skills curriculum and its impact on the sexual risk-taking behaviors of young people. As the first panel study of adolescents in the country, it is filling important gaps in knowledge about the determinants of adolescent risky sexual behavior and educational attainment in an environment characterized by both high HIV prevalence and highly unequal access to opportunities and services, including schooling, employment, and health care.

Research results indicate that poverty is associated with earlier sexual debut. Among females, poverty increases the risk of nonconsensual sex, having traded sex for goods or favors, having multiple sexual partners in the year before the survey, and teenage pregnancy.

Evaluation of the school-based life-skills curriculum reveals that coverage is rapidly increasing; knowledge about HIV prevention topics is increasing, particularly among Africans, males, and younger people; and youth exposed to the life-skills curriculum are more likely to use condoms.

Assessment of Computer Interviewing

The projects in Kenya and Malawi assess a new technique designed to improve the accuracy of the data collected on adolescent sexual and reproductive behavior. Inaccurate reports of sexual behavior affect explanations about the underlying mechanism driving the HIV epidemic and therefore intervention strategies to reduce transmission; they also provide a misleading picture of HIV/STI risk. Accurate self-reporting is also essential for clinical trials that investigate the effectiveness of technologies to prevent transmission of HIV and other sexually transmitted infections.

Kenya. In a study conducted in two districts in Kenya—Nyeri in Central Province and Kisumu in Nyanza Province—more than 6,000 interviews of unmarried adolescents ages 15–21 were collected as part of household-based surveys in 2000 and 2002. Respondents were randomly assigned to three modes of data collection: face-to-face interviews, paper-and-pencil self-administered interviews, and audio computer-assisted self-interviews (audio-CASI). The purpose of this experimental design was to assess the feasibility of computerized interviewing in Africa and to evaluate whether the increased privacy afforded by ACASI produced differential reporting of sensitive behaviors.

The ACASI technology performed quite well, despite the rigorous conditions of working in a rural area among a population largely unfamiliar with computer technology. Given the limited number of problems experienced with the ACASI software or computer hardware, and the positive response from respondents, our experience indicates that computerized interviewing is a feasible method of collecting survey data in developing countries.

Results indicate substantial and significant differences in reported rates of sex across interview modes, although not always in the expected direction. Our assumption that girls under-report sexual activity in face-to-face interviews by comparison with ACASI was not confirmed by the Nyeri data, while the Kisumu results show ACASI generated significantly higher levels of reporting of sensitive behavior among girls. As for boys, results from Kisumu, while not always significant, show reporting for the “ever had sex question” is lower with ACASI whereas reporting of more stigmatized behaviors is higher with the computer, as was expected.

Analysis of data indicated that ACASI produced a more diverse picture of adolescent sexual activity than the face-to-face interviewer-administered method. The analysis suggests that adolescent girls in Kenya have more complicated, and clearly more perilous, sex lives than traditional surveys of sexual activity indicate. With ACASI, a much wider range of sexual partners is revealed and a much higher incidence of coerced sex is observed than with face-to-face interviews.

Malawi. Given the promising results from the Kenya study, the research program on assessing and improving the measurement of sexual behavior is expanding. In collaboration with researchers at the

University of Pennsylvania, a household-based survey of female adolescents took place in Malawi in May and June 2004. Five hundred adolescent girls aged 15–21 were randomized to face-to-face and ACASI interviews. As in Kenya ACASI did not result in higher reporting for questions on “ever had sex” and “sex with a boyfriend;” however, it did produce higher reporting for more stigmatizing behaviors such as sex with a family member or teacher. Although the comparability of results across two countries provides a sense of reliability regarding the findings, it does not explain the inconsistent response patterns. Clearly more research is required to assess these issues.

Transitions in Reproductive Behavior in the Developing World

Over the past three decades, a revolution in reproductive behavior has swept through most of the developing world. Contraceptive use, once rare, is now widespread. The average number of births per woman has fallen by half—from six or more to nearly three. This program carried out four studies which shed light on several key issues related to the prospects for future trends in fertility and contraceptive use.

1) The Future Demand for Contraception

Around 1960 only a tiny fraction of couples practiced contraception, and knowledge of contraceptive methods was very limited. In contrast, today more than 60 percent of couples in the developing world are current users of contraception. While past trends in contraceptive behavior are fairly well established, there is considerable uncertainty about what lies ahead. Because contraceptive prevalence among married women of reproductive age in the developing world is approaching levels observed in many developed countries it might be tempting to conclude that contraceptive demand is about to level off.

This study found that instead of leveling off in the near future, the demand for contraception can be expected to continue to rise rapidly for the next several decades, for two main reasons:

- (a) *Population continues to grow.* According to the 1998 revision of the UN population projection, the population size of the developing world will grow from 4.5 to 7.8 billion between 1995 and 2050. The proportion of the population in the reproductive age groups is expected to remain fairly steady. As a result, the number of women of reproductive age will grow at about the same rate as the population as a whole.
- (b) *Fertility continues to decline.* The total fertility rate in the developing world has dropped to about three births per woman, but it remains 50 percent above the replacement level. Most existing population projections expect the fertility transition to continue until the replacement level is reached. To bring about this fertility decline, contraceptive prevalence will have to rise substantially. It is reasonable to assume that prevalence in the developing world will reach levels of about 75 percent as now observed in countries at replacement.

As a result of these trends, the number of users of contraception in the developing world is expected to rise from 549 million to 816 million over the next 25 years, according to the most recent UN projection. An examination of existing projection methodologies found results for prevalence to be reasonable, but method specific results are potentially problematic. A new method for projecting contraceptive use by method was developed and applied.

2) Analysis of the “Birth Dearth” Hypothesis

Fertility has dropped below the replacement level in virtually every population that has moved through the demographic transition. This trend was not widely anticipated by demographers and until recently little attention has been given to understanding the causes and consequences of low fertility in post-transitional resulting in large population declines and rapid aging.

societies. Proponents of the “birth dearth” hypothesis believe that fertility will remain at this low level, resulting in large population declines and rapid aging.

This study examined an alternative explanation for very low fertility, namely that women are postponing births to later ages, which temporarily depresses fertility owing to so-called tempo distortions. According to this view current low fertility is unlikely to decline much further and may even rise in the future in a number of post-transitional countries. The most widely used measure of fertility—the total fertility rate—was found to contain substantial tempo distortions, thus giving misleading estimates of actual levels and trends in childbearing in many post-transitional countries. Once the rise in the mean age of fertility ends—as it eventually must—the corresponding fertility-depressing effect stops, thus putting upward pressure on period fertility. Such an upward trend has already been observed in a few countries. Further evidence supporting this conclusion is found in the fact that the total fertility rate in most of these countries is well below the desired family size of about two children. The implication of these findings is that the “birth dearth” is exaggerated. Very low post-transitional fertility is unlikely to be maintained and will probably rise closer to the replacement level in the future. Even though population sizes will decline modestly in a number of countries with below replacement fertility, there is little prospect of rapid population decline throughout the world.

3) Variations in Contraceptive Prevalence at the End of the Fertility Transition

The widespread fertility declines that have occurred throughout the developing world over the past few decades have invariably been accompanied by large increases in contraceptive use. This study examined the causes of unexpected variation in contraceptive prevalence in countries that have reached the latest stage of the fertility transition (i.e. with a total fertility rate less than 3 births per woman). In these countries contraceptive prevalence among all women varies from a low of 40 percent in Colombia (1990) to 72 percent in Vietnam (1997) and among married women prevalence varies from 48 percent in India (1998/99) to 78 percent in Vietnam (2001) a range of 32 and 30 percentage points respectively. Several factors were found to be responsible for this variation:

(a) Expected variation. Some of the variation in prevalence in late transitional countries is due to small but real differences in fertility at the end of the transition.

(b) Measurement errors. Survey estimates of fertility and contraceptive prevalence contain small sampling and non-sampling errors

(c) Effects of other proximate variables. Fertility is directly determined by a set of behavioral and biological variables called the proximate determinants. Contraceptive use is the most important of these, but there are a number of others including the incidence of induced abortion, proportions married, post-partum infecundability, contraceptive effectiveness, and frequency of intercourse. Any true variation in prevalence around the expected level is caused by variation in these other proximate variables.

4) Stalling Fertility Transitions

Many developing countries experienced rapid fertility declines during the 1970s and 1980s. Conventional theory suggests that these fertility transitions will continue until fertility reaches the replacement level of 2.1 births per woman. However, contrary to expectations, fertility in the 1990s has declined less rapidly

than projected earlier in a number of countries. In fact, in Bangladesh, Colombia, the Dominican Republic, Ghana, Egypt, Kenya and Peru fertility has stalled or nearly stalled at around three births per woman. This surprising development has led the UN to revise upward its fertility assumptions for a substantial number of countries in its most recent projections (2000) and, as a result, the population projection for the world population in 2050 has been revised upward by 410 million (from 8.91 to 9.32 billion).

This study identified the main causes for this stalling, which operate at different levels of analysis ranging from proximate to more distant socioeconomic determinants:

(a) *Proximate determinants*. Stalling fertility is typically associated with a leveling off of contraceptive prevalence. This is the case, although unmet need for contraceptives to space and limit births remains substantial.

(b) *Fertility preferences*. Stalling in overall fertility is associated with stalling of fertility preferences. Stalling occurs when either wanted or unwanted fertility levels off above the expected levels at the end of the transition, and stalls in both wanted and unwanted fertility often are observed.

(c) *Access to family planning*. In all stalling countries unmet need for contraception remains substantial. No evidence of a rise in unmet need or unwanted fertility was found which suggest that there may not have been a large deterioration of family planning services.

(d) *Socioeconomic factors*. The persistence of large fertility differentials together with low levels of schooling among married women is a key cause of this stalling in several countries.

Publications

“The causes of stalling fertility transitions in the developing world” *Studies in Family Planning* 37(1) (forthcoming)

“Completing the fertility transition in the developing world: The role of educational differences and fertility preferences,” *Population Studies*, Vol. 57(3): 321-336, 2003.

“The end of the fertility transition in the developing world,” *Completing the Fertility Transition*. Department of Economic and Social Affairs, Population Division, ESA/P/WP.172/Rev.1. New York: United Nations, pp. 288-307, 2002.

“The end of the fertility transition in the developed world,” *Population and Development Review* 28(3): 419-433, 2002.

“Future trends in contraceptive prevalence and method mix in the developing world,” *Studies in Family Planning* 33(1): 24-36, 2002, (with Elof Johannson).

Urban Studies

The Urban Studies Program was comprised of two research projects focusing on urban poverty and health in developing countries which received funding under the Population Council Program III (PCP3) from USAID's Making Cities Work (MCW) Partnership Fund.

The Nairobi Urban Health and Poverty Project: Clarifying Operational Details of the Experiment

In 2000, USAID's cognizant technical officer for the PCP3 encouraged the Council to apply to the MCW Partnership Fund to match Office of Population "special initiative" funds in support of the Nairobi Urban Health and Poverty Project (NUHPP). The NUHPP is a project of the Council-affiliated African Population and Health Research Centre (APHRC) intended to address the need for systematic research and experimental interventions focusing on problems of the urban poor.

The application was successful, and consequently the PCP3 supported a needs assessment in 2002 in the four slum settlements where the NUHPP project was slated. Results from the assessment showed that while slum residents are generally aware of illnesses and treatment, their health-seeking behavior is largely limited by a lack of financial resources. Slum residents are faced with poor access to safe and adequate drinking water and lack of sanitation and disposal facilities. A lack of food in quantity and quality leads to problems with malnutrition. Slum communities rely on expensive profit-driven health facilities that operate informally and are staffed with poorly-trained professionals. With regard to livelihoods, the majority rely on small business and casual jobs for income-generating opportunities. Access to credit is also a major concern.

The assessment helped the NUHPP identify a "minimum package" of health and livelihood interventions for the experiment that followed. These included:

- *Induce behavior change* in home-based care for sick children, and child feeding practices.
- *Strengthen the capacity of public health facilities* to manage childhood illnesses.
- *Improve water and sanitation systems* using simple technologies.
- *Improve household livelihoods* by enrolling slum residents into savings schemes, credit facilities, targeted skills training programs, and a tools bank to enable those with valuable artisan skills to generate income; and by instituting a community health insurance scheme.

In 2004, the APHRC was awarded funding by the European Commission and the Government of Finland to pilot test the strategy in Kenya and to conduct exploratory research in Ghana and Malawi. The pilot will end in May 2006, and NUHPP partners are trying to raise funds for the scaled-up version of the project. The team views the USAID support as instrumental in helping to build the Kenyan research program on urban health and poverty.

The Ouagadougou Urban Health and Equity Initiative: A Pilot Antimalarial Intervention for Disadvantaged Children

The Council applied again in 2002 to the MCW Partnership Fund to match funds from USAID's West Africa Regional Program mission to support the Ouagadougou Urban Health and Equity Initiative (now

called the Ouagadougou Urban Health and Poverty Initiative), which was established in 2001 to document disparities in urban health. The MCW application was successful, and consequently the PCP3 supported research in Ouagadougou on current malaria care-seeking and home management practices, and a pilot intervention assessing the feasibility of community-based distribution (CBD) of prepackaged therapeutic units of chloroquine and paracetamol for home treatment of presumptive malaria in two neighborhoods of Ouagadougou.

The pilot intervention demonstrated that, with a minimal amount of training, community volunteers can provide quality information to local mothers and, by selling at a symbolic cost, improve the compliance of household treatments and at the same time provide a safe alternative to clinical treatment. Evaluation of the intervention also validated the hypothesis that the CBD strategy was equitable — both affluent and poor households benefited from the project, and no religious or social group was excluded.

These results were presented to the Ministry of Health in 2004 with the goal of advocating for a more comprehensive strategy of urban malaria control.

Both projects in the PCP3 Urban Studies Program were successful in conducting initial research that has improved health professionals' and policymakers' understanding of the health needs of poor urban communities.

Other Mission- and Core-Funded Initiatives

One feature of the Population Council Program III (PCP3) cooperative agreement was its ability to channel USAID mission field support to Population Council field activities that fit within the PCP3's results framework. In addition, activities that had results and objectives that matched those of the PCP3 results framework but were not part of another PCP3 program occasionally could be found worthy of core support. This additional core support came from either general USAID Office of Population and Reproductive Health (PRH) core funds or from the office's special initiative (later renamed "global leadership priority") committee on female genital cutting. What follows is a brief summary of Mission- and Core-Funded Initiatives under the PCP3.

Mission-Funded Initiatives

During Year Three, USAID/Mali requested assistance from the International Programs Division's (IPD's) former West and Central Africa regional office for studies to gain a better understanding of the trends in contraceptive use in Mali, and the demand and supply factors responsible for these trends, in order to determine how to reinvigorate the national family planning program and make available high-quality and sustainable family planning services to all who need them, thereby reducing the unmet need for family planning in Mali. Then late in Year Three, USAID/Mali requested a follow-on project to disseminate the information gleaned by the previous study. The mission supported the effort to inform regional and district health service providers of the major study findings, and to enhance use of these findings by sharing and analyzing them, and by compiling program managers' recommendations for future actions.

The USAID/Egypt mission in Year One supported Youth Livelihoods in Egypt, a two-year study on young women's labor market opportunities with the goal of identifying policy interventions that would delay marriage and childbearing sufficiently to create conditions in which more "successful" transitions to adulthood could occur. Late in Year Five, the Egypt mission funded research to better understand the slow pace of fertility decline in Egypt and to identify policies that might accelerate the decline.

In Cambodia, the USAID mission supported the Council to provide operations research for the mission Office of Public Health's new Population, Health, and Nutrition strategy for 2002–05. Through operations research the project contributed to strengthening the capacity of Cambodia's health system to provide a basic package of essential health services in predominantly rural areas.

In Year One, the Regional Economic Development Services Office for East and Southern Africa (REDSO/ESA) mission contributed to efforts of IPD's Gender, Family, and Development program in Kenya to create fact sheets on various aspects of girls' lives in East and Southern Africa and to carry out case studies of successful livelihood programs for young women in Kenya.

USAID/India funds originally allocated to the Expanding Contraceptive Choice (ECC) program in Year One were programmed by Population Council/New Delhi during Year Five for formative research whose findings will contribute to an operations research project on adolescent reproductive health in Uttaranchal.

Core-Funded Initiatives

Studies in Family Planning, a peer-reviewed international quarterly published by the Population Council since 1963, is the foremost journal in the field to provide an evidence-based approach to reproductive health programs and policies in developing countries. USAID provided funding in Year Five to help defray a loss of support from UNFPA, whose severe funding shortfalls forced it to cut back drastically on its support to NGOs. USAID's funding helped to sustain Studies during 2003 at the level of excellence that the field has come to rely on.

“Assessing the Impact of Improved Quality of Care on Women’s Ability to Reduce Unintended Childbearing” (Impact Studies) sought to document the feasibility of improving quality of care in family planning programs and to assess the impact of improved quality of care on women’s ability to reduce unplanned and unwanted childbearing in a healthful manner. The Population Council initiated the program in 1995 in response to the call for client-centered reproductive health services issued at the 1994 International Conference on Population and Development. Field studies in four countries—Pakistan, the Philippines, Senegal, and Zambia—were launched between 1997 and 1999. Interventions tested in these countries aimed to improve client–provider interactions, increase contraceptive choice, and facilitate other improvements in quality of care. USAID provided partial support for this program with USAID FY01 core funds, which assisted the program during Years Three and Four. (Some work in Zambia was also funded under the ECC program.)

The INTACT Network (the International Network to Analyze, Communicate and Transform the Campaign Against FGM/FGC/FC) addresses the limitations on research on female genital cutting through a network of researchers and research-minded activists. It contributes to the quality and productivity of research and to strengthening links among researchers and between researchers and those who can use the information they generate. During Year Five the USAID FGC Special Initiative Committee redirected funds to the INTACT Network which had been allocated during Year Four to a project in the Adolescents program that had met with delays.

Appendix 1:

Population Council

Policy Research Division Working Paper No. 208:

**“Accelerating Reproductive and Child Health
Program Development: The Navrongo Initiative in Ghana”**

**summarizing the results of the
Experimental Family Planning in Rural Africa Program**

WORKING PAPER

Accelerating Reproductive and Child Health Program Development: The Navrongo Initiative in Ghana

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Accelerating Reproductive and Child Health Program Development: The Navrongo Initiative in Ghana

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ABSTRACT

Successive global health and development agendas have been embraced by African governments—Alma Ata in 1978, the Bamako Initiative in 1987, the 1994 Cairo International Conference on Population and Development, and more recently, the Millennium Development Goals (MDGs)—only to be followed by widespread implementation failure. This paper presents an approach to program development in Ghana that is using research to accelerate policy implementation. Originally launched in 1994 as a participatory pilot project of the Navrongo Health Research Centre, a controlled experimental study was initiated in 1996 to assess the fertility and child-survival impact of alternative community health and family planning service strategies. Posting nurses to communities reduced childhood mortality rates by half, accelerating attainment of the childhood-survival MDG within five years. Adding community- mobilization strategies and volunteer outreach to this approach led to a 15 percent reduction in fertility. When a replication project in the Volta Region demonstrated that the Navrongo service model could be transferred to a nonresearch setting, the Government of Ghana adopted the Navrongo approach as the health component of its national poverty-reduction strategy. In 2000, the Community-based Health Planning and Services (CHPS) initiative was launched to accelerate implementation of this policy. By mid-2005, CHPS was fully operational in 20 districts and under development in nearly every other district of Ghana. Analysis of successive phases of the Ghana program-development process demonstrates feasible means of improving national access to reproductive and child health services.

Since the 1978 Conference on Primary Health Care held at Alma Ata, USSR, establishing “health for all” has been a priority of most African governments. Yet, as the new millennium approached, accessible health care in their community remained a distant dream for most African households. Expanding access to comprehensive reproductive health services has also been a priority of African governments since the 1994 International Conference on Population and Development (ICPD) held in Cairo. Despite more than a decade of governments’ commitment to the Cairo agenda, concern is mounting that reproductive health programs in the region are not working. What to do to about problems of implementation remains the subject of renewed international discussion and debate throughout the region in light of recent evidence that no African country is achieving the child-survival Millennium Development Goal (MDG). This paper presents lessons learned from an initiative undertaken by the Navrongo Health Research Centre (NHRC) in northern Ghana. The Navrongo initiative was launched to help resolve international health-policy debate, and it used evidence generated in the Navrongo setting to guide national efforts to develop community-based reproductive and child health services.

THE NAVRONGO INITIATIVE

The Navrongo initiative was launched to guide Ghana’s health-reform process rather than to produce research as an end product. Convened by the Ministry of Health’s Director General of Medical Services in response to mounting evidence that the health program was failing to reach the rural poor (Ministry of Health 1998), a policy committee reviewed the relative merits of two alternative strategies for providing community health care—volunteer-based care that could extend the availability of essential services at low cost versus professional community nursing and paramedical services. A protocol was developed for testing strategies that would simultaneously address health- and population-policy issues.

The health-policy debate

The Navrongo process was launched to resolve policy debate about the relative health-care development value of volunteer-versus-professional paramedic approaches to community health-service delivery.

A perspective endorsed by the UNICEF/WHO-sponsored Bamako Initiative emphasized the potential value of augmenting clinical services with community-based volunteer health services. Established by a consensus established during a 1987 conference of African ministers of health, the Bamako Initiative sought to translate the social institutions that organize African daily life into resources for organizing, financing, and sustaining community health services. Using the Bamako approach, program managers focused resources on recruiting community health-care volunteers, organizing community supervision of their work, and providing initial essential health-care resources that communities would sustain through user fees and revolving accounts (Knippenberg et al. 1990; UNICEF 1991 and 1995). The initiative soon became controversial, however, when evaluation research revealed mixed results (McPake et al. 1993). In Ghana, for example, the volunteer component of the Bamako strategy was controversial as a result of high volunteer turnover, poor quality of care, and lapses in supervision that led to problems with community financing (Adjei et al. 1995).

An alternative view, embraced by the World Bank and by some World Health Organization special programs, advocated the use of paid professional nurses for improving the range and coverage of community health care (Berman et al. 1987; World Bank 2003). Although a widespread consensus developed that existing and low-cost health technologies could reduce substantially the burden of childhood illness and that incremental health-service resources were needed, international health-care development agendas were promoted without specific evidence clarifying the means of making essential health-care technology and resources available to communities (World Bank 1993). Trials that demonstrate practical means of making these technologies and resources available locally are urgently needed (Bryce et al. 2003).

Ghana responded to international health-care development initiatives with locally tailored policies and programs. Some elements of the Bamako package were adopted as national policy, such as user fees and revolving accounts for essential drugs, but the cost of community nurses' salaries, training, and basic equipment was covered by the government program. By 1992, more than 2,000 community health nurses had been hired, trained for 18 months, and posted to districts throughout Ghana. The program encountered serious operational pitfalls, however, relating to a shortage of funds for the construction of community clinics and to other logistical problems. Lacking community facilities where nurses could work and live, the program posted all nurses to subdistrict health centers more than 10 kilometers, on average, from the rural households they were serving. They were community workers in name only (Agyepong and Marfo 1992).

The population-policy debate

For decades, questions about the demographic role of African family planning services have been the subject of policy debate (Caldwell and Caldwell 1987 and 1988). Although fertility has declined in East and Southern Africa, Sahelian West African fertility rates are double the rates observed elsewhere in the developing world. Variants of successful Asian models for developing reproductive health services have been advocated for Africa, such as community distribution of contraceptive supplies, but research in the region has provided compelling evidence that results obtained in Asia would not be replicable in Africa (Caldwell and Caldwell 1987 and 1988; van de Walle and Foster 1990; Simmons 1992; Pritchett 1994). Although contraceptive distribution was associated with increased contraceptive prevalence in several demonstration projects, research also showed that modern method adoption in rural Africa often works as a substitute for traditional fertility regulation rather than as a means of reducing fertility per se (Bledsoe et al. 1994). Large-scale family planning programs were, nonetheless, launched and funded throughout the region, often with guidance gleaned from research. A common but untested assumption concerned the proposition that accessible family planning services would reduce fertility by reducing the geographic cost of method adoption. A related perspective emphasized the potential impact of offsetting the social costs of contraception—spousal, familial, and cultural factors that prevent individuals from implementing their personal preferences (Easterlin 1978; Easterlin and Crimmins 1985). By the time of the 1994 Cairo conference, a global consensus had emerged calling for a shift in national population agendas from their demographic focus to gender-based strategies that addressed a wide range of

reproductive health needs. Little systematic evidence was available, however, demonstrating how this consensus could be implemented in African countries.

The population-policy debate in Ghana was shaped by international controversy and dialogue. First, no evidence indicated that programs of any kind would have an impact on fertility. Moreover, a consensus existed among senior policy leaders that reproductive health services were not reaching the rural poor, but no consensus was formed on how this problem could be addressed, apart from an understanding that the resources and mechanisms of the Ministry of Health could be better used to establish a fully functioning community health program for expanding access to reproductive and child health services. The Navrongo experiment was launched to clarify strategic options for this community health program, to determine the impact of particular approaches on reproductive and child health indicators, and to generate evidence for guiding the national health-care-reform process.

Experimental cells

The project site was located in a isolated rural area of northern Ghana. The study area, Kassena-Nankana District, lies in Ghana's most impoverished region, ensuring that any project success demonstrated in that locality could not be dismissed as a mere by-product of favorable circumstances. Baseline mortality rates were well above national levels. Cultural traditions were known to sustain high fertility (Adongo et al. 1997). The economy in the study area was dominated by subsistence agriculture; literacy was low (particularly among women); and traditions of marriage, kinship, and family-building emphasized the economic and security value of large families. Health-care decisionmaking was strongly influenced by traditional beliefs, animist rites, and poverty. Parental health-care-seeking behavior was governed more by tradition than by awareness of modern health-care options.

Responding to the need to resolve debate with research, the Ghana Ministry of Health developed a process for organizational change comprised of stages guided by successive generations of questions rather than of discrete research projects for producing stand-alone end products. This process of generating and using evidence is illustrated in the overlapping phases depicted in Figure 1. In Phase I, a Navrongo micropilot community-health-service implementation was conducted in conjunction with continuous social research for gauging needs and reactions to services rendered. Its goal was to clarify steps in implementing and tasks in managing community health care. Phase II tested the hypothesis that experimental strategies reduced fertility and mortality by extending approaches developed in the pilot to a districtwide experimental trial. Phase III tested the transferability of Navrongo strategies to Nkwanta District in the Volta Region with the goal of building policy consensus that the Navrongo model was replicable. Phase IV, launched in 2000, is a national program of policies, plans, and actions that comprise the Community-based Health Planning and Services (CHPS) initiative. Each phase was designed to respond to the next generation of questions as the process unfolded, each requiring contrasting research approaches as the process progressed.

PHASE I: THE PARTICIPATORY PILOT

A three-village program of social research and strategic planning was launched in 1994 for which villagers were consulted about appropriate ways to organize, staff, and implement primary-health-care and family planning services. Community dialogue about pilot service delivery was initiated to engage chiefs, elders, and women's groups about the importance of supporting community health-care service delivery (Nazzar et al. 1995). Particular attention was directed to the importance of communities' contribution of labor and materials for constructing health compounds where nurses were to be posted. The mechanics of launching this program and listening to its stakeholders generated practical insights into ways of changing programs from clinic-focused services to community-based care. These steps were clarified by modifying the program over time and reconvening focus-group discussions with pilot-community members to gauge their reactions and garner their advice. Some of the lessons that emerged from this phase are described below.

Community participation and leadership

Communities will donate labor for constructing health compounds if they can trust the program to provide nurses once the work is completed. Community investment, in turn, generates sustained community interest and involvement in the program.

Community leaders can be mobilized to support primary-health-care and family planning services. The process of mobilization encourages male involvement and reduces social tension concerning the promotion of reproductive health care and family planning services. Community leaders can reinforce and sustain supervision of health-care services.

Support systems for community nurses

Nurses may be relocated to communities, but their social isolation, work challenges, and daily living needs require sustained community and supervisory support and outreach to their spouses. Councils of chiefs and elders will assemble committees to take responsibility for this support.

Gender and social impact

The Kassena and Nankana peoples of northern Ghana have marriage and family-building customs that impose a social structure of male dominance and the notion of women as male property acquired through the tradition of bridewealth for the purpose of producing children for the lineage (Adongo et al. 1997). In this setting, where collective values are paramount, the male power system can be co-opted for the development of gender equity. Promoting family planning without addressing gender issues generates social discord (Bawah et al. 1999). Chiefs are open to sponsoring durbars (public gatherings) and other traditions for the purpose of promoting family planning, thereby putting men at ease and enabling women to assert unprecedented reproductive autonomy.

Increasing access to health care

Community-based paramedical care increased the volume of services sixfold in pilot communities, requiring adjustment to pharmaceutical fee policies. Community care dramatically improved immunization coverage and expanded the range and quality of reproductive and ambulatory health care. Women's strong preference for injectable contraceptives was addressed by doorstep and compound-based paramedical services. If convenient nurse services are combined with community mobilization, health-care and immunization coverage will improve and family planning practice will increase.

PHASE II: THE NAVRONGO EXPERIMENT

The experimental design that emerged from the pilot evaluated strategies for making use of existing resources of health services and social institutions, minimizing the need for additional funding for operational support (Binka et al. 1995). Two broad categories of resources were mobilized by the design, each corresponding to domains of the policy debate.

The "community health officer dimension" reoriented existing community health nurses to community health care and assigned these retrained paramedics to village locations as upgraded personnel, newly designated as community health officers (CHOs). Nurses entering the program were trained for 18 months in national training institutions and intensively for six weeks in methods of community engagement. National policies stipulated that these nurses would be based within communities, but logistical problems hampered the plans for their deployment. The Phase I community dialogue focused on this problem and generated ideas about how to proceed. Chiefs and elders agreed to convene community gatherings to seek volunteer support for constructing dwelling units, using local designs, materials, and resources. Once these compounds were constructed, nurses were posted to the community. The program supported all the nurses' training, essential equipment, and start-up pharmaceuticals, but each community was obligated to maintain the facility, provide security, and support the nurse's daily living needs. The CHO arm of the experiment was designed to improve geographic access to care. Nurses were provided with motorbikes and trained to provide household outreach services in addition to convenient compound-based care during well-publicized hours of duty.

The "*zurugelu* ('from the people') dimension" mobilized cultural resources of chieftaincy, social networks, village gatherings, volunteerism, and community support. Whereas community liaison in the CHO dimension focused on starting the program, liaison in the *zurugelu* arm was continuous, involving regular community gatherings, male volunteers, community-network mobilization, and other activities designed to integrate project management into the traditional system of social organization. A prominent feature of the *zurugelu* dimension was its gender component, activities designed to build male leadership, ownership, and participation in reproductive health services and to expand women's participation in community activities that traditionally have been the purview of men. This social-action agenda was designed to enhance the autonomy of women in seeking reproductive and child health care, thereby reducing the social costs of women's participation in the program. The *zurugelu* system extended to Navrongo communities the Bamako Initiative's model for recovering the cost of essential drugs by equipping volunteers with bicycles, with a start-up kit of essential drugs, and with training in

managing services and revolving accounts so that the flow of supplies would be sustainable and financed by the community.

Because the two dimensions can be mobilized independently, jointly, or not at all, a four-celled experiment was implied by the design. The joint-implementation cell tested the impact of mobilizing community-based health care through traditional institutions combined with referral support and resident ambulatory care provided by CHOs. All cells, including the comparison area, were provided with subdistrict clinical services, equivalent densities of staff, and equivalent access to supplies and technical training.

The Navrongo experiment was configured with geographic zones corresponding to cells of the design, each representing alternative intensive, low-cost, and comprehensive service-delivery operations. A demographic surveillance system that monitors births, deaths, migration, and population relationships was used to assess the impact on fertility and mortality of alternative strategies for providing community health services. The four subdistrict health-center zones of Kassena-Nankana District were randomly assigned to one of four cells, defining contiguous geographic zones of a factorial experiment (see Figure 2).

The project is formally categorized as a “plausibility design” rather than as a true experimental study (Habicht et al. 1999). Nonetheless, research systems of the Navrongo Centre provided an element of rigor that would not be obtainable with a simple cross-sectional comparison (Victora et al. 2004). The study district was equipped with a longitudinal demographic surveillance system for assessing experimental program impact. This system recorded all vital events, persons at risk, and relationships of members of extended households for the 139,000 rural residents of the district (Binka et al. 1999). Survival analyses controlled pre-experimental cluster differentials; fertility-impact assessment was adjusted for individual reproductive patterns prior to program exposure. Saturation sampling, moreover, eliminates sampling error, and prospective monitoring eliminates recall biases associated with survey research. For this reason, the Navrongo experiment is an unusually rigorous quasi-experimental assessment of the impact of community health services.

Fertility impact

Over the 1997–2003 period, the Navrongo experiment exhibited a pronounced fertility impact (Debpuur et al. 2002). On average, total fertility rates in cell 3 of the experiment were one full birth less than those expected in the absence of the intervention. Results have been regression-adjusted for the possible confounding effects of cellwise fertility differentials, educational attainment, and marriage type. Cell 3 effects persist after adjustment, supporting the hypothesis that the supply of family planning services can have an impact, even in an impoverished traditional rural African setting (Phillips et al. 2003).

Baseline research showed that unmet need for contraception in the study area was almost entirely related to demand for birth spacing and that nearly half of all women were either amenorrheic, separated from their spouses, or otherwise not at risk of becoming pregnant. Few women expressed the view that childbearing should be ended according to individual volition or through family planning. Research demonstrated a strong association, however, between stated desires to space fertility and spacing behavior. Spacing preferences are relevant to women of all

ages, and project impact reflects this underlying climate of demand for family planning. Contraceptive-method adoption typically is a means of substituting for traditional fertility regulation, but it is also a means of providing the option of birth spacing that would not otherwise be available. Figure 3 shows the implications of this climate of demand for family planning. In each five-year age group, fertility declined in experimental cell 3 (Figure 3a) relative to the comparison area (3b), where it did not decline.

Findings demonstrate the importance of prospective demographic surveillance and fertility endpoints for assessing the project's impact. Although observed trends in cell fertility differentials are consistent with reported contraceptive-use trends, the reported level of contraceptive use is a third lower than would be expected in light of the levels of fertility decline reported to the demographic surveillance system. Research suggests that this discrepancy is, in part, the result of the tendency of contraceptive users to deny that they are using a method when they are interviewed about reproductive practices. Spousal secrecy about use clearly biases survey responses. Secrecy about contraception was also evident in clinical encounters, reflected by women's tendency to prefer methods that they can readily use clandestinely. Fully 92 percent of all women reporting contraceptive use in the Navrongo experiment said they were using an injectable contraceptive, and 5 percent had adopted the hormonal implant Norplant[®]. Thus, neither oral contraceptives nor condoms were acceptable to the study population, even when these methods were easily accessible from community nurses and volunteer providers.

Results of the experiment changed with time in ways that demonstrate the concept of "fragile demand." In 1999, for example, the Government of Ghana instituted a policy of "exemptions," whereby children younger than five and pregnant women were entitled to free pharmaceuticals. This untested policy was instituted in the context of the Navrongo experiment, which had operated until that time with a user fee for cost-recovery. Because community services were accessible and the volume of clinical encounters had been increased by community nursing, stocks of essential drugs were depleted quickly, leading to a breakdown in community service operations in cells 2 and 3 for a period of nine months. This disruption was associated with a dramatic decline in contraceptive use and an increase in the total fertility rate of 0.5 births occurring nine months following the interruption. The dependency of couples on reliable services demonstrates the concept of fragile demand, whereby intermittent use is more common than sustained use in areas where social support for contraception is weak and spousal support may be inconsistent or lacking.

The study's findings demonstrate that achieving an impact on fertility requires that accessible services be established with a well-developed mechanism for offsetting the social costs of fertility regulation. The community-engagement strategies in the zurugelu arm of the project were designed to build male involvement in the program. More than 80 percent of the volunteers were men, and most community activities in cells 1 and 3 were focused on nurturing the participation of traditional leaders and heads of kinship groups and of extended families in the promotion of health-care and family planning. Community-engagement activities also involved individual women and women's social networks. The combined effect of outreach to men and women reduced gender stratification in reproductive decisionmaking. In experimental cell 2, however, where nurses were posted to communities without continuous zurugelu activities and community action was directed solely to health promotion and to the construction of health

compounds, making family planning care and commodities accessible had no impact. The contrasting impact of the experimental arms of the Navrongo experiment demonstrated, therefore, that male engagement was crucial to achieving success.

No evidence was found that the Navrongo experiment induced a fertility transition. Long-term observation of differential effects according to cells shows that early experimental effects have remained constant over time. Although the project's activities generated preferences for limiting fertility, the new climate of demand for family planning has yet to translate into an expanding and sustained fertility transition of the sort that has been observed in Asia. Results suggest that developing family planning and health services will have the intended effects, but cannot solve the problem of high fertility in a rural African setting in isolation from other social, economic, or health developments.

Child-survival impact

Although the past several decades have witnessed an overall decline in rates of child mortality in developing countries, recent United Nations reports suggest considerable variation in the rate of progress both within and between regions. Mounting evidence of stagnation and reversal of gains achieved during the 1970s and 1980s is a growing concern. This situation is particularly true of sub-Saharan Africa, which accounts for over half of all deaths of children younger than five. Obstacles to the achievement of the Millennium Development Goal (MDG) of reducing under-five mortality to two-thirds of its current levels include the poor performance of many African economies, the continued prominence of preventable illnesses such as malaria, tuberculosis, and diarrhea, and the emergence of HIV/AIDS (Hill 1993; Nicoll et al. 1994; Caldwell 1997; Timaeus 1997, 1999a, and 1999b). The recent upswing in mortality signals an urgent need to rethink strategies for promoting child survival. Lessons from the Navrongo experiment are relevant to policy deliberations on achieving the MDG.

The district in the Upper East Region of Ghana where the Navrongo Health Research Centre is located is achieving the child-survival MDG, whereas Ghana as whole lags behind. For Ghana, recent Demographic and Health Survey (GDHS) results show that national gains in child survival have stalled and that decreases in infant and child mortality have been reversed in all regions of the country except the Upper East Region. Although the national infant mortality rate declined progressively from 77 deaths per 1,000 live births in 1988 to 57 deaths in 1998, it climbed back to 64 deaths in 2003. Similarly, although under-five mortality dropped from 155 in 1988 to 108 in 1998, it rose again to 111 in 2003. In the Upper East Region, however, progress achieved in the 1980s and 1990s continued. According to the 2003 GDHS, the infant mortality rate in this region has declined consistently, from 85 deaths in 1993 to 33 deaths in 2003. Moreover, the under-five mortality rate of the region declined from 188 in 1993 to 79 in 2003 (Ghana Statistical Services et al. 2004) despite the fact that the Upper East is Ghana's poorest and most remote region. Health-care programs in the region may explain the observed trend, however. Analysis of the first three years of Navrongo project exposure shows that child-health interventions have had a pronounced impact on child mortality (Pence et al. 2005). Other studies have demonstrated dramatic effects on child mortality from insecticide-impregnated bednets (Binka et al. 1996) and other health interventions (Ghana Vitamin A Supplementation Team

1993). When research results from the Navrongo Centre were used to guide national health policy, the Upper East Region worked most intensely to scale up community health services (Nyonator et al. 2005a). At the time of the GDHS, more CHPS nurses were deployed to communities in the Upper East Region than to any other region of the country. The combined effect of various intervention activities reduced child mortality in the study district below the level set by the MDG for 2015 and reached the goal in 2004 (see Figure 4).

Posting nurses to communities accelerates progress in achieving the MDG, whereas developing volunteer services has no impact on child survival. Although child mortality declined throughout Kassena-Nankana District, including the comparison areas, declines were more pronounced in communities where nurses were assigned (Binka et al. 2005). Where volunteers worked without a nurse, trends followed the same trajectory as in comparison areas, indicating that volunteers made no contribution to child survival (see Figure 5). This finding is corroborated by qualitative research on parental health-care-seeking behavior. For impoverished families, parents dealing with childhood illness tend to seek care first from traditional healers because deferred payment customs and social arrangements make traditional healing a more feasible option than clinical care. Volunteers lack the credibility to change this dynamic, whereas community nurses substitute for traditional healers. Nurses working in concert with chiefs and elders develop social insurance mechanisms that elude other modern health-care providers. In providing a range of health-care services, community nurses introduce major means of making gains in child survival. Although volunteers made no contribution to child survival during the study, they contributed to the intervention's reproductive health impact. Therefore, cell 3 has been adopted as the service model for the national health program. Research demonstrates that by adopting this strategy, the Navrongo experiment enabled the project area to achieve the child-survival MDG within five years (see Figure 6).

PHASE III: REPLICATING THE NAVRONGO EXPERIMENT

Beginning in 1999, Nkwanta District in the Volta Region served as a demonstration ground for developing and testing practical means of transferring the Navrongo model of community health services to other districts. Tools were developed for monitoring impact through survey research (Awoonor-Williams et al. 2004). Qualitative research was conducted to gauge reactions to the program, note progress, and diagnose problems (Nyonator et al. 2005b). The research was designed to be a minor component of budgets, and implementation activities were limited to actions that could be taken using existing staff and financial resources. The phasing in of community health care by nurse-service zone resulted in variation in exposure to the program that was used in survey research to gauge the program's impact. Lessons emerged from this experience that established the credibility of the Navrongo model for implementation in nonresearch settings.

Operational indicators of nurses' activities, community responses, and volunteer deployment demonstrate that the replication of Navrongo operations was a success. Moreover, indicators of health-care service volume, coverage, and output suggest that these activities replicated elements of the Navrongo success story.

Family planning increased in response to program activity. Contraceptive-use prevalence prior to CHPS implementation was estimated to be less than 4 percent. Survey results for 2002 showed that prevalence had climbed to 8.6 percent. A 2004 survey demonstrated that the depressive effect on contraceptive use of distance to supply was eliminated by CHPS activities. Differentials by CHPS exposure suggest that CHPS activity may have a fertility impact. In 2002, family planning practice was reported as 14 percent in CHPS zones and only 4 percent in zones not yet covered by CHPS.

Results from Nkwanta provide evidence that CHPS had an impact on safe-motherhood practices. The odds of having received antenatal care were more than five times greater in service zones where CHPS was implemented compared with rates in “Not Yet CHPS” communities. Similarly, the odds of having received postnatal care were four times greater among women receiving CHPS services compared with women in “Not Yet CHPS” communities when relevant factors were controlled such as religion, wealth, age, ethnicity, marital status, and an asset index ($p < 0.01$ for both indicators).

Replication of the Navrongo approach was also associated with changes in indicators of infant and child care. For example, the odds of being fully immunized were 2.4 times greater among children living in community-based health planning and services areas compared with the odds for children in “Not Yet CHPS” areas, and parental health-care-seeking behavior was enhanced by CHPS, increasing the odds that febrile children would be treated by a trained paramedic (Awoonor-Williams et al. 2004).

Limitations to direct operational replication

Although Ghana has a population of only 20 million, it has 82 ethnolinguistic groups. Cultural diversity within Nkwanta District provided organizational challenges illustrative of problems that a national program would encounter in replicating the Navrongo experiment. The process of decentralized pilot trials, adaptive development of strategies, and scaling up within districts was more important to the success experienced in Nkwanta than was the replication of operational details of the Navrongo approach. For example, some Nkwanta communities had as many as five languages and chieftaincies, requiring implementers to rely on organizing the program through secular leaders, such as teachers, politicians, and traders rather than solely through traditional leadership systems. Pilot trials in two zones enabled the Nkwanta team to develop local strategies for overcoming ethnic complexity and building mechanisms for sustaining efforts within district scaling-up activities.

Contrasts with Navrongo findings

Several elements of the Nkwanta initiative not only have replicated Navrongo effects but also appear to have exceeded levels of impact achieved by the CHFP experiment. Activities that are best addressed by continuous community and household outreach, such as safe-motherhood services, have had a greater initial impact in Nkwanta than in Navrongo. This result may be attributed to Nkwanta’s having a unified management system (like most other districts in Ghana), whereas Navrongo has administrative operations for research that are separate from the district health-management team, a separation that weakens the integrity of supervisory support

for household service operations. Nonetheless, other key elements of the Nkwanta health-care service-delivery system have not acquired the same level of sophisticated technical and computing operations such as those found in Navrongo. In particular, precise tracking of pregnancies and births in Navrongo provides crucial information to community workers that noncomputerized procedures in Nkwanta have yet to achieve.

Building national commitment to change

The Navrongo/Nkwanta approach to developing community-based care is more complex to describe than to demonstrate, particularly when demonstration involves teams of peer counterparts learning about the initiative by seeing it in action. To achieve this, Navrongo and Nkwanta have shifted their roles from sites for research to districts for orienting regional health administrators and district health-management teams to the community health-service-development process. This demonstration function has been used to develop new demonstration sites in each of the ten regions of Ghana. Thus, the process of learning and demonstration exemplified by Nkwanta has been scaled up throughout Ghana. Extending the geographic range of sites where Navrongo's strategies are demonstrated has increased the credibility of findings from the experiment and verified conclusions from the Nkwanta project (Kuffour et al. 2005). This process was facilitated by national conferences designed to foster review of the implications of the Navrongo/Nkwanta results for national policy and action.

PHASE IV: SCALING UP WITH THE CHPS PROGRAM

CHPS is a national process of evidence-based organizational change aimed at removing geographic barriers to health care. To achieve this, CHPS seeks to enable district health-management teams throughout Ghana to adapt and develop approaches to community health care that are consistent with local traditions, sustainable with available resources, and compatible with prevailing needs. The process for pursuing this goal was developed during Phase I in Navrongo and refined in Phase III in Nkwanta. General features of the original Navrongo design serve as guidelines for the national program. Community health nurses, retrained and redeployed as community health officers, are the staff selected to reside in the community to provide health services at the client's doorstep. Community mobilization and participation in program development are central to the program. Although certain elements are common features of CHPS implementation, district teams launching the program are encouraged to adapt strategies to local circumstances, phase in operations over time, and learn through action what works and what fails.

Progress of the CHPS initiative

Only 22 of Ghana's 110 districts reported their implementation of activities at the beginning of 2001. Eighteen months later 87 districts had taken steps to launch the program. By mid-2004, 105 of the 110 district health-management teams reported having undertaken preliminary planning activities. In 2005, the Government of Ghana split 14 districts for a national

total of 138. By mid-2005 nearly all district health-management teams had launched some element of the CHPS program.

No district has implemented all activities in a single step in all work zones at once. To shift services from clinic-focused to community-based health care, CHPS requires new mechanisms for establishing community accountability, service quality, and administrative control that are integrated into traditional institutions of village governance. Establishing these mechanisms involves six milestones in organizational change that are phased in zone-by-zone over time: (1) Operational planning for CHPS begins by identifying geographic zones where nurses will be assigned and given responsibility for community health care. Once the districts have been divided into zones, scaling up proceeds by phasing in the posting of nurses. (2) A process of “community entry” is required for building leadership and commitment to collective action. Communication mechanisms build on traditions of collective leadership. For example, *durbars* are traditional public gatherings involving drumming, dancing, speechmaking, public debate, and open discussion. The *durbar* tradition was marshaled to build consensus and to foster community ownership of the CHPS program. (3) Community leaders organized the construction or renovation of community health compounds, which function as service-delivery points for community-based health care. Construction is initiated by convening councils of chiefs and elders and meeting with community leaders to mobilize volunteer labor. Community ownership of the program is nurtured by this process. (4) Posting nurses to community health compounds requires investment in equipment and supplies as well as creating new roles for supervisors in supporting logistics arrangements. (5) Prior to the CHPS initiative, nurses were trained in health-care service delivery without undergoing orientation to community organizational tasks. This gap has been filled with in-service training designed to ensure that nurses assigned to communities can do their work and deal effectively with community institutions. (6) Once the nurses are installed in their communities, community health committees are organized and volunteers are recruited, trained, and deployed to mobilize health-related activities, foster male involvement in family planning, and support the living arrangements of nurses.

The diffusion of innovation

Analysis of the national CHPS monitoring database shows that district health-management teams participating in peer exchanges between Navrongo and Nkwanta were more than two times more likely than district teams that did not participate to implement the program. This finding lends support to the national effort to scale up the number of demonstration districts and accelerate the pace of exchanges between district teams. Findings indicate that CHPS innovation spreads within districts through the diffusion of community action (Glaser et al. 1983; Mintrom 1997; Rogers 1995). CHPS has been promoted as a series of steps that can be implemented in a few work zones. Success on a small scale in a few zones galvanizes community action and resource mobilization that can be demonstrated to community leaders in neighboring zones, leading to the spread of demand for the program and grassroots political support for its operations. Significant development revenue has been allotted to district assemblies and the discretionary development-funding process. Some districts have developed procedures for training assemblies and district chief executives in setting health priorities and in allocation of

resources, greatly accelerating the spread and coverage of CHPS (Antwi et al. 2004). This finding suggests a need for policies that complete pilot projects in zones throughout Ghana to catalyze spontaneous organizational change within districts.

National consensus-building

The CHPS initiative was organized more in the manner of a social movement than as a bureaucratic program. Consensus-building and advocacy were crucial to its success. From the community level to the most senior political leaders and health officials, strategies were focused on building broad consensus by means of decentralized activities. The program's planners recognized that national health policy conferences held to disseminate the findings from the Navrongo experiment were not sufficient to achieve this end, and subsequent meetings were designed to foster discussion and debate about the practical implications of child health and family planning results in the context of scaling up.

A number of principles of consensus-building are demonstrated by CHPS strategies. Organizational change is shown to be highly effective when it is driven by committed individuals who demonstrate that not only is change feasible but also that it is in the interest of the system at large. CHPS fosters district-to-district demonstrations designed to assist implementers in developing a manageable operational change agenda. Throughout the CHPS process, research and evidence were applied by means that respect managers' ownership of the program and enhance the influence of research on decisionmaking. Changing operations from clinic-focused to community-based care involves transformations that affect the entire health-care service system. Often, when members of the community's hierarchy are ignored or bypassed, resistance to change ensues. System pilots, demonstrations, and counterpart orientation are, consequently, more effective strategies for fostering change than are training activities focused on individuals or piecemeal interventions. In the CHPS program, communication tools have been developed for the flow of "bottom-up" lessons learned in a series of newsletters entitled "What works? What fails?" Prepared by a journalist and focused on the information needs of district teams, these newsletters communicate practical experience with CHPS to stakeholders throughout the system. "Top-down" communication is built into policy conferences and guidelines, monitoring and evaluation feedback tools, and other means of communicating to district managers the government's commitment to the CHPS agenda. These means, in turn, are supported by peer-to-peer demonstration of CHPS at the district level.

Constraints to scaling up

The pace of CHPS-sponsored scaling up has been constrained by organizational and resource problems. Although nearly every district in Ghana has joined the scaling-up process, a number of obstacles have emerged. The pace of launching program planning has progressed more rapidly than the pace of implementing community-based services. Although most districts report that they have completed planning, relatively few have launched services. At the beginning of 2003, only 42 percent of the districts had completed the process of community entry in at least one service zone, although community entry is a low-cost strategic component of the program and is simple to implement. By late 2005 this situation had not improved. Moreover,

facilities are often developed without community involvement, so that the posting of nurses and development of volunteer services lag behind all other milestones. This departure from the CHPS model of community engagement deprives the program of resources for facilities and of the community's sense of ownership of the program. (Qualitative systems appraisals indicate that communities that mobilize resources for the program develop a sense of ownership of its services.) The construction of facilities without community engagement is tantamount to bypassing local support for CHPS (Nyonator 2005b). Diagnostic research clarifies the sources of such problems and is guiding corrective action.

Stakeholders at the national, regional, and district levels of government often misunderstand the CHPS program despite the considerable efforts directed to training, policy directives, conferences, and reports. Frontline workers often amplify managerial concerns about the feasibility of shifting operations from clinics to communities. Nurses who are relocated to communities must leave behind the relative comfort of subdistrict assignments, where their work is routinely supervised and technical demands are minimal. Nurses express concern about the challenges they face, and managers are anxious about embarking upon complicated changes. By contrast, workers participating in the program express satisfaction about their contribution to health-care service improvements and their appreciation of the support that communities render (Sory et al. 2003). Exchanges among peers offset anxieties by building upon positive experience. New policies integrating training of nurses with team demonstration will counteract fear of the unknown and ensure that scaling up improves service quality.

Resources for primary health care in Ghana are severely constrained. Cost analysis for Navrongo shows that CHPS adds \$US1.92 per capita per year in costs to the \$6.80 per capita currently available for primary health-care services. National economic analyses indicate costs that are low by international standards, but higher than Navrongo estimates. Increasing the coverage of community health services expands individuals' demand for health care that translates into higher costs of pharmaceuticals, fuel, equipment, and supplies. Health-sector reform has conferred authority on district health-management teams, but has not supplied the necessary resources for implementing the general health-service agenda. In the absence of earmarked donor or government funding for CHPS, incremental start-up costs severely constrain efforts to launch the program. In light of the financial and manpower limitations confronting them, many district officials are reluctant to engage in community-entry activities that will arouse public interest in services that the districts are ill-equipped to launch and sustain.

Districts progressing with scaling up have developed creative ways of solving resource constraints. Two have marshaled district assembly support and development funds for augmenting program revenue. Others have raised donations through community activities and faith-based organizations. One district has developed means of solving manpower problems by using "private practitioners," paramedics who are financed by communities rather than salaried Ghana Health Service employees.

Community nurses often are poorly equipped for making independent clinical decisions, having grown accustomed to the continuous technical supervision that subdistrict health centers afford. When they are deployed to communities, they confront major technical challenges immediately. For example, communities typically expect these nurses to have midwifery skills that few are trained to provide. CHPS requires new training protocols and procedures that are not yet in place.

Evidence indicating that nurses are often anxious about community deployment has raised fundamental questions about manpower policy. Community health nurses are trained in one of four national schools where applicants seek admission, fees are paid by the government, and graduates are deployed to subdistricts by central order. Much of the concern that nurses express derives from their not being native to the communities where they will live and work, where they may not speak the local language, and where they may be compelled to live separately from their families and kin. To address these problems, Navrongo has launched a “community-engaged” approach to training whereby communities select nurse trainees who are sent to a local training center for which the fees are paid by district assemblies and the communities to be served by the trainees. Upon graduation, nurses return home, rather than being sent to a distant post. Positive results of this strategy have generated new policies for the national nurse-training program. Ten new schools are being opened on the Navrongo community-engaged model; ten more are planned with the goal of scaling up the availability of trained providers and improving the quality and social relevance of CHPS policies. This experience attests to the importance of continuous investigation and revision of scaling-up policy as initiatives mature.

CONCLUSION

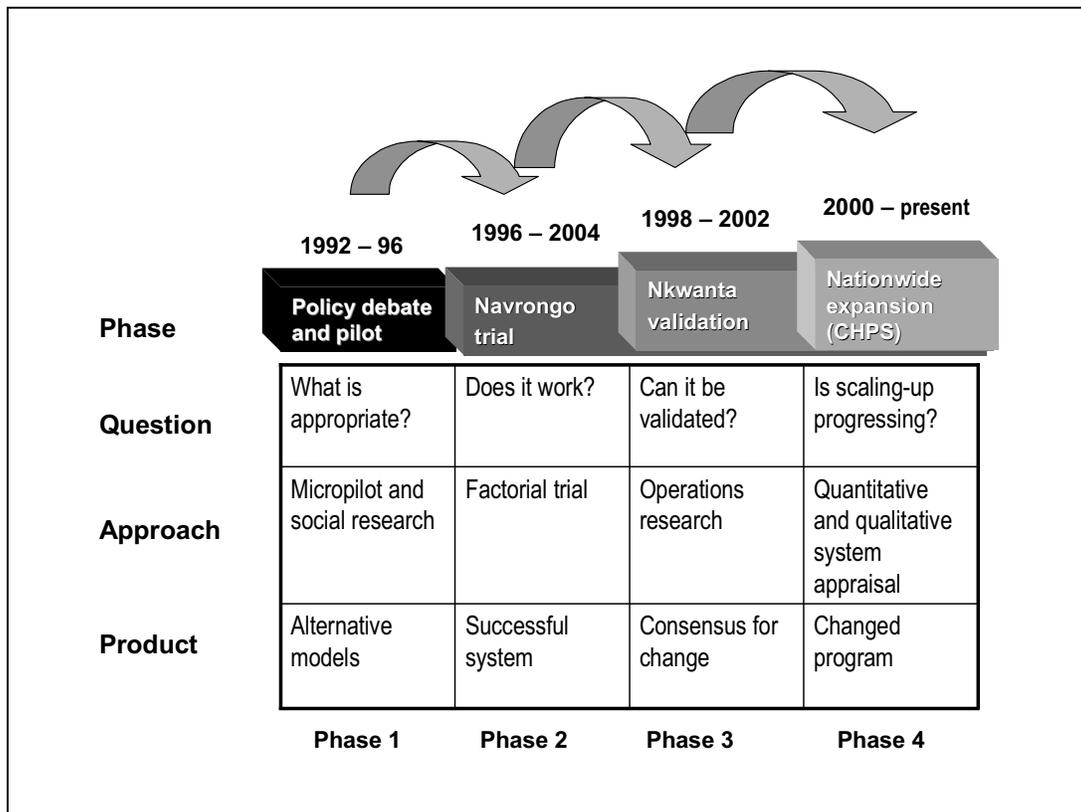
The Navrongo experiment demonstrates results that are relevant to international reproductive and child-health policy deliberations. The experiment tested the effect on fertility and child mortality of mobilizing community health services.

Findings demonstrate that family planning programs can have an impact on fertility, even in an impoverished traditional Sahelian setting. Results also indicate, however, that extending access to contraceptive supplies may fail to address adequately the social costs of fertility regulation. Achieving results with family planning services requires developing ways of offsetting the social constraints to contraceptive-method adoption.

The results from Navrongo also show that community health nurse interventions can have a dramatic impact on childhood survival. Community-volunteer approaches, however, have not had such impact, a finding that challenges the practicality of the mounting international investment in volunteer-based health programs.

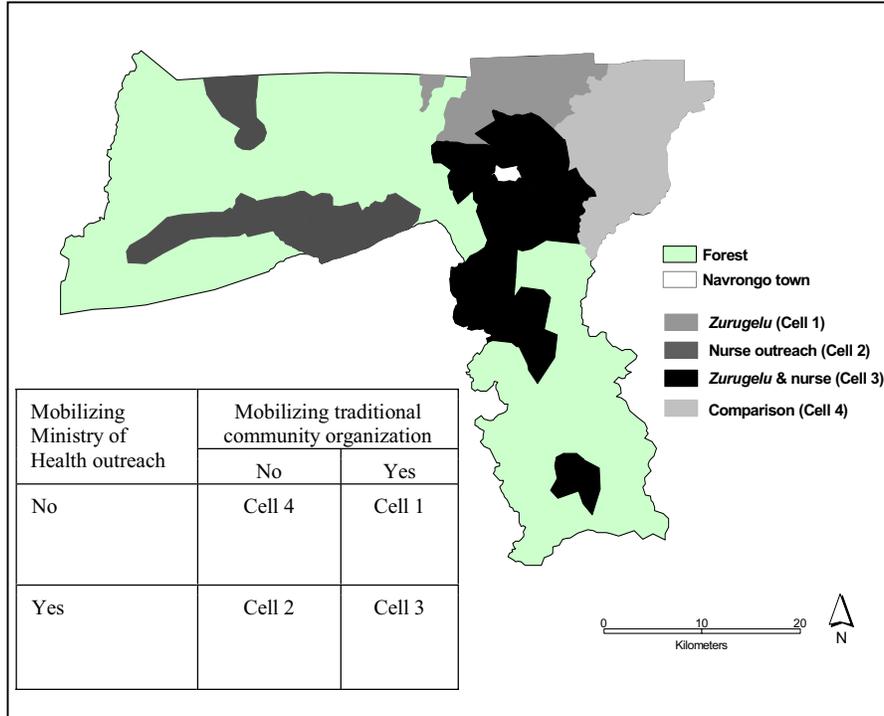
The Ghana health-care-development process demonstrates ways to address simultaneously the global agenda for accelerating access to reproductive and child health services. After a decade of global commitment to the 1994 ICPD Programme of Action, concern is mounting that family planning and reproductive health issues are receding from national health-policy agendas in Africa. Moreover, global commitment to achieving the child-survival MDGs must take into account evidence that these goals are not being met in Africa. Navrongo demonstrates affordable and sustainable means of attaining the ICPD agenda and Millennium Development Goals with existing technologies. Accumulating and using research results was crucial to building this success. The Ghana process was launched in three villages, extended to a district trial, replicated, and scaled up to a national program of community-based health-care reform that now reaches every region of Ghana. The CHPS initiative uses research as a tool for aligning national health-sector policy with vibrant traditions of community leadership, communication, and action.

Figure 1 Phases in the Ghana Ministry of Health process for organizational change



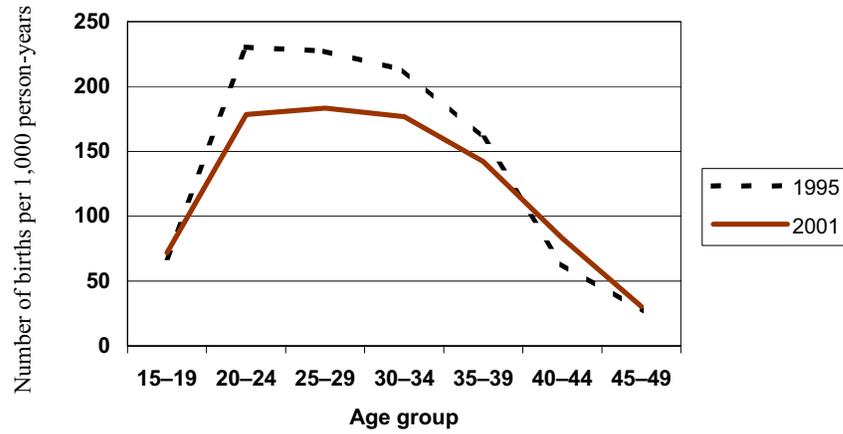
Source: Nyongator et al. (2005a).

Figure 2 Geographic zones corresponding to Community Health and Family Planning cells in Kassena-Nankana District, Ghana



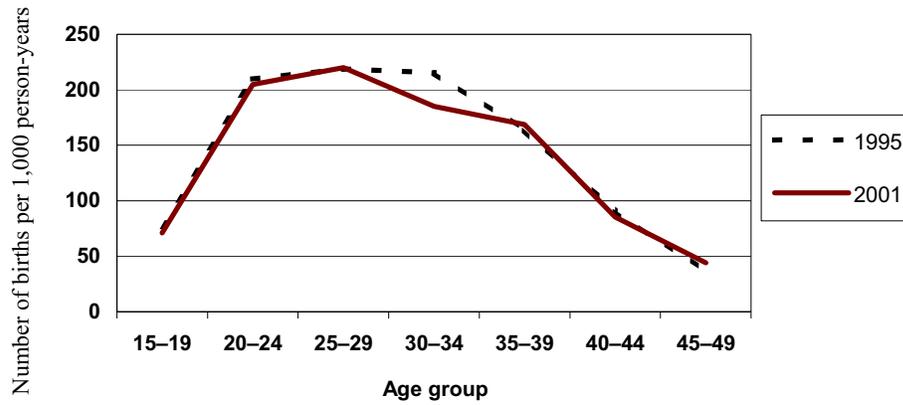
Source: Debpuur et al. (2002).

Figure 3a Age-specific fertility, combined cell 3, Navrongo, Ghana



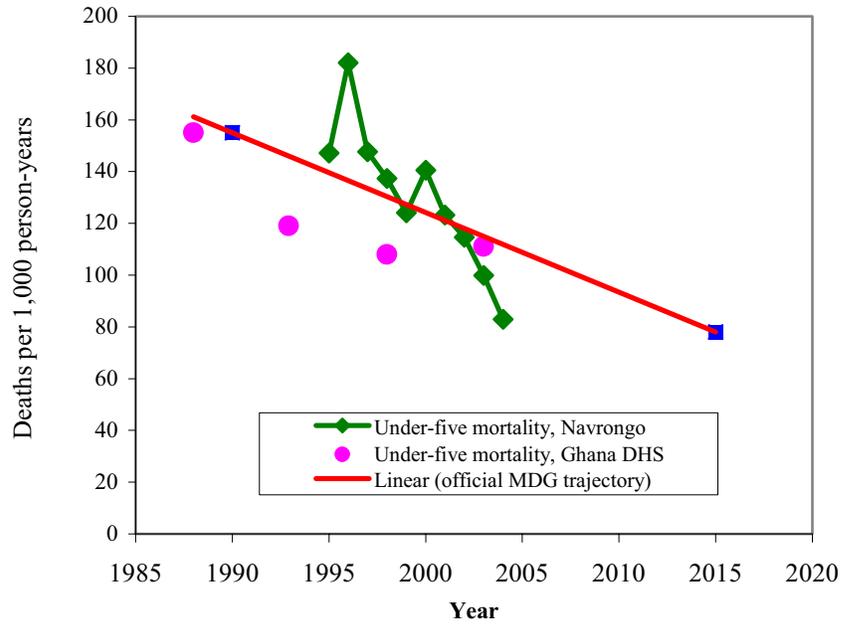
Source: Phillips et al. (2003).

Figure 3b Age-specific fertility, comparison cell 4, Navrongo, Ghana



Source: Phillips et al. (2003).

Figure 4 Trends in under-five mortality compared with MDG targets, Ghana



Source: Binka et al. (2005).

Figure 5 Trends in under-five mortality (5q0), by Community Health and Family Planning cell, Navrongo, Ghana, 1995–2003

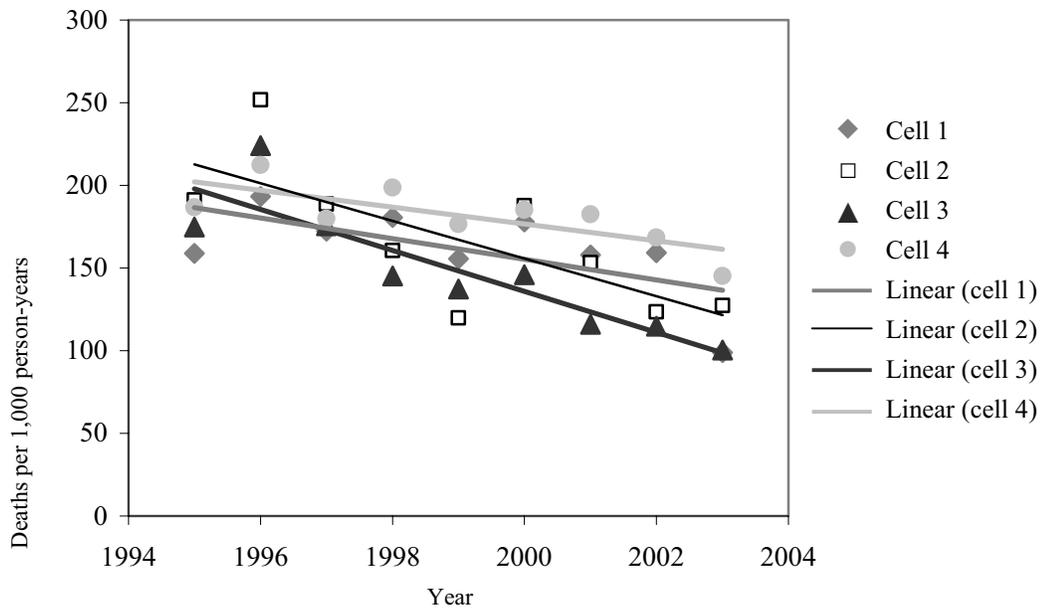
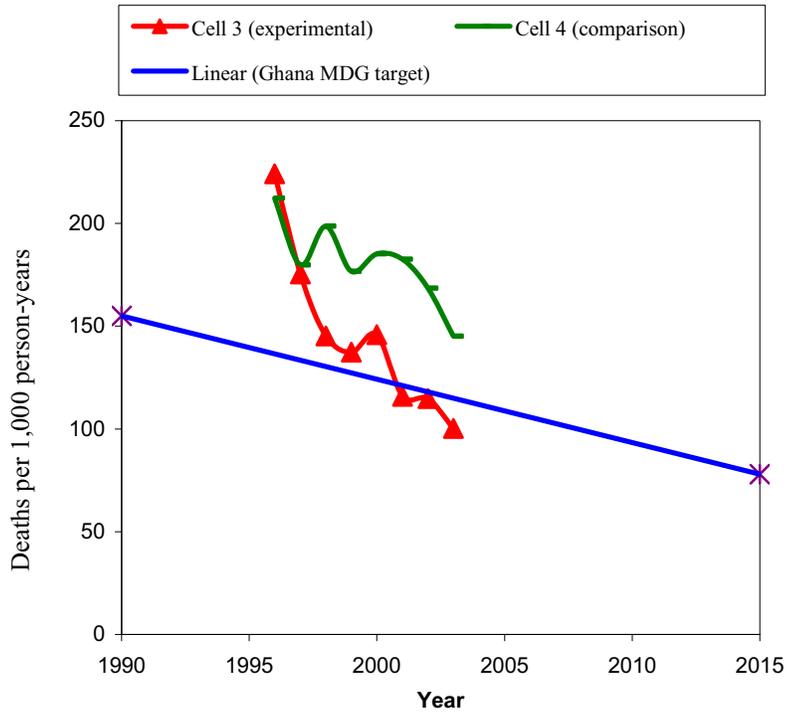


Figure 6 Trends in under-five mortality by experimental cell, Navrongo, Ghana, 1995–2003



Source: Binka et al. (2005).

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