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# FAMILY HEALTH RESEARCH

A forum for putting knowledge into practice



### RESEARCH Utilization

This, the final issue of the newsletter, explores the impact of contraceptive research in recent years.

Through a wide range of research and programmatic activities over the past five years, the Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) program—a cooperative agreement between FHI and the U.S. Agency for International Development (USAID)—has increased both access to and the range of contraceptive and reproductive health choices available to many in developing countries.

As the CRTU program comes to a close, we take this opportunity to reflect on the many positive changes the program has inspired around the world. This issue of the newsletter supplements the end-of project dissemination that took place on March 30, 2010, when approximately 100 colleagues from FHI, USAID, and multiple collaborating agencies gathered in Washington, DC, to join in a discussion on the highlights of the CRTU program.

During the CRTU program, FHI and a wide range of partners completed 211 subprojects in 26 countries. These activities developed, evaluated, and improved access to a variety of contraceptive and reproductive health technologies. They also supported the application of research results to change policies and to improve and expand evidence-based family planning practices and programs throughout the world.

The CRTU program can be measured in many ways, including by its achievements in seven focus countries (see page 2) and its accomplishments in seven key strategy areas (see page 8). Collaboration, multidisciplinary science, and global technical leadership are among the program's overall contributions to how science can be used to improve lives.

### In July 2011, FHI became FHI 360.



FHI 360 is a nonprofit human development organization dedicated to improving lives in lasting ways by advancing integrated, locally driven solutions. Our staff includes experts in health, education, nutrition, environment, economic development, civil society, gender, youth, research and technology – creating a unique mix of capabilities to address today's interrelated development challenges. FHI 360 serves more than 60 countries, all 50 U.S. states and all U.S. territories.

Visit us at www.fhi360.org.

### FOCUS COUNTRY GOALS

- Establish in-country partnerships with key stakeholders, research institutions, and service delivery programs.
- Identify and prioritize local reproductive health research and program issues.
- Promote the use of research results to guide changes in policies and programs.
- Support the scale-up of evidence-based practices and programs in the focus countries.

### FINDING FOCUS

In Depth

#### Program meets goals in seven countries.

Although the Contraceptive and

Reproductive Health Technologies Research and Utilization (CRTU) program was active in countries throughout the world, its resources and activities were strategically focused in seven countries. It was through these "focus countries" that the CRTU program made much of its public health impact.

#### **Choosing countries**

The focus country program was designed to foster partnerships and develop a strategic presence in a limited number of countries to increase efficiencies and the likelihood that research results would be translated into practice. The focus countries were chosen in part because they each had a high unmet need for family planning, a Ministry of Health (MOH) interested in addressing this need, and a local U.S. Agency for International Development (USAID) mission willing to support the program's efforts.

"One of the important aspects of the CRTU program was its clear focus on research utilization," says Mike Welsh, vice president of centrally funded programs and applied research at FHI. "The literature on research utilization clearly states the need to work with key stakeholders as early in the research

15% 31% Kenya South Africa 13% Uganda Madagascar Nigeria Tanzania India 8% Global Other 12% 7% 4% 4% 6%

#### PERCENTAGE OF CRTU ACTIVITIES BY COUNTRY

process as possible. Our focus country program, with its explicit goal of fostering in-country partnerships, was an important part of our strategy to more effectively move research into practice," he says.

#### **Documenting impact**

According to Welsh, the focus country program was successful in many ways. "Of special note would be the enormous progress made in terms of updating norms and guidelines for family planning services and bringing the focus countries more in line with current World Health Organization standards," he says.

During the CRTU program, FHI provided extensive input to the World Health Organization's (WHO's) cornerstone publications on evidence-based guidance for family planning, including *Medical Eligibility Criteria for Contraceptive Use, Selected Practice Recommendations for Contraceptive Use,* and *Family Planning: A Global Handbook for Providers.* 

An example is how CRTU-supported clinical research helped persuade WHO to change its medical eligibility criteria for contraceptive use in 2009, to increase access to the injectable depot-medroxyprogesterone acetate (DMPA) for women on antiretroviral therapy (ART). The study, conducted among 30 HIVpositive women, suggested that combination ART is not likely to affect the contraceptive effectiveness of DMPA.<sup>1</sup> Discussion about these findings led the WHO medical eligibility expert working group to recommend that use of non-nucleoside reverse transcriptase inhibitors become a category 1 condition for DMPA (in which there are no restrictions on use) instead of a category 2 condition.

The effects of changes like these can be quite far reaching, as at least 50 national program guidelines are reported to draw on recommendations from WHO's medical eligibility criteria and selected practice recommendations. Since the change regarding DMPA for women on ART, FHI has assisted the governments of Kenya, Nigeria, Senegal, and Tanzania in updating their national family planning policies to reflect the change. CRTU-supported research has also led to substantial programmatic changes, although this type of impact is always more difficult to measure. One example is how FHI's strong partnerships with the Ministry of Health and local nongovernmental organizations in the Moramanga District of Madagascar contributed to an increased number of community health workers being trained to delivery family planning services there.

"This is just a sampling of the many accomplishments we have been able to document," says Welsh. "Together, the achievements of the focus country program stand out as an important part of the CRTU legacy and represent a step forward in strengthening health systems to more effectively meet the family planning needs of women and couples."

#### Reference

1 Nanda K, Amaral E, Hays M, et al. Pharmacokinetic interactions between depot medroxyprogesterone acetate and combination antiretroviral therapy. *Fertil Steril* 2008;90(4):965-971.

#### **COUNTRY HIGHLIGHTS**

Focus country	Selected accomplishments
India	In 2007, FHI and partners began collaborating with the national government and the government of Uttar Pradesh to devise a strategy to reposition the intrauterine device (IUD) within the national family welfare program. National efforts have been successful in gaining provider support for IUDs.
	FHI collaborated with the Indian Council of Medical Research (ICMR) to develop the protocol for a randomized controlled trial comparing the effectiveness of different vasectomy techniques. FHI is now providing limited technical assistance to the ICMR on the trial. Results should provide the strongest available data on this issue.
Kenya	FHI partnered with the Ministry of Public Health and Sanitation (MOPHS) and local universities to reach more than 58,000 students with messages on abstinence, being mutually monogamous, and condom use. More than 5,000 students also received counseling and testing for HIV.
	Georgetown University's Institute for Reproductive Health (IRH) collaborated with FHI and partners to intro- duce the Standard Days Method (SDM) into 13 facilities in the Ijara district of North Eastern Province, through the APHIA project. In 2009, an assessment found that 254 clients in seven facilities had accepted the method. Ninety-three percent of them had never used a modern contraceptive before.
Madagascar	In 2007, the Madagascar Ministry of Health, Family Planning, and Social Protection (MOHFPSP) partnered with FHI and others on a pilot program to integrate DMPA into its community-based family planning programs. In 2008, the program expanded from four districts in two regions to 21 districts in 11 regions.
Nigeria	FHI collaborated with WHO, the United Nations Population Fund (UNFPA), and partners to support evidence- based family planning guidelines and practices in Nigeria. The Nigerian government updated its national guidelines to meet international standards and approved seven WHO-endorsed job aids to help providers implement them. A cohort of national trainers was established, and a cascade training was conducted for providers in three states.
South Africa	In partnership with the National Department of Health (NDoH), FHI took the lead in strengthening an inte- grated package of essential primary health care services (including family planning and reproductive health services) that is now available to all South Africans.
	To improve access to the national package of integrated services, FHI worked with the NDoH to establish five mobile service units that are delivering integrated services in four provinces.
Tanzania	With guidance from FHI, the Tanzania MOH launched a technical working group for integrating family plan- ning and HIV services in 2008. The group helped strengthen the national standard operating procedures for HIV care and treatment, which now mandate that care and treatment centers routinely address the contracep- tive needs of their clients.
Uganda	FHI collaborated with the Uganda MOH and partners to roll out community-based access to injectable contra- ceptives and to advocate for the service nationwide. Advocacy activities reached more than 30,000 people in the last half of 2009 alone.
	With technical assistance from FHI, the MOH revised its national family planning guidelines to include four evidence-based strategies for helping women initiate and continue using oral contraceptives.

### **CRTU Resources**

Implants Toolkit http://info.k4health.org/implants/

#### Improving Access to Family Planning: Community-Based Distribution of DMPA http://www.fhi.org/en/RH/Pubs/

servdelivery/cbd\_dmpa/index.htm

**IUD Toolkit** http://www.k4health.org/toolkits/iud

Long-Acting and Permanent Methods: Addressing Unmet Need for Family Planning in Africa http://www.fhi.org/en/RH/Pubs/ servdelivery/LAPM/index.htm

Provision of Injectable Contraception Services through Community-Based Distribution: Implementation Handbook http://www.fhi.org/en/rh/pubs/ booksreports/cbd\_dmpa\_imp.htm Program Dispatch

### ENCOURAGING Contraceptive Continuation

### Updated guideline helps women use injectable contraceptives.

During the Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) program, a secondary analysis of data helped prompt the World Health Organization (WHO) to extend its recommended grace period for re-injection of depot-medroxyprogesterone acetate (DMPA). The new international guideline has since been incorporated and promoted in different ways to address barriers to re-injection around the world.

FHI has assisted the governments of Kenya, Nigeria, Senegal, and Tanzania in updating their national family planning policies to reflect the change. South Africa is in the process of updating its policies as well. FHI also used the results of the secondary analysis to update two job aids that had been shown to help health care professionals in South Africa counsel and provide services to women who want to use injectables. The job aids were changed to reflect WHO's new grace period and were modified for a global audience. IntraHealth International and the Senegal Ministry of Health's Division of Reproductive Health helped field-test the job aids in Senegal in 2009, and additional versions were developed specifically for community health workers.

The job aids, which include current WHO guidelines for both DMPA and norethisterone enantate (NET-EN), have been used to train health care providers in five South African provinces and seven districts in Uganda. More than 100 community health workers in Kenya, Nigeria, and Zambia have also been trained. Global dissemination efforts are ongoing, including the distribution of more than 2,000 copies of the job aids in Kenya.

To view the job aids, see http://www.fhi.org/en/ RH/Pubs/servdelivery/reinjection\_job\_aids.htm.

Thirty-one community health workers learned about the provision of injectables, including the new re-injection window for DMPA, at this training sponsored by Kenya's APHIA II project in 2009.

#### THE CHANGE ....

WHO changed its guidelines to encourage health care providers to allow a four-week grace period—rather than the previous twoweek grace period—for a woman to return for her next injection of DMPA. The change is reflected in the second edition of *Selected Practice Recommendations for Contraceptive Use*, published in 2008.

#### . . . AND THE RESEARCH BEHIND IT

In 2005, as the CRTU program was beginning, FHI and partners surveyed more than 1,000 users of injectable contraceptives at 10 public health clinics in South Africa.<sup>1</sup> The research revealed that provider practices were affecting the continuation rates of women who wished to use DMPA. Between 29 percent and 42 percent of the women in the study arrived late for their re-injections, and two-thirds of these women were denied a re-injection—a figure that includes those who were within the two-week grace period recommended by WHO at the time.

Scientists at FHI later published a secondary analysis of data from more than 2,000 DMPA users in Uganda, Zimbabwe, and Thailand. The analysis showed that the grace period for reinjection could be safely extended, because the risk of pregnancy was no higher for women who received re-injections four weeks late than those who received re-injections two weeks late.<sup>2</sup>

#### References

**1** Baumgartner JN, Morroni C, Mlobeli RD, et al. Timeliness of contraceptive reinjections in South Africa and its relation to unintentional discontinuation. *Int Fam Plann Perspect* 2007;33:66–74.

**2** Steiner MJ, Kwok C, Stanback J, et al. Injectable contraception: what should the longest interval be for reinjections? *Contraception* 2008;77:410–414.

#### Field Research Report

### CLINICAL RESEARCH TO PREVENT HIV

### Attention shifts to antiretroviral drugs for prevention.

During the Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) program, FHI and its many partners made substantial progress evaluating topical microbicides and pre-exposure prophylaxis (PrEP) for preventing HIV and other sexually transmitted infections.

#### A partially effective vaginal microbicide

Most recently, a study led by the Centre for the AIDS Programme of Research in South Africa (CAPRISA) showed that the antiretroviral drug tenofovir, when formulated as a topical microbicide, significantly reduces a woman's risk of being infected with HIV and genital herpes. Results were presented in July 2010 at the XVIII International AIDS Conference in Vienna and published in the journal *Science*.

CAPRISA conducted the study, in partnership with FHI and CONRAD, among 889 HIVnegative women in South Africa. With support from the CRTU program, FHI provided technical assistance on many aspects of the trial, including protocol design and development, statistical design and analysis, ethical oversight, and communications. Should other studies of tenofovir gel confirm the results of the study, widespread use of the gel (at the reported level of protection) could prevent more than half a million new HIV infections in South Africa alone over the next decade.

#### Pre-exposure prophylaxis

Oral antiretroviral drugs are also being evaluated to determine whether they can prevent HIV (in the approach known as PrEP). FEM-PrEP, a Phase III clinical trial led by FHI, is currently testing the safety and effectiveness of a daily oral dose of Truvada (a combination of two antiretroviral drugs) among nearly 3,900 HIV-negative women at five sites in four sub-Saharan African countries. The trial may be completed by 2012.

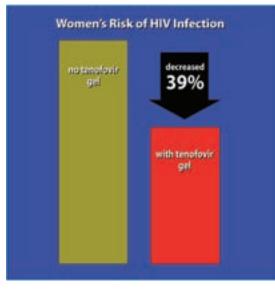
As part of the FEM-PrEP trial, scientists are also conducting a "rollout" study to develop recommendations for potential pilot programs of PrEP in Africa. Even if PrEP is found to be unsafe or ineffective, the results of this work will provide valuable information that can be used to improve existing HIV prevention services.

Several other groups, including the Microbicide Trials Network (MTN) and the U.S. Centers for Disease Control and Prevention (CDC), are also conducting trials of Truvada among populations of women and men who are at risk of HIV in other parts of the world.

#### Resource

Communications Handbook for Clinical Trials http://www.fhi.org/en/RH/Pubs/ booksReports/comm handbook.htm

The Microbicides Media and Communications Initiative (MMCI), in partnership with the Global Campaign for Microbicides and FHI, designed this handbook to provide practical guidance to clinical trial staff and research partners on how to anticipate and respond to the special communications challenges posed by clinical research in resource-limited settings.







In the CAPRISA trial, a microbicide containing 1-percent tenofovir gel was 39 percent effective at reducing a woman's risk of becoming infected with HIV during sex and 51 percent effective at preventing genital herpes infection. These results were statistically significant.

### Resources

#### HIV Counseling and Testing for Youth: A Handbook for Providers

http://www.fhi.org/en/Youth/ YouthNet/rhtrainmat/vctmanual. htm

#### Increasing Access to Contraception for Clients with HIV: A Toolkit

http://www.fhi.org/en/RH/ Training/trainmat/ARVmodule.htm

#### Strategic Considerations for Strengthening Linkages between Family Planning and HIV/AIDS Policies, Programs, and Services

http://www.fhi.org/en/RH/Pubs/ booksReports/FP-HIV\_Strategic\_ Considerations.htm Program Dispatch

### INTEGRATING Family planning And hiv services

## More evidence-based practices emerge in Africa.

Because people seeking HIV services often share common needs and concerns with those who seek family planning (FP) services, integrating these two types of services enables health care providers to serve their clients more efficiently and comprehensively.

"Momentum is building behind integration efforts in Africa, and evidence-based practices are beginning to emerge that will help providers offer better integrated services," says Rose Wilcher, a senior technical officer at FHI and an expert on integration.

A recent study supported by the Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) program is among those contributing to the growing evidence base.

#### Early integration efforts

In 2009, FHI and many local partners completed a five-country study, which provided a snapshot of early integration efforts in Ethiopia, Kenya, Rwanda, South Africa, and Uganda. The scientists used interviews of more than 2,000 stakeholders and observations of staff at more than 100 clinics to assess the state of programs that were integrating FP into HIV counseling and testing, FP into HIV care and treatment, or HIV services into FP.<sup>1</sup>

The findings were strikingly consistent across countries. Clients of HIV services in all five countries had an unmet need for FP services. Among clients of HIV counseling and testing, unmet need varied from a high of 46 percent in South Africa to a low of 17 percent in Ethiopia. Unmet need was lower among women receiving HIV care and treatment (about 20 percent), likely because a higher percentage of these women were in stable relationships and were already using contraception. (Also, a large proportion were not sexually active.)

#### TEN STEPS FOR STRENGTHENING SERVICES

- 1 Generate demand for integrated services. Advertize to clients and encourage the community to tell others about the services you provide.
- 2 Organize services. Learn how your clients move through the facility and reduce costs by making adjustments to the service-delivery area.
- **3** Ensure commodity security. Register your facility with the appropriate authorities to receive contraceptives and HIV supplies.
- **4** Train health care providers. Assess the informational needs of all levels of providers and develop a plan to update their knowledge and skills.
- 5 Screen all patients for an unmet need for contraception. All women of childbearing age and all men should be asked about their sexual activity, desire for pregnancy, and current contraceptive use.

- 6 Foster dual protection and dual-method use. Develop counseling strategies to encourage male and female clients to use condoms correctly and consistently, and to use condoms with another contraceptive method.
- 7 Challenge provider bias. Address the tendency to emphasize condom use and neglect other contraceptive methods. Correct the false belief that some methods are inappropriate for people living with HIV.
- 8 Reinforce referral systems. Identify all sources of contraceptive methods not provided on site and create a system to track completed referrals.
- **9** Strengthen skills for supportive supervision. Update provider job descriptions and other documents to reflect the provision of integrated services.
- **10** Monitor and evaluate performance. Determine whether the family planning service or the HIV service is responsible for reporting the delivery of integrated services, and use the data you collect to improve your services.

#### **Assisting providers**

The research also showed that many clients in integrated service delivery settings were not being systematically screened for unmet need. While most providers said that FP was part of the package of care they offered, few clients actually received contraceptive methods other than condoms. Insufficient training of providers was another major obstacle to the provision of FP to clients of HIV services. Misconceptions and general lack of knowledge about contraceptive options for women with HIV were common among providers. In addition, about one-half of the providers in the study did not have the job aids and supportive supervision needed to facilitate integrated service delivery.

"Because a provider's understanding of integration is critical for strengthening family planning interventions within HIV programs, we used these findings to develop a list of essential steps providers can take to deliver high-quality integrated services," says Susan Adamchack, the scientist at FHI who led the five-country study.

The successful integration of services may require some adjustments by providers, supervisors, and program managers. But, if implemented properly, FP/HIV service integration has the potential to produce tangible gains against the HIV epidemic and improve the overall health of mothers and their children.

#### Reference

1 Adamchak S, Janowitz B, Liku J, et al. Study of Family Planning and HIV Integrated Services in Five Countries. Final Report. Research Triangle Park, NC: Family Health International, 2009.

#### A FINAL SUCCESS STORY

When the CRTU program began, family planning and reproductive health were handled by separate domains within Kenya's Ministry of Public Health and Sanitation (MOPHS). The Division of Reproductive Health (DRH) was responsible for research and services related to family planning, and the National AIDS/STD Control Programme (NASCOP) was responsible for those related to reproductive health. Now, as the CRTU program is ending, the story in Kenya is very different.

During the CRTU program, a technical working group devoted to integration strategies brought representatives of the DRH and NASCOP together to share ideas and plan joint activities. The MOPHS was stronger as a result of this group, which helped position the ministry to create a national strategy for integrating family planning with HIV voluntary counseling and testing (VCT). This strategy led to three assessments conducted in partnership with FHI/Kenya and others. One considered the needs of Kenyan young people for integrating family planning and HIV services, one evaluated opportunities to promote male circumcision as an HIV prevention measure, and one considered the family planning needs of HIV-infected women. The strategy also pointed the way to the development of training materials to train 1,067 community health workers to support home-based care and 610 providers of antiretroviral therapy (ART) at comprehensive care centers to offer family planning services to their clients.

Most recently, FHI and partners worked with the DRH, NASCOP, and others to incorporate the family planning needs of women with HIV into a new national strategy for integrating reproductive health and HIV care and treatment services. With CRTU support, the collaborators also developed a provider-orientation package that was rolled out with the new strategy in July 2010.



A guest speaks in Nairobi at the July 2010 launch of Kenya's national strategy to integrate reproductive health and HIV services.

#### Family Health

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Summary

#### PROGRAM STRATEGIES AND ACCOMPLISHMENTS

The Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) program used seven "strategies" to achieve its objectives and help guide the selection and implementation of its activities. Six of the strategies were technical in nature, focusing on a specific type of family planning method or program, a particular reproductive health technology, or a subpopulation with unique family planning and reproductive health needs. A seventh "cross-cutting" strategy was named to categorize those activities that addressed multiple strategies.

#### Hormonal methods

Oral contraceptive pills and injectables are the most common reversible approach for preventing unintended pregnancy. With support from the CRTU program, FHI led efforts to remove obstacles to the initiation and safe use of these methods. FHI also addressed the issues of limited access and low continuation rates for many hormonal method users.

#### Long-acting and permanent methods

FHI worked with many governments and organizations to help them realize the potential of long-acting and permanent methods including intrauterine devices, implants, and vasectomy—to meet the reproductive health needs of family planning clients.

#### Male and female barrier methods

Barrier methods of contraception protect against pregnancy and most sexually transmitted infections. FHI worked with partners such as CONRAD to help test the safety and effectiveness of new female condoms and diaphragms, collaborated on the design of new methodologies for studying female condoms, and developed new performance standards for male and female condoms.

#### Microbicides

The CRTU program was instrumental in advancing research on microbicides. FHI

began an initiative to identify and develop the research and laboratory capacities of potential sites for future HIV prevention trials. FHI was also involved in 15 studies of six candidate microbicides. These studies helped rule out several vaginal microbicide candidates and showed that vaginal microbicides based on antiretroviral drugs, like tenofovir, hold great promise.

#### HIV and contraceptive services

FHI collaborated with many partners to increase support for family planning as an HIV prevention intervention and to promote the use of the latest scientific evidence and programming tools on integrating family planning and HIV services. FHI also conducted clinical research that improved our understanding of the safety and effectiveness of contraceptive methods for women at high risk of HIV and for HIV-positive women.

#### Youth

The CRTU program built upon the momentum and stature of FHI's YouthNet program (2001–2006) by developing a research agenda to address gaps in knowledge regarding youth and services for youth. A highlight was the establishment of the Interagency Youth Working Group (IYWG), which offered technical leadership around the world and helped create and disseminate publications, tools, and training guidelines for providers of youth services.

#### Cross-cutting

The CRTU program supported research-topractice activities that cut across all of the strategies. Examples are the focus country program, quality assurance for research efforts, and the monitoring and evaluation of the CRTU program. Because these activities facilitated and enhanced all other CRTU-supported activities, they helped ensure that the full impact of the CRTU program was realized.