Family Health International

RESEARCH IN PUBLIC HEALTH

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Introduction to FHI's Product Quality and Compliance Division (PQC)

Twenty years ago, the U.S. Agency for International Development (USAID) approached FHI to establish a system for monitoring the quality of contraceptive supplies distributed though its programs. This included evaluating the supplies as they entered the supply chain as well as monitoring their proper handling and storage.

In response, FHI designed a system to evaluate the quality of a variety of contraceptive stocks—including male and female condoms, intrauterine devices, injectables, implants, and oral contraceptives—on a global level. The system included monitoring the production of the contraceptives to ensure compliance with international standards and government procurement contracts and providing technical assistance and support to various HIV prevention and family planning programs.

Today, FHI still handles product testing and certification, supplier prequalifications, and field monitoring for USAID. FHI also continues to conduct quality assurance testing for other government agencies and commercial clients—including Ansell (manufacturer of LifeStyles condoms) and SSL International (manufacturer of Durex condoms).

Additionally, FHI's PQC Division provides technical support to FHI clinical research projects and works to improve the capacity of in-country laboratories to ensure that they are testing contraceptives and other medical commodities properly and according to the latest international standards. This work includes training laboratory technicians on proper testing techniques and how to stay abreast of the latest international testing standards. FHI also helps in-country laboratories to establish operational protocols and policies needed to obtain international accreditation.

The USAID-funded Contraceptive and Reproductive Health Technologies Research and Utilization Program (CRTU) funds most of the activities described above. The goal of the CRTU program is to expand the range, availability, and use of safe, effective, acceptable, and affordable technologies to prevent unplanned pregnancy and sexually transmitted infections, including HIV. Eli Carter, who joined FHI in 1988 to establish the quality assurance program, is the Director of the PQC Division.

PQC Services

Product Evaluations

Medical Devices

Condoms—Male and Female
Medical Gloves
Intrauterine Devices

Pharmaceuticals

Oral Contraceptives
Implants
Injectables
Spermicides
Microbicides
Antiretrovirals
Tuberculosis Drugs
Antimalarial Products

Additional Services

Product Characterization
Product Stability and Shelf-life Studies
Package Integrity Evaluation
Product Compatibility
Prototype Design and Evaluation

Assisting with the Distribution of Health Commodities: USAID | DELIVER PROJECT

The USAID | DELIVER PROJECT (DELIVER) has the goal of improving the availability of essential health pharmaceuticals and other health commodities through strengthening local supply chains, streamlining distribution systems, and providing centralized procurement services. Awarded in June 2006 to a team led by John Snow, Inc. (JSI), DELIVER is the primary project through which commodities are purchased and distributed for USAID programs. FHI is a partner on the DELIVER project and has a role in each of three task orders that have been awarded to date.

Contraceptive Supplies (Task Order 1): FHI handles the quality assurance requirements for the project, which focuses on quality assurance and supply chain management of condoms, oral contraceptives, injectables, and implants.

Avian Influenza Commodities (Task Order 2): JSI has been given the task of overseeing and distributing the U.S. stockpile of equipment related to avian influenza, such as decontamination kits, laboratory test kits, and personal protection equipment. FHI is establishing Standard Operating Procedures, providing quality technical assistance for procurement of supplies, and assisting with the audits of stockpiled equipment.

Malaria-Related Supplies (Task Order 3): The third task order involves the procurement and distribution of commodities related to the prevention and treatment of malaria, including insecticide-treated nets, rapid diagnostic test kits, and drugs. FHI provides the quality assurance oversight for this project.

Steve Hamel, Deputy Director of FHI's PQC, is manager of quality assurance for DELIVER. At FHI since 1997, Hamel coordinates the testing and compliance components of FHI's Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) program in addition to his work with DELIVER.

For more information on the USAID | DELIVER PROJECT please visit: *http://portalprd1.jsi.com/portal/page/portal/DELIVERWEBSITE/HomePage*.

Profile: David Jenkins, PhD

In 2004, David Jenkins, PhD, joined FHI as the Chemical Laboratory Manager of the Product Quality and Compliance Division (PQC). In an organization where most of the research staff has a background in medicine, public health, or fields such as economics or anthropology, Dr. Jenkins brings something unique to FHI—a PhD in fiber and polymer science from North Carolina State University.

While Dr. Jenkins' area of expertise may seem unusual in an organization focusing on public health issues such as improving reproductive health and reducing the spread of HIV, his knowledge of polymers and textiles is playing an important role in FHI's ability to explore new interventions to long-standing public health challenges.

One of these areas is malaria prevention. His efforts on antimalarial products include supporting FHI's quality assurance work for a USAID-funded project called DELIVER. Under DELIVER, which is managed by John Snow, Inc., FHI is a key partner overseeing the quality assurance of contraceptives, antimalarial commodities, and avian influenza-related products. Dr. Jenkins' contributions under DELIVER's Malaria Task Order include assisting with the development of procedures for managing and monitoring product quality throughout the supply chain for insecticide-treated bed nets, rapid diagnostic test kits, and antimalarial pharmaceuticals.

Along with his work on malaria-related projects, Dr. Jenkins' work includes analyzing contraceptive products and expanding testing capabilities for HIV- and AIDS-related products such as antiretroviral formulations and microbicide vaginal gels. The PQC tests contraceptive products (orals, injectables, and hormone-releasing implants) for donors including USAID, United Nations Population Fund, and Population Services International to make sure that they meet specifications. For example, Dr. Jenkins verifies that the products perform properly, are consistently made, and have the right amount of active ingredient. He also conducts stability studies to determine whether a product will degrade if it is stored under extreme environmental conditions such as high temperatures or humidity.

Additionally, Dr. Jenkins is helping FHI researchers to develop a textile-based delivery device for vaginal gel or liquid formulations of microbicides and other drugs. Dr. Jenkins' efforts are focused on the manufacturing and quality assurance testing of the device.

As FHI takes on new public health issues, Dr. Jenkins' work is also diversifying. His expertise in analytical chemistry will be increasingly important as FHI explores its role and involvement in programs to detect and prevent the distribution of counterfeit drugs. An issue of global concern, the problems caused by counterfeit drugs range from creating drug resistance by circulating drugs with reduced active ingredient, to causing deaths by providing individuals with drugs that have no active ingredient or harmful ingredients. In the coming years, counterfeit drugs—particularly those being marketed as antimalarial drugs—are likely to be a growing focus for Dr. Jenkins and others at FHI.

Two Laboratories, Multiple Services

FHI has two quality assurance laboratories. Our main laboratory is in Durham, North Carolina, where FHI's headquarters is based. Our second laboratory, which we opened last year, is in Bangkok, Thailand. Both laboratories test similar products, such as condoms and medical supplies, with the Bangkok laboratory playing an increasingly important role in testing USAID's offshore procurements.

In fact, the Bangkok laboratory is already testing half of the condoms procured by USAID. In addition to its work for USAID, the new facility increases FHI's capacity to test contraceptives and medical supplies for governments and other purchasers of commodities. The laboratory also conducts quality assurance services for condom manufacturers from Malaysia, Thailand, and India.

With the added capacity provided by the Bangkok laboratory, our laboratory in North Carolina has been able to expand its stability testing and testing of microbicides, antiretrovirals, insecticide-treated bed nets, and other medical commodities. The laboratory also increased its import testing of products such as condoms and examination gloves manufactured abroad and intended for use in the United States.

FHI has been offering high-quality laboratory services since 1990. Our experience includes:

- Testing more than 3,000 condom batches annually
- Evaluating contraceptives and other products using international standards and specifications
- Assisting clients to resolve regualtory issues, complaints, and quality disputes
- Guiding organizations, manufacturers, and governments through compliance with international standards
- Collaborating with international sponsors, international standards organizations, and countries around the world to improve product quality

FHI's strengths also include state-of-the-art testing facilities that comply with international standards and accreditation by the American Association for Laboratory Accreditation.

Family Health International (FHI) is a nonprofit organization dedicated to improving lives, knowledge, and understanding worldwide through a highly diversified program of research, education, and services in family health.

Contributors: *Eli Carter, Steve Hamel, David Jenkins*
Photos: *FHI (front), FHI (inside left top), Cynthia Waszak Geary/FHI (inside left center), USAID (inside left bottom), Eva Canoutas/FHI (inside right), Bryan Regan (back)*

FAMILY HEALTH INTERNATIONAL HEADQUARTERS

P.O. Box 13950
Research Triangle Park, NC 27709 USA

Courier 2224 East NC Highway 54
Durham, NC 27713 USA

For more information, contact Lucy Siegel
E-mail: lsiegel@fhi.org
Tel: 1.919.544.7040, ext. 442
Please visit our Web site at www.fhi.org