

## Laboratory improvement includes:

- Implementation of a comprehensive quality management system
- Sufficiently trained laboratory technicians supervised by laboratory management
- Standardized, written testing procedures
- Adequate supplies of reliable laboratory equipment, reagents, and quality controls
- Local support for equipment maintenance
- External quality assurance systems
- Oversight and accreditation by independent national or international authorities

## FHI Helps Navigate the Laboratory-Improvement Process

For more than 50 years, scientific and technological advances have created tremendous opportunities for progress in providing quality health care and combating disease. However, resource-constrained countries often struggle to incorporate these advances into health care systems, particularly laboratory services. But, FHI is prepared to assist in meeting this challenge.

Inadequate laboratory services can lead to inappropriate treatment decisions, lapses in surveillance of epidemic or pandemic diseases, and errors in clinical research studies. In addition to the human cost of inappropriate or delayed medical treatment, there are obvious financial costs to the health care system and clients, and these can be substantial.

Over the past few years, national and international organizations, governments, and funders have begun to tackle the challenge of improving laboratory services. They have acknowledged that while laboratory staff and management are committed to high quality services, they are often unable to provide these because of limited resources and inadequate strategic direction and policies.

Laboratory strengthening and quality improvement have emerged as cross-cutting themes in many public health programs supported by organizations such as the World Health Organization and the Global Fund. To address these challenges, many countries are beginning to draft a national strategic plan for laboratories, with a focus on standardization and quality of diagnostic services.

Increasingly, International Organization for Standardization (ISO) 15189 (which identifies requirements for quality and competence in medical laboratories) is the standard for institutions working toward national or international

accreditation. Indeed, many national strategic plans refer to ISO 15189, which was revised in 2007, and encourage laboratories to strive to meet this standard. It can be used by laboratories in developing their quality management systems and assessing their competence. It is also used by accreditation bodies to confirm and recognize the competence of medical laboratories. Internationally, many hundreds of laboratories have received accreditation as measured by ISO 15189, although the majority of these are in industrialized countries.

FHI has long recognized the challenges facing medical laboratories in resource-poor settings. Staff in our Laboratory Sciences Division provide technical assistance, training, and scientific services to research studies and public health programs globally. Our laboratory support activities take place at all levels in the laboratory system, from primary health care point-of-service facilities in Vietnam to sophisticated national reference laboratories seeking ISO 15189 accreditation in countries such as China, Indonesia, Thailand, Bangladesh, Kenya, and Zambia. We have demonstrated that, with adequate resources and support, ISO 15189 compliance is an achievable goal for any medical laboratory.



## Improving Laboratory Services in Vietnam

Laboratory strengthening involves improving laboratory services for accurate and timely diagnoses of diseases such as HIV, tuberculosis, or avian influenza. This involves assessment, training, and technical assistance to establish the necessary quality management systems to achieve ISO 15189 accreditation, which identifies a laboratory as having met an internationally recognized standard of quality and competency.

FHI provides these services to clinical laboratories supporting research and public health programs. One example of FHI's work in the public sector is a project in Vietnam.

The government of Vietnam has prioritized improving primary health care (PHC) at the commune level. Upgrading the quality of laboratory services is an important part of this initiative. Under-resourced laboratories at the commune level not only limit the ability of health care workers to alert the public health system of potential epidemics such as cholera, dengue, malaria, meningitis, and tuberculosis, but also compromise the ability of the laboratories to provide basic diagnostic services.

To help improve laboratory services, FHI conducted a laboratory needs and capacity assessment in 2007-2008 at representative

commune- and district-level health facilities in Da Nang and Khanh Hoa provinces. Funding was provided by the Atlantic Philanthropies foundation. The assessment found that most of the PHC facilities in these two provinces are unable to perform the majority of laboratory tests recommended by Vietnam's Ministry of Health. The focus of the assessment was to identify the extent and quality of current commune-level PHC laboratory services and to make recommendations on how they could be improved to better meet the needs of clients and health care providers.

The assessment included 17 commune health posts (CHPs) and 4 district health (DH) facilities in Da Nang and 35 CHPs, 3 DH facilities, and 5 polyclinics in Khanh Hoa. Key findings included:

- There was a significant lack of laboratory human resources, equipment, and reagents.
- All of the CHPs have clients who need laboratory testing services, but few of the CHPs can provide them.
- Health workers felt that if they were able to perform simple diagnostic tests, they would improve their capability for the early detection and treatment of diseases, reduce the client overload at higher level facilities, help identify and prevent epidemics, and reduce the clients' cost of treatment.

Following the completion of the assessment, the FHI team of laboratory specialists presented recommendations to the provincial health authorities in both provinces. Those authorities concluded that it is essential to establish functional laboratories at primary health care units offering a minimum basic diagnostic service. As the project continues, FHI will work with provincial health authorities in Da Nang and Khanh Hoa to create evidence-based plans for implementing the needed improvements.





# Laboratory Strengthening and Staff Training Improve Public Health

FHI works with organizations such as the U.S. National Institutes of Health (NIH), the U.S. Agency for International Development, the World Health Organization, local ministries of health, and U.S.-based foundations to enhance the quality of laboratories in resource-poor countries so that they can provide accurate and efficient laboratory diagnostic services.

As part of its laboratory strengthening program, FHI has developed a training curriculum based on ISO 15189 requirements for quality and competence in medical laboratories. We have delivered this training to more than 500 laboratory technicians and managers, in locally appropriate languages including Chinese, Indonesian, Thai, and Vietnamese. Additional modules have been created to supplement special needs, such as biosafety for laboratories working with respiratory pathogens, including avian influenza and multi-drug resistant and extra-drug resistant tuberculosis. To support a more accurate diagnosis of malaria, FHI has developed a microscopy-training program that covers slide preparation and staining, species identification, parasite counts, and an external quality-control component. Using this program, we have trained microscopists in six countries in Southeast Asia to reliably diagnose malaria and determine the success of treatment.

FHI currently provides laboratory strengthening services to 12 leading infectious disease institutions in Indonesia, Thailand, and Vietnam as part of the South East Asia Infectious Disease Clinical Research Network, funded by NIH. FHI's Laboratory Sciences Division provides technical assistance and capacity building services to laboratories participating in clinical research studies and public health program activities in eight Asian countries. Additionally, the division advises the ministries of health in Indonesia and Vietnam regarding national laboratory strengthening programs.



Demand for laboratory strengthening services is so high that FHI has begun providing technical services to laboratories in Africa. We plan to launch a Nairobi-based branch of the Laboratory Sciences Division in the near future.

In 2008, in recognition of its work in laboratory strengthening, FHI was accepted as an Associate Member of the Asia Pacific Laboratory Accreditation Cooperation (APLAC). This is a regional body that coordinates the accreditation of laboratories under a mutual recognition system. It also supports laboratory strengthening activities and external quality assurance. FHI is the first and only international nongovernmental organization to be accepted in APLAC's global membership.

## FHI's Laboratory Sciences Division: Highlights of Selected Projects

Location	Partner	Project
Asia Region	U.S. National Institutes of Health (NIH)	Providing support to 12 laboratories, which are part of NIH's South East Asia Infectious Disease Clinical Research Network, to achieve ISO 15189 accreditation
Bangladesh	International Centre for Diarrhoeal Disease Research, Bangladesh	Assessed clinical laboratories; providing support to achieve ISO 15189 accreditation
Cambodia	National Center for Tuberculosis and Leprosy Control	Conducted a baseline assessment of the national tuberculosis reference laboratory, Phnom Penh
China	China National Tuberculosis Reference Laboratory	Collaborating with the laboratory to improve safety and enhance quality to meet ISO 15189 standards
China	NIH	Provided training and conducted laboratory assessments (against ISO standards) in preparation for a tuberculosis clinical research study
Nepal	Nepal National Public Health Laboratory	Designed layout for and provided technical assistance to a new HIV laboratory; provided technical assistance to establish an external quality assurance scheme for rapid HIV diagnostics; providing technical and diagnostic support for the early diagnosis of HIV in infants
Pakistan	Government of Pakistan	Provided technical assistance to establish an external quality assurance scheme for rapid HIV diagnostics
Vietnam	Oxford University Clinical Research Unit, Ho Chi Minh City	Providing technical assistance to validate a new polymerase chain reaction (PCR) assay to meet U.S. Food and Drug Administration standards in support of an investigational treatment drug for dengue
Zambia	Arthur Davison Hospital	Provided technical assistance to establish PCR capabilities for the early diagnosis of HIV in infants



Ms. Robinson



Dr. Rahman

### Key FHI Staff, Laboratory Sciences Division

Janet Robinson, FIBS, is FHI's Director of Laboratory Sciences. She has a thorough knowledge of regulatory, ethical, and legal requirements, including Good Clinical Practices, Good Manufacturing Practices, Good Laboratory Practices, Good Clinical Laboratory Practices, and ISOs 15189 and 17025. Ms. Robinson has more than 25 years of experience in medical laboratory diagnostics. At FHI, Ms. Robinson is responsible for overseeing all activities of the Laboratory Sciences Division worldwide, including ISO 15189 laboratory assessments and accreditation, laboratory strengthening, and technical assistance.

Motiur Rahman, MBBS, PhD, is the Associate Director of Laboratory Sciences for FHI's Asia Pacific Regional Office. In this capacity, Dr. Rahman oversees laboratory strengthening initiatives and provides technical assistance to governments and units within the health care setting. He is also actively involved in providing training programs for ISO accreditation. Prior to FHI, Dr. Rahman worked as a Scientist and Head of the Reproductive Tract Infections/Sexually Transmitted Infections Laboratory and DNA Sequencing and Bioinformatics section for the Laboratory Science Division of the International Centre for Diarrhoeal Disease Research, Bangladesh. His professional experience also includes several years at the Microbiology and Tumourbiology Centre at the Karolinska Institute in Stockholm, Sweden.

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.

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