National Laboratory Capacity Building Program

Vietnam

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Background

As part of an effort to improve standards of quality and quality management systems (QMS) in government laboratories throughout Vietnam, the National Laboratory Capacity Building Program (NLCBP) was initiated in 2010 with funding from the United States Centers for Disease Control and Prevention (CDC) and the United States President’s Emergency Plan for AIDS Relief. The main objectives of the program are to establish standardized QMS in select laboratories, to improve their efficiency, to ensure more reliable test results, and to improve overall health care for clients who access services at government sites.

CDC and FHI 360 collaborated with the Government of Vietnam to assist six medical laboratories in central and provincial hospitals to operate at International Standards Organization (ISO) 15189 standards. After 18 months of program implementation, five of the six laboratories successfully passed ISO 15189 certificate assessment by the ISO Bureau of Accreditation. A description of each these six facilities is provided on the following pages.

Central and provincial hospitals play a critical role in providing care and laboratory services for Vietnamese. However, these hospitals experience overcrowding and high patient burden because of limited capacity at commune and district levels. A 2008 study found that only 40 percent of district facilities surveyed in two key provinces met national recommended laboratory standards set by the Government of Vietnam. In order to address this disparity, the NLCBP is looking at ways of expanding capacity-building efforts to district level facilities in select provinces.
**Hue Central Hospital Microbiology Laboratory, Hue**

Hue General Central Hospital's Microbiology Laboratory has six units which include Microscopy, Culture, Serology, TB, Bio-molecular, and Media Preparation. The laboratory provides disease screening and diagnosis and forecasting for in and outpatient clients within the hospital and for research programs and other hospitals as needed. It also performs the surveillance and control of nosocomial infections in the hospital; and trains medical student from Hue Medical College, Hue Medical University, and technicians and physicians from 14 other provinces in central Vietnam. Approximately 100-150 specimens and 300-400 tests are processed each day.

The laboratory was accredited ISO 15189:2007.

**Preventive Medicine Center Microbiology Laboratory, Ho Chi Minh City**

The Preventive Medicine Center (PMC) Microbiology Laboratory provides clinical serology, molecular diagnostics, and microbiology services. In addition, it also provides the following:

- Training for district PMC laboratory staff on laboratory safety, infection prevention and HIV rapid testing
- Facilitation of several annual training programs, including training for approximately 120-150 health professionals
- Research in collaboration with national and international organizations

The laboratory receives approximately 300 specimens per week and performs approximately 500-700 tests. Specimens come from over 100 different clinics and health centers. The laboratory was accredited ISO 15189:2007.

**Pham Ngoc Thach Hospital Microbiology Laboratory, Ho Chi Minh City**

The Microbiology Laboratory at Pham Ngoc Thach Hospital in Ho Chi Minh City has six units including Mycobacteria Tuberculosis (TB) Microscopy, TB culture, TB Drug Susceptibility Testing (DST), Non-TB and Bio-molecular Testing, Quality Control, and Media Preparation. It has the following functions:

- Serves as a reference laboratory for smear microscopy, TB culture and DST
- Implements lot quality assurance sampling (LQAS) for sputum smear microscopy for all TB units in Ho Chi Minh City
- Provides technical assistance on microbiology TB diagnostics issues for southern provinces
- Participates in training and improving human resources for the National TB Program
- Conducts research initiatives in the field

Pham Ngoc Thach Hospital is also a leading TB research laboratory in Vietnam, in collaboration with Oxford University and other institutes. The TB units examine approximately 23,000 sputum smears, 3,400 sputum cultures, and 550 DST per month. The Non-TB and Bio-molecular unit runs approximately 1,750 tests per month. The laboratory was accredited with ISO 15189:2007.
Bach Mai Hospital Microbiology Laboratory, Hanoi

The Microbiology Department at Bach Mai Hospital is divided into six units: Virology and Immunology, Molecular Diagnostics, Bacteriology, Parasitology, Media Preparation, and Sterilization. The department serves approximately 1,000 patients with an estimated 3,000 tests each day. It also serves as an important training center for pre-service students from Hanoi Medical University and Bach Mai Medical School, and laboratory staff from provincial and district hospitals in the north. In addition, there are numerous research programs and initiatives based at the department that receive both domestic and international support.

With technical support from CDC and FHI 360, Bach Mai’s Microbiology Department established a quality management system at par with ISO 15189 in July 2010. Services have been maintained at the ISO standard since its establishment. The Vietnam Bureau of Accreditation (BoA) assessed the department for accreditation for 20 official tests in early March 2012. The department is in the process of updating its procedures and carrying out recommended actions for official accreditation.

National Lung Hospital Microbiology Laboratory, Hanoi

The Microbiology Laboratory at the National Lung Hospital in Hanoi functions as a national TB reference laboratory, providing direct supervision to 35 northern and central provinces in Vietnam. Services and initiatives include the following:
- Routine clinical services (TB and microbiology)
- Reference laboratory services for AFB smear microscopy, and AFB culture and drug susceptibility testing (DST)
- LQAS for sputum smear microscopy in the northern provinces
- Support for TB diagnostic and capacity building initiatives
- Teaching and training for the national TB program
- Various research initiatives

The Microbiology laboratory at the National Lung Hospital in Hanoi examines approximately 4,000 sputum smears, 1,000 sputum TB cultures, and 300 TB drug susceptibility tests (DST) each month. The department established and has maintained a QSM to meet ISO 15189 standards for seven critical tests since July 2010, and was assessed for accreditation in March 2012. The department is in the process of updating its procedures and carrying out recommended actions for official accreditation.

Quang Ninh General Hospital Hematology and Blood Transfusion Laboratory, Quang Ninh

The Hematology Department at the Quang Ninh General Hospital has three units: Hematology, Serology, and the Blood Bank. The laboratory receives specimens from inpatient and outpatient clients from the hospital, and from private hospitals in the province. It participates actively in the national CD4 testing laboratory network, and also provides training and technical assistance to district level laboratories throughout the province. The laboratory is currently applying for an accreditation assessment.