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TB CARE I

**TB CARE I - Vietnam
Final Report**

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List of Abbreviations

ACSM	Advocacy, Communication and Social Mobilization
APA	Annual Plan of Activity
CA	Cooperative Agreement
DAV	Drug Administration of Vietnam
DTU	District TB Unit
EPTB	Extra pulmonary TB
EQA	External Quality Assurance
FLD	First Line Drugs
GF\GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practice
HCMC	Ho Chi Minh City
HCW	Health care worker
IEC	Information, education and communication
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
KNCV	KNCV Tuberculosis Foundation
LED FM	Fluorescence Microscopy with LED light technique
MDR-TB	Multi-drug resistance TB
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MOPS	Ministry of Public Security
MSH	Management Sciences for Health
NSP	National Strategic Plan
<i>MTB</i>	<i>Mycobacterium tuberculosis</i>
NTP	National Tuberculosis Control Program
OR	Operational Research
OPC	Out Patient Clinic (HIV)
PEPFAR	The U.S. President's Emergency Plan for AIDS Relief
PMĐT	Programatic Management Drug resistant TB
PLHIV	People Living with HIV
PTB	Pulmonary tuberculosis
RR-TB	Rifampicin resistant TB
SA	Sub-Agreement
SLD	Second Line Drugs
SS	Sputum smear
SOP	Standard Operating Procedures

TA	Technical assistance
TB	Tuberculosis
TBIC	TB Infection Control
TRP	Technical Review Panel
USAID	United States Agency for International Development
VAAC	Vietnam Administration AIDS Control
VITIMES	Vietnam TB Information Management Electronic System
VNPCA	Vietnam Pharmaceutical Companies Association
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis

Executive Summary

The objective of the 5-year United States Agency for International Development (USAID)-funded project, TB CARE I-Vietnam, is to reduce the number of deaths due to TB by increasing access to timely and quality assured diagnosis and treatment of TB and MDR-TB, with special attention to vulnerable groups (people living with HIV (PLHIV), children, and prisoners).

KNCV has the lead in the implementation with other coalition partners: World Health Organization (WHO) and Management Sciences for Health (MSH) (since quarter 4 of APA2). The total budget allocated for TB CARE I in four years was USD 6,537,084.

The eight technical areas that have been covered by TB CARE I in Vietnam over the past 4 years are: early and universal access, laboratory system strengthening, TB infection control, Programmatic Management of Drug Resistant-TB (PMDT); TB/HIV; health system strengthening, TB surveillance with operational research, and drug supply management came into the program later in year three with assistance from MSH. Several activities of TB CARE I have benefited all 63 provinces across the nation over the 4 year term; however, the key focus of the project in APA4 primarily assisted 15 Provinces (including 18 clinical sites, 10 principal PMDT sites, the Central Hospital 74, 1 Regional Hospital, 1 Pediatrics Hospital, and two PMDT satellite sites). With this coverage in AP4, the Project has supported 38.6 million people in 3,232 communes of 193 districts, an equivalent of 39% Vietnam's total population as of Dec 2013. Additionally, the Project also continued its support for access to the WHO-approved rapid diagnostic platforms in all 41 provinces within the framework of the PMDT of National Tuberculosis Control Program.

The key outcomes from TB CARE I are identified below:

Management of TB in children – A new strategy has been successfully piloted in 4 provinces with high HIV burden, covering a total of 38 districts and 704 communes/wards. The project started late in APA2, and now involves 1,578 health care staff in the health system of the four pilot provinces who have been trained on the new WHO endorsed strategy on childhood TB. In year four, 7144 children that were household contacts of sputum smear-positive TB patients were screened and registered; 459 (6.4%) were diagnosed with TB (all forms). The success of this new strategy has resulted in this approach becoming a model for the National program which intends to expand this strategy to 18 provinces with Global Fund support. With gains from the new strategy, the representatives of TB CARE I and the National TB Program (NTP)-Vietnam were invited to share experiences and lesson learned on implementation of the new approach for the management of TB in children at the Global Consultation on Childhood TB for High Burden Countries in the Eastern Mediterranean, South East Asia and Western Pacific regions in Jakarta, Indonesia (September 2014) and in the WHO Annual Meeting of the Childhood TB subgroup, Barcelona, Spain (October 2014).

TB infection control (TBIC) - New strategies for TBIC were introduced in Vietnam with a special focus on nine TB hospitals, which were chosen to become the country's primary PMDT treatment centers. HIV clinics and district TB centers were also included in the project. After the development of a national TBIC policy with complementary standard operating procedures (SOPs) and training materials for HIV clinics and district TB Unites, training and on – the – job support was given on administrative, engineering, and personal protection measures, as well as support for necessary renovations. Improvements in TBIC within MDR-TB wards was extremely appreciated. With substantial TB CARE I support, 9 PMDT treatment centers have met minimum requirements for diagnosis and treatment of MDR-TB in these provinces, which contributed to the increased enrollment of MDR-TB patients over the past four years. From 2011-2014, 3,094 MDR-TB patients have been initiated on treatment under safe conditions. In 2012 Vietnam introduced surveillance of TB among healthcare workers, starting in high risk settings (TB hospitals). This resulted in the first ever report on TB among healthcare workers in 2013.

Biosafety in Laboratories - Bio-safety was improved by several interventions: i) technical assistance and partial funds for upgrading laboratory facility layout to ensure minimum biosafety requirements; ii) providing adequate equipment for ensuring the implementation of requested advanced TB testing with required maintenance programs; and iii) establishing a safe working environment through implementation of standard operational procedures and management activities to ensure bio-safety for all laboratory staff. All laboratories working with MDR-TB strains are now required by law to fit the

National Technical Standards on lab practice and bio-safety starting in January 2015. The NTP is investing part of its GF grant to meet this deadline for all related laboratories.

Xpert MTB/RIF Implementation - Through substantial TB CARE I support, Xpert MTB/RIF testing was introduced and rolled out in Vietnam. TB CARE I provided the necessary management, coordination, cartridge supply management system, recording and reporting and technical support for the routine use of Xpert MTB/RIF. 17 GeneXpert systems are running, with the total number of test done over four years being 22,752 tests. Among the 22,752 tests, 17,308 (76%) were presumed MDR-TB patients, and 3,753 (16.5%) were presumed TB in PLHIV and 1,635 (%) were presumed TB in children. Over 3 years of testing, 10,831 (49.3%) TB cases were detected of which 2,554 TB cases (24%) were RR-TB. This was a a tremendous contribution by TB CARE I for the diagnosis of MDR-TB in Vietnam.

PMDT Expansion - The expansion of PMDT in Vietnam has been supported through Project's lifetime. In-depth technical assistance from KNCV's Head Office provided continuous and consistent advice on development, management, coordination and professional expertise in PMDT. The TA supported program and laboratory management systems to build and strengthen capacity, policies for detection and management of cases of drug-resistant TB (regimen, support, monitoring of adverse drug reactions), drug supply management, human resource management, data management (recording-reporting, patient management via e-TB manager software); TBIC and access for special targeted groups. With such contributions, it was possible for PMDT in Vietnam to scale up from one treatment center in 2009 with 101 MDR-TB patients to more than 3,000 patients enrolled at 41 treatment centers and satellite sites nationwide.

Implementation of an electronic data management system (e-TB Manager) - A powerful web-based tool, e-TB Manager, was introduced, for managing all information needed by the national TB control program for PMDT. The new system is readily available at all current PMDT treatment centers and treatment satellites (total 41 by the end of 2014). With e-TB manager, all data across all aspects of MDR-Management of TB, including information on presumptive (MDR) TB patients, the management of co-morbidities like HIV drug supply management, laboratory test results for diagnosis and follow-up, treatment, and outcome for all MDR-TB patients at all sites can be conveniently accessible just in one click. Thus, the new system plays an increasingly important role in the management of MDR-TB. This contribution of TB CARE I has laid the foundation for the NTP to further utilize the tool in the coming year to support its current plans for the expansion of PMDT across the nation.

Vietnam's National Tuberculosis Strategy for 2020 with a vision up to 2030 - a new strategy for TB Control was approved in March 2014 by the Prime Minister. This platform for the NTP allows mobilized support from domestic and external sources for its activities towards the approved targets. The approval marks an increase in the political commitment of the Vietnamese Government for TB control in Vietnam. With this new policy, Vietnam became the first TB and HIV high burden lower middle income country to demonstrate a strong political commitment to eliminate TB by 2050.

GFATM Concept Note 2015-2017 - Staff of the coalition partners of TB CARE I also supported NTP to develop the strategic plan for 2015-2020 and concept note proposal for GF in 2015-2017 period. The document was submitted by the NTP in August 2014.

Introduction

In Vietnam, the allocated budget for TB CARE I 2011-2014 period was USD 6,537,084 with three implementing partners being KNCV (the lead), WHO and MSH (collaborating partners). MSH joined TB CARE I since quarter 4/2012.

Partners involved in the implementation of TB CARE I Project at Central level include: National Tuberculosis Control Program, the Vietnam Administration of HIV/AIDS Control, Ministry of Public Security, National Assembly's Committee for Social Affairs, and General Department of Post and the Vietnam Post Office. In addition, TB CARE I has been collaborating closely with a network of 15 provincial TB and Lung Disease Hospitals. These included 9 PMDT treatment centers (including 3 provinces overlapping with high HIV prevalence provinces), 2 PMDT satellite provinces and 4 additional high HIV prevalence provinces.

In 4 years of TB CARE I in Vietnam, 8 technical areas were targeted, being: early and universal access, laboratory system strengthening, TB infection control, Programmatic Management of Drug Resistant-TB (PMDT); TB/HIV; Health system strengthening, TB surveillance & operational research, and Drug Supply and Management (which commenced in APA3 only). The technical areas implemented in the TB CARE I Project were in line with USAID Vietnam's targets and strategies on TB control with the National Strategic Plan for Tuberculosis Control 2011-2015, targeting gaps identified in collaboration with the Vietnam NTP. During the past four years, the activities implemented by the KNCV cover seven of the eight project technical areas except for the drug supply and management. The activities carried out by the WHO focuses on the technical area of health system strengthening: advocacy and resource mobilization including promotion of health insurance for TB diagnosis and treatment and drug quality management. MSH focused mainly on the development of a specimen referral system, e-TB manager implementation and drug supply management.

The key approach of TB CARE I is supporting NTP in introducing the pilot of innovation such as the introduction of GeneXpert MTB/RIF (Xpert), new policy on Management of TB in children, PMDT management supporting tools like e-TB manager, introduction of new drug regimens for TB treatment, as well as assessing the implementation of such innovation based on data, evidence collected from pilot sites/provinces and handing over to NTP for further rolling out these innovation using Global Funds or other sources of NTP. With this key approach, TB CARE I has been successful in piloting and handing over innovation to the NTP for further expanding in the whole nation, i.e. Xpert MTB/RIF diagnostic technique, new model for Management of TB in children, software for MDT TB patient management. These innovations support the expansion of PMDT in 41 provinces and currently TB CARE I is supporting NTP in preparing for the introduction of new anti-TB drugs (Bedaquiline, Delamanid) and 9-month regimen (which is shorter than the current regimen of 18-24 months) for the treatment of MDR-TB patients

The 15 provinces under TB CARE I focus support are Hanoi, Vinh phuc (National Hospital 74), Thanh Hoa, Da Nang, Binh Dinh, Binh Thuan, Ho Chi Minh City, Can Tho, Tien Giang (since APA1), 02 provinces as the PMDT satellite provinces including Thai Binh (since early APA3) and 4 additional provinces with high prevalence of HIV-infection including Hai Phong, Quang Ninh, Dien Bien, An Giang (since APA2). Thus, by the third year, the Project has been implemented in 15 provinces, 193 districts, 3,232 communes of the whole country, with the number of population benefited from the Project represented 34.6 million, accounted for about 39% of the whole population of the country. Additionally, the Project supported the WHO-approved rapid diagnostics for all 41 provinces within the framework of the PMDT of the NTP.

Core Indicators

TB CARE I has seven core indicators that the program as a whole is working to improve across all countries. Table 1 summarizes the core indicator results across the life of the project for TB CARE I-Vietnam as well as the Tuberculosis Control Assistance Program (TB CAP), the precursor to TB CARE I, implemented led by KNCV.

		C1. Number of cases notified (all forms)	C2. Number of cases notified (new confirmed)	C3. Case Detection Rate (all forms)	C4. Number (and percent per 100,000) of TB cases among healthcare workers	C5. Treatment Success Rate of confirmed cases	C6. Number of MDR cases diagnosed	C7. Number of MDR cases put on treatment
	2005	94,916	55,492	56%	NA	92%	NA	NA
TB CAP	2006	97,363	56,437	56%	NA	93%	NA	NA
	2007	97,400	54,457	56%	NA	92%	NA	NA
	2008	97,772	53,484	56%	NA	92%	NA	NA
	2009	95,036	51,291	54%	522	92%	217	307
	2010	99,022	52,145	54%	476	92%	101	101
TB CARE I	2011	100,176	50,719	74%*	272	92,9%	601	578
	2012	103,906	51,031	76%	265	93%	273	713
	2013	102,196	50,607	76%	295	91%	1204	948

*: In January 2013, the National TB Control Program (NTP), in cooperation with WHO, launched a workshop to assess the TB epidemiological status in Vietnam. Based on the findings of the workshop, WHO revised its estimates for TB epidemiology in Vietnam (where TB related prevalence, incidence and mortality were all estimated to be significantly lower than previous figures in the 2013 TB global report), which changed the case detection rate of all forms from 54% to 74%.

Table 1: TB CARE I core indicator results for Vietnam

1. Universal Access

In this technical area, the Project focused on the control of TB for two vulnerable groups that currently have limited access to diagnostic services and treatment of tuberculosis of NTP: people in congregate settings (prisoners, etc.) and children.

Technical Outcomes

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y4	Y4
1.2.4	Children younger than 5 (contacts of ss+ adults) that were put on IPT		700 (in 4 pilot provinces)	1,000 (in 4 pilot provinces)	909 (By Sep 2014. The data for Oct is not yet available)
1.2.5	Childhood TB approach implemented		2	2	2
1.2.6	Number of TB cases (all forms) diagnosed in children 0-4		35 (sputum smear positive cases – NTP data 2013)	50 (sputum smear positive cases – NTP data 2014)	37 (sputum smear positive cases – Jan Sep 2014)

Key Results

1.1 TB/HIV/MDR-TB control in congregate settings

After preparation in APA1, in APA2, a study visit was organized in Indonesia on TB and TB-HIV control in prisons with participation of high ranking governmental officers from Vietnam Parliament's Social Affairs Committee, Ministry of Public Security, Vietnam National Tuberculosis Control Program-Ministry of Health, Vietnam Administration for HIV/AIDS Control – Ministry of Health, USAID country Mission, KNCV Country Office (TB CARE I), and FHI360 Vietnam. The study visit showed the necessity and models for comprehensive TB/HIV/MDR-TB control, as implemented in Jakarta. Thanks to the study tour, the delegation was exposed, explored, and learnt lessons on a model of integrated HIV/TB/MDR-TB service package in prisons, service linkages inside and outside prisons, especially the psychological/social/economic support to prisoners to continue treatment after release.

Following coordination and supportive activities with NTP in the second year of the Project, in the 3rd year, TB CARE I Project continued supporting NTP to strengthen the services of diagnosis, treatment, care and linkage between prison and civilian service. To this end, TB CARE I supported the NTP in development of a framework for 3-year workplan on TB, TB/HIV and MDR-TB control in closed settings, update/develop national guideline on the management of TB/HIV/MDR-TB in congregate settings, and to develop a transitional care and treatment model of TB/HIV/MDR-TB when inmates are released. The framework has been included in GF reprogramming for 2015-2017.

Two workshops were organized in April 2013 with the participation of representatives from NTP, VAAC, the Ministry of Public Security (Department of Health and the General Logistics Department (in charge of the prison), the Ministry of Labor, War Invalids and Social Affairs, a number of Tuberculosis & Lung disease Hospitals from provinces, a number of prisons, and social organizations (Women's Union,

Farmers' Association, Red Cross, the Youth Union): one held in Hanoi to discuss and get agreed on the contents of the National Guidelines and training materials on the management of TB/HIV/MDR-TB in congregate settings; and one held in Thanh Hoa to discuss the transition model of care and treatment of TB/HIV/MDR-TB for inmates after being released. The updated national guideline on the management of TB/HIV/MDR-TB in congregate settings has been finalized and printed. 2,100 copies of this guidelines are being printed for for distribution to all related health facilities in the Ministry of Public Security and NTP network in November 2014. The guideline has actively supported health care facilities in closed settings in strengthening the diagnosis, care and treatment of TB/HIV patients, referring patients as well as in observing other regulations of NTP and MOPS.

Beside the framework for 3-year workplan in TB, TB\HIV and MDR-TB control in close settings and the updated guidelines, General Department 8 under Ministry of Public Security of Vietnam set up the Coordination Committee for the TB/HIV control in prisons. With the establishment of this Coordination Committee, the activities of TB/HIV/MDR-TB, especially the implementation of MDR-TB in prisons will be paid more attention by the two ministries in the future.



Figure 1: Workshop for updating national guidelines and training materials on the management of TB/HIV/MDR-TB in congregate settings

1.2 Management of TB in children

Management of TB in children is important to TB CARE I in Vietnam and globally.

In Vietnam, accurate data on childhood TB are not available. According to the General Department of Population Statistics 2010, the Children aged under 5 years old account for 24% of the population (21 million children). The annual risk of TB infection (NTP prevalence survey in 2006-2007) was 1.7%, i.e approximate 351,000 children are estimated to be infected with TB annually and around 13,000 children are estimated to develop TB annually (WHO estimation of 6% of total incident cases). However, the NTP reports only 1200 - 1300 childhood TB cases each year and Isoniazid Preventive Therapy (IPT) is not widely implemented in the country and only recommended since 2011 following the TB CARE I pilot.

With technical and financial support from TB CARE I, Vietnam is among the first countries in the world to implement and scale up the WHO recommended approach in management of TB in children with focuses on: i) Screen and manage children that are close contacts (living in the same household) of a sputum smear positive TB case in community; ii) Provide IPT for child contacts aged <5 and children having HIV (once TB excluded) at communal (primary care) health center level; iii) Develop a diagnostic algorithm to be applied for diagnosis of TB in children at the district (second care) level; iv)

Engage the wider health care sector by the NTP strengthening links and collaborating with the child health sector.

In 2010 (APA1) the childhood TB working group of NTP was established including members from NTP central and provincial levels also including representatives from the Pediatrician Association and Acute Respiratory Infection Program.

In the period of 2011-2012, the childhood TB working group has worked under the technical support of the TB CARE I consultant (Prof Steve Graham – chair of the WHO Childhood TB sub group). The group developed the national guidelines on management of TB in children including child contact screening and diagnostic and treatment algorithms, forms & registers, M&E (monitoring checklist) , etc (Figure 2 and 3). 840 copies of this guidelines have been distributed to all districts and communes in 4 pilot provinces.

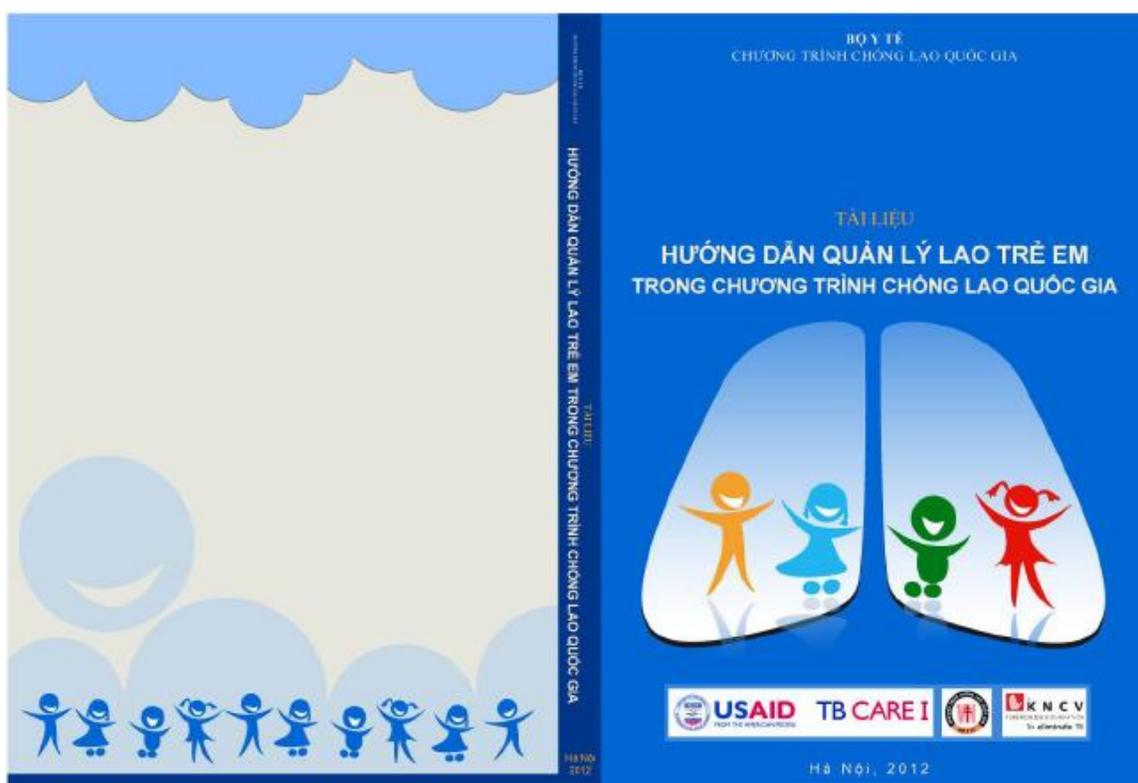
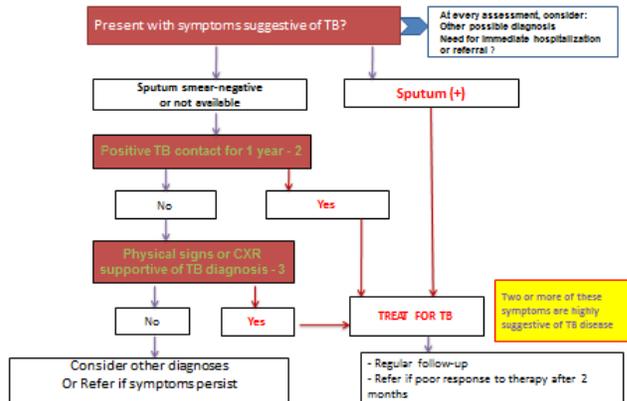


Figure 2. Guidelines on implementation of management of TB in children

GUIDANCE for the diagnosis of children who present with symptoms suggestive of TB



GUIDANCE for the screening of children in close contact with a newly diagnosed pulmonary TB

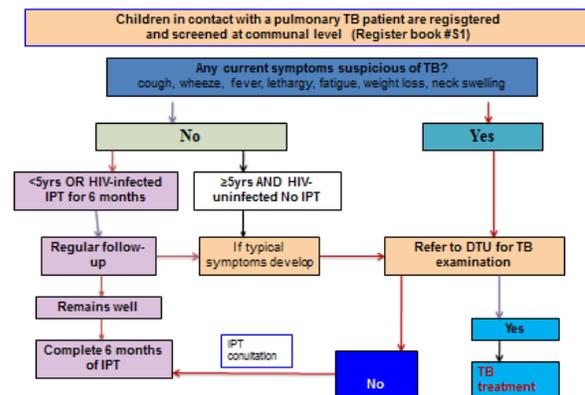


Figure 3: Guidance for the screening of children in close contact with a newly diagnosed pulmonary TB and Guidance for the screening of children in close contact with a newly diagnosed pulmonary TB

Additionally, to support commune level in implementing the new strategy of managing TB in children, as well as providing relevant information to people in the community, 2 information, communication and education materials have been developed in APA3. 554,400 posters and 12,750 leaflets (Figure 4) were printed and widely available to provincial, district and commune levels of 4 pilot provinces and 21 other provinces implementing the new strategy on management of TB in children under the Global Fund support.



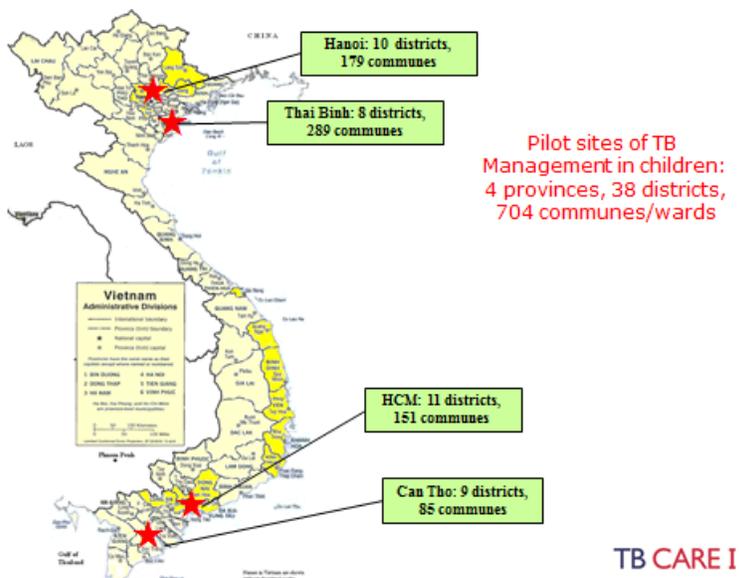
Figure 4: Poster and leaflet on Management of TB in children

TOT training on communication methods was given in APA2. The HCWs use these leaflets as job-aid to ensure they discuss all topics with the patients and their families (job-aid). The leaflets are given to the patients and families to read and share with others at home (information).



Figure 5. Training on the use of IEC materials for NTP staff in PMDT treatment and satellite sites (2012)

4 provinces (38 districts, 704 communes) were selected to participate in the implementation of the pilot model on Management of TB in children. These four provinces are Hanoi, Thai Binh, HCMC and Can Tho (Figure 6).



In 2012, four (4) trainings for 100 NTP staff at provincial and district level, 7 trainings for 140 general practitioners, pediatricians at provincial and district level, and 40 trainings for 1,240 health care workers at commune level were conducted. Total number of health care staff in the health system of the four pilot provinces were trained on management of TB in children is 1,480 people. In APA4, the retraining was provided for healthcare staff in three districts and their corresponding communes of Hanoi with total number of 98 participants. Therefore, during the Project lifetime, in these four pilot provinces, 11 training classes were organized for 154 participants from provincial and district staff (general practitioners, NTP staff, pediatricians), 43 training classes were provided for 1,578 healthcare workers at communes level. After the training, healthcare workers at commune, district and province level have equipped basic knowledge for implementing Management of TB at district level.

Also in this pilot period, INH has been sufficiently provided and arranged for the four provinces. At the end of APA2, 91,000 tablets (50 mg) of INH were provided, 502,500 in early APA3 and 161,000 tablets in August 2014. Cumulatively, by August 2014, TB CARE I has provided 754,500 tablets of INH to all levels (provincial, district and commune) in 4 provinces participating in the pilot.



Figure 7: Training on the pilot implementation of management of TB in children for health care staff in Thai Binh province in Feb and Mar 2013

	2012 (Q4)	2013 (Q1,2,3,4)	2014 (Q1,2,3)	Total
No. of close contact children screened and managed	1,084	3,025	3,035	7,144
No. of eligible children for IPT	339	1,238	1,226	2,803
No. of children put on IPT	184	805	721	1,710
% put on IPT	54.3%	65%	58.8%	61%
No. of children with TB disease	57	288	204	549
- Pulmonary TB sputum smear(+)	7	30	10	47
- Pulmonary TB sputum smear(-)	27	130	100	257
- Extra-pulmonary TB	23	128	94	245

Table 2: Results of community TB contact screening and management in 4 pilot provinces in Viet Nam

In the period from quarter 4/2012 to quarter 3/2014, 7,144 children who are close contacts (living in the same household) of a sputum smear positive TB case were screened and registered for the management in these four provinces. Of these children, 2,803 children are eligible for Isoniazid preventive therapy (IPT). Among children eligible for IPT, 1,710 children (61%), as agreed by their families, participated in IPT. In this period, 549 pediatric patients with TB of all forms were detected (Table 3).

	2012	2013			Total
	Q4	Q1	Q2	Q3	
No. of children put on IPT	184	146	262	168	760
No. of children with IPT completion	153	117	213	135	618
% IPT completion	83.2	80.1	81.3	80.4	81.3

Table 3: Results of isoniazid preventive therapy in children who are close contact of a sputum smear positive TB case in 4 pilot provinces in Viet Nam

Until now 760 children on IPT in cohorts of quarter 4 of 2012 and quarters 1, 2, 3 of 2013 have been evaluated. Among them, 618 children completed six months of IPT accounting for 81.3% (Table 4).

Key among activities in this technical area is the monitoring and supervision with technical support and on-site guidance for staff participating in the pilot implementation at the provincial, district and commune level. In FY2014, 8 monitoring and supervision trips have been conducted by NTP Management of TB in Children Group under support of TB CARE I, with 2 supervision trips made to each province during the fiscal year. Operational issues and techniques in the implementation were discussed and recommended.



Figure 8: Monitoring visit conducted by Prof. Steve Graham, KNCV and NTP staff on childhood management of TB in Nhon Nghia commune, Phong dien district, Can tho province, in March 2013

A National Review Meeting to review the progress, share experiences on the management of childhood TB was held in quarter 4 of FY2014 for comprehensively reviewing the implementation of Management of TB in children in the four pilot provinces. The implementation outputs of piloting the new strategy

on Management of TB in children were presented at the meeting. An important session during the meeting was the sharing of lessons learned from involved provinces on all operational and technical issues such as standard operating procedures, forms and register for recording and reporting, appropriate type of Isoniazid, counseling skills, communication and education materials. The implementation outputs have been highlighted by Vietnam NTP Management Board and implementing provinces to achieve great successes for they have helped NTP establish an enabling environment with all necessary administrative, regulatory, technical and logistics foundations for further multiplying in all other provinces in Vietnam. A fact is that NTP has decided to use funds from the Global Fund to expand this strategy to 6 provinces for the period 2013-2014 (3 provinces in 2013 and 3 provinces in 2014).

With TB CARE I support, in 2014, the national workplan for roll-out of the management of TB in children in 2015-2020 period has been developed. This national workplan has been approved by the board of NTP and submitted to the WHO Office for the Western Pacific Region in August 2014. This workplan has been included in the NTP National Strategic plan for 2015-2020 which has been approved by the MOH and included in the Proposal and Concept Note to the Global Fund under the New Funding Model in August.

With the clear goal, objectives and targets in the national workplan for roll-out of the management of TB in children in 2015-2020 period, the new model of the management of TB in children piloted and evaluated in TB CARE I will be rolled out nationwide between 2015-2020.

With achievement gained through the model pilot, representatives of TB CARE I and NTP Vietnam were invited to share experiences and lesson learnt on implementation of the new approach on management of TB in children in the Global Consultation on Childhood TB for High Burden Countries in the Eastern Mediterranean, South East Asia and Western Pacific regions organized by WHO, 29 September to 1 October 2014, in Jakarta, Indonesia and in the WHO Annual Meeting of the Childhood TB subgroup, 27 October 2014, in Barcelona, Spain.

2. Laboratories

Technical Outcomes

#	Outcome Indicator	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y4	Y4
2.3.1	Diagnostic sites offering advanced technologies for TB or drug-resistant TB		17 (Xpert MTB/RIF)	17 (Xpert MTB/RIF)	17 (Xpert MTB/RIF)
2.3.3	Patients diagnosed with GeneXpert		6,621 (Jun 2012 – Dec 2013)	7,500 (Jan-Dec 2014)	5,210 (Jan-Sep 2014 – from 17 TB CARE I machines only)
2.1.4	The sites use TB specimen referral system Number (%) of sites referring specimens for diagnosis of drug resistant TB Numerator: Number of provincial and district TB facilities implementing specimen referral system Denominator: Total Number of USAID/NTP priority TB facilities	Number of provincial and district TB facilities implementing specimen referral system Denominator: Total Number of USAID/NTP priority TB facilities	- 0 sites in 2011. - 7 sites in APA 2. - 42 sites in APA 3.	350 sites (350/637 or 55%)	188 sites ¹ (53.7%)
2.1.5	Number of specimens referred (using the referral system for diagnosis of Drug Resistant TB)		0 specimens referred in APA2. 2,566 specimens referred in APA 3.	15,000 specimens	6,675 samples
2.1.6	Number of drug resistant cases identified from referred specimens		601 cases	1,500 cases	936 MDR-TB cases

Key Results

In laboratory strengthening technical area, in support of PMDT's roll-out, TB CARE I Vietnam have been supporting the upgrade of TB laboratory, introduction and roll-out of the optimal use of new diagnostic techniques (LED FM, GeneXpert) in Vietnam and development and roll-out of the specimen referral system.

2.1. Strengthening laboratory system in support of PMDT implementation and roll-out

The activities of strengthening of biosafety condition of the TB laboratory system for diagnosis and monitoring treatment of MDR-TB under TB CARE I project consists of 3 components: i) improving laboratory facility layout to ensure minimum requirements for biosafety; ii) providing adequate equipment for ensuring the implementation of requested technical tests, and ensuring specifications and maintenance; and iii) enhancing work practices for laboratory staff (lab management and bio-safety).

2.1.1. Improving laboratory facility layout and equipment

In the first and second years (2010-2012), 9 laboratories at MDR-TB centers in the country have been comprehensively upgraded for three elements mentioned above and were put into use, which has been making significant support to the implementation progress and expansion of PMDT in Vietnam.

By the end of year 3, the comprehensive physical upgrade of nine laboratories at nine MDR-TB centers (provincial level) was completed and put into operation: i) improved laboratory facility layout to ensure minimum requirements for biosafety; ii) adequate equipment provided for ensuring the implementation of requested technical tests with secured specifications and maintenance (Figure 9).

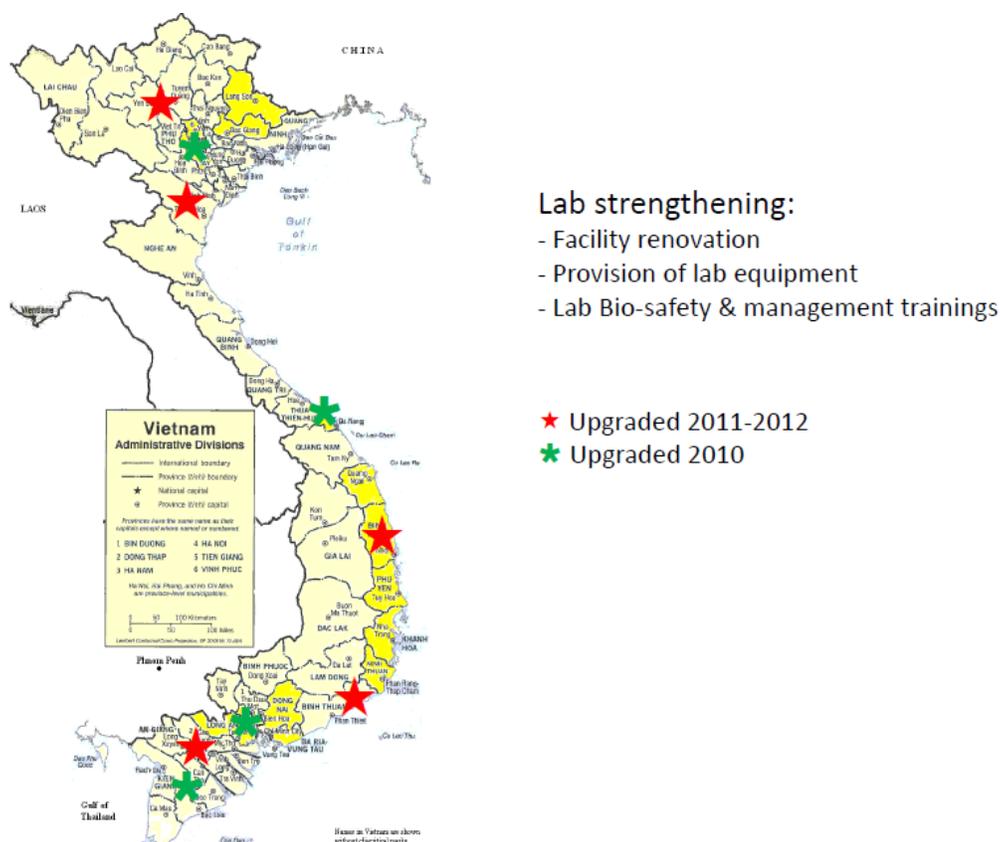


Figure 9: Map of labs upgraded in 2010-2012 period

In addition, to meet conditions for the installation and operation of GeneXpert system, some small laboratory upgrades were supported at the Tuberculosis and Lung Diseases Hospitals of Dien Bien, Hai Phong, An Giang Preventive Center, and Tay Ninh (in APA3). The support was for such items as sputum collection area, ventilation system in lab (smear preparation room, culture room, sterilization room, etc.).



Figure 10. Labs in all 9 MDR-TB centers are fully upgraded and put into use for diagnosis and treatment follow-up of TB and MDR-TB

In 2014, as per request by NTP for the technical assistance, TB CARE I continued to provide technical support for 11 PMDT satellite sites supported by GF on improving the layout for lab and MDR-TB treatment department. The technical assistance was for practically improving the layout of labs and MDR-TB treatment departments of 11 satellite sites of Hue, Ninh Thuan, Soc Trang, Hau Giang, Long An, Quang Nam, Quang Ngai, Thai Binh, Dong Nai, Nghe An and Quang ninh.

2.1.2. Strengthening work practices for TB lab staff

This activity is one of three components to enhance and strengthen the system of laboratories in the Project.

The project supported the updating of the Guidelines on the SOPs for TB lab services in 2011-2012 with significant contributions from national and international experts. This is the first time, NTP updated all TB lab services, including procedures for specimen packaging and referral to smear examination, culture, identification, and DST and molecular techniques. The document has been printed and 3000 copies (Figure 11) were distributed widely for using in all TB laboratories nationwide.

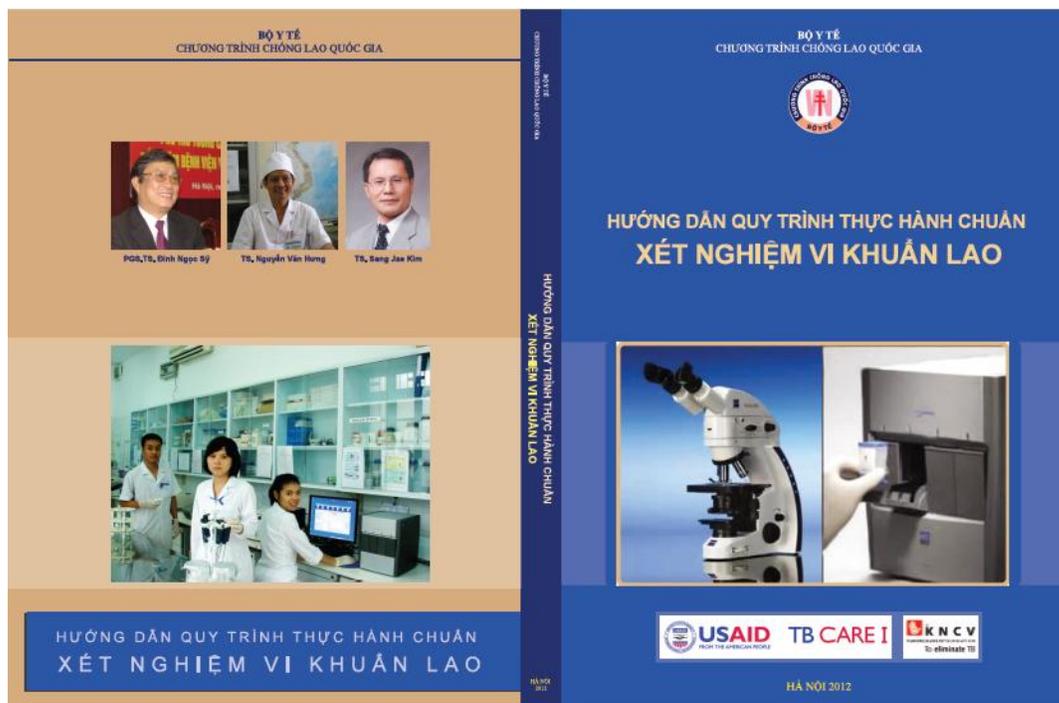


Figure 11. Guidelines on the SOPs for TB lab services, 2012

With technical assistance from TB CARE I, the Department of Biological Safety & Quality Management, National Institute of Hygiene and Epidemiology, a 5-day training program consisting of theory, practice, and training materials on TB laboratory management and biosafety was developed.

In the first and second years, 6 training courses on biosafety and laboratory management were held for lab technicians at provincial and district levels in 6 provinces where MDR-TB treatment center locates: in Hanoi (in 2011) and Central Hospital 74, Da Nang, Binh Dinh Ho Chi Minh City, Can Tho (in 2012).

In the 3rd year, the Project continued the organization of 3 training courses for 3 remaining MDR-TB centers of the nation that are in Tien Giang (8-12/7/2013), Binh Thuan (15-19/7/2013) and Thanh Hoa (12-16/8/2013) (Figure 12). In total 156 staff and lab technicians at provincial and district in all MDR-TB treatment centers were trained in biosafety and laboratory management.



Figure 12: Training on bio-safety practice and lab management

2.2. Introduction of new diagnostic techniques

Two new diagnostic techniques introduced by the Project and NTP within the framework of TB CARE I include: direct sputum test by fluorescence microscopy with LED light technique and rapid molecular TB diagnostic technique with Xpert MTB/RIF. The introduction of new diagnostic techniques strengthened the support to get access to diagnosis and treatment of TB for children, PLHIV as well as in support of the implementation and scale up of PMDT.

2.2.1. LED Fluorescence Microscopy (LED FM)

NTP and TB CARE I agreed to implement pilot LED FM at district level to draw experiences in gradually replacing the normal fluorescence microscopy for this level in the future. In TB CARE I year 2, a total of 14 LED FM units and consumables have been provided to 10 selected districts in HCMC (3 high, 3 medium and 4 low workload) and 2 MDR-TB treatment centers in Binh Dinh and National Hospital 74.

Training courses on using LED FM and implementing this new technique have been organized, in which one was conducted in Pham Ngoc Thach hospital for technicians of the hospital and technicians from 10 districts in Ho Chi Minh city, and one was taken place in National Lung hospital for technicians from Central Hospital 74 and Binh Dinh TB & Lung Disease hospital. The total number of trainees for the two courses is 29 technicians. The training program consists of 2 stages: (i) 5 days training focused on the slide reading skills with LED FM; (ii) self-practicing (5 slides/day x 20 days) and sending results of the set of panel slides that have been read to provincial level for EQA. After this stage, if any settings meet the EQA requirements, those will be allowed to implement routine LED FM to replace for the normal ZN. The LED FM routine implementation is scheduled from the fourth quarter of 2013 in 10 districts of Ho Chi Minh city.



Figure 13: Monitoring mission visit of laboratory strengthening area and LED FM implementation by Dr. Sang Jea Kim, senior lab consultant, in HCMC in August 2013

The recommendations on technical issues for the implementation of LED FM to NTP for further consideration before rolling out this technique to other provinces are as follows:

- To conduct a small study to determine the time of the fluorescence fading of AFB during template storage in order to specify the maximum possible time for testing specimen (EQA) without re-staining the slides.
- If the EQA is required to re-stain the slides, it is necessary to conduct a small study to check the frequency of negative false due to possible AFB contamination from tap water during the initial fluorescent staining to determine the use of clean water (distilled water) for initial staining.
- In Ho Chi Minh city, methylene blue should be used as a substitute for potassium when staining slides after determining the concentration of methylene blue and proper time through the implementation of small experiments.

2.2.2. Introduction of TB diagnostic technique using Xpert MTB/RIF

Xpert MTB/RIF is recommended for use by World Health Organization since October 2010. In the framework of the TB CARE I project, Xpert MTB\RIF test focused on three groups: i) Presumed MDR-TB (previously treated for TB or other MDR-TB high-risk categories) for early detection of MDR-TB, ii) Presumed TB in PLHIV (HIV+ person symptomatic for TB) to detect early tuberculosis for PLHIV and iii) Presumed TB in children for early detection of TB for this group.

In the first and second years of the Project, the preparatory activities for the implementation of GeneXpert (preparing guidance and training materials, including: procedures, diagnostic diagrams, report forms and templates, cartridge supply chain and management system, etc., survey, site selection and assessment, support to improve conditions of laboratories to meet the requirements for installation and operation) and training courses for managers, clinical staff, machine operators were carried out and completed. Books and forms to make records were also provided by the Project for 17 GeneXpert sites.

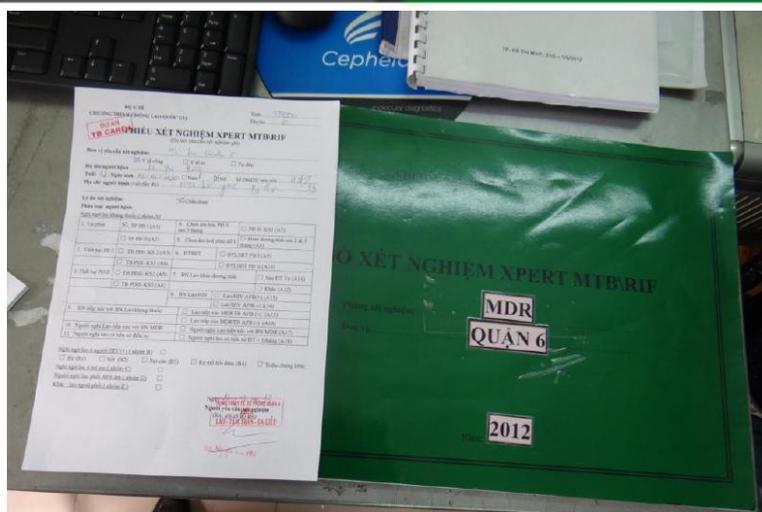
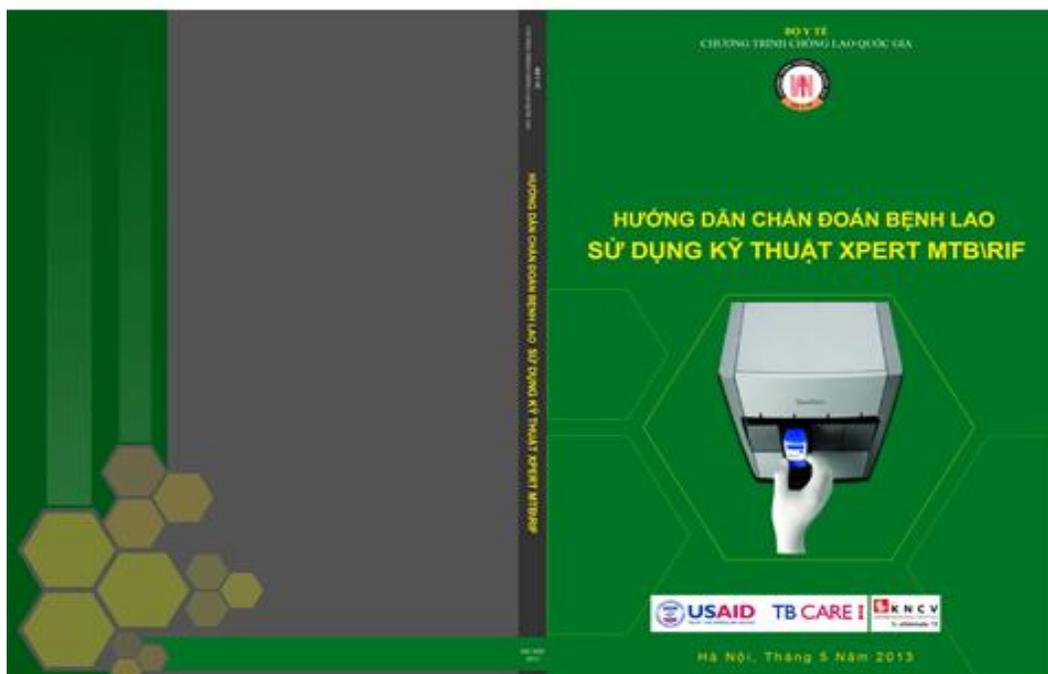
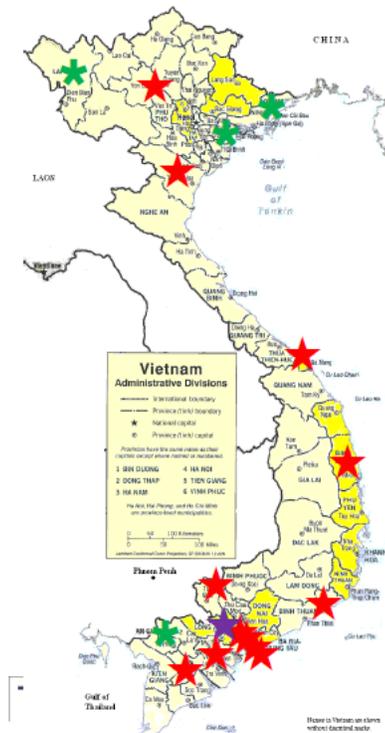


Figure 14. Guidelines on TB diagnosis using Xpert MTB\RIF and register and forms

By the end of 2012, 17 GeneXpert systems have been successfully installed and operated at 17 laboratories in 8 MDR-TB treatment centers (8 province, 3 districts), 4 provinces with high HIV prevalence and 2 Pediatric hospitals (Figure 15). Due to operational problems and efficiency, NTP and TB CARE I project decided to move the GeneXpert machine located at the National Hospital of Pediatrics to Tay Ninh TB and Lung Disease hospital.



GeneXpert implementation

- ★ 8 PMDT treatment centers, 1 PMDT satellite province & 3 districts
- ★ 4 province with high HIV prevalence
- ★ 1 Hospital of Pediatrics

17 GeneXpert systems have been installed and put on operation (2012)

962 NTP staff/technicians have been trained on Xpert MTB\RIF implementation (2012, 2013)

Figure 15. Map of the implementation of GeneXpert, TB CARE I project

In addition to GeneXpert training for HIV and TB control staff in 2012 (Figure 16) at 17 GeneXpert sites, in the third year, GeneXpert training is further conducted for HIV outpatient clinics (OPCs) in Ho Chi Minh City, Can Tho and Hanoi to increase access to Xpert MTB\RIF for HIV(+) group with TB suspicious. In overall, by the end of 3 quarter of 2013, a total of 962 health care staff nationwide has been trained on implementation of Xpert MTB/RIF.



Figure 16: Training on pilot implementation of Xpert MTB/RIF for HIV OPC doctors in Can Tho and HCM, March 2013

According to NTP's reports on Xpert MTB\RIF, for after more than two year of implementation from June 2012 to September 2014, 22,752 Xpert MTB\RIF tests have been done among the 17 TB CARE I-supported machines. In total, 11,118 tests (50.7%) found no *Mycobacterium tuberculosis* (MTB), 10,831 (49.3%) found MTB. Of the 10,831 TB tests, 2,554 (23.6%) results showed resistance to rifampicin (Table 5 and Figure 17).

Duration	Total	Xpert MTB\RIF results									
		MTB(-)		MTB(+)						Error/indeterminate	
			Sub-total		MTB(+)/R(-)		MTB(+)\R(+)				
	n	n	%	n	%	n	%	n	%	n	%
Jun-Dec 2012	2,152	563	27.2	1,507	72.8	1,110	73.7	397	26.3	82	3.8
Jan - Dec 2013	7,423	3,010	42.3	4,114	57.7	3,116	75.7	998	24.3	299	4.0
Jan - Sep 2014	13,177	7,545	59.2	5,210	40.8	4,051	77.8	1,159	22.2	422	3.2
Total	22,752	11,118	50.7	10,831	49.3	8,277	76.4	2,554	23.6	803	3.5

Table 4. Results of Xpert MTB\RIF test, from June 2012 to September 2014

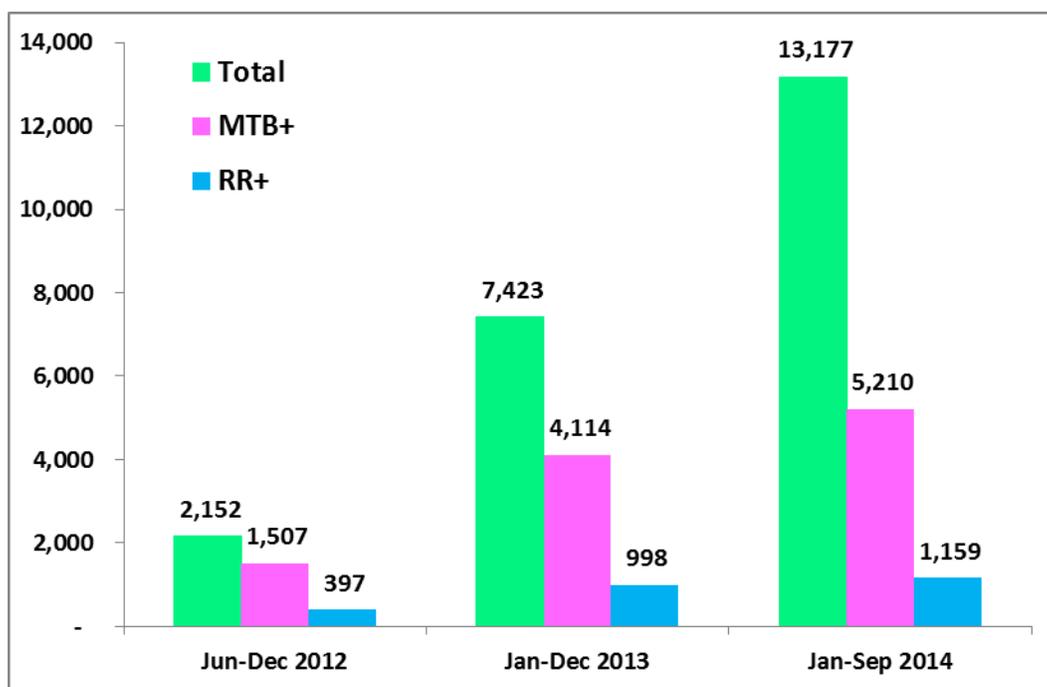


Figure 17: Results of Xpert MTB\RIF testing by calendar year for June 2012-Sep 2014 period

Priority groups	Total		Xpert MTB\RIF results									Error/indetermined	
			MTB(-)		MTB(+)								
	Sub-total				MTB(+)/R(-)		MTB(+)\R(+)						
	n	%	n	%	n	%	n	%	n	%	n	%	
Presumed MDR-TB	17,308	76.3	6,601	39.6	10,071	60.4	7,614	75.6	2,457	24.4	636	3.7	
Presumed TB in PLHIV	3,753	16.5	2,999	82.7	627	17.3	548	87.4	79	12.6	127	3.4	
Presumed TB in Children	1,635	7.2	1,485	93.1	110	6.9	98	89.1	12	10.9	40	2.4	
Total	22,696	100.0	11,085	50.6	10,808	49.4	8,260	76.4	2,548	23.6	803	3.5	

Table 5. Results of Xpert MTB\RIF test by priority groups, from June 2012 to September 2014

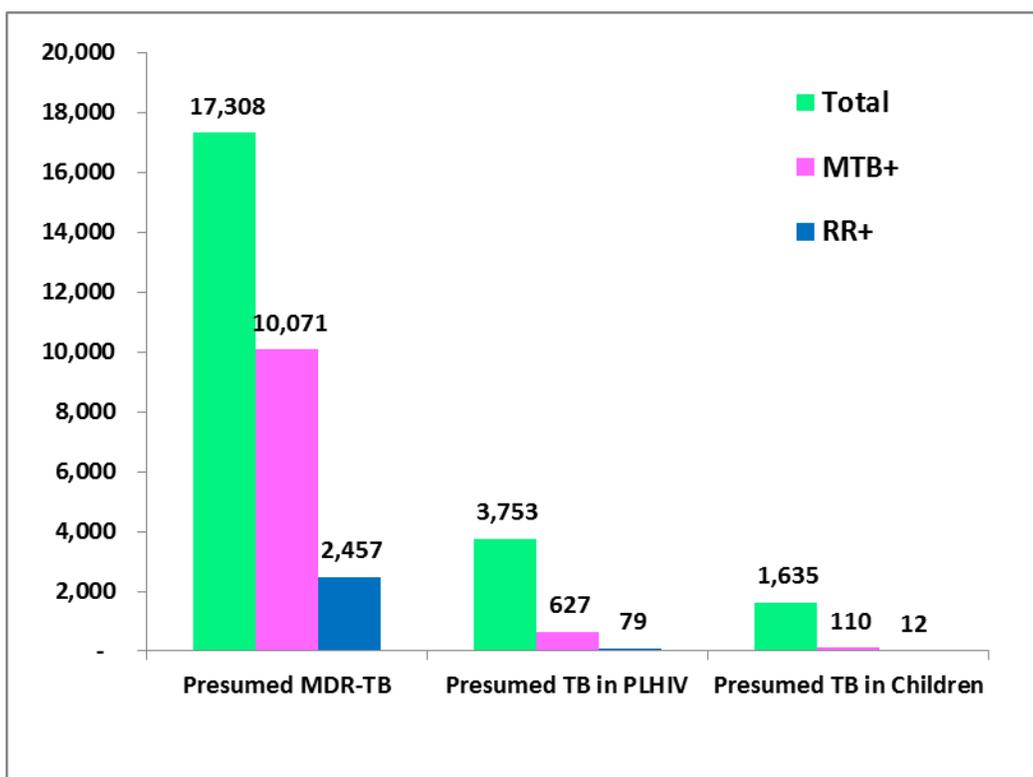


Figure 18: Results of Xpert MTB\RIF test by priority groups, from June 2012 to September 2014

Of the 22,696 persons who were tested with Xpert MTB\RIF, 17,308 (76.7%) are presumed MDR, 3,753 (16.5%) of presumed TB in PLHIV and 1,635 (7.2%) of children suspicious with TB. Thus, at this stage, the access of the two groups of PLHIV and children to Xpert MTB\RIF test remains low.

	2012	2013
Number of MDR-TB patients are diagnosed*	769	994
Number of MDR-TB patients are treated	713	943
Percentage (%)**	93%	95%

* Number diagnosed from all techniques available (Xpert, Hain, DST).

** Cohort of diagnosed patients is the same as the cohort that were put on treatment.

Table 6: Situation of diagnosis and enrolment in MDR-TB treatment in PMDT

Data from NTP's PMDT project shows that the rate of MDR-TB patients who are diagnosed and put on treatment was 93% in 2012 and 95% in 2013. Since 2013, the diagnosis of rifampicin resistance TB by Xpert MTB\RIF test has been rolled out in all 41 PMDT treatment centers and satellite provinces, in which TB CARE I has been making main contribution to the diagnosis and treatment of MDR-TB in Vietnam. TB CARE I also supported NTP in choosing targets in diagnosis and treatment of MDR-TB patients for NTP under GF support.

The operation of GeneXpert under TB CARE I support have been making good progress since being introduced in June 2012. The chart below shows the number of GeneXpert tests performed by month. In the introduction period, the test performance reached only 30-50 tests per GeneXpert unit per month. However, since quarter 2 of 2014 the Xpert MTB\RIF tests have been increased rapidly at roughly 100 tests/unit/month (Figure 19), though this amount remains under the optimal utilization rate. This was the result of various efforts including the review meeting of pilot implementation of Xpert MTB/RIF which was held in May 2013 to share experiences, exchange lessons learnt, difficulties, challenges faced in the implementation of GeneXpert; 14 workshops were organized with participants from DTUs, PTBH, OPCs from February to June 2014 aiming in identifying the targeted groups of Xpert MTB\RIF and estimating the quantity for the targeted groups based on the NTP recording-reporting system and discussing the route causes of the low uptake of Xpert MTB\RIF test (fish born analysis) and development of plan for improvement uptake of Xpert MTB\RIF test for each site (provincial – district level); and the effort to improve the linkage between diagnosis and treatment in the PMDT centers and intensive monitoring visits conducted in early 2014 (Figures 19-22).

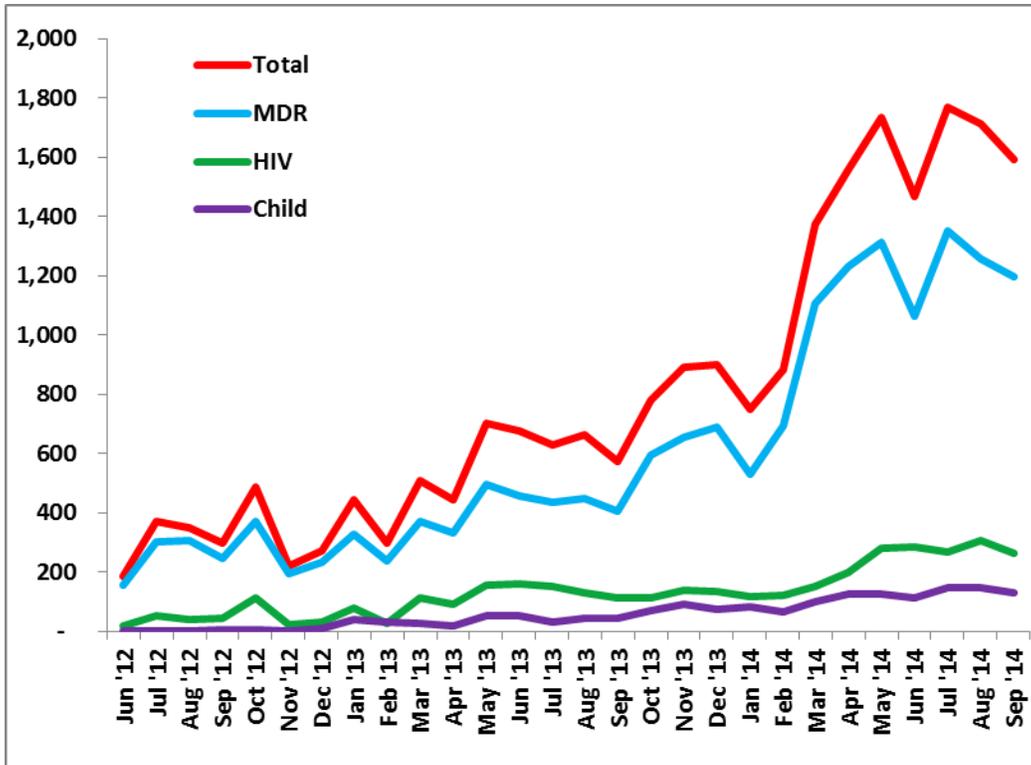


Figure 19. Number of Xpert MTB\RIF test by month and priority group (17 TB CARE I-supported GeneXpert machines)



Figure 20: Review Meeting on pilot implementation of TB diagnosis using Xpert MTB/RIF, May 2013



Figure 21. Discussion and presentation on plan to improve the Xpert MTB/RIF intake at the workshops on accelerating Xpert MTB/RIF intake in provinces



Figure 22: GeneXpert monitoring in the project sites

Meeting of GeneXpert technical group is monthly organized as a critical coordination activity for the implementation of Xpert MTB/RIF in the framework of the TB CARE I project, with representatives from the NTP, TB CARE I, and TB CARE I's partners. This monthly session is held regularly in order to review the performance of Xpert MTB/RIF activities locally, follow up reports and operational issues as well as technical issues arisen, timely discuss and propose solutions for addressing or submitting to NTP's leaders for the problems that are not within the capacity of the technical group. By maintaining the monthly meeting, the technical team has been helping keep track on and closely managing the Xpert implementation at all GeneXpert sites.

GeneXpert calibration according to the manufacture's requirements after one- year operation or every 2,000 test was planned and implemented yearly. Key technicians from 17 GeneXpert sites were trained on self-conducting the calibration; calibration kits were provided with local technical support team that have been set up and enhanced with capacity by TB CARE I support. The local technical support team, that will be more elaborated in the following paragraph, are lab technicians from Microbiology Departments of National Lung Hospital and Pham Ngoc Thach Hospital. So far, two

calibration rounds have been carried out in 2013 and 2014. The below table shows the results of the two calibration rounds.

Round	No. of GeneXpert units and modules	No. of modules calibrated	No. of modules failed	No. of modules replaced
2013	17 GeneXpert units, 68 modules	68	2	2
2014	17 GeneXpert units, 68 modules	68	2	2

Table 7. Calibration results of GeneXpert in 2013 and 2014

In the first round of calibration in 2013, 17 GeneXpert machines with a total of 68 modules has been calibrated, among which, 2 modules (2.9%) of the GeneXpert machine located at Pham Ngoc Thach Hospital and Da Nang TB and Lung Disease Hospital failed. Two failed modules were replaced according to the warranty policy. In the second round of calibration in 2013, 17 GeneXpert machines with a total of 68 modules has been calibrated, among which, 2 modules (2.9%) of the GeneXpert machine located at Pham Ngoc Thach Hospital and Nhi dong I Hospital did not pass the calibration. Two failed modules were purchased and replaced with support from TB CARE I.

In order to build capacity for NTP to self-undertake such technical work as troubleshooting, calibration, maintenance of the GeneXpert system to ensure the sustainability in the implementation and roll-out of Xpert MTB\RIF test in Vietnam, meanwhile minimizing the cost of hiring external services for such needs as repairs, replacement of parts, maintenance of GeneXpert system after the warranty period, TB CARE I has proposed and supported NTP to establish a GeneXpert technical assistance team within NTP. TB CARE I also substantially supported capacity building for the team that consists of capable technicians from National Lung Hospital, Pham Ngoc Thach Hospital and Da Nang TB and Lung Disease Hospital. Capacity building is focused y on the troubleshooting, maintenance and calibration of the machine, with step by step handling problems, from the simplest to the complex via learning by doing. An advanced training on the operation and troubleshooting for GeneXpert machines in Vietnam with the faculty staff from Cepheid was organized for some selected staff September 2013.

In 2014, this team actively provides technical support in roll-out of Xpert MTB\RIF implementation in Vietnam such as providing of installation and training services for 9 provinces receiving GeneXpert system from the UNITAID project or solving of troubleshooting in project sites.

Operational Research in support of GeneXpert implementation titled "Evaluation on the pilot implementation of GeneXpert in Vietnam has been developed and implemented in 2014. The data from the research will be served as evidence for NTP planning on GeneXpert expansion in the country.

Cartridge supply management for Xpert MTB\RIF has been established and operational within NTP. By far, no cartridge stock out and no cartridge expired happened in sites. Due to the short shelf-life of cartridge for Xpert MTB\RIF (6-8 months when the cartridge arrive in Vietnam), therefore, GeneXpert TWG needs to meet montly to review progress, discuss and solve any management issue on cartridge supply, quantification, etc.... and other related technical issues.



Figure 23. Advanced training on GeneXpert for NTP staff, September 2013

2.3 Development and scale-up of TB specimen referral system at provincial and district levels:

In August 2010, MSH's '*Strengthening Pharmaceutical Systems*' (SPS) Program was asked by USAID-Vietnam to develop a work plan for the development of Vietnam's national policy, guidelines, capacity building strategies and system for the implementation of a referral, reporting and transport system for laboratory specimens for CD4, viral load, MDR-TB culture (including identification and DST), and line probe assay. Preliminary work was undertaken during short TA visits in 2010 and early 2011, at which time USAID decided to limit the assignment to referral of specimens for TB culture, DST and Line Probe Assay from seven sites to the reference laboratories in Hanoi and HCMC and for follow-up specimens from clients already on 2nd line TB drug treatment for TB culture at five additional sites being set up as MDR-TB treatment centres. The use of a courier service was initiated for this purposes and the costs met temporarily by the SPS program. As the SPS Program was coming to an end, USAID transferred this activity to TB CARE I from the last quarter of 2012 (1/7/2012 – 30/9/2012).

This TB specimen referral system was intended to support TB CARE I's mandate to increase access to diagnosis, care and treatment of drug resistant TB. However, the introduction of GeneXpert not only

completely changed the whole perspective of MDR-TB diagnosis and treatment in Vietnam, but also changed the need for and the scope, design and functioning of a specimen referral system. It became clear that the primary need was to collect and transport specimens from the districts and provinces to GeneXpert sites and send back results in a timely manner so that those identified with rifampicin resistant TB could be referred to one of the MDR-TB treatment centres for their management. Initially working in several PEPFAR funded provinces with high TB and MDR-TB prevalence, TB CARE I supported the NTP to establish national policies, guidelines, capacity building for the implementation of a specimen referral system in 35 targeted provinces and an expanded system at the district level.

Major activities include supporting the NTP to develop and implement national guidelines on specimen referral as part of the PMDT guidelines, setting up the system at provincial level, and training the facility personnel to collect and pack specimens following internationally recognized biosafety standards. Although setting up the specimen referral system was deemed to be straight forward and easy to implement laboratory activity, this was not the case. TB CARE I worked, not only with laboratory staff as was originally intended, but with all cadres of medical and nursing staff in the designated provinces and nationally with the NTP to solve complex problems and barriers restricting implementation of the referral system.

Key activities in APA4 included:

- Finalization of the formal agreement between the MOH/NTP and Vietnam Postal Service. After lengthy negotiations, this was eventually signed in October 2013. The document provided a detailed list of all health facilities in the country, the designated facility to where each would refer specimens and the price of providing post office transport by post between each of the two points.
- 3 TOT workshops on specimen referral system for 35 PMDT provinces were carried out for 49 healthcare providers and lab technicians. The training focused on three-layer packaging that gives hands-on guidance for those who send specimen for MDR-TB testing to ensure WHO's biosafety standards and lab quality. After the workshops, provinces continued providing training and technical review meetings to all NTP staff of districts to ensure full coverage of the knowledge about specimen packaging and implementation of the specimen referral system.
- Monitoring visits were carried out by the PMDT and lab groups of the NTP in five provinces: Ha Noi, Hai Phong, Ho Chi Minh City, Vung Tau and Dong Nai. During the meetings, MSH and the NTP carried out "problem solving" exercises with several different provinces and supported them to identify barriers in the collection of samples and referrals.
- Working with the NTP to discuss problems that need central support, such as the lack of budget and guidance to procure supplies for specimen packaging and problems related to accessibility to MDR-TB treatment. The NTP has released the guidance in the procurement of supplies for specimen packaging and fees to transport specimen for GeneXpert testing to all provinces. In the South, the Pham Ngoc Thach hospital is supporting provinces to provide treatment to MDR-TB patients without referring them to higher level.
- An assessment of the specimen referral system was conducted by MSH in collaboration with the NTP by the end of the 2nd quarter in 2014. This assessment provides insight into the system and provides data for further follow up.

Major achievements:

- The specimen referral system has started and functioned in some provinces (Ho Chi Minh city, Nghe An, Khanh Hoa, Ben Tre) but has not been implemented yet or is not well established in other provinces (Ha Noi, Hai Phong, Ba Ria – Vung Tau, Kon Tum, Soc Trang etc). Provinces

that do not have GeneXpert machines sent specimens to closest provinces that have GeneXpert, but the number of specimens sent is still very limited. The reasons for this are multifactorial. The decision to order a GeneXpert test lies with DTU and clinical staff and is outside the control of the laboratory. Many district staff in TB units have not been sufficiently trained or oriented in the use of the laboratory and when to order the various tests, including Xpert. Others are reluctant to order Xpert tests because of the need to refer patients who are rifampicin resistant to MDR-TB. In addition, the tubes for collecting the sputum for Xpert testing had not been distributed by the NTP/NTRL to many provinces, who in turn would need to supply their districts.

- There are 70% of the non-GeneXpert provinces sending specimens to provinces for MDR- TB testing (14/20 provinces). Among the 414 district TB Units in 35 provinces, there are currently 6 GeneXpert machines and 42.6% of non-GeneXpert districts are sending specimens for GeneXpert testing (174/408 district TB Units).
- The total number of specimens referred from 2013 to June 2014 was 6,675 samples, in which 936 MDR-TB cases (14%) were detected. It is noted that although the case detection rate at the provincial TB Units is much higher than the district TB Units, 33.75% versus 4.1% respectively, the district TB Units contributed to identifying 74% of the cases (692 MDR-TB cases) versus 26% of the MDR-TB cases from provincial TB Units (244 MDR- TB cases) (Figure 1 below show the total number of specimens referred for GeneXpert testing and MDR-TB cases detected from the specimen referral system).

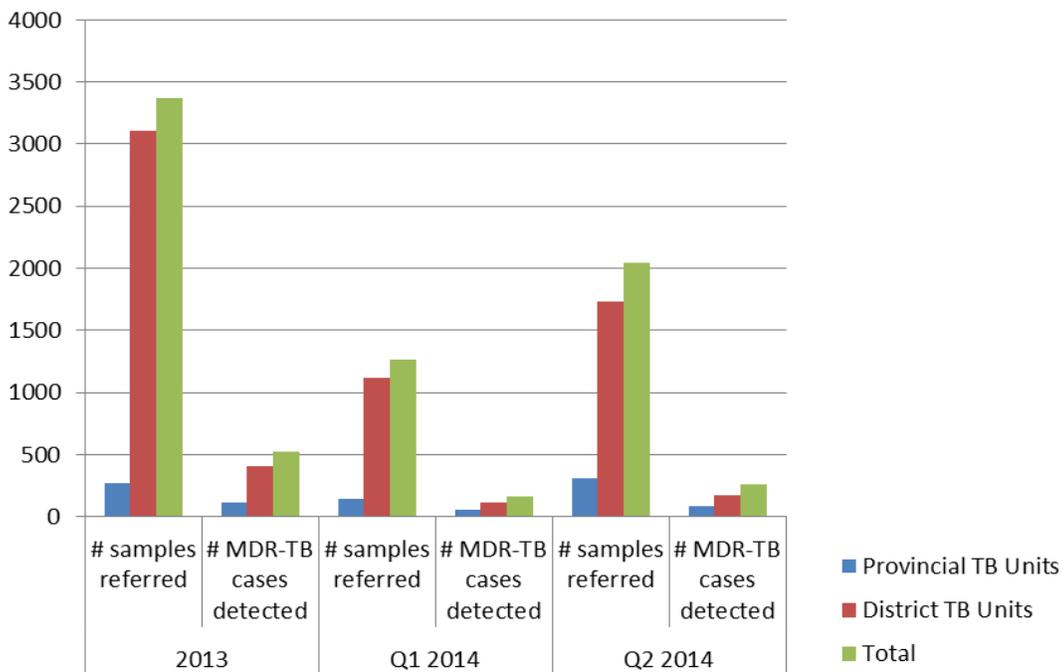


Figure 24: Total number of specimens referred for GeneXpert testing and MDR-TB cases detected from the specimen referral system

Challenges

There are a number of challenges that need to be focused on during the following phase in order to strengthen the specimen referral system:

- Although incentives are provided by the NTP through the Global Fund, motivation to send specimens from the DTU to provincial TB Units or to GeneXpert sites is low. The patient referral process is still the main practice at DTUs.
- Funding from the Global Fund for the activities is unstable. For example, the announcement regarding funding for 2014 activities was released in July 2014. Some provinces were able to cope with this (e.g., use local fund or flexible advance), others did not, and activities were postponed or delayed.
- Data reporting, monitoring and evaluation remain a challenge. Data about specimen referral at the district level is not systematically collected by NTP, therefore information of the specimen transfer from districts to provinces is limited. MSH has supported the NTP to conduct the first assessment of the specimen referral system to have an overview of the existing system. However, participation in the assessment survey was very low with a response rate of about 70% from districts. MSH also advocated for a data collection system and developed data collection forms to send it to NTP. It is expected that the NTP will be reviewing and using them in their routine report system. After debriefing with the NTP, it was decided that an assessment of the specimen referral system needed be carried out before the NTP would review and approve the forms.
- The specimen referral system is seen as solely a laboratory activity; the effort to merge the system with PMDT activities poses a challenge and is not well understood among partners and stakeholders. The challenges are seen at all levels and also shown in the project activities. In view of the health systems approach, a full coherent service package needs to be provided. The specimen referral system, therefore, should be developed as an integral part of the PMDT activities. The new phase of the project should focus on developing a strategy to combine these services in one common framework under good governance, leadership and management for MDT-TB treatment and control.



Figure 25. A nurse reviews file for suspected MDR-TB patient who arrived after the second round of TB treatment failure with first- line TB drugs. Ba Ria, Vung Tau, May 2014.

Consolidation of transportation support provided to PLHIV referred from OPCs to DTUs for GeneXpert test

One of the key elements of the specimen referral system is to expand the system to PLHIV for GeneXpert testing which is proven to be a good tool for diagnosis of TB and MDR-TB among HIV/AIDS patients. MSH worked with the National Committee on HIV/AIDS Prevention and Control to send a letter to all Provincial HIV/AIDS Committees about referring HIV/AIDS patients or sending specimen to GeneXpert sites for TB and MDR-TB testing. In addition, training was provided to healthcare providers working at Out-Patient-Centers (OPCs) for HIV/AIDS Care and treatment about using GeneXpert in diagnosis of MDR-TB and orientation about triple packaging and advocating for more patient referral from OPC to DTU. The training was conducted in collaboration with HAIVN (Harvard Medical School AIDS Initiative in Vietnam) to 22 provinces funded by PEPFAR through webcast. There were 74 healthcare providers from 16 provinces (both PMDT and non-PMDT) participating in the training. After the webcast training HAIVN continued providing support for the screening of HIV/AIDS patients to DTU through monitoring visits.

3. Infection Control

Technical Outcomes

#	Outcome Indicator	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y4	Y4
3.1.1	National TB-IC guidelines that are in accordance with the WHO TB-IC policy have been approved		Yes	Yes	Yes
3.1.2	TB-IC measures included in the overall national IPC policy		Yes	Yes	Yes
3.2.2	Facilities implementing TB IC measures with TB CARE support		60 (Cumulative)	60 (Cumulative)	70 (Cumulative)
3.3.1	Annual reporting on TB disease (all forms) among HCWs is available as part of the national R&R system		Yes (TB facilities at national provincial level)	Yes (TB facilities at national, provincial and district level)	Yes (NTP conducts the data collection with TB CARE I support: TB facilities at national, provincial and district level)

Key Results

TB infection control (TBIC) is one of important technical area that is focused by TB CARE I project in support of the roll-out of PMDT at provincial and district levels. Over the project time, TB CARE I supported NTP with strengthening TBIC facility program, improving TBIC health facility, and TBIC surveillance establishment and maintenance.

3.1 TBIC facility strengthening program

In APA1, TB CARE I support the NTP to develop the strengthening TBIC facility program consist of 3 stages: i) Training on TBIC knowledge and skills for NTP staff at provincial and district level, ii) TBIC facility assessment with technical support by higher level (provincial and national levels) and development of TBIC facility plans, iii) implementation of TBIC facility plans. The strengthening TBIC facility program has implemented successfully in 4 provinces and 50 districts in APA2. During the time of TB CARE I implementation, training on TBIC was organized in 18 PMDT provinces for staff of district and provincial TB units and staff of some HIV OPCs. 18 provincial TB and Lung disease hospital, 50 selected DTUs implemented the program of TBIC strengthening. Activities of training and IEC on TBIC measures: administrative, environmental and PPE were included in the planning and implemented in

these units. MDR-TB treatment wards were renovated and have been receiving MDR-TB patients for treatment.



Figure 26. Training on TB infection control for NTP staff at provincial and district levels, in 2014



Figure 27. Upgraded TBIC condition in MDR-TB treatment departments in 5 PMDT treatment center (provinces) in 2012

In 2014, TB CARE I provided technical support to NTP in improvement of TBIC conditions in 14 PMDT provinces in order to scale up PMDT. TB CARE I local consultants carried out the TBIC site assessment of the MDR treatment department and other high risk areas in the provincial TB hospitals and proposed the layout for MDR-TB treatment wards and the ventilation system for these facilities which were then renovated using funds from local authority and NTP. 14 MDR-TB treatment departments will be renovated and put in to use in the last quarter of 2014 that helps expand the diagnosis of MDR-TB.

3.3. TBIC surveillance establishment

In the first and second years of the Project implementation, TBIC indicators have been put in discussions and NTP selected 4 indicators for collecting and monitoring of TBIC activities. These four indicators are:

- Annual reporting on TB disease (all forms) among HCWs
- The availability of an TBIC plan of each unit
- The availability of a focal point person for TBIC activities in each unit
- Personal protection equipment (particulate respirator (N95, FFP2) available for HCW who directly involve in the care of MDR-TB patients or lab technicians handling cultures (DST if any)

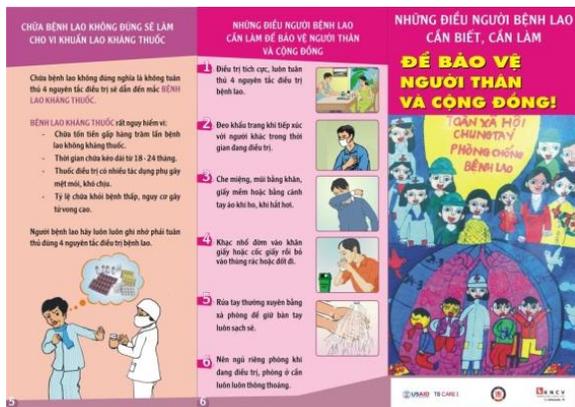
In Vietnam, annual mandatory health check for health care staff is under by labour law. These indicators have been collecting annually from 67 units of TB control at central and provincial levels since 2012 and has been expanded to district and commune level in 2014.

Year	Total number of health care workers	Total no. of HCWs having TB of all forms	Rate per 100.000
2009	6134	32	522
2010	6514	31	476
2011	6989	19	272
2012	7544	20	265
2013	7779	23	295

Table 8. Annual reporting on TB disease (all forms) among HCWs in 67 TB units at central and provincial levels in 2009 – 2013 period

Preliminary collected data shows that the proportion of health care staff having TB in 67 units of TB control at central and provincial level is 522/100.000 (2009), 476/100.000 (2010), 272/100.000 (2011), 265 (2012), 295/100,000 (2013), which shows a decrease trend over 2009-2013 period. Operational research should be conducted to identify the reasons for this decline.

Another activity in this technical area, aimed at raising awareness on TBIC, in the third year of the Project implementation, 2 IEC materials on TBIC for health care staff and community were supported by TB CARE I to develop, print and distribute nationwide. 28,350 posters and 1,301,200 leaflets have been printed and distributed widely to TB control units at provincial, district and communal level across the nation.



4 ĐIỀU NGƯỜI BỆNH LAO CẦN LÀM ĐỂ BẢO VỆ NGƯỜI THÂN VÀ CỘNG ĐỒNG

1.  Đeo khẩu trang khi tiếp xúc với người khác khi còn đang điều trị.
2.  Che miệng, mũi bằng khăn, giấy mềm hoặc bằng cánh tay áo khi ho, khi hắt hơi.
3.  Khạc nhổ đờm vào khăn giấy hoặc cốc giấy rồi bỏ vào thùng rác hoặc đốt đi.
4.  Rửa tay thường xuyên bằng xà phòng để giữ bàn tay luôn sạch.

Logos: USAID TB CARE I, KNCV (KHOA VI SINH VẬT HỌC VÀ BỆNH LÝ) To eliminate TB

HƯỚNG DẪN KIỂM SOÁT LÂY TRUYỀN BỆNH LAO

CHIỀU THÔNG KHÍ

Thông khí tốt trong phòng bệnh và nơi khám bệnh

Trong khi đang điều trị, người bệnh lao cần đeo khẩu trang khi tiếp xúc với người khác

Người bệnh lao nên khạc đờm vào cốc giấy rồi đốt đi

Logos: USAID TB CARE I, KNCV (KHOA VI SINH VẬT HỌC VÀ BỆNH LÝ) To eliminate TB



Figure 28: IEC materials on TBIC for health care staff and community

4. Programmatic Management of Drug Resistant TB (PMDT)

Technical Outcomes

#	Outcome Indicator	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y4	Y4
4.1.2	MDR-TB patients who are still on treatment and have a sputum culture conversion 6 months after starting MDR-TB treatment	Patients that started treatment from September 2012 until March/2014	>75%	>75%	1176/1483 = 79%
4.1.3	MDR-TB patients who have completed the full course of MDR-TB treatment regimen and have a negative sputum culture	Data from the beginning of the PMDT program till Sept 2014	>75%	>75%	1041/1581 =65%
4.1.4	A functioning National PMDT coordinating body		Yes	Yes	Yes
4.1.5	<i>A model for PPM-PMDT is developed and piloted</i> Description: A pilot involving a regional treatment center (PNT, HCMC), non-PMDT (private) doctors in provinces outside HCMC	A referral mechanism of MDR-TB treating outside of NTP will be developed. It will benefit the MDR-TB patients to continue MDR-TB treatment and care in line with the NTP guideline	No (2013)	Yes (2014)	Yes (2014)

Key Results

4.1 Technical advice and assistance on PMDT implementation and expansion

TB CARE I plays an important role in advising and supporting NTP in terms of policy, workplan development, implementation and quality assessment for PMDT implementation and roll-out. Consistently over the Project lifetime, TB CARE I has been continuing to provide in-depth technical advice for the implementation and expansion of PMDT activities through in-country and external technical assistance. Agenda for missions of technical assistance have been such issues as management, coordination and professional expertise in PMDT. Recommendations as a result of field trips of intensively working with sites were provided for NTP at central and local provinces for such issues as the commitment of leaders at all levels, program and laboratory management system (the status and capacity), policies of detection and management of cases of drug-resistant TB (regimen, support, monitoring of adverse drug reactions), drug management, human resource management, data management (recording-reporting, management via e-TB manager software); TBIC and special targeted groups. This is great assistance and has been very much appreciated by NTP leader and NTP at provincial level.



Figure 29: Monitoring and technical assistance missions for PMDT implementation and roll-out in Vietnam

	2009	2010	2011	2012	2013	2014 (9 months)
PMDT treatment centers	1	6	6	10	10	10
PMDT satellite sites			14	25	30	31
Total PMDT provinces	1	6	20	35	40	41
MDR-TB patients enrolment	101	97	578	713	943	1072
MDR-TB treatment success rate(*)	73%	78%	72%			

(*) Treatment outcomes are available for the cohort of 2009, 2010 and 2011

Table 9: PMDT implementation and roll-out in Vietnam

Vietnam has diagnosed and enrolled 3,504 patients for MDR-TB treatment between September 2011 and September 2014. The success rates of MDR-TB treatment for the cohorts of patients enrolled in 2009, 2010 and 2011 are quite high at 73%, 78% and 72% respectively. The number of patients diagnosed and enrolled increased significantly after the start of TB CARE I in 2011: with nearly 6 time increases in 2011, 7 folds in 2012, 9 folds in 2013 and 10 folds in 2014 compared to the baseline of 2010 before the start of TB CARE I. This increase was attributed by a number of factors, of which, TB CARE I accounted for an important contributions.

In 2014, 5 workshops in 3 regions (2 workshops in the northern region, 2 in southern region and 1 in central region) were organized with the participation of 239 NTP staff who are directly managing and coordinating PMDT activities from 41 provinces/cities within PMDT framework to discuss and agree between different levels: central level with MDR-TB centers and satellite sites. The final purpose of the workshops has been achieved in the sense that all standard procedures involved in the management, coordination and communication of PMDT have been discussed and agreed. In terms of coordination, discussion has been made and identified specific focal point of those who involve in each procedure in satellite sites and treatment site. The action plan on PMDT in 2014 for each province has been developed.



Figure 30. Discussion and presentation on plan to strengthen the PMDT at the workshop on PMDT strengthening in HCMC (April 16-17, 2014)

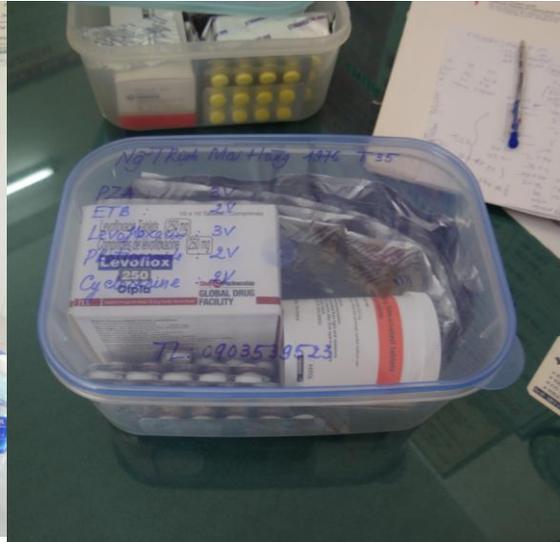


Figure 31. GeneXpert and PMDT monitoring mission conducted by NTP and TB CARE I staff in PMDT treatment centers and satellite provinces

From perspective of policy/guideline support for PMDT, TB CARE I/KNCV supported the update of PMDT guidelines on SOPs and develop training modules (based on the WHO PMDT training modules) for PMDT implementation and scale up. The Writing team consisting of all key figures from principal PMDT sites of Vietnam who has been working on the guideline update and training module development based on the WHO PMDT training module. The first draft of this updated guideline and training module have been available as of Nov 5 for further refining before officially approving by NTP in December 2014.

Also in 2014, the guidelines and SOPs for PMDT implementation have been updated with technical and financial support by TB CARE I. The update of these 2 documents will help the PMDT expansion be at a faster rate and in a consistent manner among PMDT provinces.

4.2. Introduction of new drugs and regimen

Even under the most successful conditions, the treatment of multidrug-resistant forms of TB (MDR-TB) is complicated, costly and difficult for patients. Current approaches for the programmatic management of MDR-TB (PMDT) require the use of multiple drugs with limited efficacy be given for a prolonged period of time (i.e. 18-24 months). New TB drugs and treatment strategies are being approved and tested for the management of MDR-TB, offering patients and their providers hope for shorter, better therapy for the first time in decades.

Although Vietnam has a high rate of success in the management of MDR-TB in the country, the difficult and costly regimen has meant that a significant number of patients with the disease are unable to access optimal therapy. Furthermore, patients who fail MDR-TB therapy or have highly resistant forms of TB (i.e additional resistance to fluoroquinolones or second-line injectable, XDR-TB) currently have very limited therapeutic options in Vietnam, leaving them, their families, and their providers in a quite desperate situation.

In order to address these problems, Vietnam is committed to introducing new drugs (bedaquiline, delamanid) and new treatment strategies (9 months regimen for MDR-TB treatment) into the country when evidence shows that these are likely to benefit patients and the program. The program will do this in a comprehensive way that reinforces principles of PMDT, ensuring that the introduction of such drugs and regimens in Vietnam maximizes the benefits to patients, communities, and programs while minimizing the risks to these populations.

In 2014, TB CARE I provided technical and financial support to NTP in preparation of new drugs and regimen in Vietnam. A technical working group (TWG) for implementation of new drugs and regimen was established on 31 March 2014 and the steering committee for implementation of new drugs and regimen was established on 16 July 2014 by the minister of Health that led by the vice minister. The three meetings of TWG on BDQ were supported in FY2014 by TB CARE I where the Group (i) updated the status of preparation of Vietnam for BDQ implementation plan; (ii) discussed and commented for the first draft National Strategy for BDQ implementation; and (iii) agreed on next steps and person-in-charge for each task for each stage. The expectation was that all preparation is ready for the implementation starting June 2015.

The plan for introduction of new TB drug (Bedaquiline) and the new regimen (9 months) for treatment of MDR-TB, XRD-TB has been developed and will be submit to MOH for approval in December 2014.

To enhance capacity for NTP staff in this field, TB CARE I supported NTP to send a staff for a training course on pharmacovigilance and cohort event monitoring for patients on treatment for drug-resistant tuberculosis Copenhagen, Denmark, 3 to 7 March 2014 and Meeting on preparing for the introduction of new TB drugs based on WHO policy and Inter-regional workshop on pharmacovigilance for new drugs and novel regimens for the treatment of drug-resistant TB in Hanoi, Viet Nam, 10 to 14 November 2014.

4.2 e-TB manager implementation

e-TB Manager is an electronic system developed by Strengthening Pharmaceutical System (SPS), a USAID funded project for TB/DR-TB patients, FLDs/SLDs drugs management with a full module for creating WHO standardized reports for regular monitoring and evaluation. TB CARE I along with NTP staff and all other TB CARE I partners in Vietnam, have successfully implemented the e-TB manager which has been incorporated at all treatment sites and District Units countrywide (total 49). The Medicine Management Module has also been regularly updated by the NTP National Warehouse and all other facilities. Both the Case Management and Medicine Management Module became a strong data source for the NTP in terms of decision making related to monitoring patient treatment and supply chain management. For example, the interim outcome assessment of confirmed MDR-TB cases, the outcomes report, the incidence and prevalence reports are available since 2013. The monitoring report documents were shared with the PMDT team and are being updated with the comparison between the official paper-based numbers for enrolled cases.

Data entry evaluation has demonstrated a great evolution in quantity (number of sites using the system and case data from each one of them). Figure 2 below shows the case data entry levels through the end of September 2014.

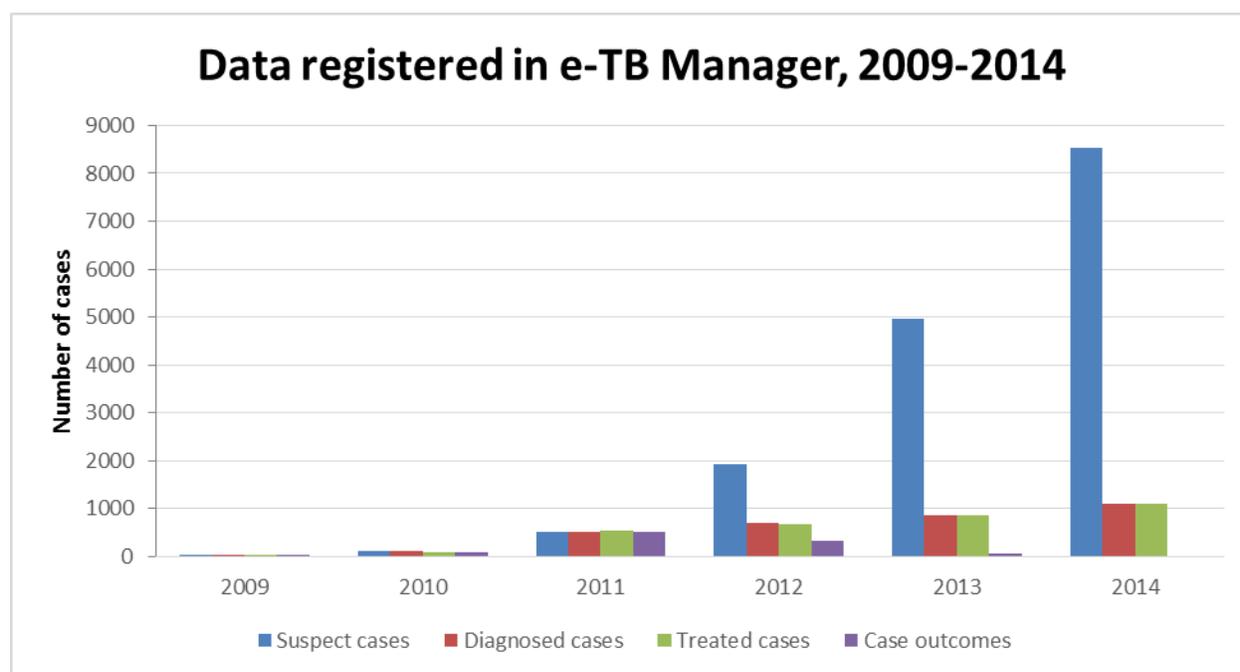


Figure 32. Case data entry levels, 2009-2014

TB CARE I and NTP PMDT team have created an e-mail group account that includes users from all sites and this has allowed a stronger communication channel between PMDT staff and end-users, facilitating the integration and dissemination of relevant information linked to troubleshooting, information dissemination and technical assistance overall aspects.

During the implementation of the APA4 work plan, TB CARE I trained all PMDT sites in accordance to NTP's planning. MSH also provided a refresher training class for people that were already using e-TB manager. This has also significantly improved the amount of data entered in the system, as well as the quality aspects. Regular supervision visits performed by NTP staff have also contributed to this.

The e-TB manager system has demonstrated great capacity for supporting treatment sites on all case management aspects. An example that can clearly highlight this is the Phạm Ngọc Thạch Hospital in Ho Chi Minh city. This treatment site has been capable of tracking and monitoring on-line all patients from the 24 different District Units that are under the hospital since the implementation of e-TB manager. This is an outstanding achievement and has allowed a better management and monitoring of all cases and TB medicines for the treatment sites and districts units. The integration process between e-TB manager and VITIMES has been launched. MSH has implemented the National Identification card as a required field for case data entry in e-TB manager - this is the connection field between both systems.

Due to financial challenges, the last short-term technical assistance was not carried out, which has unfortunately compromised some of the key planned activities. Specifically, the activities include an assessment of the system's implementation, an M&E meeting and an additional visit from MSH headquarters' IT programmer for final adjustments and customizations in alignment with NTP' needs. However, in terms of implementation of the system, TB CARE I achieved promising and incredible numbers in Vietnam during the life of the project.

Challenges

Currently, a significant number (250) of MDR-TB patients were treated with non-GLC drugs in MDR-TB treatment centers (Pham Ngoc Thach and 74 Central Hospital). The regimen is similar to that of NTP PMDT guideline. However, no DOT or limited supervision was in place. The reason given is that most of them come from provinces where MDR-TB services are not available. TBCARE I APA4 is supporting NTP to develop a referral mechanism that allows MDR-TB patients currently on a non-GLC regimen to be referred and enrolled in their province with the PMDT drugs.

Although having improved in the enrolment and treatment capacity, there is still room for further improvements in treatment initiation, monitoring and care of MDR-TB patients in Vietnam.

5. TB/HIV

Technical Outcomes

#	Outcome Indicator	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y4	Y4
5.1.2	<i>National guidelines on collaborative TB/HIV activities updated</i> Description: Development of the national guidelines on collaborative TB/HIV activities for MOH decision on TB/HIV collaborative framework		Old version, 2013	Yes	First draft written. In process
5.1.3	<i>Training curriculum and materials on collaborative TB/HIV activities updated</i> Description: Development of the training curriculum and materials on collaborative TB/HIV activities		Old version, 2013	Yes	No

Key Results

With TB/HIV technical area, in the first and second year, the Project carried out a research on Tuberculosis Screening and Referral services for PLHIV at Out-patient Clinics in Vietnam. The research found out that according to the patient files in studied sites of high TB/HIV prevalence (Ha Noi, Ho Chi Minh and Dien Bien), nearly 60% PLHIV were screened for TB in the monthly clinic visits, only 9% reported that they were asked all 4 screening questions (productive cough, prolong fever, weight loss and night sweat) that are used for TB screening in Vietnam. 57% of TB-suspected PLHIV reported that they were referred by OPC staff to higher level (district TB unit, TB hospital or central hospital) for further TB diagnostics. 32% of TB-suspected patients who were not referred by OPC staff sought diagnostic services for TB themselves. These findings have provided a better picture of the current situation of TB screening for PLHIV for NTP and VAAC information.

Since the 3rd year, on the basis of suggestion of Vietnam Administration of HIV/AIDS Control (VACC), TB CARE I has been supporting VAAC to develop the Guidance document on the implementation of collaborative activities between the national targeted program of HIV/AIDS and Tuberculosis Control Project, and Technical Guidance on the implementation of collaborative TB/HIV activities. A Drafting Committee has been established comprising representatives from the Vietnam Administration of HIV/AIDS Control, Care and Treatment Administration - Department of Health, National TB Program and Pham Ngoc Thach Hospital. The first draft of the documents has been available as of this reporting date.

6. Health System Strengthening (HSS)

Technical Outcomes

#	Outcome Indicator	Indicator Definition	Baseline (2013/ timeframe)	Target	Result
				Y4	Y4
6.1.3	Health insurance includes elements of TB care (WHO)	A circular for provision of TB diagnosis and treatment under health insurance is nearly finalized	No	Yes	Discussion is still on-going
6.1.4	5 year TB control plan incorporated into provincial workplans (WHO)	Provincial TB control plan developed and advocated for local authorities	0	2	2 (developed, and is planned to be advocated in provinces – Jan 2015)
6.2.3	Number of paired/guided Good Manufacturing Practice(GMP) inspections conducted (WHO)	Inspections postponed due partially to prioritization of planned activities in technical assistance in pharmaceutical areas	0	2	0
6.2.4	Number of trainings and quality circle sessions conducted (WHO)	Training in GMP for the quality standards in the local TB medicine manufacturing is planned, but delayed due to other priority activities under DAV.	0	2	Scheduled to take place in late December

Key Results

In this technical area, the Project focuses on advocacy and resource mobilization for TB control, in which the implementation is mainly responsible by WHO and NTP. In APA2 a number of advocacy workshops have been organized with National Assembly' Social Affairs Committee, as well as training for journalists to raise awareness on as well as to advocate for the necessity to fund TB control in Vietnam.

In continuation of APA2, capacity building for national and provincial TB staff in high TB burden provinces was maintained to develop and implement advocacy plans for sustained and increased TB funding with full support of key national NTP staff. Two of four high burden TB provinces developed action plans to advocate for more TB funding.

A looming crisis – stock-out of first line TB drugs – became apparent in January 2013, when Ministry of Health informed the NTP on a decreasing financial allocation for TB control including TB drug procurement resulting in potential stock-outs early in 2014. While maintaining high-level advocacy with the Government of Vietnam, WHO (not through TB CARE I) facilitated access to a grant by the Global Drug Facility (GDF) covering drugs needed for one year and a 50% buffer with procurement starting in early 2014.



Figure 33: Advocacy workshops on TB control policies for Central and provincial Parliamentary members

TB CARE I/WHO is using this incident as entry point to further sensitize the Social Affairs Committee of the National Assembly, MoH, Ministry of Finance on the urgent need for sustainable TB funding both from central sources and provincial allocations.

The Quality Circle program was launched with the Vietnam National Pharmaceutical Companies Association (VNPCA) and Drug Administration of Viet Nam (DAV) in June 2013 with the participation of 80 local pharmaceutical companies. This has resulted into a renewed interest and commitment by the industry to implement quality assurance programs in the production and supply of essential medicines. The quality circle sessions and on-line training on quality assurance using WHO modules are now being set up.

The Drug Administration of Viet Nam has the GMP Strengthening Program roadmap. The GMP certification assessments are now included in this more comprehensive GMP Program. One of the key results that was targeted was the initial assessment of the GMP certification protocol and inspection of selected manufacturing plants. However, this specific assessment has been delayed due the difficulties in arranging the availability of experts during the period that could meet DAV requirements.

In FY2014, WHO has been continuing a number of different activities for advocacy and policy advice, namely:

a) Advocacy meeting

- Organized field monitoring missions for the Members of the Parliament to district TB control with the Provincial TB programme and commune health posts to advocate more sustainable funding for TB control (focus on FLD and human resource management)
- Organized 3 regional advocacy meeting with the Members of the Parliament and the Provincial People Committees to advocate local support for TB control (human resource and allowance for health staff working on TB)

- Provided technical assistance for Provincial TB Programme (Hai Duong and Thai Binh) to develop provincial TB control plan (2015-2020) and advocate decision-makers and support from local authorities
- b) Policy advice
- Supporting Health Insurance Department of MOH to develop a circular of provision for TB services (diagnosis and treatment) under the Health Insurance system. As the implication is significant, discussion within the government including MOH is on-going. Series of consultation meeting including the one with the TB program have been schedule toward the end of the year.
 - Supporting Drug Administration of Viet Nam, MOH to develop a policy document to strengthen the regulation of TB drugs in Viet Nam. It is proposed TB-drug will be sold in designated GMP pharmacies (limited number, for example 1 or 2 pharmacies per province) with stricter recording and reporting.
- c) Rational introduction of new drug (Bedaquiline)
- Technical support provided to NTP to prepare national implementation plan for the introduction of bedaquiline for the treatment of pre-XDR and XDR TB. Two advocacy workshops were held with senior officers of MOH. WHO is a member of the technical working group, and supported the first Task Force meeting in Nov 2014.
- d) GMP strengthening and quality circle
- In Viet Nam, pharmaceutical enterprises have little information on GMP. In order to improve the quality of domestic drugs including TB medicines, a workshop is planned to provide information, share experiences from other countries, and to develop skills for risk management on the quality in manufacturing medicines.
- e) Assessment and TA for development of aligned national GMP
- An assessment framework to assess the over-all quality assurance system and the standards and protocols implemented on GMP has been developed. WHO-GMP updated guidelines are used as the basis. Implementation of the assessments including paired audits to three identified local manufacturing plants will be starting soon.

7. Monitoring & Evaluation, Surveillance and Operational Research

Technical Outcomes

#	Outcome Indicator	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y4	Y4
7.1.1	An electronic recording and reporting system for routine surveillance exists at national and/or sub-national levels		Yes	Yes	Yes
7.2.2	NTP provides regular feedback from central to intermediate level		Yes	Yes	Yes
7.3.1	OR studies completed	Assessment report developed. Based on that, national guideline and practical handbook will be adapted/adopted to guide clinical doctors/nurses in implementation	9 (Years 1-4)	9	6
7.3.2	OR study results disseminated	A handbooks for TB diagnosis and treatment for non-TB health staff (general hospital and peripheral level)	No	Yes	Yes

Key Results

7.1 TB surveillance system (VITIMES)

VITIMES (Vietnam TB Information Management Electronic System) is the internet based TB surveillance tool for susceptible TB developed by the NTP in close cooperation with 2 local IT companies and technical support from KNCV.

In APA3, there were two missions of experts on surveillance systems (TB surveillance. In the first mission of support, along with an expert from WHO, a comprehensive assessment of the TB surveillance system of NTP was made making use of the WHO guide 'Standards and benchmarks for tuberculosis surveillance and vital registration systems'. Among the 13 tuberculosis surveillance standards, 3 standards have been met, 2 standards partial met, 6 standards are not met, and 2 standards were not fully assessed and need to be further evaluated. Also during this mission, together with the expert from the WHO, Ministry of Health and NTP, a roadmap to 2015 for the various components to improve VITIMES systems and data exchange between VITIMES and e-TB manager was formed.

In APA4, two TA missions of experts on surveillance systems (TB surveillance) were provided to NTP to review the progress of upgrading of the development and implementation of VITIMES. This is an

important contribution of technical support from TB CARE I for the TB surveillance system of the NTP which was taken seriously by NTP resulting into the uptake of several recommendations to improve VITIMES in the upgrade plan for VITIMES (as well as e-TB manager) using Global Funds support. A further contribution of TB CARE I in this technical area in 2014 is the support to develop the Data Management Manual for VITIMES that is scheduled to be finalized and will be considered for being distributed to all provinces in Vietnam to improve the implementation of VITIMES in province and at district level.

7.2. Operational research

TB CARE I project supported the NTP in operational research capacity building through the development of an operational research protocol and conducting ORs to evaluate the Project's intervention.

Over the Project lifetime, 9 ORs have been supported. The 6 completed ORs include: (i) the Research on Tuberculosis Screening and Referral services for People Living With HIV/AIDS at Out-patient Clinics in Vietnam; (ii) OR on multidrug-resistant tuberculosis prescription behavior (GLC and non-GLC); and (iii) OR on the availability and pricing of tuberculosis drug (first line and second line drugs); (iv) Gender disparities in TB diagnosis (v) Obstacles to access to health insurance for TB diagnosis and treatment; (vi) Palliative care for MDR-TB patients.

#	Title	Study Results	Means of Dissemination
1	TB screening and referral service for PLHIV at out-patient clinics in Vietnam	60% PLWHA were screened for TB in the monthly clinic visits, only 9% reported that they were asked all 4 screening questions (productive cough, prolong fever, weight loss and night sweat) that are used for TB screening in Vietnam. While 7% PLWHA were found positive with TB screening by OPC staff, 34% of the same patients on the same days answered positive to one of the four questions. 57% of TB-suspected PLWHA reported that they got referred by OPC staff to a higher level (district TB unit, TB hospital or central hospital) for further TB diagnostics. 32% of presumptive TB patients who were not referred by OPC staff sought diagnostic services for TB themselves. Being referred by OPC staff, registering at OPCs in HCMC and having a history of TB were found associated with seeking TB diagnosis among TB- suspected PLWHA (OR= 4.8; 4.0; and 3.4, respectively) through multivariate analysis.	Presentation at the Union Asia-Pacific Region conference, April 10-13, 2013 in Hanoi, Vietnam
2	Prescription habits for MDR (GLC and non-GLC drugs)	A total of 282 MDR-TB patients, including 79 (28%) GLC MDR-TB patients and 203 (72%) non-GLC MDR-TB patients, were enrolled. Treatment delay was significantly higher in the GLC group (12.8 days) as compared to the non-GLC group (2.3 days), ($p=0.004$). The success rate was significantly better in GLC patients (84.8%) than in non-GLC patients (53.7%) ($p < 0.001$). The default rate was significantly higher in non-GLC patients than in GLC patients (25.6% vs. 6.3%), ($p < 0.001$). The risk of unsuccessful outcome was higher in non-GLC patients (Hazard ratio = 4.6, 95% CI: 1.8 – 11.8).	Presentation at UNION Hanoi conference April 2013; policy dialogue with MoH; accepted for publication in the Journal of Tropical Medicine & International Health
3	Availability and pricing of TB drugs (FLD&SLD)	Access to medications for the treatment of TB varies by province and by sector. Binh Duong had the lowest access in private outlets, with no surveyed private outlets selling TB medications other than quinolones, and Ho Chi Minh City had the highest access with 86% of private outlets able to provide TB medications other than quinolones. In every province, private access to TB medications was possible through selected outlets, which in some cases, could be observed but not surveyed. Pricing in the private sector for the	Presentation at UNION Hanoi conference April 2013; policy dialogue with MoH & Drug Administration to suggest a

		lowest cost generics was 99.5% higher (approximately twice the price) of the NTP acquisition cost for first line treatment. The highest priced generic products were 250% higher than the NTP acquisition price (3.5 times the price).	circular to regulate availability of TB medicines
4	Gender disparities in TB diagnosis	The case detection rates in women are higher than that in men. The sex difference in TB notification in Vietnam reflects a true difference in disease occurrence rather than a difference in access to diagnosis and treatment as some previous studies have suggested. More research to investigate potential differences in the epidemiology of TB between men and women is needed. The NTP should pay more attention to case-finding among men to improve case detection.	1. Report 2. Policy dialogue
5	Obstacles to access health insurance for Tb diagnosis and treatment	1) the health insurance coverage of TB patients was lower than that of the whole country (65%); 2) There is a need to strengthen compliance with the NTP guidelines and implement a standard package of TB diagnosis and treatment at each level; 3) Having District TB Units located in district health centers is a huge challenge for TB patients to benefit from their health insurance as DHCs are not allowed to provide HI services. Policy advocacy is needed to support DHCs to become HI service providers.	Report
6	Assessment of palliative care for MDR-TB patients in Vietnam	The entire package of palliative care is not yet incorporated in the management of patients with MDR-TB. Though physicians at the level of the commune may be able to identify adverse drug reactions (ADRs), ancillary drugs to relieve these ADRs were not available. Currently, there is no protocol or further care plan for patients who failed DR-TB treatment. Advice from hospital staff is limited to reminding the patient to wear surgical masks and to taking TB-IC precautions—cough etiquette, opening of windows at home. Codeine and morphine are available in Vietnam, but not used for TB patients with uncontrollable cough.	Report to NTP

Two ORs have been underway and are set to complete before the end of the project:

- Operational research in support of introducing Xpert MTB / RIF in Vietnam. This study will support NTP in its decision making for GeneXpert implementation scale up in the nation for issues related to the operations, human resource needed, and so forth;
- Costing study to estimate cost of TB diagnosis and treatment (both susceptible TB and MDR-TB) at different level (national-provincial-district). This study will serve as an evidence to discuss/negotiate with HI of inclusion of TB services under HI benefits; and

Following the palliative care assessment, a practical handbook is being developed for clinical doctors/nurses while handling MDR-TB/XDR-TB patients. With support from TB CARE I/WHO, development of a practical handbook for TB diagnosis and treatment for peripheral health staff and non-TB health staff has been underway. This document will help strengthening PPM approaches and contribute improved and earlier TB case detection.

8. Drug supply and management

Technical Outcomes

Code	Outcome Indicator	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y4	Y4
8.1.1	National forecast for the next calendar year is available		Yes (Year 3)	1	1
8.1.2	Updated SOPs for selection, quantification, procurement, and management of TB medicines available		Yes (Year 3)	6	6
8.1.3	Percentage of provinces (will be given TA on TB PSCM) per total 63 provinces	Indicator Value: Number of percentage of provinces (will be given TA on TB PSCM) per total 63 provinces in Vietnam Level: nationwide Source: TA Report Numerator: Number of provinces will be given TA on TB PSCM Denominator : Total 63 provinces in Vietnam	Yes (y1=y2=0% Y3=6.3%)	23.8% (15/63 provinces)	23.8% (15/63 provinces)
8.1.4	Final report of TB pharmaceutical supply chain systems and performance assessment is available	Description: As a result of the "Support the NTP to prepare and complete the next steps of TB pharmaceutical supply chain systems and performance assessment" activity, the final report must be approved by NTP leaders and shared to all related partners.	y1, y2, y3: have no report of TB pharmaceutic al supply chain systems and performance assessment	Yes	Yes

Key Results

a) Supported the NTP to develop an action plan for drug supply chain management:

- Together with the staff in-charge of TB first-line and second-line drug management in the Supply Group of the NTP, TB CARE I helped to develop a detailed action plan for January – December, 2014 (breaking down each step to include: collecting reports, entering data in the database, forecasting, procuring, distributing, training, etc.). Based on these plans and the agreed upon timeline, TB CARE I staff followed up with NTP to remind them to do all related activities on schedule.

b) Supported the NTP to conduct TB pharmaceutical supply chain systems and performance assessments by using NTP approved assessment tool:

The final TB pharmaceutical supply chain systems and performance assessment report is available with some key assessment findings:

- No site currently qualifies as being fully GSP/GDP compliant, but numerous sites are close to this target, and relatively small changes and strengthening activities could help them reach this goal.
- Areas of particular weakness in logistics across the surveyed sites are:
 - Distribution – (Average Score 13%): The difficulty here is that many Provinces are not undertaking the distribution themselves. Rather, Districts and treatment sites come to collect the medicines themselves and Provinces feel little responsibility for the process. Unfortunately the ad-hoc transport mechanism being used does not ensure safe and reliable treatment of the commodities and it will be necessary to address this issue through improved Province District interactions and SOPs.
 - Budgets and financing - (Average score 17%): The difficulty here is probably not so much the deficiency in funding levels, but there is simply no knowledge of the budget. The current budget structures are not activity specific so that, for example, all staff within a hospital appear to be classified as staff costs; breakdowns between department and units are not apparent. The overall impression is that budgets probably are too low in relation to commodity values being handled – with the exception being the central stores in Hanoi, which are close to the target levels.
 - Lack of written procedures (SOPs) at provincial level - (Average Score 20%)

c) Supported NTP to review and update the currently available TB drug supply chain management forms:

- TB drug supply chain management forms (report forms, log books forms, etc.) both for TB first-line and second-line drugs were updated and approved by the NTP.

d) Supported NTP in conducting the training on the use of updated TB drug supply chain management forms:

- 2 training of trainers (TOTs) on the use of updated TB drug supply chain management forms were conducted in April 2014:
 - TOT in Hai Phong: 37 trainees
 - TOT in Hochiminh: 33 trainees
 - Total: 70 trainees (37 female, 33 male) from provincial TB system and central/regional hospital (like 174, 171, 108, 103, 198 hospitals – which received TB drug directly from NTP).

e) Supported NTP through TA at the provincial, district, and site level to improve the performance of the supply chain management activities in 15/63 provinces:

The 15 priority provinces were: Ha Giang, Long An, Binh Duong, Gia Lai, Kon Tum, Hai Phong, Ben Tre, Dong Thap, Khanh Hoa, Lam Dong, Cao Bang, Bac Kan, Quang Ngai, Nghe An and Ha Tinh. Some key finding and achievements included:

- The need for technical assistance on TB DSCM directly for on-site staff is significant. Although the NTP system was established many years before, there is a lack of detailed guidance for DSCM implementation at the central/ provincial/ district level; there are many mistakes on planning/ receiving/ storage/ distribution/ dispensing/ reporting activities.
- Common mistakes include: documents are not the right forms issued by NTP/ MOH (lack of some necessary information like batch number, expiry date, code of TB drug source, etc.); there is no regularly monitoring of the temperature and humidity in the store; placement of the drug carton box directly on the floor or against the wall; quantification of the amount of TB drug distribution for districts is not scientific calculated.
- TB CARE I supported all sites on proper implementation and all steps of TB DSCM procedures like on planning, receiving, storage, distribution, dispensing and reporting activities. These trainings were well received.

- The project not only supported the 15 priority provinces, but also trained NTP staff to conduct supportive supervision using the checklist that was developed by TB CARE I and then approved by NTP for use nationwide.
- Staff at the national and provincial level greatly appreciated the on-site technical support, which they had not received before. They also valued this activity as a key step to improving TB DSCM.

f) Supported NTP in TB second line drug forecasting, procurement and distribution:

- Facing the high risk of TB second-line drug stock out in Vietnam in mid-2014, TB CARE I proposed this (new) activity to support NTP in TB second line drug forecasting, procurement and distribution.
- Support was provided to the NTP (for both financial and technical issues) during one quarter (Q2/2014). A technical group meeting in TB second line drug forecasting, procurement and distribution was also created.
- TA was provided to Pham Ngoc Thach hospital in Q3/2014 TB second-line drug distribution for 22 Southern provinces (B2 region).
- Technical support was provided to the NTP in making the Q3, Q4 TB second-line drug distribution plan.
- Technical support was provided to the NTP in developing a training toolkit (agenda, presentations) and conducted TB second-line drug supply chain management trainings (TOTs) for 35 PMDT provinces in July, 2014.
- To date, every step of the TB second-line drug management of NTP is on track, there is no risk of TB second-line drug stock out, and the database system of TB drug stock on hand and drug use can be updated every month; QuanTB, an MSH tool, is being used for TB second-line drugs forecasting and distribution.

TB CARE I's support to Global Fund implementation

The Global Fund currently being implemented in Viet Nam is the Phase II of the Round 9: Scaling up Technical Components and Partnerships for Expanded Impact in TB control in Vietnam (1 Jan 2011-31 Dec 2015). The current status for the period from January to June 2014 has scored A1 rating. The program supported by this grant aims to reduce the transmission of TB by scaling up essential TB program components such as Programmatic Management of Drug-Resistant TB (PMDT), TB control in congregate settings and Advocacy, Communication, and Social Mobilization (ACSM) through new partnerships. The current grant supports the NTP and the next Mid-Term Development Plan (MTDP). The activities focus on gaining political commitment to increase human and financial resources and make TB control a nationwide priority integral to the national health system, on granting access to quality assured TB sputum microscopy, standardized and quality TB treatments and on improving reporting, monitoring and evaluation.

For the new funding model of the Global Fund, the TB and HIV Concept Note was jointly developed by the NTP and Vietnam Administration of HIV/AIDS control with technical support by TB CARE I (KNCV and WHO headquarter and country team), and submitted to the Global Fund on 15 August 2014, the deadline for submission. The funding request covers the period of 3 years from 1 January 2015 through 31 December 2017. The requested fund allocation is expected to enroll 7,600 MDR-TB patients in 2015-2017 period (2,200 MDR-TB patients in 2015, 2,500 in 2016 and 2,900 in 2017). The particular strength of this Concept Note was on the integrated approach to TB and HIV joint interventions. The Concept Note received positive feedback from the Technical Review Panel (TRP).

With successful innovations from TB CAP and TB CARE I on the improved bio-safety condition and TBIC for health facility, in 2014, as per request by NTP for the technical assistance, TB CARE I continued to provide technical support for 11 PMDT satellite sites supported by GF on improving the layout for lab and MDR-TB treatment department. The technical assistance was for practically improving the layout of labs and MDR-TB treatment departments of 11 satellite sites of Hue, Ninh Thuan, Soc Trang, Hau Giang, Long An, Quang Nam, Quang Ngai, Thai Binh, Dong Nai, Nghe An and Quang ninh.

LESSONS LEARNT AND RECOMMENDATIONS

Reflecting on TB CARE I results through the lenses of the US Government TB strategy and the Post-2015 Global TB Strategy, there are many lessons to learn from TB CARE I and new approaches to prioritize going forward. Lessons learned from the project and an analysis of strategic priorities for the country are summarized below, which can inform future work and investment in the country.

Universal Access: Management of TB in children

- The management of TB in children should be considered a routine activity at all levels of NTP.
- M&E visits should be made more frequent to maintain the implementation and enhance capacity in diagnosing TB in children for TB staff at lower levels.
- The direction of Provincial Department of Health is critical for maintaining the collaboration between health facilities in childhood Management of TB.
- R&R forms and registers should be updated more simplified for convenience in the use at commune level.
- Integrate the management of information and data on childhood TB in the NTP surveillance system
- There needs IEC activities to enhance awareness and cooperation of people and HCWs from non-NTP on IPT for children.
- Commune health worker needs to have skills and IEC materials for supporting the IPT consultation.

Laboratories

GeneXpert experiences & lessons for organization

- Zoning of diagnosis coverage for sites with GeneXpert to maximize workload of machines
- Sputum specimen referral system, Xpert sputum specimens referred to Xpert lab from districts and "satellite" provinces.
- Clear division of responsibilities for feedback of Xpert test results to requesting clinics by email, fax, post or lab staff using result feedback form,
- Zoning treatment coverage to ensure all MDR-TB patients are enrolled in treatment after diagnosis

GeneXpert experiences & lessons for care and coordination

- Early SLD planning and procurement to ensure adequate drugs for patients
- MDR-TB Tx sites with qualified staff, well prepared facilities, uninterrupted FL&SLDs supply and quarterly interim cohort analysis to ensure quality of treatment for patients
- Intensive monitoring & supervision of progress of implementation, identify obstacles & solutions
- Monthly PMDT - GeneXpert TWG meetings for coordination, management, discussion and solution for implementation and technical issues

PMDT: e-TB manager

With the effective engagement from the NTP team, the e-TB manager implementation in Vietnam has reached significant results demonstrating that a strong commitment and better planning can be used to successfully incorporate all treatment sites and district units on a web-based and on-line system for MDR-TB cases and medicines management. However, this is a continuous process and technically there are gaps that need to be addressed. Currently, there are more than 100 staff members who are regularly updating the system with case and medicine data. As we have more staff engaged, there will be more suggestions and comments on how to improve the system. The NTP has joined with MSH and all TB CARE I partners to work hard on the consolidation of the implementation of the tool, this

has been achieved. However, there is a clear need to improve the tool based upon the recommendations from end-users and additionally to this how NTP can promote better decision making with the huge amount of data that is being collected on daily basis. This is a major step that needs to be taken.

Another relevant and strong recommendation is that the e-TB Manager system be integrated with VITIMES. MSH has focused strongly on improving the implementation side and the flow has been discussed and agreed upon, but not yet implemented. The way forward for a full incorporation, sustainability and ownership of e-TB manager from NTP Vietnam involves, as mentioned above:

- Incorporation of all customizations requested by end users
- An established, routine data quality assurance system, and once this has been achieved, how to reduce the workload at the facility level in terms of paper-based forms/files to be completed
- Relevant indicators from the database for better decision making
- Integrate in automatically basis e-TB manager and VITIMES

Annex I: Knowledge Exchange

Below is a list of tools and publications that were developed with support from TB CARE I Vietnam over the life of the project. Please contact the project staff for copies of or links to any of the listed documents.

Technical Tools:

1. Guideline on the Implementation of Xpert MTB/RIF in Vietnam
2. Guideline on the Implementation of Management of TB in children in Vietnam
3. Manual on the SOPs of TB Lab Service in Vietnam
4. Guidelines and SOPs on PMDT implementation
5. TB program procurement entity assessment tool
6. TB logistics assessment tool
7. Development of monitoring forms of the specimen referral system

Scientific Publications or presentations:

1. Research on Tuberculosis Screening and Referral services for People Living With HIV/AIDS at Out-patient Clinics in Vietnam
2. Strengthening the specimen referral system for diagnosis and treatment of TB and MDR-TB

Educational materials:

1. Leaflet on Management of TB in children
2. Poster on Management of TB in children
3. Poster on TB infection controls (02)
4. Visual aid to guide three layer specimen packaging