



Challenge TB - VIETNAM
Year 1
Annual Report
October 1, 2014 – September 30, 2015

October 30, 2015

Cover photo: Childhood TB patient: Nguyen Thi Kha Vy is 7 years old and living in Vinh City, Nghe An Province. She had cough, slight fever, weight loss, fatigue and could not walk for 3 months duration before being admitted to the National Lung Hospital on 16 July 2015. Nobody in her family had TB. Her sputum was sputum-smear negative. Based on her clinical symptoms and abnormal CXR film, she was diagnosed with pulmonary TB. She started TB treatment with the 2RHZE/4RH regimen, which she was tolerating very well. After 1 month of TB treatment, she had no more clinical symptoms, had gained 1 kg bodyweight and could walk on her own again.

Photo: Dr. Pham Quang Tue, National Lung Hospital – National TB Control Program, Hanoi, Vietnam

This report was made possible through the support for Challenge TB provided by the United States Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-14-00029.

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List of Abbreviations and Acronyms

ACSM	Advocacy, Communication and Social Mobilization
APA	Annual Plan of Activity
BDQ	Bedaquiline
CA	Cooperative Agreement
CTB	USAID \ Challenge TB Project
DAV	Drug Administration of Vietnam
DCA	Diagnostic cascade analysis
DLM	Delamanid
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
MDR-TB	Multi-drug resistance TB
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MOLISA	The Ministry of Labor, Invalid and Social Affair
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
NRL	National TB reference laboratory
OR	Operational Research
OPC	Out Patient Clinic (HIV)
PEPFAR	The U.S. President's Emergency Plan for AIDS Relief
PMDT	Programmatic Management of Drug resistant TB
PLHIV	People Living with HIV

PTB	Pulmonary tuberculosis
QICA	Quarterly Interim Cohort Analysis
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

1. Executive Summary

The objective of the United States Agency for International Development (USAID)-funded project, Challenge TB (CTB) Vietnam, is to reduce the number of deaths due to TB and TB/HIV co-infection by increasing access to timely and quality assured diagnosis and treatment of TB and MDR TB, especially among vulnerable groups (PLHIV, children, and prisoners). KNCV has the lead in the implementation with World Health Organization (WHO) as the coalition partner. The total budget allocated for CTB in the first year was USD 1,035,000. The total budget for the first year was broken into 2 phases. The first phase with USD 735,000 was approved in February 2015 and the second phase with USD 300,000 was approved in June 2015.

The nine technical areas that have been covered by CTB year 1 in Vietnam are: i) Enabling environment, ii) Comprehensive high quality diagnostic network, iii) Patient centered care and treatment, iv) Infection control, v) Political commitment and leadership, vi) Comprehensive partnerships and informed community involvement, vii) Quality data, surveillance and M&E, viii) Human resource development and ix) overall technical supervision. Several activities of CTB have benefited all 63 provinces across the nation; however, the key focus of the project in APA1 primarily assisted 15 Provinces (4 HIV and TB high prevalence provinces, 9 MDR-TB treatment centers (provinces), and two PMDT satellite provinces). With this coverage in AP1, the Project has supported 38.6 million people in 3,232 communes of 193 districts, an equivalent of 39% Vietnam's total population (2013). Additionally, the Project also continued its support for access to the WHO-approved rapid diagnostic platforms in all 45 provinces within the framework of the PMDT of National Tuberculosis Control Program

The outputs/outcomes from CTB are identified below:

- Building on TB CARE I, the project provided technical assistance and supervision to the rollout of GeneXpert testing for key affected populations in PMDT provinces. These activities were supporting the NTP NSP and GF Concept Note objectives in close coordination with NTP and HIV Program. In addition to the existing 33 GeneXpert systems, 10 new systems have been provided by GF. The total number of tests done with GeneXpert from January – June 2015 was 9,885. From the 9,885 tests done (largely among retreatment patients with presumed MDR-TB), 4,130 (42%) patients were diagnosed with TB of whom 873 (21%) were RR-TB. The introduction and scale-up of the GeneXpert platforms obviously provides a tremendous contribution to the diagnosis of MDR-TB in Vietnam.
- The national circular on biosafety, which was developed in 2012, with inputs by TB CAP and TB CARE I in strengthening biosafety conditions in the TB laboratory system, came into force by January 2015. All laboratories involved in testing for and monitoring of MDR-TB treatment are now required by law to fit the National Technical Standards on lab practice and bio-safety. This urges many laboratories to invest in biosafety measures. The CTB project will provide TA to this work, while capital investments are covered by domestic (or GF) funding. Under TB CARE I laboratories in 20 out of the 45 PMDT provinces received TA from KNCV to upgrade their biosafety status. In CTB APA1, 3 more PMDT provinces of Vinh Long, Dac Lac and Bac Giang with TB culture laboratories received the local CTB/KNCV TA, to be upgraded to bio-safety level 2.
- In follow-up of TB CARE I during which TA was provided to the development and implementation of a national childhood TB policy based on international policy (WHO and The Union), the project provided TA (international and local) to the roll-out and evaluation of the childhood TB work plan for 2015-2020 in 3 more provinces (Hai Duong, Da Nang and Bac Giang) in 2015. Three contact screening and management registers were reviewed and combined into one register. 10,000 copies of this register were printed and distributed for roll-out of child TB contact screening and management in all commune health centers countrywide in quarter 1 of 2015.
- The scale-up of programs for the Programmatic Management of Drug Resistant TB (PMDT) is well under way in Vietnam. CTB/KNCV continued playing an important role in advising and supporting NTP in terms of policy, workplan development, implementation and quality assessment for PMDT

implementation. In March 2015 CTB/KNCV introduced to national and regional supervisors Quarterly Interim Cohort Analysis (QICA), resulting in improvement of patient management by addressing the identified problems in patient management and supportive systems for patients.

- CTB continued the work started under TB CARE I for the introduction of new anti TB drugs (Bedaquiline and Delamanid for pre-XDR and XDR patients and otherwise complicated forms of MDR TB) and shorter MDR TB regimens in 3 provinces (Ha Noi, Ho Chi Minh City and Can Tho). National SOPs and Pharmacovigilance (forms and SOPs) for the safe use of new drugs (which are conditions defined by WHO for countries that introduce the deployment of Bedaquiline (BDQ) and Delamanid (DLM) and shorter MDR TB regimens) were developed. As a result NTP organized trainings on implementation of BDQ in July 2015 and the MDR-TB 9-months regimen in September 2015 in 3 pilot provinces.
- A joint planning workshop on strengthening HIV/TB collaboration activities was organized in Hanoi on August 17-18, 2015 with technical support by a CTB/KNCV senior consultant. This workshop followed a joint assessment on HIV/TB collaboration conducted in June 2015, aimed at identifying prioritized steps towards good quality joint HIV/TB service delivery to feed into GFATM and Challenge TB planning. At national level, the workshop played a crucial role in promoting national coordination, which is essential to reach policy consensus, develop joint strategic plans, mobilize resources, build capacity, and implement and monitor collaborative TB/HIV activities. At local level the presence of comprehensive and linked information and education on TB/HIV is an important step in ensuring community awareness about HIV, TB, the link between them, and the prevention, treatment and care opportunities that are available.
- A needs assessment and situational assessment regarding functioning of the HIV, TB-HIV reporting and recording systems was conducted in collaboration with VAAC and NTP by a CTB/KNCV consultant from 5-9 October 2015. This surveillance system assessment is a follow-up step after the recent assessment mentioned above. While leveraging investments made during TB CARE I in the development of the web based, case based electronic TB surveillance and program management system (VITIMES).
- Based on the good collaboration between KNCV and NTP in the first national TB prevalence survey, CTB/KNCV consultants provided technical assistance to NTP in the development of the 2nd National TB Prevalence Survey (TBPS) protocol and data management plan in collaboration with prevalence survey coordinator, data manager and other stakeholders in June-July 2015. This is an important survey to get a precise estimate of the trend of TB prevalence compared to 2006 and identify novel ways in which TB care and prevention can be improved.

2. Introduction

In Vietnam, the allocated budget for Challenge TB (CTB) project in year 1 (1 January – 30 September 2015 period) was USD 1,035,000 with two implementing partners (KNCV as lead and WHO).

The overall strategy of CTB in Viet Nam is to develop, pilot and evaluate TB care and prevention innovations that are planned under the National Strategic Plan 2015-2020, in close collaboration with the NTP, VAAC, the USAID Mission and partners. After evaluation and ensuring adjustments, the innovations will be mainstreamed by the NTP with domestic and other donor (mainly GF) resources. This approach was shown to be effective during TB CAP and TB CARE I implementation. In this way CTB investments will leverage other resources, while spearheading program innovation. Moreover CTB will ensure effective use of Global Fund investments, by providing technical assistance to the rollout of the innovations. Evidence will be collected to document the operational processes and their impact.

Challenge TB has been collaborating closely with a network of 15 provincial TB and Lung Disease Hospital. These included 9 MDR-TB treatment centers (including 3 provinces overlapping with high HIV prevalence provinces (Hanoi, Vinh Phuc (National Hospital 74), Thanh Hoa, Da Nang, Binh Dinh, Binh Thuan, Ho Chi Minh City, Can Tho, Tien Giang), two PMDT satellite provinces (Thai Binh and Tay Ninh) and four additional provinces with high prevalence of HIV-infection (Hai Phong, Quang Ninh, Dien Bien and An Giang). The project was thus implemented in support of 38.6 million people in 3,232 communes and 193 districts, an equivalent of 39% of Vietnam's total population (2013). Additionally, the project supported the WHO-approved rapid diagnostics for all 45 provinces within the framework of PMDT. Several activities of CTB have benefited all 63 provinces across the nation.

The nine technical areas that have been covered by CTB year 1 in Vietnam are: i) Enabling environment; ii) Comprehensive high quality diagnostic network; iii) Patient centered care and treatment; iv) TB infection control; v) Political commitment and leadership; vi) Comprehensive partnerships and informed community involvement; vii) Quality data, surveillance and M&; viii) Human resource development, and; ix) overall technical supervision.

CTB is led by KNCV Tuberculosis Foundation (KNCV) with WHO as collaborating partner, in sequence of TB CARE I (2010-2015), TB CAP (2008-2010). Coalition partners FHI 360, MSH and PATH are also active in Viet Nam, especially in HIV/AIDS care with other USAID funding. PATH is also a sub recipient of GF funding through NTP under GF Round 9 Phase 2. Close coordination of activities with these partners will take place. The key partners involved in the implementation of Challenge TB at Central level include: National Tuberculosis Control Program, and the Viet Nam Administration of HIV/AIDS Control (HIV/AIDS Program). The project has been collaborating closely with a network of 15 provincial TB and Lung Disease Hospitals with focus on PMDT MDR-TB treatment centers (provinces) and provinces with high prevalence of TB and HIV.

3. Country Achievements by Objective/Sub-Objective

Objective 1. Improved Access

Sub-objective 1. Enabling environment

In this sub-objective, CTB has been focusing on strengthening of the patient centered approach being integrated into routine TB services for all care providers to create a supportive environment: i) assessment of social support needs for TB, MDR-TB and TB/HIV patients, and; ii) Policy discussion with The Ministry of Labor, Invalid and Social Affair (MOLISA).

TB patients often lose means to support the family by being unable to work or by losing their job. As a result, the worsening socio-economic situation coupled with the psychological stress may negatively the outcome of their treatment. The Ministry of Labor, Invalid and Social Affair (MOLISA) of the Government has a scheme to provide social support for the handicapped, and those who are in need of assistance. TB patients are not included in the list so far.

Socio-economic support to patients during the treatment is crucial in order to provide patient-centered care, including to those affected by drug-resistant TB and TB/HIV co-infection.

Although the necessity of social support for TB patients has been globally recognized and patient's needs are clear, information on social support at provincial level is still very limited. A situation analysis is therefore needed to clarify the local situation and the policy discussion with the relevant stakeholders including MOH and MOLISA should follow in order to develop a national policy.

In order to support MDR-TB patient to overcome the difficulties related to social economic factors, a group of experts of the Ministry of Labor, Invalid and Social Affair (MOLISA) in collaboration with NTP conducted a situational and needs assessment and discussed potential collaboration between health facilities and social support network in providing social support for MDR-TB patients. The assessment was implemented in 5 provinces Quang Ninh, Quang Nam, Khanh Hoa, Vinh Long and Can Tho. The study will be completed by the end of October 2015 and will inform the development of a collaborative framework between NTP and the social support systems.

Key Results

- Desk review was completed.
- Data collection in the field is ongoing and reports will be available by November, followed by policy discussion in Dec 2015.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
1.4	Provider side: Patient centered approach integrated into routine TB services for all care providers for a supportive environment	1.4.6 Assessment of social support needs for TB, DR-TB and TB/HIV patients	No	Yes	Yes
		1.4.7. Policy discussion with MOLISA	No	Yes	Policy discussion is planned in Dec 2015

Sub-objective 2. Comprehensive, high quality diagnostics

In Sub-objective 2, CTB focuses on 5 main intervention areas: i) 2.1 Access to quality TB diagnosis ensured; ii) 2.3. Access to quality culture/DST ensured; iii) 2.4. Access, operation and utilization of rapid diagnostics (i.e. Xpert) ensured for priority populations; iv) 2.6. Expedient laboratory specimen transport and results feedback system operational; v) 2.7. Bio-safety measures in laboratories ensured.

2.1 Access to quality TB diagnosis ensured

Under CTB APA1 supervisors from the NTP central (NLH) and regional (PNTH) unit were trained on the (participatory) Diagnostic Cascade Analysis (DCA) in Hanoi City in March 2015. The method enables identification of gaps in implementation of the diagnostic algorithms and enables formulation of focused corrective interventions to increase access to quality TB diagnosis.

In CTB APA2, with KNCV STTA, the NTP will train provincial NTP staff and apply this method in Hanoi, HCM City and Can Tho provinces. KNCV local staff (with distance TA from HQ) will work with the NTP to adjust the NTP's M&E checklists and reporting for integration of this method in the routine NTP (quarterly) monitoring system of the coverage and yield of diagnostic effort for early diagnosis of TB, TB/HIV and MDR-TB.

Figure 1. Training for supervisors from the NTP central (NLH) and regional (PNTH) unit on diagnostic cascade analysis (DCA) and QICA was organized on March 19-20, 2015



2.3. Access to quality culture/DST ensured

Under TB CARE I funding KNCV gained a lot of experience in supporting the introduction of diagnostic algorithms using Xpert testing, not only regarding the laboratory aspects, but especially regarding the uptake by clinicians, in accordance with the national guidelines. Building on this experience the CTB project will support the introduction and rollout of second line resistance testing in all MDR-TB patients, first in 3 selected provinces (Hanoi, HCMC and Can Tho), after evaluation for uptake by the NTP under GF funding, as prioritized in the newly allocated NFM.

Under CTB APA1, the draft advanced diagnostic algorithms and SOPs have been developed that underlie the introduction of new drugs (Bedaquiline) and regimens (9 months for MDR-TB treatment). The workshop to discuss and finalize the draft advanced diagnostic algorithms and SOPs will be conducted in CTB APA2.

2.4. Access, operation and utilization of rapid diagnostics (i.e. Xpert) ensured for priority populations

Through substantial TB CARE I support, Xpert MTB/RIF testing was introduced and rolled out in Vietnam, also providing the necessary management, coordination, cartridge supply management system, recording and reporting and technical support for the routine use of Xpert MTB/RIF. Under CTB KNCV will build capacity of NTP to self-undertake such technical work (troubleshooting, calibration, maintenance) on the GeneXpert system to ensure the sustainability in the implementation and rollout of Xpert MTB/RIF test in Vietnam. This will also minimize the cost of hiring external services for repairs, after the warranty period. TB CARE I has proposed and supported NTP to establish a GeneXpert technical assistance team within NTP and capacity building for this team.

Building on the experience from TB CARE I, CTB APA1 has provided technical assistance and supervision to the rollout of GeneXpert testing patients with presumed MDR-TB, PLHIV with presumed TB and children with presumed TB in provinces with PMDT services.

Table 1. Results of Xpert MTB/RIF implementation in Vietnam

Period	Total tests conducted	Xpert MTB/RIF results									
		MTB(-)		MTB(+)						Error/ indeterminate	
		n	%	Sub-total		MTB(+)/R(-)		MTB(+)\R(+)		n	%
				n	%	n	%	n	%		
Jun-Dec 2012	2,152	563	26.2	1,507	70.0	1,110	73.7	397	26.3	82	3.8
Jan – Dec 2013	7,423	3,010	40.5	4,114	55.4	3,116	75.7	998	24.3	299	4,0
Jan - Dec 2014	21,799	12,524	57.5	8,309	38.1	6,519	78.5	1,790	21.5	966	4.4
Jan – Jun 2015	9,885	5,118	51.8	4,130	41.8	3,257	78.9	873	21.1	637	6.4
Total	41,259	21,215	51.4	18,060	43.8	14,002	77.5	4,058	22.5	1,984	4.8

In addition to the current 43 GeneXpert systems, 20 new GeneXpert systems were provided to the NTP by GF by the end of September. The installation of these systems is planned in the last quarter of 2015. KNCV local staff will co-facilitate with NTP in trainings on GeneXpert implementation in TB/HIV settings in 20 provinces (20 new GeneXpert platforms) in CTB APA2. By the end of 2015, a total of 63 GeneXpert systems will be operational in 46/63 provinces. The rollout of PMDT in all provinces is scheduled under NSP 2016-2020, planned to be completed in 2018.

CTB has contributed to the stable in-country supply of MTB/RIF cartridges through regular review of utilization reports, quantification for orders and shipments, quarterly distribution and reallocation. CTB/KNCV also supported the establishment of and coordination among the NTP's GeneXpert internal technical team to handle technical problems and maintain well-functioning GeneXpert systems. During APA1, various minor problems with Genexpert platforms were effectively handled through remote consultancy by CTB technical team members. Only 20 incidents of technical troubles on 13 machines had to be reported to Cepheid for on-site intervention with a total of 13 modules having been replaced. Three machines in Binh Dinh, Hai Phong and Children No.1 Hospital remained out of work since the beginning of the year due to the unavailability of replacement parts which was held up by the progress of GF NFM Concept Note and the process of procurement procedures between the NTP and Cepheid. For the same reason, only 4 machines have been calibrated during APA1 resulting in all well-functioning modules. The majority of machines are planned to be calibrated in the last quarter of 2015.

CTB/KNCV carried out supportive supervision in improvement of Xpert MTB/RIF utilization in 4 provinces, which were An Giang (April 2015), Tay Ninh (May 2015), Hai Phong and Nghe An (June 2015).

2.6. Expedient laboratory specimen transport and results feedback system operational

Under the TB CARE I project MSH developed a specimen referral system. This TB specimen referral system was intended to support increased access to diagnosis, care and treatment of drug resistant TB. Data reporting, monitoring and evaluation remain a challenge. The indicators for performance of this system have not yet been agreed and are not yet part of the routine NTP monitoring system.

Under CTB APA1, the data collection forms to generate the reports for performance indicators of the specimen transportation system were developed. The pilot phase in 4 selected provinces (Thai Binh, Quang Nam, An Giang and Kien Giang) and evaluation will be conducted in APA2.

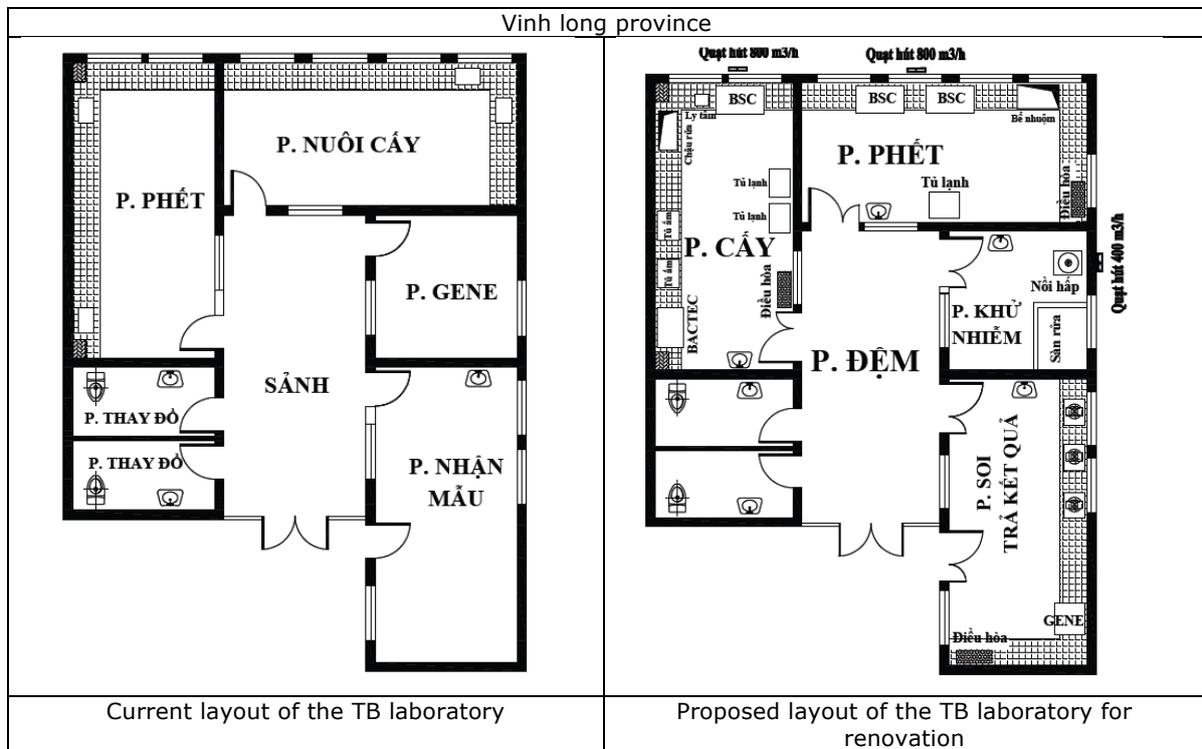
2.7. Bio-safety measures in laboratories ensured

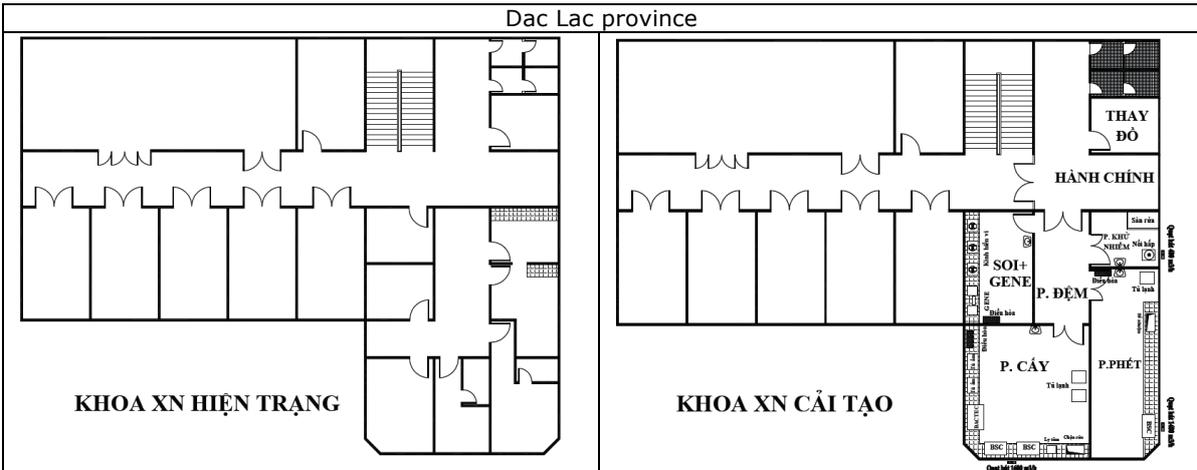
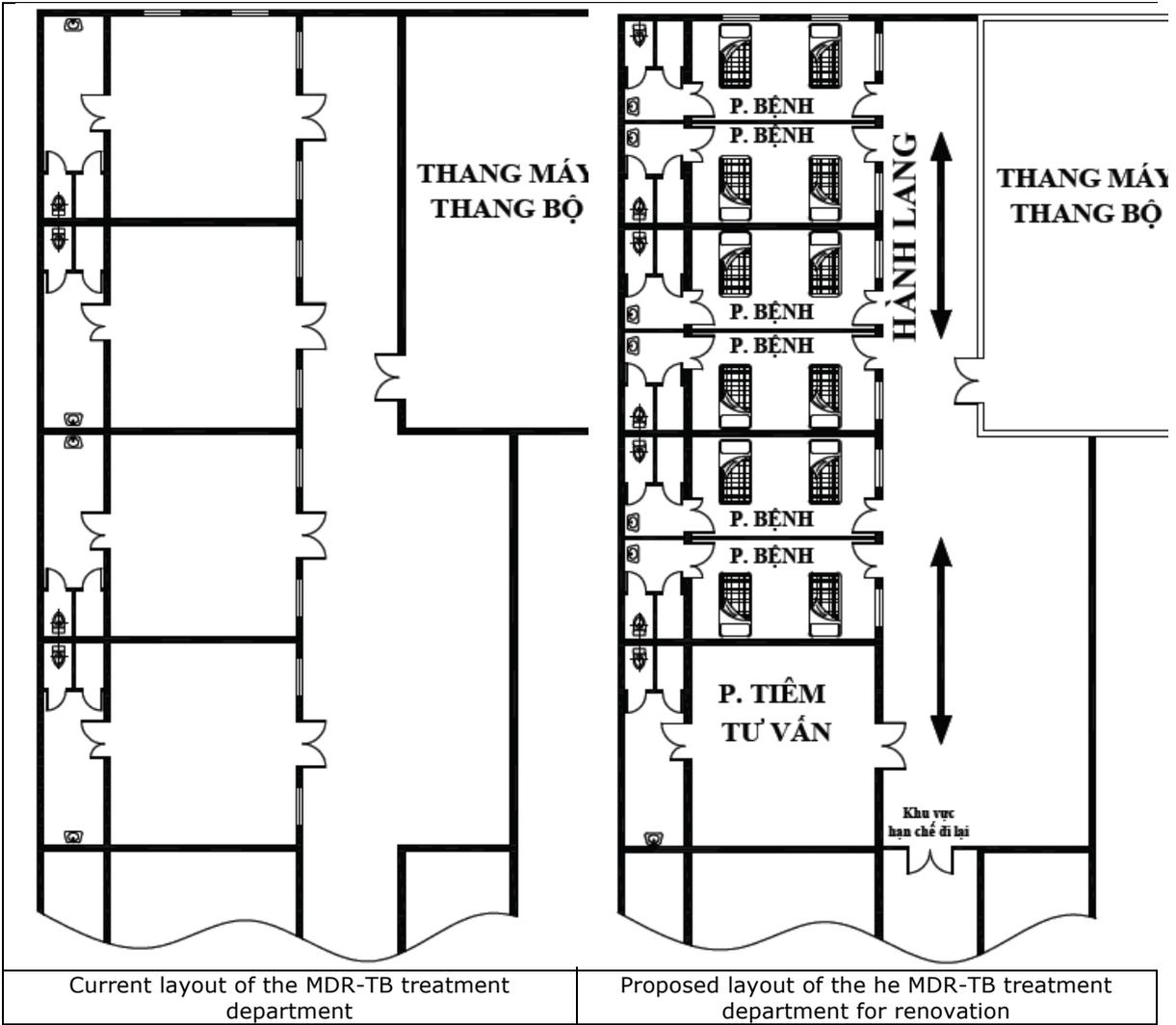
Bio-safety is improved by several interventions: i) improving laboratory facility layout to ensure minimum requirements for biosafety (bio-safety level 2 – BSL2); ii) providing adequate equipment for ensuring the implementation of requested technical tests, and ensuring specifications and maintenance; and iii) establishing a safe working environment through implementation of standard operational procedures and management activities to ensure bio-safety for all laboratory staff.

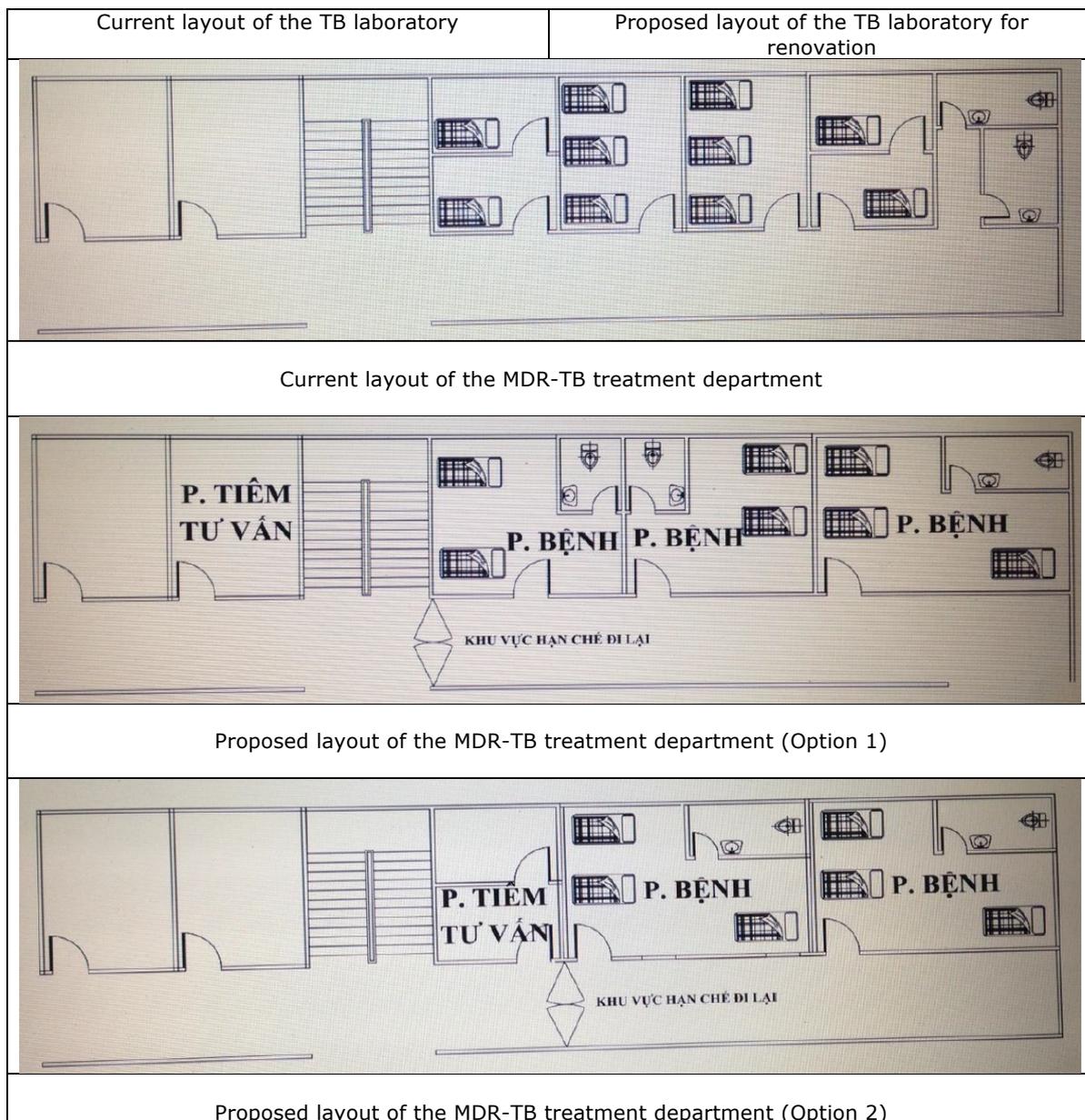
With support by TB CAP and TB CARE I in strengthening of biosafety condition of the TB laboratory system, the national legislation on biosafety for laboratories was updated by the MOH's circular #25 in 2012. This circular came into force by the first of January 2015. All laboratories in the TB laboratory system for diagnosis and monitoring treatment of MDR-TB are now required by law to fit the National Technical Standards on lab practice and bio-safety starting in January 2015. This urges many laboratories to invest in biosafety measures. The CTB project will provide TA to this work, while capital investments are covered by domestic (or GF) funding, as these laboratories are of utmost importance to enable expansion of treatment of MDR TB and this TA ensures effectiveness of the investments from GF and the Government of VN. The laboratories in 20 out of the 45 PMDT provinces received TA from KNCV to upgrade their biosafety status.

Under APA1, 3 more PMDT provinces of Vinh Long, Dac Lac and Bac Giang with TB culture laboratories received local CTB/KNCV TA, to be upgraded to bio-safety level 2. Beside laboratories, MDR-TB treatment departments also received local CTB/KNCV TA to improve TB-IC conditions in support of roll out of PMDT

Figure 2. Local TA to lab biosafety and TB-IC improvement in PMDT provinces (Vinh Long and Dac Lac)







#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target Y1	Result Y1
	2.1. Access to quality TB diagnosis ensured	2.1.3. Number of provinces providing full information on the completeness and yield of their diagnostic algorithms	0 province (2014)	3 provinces (2015)	0 province

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
	2.3. Access to quality culture/DST ensured	2.3.1. % of confirmed TB cases who undergo DST and receive their results, disaggregated by new and previously treated cases	37.1% (2014)	TBD (2015)	70% (16,731/24,031)
		2.3.4. % of confirmed R resistant TB cases who undergo SL DST and receive their results, disaggregated by new and previously treated cases	NA (2014)	TBD (2015)	On-going activity (SL DST for confirmed R cases will be applied in 3 pilot provinces where BDQ & 9 months' regimen is introduced. There is delay due to late arrival of BDQ & clofazimine. It is expected to be implemented in November 2015).
		2.3.5. Number of provinces applying advanced diagnostic algorithms including Xpert, SL Hain and phenotypic SL DST	0 province (2014)	0 provinces (2015)	On-going activity
	2.4. Access, operation and utilization of rapid diagnostics (i.e. Xpert) ensured for priority populations	2.4.1. GeneXpert machine coverage per population (stratified by Challenge TB, other)	2.0M/1 GeneXpert (2014)	1.4M/1Gene Xpert	1.4M/1Gene Xpert
		2.4.2. #/% of Xpert machines that are functional in country (stratified by Challenge TB, other)	100% (2014, 43 machines)	100% (2015, 43 machines)	100% (2015, 43 machines)
	2.6. Expedient laboratory specimen transport and results feedback system operational	2.6.4. # of specimens transported for TB diagnostic services	NA (2014)	TBD (2015)	On-going activity (Data collection will be done in APA2)
		2.6.5. #/% of TB cases detected through a specimen transport system	NA (2014)	TBD (2015)	On-going activity
	2.7. Bio-safety measures in laboratories ensured	2.7.1. #/% of laboratories implementing national biosafety standards (stratified by laboratories performing culture, DST and Xpert)	20 PMDT provinces (2014)	25 PMDT provinces (2015, cumulative)	23 PMDT Provinces (2015, cumulative)

Sub-objective 3. Patient-centered care and treatment

Patient-centered care and treatment (PACT) is an important sub-objective of the by CTB project in support of implementation and roll out of the new WHO policy in management of TB in children, PMDT

and introduction of new TB drugs (Bedaquiline) and regimen (9 months for MDR-TB treatment), and strengthening of TB/HIV care.

3.1 Ensured intensified case finding for all risk groups by all care providers

With substantial support from TB CARE I, Vietnam is among the first countries in the world to implement and scale up the WHO recommended strategy in management of TB in children with focuses on: i) the implementation of child TB contact screening and management at the communal health care level; ii) Offer isoniazid preventive therapy (IPT) – 6 months of daily isoniazid at 10 mg/kg/day or 6H for child contacts aged <5 and children having HIV (once TB excluded) at communal (primary care) health center level; iii) supporting and improving clinical diagnosis of children with suspected TB at the district hospital level; iv) NTP engage the child health care sector.

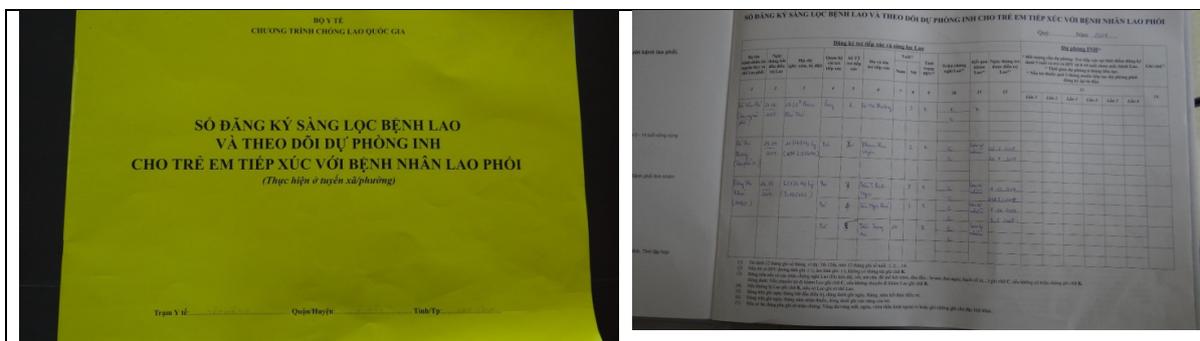
In 2014, with TB CARE I support, the national work plan for roll-out of the strategy in management of TB in children in 2015-2020 period was developed and included in the NTP National Strategic plan for 2015-2020 which has been approved by the MOH and included in the Global Fund Concept Note under the New Funding Model in 2014. With the clear goal, objectives and targets in the national workplan for rollout 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. The overall objectives are to strengthen: i) advocacy, communication and social mobilization in childhood TB control; ii) early detection and treatment for childhood TB; iii) child TB contact management; iv) monitoring and evaluation; and v) research. Targets have been set and include: i) increase the proportion of child TB nationally to 6% in 2020; ii) treatment success rate >90% from 2016; and iii) at least 80% eligible child contacts receive IPT.

A new strategy has been successfully piloted in 4 provinces with high TB and HIV burden since 2012. The success of this new strategy has resulted in this strategy becoming a model for the NTP to roll out to 9 other provinces with Global Fund support include Nam Dinh, Hung Yen and Khanh Hoa (2013), Hai Phong, Dong Nai and Binh Thuan (2014) and Hai Duong (2015) with Da Nang and Bac Giang to be included before end 2015.

In 2015, the CTB project provided TA (international and local) to the rollout and evaluation of the childhood TB work plan for 2015-2020.

For the previous pilot implementation, three registers were developed and in use at the communal health center: i) a contact screening register, ii) an IPT register and iii) a referral register. With technical and financial support by CTB, these registers were combined into one contact screening register (please see Fig 3 below). More than 10,000 copies of the new TB contact screening and management register were printed and distributed for roll-out of child TB contact screening and management in all commune health centers in the country in quarter 1 of 2015.

Figure 3. The new TB contact screening and management register



The Table 2 below shows data on screening and management of contacted children from quarter 4 of 2012 to quarter 1 of 2015 in 4 pilot provinces. 9,741 children having close contact with patients who are sputum smear positive were screened and registered for the management. Of these children, 3,858 children are eligible for (IPT), and 289 children (3%) have signs of TB who were suspected and moved to a higher level for TB diagnosis. In those eligible, around two-thirds accepted to take IPT and adherence to date to 6 months of IPT is quite high. At the same period, 715 pediatric patients with TB of all forms were detected. Among those, 14% were sputum smear-positive 47% were sputum smear-negative and 39% were extra-pulmonary TB (EPTB) would strongly suggest that there was not a problem of over-diagnosis in those with "sputum smear negative" or smear not done pulmonary TB (PTB). Epidemiological data for child TB would expect that around 5% are sputum smear-positive and around 30% have EPTB.

Table 2. Results of community TB contact screening and TB case detection in 4 pilot provinces in Viet Nam, Q4-2012 – Q1-2015

Child contacts screened (<15 years)	9,741
Symptomatic children referred	289 (3%)
Eligible for IPT i.e. < 5 years and no TB	3,858
Numbers received IPT (% eligible)	2,514 (65%)
IPT course completion to date	N=1,154
N (%) full IPT adherence to date	964 (84%)
Children diagnosed with TB	715
Sputum smear positive PTB	99 (14%)
Sputum smear negative PTB	336 (47%)
EPTB	280 (39%)

Since 2011, a senior paediatric TB consultant (Prof. Steve Graham) has been engaged in STTA to the implementation and roll out of novel child TB care and prevention activities in Vietnam. Beside the monitoring and supervision by NTP staff, in September 2015, the consultant, KNCV office staff and NTP carried out the monitoring mission to review progress in the roll-out by NTP to other provinces of the community-based contact screening intervention with field visits in Nam Dinh and Hai Phong. Operational issues and techniques in the implementation were discussed and recommended.

The registers and quarterly reporting forms were developed and these contain demographic and management data of the contacts identified through community-based screening.

Data in the registers and quarterly reporting forms, which were developed and these contain demographic and management data of the contacts identified through community-based screening is collected in 4 pilot provinces in CTB APA1. This data will be analyzed and disseminated in APA2. Data from this pilot will provide original data of global relevance as this project represents the first attempt to implement community-based contact screening on a large scale in a TB endemic, resource-limited setting and well as lesson learned as the Vietnam NTP aims to roll out the community-based contact screening to nationwide in 2015

Figure 4. Monitoring visit conducted by Prof. Steve Graham, KNCV and NTP staff on childhood management of TB at commune level in Nam Dinh and Hai Phong provinces, from 14-16 September 2015



3.2. Access to quality treatment and care ensured for TB, MDR-TB and TB/HIV for all risk groups by all care providers.

CTB/KNCV plays an important role in advising and supporting NTP in terms of policy, workplan development, implementation and quality assessment for PMDT implementation including introduction of new TB drugs and regimens and rollout.

Quality of MDR-TB care

The scale-up of PMDT is well under way in Vietnam. Increasing numbers of patients with MDR-TB are diagnosed and start treatment: from 101 MDR-TB patients treated in 2009 to 1.533 patients in 2014. In most countries the scale-up of PMDT implies decentralization of the responsibility for MDR-TB diagnosis and treatment to provinces and even districts. MDR-TB care is transitioning from often small, hospital based pilot projects to nationwide management of MDR-TB, applying ambulatory models of care with facility based treatment initiation and back-up. During the scale-up health workers struggle to maintain the quality of care, necessary to make treatment a success. NTP's struggles to organize and maintain the supporting systems for PMDT include: laboratory services and sample transportation networks, procurement and supply management for SLTB drugs, ancillary drugs, psycho-socio-economic support for patients, psychological support to health care workers, recording and reporting etc. The WHO Second line drug register is an invaluable source of information to assess patient management and identify problems in care delivery. While the cohort analysis is widely used for this goal in basic DOTS programs, in PMDT this has been neglected, resulting in less than comprehensive treatment provision with high rates of treatment interruption. Next to intensifying monitoring and supervision and other interventions aimed at strengthening of PMDT, the optimization of the use of the SLTB register at the responsible treatment facility level is needed to improve both patient relevant outcomes and the reliability of MDR-TB data for better PMDT. Doing regular PMDT cohort reviews is the key to early identification of problems in service delivery and for monitoring of action plans for improvement of the services.

MDR-TB treatment quality will be improved by introducing a combination of clinical audit meetings and quarterly interim cohort analysis (QICA) resulting in improvement of patient management and addressing the identified problems in patient management and supportive systems for patients and health workers. Under APA1 the QICA method with additional clinical audits was introduced to the NTP and national and regional level NTP supervisors. The training on QICA method was organized in March 2015.

Under APA2 the project will monitor and provide TA to the implementation of the method in the three key treatment centers in Hanoi, HCMC and Can Tho, which are also involved in the use of new drugs and shorter MDR regimens. The NTP plans to include this in their routine program monitoring and supervision activities.

Introduction of new TB drugs and regimens

In APA1, CTB continued the work started under TB CARE I for the introduction of new anti TB drugs (Bedaquiline and Delamanid for pre-XDR and XDR patients and otherwise complicated forms of MDR TB) and shorter MDR TB regimens in 3 provinces (Ha Noi, Ho Chi Minh City and Can Tho).

CTB/KNCV HQ and local have provided TA to NTP to develop and finalize the guidelines, SOPs and Pharmacovigilance (forms and SOPs) for the safe use of new drugs which are conditions defined by WHO for countries that introduce the deployment of Bedaquiline (BDQ) and Delamanid (DLM) and shorter MDR TB regimens. NTP organized the trainings on implementation of BDQ in July 2015 and MDR-TB 9 months regimen in September 2015 in 3 pilot provinces of Hanoi, HCMC and Can Tho. The first patient expected initiating BDQ in early November 2015.

Figure 5. Training on BDQ implementation the HCMC (one of 3 pilot provinces), 29-31 July 2015



Strengthen TB-HIV collaboration activities

At provincial and district levels, the extent of collaboration and joint programming vary considerably depending provinces and districts: while all districts have TB treatment sites, treatment sites for HIV are limited (approximately 200 districts have HIV care OPC) and very few districts have joint TB/HIV service delivery. Cross referral between TB service and HIV service is the national strategy. However referral is weak in practice, with a substantial number of patients are lost between referral and linkage to care. Currently, the mechanisms for data sharing between the two programs are limited.

In June 2015, in collaboration with Viet Nam Administration of HIV/AIDS Control (VAAC), NTP and other partners (WHO, FHI, etc.), CTB/KNCV senior external consultants carried out an assessment of the system of HIV/TB collaboration. The stakeholders workshop was organized with participation of NTP and VAAC leaders and staff, representatives of the provincial health service, TB hospital and PAC

in 5 provinces (Hanoi, Bac Giang, Hai Phong, Nghe An and HCMC) and partners to discuss the situational assessment, barriers to access and identify the most appropriate interventions for planning under Global Fund and Challenge TB year 2.

Figure 6. Assessment of TB-HIV collaborative activities and stakeholders' workshop, 15-26 June 2015



After the assessment CTB/KNCV organized a joint planning workshop on strengthening HIV-TB collaboration activities was organized in Hanoi on August 17-18, 2015 with technical support by CTB \ KNCV's senior consultant. This workshop is under the framework of supportive interventions to strengthen HIV/TB collaboration of KNCV funded by USAID (Challenge TB project). The workshop is aimed at identifying prioritized steps towards good quality joint HIV/TB service delivery based on June HIV TB assessment to feed into GFATM and Challenge TB planning. Quite a few key action points were reached: 1. Establish the mechanisms for collaboration. HIV control programs may be performing activities and collecting data of interest for TB control program management, and vice versa: information on program management and patient management must flow between the programs; 2. Review recording and reporting system of TB and HIV programs and work out a monitoring mechanism for both programs. Establishing standard indicators and reporting and recording templates supports the streamlining of M&E processes; 3) Provide the means to assess the quality, effectiveness, coverage and delivery of services to ensure continual health improvement.

At national level, the workshop played a crucial role in promoting national coordination. A functioning mechanism that can coordinate the activities of the TB and HIV control programs is critical for Vietnam. The absence of such a mechanism may cause a lack of commitment to TB/HIV collaboration and may prevent successful national implementation of such activities.

At local level the presence of comprehensive and linked information and education on TB/HIV is an important step in ensuring community awareness about HIV, TB, the link between them, and the prevention, treatment and care opportunities that are available.

TB palliative care

MDR-TB in Viet Nam is on the rise. A part of the patients cannot be cured with the available treatment options. In such cases, palliative care together with infection control at households is necessary to support the patients and prevent the transmission in the community. CTB supported NTP to develop capacity through trainings on palliative care/end of life care in 3 pilot provinces (all three priority areas for MDR TB and HIV) (Sept – Oct 2015). Impact of training will be followed through monitoring and assessment of performance of piloting health care providers (Nov – Dec 2015).

Pre-XDR and XDR-TB patients will be treated by Bedaquiline together with the current treatment regimen in 3 pilot provinces. For those patients who are not eligible for treatment, palliative care is crucial to support them to overcome the end-of-life disease as well as to prevent the transmission. Palliative care training is provided to TB staff followed by technical monitoring missions in these provinces.

Training on palliative care implementation has been organized in Ha Noi, HCMC and Can Tho in Sep – Oct 2015. Monitoring will be organized in Dec 2015.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
	3.1. Ensured intensified case finding for all risk groups by all care providers	3.1.7. Childhood TB approach implemented (0=childhood TB is not mentioned in the NTP Strategic Plan; 1=Childhood TB is in the strategic plan, but no activities are implemented on childhood TB; 2=activities are being piloted or are implemented in select sites; 3=childhood TB is an integral part of the NTP strategic plan and regular activities nationwide.)	2.5 (2014, childhood TB is an integral part of the NTP strategic plan and regular activities in selected provinces)	3 (2014)	3

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
		3.1.8. % of TB cases (all forms) diagnosed among children (0-14)	1.2% (2014)	1.5% (2015)	615 (1.5%)
		3.1.5. #/% health facilities implementing intensified case finding (i.e. using SOPs)	NA	This indicator will be reported in APA2	
	3.2. Access to quality treatment and care ensured for TB, DR TB and TB/HIV for all risk groups from all care providers	3.2.9. % of MDR-TB patients still on treatment and culture negative 6 months after starting MDR-TB treatment	66% (cohort 2013)	70% (cohort 2014)	>70%
		3.2.10. #/% of planned cohort reviews conducted	NA (2014)	2 pilot provinces for QICA (2015)	On-going (The pilot will be implemented in APA2)
		3.2.27 % MDR-TB treatment sites implement palliative care/end of life care for DR TB patients Description: Indicator Value: percentage Level: national Means of Verification: report/ monitoring Numerator: # of MDR-TB treatment sites implement activity Denominator: total # of trained MDR-TB treatment sites	0 (2014)	100% (2015: 3 pilot provinces)	On-going activity. Will accomplish by Dec 2015

Objective 2. Prevention

Sub-objective 5. Infection control

TB infection control (TB-IC) is one of important technical area that is focused by CTB project in support of the roll-out of PMDT at provincial and district levels and joint TB-HIV services at district level. In APA1, CTB supported NTP and VAAC with strengthening a TB-IC facility program, improving TB-IC health facilities, and TB-IC surveillance establishment and maintenance.

5.1. Compliance with quality TB-IC in health care, community and congregate settings ensured.

A pilot for joint TB/HIV service provision is ongoing in Ninh Binh and Thai Binh (1 district each province, since 2014) with an additional 5 provinces (12 districts) in 2015 under the GF NFM concept note. People living with HIV are very vulnerable to the risk of nosocomial TB transmission. The increasing threat of multi-drug resistant TB (MDR-TB) among PLHIV, and the drive towards joint TB/HIV services provision in district health facilities means that it is essential that TB infection control policies are being implemented.

With TB CARE I support NTP developed the TB-IC facility improvement program consisting of 3 stages: i) Training on TB-IC knowledge and skills for NTP staff at provincial and district level; ii) TB-IC facility assessment with technical support by higher level (provincial and national levels) and development of TB-IC facility plans; iii) implementation of TB-IC facility plans.

CTB supported, in collaboration with NTP and VAAC, TB-IC training for 199 (male: 99, female: 100) TB and HIV staff (OPC, VCT, methadone clinics) at provincial and district level in Ninh Binh in September 2015. The TB-IC training for other 4 provinces and other stages of TBIC facility improvement program will be conducted in APA2.

Figure 7. TBIC training for TB and HIV staff (OPC, VCT, methadone clinics) at provincial and district level in Ninh Binh, 9-11 September 2015



In APA1, CTB provided technical support to NTP in improvement of TBIC conditions in three PMDT provinces in order to scale up PMDT. CTB/KNCV 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 (the Global Fund). Three MDR-TB treatment departments are being renovated and will be put into use in 2015 that helps expand the diagnosis of MDR-TB (please see figure 2)

5.2. TB surveillance among HCW ensured.

NTP selected 4 indicators for collecting and monitoring of TB-IC activities (% of HCW with TB among all HCW annually, % of health facilities with TB-IC plan, % of health facilities with IC focal person and % of staff caring for MDR-TB patients/working in culture/DST section of laboratory that is provided at least 1 respirator /week). As a stepwise approach, these indicators will be collected in all TB/lung disease hospitals at national and provincial level to NTP's district and commune level and to all facilities (outside NTP). Data collection forms should be developed, pre-tested and adapted for each level before including in VITIMES.

In APA1, the TB-IC data sheets were collected in 67 TB units at national and provincial level and in more than 850 TB units. Data will be analyzed and reported in quarter 1 of CTB year 2.

Table 3. Annual reporting on TB disease (all forms) among HCWs n 67 TB units at central and provincial levels in 2009–2013 period

Year	Total number of health care workers	Total no. of HCWs having TB of all forms	Rate per 100.000
2009	6,134	32	522
2010	6,514	31	476
2011	6,989	19	272
2012	7,544	20	265
2013	7,779	23	295

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
	5.2. TB surveillance among HCW ensured	5.2.1. Status of TB disease monitoring among HCWs	2 (2014)	3 (2015)	3
	5.1. Compliance with quality TB-IC measures in health care, community and congregate settings ensured	5.1.1. Status of health facility TB-IC (0=no TB IC guidelines & no organized TB-IC activities; 1=national, WHO-aligned TB-IC guidelines disseminated; 2=TB-IC implemented in select sites; 3=TB-IC implemented nationally and/or nat. cert. prog. implemented)	NA	2	3

Objective 3. Strengthened TB Platforms

In this objective, CTB provides TA to NTP to develop and include TB diagnosis and treatment services in the national Health Insurance System.

Sub-objective 7. Political commitment and leadership

The TB services in Viet Nam are undergoing drastic changes in the service delivery systems. To make the TB program sustainable and to contribute to the Universal Health Coverage, TB services will be covered by the Health Insurance system. The circular on the provision of health services under the National Health Insurance (NHI) prioritizes the accessibility to TB services. The circular promotes early TB case detection and a patient-centered approach to TB treatment.

To maintain the NTP's achievements and contribute to the Universal Health Coverage, TB diagnosis and treatment services will be covered by the national health insurance system. While the basic TB services are sustained in the country, there are possible risks that some of other necessary TB services including training, monitoring and supervision, and research may not be financially covered by the available health insurance scheme. The development of a roadmap for TB financing in transitional period (2016-2020) may help NTP prioritizing the government and donor support in the future.

These are the key results:

- Outline of situation analysis developed;
- Meeting with NTP key persons and relevant ministries and person-in-charge is being prepared;
- Data collection has been starting;
- Final report will be available by December 2015.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
	7.2. In-country political commitment strengthened	7.2.3. Financial assessment tool for budget allocation at national and provincial level developed and validated Description: Indicator Value: Yes Level: National Means of Verification: report, monitoring	No	Yes	No. (This activity was canceled due to late receiving CTB\WHO budget (30 June 2015) there for it is difficult to invite qualified consultant and implement activity)
		7.2.4. A Plan of funding mechanism for TB control during transitional period (shifting from National target program to HI and donor exit duration) drafted Description: Indicator Value: Yes Level: national Means of Verification: Report	No	Yes	Yes. On-going activity. Will accomplish by Dec 2015

Sub-objective 8. Comprehensive partnerships and informed community involvement

The close involvement of CTB with the NTP and GF and the presence of different international partners in HIV/TB care and prevention require regular project reviews and joint planning necessary, especially when new plans are made. The annual project review and planning working session with participation of the MOH (HIV program), NTP and partners was conducted to discuss on NTP and CTB activities in APA1, to identify the gaps and technical areas to be included in APA2.

KNCV and WHO country staff carried out monitoring and supervision of the CTB project implementation alongside with NTP NSP, and GF NFM implementation.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
	8.1. National partnership and coordinating bodies functioning with appropriate representation and capacity	8.1.4. Annual project review and planning meeting Description: Annual project review and planning meeting Indicator Value: Yes Level: National Source: NTP/Challenge TB Means of Verification: Challenge TB report Numerator: Denominator:	Yes (2014)	Yes (2015)	Yes (2015)

Sub-objective 10. Quality data, surveillance and M&E

The sub-objective of quality data, surveillance and M&E under CTB year 1 focuses on provision of TA to the following areas: i) eTB Manager implementation and roll out; ii) strengthening the TB and HIV surveillance system; and iii) the 2nd national TB prevalence survey.

10.1. Well-functioning case or patient-based electronic recording and reporting system is in place.

eTB Manager

The introduction of e-TB Manager (e-TBM) as the PMDT's electronic patient and program management system started in 2010 and is expanding to 45 among 63 provinces. Although it has improved the MIS for MDR-TB, there are some technical constraints encountered in the field settings as well as operational errors. Technical assistance is provided by IT experts to fix problems and develop the linkage between test results (Gene Alert system). The final report will be available by end Nov 2015.

HIV and TB surveillance system

This activity aims to develop a joint TB/HIV electronic recording and reporting system (through interoperability or integration), that would improve patient relevant outcomes by enabling case-based monitoring of the diagnostic and treatment processes for LTBI, TB and HIV, while supporting service provision by generating accurate health information for management purposes and accurate data for joint TB/HIV surveillance (while safeguarding patients privacy).

A needs assessment and situational assessment regarding functioning of the HIV, TB-HIV reporting and recording systems was conducted in collaboration with VAAC and NTP by CTB/KNCV consultant from 5-9 October 2015. This surveillance system assessment is a follow-up step after the recent assessment of HIV/TB collaboration and identification of barriers to care and the identification of strategies for further development and strengthening of comprehensive HIV-TB case management and control. The expected deliverables are to present several options for the future of recording and reporting for HIV (and TB/HIV) based on the situational and needs assessment.

For TB the overview is clear cut. Reporting and recording starts at the District TB Units (DTU), who report to the Provincial TB&LD hospitals, who report to NTP. All susceptible TB patients are recorded in VITIMES and all MDR-TB patients are recorded in eTB-Manager. Both systems are used for local patient management as well as national reporting and the NTP is responsible for system and data management. Currently, the NTP is in development of a linkage to exchange patient level data between VITIMES and eTB-Manager.

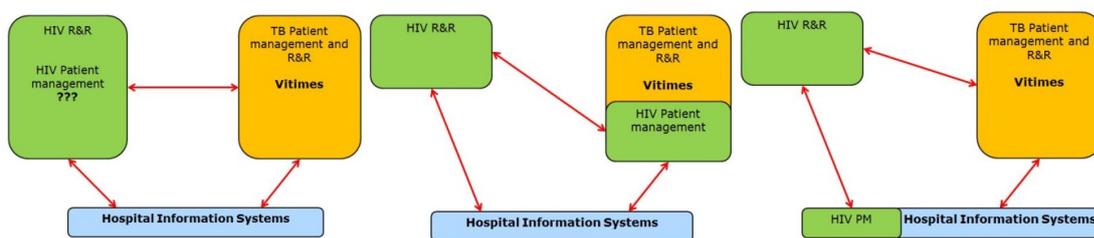
For HIV recording and reporting, the overview is a bit more complicated. National reporting and recording starts at the District Health Centers (DHC), which report to the Provincial AIDS Coordinator (PAC), who reports to the VAAC at national level. There are two main systems in place for national recording and reporting. Circular 03 for reporting of aggregated indicators for all aspects of the HIV program and Circular 09 (HIV info 3.0) for case-based patient management of HIV positive persons.

Due to separate funding mechanisms in the past, there are several systems in use (and in pilot) for the main part of the HIV program – Out Patient Clinics (OPC), Voluntarily Counseling and Testing (VCT), Methadone clinic and Harm reduction - at the district level. For patient management within the OPC there are currently three systems in use namely (1) electronic Patient Monitoring System (ePMS) developed and supported by VAAC, WHO, CHAI and CDC, (2) e-logbook developed and supported by FHI360 and USAID, (3) Eclinica 1.0 developed and supported by CDC, CHAI and iTECH. At the VCT sites there are two systems in place namely; Preven (also used for harm reduction) and e-logbook VCT. For the Methadone Maintenance Treatment (MMT) clinics there are three systems/tools for case management and medication management in place namely, (1) OSCAR and (2) EMMT logbook, both supported by USAID SMARTTA and (3) standardized Excel templates used by SCMS sites. Next to these systems there are several noteworthy system in place that do not fit the previous categories well. For patient referral between TB and HIV clinics a system called Access to Care information System (ACIS) is used and Master Patient Index (MPI) is a supportive system in place used for patient identification between clinics in HIV care. The last category of systems to mention is the Hospital

Information System (HIS). Most hospitals have a custom-build system in place, primarily developed for financial management.

Based on this assessment, there are three noteworthy models for the near future of HIV (and TB/HIV) recording and reporting (see figure 3): (1) a parallel recording and reporting system for HIV and TB with linkage between both systems as well as with the hospital management systems; (2) Integration of HIV patient management within the IT infrastructure for susceptible TB (VITIMES), while still making use of the national recording and reporting systems in place for HIV and with a linkage to the hospital management information systems; (3) Integration of HIV patient management within the hospital management systems while still making use of the national recording and reporting system in place for HIV and with linkage to the TB recording and reporting systems.

Figure 8. Models for the future of HIV (and TB/HIV) recording and reporting.



The main advantage and strength of having separate systems in place for TB and HIV is that the ownership of the software will stay with the organization that is responsible for the program. This allows for a high level of customization for specific programmatic needs while still allowing for interoperability between applications e.g. online-online (web service), online-offline (in-software synchronization) and offline-offline (connector). As long as patient care for TB and HIV patients is separated, the need for an integrated software solution for patient management as well as national recording and reporting is not crucial. Interoperability between (disease) program specific software can provide in the needed data exchange between the TB and HIV programs.

Independently of the model used in the future, the different systems used for all aspects of the HIV program at district level should be minimized without sacrificing any specific functionality. Modular integration of the specific functionalities within one system currently used for HIV patient management would be ideal.

Leveraging investments under TB CARE I in the development of the web based, case based electronic TB surveillance and program management system (VITIMES), the CTB project will engage all stakeholders in the realization of interoperability or (partial) integration of the TB and HIV eR&R systems. Over the duration of the Challenge TB project such a system will be developed and implemented.

10.2. Epidemiologic assessments conducted and results incorporated into national strategic plans

In 2006-2007 the first national TB prevalence survey took place, showing a higher than expected TB burden. In the following years NTP introduced additional efforts to increase detection of all forms of TB such as PPM, PAL, intensified case finding in PLHIV, cough screening of patients attending in OPD, Childhood TB, active case finding in prisons, while sustaining the routine NTP services and introducing PMDT.

A WHO re-estimation of the TB burden in Vietnam was done in January 2013. With Vietnam embarking on an ambitious 15-year plan to reduce the epidemic to a prevalence level of 20/100,000 in 2030, it is important to measure the situation after 10 years. This will allow measuring the trend of TB

prevalence between the first and second survey as an indicator for the impact of the combination of public health interventions and demographic and socio-economic changes over the past 10 years. The second survey point prevalence will provide the base line and other essential information for the design and funding of the two-phase elimination strategy. With Vietnam aiming to be one of the first Asian countries to go into the TB elimination phase, documenting the Vietnamese experience will be an important contribution to the global elimination effort.

Figure 9. Working sessions to discuss and finalize the outlines of the 2nd National TB Prevalence Survey protocol and data management plan, June 29 – July 3, 2015



On June 29 – July 3, 2015, Challenge TB senior consultants provided technical assistance to NTP in development of the 2nd National TB Prevalence Survey (TBPS) protocol and data management plan in collaboration with prevalence survey coordinator, data manager and other stakeholders. The main topics for TBPS protocol development were discussed and agreed including: i) Define roles and responsibilities; ii) sampling methodology and sampling frame screening and diagnostics algorithms; iii) digitalization of data collection and management processes; iv) data management tools to be used (hardware and software); v) data management procedures for all levels involved. The outlines the protocol and data management plan and budget estimation will be finalized for GFATM submission with NTP early August. The detailed protocol will be finalized and ready for MOH approval in Q4 2015.

The field data collection is expected to start in the second half of 2016. This is an important survey to get a precise estimate of the current burden of TB disease compared to 2006 and to identify ways in which TB control can be improved.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
	10.1. Well-functioning case or patient-based electronic recording and reporting system is in place	10.1.1. #/% of PMDT sites reporting consistently via the ERR	50% (2014)	100% (2015)	On-going activity. Will accomplish by Dec 2015
		10.1.4. Status of electronic R&R (0=R&R system is entirely paper-based; 1=electronic reporting to national level, but not patient/case-based or real time; 2= patient/case-based ERR system implemented in pilot or select sites (TB or MDR-TB); 3=a patient/case-based, real-time ERR system functions at national and subnational levels for both TB and MDR-TB)	2 (2014)	3 (2015)	3
	10.2. Epidemiologic assessments conducted and results incorporated into national strategic plans	10.2.4. #/% of operations research, evaluation or epidemiological assessment study results disseminated (stratified by level of dissemination: report, presentation, publication)	3 (2014)	1 (2015)	1 (2015) On-going

Sub-objective 11. Human resource development

A training on ATS Methods in Epidemiologic, Clinical and Operational Research (MECOR) was jointly organized by NTP, Challenge TB/KNCV and Woolcock Institute of Medical Research Vietnam, from 8 – 14 March, 2015 in Da lat. 39 trainees participated (29 female and 10 male) including 2 Cambodian, 1 Laos and 36 Vietnamese, 2 trainees from NTP and 2 from KNCV Vietnam.

There are 2 levels where students learn to develop a complete research protocol. At the last day of the course, each group and individuals presented their protocol work for feedback and inputs from lecturers and other students to improve their protocol.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y1	Y1
	11.1. Qualified staff available and supportive supervisory systems in place	11.1.3. # of healthcare workers trained, by gender and technical area	20 (2014)	20 (2015)	39 (2015)

4. Challenge TB Support to Global Fund Implementation

Current Global Fund TB Grants

Name of grant, year signed, & principal recipient(s) (e.g., Tuberculosis NFM - 2014 - MoH)	Average Rating*	Current Rating	Total Approved Amount	Total Disbursed to Date	Total expensed (if available)
The GFATM Round 9 for TB Control in Vietnam (2011-2015)	A2	A2	51,206,435 USD	41,896,4731 USD	Data is not available as of 30/6/2015

In-country Global Fund status - key updates, current conditions, challenges and bottlenecks

Vietnam is among 8 countries in the high impact Asia cluster, which are encouraged to be more ambitious than other countries in their targets. The GF contribution to Vietnam in 2014-2017 is \$192m (HIV 77m [including \$10m for HSS], TB \$53m (including \$20m incentive funding), Malaria \$15m, HSS \$32m and Regional Artemisinin Initiative (RAI) \$15m). In 2014, \$33m was disbursed out of \$45m planned. Relative to the allocation, expenditure was 18% within 25% of time elapsed.

For the TB grant, negotiations are essentially completed with minor fine-tuning of the PSM plan and budget. The budget as it stands now provides for important training in support of an ambitious scale up of PMDT to treat 2,200 MDR-TB patients in 2015, 2,500 in 2016 and 2,900 in 2017 as per the Concept Note targets thus reaching a 100% of national targets and 60% of the needs. Unfunded quality demand is registered on the GF website for about \$29m for TB (down from \$49m as \$20m was provided for incentive funding) and includes the budget for the TB prevalence survey.

Strengths: Global Fund grant implementation is integrated into the national TB program structure, i.e. in the NTP secretariat, under the NTP management board, together with other international projects; GF has not created parallel implementation structures.

The National TB Strategy 2014-2020, vision 2030 was approved by the Prime Minister in March 2014. The National Strategic Plan 2016-2020 was approved by the MOH and included in the joint concept note for the Global Fund NFM for the period 2015-2017.

Challenges: there is considerable uncertainty, to what extent Vietnam will be able to mobilize additional national resources to maintain the gains in TB control and address the challenges.

For 2015, the GFATM project contained two periods: the 1st one started from 1 Jan - 30 Jun with the continued implementation of Phase 2, Round 9 activities. The 2nd period started from 1 Jul with the beginning of the activities approved under the TB/HIV Concept Note, New Funding Mechanism (NFM)

- 1st period (1 January – 30 June): 5,504,924 USD
- 2nd period (1 July – 31 December): 11,358,823 USD

The work plan for the first 6 months of 2015 was approved by the GFATM on 17 Mar 2015 with the main activities being focused on Preventive treatment and TB treatment, TB/HIV, TB in congregate settings, MDR TB, health information system, M&E and strengthening community network. There were 9 implementing partners, which included PATH, Center for Community Health Development (CCHD), Farmers Union (FU), Military Medical University (MMU), Ministry of Public Security (MOPS), FIND, KNCV Tuberculosis Foundation and Center for Health Studies, Consultation and Support (RDH).

Until 30 June 2015, most activities have been completed as per the work plan and several activities encountered delay. These included procurement activities (only when procurement plan was approved by the MOH on 26 June 2015 could the following procedures be processed) and several activities taken by new partners (contract negotiation and signing took a long time), etc.

Regarding the 1 July – 31 December 2015 period, the final versions of all required documents has been submitted to the GFATM and the proposal for budget supplement and reallocation has been submitted to the Ministry of Planning and Investment. At present, the Cooperation Framework Agreement is expected to be signed between GFATM and the Government of Vietnam, granting the budget for the coming 6 months.

Challenge TB involvement in GF support/implementation, any actions taken during Year 1

Under GF CCM in Vietnam, WHO is a member of CCM and the oversight committee. Under GF CCM, TB sub-group, WHO is a chair of the CCM TB sub-group and KNCV is member. Both WHO and KNCV actively involved in all GF CCM and GF CCM TB sub-group meetings, discussions.

Challenge TB activities are focused on provision of technical assistance to different components or projects in NTP, particularly the different components of the NTP/Global Fund project. In CTB APA1, CTB provided TA to and CTB country team was actively involved in implementation of major components/modules under GF round 9 (first 6 months 2015) and GF NFM Concept Note (last 6 months) in support GF project implementation as follows:

- Creating an enabling environment with assessment of social support needs for TB, DR-TB and TB/HIV patients;
- Enhancing a comprehensive high quality diagnostic network with training on the diagnostic cascade analysis (DCA), development of advanced diagnostic algorithms and SOPs, Xpert MTB/RIF implementation and roll-out, improvement of laboratory bio-safety in PMDT provinces;
- Strengthening patient centered care and treatment with roll-out of management of TB in children, improvement of quality MDR-TB treatment, introduction of new TB drugs (BDQ) and regimens (9 month regimen for MDR-TB), assessment on HIV/TB collaboration, TB palliative care;
- Strengthening TB infection control with improvement of TB-IC conditions in three PMDT provinces in order to scale up PMDT; annual data collection for TB-IC monitoring;
- Strengthening political commitment and leadership by developing a draft plan of funding for TB control during transitional period;
- Strengthened quality data, surveillance and M&E with eTB-manager implementation and roll out, strengthening the TB and HIV surveillance system and development of the protocol for the second TB prevalence survey.

5. Challenge TB Success Story

In 2015, the project continued supporting the successful roll-out and evaluation of the childhood TB work plan for 2015-2020 in 3 more provinces (Hai Duong, Da Nang and Bac Giang), besides the four supported under TB CARE I. Vietnam is among the first countries in the world to implement and scale up the WHO recommended strategy in management of TB in children. This strategy has become a model for the NTP to roll out to 6 more provinces with Global Fund support in 2013-2014.

In late 2014 and early 2015, NTP in collaboration with CTB reviewed and adjusted 3 registers, which were developed and in use at the communal health centers in TB CARE I and combined into one a new TB contact screening and management register. 10,000 copies of this register were printed and distributed for rollout of child TB contact screening and management in all commune health centers countrywide in quarter 1 of 2015.

Community contact screening activity was now implemented. Vietnamese children will be diagnosed and treated earlier for TB, and will have access to IPT.

6. Operations Research

Not applicable - no OR conducted in APA1.

7. Key Challenges during Implementation and Actions to Overcome Them

Administratively, the main challenge has been the transition from TB CARE I to Challenge TB and moving from one technical framework to another. However, the Challenge TB team is successfully managing the project as expected.

The CTB workplan was approved in February 2015 and the additional budget for TB-HIV was approved in June 2015. The fund for WHO activities arrived late (30 June 2015). Time for project implementation is limited.

Technically, for the establishment of the patient-centered TB services, both medical services and social support are crucial in order to detect infectious cases and put them under appropriate care as early as possible. Although the importance in collaboration between crosscutting sectors is well recognized amongst all stakeholders, coordination between the different ministries can be challenging.

Challenge TB activities are focused on provision of technical assistance to different components or projects in NTP, particularly the different components of the NTP\Global Fund project. However, the Global Fund budgeted for NTP in 2015 was approved late. Challenge TB activities were delayed in implementation due to the late start of GF activities.

8. Lessons Learnt/ Next Steps

Comprehensive high quality diagnostic network: GeneXpert experiences & lessons for care and coordination:

- Early SLD planning and procurement to ensure adequate drugs for patients is a condition for success;
- Presence of MDR-TB treatment sites with qualified staff, well prepared facilities, uninterrupted FL&SLDs supply and quarterly interim cohort analysis is critical to ensure quality of treatment for patients;
- Intensive monitoring & supervision of progress of implementation, identify obstacles & solutions is key;
- Monthly PMDT/GeneXpert TWG meetings have been instrumental for coordination, management, discussion and solution for implementation and technical issues.

Patient centered care and treatment: Management of TB in children lessons:

- 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 leadership of the Provincial Department of Health is critical for maintaining the collaboration of health facilities in management of childhood TB;
- R&R forms and registers should be updated and more simplified for convenience of use at commune level;
- There is need for integration of data on childhood TB in the NTP surveillance system;
- There is a need for IEC to enhance awareness and gain cooperation of the population and HCWs from non-NTP sites on preventive therapy for children;
- The commune health worker needs to be provided with the skills and IEC materials in order to support preventive therapy.

Annex I: Year 1 Results on Mandatory Indicators

MANDATORY Indicators

Please provide data for the following mandatory indicators:

2.1.2 A current national TB laboratory operational plan exists and is used to prioritize, plan and implement interventions.	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Score as of September 30, 2015	2	N/A	None	
2.2.6 Number and percent of TB reference laboratories (national and intermediate) within the country implementing a TB-specific quality improvement program i.e. Laboratory Quality Management System	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Number and percent as of September 30, 2015	0% (0/2)	N/A	None	
2.2.7 Number of GLI-approved TB microscopy network standards met	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Number of standards met as of September 30, 2015	Not evaluated	N/A	None	The evaluation using the special checklist is scheduled in November 2015 with participation of NRL, NTP and CTB (NRL & NTP is not available in October)
2.3.1 Percent of bacteriologically confirmed TB cases who are tested for drug resistance with a recorded result.	National 2014	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Percent (new cases) , include numerator/denominator	27.3% (13,590/49,844)	NA	Limited	Numerator is available for Xpert test only and aggregated from the

Percent (previously treated cases) , include numerator/denominator	92.9% (8,209/8,837)	NA		monthly reports on Xpert MTB\RIF test in 2014
Percent (total cases) , include numerator/denominator	37.1% (21,799/58,681)	69.6% (16,731/24,031)		
3.1.1. Number and percent of cases notified by setting (i.e. private sector, pharmacies, prisons, etc.) and/or population (i.e. gender, children, miners, urban slums, etc.) and/or case finding approach	National 2014	CTB 2014	CTB APA 1 investment	Additional Information/Comments
Number and percent	Total: 102,128 Childhood TB: 1,918 (1.9%)	Total: 42,331 Childhood TB: 615 (1.5%)	Limited	
3.1.4. Number of MDR-TB cases detected	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Total 2014	1,702	NA	Limited	NTP can only provide this information
Jan-Mar 2015	887 (Only Xpert MTB\RIF)	NA		
Apr-June 2015	U	NA		
Jul-Sept 2015	U	NA		
To date in 2015	0	0		
3.2.1. Number and percent of TB cases successfully treated (all forms) by setting (i.e. private sector, pharmacies, prisons, etc.) and/or by population (i.e. gender, children, miners, urban slums, etc.).	National 2013 cohort	CTB 2013 cohort	CTB APA 1 investment	Additional Information/Comments
Number and percent of TB cases successfully treated in a calendar year cohort	Getting from WHO	Total: 38,205 (88.8%) Childhood TB: U	Limited	CTB invested very limited for management TB in children. Data on childhood TB is not available in the NTP RR system

3.2.4. Number of MDR-TB cases initiating second-line treatment	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Total 2014	1522	U	Limited	Data for Jun-Sep 2015 is incomplete. Data in CTB is not available in NTP RR system
Jan-Mar 2015	371	U		
Apr-June 2015	516	U		
Jul-Sept 2015	345	U		
To date in 2015	1232	0		
3.2.7. Number and percent of MDR-TB cases successfully treated	National 2012 cohort	CTB 2012 cohort	CTB APA 1 investment	Additional Information/Comments
Number and percent of MDR-TB cases successfully treated in a calendar year cohort	Getting from WHO	U	Limited	National 2012 cohort: 503 (71%). Data in CTB sites is not available in NTP
5.2.3. Number and % of health care workers diagnosed with TB during reporting period	National 2014	CTB 2014	CTB APA 1 investment	Additional Information/Comments
Number and percent reported annually	U	U	Limited	National 2013: 23 (0.3%). Annual data for 2014 will be available by end 2015
6.1.1.1. Number of children under the age of 5 years who initiate IPT	National 2014	CTB 2014	CTB APA 1 investment	Additional Information/Comments
Number reported annually	2,134	1,205	Limited	
7.2.3. % of activity budget covered by private sector cost share, by specific activity	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments

Percent as of September 30, 2015 (include numerator/denominator)	N/A	NA	None	This indicator is not applicable. Partners involved in the implementation of Challenge TB Project at Central level include: National Tuberculosis Control Program, the Vietnam Administration of HIV/AIDS Control. In addition, Challenge TB has been collaborating closely with a network of 15 governmental provincial TB and Lung Disease Hospitals. Challenge TB hasn't been collaborating with private sector.
8.1.3. Status of National Stop TB Partnerships	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Score as of September 30, 2015	3	N/A	None	
8.1.4. % of local partners' operating budget covered by diverse non-USG funding sources	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Percent as of September 30, 2015 (include numerator/denominator)	N/A	NA	None	No local Partners
8.2.1. Global Fund grant rating	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Score as of September 30, 2015	A1	N/A	Limited	
9.1.1. Number of stock outs of anti-TB drugs, by type (first and second line) and level (ex, national, provincial, district)	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Number as of September 30, 2015	0	0	Limited	NTP performance review report 2014

10.1.4. Status of electronic recording and reporting system	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Score as of September 30, 2015	3	N/A	Limited	
10.2.1. Standards and benchmarks to certify surveillance systems and vital registration for direct measurement of TB burden have been implemented	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Yes or No as of September 30, 2015	No	N/A	None	
10.2.6. % of operations research project funding provided to local partner (provide % for each OR project)	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Percent as of September 30, 2015 (include numerator/denominator)	N/A	NA	None	Currently no collaboration exists with local research partners. Challenge TB however closely collaborates with the VN Universities for capacity building and joint activities in support of operational research in VN
10.2.7. Operational research findings are used to change policy or practices (ex, change guidelines or implementation approach)	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Yes or No as of September 30, 2015	N/A	NA	None	Currently no collaboration exists with local research partners. Challenge TB however closely collaborates with the VN Universities for capacity building and joint activities in support of operational research in VN
11.1.3. Number of health care workers trained, by gender and technical area	CTB APA 1	CTB APA 1 investment	CTB APA 1 investment	Additional Information/Comments
		Limited	Limited	

	# trained males APA 1	# trained females APA 1	Total # trained in APA 1	Total # planned trainees in APA 1
1. Enabling environment			0	
2. Comprehensive, high quality diagnostics			0	
3. Patient-centered care and treatment	28	44	72	60
4. Targeted screening for active TB			0	
5. Infection control	99	100	199	160
6. Management of latent TB infection			0	
7. Political commitment and leadership			0	
8. Comprehensive partnerships and informed community involvement			0	
9. Drug and commodity management systems			0	
10. Quality data, surveillance and M&E			0	
11. Human resource development			0	
Other (explain)			0	
Other (explain)			0	
Grand Total	127	144	271	220
11.1.5. % of USAID TB funding directed to local partners	National APA 1	CTB APA 1	CTB APA 1 investment	Additional Information/Comments
Percent as of September 30, 2015 (include numerator/denominator)	N/A	NA	None	Challenge TB is working with many local governmental partners, who are not directly paid by the project

Annex II: Status of EMMP activities

Year 1 Mitigation Measures	Status of Mitigation Measures	Outstanding issues to address in Year 2	Additional Remarks
<p>Challenge TB will provide necessary precautions on environmental impacts through the technical assistance provided (training, on-site technical assistance and on-the-job training and monitoring) to support proper storage, distribution, and handling of Gene Xpert cartridges.</p>	<p>On-site technical assistance and on-the-job training was provided to NTP staff at national and provincial level during monitoring and supervision of the Xpert MTB\RIF activities.</p>		
<p>Challenge TB will contribute to NTP trainings GXP implementation in TB & HIV settings. The training will address management of waste from Xpert MTB\RIF, which is included in the NTP guidelines on Xpert MTB\RIF implementation.</p> <p>Challenge TB will also support bi-annual supervision of GXP sites; adequate focus will be made to make sure that the waste from Xpert MTB\RIF test is managed according to the MOH's Decree No. 43/QD-BYT, on 30 November 2007, on medical waste management.</p>	<p>20 new GeneXpert systems are arrived the country in October 2015. Training on Xpert MTB\RIF implementation including management of waste will be organized in quarter 4 2015</p>		