

**CHALLENGE TB** 

ANNUAL REPORT YEAR 4

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FRONT COVER: 14-year-old Sabir sought care from 5 private doctors and suffered for 22 days before he went to a Challenge TB site in Surat. There our project staff helped him to finally get diagnosed and treated. He is one of 11,993 children tested by Challenge TB with GeneXpert in India this year.

Photo: Ren Phillips/FINIT









Challenge TB is USAID's flagship TB care and prevention project. It is implemented by a unique coalition of nine international organizations.

LED AND MANAGED BY KNCV Tuberculosis Foundation

#### **COALITION PARTNERS**

The Union

American Thoracic Society (ATS)

FHI 360

Interactive Research & Development (IRD)

International Union Against Tuberculosis and Lung Disease (The Union)

Japan Anti-Tuberculosis Association (JATA)

Management Sciences for Health (MSH)

PATH

World Health Organization (WHO)

### **ABBREVIATIONS**

ACF aDSM	Active Case-Finding Active Drug Safety Monitoring	MoH MSH	Ministry of Health Management Sciences for Health
ATS	Active Drug Salety Monitoring  American Thoracic Society	MTB	Mycobacterium Tuberculosis
ART	Antiretroviral Therapy	ND&R	New Drugs & Regimens
BDQ	Bedaquiline	NTP	National TB Program
	Community-Based DOTS	NTRL	National TB Reference Laboratory
CCM	Country Coordinating Mechanism	OPD	Outpatient Department
C/DST	Culture & Drug Susceptibility Testing	OPD	Operations Research
Cl	Contact Investigation	PEPFAR	
CP	Contact investigation Community Pharmacist	PLPFAR	President's Emergency Plan for AIDS
CTB	,	PLHIV	Provider Initiated Counseling and Testing
DLM	Challenge TB Delamanid	PLHIV	People Living with HIV
DOTS	Directly Observed Treatment Shortcourse	PPIA	Programmatic Management of Drug-Resistant TB
DPPM	District Public Private Mix	PPIA	Private Provider Interface Agency Public-Private Mix
DPPIMI DR		PPSA	
	Drug-Resistant		Patient Provider Support Agency
DSMB	Data Safety and Monitoring Board	QI DED	Quality Improvement
DST	Drug-Susceptibility Testing	RFP	Request for Proposals
EPHI	The Ethiopian Public Health Institute	RR	Rifampicin-Resistant
FAST	Finding, Actively, Separating, Treating	SAE	Severe Adverse Event
GF	Global Fund	SL-DST	Second-Line Drug Susceptibility Testing
GDI	Global Drug-Resistant TB Initiative	SL-LPA	Line Probe Assay for Second-Line Drugs
GLC	Green Light Committee	SNRL	Supranational Reference Laboratory
HCW	Health Care Worker	SOP	Standard Operating Procedure
HIV	Human Immunodeficiency Virus	STR	Shorter Treatment Regimen
ICF	Intensified Case-Finding	STTA	Short-term Technical Assistance
IPT	Isoniazid Preventive Therapy	TB	Tuberculosis
ITR	Individualized Treatment Regimen	UNSE	UN Special Envoy
IRD	Interactive Research and Development	USAID	United States Agency for International Development
JATA	Japan Anti-Tuberculosis Association	WHO	World Health Organization
MDR	Multidrug-resistant	WoW	Wellness on Wheels
MDU	Mobile Diagnostic Unit		



# CONTENTS

ALTERNATIVE SUMMARY	ESSAGE FROM THE PROJECT DIRECTOR	6
AJOR CHALLENCES  19 PRORT DEVELOPMENT  9 PRORT DEVELOPMENT  9 PHAT IS CHALLENGE TB?  10 EY ACHIEVEMENTS  13 CASE-INDING, TREATMENT, AND CARE  14 CONTACT INVESTIGATION  15 COMMUNITY REFERRAL  17 ACTIVE CASE-FINDING  19 CHILDHOOD TB  27 CHILDHOOD TB  27 CHILDHOOD TB  28 CHILDHOOD TB  29 CHILDHOOD TB  20 CHILDHOOD TB  21 TREATMENT OUTCOMES  26 MANAGING GENEXPERT SCALE-UP  27 NUMBER OF MACHINES ELIVENCTIONALITY, AND UTILIZATION  29 DIAGNOSTIC CONNECTIVITY  31 NUMBER OF SPECIMENS TRANSPORTED  32 DIAGNOSTIC CONNECTIVITY  33 NUMBER OF SPECIMENS TRANSPORTED  34 SECOND-LINE LPA  NUMBER OF SPECIMENS TRANSPORTED  35 SECOND-LINE LPA  NUMBER OF SPECIMENS TRANSPORTED  36 NUMBER OF SPECIMENS TRANSPORTED  37 DEVELOPMENT TO TRANSPORTED  38 DEVELOPMENT TO TRANSPORTED  39 TREATMENT OUTCOMES FOR NOBR  40 AND TREATMENT OUTCOMES FOR NOBR  41 ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT  42 TB/HIV  43 JUCCESS STORY - HOPE AND HEALING  44 LOBAL FUND  45 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  46 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  47 ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT  48 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  49 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  40 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  41 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  42 TB/HIV  43 JUCCESS STORY - HOPE AND HEALING  44 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  45 JUCCESS STORY - HOPE AND HEALING  46 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  47 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  48 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  49 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  49 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  40 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  41 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  42 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  43 JUCCESS STORY - HOPE AND HEALING  44 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  45 JUCCESS STORY - HOPE AND HEALING  46 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  47 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  48 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  49 ASSISTANCE TO GLOBAL FUND IMPLEME	KECLITIVE SLIMMARY	7
### STORY DEVELOPMENT    9		
### PROPRET DEVELOPMENT  ### IS CHALLENGE TB?  ### IS CASE-RINDING, TREATMENT, AND CARE  ### IS CHALLENGE TB.		
HAT IS CHALLENGE TB?  10. PY ACHIEVEMENTS. 135 CASE FINDING, TREATMENT, AND CARE 144 CONTACT INVESTIGATION 155 COMMUNITY REFERRAL 177 ACTIVE CASE FINDING 197 CHILDHOOD TB 192 HOSPITAL ENGAGEMENT 223 JUCCESS STORY - THE DRESSMAKERS TALE 224 TREATMENT OUTCOMES 226 MANAGING GENEXPERT SCALE-UP 227 NUMBER OF MACHINES FUNCTIONALITY, AND UTILIZATION 228 JUCCESS STORY - SMALL WONDERS 235 JUCCESS STORY - SMALL WONDERS 236 JUCCESS STORY - SMALL WONDERS 237 JUCCESS STORY - MORE AND RECOMMENDED RAPID DIAGNOSTIC TEST 37 JUCCESS STORY - MORE AND RECOMMENDED RAPID DIAGNOSTIC TEST 37 JUCCESS STORY - MORE AND RECOMMENDED RAPID DIAGNOSTIC TEST 37 JUCCESS STORY - HOPE AND HEALING 347 JUCCESS STORY - HOPE AND HEALING 447 JUCCESS STORY - HOPE AND HEALING 547 JULY - MORE AND JUL	FPORT DEVELOPMENT	9 9
SECOND-LINE LPA   SECOND-LINE LENGES   SECOND-LIN		
CASS-FINDING, TREATMENT, AND CARE	HAT IS CHALLENGE TB?	10
CASS-FINDING, TREATMENT, AND CARE	EY ACHIEVEMENTS	13
CONTACT INVESTIGATION         15           COMMUNITY REFERRAL         17           ACTIVE CASE-FINDING         19           CHILDHOOD TB         22           HOSPITAL ENCAGEMENT         23           JCCESS STORY - THE DRESSMAKER'S TALE         24           TREATMENT OUTCOMES         26           MANAGING GENEXPERT SCALE-UP         27           NUMBER OF MACHINES, FUNCTIONALITY, AND UTILIZATION         28           DIAGNOSTIC CONNECTIVITY         31           INUMBER OF SPECIMENS TRANSPORTED         32           JCCESS STORY - SMALL WONDERS         35           SECOND-LINE LPA         36           NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST         37           PMDT AND NEW DRUGS AND REGIMENS         38           DR-TER BOTTIFICATION AND TREATMENT         39           TREATMENT OUTCOMES FOR ND&R         40           ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT         42           JCCESS STORY - HOPE AND HEALING         44           LOBAL FUND         46           ASSISTANCE TO GLOBAL FUND IMPLEMENTATION         47           GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS         47           OUNTRY HIGHLIGHTS         49           ORE PROJECTS         74<	CASE-FINDING, TREATMENT, AND CARE	14
COMMUNITY REFERRAL		
ACTIVE CASE-FINDING CHILDHOOD TB HOSPITAL ENGAGEMENT		
CHILDHOOD TB         22           HOSPITAL ENGAGEMENT         23           JCCESS STORY - THE DRESSMAKERS TALE         24           TREATMENT OUTCOMES         26           MANAGING GENEXPERT SCALE-UP         27           NUMBER OF MACHINES FUNCTIONALITY, AND UTILIZATION         28           DIAGNOSTIC CONNECTIVITY         31           NUMBER OF SPECIMENS TRANSPORTED         32           JCCESS STORY - SMALL WONDERS         35           SECOND-LINE LPA         36           NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST         37           PMDT AND NEW DRUGS AND REGIMENS         38           DR-TB NOTHIFICATION AND TREATMENT         39           DR-TB NOTHIFICATION AND TREATMENT         39           DR-TB NOTHIFICATION AND TREATMENT         40           ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT         42           TB/HIV.         43           JCCESS STORY - HOPE AND HEALING.         44           LOBAL FUND         46           ASSISTANCE TO GLOBAL FUND IMPLEMENTATION         47           GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS         47           OUNTER PROJECTS         74           UNIS SPECIAL ENVOY FOR TB         75           INDIA         76		
HOSPITAL ENGAGEMENT		
JOCCESS STORY - THE DRESSMAKER'S TALE       24         TREATMENT OUTCOMES       26         MANAGING GENEXPERT SCALE-UP       27         NUMBER OF MACHINES, FUNCTIONALITY, AND UTILIZATION       28         DIAGNOSTIC CONNECTIVITY       31         NUMBER OF SPECIMENS TRANSPORTED       32         JOCCESS STORY - SMALL WONDERS       35         SECOND-LINE LPA       36         NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST       37         PMDT AND NEW DRUGS AND REGIMENS       38         DR-TB NOTIFICATION AND TREATMENT       39         TREATMENT OUTCOMES FOR NDRR       40         ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT       42         TB/HIV       43         JCCESS STORY - HOPE AND HEALING       44         LOBAL FUND       46         ASSISTANCE TO GLOBAL FUND IMPLEMENTATION       47         GLOBAL FUND IMPLEMENTATION CHALLENGES       47         GLOBAL FUND IMPLEMENTATION       76         PREVENTION       76         PREVENTION		
TREATMENT OUTCOMES  MANAGING GENEXPERT SCALE-UP  NUMBER OF MACHINES, FUNCTIONALITY, AND UTILIZATION  27  NUMBER OF MACHINES, FUNCTIONALITY, AND UTILIZATION  28  DIAGNOSTIC CONNECTIVITY  31  NUMBER OF SPECIMENS TRANSPORTED  32  JCCESS STORY - SMALL WONDERS  35  SECOND-LINE LPA  NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST  37  PMDT AND NEW DRUGS AND REGIMENS  38  DRTEB NOTIFICATION AND TREATMENT  39  TREATMENT OUTCOMES FOR ND&R  40  ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT  42  JCCESS STORY - HOPE AND HEALING  44  LOBAL FUND  45  ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  GLOBAL FUND IMPLEMENTATION CHALLENGES  47  GLOBAL FUND IMPLEMENTATION CHALLENGES  47  GLOBAL FUND IMPLEMENTATION CHALLENGES  47  GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS  47  DUNTRY HIGHLIGHTS  49  ORE PROJECTS  49  ONTRIBUTION TO SCIENCE  80  ONCLUSIONS & NEXT STEPS  81		
MANAGING GEREXPERT SCALE-UP  NUMBER OF MACHINES FUNCTIONALITY, AND UTILIZATION  28 DIAGNOSTIC CONNECTIVITY  31 NUMBER OF SPECIMENS TRANSPORTED  32 JCCESS STORY - SMALL WONDERS  35 SECOND-LINE LPA  NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST  57 PMDT AND NEW DRUGS AND REGIMENS  38 DRTE B NOTIFICATION AND TREATMENT  39 TREATMENT OUTCOMES FOR ND&R  40 ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT  42 JCCESS STORY - HOPE AND HEALING  43 JCCESS STORY - HOPE AND HEALING  44 LOBAL FUND  ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  47 GLOBAL FUND IMPLEMENTATION CHALLENGES  47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS  47 DUNTRY HIGHLIGHTS  49 ORE PROJECTS  40 DONE PROJECTS  41 BEDAQUILINE COORDINATION  79 PERATIONS RESEARCH  80 ONTRIBUTION TO SCIENCE  80 ONCLUSIONS & NEXT STEPS  81	JCCESS STORY - THE DRESSMAKER'S TALE	24
NUMBER OF MACHINES, FUNCTIONALITY, AND UTILIZATION		
DIAGNOSTIC CONNECTIVITY.  NUMBER OF SPECIMENS TRANSPORTED  32  JCCESS STORY - SMALL WONDERS  SECOND-LINE LPA  NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST  PMDT AND NEW DRUGS AND REGIMENS  SABDATE IN CONTINCATION AND TREATMENT  39  TREATMENT OUTCOMES FOR ND&R  ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT  42  TB/HIV  43  JCCESS STORY - HOPE AND HEALING  44  LOBAL FUND  45  ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  47  GLOBAL FUND IMPLEMENTATION CHALLENGES  47  GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS  47  OUNTRY HIGHLIGHTS  49  ORE PROJECTS.  UN SPECIAL ENVOY FOR TB.  INDIA  PREVENTION.  76  PREVENTION.  77  MEASURING STIGMA  BEDAGUILINE COORDINATION.  79  PERATIONS RESEARCH.  80  ONCLUSIONS & NEXT STEPS.  81	MANAGING GENEXPERT SCALE-UP	27
DIAGNOSTIC CONNECTIVITY.  NUMBER OF SPECIMENS TRANSPORTED  32  JCCESS STORY - SMALL WONDERS  SECOND-LINE LPA  NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST  PMDT AND NEW DRUGS AND REGIMENS  SABDATE IN CONTINCATION AND TREATMENT  39  TREATMENT OUTCOMES FOR ND&R  ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT  42  TB/HIV  43  JCCESS STORY - HOPE AND HEALING  44  LOBAL FUND  45  ASSISTANCE TO GLOBAL FUND IMPLEMENTATION  47  GLOBAL FUND IMPLEMENTATION CHALLENGES  47  GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS  47  OUNTRY HIGHLIGHTS  49  ORE PROJECTS.  UN SPECIAL ENVOY FOR TB.  INDIA  PREVENTION.  76  PREVENTION.  77  MEASURING STIGMA  BEDAGUILINE COORDINATION.  79  PERATIONS RESEARCH.  80  ONCLUSIONS & NEXT STEPS.  81	NUMBER OF MACHINES, FUNCTIONALITY, AND UTILIZATION	28
NUMBER OF SPECIMENS TRANSPORTED  32  JCCESS STORY - SMALL WONDERS  35  SECOND-LINE LPA  NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST  77  PMDT AND NEW DRUGS AND REGIMENS 38  DR-TB NOTIFICATION AND TREATMENT 39  TREATMENT OUTCOMES FOR ND&R 40  ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT 42  TB/HIV 43  JCCESS STORY - HOPE AND HEALING. 44  LOBAL FUND 46  ASSISTANCE TO GLOBAL FUND IMPLEMENTATION 47  GLOBAL FUND IMPLEMENTATION CHALLENGES 47  GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47  OUNTRY HIGHLIGHTS 49  ORE PROJECTS 49  ONE PROJECTS 40  ONE PROJECTS 40	DIAGNOSTIC CONNECTIVITY	31
SECOND-LINE LPA		
NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST	JCCESS STORY - SMALL WONDERS	35
NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST	CECOND LINE LDA	74
PMDT AND NEW DRUGS AND REGIMENS	SECOND-LINE LPA	50
DR-TB NOTIFICATION AND TREATMENT 39 TREATMENT OUTCOMES FOR ND&R 40 ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT 42 TB/HIV. 43  JCCESS STORY - HOPE AND HEALING 44  LOBAL FUND 46 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION 47 GLOBAL FUND IMPLEMENTATION CHALLENGES 47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47  OUNTRY HIGHLIGHTS 49  ORE PROJECTS 74 UN SPECIAL ENVOY FOR TB 75 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79  PERATIONS RESEARCH 80  ONTRIBUTION TO SCIENCE 80  ONCLUSIONS & NEXT STEPS 81  A11		
TREATMENT OUTCOMES FOR ND&R ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT 42 TB/HIV. 43  JCCESS STORY - HOPE AND HEALING. 44  LOBAL FUND. 46 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION 47 GLOBAL FUND IMPLEMENTATION CHALLENGES. 47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47  OUNTRY HIGHLIGHTS. 49  ORE PROJECTS. 49  ORE PROJECTS. 74 UN SPECIAL ENVOY FOR TB 175 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79  PERATIONS RESEARCH. 80  ONTRIBUTION TO SCIENCE 80  ONCLUSIONS & NEXT STEPS. 81		
ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT . 42 TB/HIV. 43  JCCESS STORY - HOPE AND HEALING . 44  LOBAL FUND . 46 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION . 47 GLOBAL FUND IMPLEMENTATION CHALLENGES . 47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS . 47  OUNTRY HIGHLIGHTS . 49  ORE PROJECTS . 74 UN SPECIAL ENVOY FOR TB . 75 INDIA . 76 PREVENTION . 77 MEASURING STIGMA . 78 BEDAQUILINE COORDINATION . 79  PERATIONS RESEARCH . 80  ONTRIBUTION TO SCIENCE . 80  ONCLUSIONS & NEXT STEPS . 81		
TB/HIV 43  JCCESS STORY - HOPE AND HEALING. 44  LOBAL FUND 46  ASSISTANCE TO GLOBAL FUND IMPLEMENTATION 47  GLOBAL FUND IMPLEMENTATION CHALLENGES 47  GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47  OUNTRY HIGHLIGHTS 49  ORE PROJECTS 74  UN SPECIAL ENVOY FOR TB 75  INDIA 76  PREVENTION 77  MEASURING STIGMA 78  BEDAQUILINE COORDINATION 79  PERATIONS RESEARCH 80  ONTRIBUTION TO SCIENCE 80  ONCLUSIONS & NEXT STEPS 81		
JCCESS STORY - HOPE AND HEALING.  LOBAL FUND  ASSISTANCE TO GLOBAL FUND IMPLEMENTATION 47 GLOBAL FUND IMPLEMENTATION CHALLENGES. 47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47 OUNTRY HIGHLIGHTS 49 ORE PROJECTS 74 UN SPECIAL ENVOY FOR TB 75 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79 PERATIONS RESEARCH 80 ONTRIBUTION TO SCIENCE 80 ONCLUSIONS & NEXT STEPS 81		
LOBAL FUND. 46 ASSISTANCE TO GLOBAL FUND IMPLEMENTATION 47 GLOBAL FUND IMPLEMENTATION CHALLENGES 47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47  OUNTRY HIGHLIGHTS 49  ORE PROJECTS 74 UN SPECIAL ENVOY FOR TB 75 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 77  PERATIONS RESEARCH 80  ONTRIBUTION TO SCIENCE 80  ONCLUSIONS & NEXT STEPS 81	TB/HIV	43
ASSISTANCE TO GLOBAL FUND IMPLEMENTATION 47 GLOBAL FUND IMPLEMENTATION CHALLENGES 47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47 OUNTRY HIGHLIGHTS 49 ORE PROJECTS 74 UN SPECIAL ENVOY FOR TB 75 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79 PERATIONS RESEARCH 80 ONTRIBUTION TO SCIENCE 80 UB-AWARDS 81	JCCESS STORY - HOPE AND HEALING	44
ASSISTANCE TO GLOBAL FUND IMPLEMENTATION 47 GLOBAL FUND IMPLEMENTATION CHALLENGES 47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47 OUNTRY HIGHLIGHTS 49 ORE PROJECTS 74 UN SPECIAL ENVOY FOR TB 75 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79 PERATIONS RESEARCH 80 ONTRIBUTION TO SCIENCE 80 UB-AWARDS 81	LORAL FLIND	46
GLOBAL FUND IMPLEMENTATION CHALLENGES 47 GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS 47  OUNTRY HIGHLIGHTS 49  ORE PROJECTS 74 UN SPECIAL ENVOY FOR TB 75 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79  PERATIONS RESEARCH 80  ONTRIBUTION TO SCIENCE 80  UB-AWARDS 81		
GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS		
OUNTRY HIGHLIGHTS	CLODAL FUND INVESTING IN THE COALFUNDES	47 47
ORE PROJECTS 74  UN SPECIAL ENVOY FOR TB 75  INDIA 76  PREVENTION 77  MEASURING STIGMA 78  BEDAQUILINE COORDINATION 79  PERATIONS RESEARCH 80  ONTRIBUTION TO SCIENCE 80  ONCLUSIONS & NEXT STEPS 81	GLOBAL FUND INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS	4/
UN SPECIAL ENVOY FOR TB 75 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79 PERATIONS RESEARCH 80 ONTRIBUTION TO SCIENCE 80 ONCLUSIONS & NEXT STEPS 81	OUNTRY HIGHLIGHTS	49
UN SPECIAL ENVOY FOR TB 75 INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79 PERATIONS RESEARCH 80 ONTRIBUTION TO SCIENCE 80 ONCLUSIONS & NEXT STEPS 81	ORE PROJECTS	74
INDIA 76 PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79 PERATIONS RESEARCH 80 ONTRIBUTION TO SCIENCE 80 UB-AWARDS 80 ONCLUSIONS & NEXT STEPS 81		
PREVENTION 77 MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79 PERATIONS RESEARCH 80 ONTRIBUTION TO SCIENCE 80  JB-AWARDS 80 ONCLUSIONS & NEXT STEPS 81		
MEASURING STIGMA 78 BEDAQUILINE COORDINATION 79 PERATIONS RESEARCH 80 ONTRIBUTION TO SCIENCE 80 JB-AWARDS 80 ONCLUSIONS & NEXT STEPS 81		
BEDAQUILINE COORDINATION		
PERATIONS RESEARCH		
ONTRIBUTION TO SCIENCE 80  JB-AWARDS 80  ONCLUSIONS & NEXT STEPS 81	DEDAGOILINE COORDINATION	
JB-AWARDS	PERATIONS RESEARCH	80
ONCLUSIONS & NEXT STEPS	ONTRIBUTION TO SCIENCE	80
ONCLUSIONS & NEXT STEPS	JB-AWARDS	 80
HOTOS	ONCLUSIONS & NEXT STEPS	81
	HOTOS	83

#### CHALLENGE TB ANNUAL REPORT YEAR 4

#### MESSAGE FROM THE PROJECT DIRECTOR

In collaboration with our partners, we pledge to reach out to all TB affected people and their families, and to continue the fight to end the TB epidemic.

If we fail to act and invest in TB care and prevention, the ultimate cost will be high. It is measured not just in dollars, but in lives tragically cut short, and in families, communities, and nations threatened.

The End TB Strategy was endorsed by all WHO Member States at the 2014 World Health Assembly, and covers the period 2016–2035, target 3.3 covers TB:

"By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases."

This translates into a 95 percent reduction in the absolute number of TB deaths, a 90 percent reduction in the TB incidence rate, and no TB-affected households experiencing catastrophic costs due to TB.

As this report shows, we are making significant strides towards these goals, but we still have a long way to go to reach our targets. Now more than ever we need to strengthen our resolve.

In the final year of Challenge 1B, we are translating our investments into sustainable actions so that the momentum we have built to combat this disease not only remains but increases.

I want to send my heartfelt thanks to all our staff and our front-line health care workers for their contribution to reaching these goals, saving lives, and reducing the suffering of TB, DR-TB and TB/HIV patients, their families, and their communities

Only together can we end 1 b



Gidado Mutstapha Challenge TB Project Director



#### **EXECUTIVE SUMMARY**

Challenge TB (CTB) is the flagship global technical assistance mechanism of the United States Agency for International Development (USAID) to prevent and control tuberculosis (TB).

This report summarizes project progress and achievements for Year 4, October 2017 – September 2018, across the 23 country projects, the East Africa Regional project, and five core projects.

# PROGRESS ON KEY PERFORMANCE INDICATORS

#### **CASE NOTIFICATION**

In 2017, 23 CTB countries altogether notified 3,471,848 patients, 60 percent of the estimated incident TB cases, an increase from 3,147,280 (52%) in 2014. This increasing trend in the number of notified patients reflects the significant contribution of CTB interventions in coordination with Global Fund (GF) and other partners. In 2017, 464,187 TB cases (13% of the national TB cases) were notified in CTB-supported geographical areas (a considerable contribution given the low geographic coverage in many CTB countries). In Year 4, 50,594 childhood TB cases (13% of all notified cases) were notified in CTB-supported areas; this percentage has remained stable from 2014-2017

Out of 23 countries, 19 reported a proportion of notified new and relapse TB patients with a documented HIV test result higher than the global average of 60 percent in 2017. In 2017, 13 CTB countries reported a proportion of notified HIV-positive TB patients on ART higher than the global average of 84 percent. Five CTB-supported countries showed proportions higher than 95 percent for both indicators: Namibia, Tanzania, Uzbekistan, Malawi, and Mozambique.

# CONTRIBUTIONS OF SPECIFIC INTERVENTIONS TOWARDS CASE NOTIFICATION

In Year 4, three interventions demonstrated significant contribution to TB case-finding in the following order based on percentage contribution to overall case-finding; intensified case-finding (ICF) in hospital settings (46,541 TB cases/43%), community referral (54,546 TB cases/21%), active case-finding (14,969/6%), and contact investigation with 12,483 TB cases (all forms 5%).

#### **GENEXPERT SCALE-UP**

By the end of Year 4 in collaboration with NTP and all partners, a total of 3,836 GeneXpert machines (15,467 modules) were installed in CTB countries as compared to 988 machines (4,015 modules) in 2015, 1,441 machines (5,947 modules) in 2016 and 3,402 machines (13,623 modules) in 2017; 14 out of 19 countries with complete data reported functionality rates above 90 percent. The total number of tests done in the first six months of 2018 is 1,019,529, which is higher than each half of 2017 (766,785 and 944,963); the data for both years excludes India (due to the lack of 2018 data India was excluded from 2017 to ensure comparability). By the end of June 2018, 13 countries implementing diagnostic connectivity systems, reported that 71 percent of the Xpert machines were connected. The overall utilization rate (all CTB supported countries) has doubled since the beginning of CTB from 16 percent (2015) to 31 percent (Jan-Jun 2018), which is considerable progress despite the methodological challenges WHO faced with the definition of this indicator. To ensure the optimal use of GeneXpert machines, in Year 4, 281,702 specimens were transported in CTB-supported areas (13 countries) compared to 181,740 in 2017 (14 countries) and 146,883 in 2016 (eight countries). In two countries (Zimbabwe and Ukraine) CTB support covered 100 percent of the national specimen transportation efforts.

EXECUTIVE SUMMARY

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#### DIAGNOSIS AND TREATMENT OF MDR-TB

WHO 2017 data shows that in CTB-supported countries there has been a steady increase in the proportion of bacteriologically confirmed new TB patients tested for rifamipicin-resistant/multidrug-resistant TB (RR-/MDR-TB), from 7 percent (2014) to 50 percent (2017); and access to second-line line probe assay (SL-LPA) shows an increase from 47 percent in 2015 to 56 percent in 2017. A total of 75,127 MDR-TB patients were diagnosed, and 68,872 MDR-TB patients were started on treatment in 2017, which is an increase compared to previous years (71,913 diagnosed, 64,405 put on treatment in 2016; 61,915 diagnosed, 56,276 put on treatment in 2015).

The introduction of new drugs and regimens (ND&R) has increased exponentially: by the end of Year 4, the shorter treatment regimen (STR) was being implemented in 20 CTB supported countries compared to 11 in Year 3, with 815 sites providing the STR (compared to 559 sites by the end of 2017) to 6,045 patients. By the end of Year 4, 329 sites offered BDQ treatment in 23 countries to 2,373 patients (including India); 104 sites in 16 countries offered delamanid (DLM) treatment to 230 patients, and 116 patients started treatment with both BDQ and DLM.

CTB reported very high success rates (between 78%

and 95%) for the final treatment outcomes of the STR in Tajikistan, Kyrgyzstan, DR Congo, and Vietnam: 83 percent (39/47), 78 percent (69/88), 95 percent (242/257), and 80 percent (79/99), respectively. These good results demonstrate not only the feasibility of implementing the STR in different settings but also the effectiveness of the triage approach.

## LOCAL CAPACITY BUILDING TOWARDS RESILIENCE

From Year 1-Year 4, CTB worked with a total of 326 sub-awardees across 21 countries, of which 103 sub-awardees (92 local and 11 international) were sub-contracted in Year 4 alone.

#### **CONTRIBUTION TO SCIENCE**

Over 60 abstracts (posters and oral presentations) were presented at the 2017 Union Conference in Mexico. This year 110 abstracts were approved for the 2018 Union Conference in the Hague. Several guidelines and publications were published on ND&R and stigma:

https://www.challengetb.org/library/pmdt/

http://www.ingentaconnect.com/content/iuatld/ijtld/2017/00000021/a00111s1



#### **MAJOR CHALLENGES**

The release of the "Rapid Communication on Key Changes to the Treatment of Multi-Drug and Rifampicin-Resistant Tuberculosis" created significant concerns in the field, especially with the current effort of rolling-out BDQ. As a consequence, there will be a need to adjust national guidelines and tools, drug supplies, and it will slow the uptake of the STR.

Looking at current WHO Standards the Xpert MTB/ RIF Ultra assay should be the initial diagnostic test to detect TB and rifampicin-resistance for all patients with signs and symptoms of TB, including children and persons living with HIV. In order to meet the UN High-Level Meeting "40 by 2022" commitment, an increase in rapid diagnostic testing needs to happen using a two-pronged approach: increasing access (expansion) and the optimization of existing machines.

#### **ACTIONS**

In Year 5, CTB will focus on providing technical assistance to countries to support them with adjusting to the changes in treatment for multidrug and rifampicinresistant TB through country support and the BDQ Coordination Project.

A coordinated effort will be made to support countries with the change in approaches to close the gap in rapid diagnostic testing in order to meet the UN High-Level Meeting "40 by 2022" commitment.

#### REPORT DEVELOPMENT

The main focus of this report is on the achievements of CTB key priority interventions in all supported countries, including case-finding, treatment, and care; Xpert scale-up; the programmatic management of drug-resistant TB (PMDT) and ND&R; TB/HIV; as well as CTB achievements to Global Fund (GF) requests and CTB geographic allocations/district approaches.

Alongside the data results, selected country-specific examples are provided in each respective thematic area to illustrate the achievements, lesson learned and challenges.

Country-specific key results and most significant achievements are reported in the individual country profiles (see page 49).

The results are reported based on the CTB Monitoring & Evaluation (M&E) framework, including mandatory indicators, and some key process indicators. National results (2014-2017) on population based indicators (e.g., case notifications and treatment success) are reported from the WHO 2018 database. CTB area results (2014-2018) are reported based on National TB Program (NTP) data collected through CTB. Data trends are based on validated calendar years (2014 is the baseline), however, we provide appropriate information on the project achievement for Year 4 (Oct 2017 – Sep 2018), while including projections for 2018 (based on CTB Year 4 Q1-3 data). The results reported are guided by investment and reports from specific countries, which explains the variations in the number of countries for certain reported indicators.

#### WHAT IS CHALLENGE TB?

Challenge TB (CTB) is USAID's flagship global mechanism for implementing the United States Government (USG) TB strategy as well as contributing to TB/HIV activities under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Launched on October 1, 2014, this five-year cooperative agreement (2014-2019) builds and expands upon previous USAID global programs, namely TB CARE I (2010-2015), the Tuberculosis Control Assistance Program (TB CAP, 2005-2010) and Tuberculosis Control Technical Assistance (TBCTA, 2000-2005). KNCV Tuberculosis Foundation (KNCV), which also led the aforementioned programs, leads a unique and experienced coalition of nine partners implementing CTB. The coalition partners are: American Thoracic Society (ATS), FHI 360, Interactive Research and Development (IRD), International Union Against Tuberculosis and Lung Disease (The Union), Japan Anti-Tuberculosis Association (JATA), Management Sciences for Health (MSH), PATH, and the World Health Organization (WHO).

Working closely with Ministries of Health, USAID, Global Fund, the STOP TB Partnership and other key stakeholders at a global, regional, national and community level, CTB contributes to the WHO End TB Strategy targets:

Vision: A world free of TB

Goal: To end the global TB epidemic

**By 2025:** A 75% reduction in TB deaths (compared with 2015) and less than 50 cases per 100,000 population.

CTB is aligned with the USG strategy to prevent and control TB, and has three objectives, each with several focus areas for interventions:

# Objective 1: Improved access to high-quality patient-centered TB, DR-TB & TB/HIV services by:

Improving the enabling environment
Ensuring a comprehensive, high quality diagnostic network
Strengthening patient-centered care and treatment

#### Objective 2: Prevent transmission and disease progression by:

Targeted screening for active TB Implementing infection control measures Managing latent TB infection

#### Objective 3: Strengthen TB service delivery platforms by:

Enhancing political commitment and leadership
Strengthening drug and commodity management systems
Ensuring quality data, surveillance and monitoring & evaluation
Supporting human resource development
Building comprehensive partnerships and informed community engagement.

CTB implements projects at the country, regional, and international/global level with the majority of the project's work being done through country-specific projects. As of September 30, 2018, 23 countries were implementing CTB. During Year 4, two new countries were started: Kazakhstan and Turkmenistan.

At the regional level, CTB continued implementation of the East African Region project, and also continued implementation of five core projects (see page 74).



# CHALLENGE TB COUNTRIES

In Year 4 Challenge TB worked in 23 countries, covering the whole country in Bangladesh, Botswana, Cambodia, Turkmenistan, and Zimbabwe, and specific regions in Afghanistan, DR Congo, Ethiopia, India, Indonesia, Kazakhstan, Kyrgyzstan, Malawi, Mozambique, Burma, Namibia, Nigeria, Tajikistan, Tanzania, Ukraine, Uzbekistan Vietnam, and Zambia.

Each country project has a specific set of objectives depending on the needs of the country and the nature of the TB epidemic.





KEY ACHIEVEMENTS

KEY ACHIEVEMENTS

#### CASE-FINDING, TREATMENT, AND CARE

Increasing TB case-finding is a priority in all Challenge TB countries. In 2017, the 23 countries combined notified 3,471,848 patients, 60 percent of the estimated incidence (reflecting treatment coverage as defined by WHO), an increase from 3,147,280 (52%) in 2014. The increasing trend in the number of notified patients reflects the significant contribution of Challenge TB interventions in coordination with Global Fund and other partners.

In 2017, 464,187 (13% of the national) patients were notified in Challenge TB-supported geographical areas; in Year 4, a total of 395,614 (12% out of national for 20 countries with complete data) patients were notified in Challenge TB areas.

Strategies supported by Challenge TB to increase case-finding are country-specific and designed based on country dialogue and national strategic plans. In general, these interventions include:

- 1. Active case-finding by contact investigation (CI), mobilizing community TB care programs in finding and referring persons with presumed TB and to participate in CI and door-to-door screening, and the systematic screening of presumed high-risk and vulnerable populations (e.g., elderly, prisoners, miners, urban poor communities, and healthcare workers);
- 2. Public-private and public-public mix, and;
- 3. Systematic TB screening in health care facilities (also called triage) among children, PLHIV, persons with diabetes, and outpatient department (OPD) attendees (FAST approach/strategy).

Total number and percentage of cases notified in CTB areas/nationwide and treatment coverage, 23 CTB countries, 2014-2018 (WHO 2014-2017, CTB 2018)



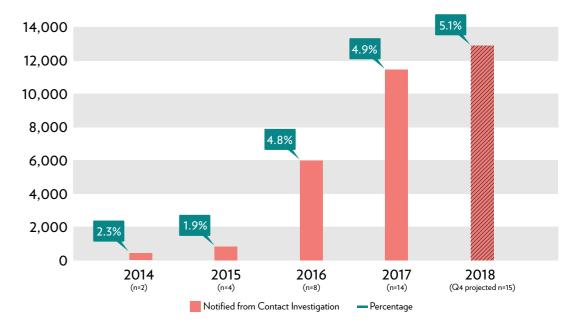
2017 CTB area data for 22 countries (except Turkmenistan)
2018 CTB area data 21 countries (except Turkmenistan and Uzbekistan)
2018 National data 20 countries (except India, Turkmenistan and Uzbekistan)
The projected 2018 data based on projected national (2014-2017) and CTB data (Year 4 Q1-3) for 2018.

#### CONTACT INVESTIGATION

In Year 4, 15 CTB countries implemented CI, and reported the respective data. For 2017, a total of 11,371 TB patients were notified after CI in 2017 (14 countries), representing 5 percent of all patients notified in the CTB areas implementing CI. In Year

4 (Oct 2017 – Sep 2018), 12,483 (5%) patients were notified in CTB areas; with Tanzania, Mozambique, Nigeria, DR Congo, and Indonesia reporting the highest number/contribution of patients through this intervention in 2018.

Total number and percentage of TB cases notified through Cl in CTB areas, 2014-2018 (CTB 2018)



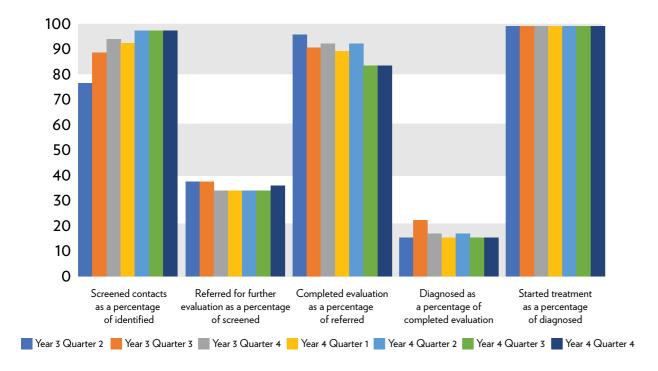


The Challenge TB project in Tanzania made good progress on CI by involving community-based organizations and their volunteers in 42 districts. Community volunteers collect information from index patients on their contacts at the DOT health facility on a biweekly basis. Community volunteers were trained on conducting CI and on how to transport sputum specimens. When visiting patient households, they provide TB infection control information, screen household contacts for TB, provide referrals for TB testing, and later they return the examination results. Monthly follow-up visits were carried out by district TB coordinators and CTB field coordinators to support and monitor the performance of the volunteers. During Year 4, 12,255 bacteriologically confirmed TB patients were notified; 79 percent of them received Cl. During their field visits, community volunteers identified a total of 57,225 close contacts of TB patients, of which 54,934 (96%) were screened for TB symptoms. Of those screened, 20,398 (37%) were identified as presumptive TB patients and 2,367 (15%) were diagnosed with TB. Of those diagnosed with TB, 30 percent were diagnosed by GeneXpert, 49 percent by smear microscopy, and the remaining by

chest X-ray and pediatric score charts. Almost all the diagnosed patients started anti-TB medication (n=2,363). Of the patients confirmed with TB through Cl, 27 were found to have rifampicin-resistant TB and were referred to start MDR-TB treatment.

The total number of contacts identified has increased threefold between the first quarter of Year 3 (n=5,209) and the last guarter of Year 4 (n=15,808). Across the cascade of care, the proportion of screened contacts has increased over the quarters reaching 97 percent at the end of Year 4. While one-third of the contacts screened were referred for further evaluation across reported quarters, the proportion of those who completed evaluation has remained above 80 percent. The decrease in the last two quarters may be related to under-reporting, and the sharp increase in the number of contacts screened and referred, which rose from 1.492 in Year 3 Q2 to 5,436 in Year 4 Q4. The drop could also reflect a change of the targeted contact population facing more barriers to visit a health facility for clinical evaluation. Across all quarters, 99-100 percent of the contacts diagnosed with active TB were started on treatment.

#### Contact Investigation Cascade in Tanzania, 2017-2018 (CTB 2018)



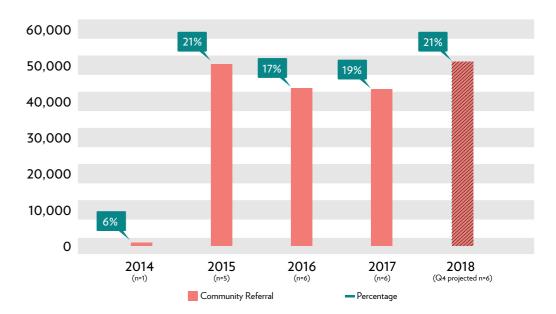
#### **COMMUNITY REFERRAL**

Community referral is comprised of a mix of interventions involving community volunteers. In 2017, 42,868 patients were notified with TB after referral through community-based workers in Challenge TB areas, which represents 19 percent of all notified patients in this period in the Challenge TB areas in the six countries (Afghanistan, DR Congo, Ethiopia, Mozambique, Nigeria, and Tanzania)

reporting on this intervention.

A total of 54,546 (21%) patients were notified in Oct 2017 – Sep 2018 in Challenge TB areas; almost two-thirds of these 54,546 patients were identified in Mozambique (40%) and Ethiopia (28%). See the graph below for the community contribution to TB case-finding.

Number and percentage of TB cases notified through community referral in CTB areas, 2014-2018 (CTB 2018)



The Challenge TB project in Mozambique has had a community referral project since the start of Challenge TB implementation. TB activists are connected to the peripheral health facilities and are supporting efforts to identify and refer presumptive TB patients to the facilities. In addition, they are involved in implementing the FAST approach at the facility level. The contribution from the Mozambique

project on community referral towards the total number of cases notified in the areas implementing this intervention has increased over the years, from 12 percent in 2015 to 27 percent in 2016, 36 percent in 2017 and reaching 40 percent between Jan-Sep 2018. This trend shows the positive effect that building CB-DOTS capacity has on finding more TB patients.

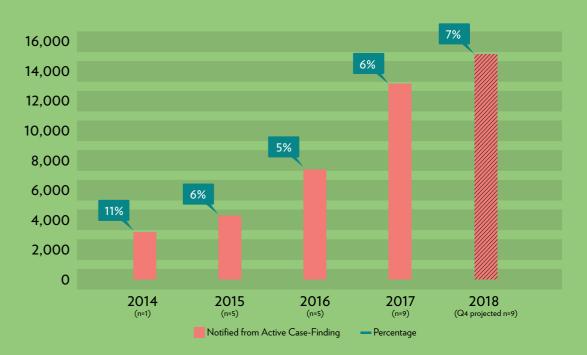


#### **ACTIVE CASE-FINDING**

In Year 4, nine CTB countries implemented and reported on active case-finding (ACF). In the period Jan-Sept 2018, a total of 11,197 patients were notified through ACF, reflecting a 7 percent contribution to all notified patients in CTB-supported areas; 14,969 patients were notified between Oct 2017–Sep 2018,

which represents 6 percent of all notified patients in CTB areas implementing ACF this period; with Indonesia, Tanzania, and Burma reporting the highest number/contribution of patients through this intervention in 2018. The graph below shows the annual trend within the project period.

Number and percentage of TB cases notified through ACF in CTB areas, 2014-2018 (CTB 2018)



The project in Nigeria is supporting two mobile diagnostic units called the Wellness on Wheels (WoW) trucks. In Year 4, these were deployed at quarterly intervals to four states: Nasarawa, Ogun, Lagos, and Kano, where they were used to screen populations in hard-to-reach locations using X-ray screening and same-day GeneXpert testing. Of the 49,086 people screened, 610 patients have been

diagnosed with TB and referred for treatment from the start of this intervention in Q1 Y4 (544 patients diagnosed in Jan-Sep 2018). The project continues to review its targeted screening approach in order to reduce its 'Number Needed to Screen' (80) in order to improve the efficiency of the intervention. The 'Number Needed to Test' was 8, which is a satisfactory score.



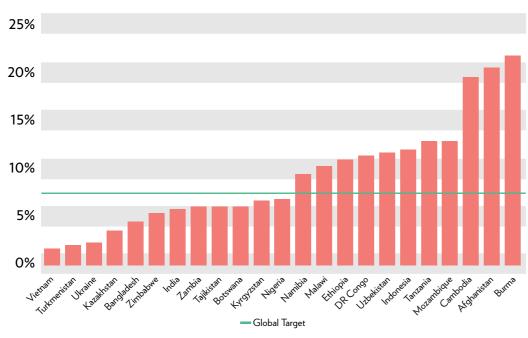
**KEY ACHIEVEMENTS KEY ACHIEVEMENTS** 

#### CHILDHOOD TB

Children (aged <15 years) accounted for 7.1 percent of the new and relapse cases that were notified globally in 2017 (WHO Global TB Report 2018). Nationwide data presented below shows that most CTB countries are within the 6-13 percent range,

with a few countries showing considerably lower proportions (e.g., Vietnam, Turkmenistan, and Ukraine) and a few showing higher proportions (Burma, Cambodia, and Afghanistan).

Percentage new and relapse TB cases notified among children, 2014-2017 (WHO 2018)

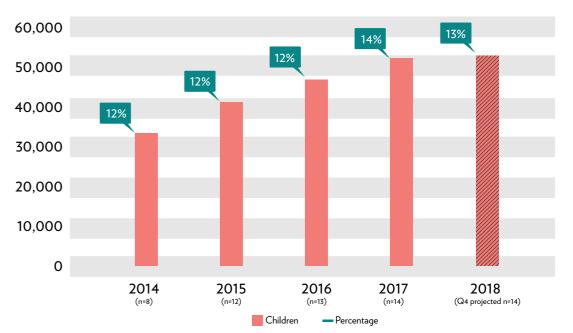




Fourteen CTB countries implement specific interventions and report data on the diagnosis of children with TB from targeted areas. From Jan-Sept 2018, a total of 35,431 children were notified. reflecting a 14 percent contribution to all notified

patients in CTB supported areas. This percentage, comparable to the aforementioned WHO-reported figure, remained stable from 2014-2017. From Oct 2017-Sep 2018, 50,594 children were notified (13% contribution) - also stable for the guarter trend.

Number and Percentage of new and relapse TB cases notified among children, 2014-2017 (WHO 2018)



In Jan-Sep 2018, the Indonesia project alone notified 7,390 patients aged under 15, which is 16 percent of all notified patients in the same period in CTB supported areas, and reflects a slow-rising trend

from 7 percent reported in 2014. This is achieved by constant training and mentoring during the supervision of health staff and as part of the district PPM approach.

#### HOSPITAL ENGAGEMENT

Five CTB countries report on this intervention, through which 45,664 patients were notified, i.e. 43 percent of the total number of patients notified in the CTB areas implementing this intervention in Jan-Sep 2018; while for the entire Year 4 (Oct 2017-Sep 2018) a total of 46,541 (43%) patients were notified. The intervention includes a combination of OPD TB screening (FAST) and the development of referral and notification systems for diagnosed TB patients. The largest number/contribution was reported from Ethiopia and Nigeria.

The CTB project in Ethiopia supported the NTP in designing hospital-specific strategies to improve TB diagnosis, management, and notification. The Ethiopia project supported as a high priority intervention the integration of TB screening in the OPDs of hospital facilities and the successful referral of TB patients diagnosed at hospitals to the

most patient-convenient facility. As a result, among 19,349,018 OPD visitors, 94 percent were screened for TB, among whom 374,311 (2%) presumptive patients were identified, and 34,672 (9%) were diagnosed with TB (all forms). OPD screening contributed to 41 percent (34,672/84,566) of all the TB patients notified in the same period and geographic area. CTB printed and distributed 1,000 registers to all the 266 hospitals to improve the referral linkage and tracking mechanisms. TB cases that were referred from hospitals to health centers were tracked and confirmed to have started treatment. In Addis Ababa, a mobile chat group linked TB focal persons of 99 health centers and 11 hospitals so they could share TB patient referral and acceptance messages. The percentage of referred patients who were tracked successfully across the Tigray and Gambella regions, reached 80 percent and 95 percent respectively.

**SUCCESS STORY** SUCCESS STORY

# The dressmaker's tale

As Esther passes the measuring tape around her customer's waist, the smile on her face says it all. She feels elated to be back doing what she loves.

Esther only began her treatment for drugresistant TB just three months ago, but she is already well enough to be back working. Her workshop is filled with colorful fabrics, beautiful dresses, and the tool of her trade, a treadle sewing machine.

It was not so long ago that Esther began feeling chest pains and developed a terrible cough. The wet season in Markurdi, Nigeria, had just started, and Esther initially thought that her symptoms were caused by the change in the weather. She started self-medicating with drugs she bought at a local pharmacy but her condition did not improve, and she began to lose weight. Before long, she was forced to close her shop as she no longer had the strength to continue working.

Closing her shop meant that she could not provide for her family. As the only breadwinner, her parents and two younger sisters, Elizabeth and Ezra, are dependent on Esther and the income from the shop.

Just when Esther had given up all hope of getting better, one of her customers told her about the Challenge TB project which she said was providing free TB diagnosis and treatment to people who suffered from similar symptoms.

"This really nice customer encouraged me to visit the Teaching Hospital in Benue State. When I went there, they tested me for free," Esther explains.

Esther was diagnosed with drug-resistant TB and put on treatment. Her treatment will take up to 20 months, during which she will undergo many painful injections and will have to take many different pills of which some can have nasty side effects.

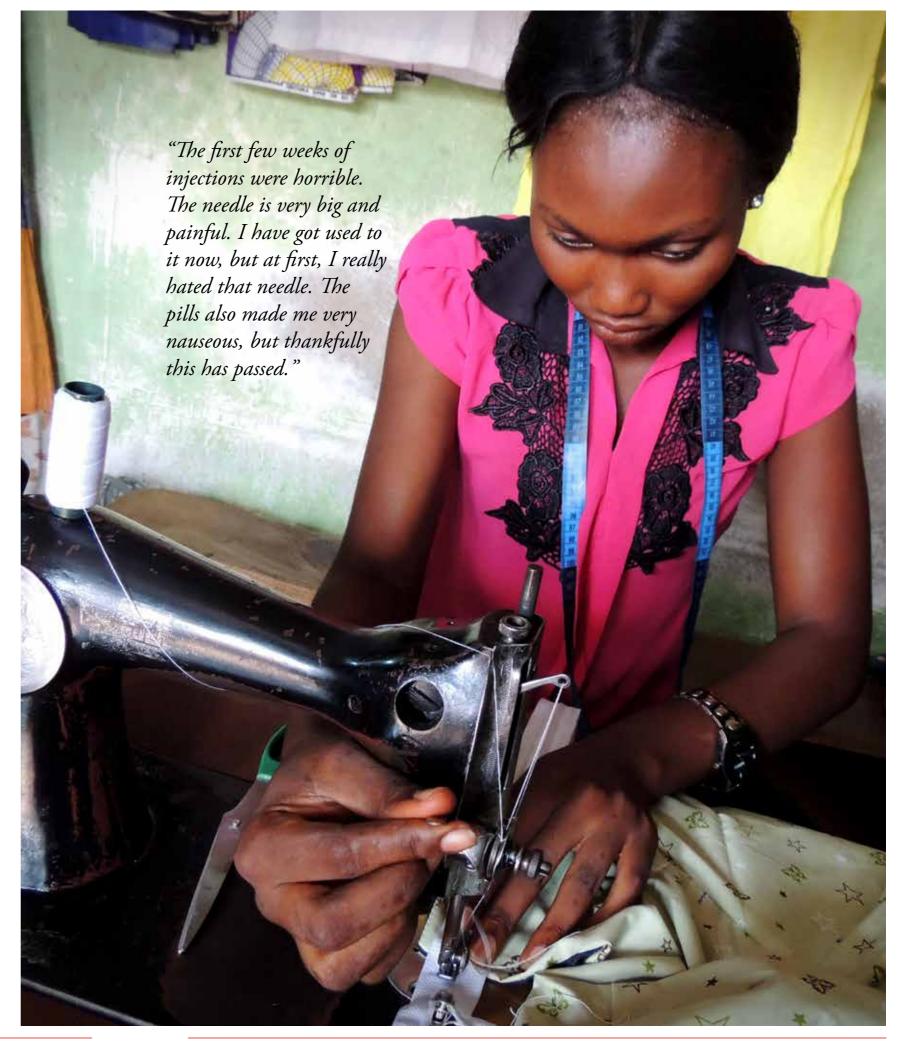
"The first few weeks of injections were horrible. The needle is very big and painful. I have got used to it now, but at first, I really hated that needle. The pills also made me very nauseous, but thankfully this has passed."

Three months into her treatment Esther has returned to work in her shop. Her customers are happy she is back to work as she is one of the few good tailors in the area.

"We really missed Esther. It is a bit more expensive to have your clothes tailor-made, but it is definitely worth the extra money," says one of her customers while Esther takes her measurements.

Business is going well, but Esther realizes that her battle with TB has only just begun. Many people are tempted to stop taking their TB medication once they start feeling better but she knows that taking her medicine every day until her treatment is complete is the only way she will be completely cured.

"I will do everything in my power to beat this terrible disease. My work not only supports myself but my parents and siblings as well. Being able to go back to work is a blessing which I do not take for granted. I just want to thank the Challenge TB project staff for all their help and support during this tough time."

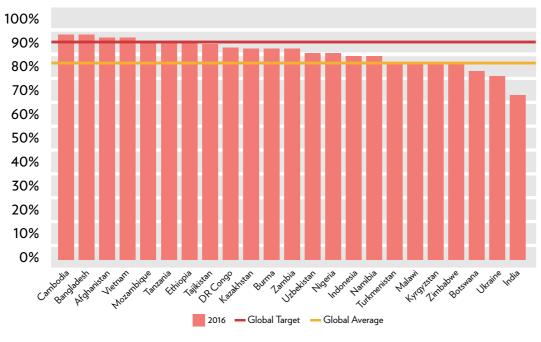


#### TREATMENT OUTCOMES

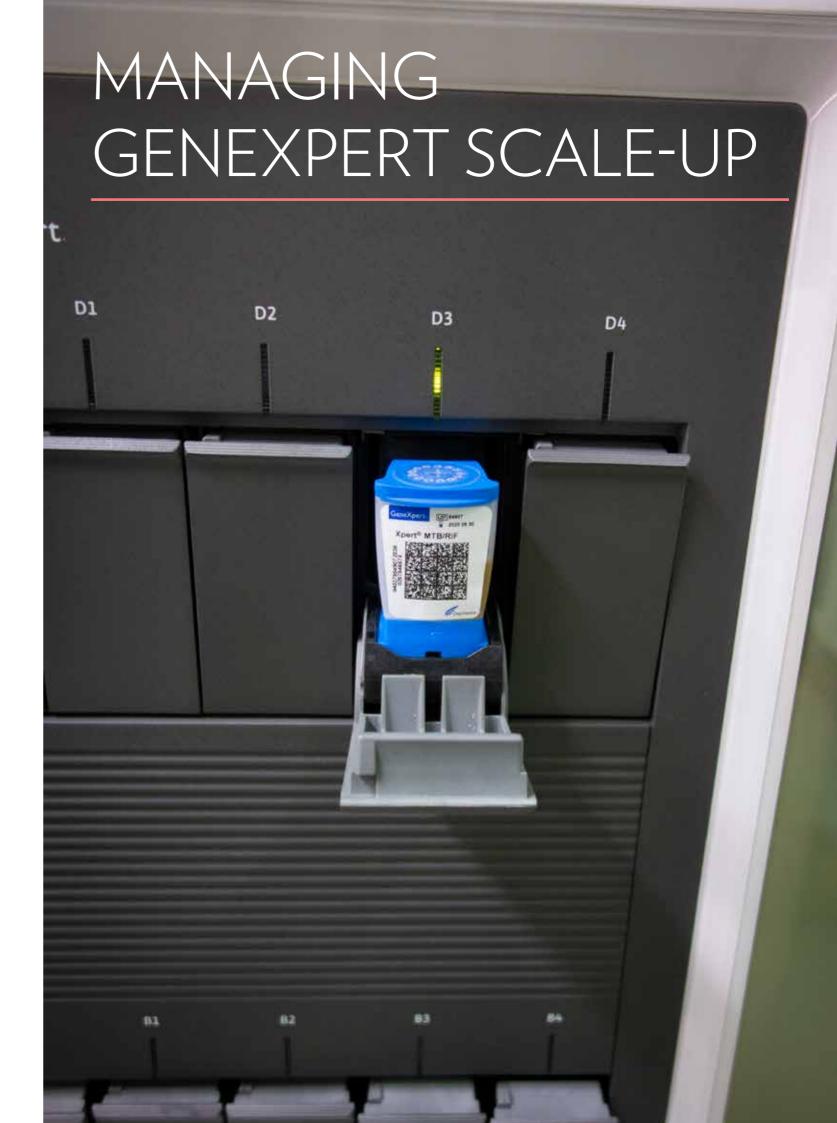
All CTB projects support general or specific interventions to improve treatment outcomes for patients with all forms of TB, and some projects work specifically on improving MDR-TB treatment success. Globally, the treatment success rate for new and relapse cases who were treated in the 2016 cohort was 82 percent (WHO Global TB Report 2018). As the graph below shows, seven countries

were above the 90 percent End TB Strategy target (compared with five countries in the 2014 and 2015 cohorts and two countries for 2013 cohort), and 19 countries were on/above the 82 percent global average for the 2016 cohort. The best performers in the 2016 cohort are Bangladesh and Cambodia with 94 percent.

#### TB Treatment Success Rate, 2016 cohort (WHO 2018)







**KEY ACHIEVEMENTS KEY ACHIEVEMENTS** 

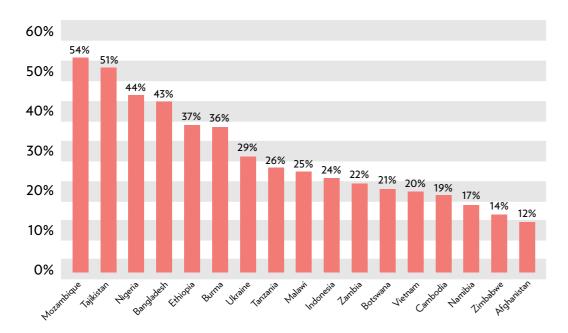
#### NUMBER OF MACHINES, FUNCTIONALITY, AND UTILIZATION

In Year 4, the number of GeneXpert machines increased substantially in countries, including in CTB supported areas. In CTB countries, a total of 3.836 GeneXpert machines had been installed by the end of June 2018, compared to 988 in 2015, 1,441 in 2016, and 3,402 in 2017. Out of the 3,836 GeneXpert machines, data on functionality is available for 2,576 machines (in 19 countries) with the total number of modules at 10,287, of which 9,752 (95%) were functional, 14/19 countries reported functionality rates above 90 percent. Over the past years (since 2015) functionality has remained high across CTBsupported countries. The total number of tests done in the first six months of 2018 is 1,019,529, which is higher than each half of 2017 (766,785 and 944,963) the data for both years exclude India.

The utilization rate is an indicator which measures the efficient utilization of this high-cost investment. In the process of scaling-up the GeneXpert system, the utilization rate may vary, especially between existing and new sites given that the health system required to utilize the test facility needs to develop. In line with WHO recommendations, the maximum utilization is calculated as the number of modules multiplied by three tests per day multiplied by 240 days per year. The following countries reported a utilization rate of 50 percent and above by the end of June 2018: Mozambique (54%) and Tajikistan (51%).

GeneXpert Utilization Rate, by June 2018 (CTB 2018)

28



In Year 4, Ethiopia procured 143 GeneXpert machines through the Global Fund, and CTB supported the installation, sensitization, and training in their proper use. The GeneXpert utilization rate has significantly increased from 28 percent in existing sites in the last quarter of 2015 to 78 percent in 2018. Newly installed sites reported a utilization rate of 14 percent which reduced the average utilization rate to 37 percent. The number of Xpert tests has increased from 90.011 in Year 3 to 268.717 in Year 4, a threefold increase. Of the 272,815 Xpert tests done, 26,155 were MTB+ cases (25,045 MTB+ RRand 1,110 MTB+ RR+). The increase is mainly due to the change in the algorithm for TB testing using GeneXpert where it became the primary test for all presumptive TB in all GeneXpert sites, while test results can be delivered within one day. Expansion of Xpert testing and improving access to universal DST was spearheaded by CTB and staff seconded by CTB at the Ethiopian Public Health Institute (EPHI). Regional offices have contributed to building the capacity of the health system to increase utilization of Xpert testing. In addition, training laboratory

professionals to do preventive maintenance, procurement of commodities, and training have significantly contributed to the increased utilization of GeneXpert machines.

With the installation of the GeneXpert machines in Tajikistan, the access to rapid diagnosis of (RR-) TB patients improved and the workload of culture labs as well as the specimen transportation costs were reduced. From Oct 2017-Sep 2018, a total of 20,942 patients with presumptive TB were tested of whom 2,244 were MTB+ and 552 RR+. CTB and NTP teams regularly conducted supervision visits to GeneXpert sites to provide technical support and provided on-the-job training for specialists on-site to familiarize them with the test and create demand. data verification, and in previously existing sites updated the diagnostic algorithm and calibrated modules. CTB also facilitated four quarterly meetings with the participation of key lab specialists from the regions to provide and get updates on lab networking and ongoing lab activities.



CHALLENGE TB ANNUAL REPORT YEAR 4

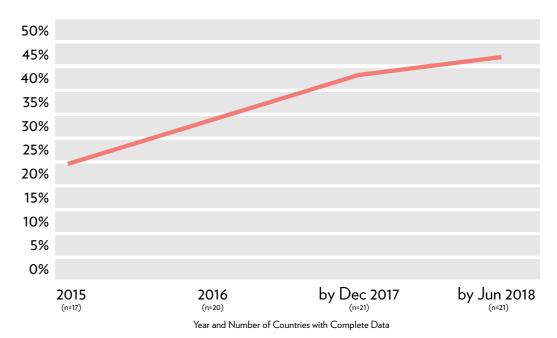


#### DIAGNOSTIC CONNECTIVITY

The percentage of GeneXpert machines connected to a connectivity system increased in CTB countries during Year 4. By the end of June 2018, 13 countries implemented and reported on diagnostic connectivity systems, with 71 percent of the GeneXpert machines connected; four CTB-supported countries reported a 100 percent connectivity rate: Bangladesh, Burma, Malawi, and Namibia. The graph shows data for all the GeneXpert machines in all 23 countries taken

together, the proportion of machines connected doubled from the baseline figure of 22 percent in 2015 to 44 percent in the first half of 2018. This shows important progress towards Indicator 4 of the targets for laboratory strengthening under the End TB Strategy (by 2020 in 100 percent of testing sites that use rapid diagnostics a data system has been established that transmits results electronically to clinicians and to an information management system).

#### Percentage of GeneXpert machines connected in CTB countries, 2015-2018 (CTB 2018)



Technical assistance was provided to teams in Afghanistan and Tajikistan to use the CTB Diagnostic Connectivity Request for Proposals (RFP) document to solicit bids from different vendors and support a transparent selection process. As a result, both countries started implementation efforts at the end of Year 4. At the global level, CTB shared experiences with the GLI TB Diagnostic Connectivity Task Force and WHO to support the development of a tool that can be used at the country level for the identification, comparison and selection of diagnostic connectivity systems during procurement.

In July 2018, representatives from Ethiopia, Bangladesh, Malawi, and Mozambique began participating in a TB Data Fellowship program. This program will provide year-long training and mentoring and several sessions are facilitated by CTB. Participants will be professionally trained to become TB connectivity data analysts, capable of supporting the Ministry of Health, NTP, and NTRL with data-driven insights and recommendations. A country-specific TB Data Fellowship program was implemented in Nigeria to accommodate the large demand for training.

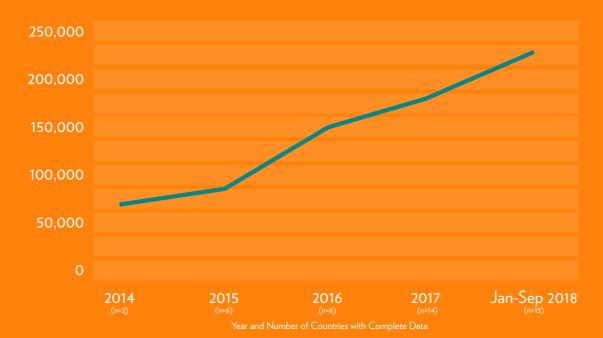
The CTB project management unit conducted a survey to better understand current implementation status, the level of utilization of diagnostic connectivity and to identify success and lessons learned in CTB countries. The results of this study will be used to develop a project monitoring dashboard and rating system defining different development stages of diagnostic connectivity. The overview of current status and efforts will help CTB to identify how to best support this important and critical technical system in Year 5.

#### NUMBER OF SPECIMENS TRANSPORTED

CTB continues to work on the strengthening of specimen transportation systems across the supported countries. There has been a major increase with 281,702 specimens transported from Oct 2017–Sep 2018 in CTB-supported areas, of which 227,339 specimens were transported within the first

nine months of 2018, in 13 CTB countries compared to 146,883 in 2016 (with only eight countries) and 181,740 in 2017 (14 countries). Zimbabwe, Ukraine (both 100%), Tanzania (86%), and Afghanistan (83% made large contributions to national specimen transportation.

#### Number of Specimens Transported in CTB Areas in 14 Countries, 2014-2018 (CTB 2018)



In Zimbabwe, there was an 18 percent increase in samples transported; a total of 36,117 TB samples (both diagnostic and follow-up) were transported between Oct 1, 2017 and Sep 30, 2018 compared to 30,537 TB samples transported in the same period of Year 3. In addition, 247,716 other non-TB samples were transported in the same period compared to 115,763 in Year 3, an increase of 114 percent. The significant improvements can be attributed to efficiency gains realized when the system was transferred from Riders for Health to CTB, where the system is now integrated in the general healthcare

system. The role of CTB is the provision of salary support for the dedicated couriers and remote management support, including funding for fuel an the routine maintenance of the motorcycles.

In Tanzania, a total of 10,685 specimens were collected and transported to GeneXpert facilities for testing between Oct 2017-Sept 2018; out of them 648 specimens were MTB+ and 35 RR+. All the patients were initiated on treatment, half of the patients were under HIV care.





# Small Wonders

If you don't fear TB, just visit a TB ward. They are not places for the faint-hearted and definitely not places to linger.

Here you will see the destruction this disease wreaks on the body. Infected people cough so violently they spit up blood and all around once healthy bodies are reduced to skeletal frames. Fathers who should be working to support their families are confined to bed, mothers who should be looking after their children are dejected, and children who should be playing with their friends or at school are listless and lost.

This is a disease of the poor and dispossessed, a sickness so terrible it will take the lives of around 59,000 Bangladeshis this year alone.

Aisha, aged only seven, has multidrug-resistant TB (MDR-TB). TB is the world's deadliest infectious disease, it is unclear how Aisha got it, but just sitting in a classroom with someone who is infected can result in transmission.

Drug-resistant TB develops when the bacterium that causes TB stops responding to the drugs used to treat it, and infected people can spread it through the air when they cough. Four drugs make up the first line of defense against TB, if a patient's strain is immune to at least two of these, it is MDR-TB.

Aisha's mother says she knew something was wrong when she saw her daughter losing weight fast, and then there was the vomiting and the fevers that came in the night.

Aisha has now been here for twenty days, the only child in a ward full of adults. MDR-TB can take up to two years to treat, and patients often stay in hospital for the first few months until they become non-infectious. Fortunately, Aisha is on a new shorter form of treatment, which means that soon she will be able to leave and continue her treatment as an outpatient, but it will still take her nine months to finish.

All forms of TB are here, mixed together, which is not only dangerous for the relatives but also the

patients themselves, as there is a high risk of crossinfection. Everyone must wear a mask at all times, something which is especially hard in the stifling heat and so some people don't.

All Aisha can think about are her studies, she is very smart and dreams of becoming a doctor. Her mother says she is third in her class but would have been first if it wasn't for TB. She can already talk and read in basic English, but she worries about how long it will take to get well. "The longer it takes, the more I will forget, and I will be unable to complete my classes," she says.

This makes her mother cry, and for a moment there is nothing more to say.

She may be small, but don't be fooled, she is very brave. She endures the daily injections with little complaint. These injections strike fear into the heart of most MDR-TB patients as the pain can be intense, imagine a burning, stinging and a piercing pain that shoots up your back and then moves all the way down your legs. The pills she must take every day are numerous and so large she finds it daunting to swallow them, but she does, this is a matter of life or death.

Aisha passes the time reading her books, watching cartoons on a mobile phone, or listening to ghazal, melancholic poems set to music. At night, both her and her mother squeeze together on the narrow bed, this is all her mother can do, look after her, be close, offer comfort, and give words of encouragement.

Aisha is counting the days until she can leave this place, and when that day comes, it won't be a moment too soon.

The USAID-funded Challenge TB project works with the national TB program and local NGOs to increase the detection of childhood TB in Bangladesh. To this end, the project had implemented a child TB screening system in the pediatric outpatient departments of six selected tertiary health facilities and developed an electronic tool to help screen children for TB.

**KEY ACHIEVEMENTS KEY ACHIEVEMENTS** 

#### SECOND-LINE LPA

Countries are increasingly using SL-LPA as their method of choice to provide a more rapid result than conventional SL-DST, which is important for triaging MDR-TB patients for the STR or individualized treatment regimen (ITR) using the new drugs. The WHO data for notified RR-TB cases tested with SL-LPA showed an increase from 47 percent in 2015 to 56 percent in 2017. Even though the coverage of SL-LPA is increasing in CTB supported areas, this area will need close attention in Year 5.

In Ethiopia, CTB closely worked with EPHI, the national reference laboratory and other stakeholders and played a key role in the national laboratory personnel and institutions capacity building to ensure standard of care. With the Challenge TB support, currently there are 10 (100%) functional culture labs

that implement laboratory quality management service (LQMS). In Challenge TB supported regions, 84 percent of previously treated presumptive TB patients underwent RR-/MDR-TB testing (GeneXpert), while 64 percent of 332 RR-TB cases reported were tested for first and second line drugs DST by LPA.

Vietnam pioneered the patient triage approach for RR-TB patients, and uses SL-LPA as the initial diagnostic test for the detection of fluoroguinoloneand second-line injectable resistance. After two years of triage implementation, among 51,262 patients tested, Xpert detected 4.4 percent (2,275), of whom 1244 (55%) were tested with SL-LPA. National SL-LPA coverage increased from 49 to 68 percent between 2017 and the first half of 2018.

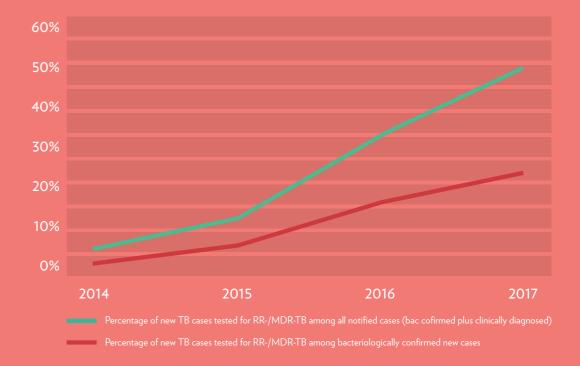


#### NUMBER TESTED WITH A WHO-RECOMMENDED RAPID DIAGNOSTIC TEST

bacteriologically confirmed new TB patients tested for RR-/MDR-TB: 7 percent (2014), 14 percent

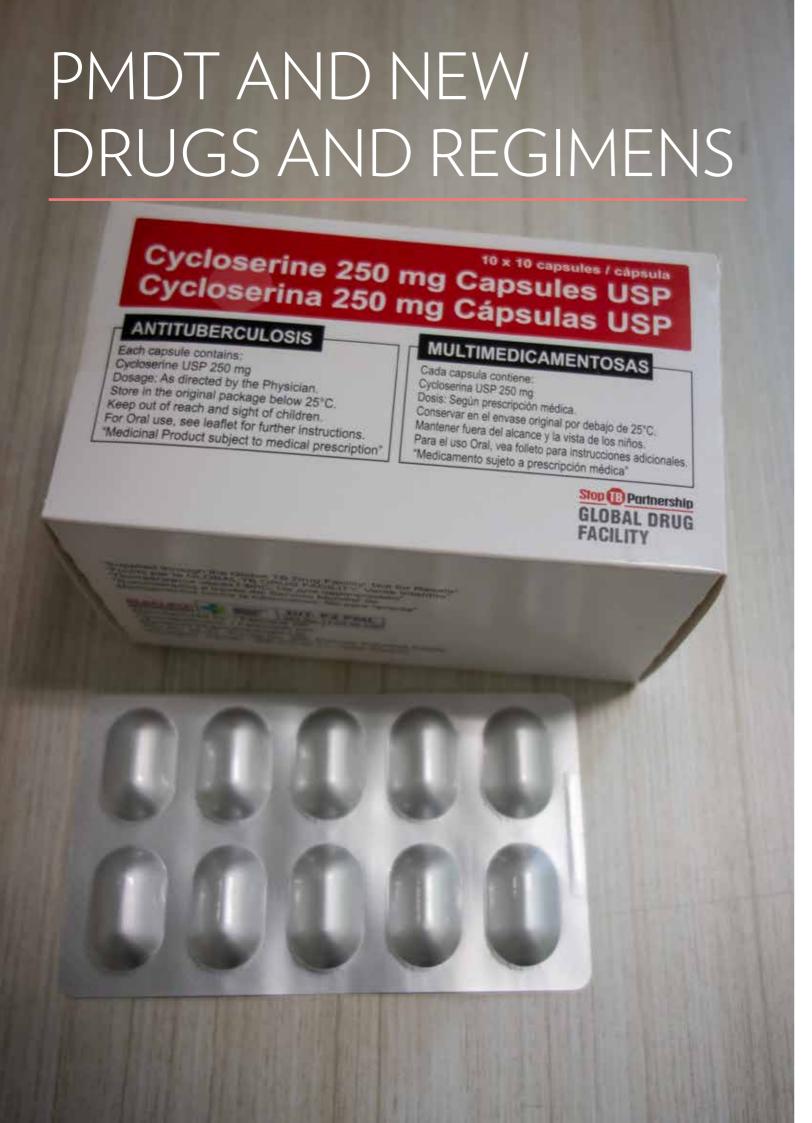
(2017) reflecting the use of Xpert as primary test for

#### DST Coverage, New TB Cases, 2014-2017 in 23 Countries (WHO 2018)



of new patients tested for RR-TB in CTB-supported areas from 52 percent (end of 2017) to 96 percent increase was seen from 40 percent (end of 2017) to

clinical staff in the Central, Luapula, Copperbelt, algorithms, sample collection and requisition,

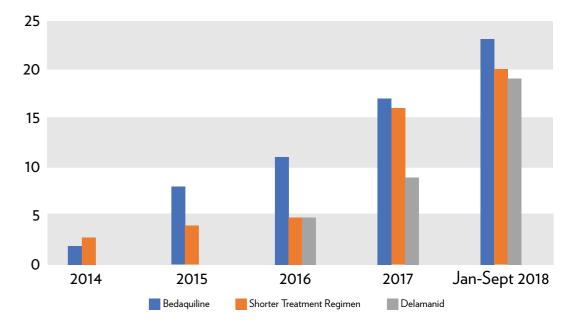


#### DR-TB NOTIFICATION AND TREATMENT

Thanks to the increased diagnostic capacity built for DR-TB in CTB countries, the notification of patients with DR-TB has steadily increased over the last five years. Based on WHO data, the proportion of cases notified compared to estimated number of RR-/MDR-TB cases has increased from 27 percent in 2012 (18 countries with complete data) to 54 percent in 2017 (23 countries). Despite the increase in the number of RR-/MDR-TB cases notified, the proportion of those starting on treatment remained above 90 percent between 2012 and 2017. There has also been a gradual increase in the proportion of successfully treated cases based on treatment cohorts between 2012 (53%) and 2015 (56%).

The graph below shows the national numbers for MDR-TB diagnosis, treatment, and care cascade. A total of 75,127 MDR-TB patients were diagnosed, and 68,872 MDR-TB patients started on treatment in 2017, which is an increase compared to previous years. The number of patients initiating appropriate treatment in CTB supported areas has also increased, with 8,675 patients initiating treatment in the first nine months of 2018 (a total of 12,296 patients initiated treatment in Year 4), which is an increase in comparison with the same period in 2017, when 7,674 patients initiated treatment.

#### Number of Countries Introducing New Drugs and Regimens (CTB 2018)



For Year 4 of the project (Oct 2017 – Sep 2018), 2,373 patients were started on BDQ, the highest level of initiation of patients on the drug since the beginning of the project. In the first nine months of 2018, the number of patients put on treatment with BDQ continued to increase with 1,927 patients starting treatment; almost half of them (942 patients) in India. The other top five countries with the highest enrollment for BDQ are: Kyrgyzstan (135 patients), Indonesia (124), Tajikistan (122), Kazakhstan (110), and Ukraine (98).

For DLM, the number of patients starting treatment in Year 4 is 230. During the first nine months of 2018, the number was 127, which is also an increase from previous years. The top three countries are: Kyrgyzstan (18 patients), Tajikistan (16 patients), and Bangladesh (15 patients).

As they were diagnosed with an extensive pattern of drug resistance and with the authorization of the national authorities, 113 patients started concomitant treatment with BDQ and DLM in the first nine

KEY ACHIEVEMENTS

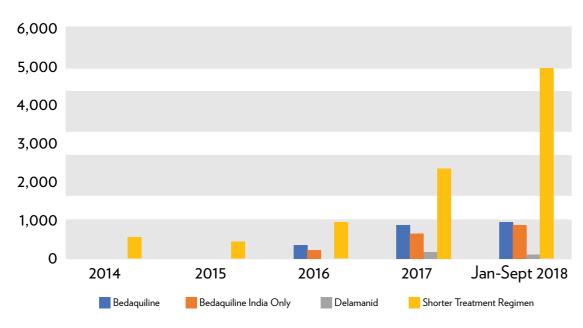
KEY ACHIEVEMENTS

months of 2018. The top three countries are: Ethiopia (36 patients), Mozambique (23), and Burma (14).

Finally, there has been a significant increase in the number of patients initiating the STR in Year 4 with 6,045 patients. For the first nine months of 2018,

4,903 patients initiated treatment on the STR; more than double the number of patients that started the STR treatment in the whole of 2017. The top three countries are: Indonesia (1,493 patients), Nigeria (881), and Bangladesh (566).

#### Cumulative Numbers of Patients Enrolled on ND&Rs in 23 CTB Countries (CTB 2018)\*



\* The number of patients started on BDQ in India is presented separately

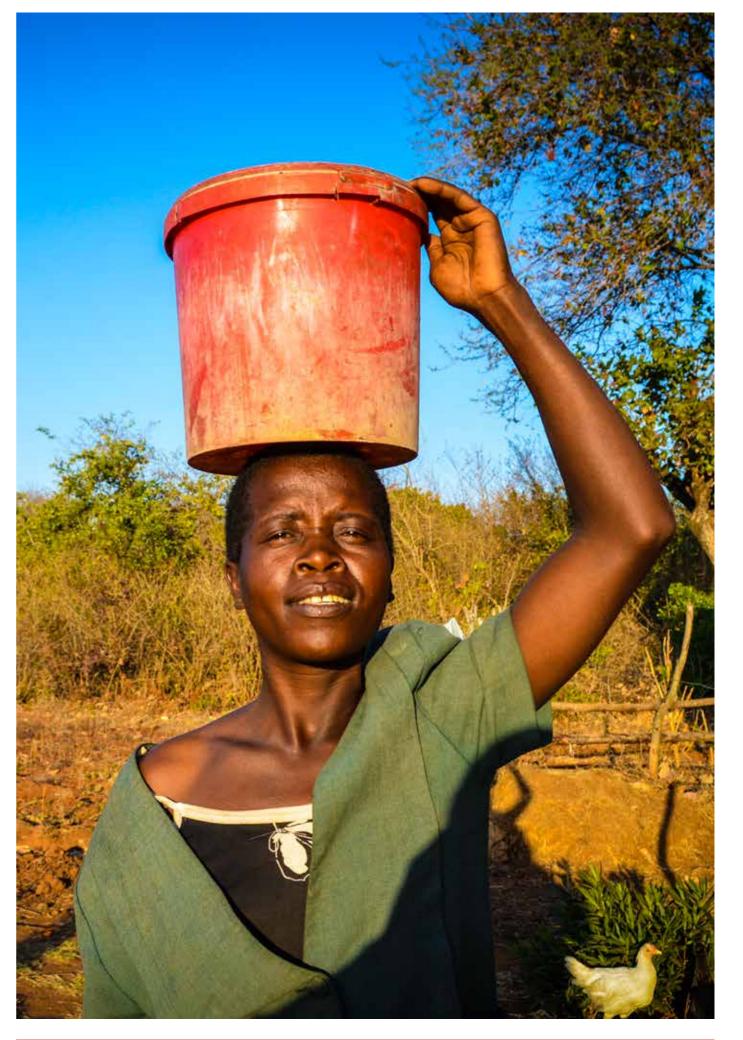
#### TREATMENT OUTCOMES FOR ND&R

The introduction of ND&R also aims to improve the treatment outcomes by improving adherence to treatment. The treatment outcomes of patients receiving treatment with BDQ are not yet available as not enough time has passed since the beginning of the treatment. Only Kyrgyzstan can report that all the patients in the 2016 cohort on ITRs that received BDQ at one point in their treatment have been declared cured (8/8). Intermediate outcomes are available for selected countries such as Ukraine that presents a negative culture rate of 90 percent at 6 months (38/42), Ethiopia an 80 percent rate at 6 months (12/15), Burma a 100 percent rate at 6 months (11/11), Indonesia a 41 percent rate at 6 months (64/155), Tajikistan 78 percent rate at 6 months (42/54), and Kyrgyzstan a 59 percent rate at 6 months (85/144). These very high rates of negative culture after 6 months of treatment predict a high treatment success rate, substantially higher than that reported with the longer conventional MDR-TB treatment with an injectable.

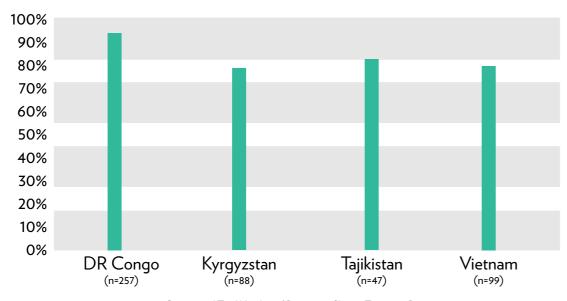
The treatment outcomes of patients receiving DLM are not available for all countries as not

enough time has passed since the beginning of the treatment. The intermediate outcomes for patients that started treatment between Jan 1–Dec 31 2017 are available for Ethiopia, Burma, Tajikistan, and Kyrgyzstan, with a respective rate of negative culture at 6 months of 100 percent (7/7), 77 percent (7/9), 77 percent (42/54), and 50 percent (3/6). Of the six patients in Kyrgyzstan, four are children and despite the difficulties they have producing sputum for monitoring, they are all showing good progress.

Although the treatment outcomes for patients on the STR are not available for most countries as not enough time has passed since the beginning of the treatment, some countries are able to report final treatment outcomes. Among them are Tajikistan, Kyrgyzstan, DR Congo, and Vietnam, with success rates of 83 percent (39/47), 78 percent (69/88), 94 percent (242/257), and 80 percent (79/99), respectively. These very high rates of success demonstrate not only the feasibility of implementing the STR in different settings but also the effectiveness of the triage approach.



Shorter Treatment Regimen Treatment Outcomes in Four CTB Countries (CTB 2018)



Country and Total Number of Patients on Shorter Treatment Regimen

# ACTIVE TB DRUG-SAFETY MONITORING AND MANAGEMENT

Active TB drug-safety monitoring and management (aDSM) is a new TB program component that is required for the introduction of ND&R. aDSM provides for the active and systematic clinical and laboratory assessment of patients on treatment with ND&R and helps detect, manage, and report suspected or confirmed drug toxicities. CTB has supported the implementation of aDSM as a key component of PMDT, and its introduction has been

hand in hand with the introduction of ND&R in CTB countries. The recording and reporting of serious adverse events (SAEs) is the basis of aDSM as well as the timely management of adverse drug reactions. In the countries where ND&R have been introduced, 440 SAEs have been reported for patients receiving BDQ, 13 for patients receiving DLM, and 74 for patients receiving the STR.



#### TB/HIV

CTB country projects broadly and consistently support the expansion and sustaining of provider-initiated counseling and testing (PICT) for all diagnosed TB patients, followed by the immediate start of ART before the end of the intensive TB treatment phase. The scale-up of TB preventive treatment is also a high priority, particularly in countries entirely supported by PEPFAR (Botswana, Namibia, Tanzania, and Vietnam).

In 2017, WHO reported 3.8 million notified new and relapse TB patients with a documented HIV test result globally, equivalent to 60 percent of notified TB cases (WHO Global TB Report 2018). Out of 23 CTB supported countries, 19 countries reported a higher proportion (i.e. more than 60 percent)

of notified new and relapse TB patients with a documented HIV test result in 2017 (19 countries in 2016 and 2015); Bangladesh and Indonesia report 2 percent and 29 percent, respectively; Afghanistan 48 percent, India and DR Congo 64 percent and 65 percent, respectively; Vietnam 85 percent; all the other countries are over 85 percent up to 100 percent. Several countries considerably improved their results - namely, Indonesia reported an increase from 13 percent to 29 percent between 2016 and 2017, Burma reported an increase from 65 percent in 2015 to 90 percent in 2017, DR Congo from 50 percent in 2015 to 65 percent in 2017, and Ethiopia from 77 percent in 2015 to 87 percent in 2017.

Percentage of Registered New and Relapse TB Cases with a Documented HIV Status (WHO 2018)



SUCCESS STORY SUCCESS STORY

# Hope and Healing

When Dotto Mwala was caught stealing it was the last straw, and his family kicked him out of the house. From there, his life quickly spiraled out of control and he not only wound up living on the streets of Dar es Salaam, but he was addicted to heroin.

In the 1990s, control measures in Eastern Europe and war in the Middle East led to increasing qualities of drugs being shipped through Tanzania, and brown heroin found its way onto the streets of the city, where a dose can cost as little as a dollar. Drug use soon rose to epidemic proportions with more than 40,000 addicts, and the government opened the first public methadone clinic in sub-Saharan Africa in 2011 at the city's Muhimbili National Hospital.

Ashraf Ally left his home in northern Tanzania to seek a better life in Dar es Salaam. He was only 14, but he wanted to earn enough money to go back to school. Things did not go to plan, and it turned out that finding a job was not as easy as he had hoped. He found himself living on the streets, alone, and with no one to support him, and he slipped into the dark world of drug use and addiction.

After eight years on the streets, earning money as a courier in the market to feed his habit, Dotto began to feel ill in early February 2018. At first, he thought it was just because of the drugs. But as time passed, his condition became more serious, and finally, he visited a local pharmacy where he was given malaria medication. The medication didn't work, and before long he slipped into unconsciousness. Not knowing what they should do, some friends took him to Mnazi Mmoja hospital and left him in the backyard in the hope he would be treated. It was here that Fatuma Isihaka, a community volunteer at the hospital and former TB patient, found him. Dotto was taken to the emergency room and treated, and while he was there, he was tested for both TB and HIV. both of which came back positive.

About 5 percent of Tanzanians are HIV-positive, a number which rises to around 40 percent among those who inject drugs. That's partly because of a practice known as flashblood, where one user shoots up, then draws their own blood and gives it to someone else for a secondhand high.

Dotto was put on TB treatment, and for the first two months, it was going well. Then he suddenly stopped coming to the hospital for his daily medication. Fatuma grew concerned and set out to find him, luckily it was not long before she located him, but he was weak and unable to move at Kariakoo market where he sleeps. She persuaded him to return to the hospital to continue with his treatment, and he agreed as long as she would be his treatment supporter. With Fatuma's support, he has been diligent in taking medication and is being counseled on stopping his heroin use, but that will take a lot more time.

As he and Fatuma became friends, Fatuma believed he could play a part in reaching out to other drug users, and she asked him to help find more people with TB in the 'camps'- the shooting galleries where drug users go to get high. On their first outing, they screened 28 people and found 5 with TB. "This is just the beginning, and we only covered one street. When we go to Msimbazi, where there are many more camps, I know we will find a lot more people who are sick like me," says Dotto.





Building on this initiative, Challenge TB enlisted the help of TOKKIUKI, a local community-based organization whose members are former TB patients who volunteer their time to raise TB awareness in the community.

Shabani Bwanga, a resident of the district and a peer educator with TOKKIUKI, found Ashraf who was suffering from a cough, weight-loss, and night sweats, the classic symptoms of TB. He was taken to be tested, and he too was positive.

As TB treatment requires daily medication and Ashraf was living in a camp, it was going to be a challenge.

"It is difficult to work with drug users, especially when you identify someone with TB and you need to provide them with treatment. They move from one place to another, they don't have a permanent place to stay," said Fatuma.

TOKKIUKI were not going to let circumstances get in the way of Ashraf getting the help he needed, so they found him a place in an orphanage. This proved to be another challenge as it wasn't long before Ashraf craved another fix and he was back on the streets. Despite this setback, TOKKIUKI remained committed, and they counseled Ashraf to stop using drugs and persuaded him to enroll in a clinic where he could receive methadone to help him quit. Amazingly Ashraf is now on his fourth month of treatment and has gained both weight and strength. He says he is going to get clean, whatever it takes.

The Challenge TB project is working with community organizations to enlist the help of former drug-users to find people with TB. Since May 2018, 39 former

drug users, 12 from Ilala, 16 from Kinondoni in Dar es Salaam, and 11 from Arusha have been trained to recognize TB symptoms, how to refer people for testing, and perhaps most importantly how to be a treatment supporter to those who need it most.

"Life on the street was tough. I couldn't get proper food or even a place to sleep. I thank God, through this illness, my lifestyle has changed. Now I have stopped using drugs, and I am concentrating on finishing my treatment and volunteering to find people with TB in the camps," say Dotto.

The newly trained volunteers have already screened 1,074 people, of which 496 had TB symptoms and were tested, 31 were diagnosed with TB, and 29 started TB treatment and are being guided, helped, and encouraged by their treatment supporters.

Thabit a former drug user and one of those trained says: "Challenge TB trained me how to screen people for TB, and I know all the hidden areas where people who inject drugs are staying because I was one of them. At the camp I normally provide education about TB and refer anyone with symptoms for a TB test. If they don't go, I collect a sample for testing and bring them their results the next day."

When Thabit visits the camps to screen people he has been chased away, sometimes people simply refused his offers of help, and he has even been robbed. But he is not one to give up easily. He wants to save as many lives as possible as he knows how lucky he was to have been saved.



# GLOBAL **FUND** Supported by The Global Fund

#### ASSISTANCE TO IMPLEMENTATION

During Year 4, CTB country projects assisted the development of Global Fund requests or requests for reallocation of savings and remaining funds, assisted principle recipients with grant making, and helped in the development of M&E and implementation plans. In this way, CTB contributed to the conclusion of 21 new grants and a regional project allocation. During project implementation, CTB participated in Country Coordination Mechanism technical working groups and in some countries also as members of oversight committees. All 23 CTB country projects and the East Africa Regional project closely collaborated with NTPs and principal recipients, ensuring the alignment and complementarity of Year 4, Year 5, and Global Fund grant activities.

During grant management, CTB provided assistance on many of the technical aspects of grant implementation, mainly by capacity building of implementing partners such as training in the programmatic management of drug-resistant TB, and especially the management of patients on shorter and new drugs containing regimens, finding the "missing" persons with TB, TB/HIV collaborative approaches and laboratory strengthening, especially GeneXpert implementation. CTB consistently provided TA to countries for quantification and procurement of laboratory supplies, especially GeneXpert cartridges and second-line TB drugs. CTB contributed to the successful start and implementation of the new and current rounds of Global Fund implementation in CTB countries and the efficient use of funding.

#### IMPLEMENTATION CHALLENGES

In a number of countries, Global Fund grant management met challenges, varying from under-funding of essential program elements to unexpected difficulties in procurement and supply chain management. The misalignment of domestic and Global Fund budgets or delayed disbursements often hindered smooth implementation. Some countries struggle with domestic and Global Fund

procurement procedures. With procurement being such a key element in the management of TB and MDR-TB, in most countries CTB is active in the quantification and, together with other USAID projects, the provision of technical assistance in procurement and supply chain management, to prevent and mitigate procurement problems as much as possible.

# INVESTING IN THE SCALE-UP OF CTB SUPPORTED INNOVATIONS

Overall CTB technical assistance on guideline development, planning, and procurement has a nationwide impact. Furthermore, through the close coordination of CTB and the NTPs in many countries, the scale-up of CTB supported innovations was channeled through Global Fund grants, ensuring the rapid transition from pilot implementation to national scale-up of essential interventions. This collaborative approach is amplifying the impact of the CTB project.

Examples of CTB supported interventions scaled-up with the Global Fund include the engagement of hospitals and private sector providers, GeneXpert expansion, the scale-up of the triage approach for the management of drug-resistant TB, and using shorter and new drug containing treatment regimens. In some instances, CTB partners were invited to become implementing partners under the Global Fund, especially regarding PPM approaches in India, Indonesia, and Nigeria.





Challenge TB trained over 150 cured TB patients and community leaders to identify and refer presumptive TB patients for diagnosis and treatment

"The majority of us suffered from TB, and so we feel the pain and suffering of other people who are suffering from TB, it makes us happy to help TB patients, and to change their lives for the better." – TB Association Member

association referred 601 presumptive TB patients, 81 were diagnosed with TB, the majority were close relatives, neighbors, and villagers.

#### GeneXpert

Challenge TB has procured 27 GeneXpert machines and distributed them to health facilities across the country. Between Year 3 and Year 4 there was a six-fold increase in the number of GeneXpert tests, and 218 rifampicin-resistant TB cases were notified - 59 percent of all the total notified nationwide.

#### Urban DOTS

Across nine cities, Urban DOTS is now implemented in 291 of the 633 health facilities. In Kabul, the case notification increased by 5 percent in Year 4 compared to Year 3, while the proportion of bacteriologically confirmed cases remained at around 30-32 percent. In the other eight cities, Urban DOTS increased TB case notification by 18 percent over the previous year. The number of new bacteriologically confirmed TB cases notified was 3,218, a 20 percent increase from Year 3. The treatment success rate remained above 89 percent.

#### **CB-DOTS**

Challenge TB expanded CB-DOTS to an additional 97 public health facilities making a total of 715. Training was conducted for 613 health facility directors, 612 community health supervisors, and 14,655 community health workers. In Year 4, community health workers identified and referred 46,850 presumptive TB patients for testing and 3,977 were diagnosed with TB (all forms) and put on treatment. At the intervention facilities, the treatment success rate was sustained at 95 percent.



#### GeneXpert

The project is supporting the maintenance of 39 GeneXpert machines nationally. A total of 14 modules have been replaced and an Xpert calibration test was conducted at four GeneXpert sites. Challenge TB laboratory coordinators conducted routine visits to 25 GeneXpert sites and provided support. Between October 2017 and July 2018, 59,399 tests were conducted.

#### GxAlert

Challenge TB has started installing the GxAlert system in all 39 GeneXpert machines and is currently developing a mechanism to monitor the functionality of the network, which is planned to be implemented next year.

#### Childhood TB

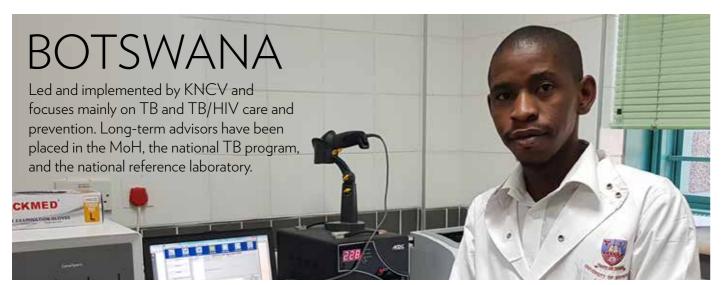
Challenge TB organized training for 29 staff members on childhood TB and the screening algorithm. A total of 90 physicians from the pediatric departments of the participating facilities were trained on the new guidelines for childhood TB. In Year 4, Challenge TB screened 334,622 children, identifying 8,313 (3%) presumptive cases. A total of 6,762 (81%) children were tested, and 554 (8%) children were diagnosed with TB and started on treatment. Among those diagnosed with TB, 251 (45%) had pulmonary TB, and the remaining 303 (55%) had extra-pulmonary TB.

#### TB/Diabetes

The project worked with a local NGO (BADAS) to integrate TB services into diabetes service delivery and to increase access to TB services for diabetic patients. Between October 2017 and June 2018, a total of 1,414 TB cases were identified among DM and 1,403 patients initiated on TB treatment, the intervention ended in June 2018.

I will never forget the 12th of July 2016. That was the day the doctor told me that my child had drug-resistant TB. I walked home from the hospital in a state of bewilderment and shock. How could my child have drug-resistant TB?" - Rahat's mother, Nasrin (both pictured above)

to cover the costs of checkups, tests, and nutritious food, Rahat's life has been restored. His treatment will take another three months to complete, but he put on 3 kg of weight after just two months, and he is already back to his former self. He is not only smiling again, but he is active and playing like other children his age.



Challenge TB has supported the national roll-out of GxAlert. A total of 29 GeneXpert machines are currently connected to the system, enabling real-time results, and allowing newly diagnosed TB patients to start life-saving treatment more quickly.

Matilda is one such patient: "I was asked to provide a sputum sample, and the next morning I was called back to receive my results. The nurse told me that I had TB. I was both afraid and confused at the same time, I didn't know what TB was, and how it would impact my life."

Four months into her treatment Matilda is doing much better, with only another two months of treatment to go, she is looking forward to being cured of TB.

#### GeneXpert Expansion

Challenge TB is providing supervision and mentoring to 32 of the 33 GeneXpert sites. During these visits, the team analyzed the pre- and post-test operational processes in order to maximize the use and quality of GeneXpert implementation. Health care workers were mentored on the implementation of the revised national TB diagnostic algorithm, and as a result, the number of Xpert MTB/RIF tests has increased from 1,181 in Year 1 to 15,583 in Year 4. The number of patients diagnosed with MDR-TB also increased, with 1,605 diagnosed in Year 4 up from 227 in Year 1.

#### GxAlert

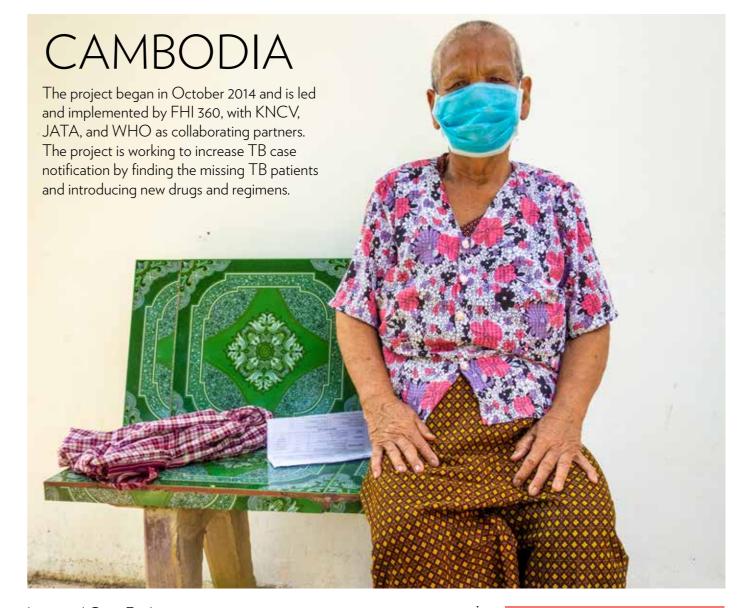
The project supported the national implementation of GxAlert connecting 97 percent of the GeneXpert devices. At the end of Year 4, 25 sites out of 32 Xpert sites (78%) transmit data to the central server; seven Xpert machines are in repair. GxAlert was integrated with OpenMRS and shares data real-time, allowing test results to be accessed quickly and patients initiated on treatment promptly. CTB supports an in-country full-time data scientist who is placed at NTP to support the roll-out and implementation of GxAlert.

#### TB and HIV Prevalence Survey

Botswana is the first country to conduct a combined national TB and HIV survey. Challenge TB provides technical assistance to the TB component of the survey. In Year 4, the project supported the development of standard operating procedures, a training manual, data management plan and input for the development of electronic data management system, updating of the survey protocol, updating TB lab algorithm, and quantification of the lab consumables based on the updated lab algorithm and logistic preparation for the piloting.

#### New Drugs and Regimens

Six patients were initiated on treatment during the last quarter of Year 4, and more eligible patients are being identified to be enrolled in the next quarter. During Year 4, the number of specialized treatment centers for complicated forms of TB/HIV and DR-TB patients expanded from five to six. Challenge TB also supported the development of aDSM to ensure the safe use of the new medicines.



#### Increased Case-Finding

The expanded approach to case-finding included intensive screening among people over the age of 55 in places such as pagodas and mosques, contact investigation in the community surrounding TB patients' households, and intensified TB symptom screening at hospitals. From October 2017 to March 2018, Challenge TB identified and treated 4,970 new TB patients among adults, a 54 percent increase compared to the previous year, and 29 percent of the NTP's overall patient notification in the same period. The project's approaches have been adapted and expanded for countrywide scale-up by the NTP with Global Fund support.

#### New Drugs and Regimens

Challenge TB trained 49 MDR-TB doctors, nurses, and partners on new drugs and regimens, aDSM, and electrocardiograph reading (including QT interpretation).

Since December 2017, 11 MDR-TB sites throughout the country have had the capacity to implement new drugs and regimens. A total of 99 MDR-TB patients were enrolled into treatment from October 2017 to September 2018, 89 were enrolled on the shorter treatment regimen, and 10 on BDQ.

Thun Sokmoth is a TB manager in one of the operational districts of Kampong Speu Province in Cambodia which receives financial support, coaching, and training from Challenge TB.

ram really happy because I can save the lives of vulnerable people from a disease for which treatment is easily available and provided free of charge. I want my community to be free from TB."



"I want to thank everyone involved in the Challenge TB project for their support starting from those who helped my daughter and me to get the correct diagnosis, to those who treated us and provided us with nutritional support and travel allowance. I'm forever grateful for all that you have done for my family and me." - Kankienza a cured TB patient.

#### Active Case-Finding

The contribution of local NGOs and community workers in TB detection continued to increase rising from 3 percent in 2015 to 16 percent in 2018.

#### Strengthening Diagnostic Systems

By increasing the frequency at which samples are collected/sent, the Challenge TB contribution to the national level increased from 32 percent in 215 to 62 percent in 2017. The number of sample increase from 4,492 in 2015 to 20,577 in the first nine months of 2018. Lab oratory technicians were trained in the use of a spectrophotometer to facilitate the initial assessment of DR-TB patients and their follow-up during treatment.

#### Improved DR-TB management

The number of DR-TB cases notified in Challenge TB supported areas increased from 71 in 2014 to 254 in 2017, and reached 173 by the end of September 2018. Challenge TB's contribution to the detection of DR-TB increased from 16 percent in 2014 to 32 percent in 2018.

#### Contact Investigation

In Year 4, contact investigation was done for 18,505 index cases; 87,207 household contacts of these index cases were visited, among whom 23,341 presumptive TB cases were identified and 20,706 (89%) were tested, 2,019 TB cases were found, and 1,995 (96%) started treatment.

#### Active Case-Finding

With the involvement of community workers and private health facilities, active case-finding was undertaken among high-risk populations (e.g., PLHIV, contacts of persons with TB, prisoners, and miners) yielding 152,804 presumptive TB patients, of whom, 38,721 were diagnosed with TB.



#### GeneXpert Expansion

There are 314 GeneXpert machines, up from 156 in Year 3. CTB procured 12 and provided support for installation. The number of tests done increased from 90,011 in Year 3 to 268,717 in Year 4. The number of MTB+ patients went from 13,689 to 26,155, and there was a fivefold increase in the number of RR-TB patients identified (1,110 vs. 224).

#### GxAlert Roll-out and Implementation

Half of the 314 Gene Xpert machines are connected, 112 of those were activated and now send automated reports. Challenge TB supported regions contributed to 95 percent of Xpert testing, 99 percent of MTB+ cases diagnosed, and 98 percent of the RR-TB cases notified.

#### Sample Transportation

50,066 samples were transported for TB diagnosis/follow-up service from 28 health facilities: 4,445 samples for culture, 3,213 for GeneXpert, and the rest for HIV viral load. The percentage of samples rejected from 3.4 percent in Y3 to 0.3 percent in Y4.

#### Increased Case-Finding

The contacts (106,982) of 28,111 index TB patients were identified, and 104,600 (98%) were screened, yielding 438 TB patients. In addition, 23,595 mining workers were screened for TB; 2,766 (11,7%) were tested, and 396 (14%) TB patients were diagnosed.

#### TB/HIV

The percentage of TB patients tested for HIV reached 94 percent in the last quarter, 92 percent of TB/HIV patients were on ART, and 40 percent of enrolled PLHIV started on IPT. GeneXpert was used to screened 9,454 PLHIV and 927 MTB+ patients were diagnosed, including 49 RR-TB.

#### New Drugs and Regimens

The project procured DLM for 20 patients, supported the shipment of BDQ for 70 patients, and also supported treatment monitoring. There are 39 patients on ND&R and 83 are currently on the STR. Healthcare workers from all treatment initiation centers were trained on aDSM.

Worknesh is on treatment for DR-TB, after 3 months of treatment she started to suffer from a ringing in her ears, which was soon followed by a loss of hearing. With Challenge TB support her hearing impairment was detected early and a treatment new drugs was designed especially for her.

"I feel better now, and since I'v been on the new medication, I'm able to communicate with my friends without difficulty. Thank God.

Thanks to Challenge TB and my physician, my hearing is now back to normal. The current drugs are working well, and I am able to live a relativel normal life."



"A few months back, being able to walk, go outside, and study seemed like a distant dream. But today, I am back on my feet, and in college, it's amazing." - TB patient Keerti Gurav (pictured)

It is now 12 months since Keert started treatment and she is strong and healthy enough to resume her college. She is in the final year of her bachelor's degree at Mumbai University and is confident of graduating in 2019

#### New Drugs and Regimens

Challenge TB supported the introduction of new drugs and the shorter treatment regimen at the national, state, and site levels. The project trained more than 300 government staff as trainers on PMDT and the use of new drugs. Twenty-four of the 156 initiation treatment sites (15%) for bedaquiline are supported by Challenge TB, and 1,124 patients were enrolled on BDQ in Year 4.

#### Patient-Centered Care

The project is building on the experience of the Private Provider TB project in Mumbai. The aim is to establish a 'test and refer' model for DR-TB cases in the private sector in Mumbai. The project engaged 137 providers in the implementation which covered more than 80 percent of TB patients. The time required to initiate RR-TB patients on treatment was 13 days from the date of diagnosis compared to 20 days in non-intervention areas. In the last year, 649 RR-TB patients were diagnosed by private providers, up from 327 in the previous year, 502 RR-TB patients were linked to public sector for treatment, and 46 imitated treatment in the private sector.

#### Childhood TB

This intervention to increase access to GeneXpert among the children contacts of TB patients. A total of 11,993 presumptive pediatric TB and DR-TB patients have been tested between October 2017 and March 2018. Of these, 524 (4.4%) were diagnosed as Xpert-TB positive, and 30 (5.7%) were found to be rifampicin-resistant. The project generated evidence to guide the national policy of GeneXpert as diagnostic of choice for pediatric TB. Four scientific papers were published in peer-reviewed journal. In September 2018, the WHO published best practices in their guidance document: "Best practices in child and adolescent Tuberculosis" citing FIND's project under Challenge TB as a model recommended for replication.



#### GeneXpert

Challenge TB assisted Xpert expansion in terms of planning, updating the Xpert manual, developing materials for workshops/training, and preparing the installation schedule. A total of 559 GeneXpert machines with 2,258 modules are now operational nationwide. Challenge TB provinces contributed about 70 percent of GeneXpert testing, with a utilization rate of 38 percent in August 2018, compared to just 18 percent in non-Challenge TB supported provinces.

#### Case Notification

The acceleration in case notification started in 2017 and is the result of more complete and more timely reporting, the inclusion of TB cases lacking a recorded laboratory test, more intensive use of diagnostic tests, and better engagement of hospitals, especially those in the private sector. The private sector contribution increased from 24 percent (16,433/68,914) in 2016 to 28 percent (16,172/57,006) in Jan-Sep 2018.

#### New Drugs and Regimens

The implementation of the STR started in September 2017 at six treatment sites. By the end of June 2018, access had increased to 89 treatment sites in 31 provinces, enrolling 1,746 MDR-TB patients. Access to BDQ has also expanded from 9 to 22 hospitals in five supported provinces and two other provinces, with 195 patients enrolled during this period, and 353 since 2015. The revised PMDT guidelines were finalized in May 2018 and include DLM, which is now available in three site and with 12 patients already enrolled.

In support of patient triage and treatment follow-up, Challenge TB also supported the development of SL-LPA capacity in culture laboratories and the restructuring and strengthening of the national TB reference laboratory network, by providing technical assistance to three new regional reference laboratories and introducing a laboratory quality management systems in seven regional reference laboratories.

Twenty-four-year-old Anjar, from West Java, was one of 14 patients to be put on the newly introduced shorter treatment regimen

In July 2018, she successfully completed her treatment making her the first person in Indonesia to do so. She said: "I am so grateful – all the hard work and effort to introduce these new treatments have paid off, and I was cured in such a short time."

She has joined a group for ex-drug-resistant TB patients, and she visits TB patients at home or in the hospital to offer muchneeded support, counseling, and encouragement during treatment. Anjar knows how important this is, and she doesn't want anyone else to die from this terrible disease. She tells them, "Never give up, keep fighting, and be confident you can be cured.



"When I was diagnosed with multidrug-resistant TB it felt like a death sentence, but the doctor told me the disease is curable and I would return to my work very soon. I was relieved to find out that I would be put on the shorter treatment regimen. I'm already three months into my treatment, and in six months I will be cured, and then I can get back to my normal life."

Guliya, 33, MDR-TB patient on

#### New Drugs and Regimens

Five regions were prepared for the implementation of new treatment regimens with technical support from Challenge TB. After three months enrollment on new treatment regimens started in all five regions. One-hundred and fifty-seven patients were enrolled on individualized treatment (155 on bedaquiline/delamanid and two on repurposed drugs) and 61 on the shorter treatment regimen.

Active TB drugs safety monitoring and management Challenge TB focused on improving the quality of clinical management and on creating a system for recording and reporting adverse events. Among the patients enrolled on new treatment regimens, there were six serious adverse events reported from five sites.

The project provided technical support in the development of a clinical protocol on the use of new drugs and the shorter treatment regimen, a tool for data collection on patients enrolled on the new treatments, and forms for reporting adverse events. These were all approved by the national TB program and disseminated across the country.



#### New Drugs and Regimens

More than 700 patients have so far benefited, and 76 have already been cured. Ten children and adolescents who had started on the STR were cured in half the time, and two patients with XDR-TB were cured. The treatment success rate for the STR was 78 percent for patients enrolled between Oct 2016–Sept 2017. A total of 1,435 doctors and nurses from every region have been trained on new approaches to the management of DR-TB.

#### Patient-Centered Treatment

All patients on ND&Rs benefited from psychological, medical, and social support from case managers, which increased their adherence to treatment. The number lost to follow-up in the first six months of treatment dropped from 22 percent in 2015 (standard regimen) to 7 percent among all patients treated with ND&Rs in the first six months of 2017. Nearly 90 patients were able to be treated at home and avoided daily hospital visits. By the end of Year 4, 37 patients had been enrolled on video supported treatment and were able to continue with their regular activities while receiving their treatment.

#### Contact Investigation

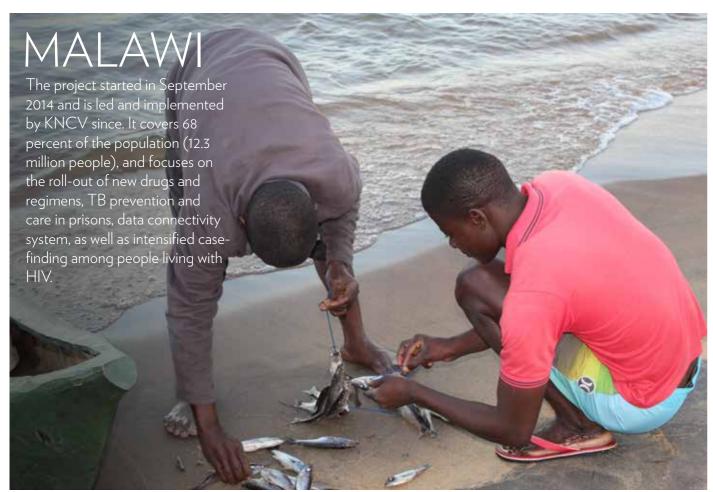
Since Year 3, the project has also supported contact investigation activities. By the end of Year 4, a total of 1,427 contacts of 1,385 drugresistant TB patients were screened, and 15 people were diagnosed with TB. Out of these, 11 were put on treatment, two refused treatment, and two left the country.

#### Quality Diagnostics

The Osh Inter-Oblast Laboratory, which ensures timely enrollment on appropriate treatment, and monitors treatment in the country's southern regions, resumed its activities by the end of Year 4. The collective efforts of Challenge TB and partners, led to the development of a specimen transportation mechanism, maintained equipment, built capacity, and improved collaboration.

After a fight with TB that had lasted more than a decade, Kyzylgul is finally cured. What ultimately saved her life was the introduction of the new drug bedaguiline in Kyrgyzstar

"Happiness for me is when everyone you love is healthy the rest can always be solved later." - Kyzylgul



All 1,900 inmates in the prison were screened, and Madalitso was one of 75 who tested positive for TB and to make matters worse he also tested positive for HIV.

He completed his jail term at the same time as completing his TB treatment.

He said: "I hanks to Challenge TB I am now healthy and back working as a fisherman on Lake Malawi to support my family. The future looks good."

#### New Drugs and Regimens

After a training of trainers on ND&R as well as aDSM management were conducted in April 2018, ND&R have been rolled out from 1st of June 2018 onwards. Currently 40 patients have been initiated on individualized (14) new drugs and shorter (26) treatment regimens. CTB provides continued mentoring to the clinicians in the sixteen treatment sites.

#### Prisons

Challenge TB supported mass screening exercises at four prisons. Prisoners were asked four symptomatic questions and they were examined by mobile digital X-ray provided. All presumptive TB cases screened positive by questionnaire and/or X-ray were also examined by Xpert.

#### GeneXpert

Challenge TB supported the introduction and roll-out of GxAlert, in all of the 69 the GeneXpert sites.

#### TB/HIV

Intensified case-finding among PLHIV is being implemented in 16 facilities with a high TB/HIV burden. There was a notable increase in the number of TB cases notified among PLHIV. From Oct 2017 - Sept 2018, 9 percent (389/4,404) of the TB patients were notified among PLHIV improving from 7 percent (297/4,505) from Oct 2016 – Sept 2017. All 389 patients were put on TB treatment



#### **CB-DOTS** Activities

Challenge TB's contribution to TB case notification has steadily increased from 12 percent in 2015 to 40 percent in September 2018, showing that CB-DOTS support is making a significant contribution to finding the missing people with TB.

#### TB prevalence Survey and DHIS2

The project is supporting MoH and NTP in the first national TB prevalence survey. The survey is ongoing and is expected to finish in 2019. Challenge TB has developed a community DHIS2 system to improve reporting on project indicators and align its data at health facilities with the NTP system.

#### Laboratory System Strengthening

The project supported the expansion of the microscopy network to an additional 13 health facilities, giving a total of 212 laboratories in Challenge TB-supported provinces. Through the support of the implementation of second-line line probe assay in the regional reference laboratories in Maputo, Beira, and Nampula, 387 samples were processed from Jan to Sept 2018. Of these, 324 were drugsusceptible TB, 47 (12%) were pre-XDR, and 16 (4%) were XDR-TB patients. Notably, eight pre-XDR patients were detected in CTB-supported provinces. CTB also supported the specimen transportation system in six districts in Zambézia and Nampula which contributed 28 percent of all the patient samples referred, and 32 percent of all bacteriologically confirmed TB cases in these districts.

#### New Drugs and Regimens

Challenge TB is supporting the introduction of new drugs and regimens in the four supported provinces. Four patients were initiated on individualized treatment regimens, three in Zambézia and one in Nampula. Two new patients were initiated on the shorter treatment regimen in Zambézia.

Zita was first diagnosed with TB in 2012, but she found it hard to stay on the long months of treatment, and she gave up when she started to feel better. As a result, she developed MDR-TB, she was treated for that, but gave up again when she got pregnant and then she developed XDR-TB

She is now on an individualized treatment regimen that will take 24 months to complete.

Im so happy that after six years of treatment I'm finally making progress. I still have a long way to go, but this time I'm sure I will be cured," says Zita.



Through community-based case-finding Lian Tial was diagnosed and treated for TB. She successfully completed her treatment in March 2018, and she is now cured and back to full strength.

"It was an unforgettable moment in my life. I am so grateful to Van, who found me and convinced me to get treated, and to Challenge TB God bless you all!"

#### Increasing Case-Finding

The project is implementing community-based TB case-finding approach in 22 hard-to-reach townships in Sagaing, Chin and Kayah states with a total estimated population of 2.3 million people, and a public-private mix/drug vendor intervention in 15 urban poor townships in Bago region with a total estimated population of 3.2 million. These two interventions contributed to the notification of 2,812 TB patients (all forms). 36,027 presumptive TB patients were referred for TB diagnosis, 67 percent (1,895) were diagnosed and notified through the community-based TB care intervention, and 33 percent (917) through the drug vendor intervention.

#### Laboratory Strengthening

The staff at three TB reference laboratories were supported, trained, and mentored by Challenge TB. The training focused on the implementation of a laboratory quality management system as it is a key component of ISO 15189 accreditation. A recent assessment by the Challenge TB laboratory team found that two laboratories had achieved 51 percent of the accreditation process. Challenge TB also strengthened biosafety measures in the BSL3 laboratories in Yangon, Mandalay and Taunggyi, and trained staff on quality DST.

#### New Drugs and Regimens

With Challenge TB support the STR for MDR-TB was introduced in December 2017. So far 237 patients have been enrolled on the shorter treatment regimen, 93 on bedaquiline, 5 on delamanid, and 14 on a combination of both. CTB facilitated four meetings for the National Core Committee for aDSM (NCCA) to conduct causality assessments of the 93 serious adverse events reported in Year 4. As a result, Myanmar submitted its first set of SAE data (December 2017 to June 2018) to the WHO Global aDSM database for new drugs and the shorter regimen.



#### TB/HIV

Challenge TB, did a rapid assessment on the implementation of TB preventive treatment in supported districts. The team reviewed the patient care booklets of 2,145 PLHIV. The assessment facilitated the immediate updating of records and on-site mentoring of HCWs and the findings contributed to making preventive treatment a key focus of the Namibia Linkage, Viral load and End TB (NamLiVE) quality improvement collaboration. The project also provided technical support to NamLiVE in the planning and implementation of the SOP and developed stickers for the patient booklet reminding the healthcare worker to initiate TB preventive treatment on the next visit.

#### Contact Investigation

The project supported the implementation of existing national guidelines on TB Contact Investigation by training and working with community health workers as well as facility staff on a systematic approach to contact investigation. A total of 2,143 close contacts of TB index patients were screened, 43 (2%) were diagnosed with TB and 42 were started on treatment.

#### New Drugs and Regimens

Challenge TB supported the introduction of the STR, and as a result, 72 MDR-TB patients were started on treatment. The project also supported the introduction of new drugs: 89 patients were started on an individualized treatment regimen with bedaquiline, 17 patients on delamanid, of which 9 are using both. The first patients started on bedaquiline in 2016 were declared cured this year.

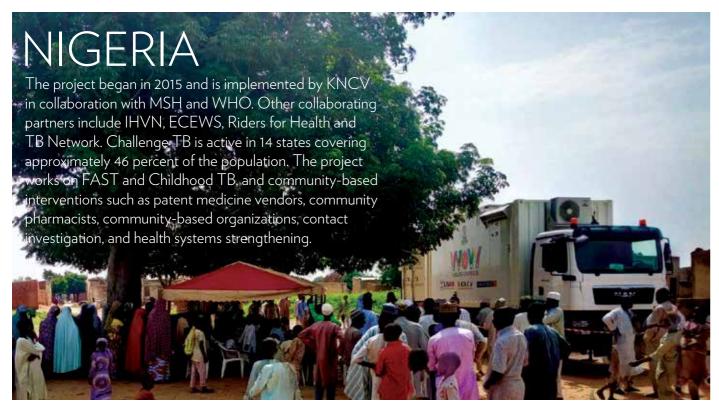
#### Prevalence Survey

The project provided technical assistance to implement and complete the first national TB prevalence survey. 15,410 households with 29,495 adults participated: 27,751 chest x-rays and 9,462 GeneXpert tests were done.

When Andre, a teacher from Rehoboth a town in central Namibia, was diagnosed with TB in March 2018 he was offered an HIV test, but he declined, saying that he feared a positive result

Thanks to counseling from Esther Gwanyanya, the local nurse responsible for TB management who was trained by Challenge TB, he ultimately decided to change his mind and the result was thankfully negative.

"I think life has given me another chance, now that I know my status, I will try to take better care of myself, including reducing my risk for contracting HIV. I have learned about safer-sex and how to be more careful."



"We go wherever TB might be. Every day presents an opportunity to help somebody, and each patient we diagnose motivates us to find and treat even more," - Chimezie Dimkpa, a radiographer onboard one of the trucks.

#### Intensified Case-Finding

From Jan-Sep 2018 the 143 Challenge TB supported health facilities implementing FAST identified 53,918 presumptive TB patients leading to the diagnosis of 7,420 TB patients. By the end of June 2018, FAST had contributed 38 percent of the total TB patients notified across the Challenge TB areas implementing this approach.

#### GeneXpert Connectivity

All the Challenge TB supported GeneXpert machines are connected to GxAlert with 88 percent (345/394) uploading data to the central server by the end of September 2018.

#### New Drugs and Regimens

Challenge TB assisted in the finalization of the Guidelines on the use of the shorter regimen and new drugs in the clinical and programmatic management of drug-resistant TB and co-infections of Nigeria. The country started enrolling patients on new drugs and regimens in the second half of 2017, and by September 2018 a total of 1,724 patients were on the STR, 44 patients were on individualized treatment containing bedaquiline, and 2 patients were on containing delamanid.

In addition, the project provided technical support to establish an intermediate aDSM package, including printed and distributed aDSM guidelines, and SAE forms. The national roll-out of aDSM training started in September 2018. In the first batch of six states, 120 clinicians, program staff, and staff from the drug regulatory agency were trained.

#### Active Case-Finding

Challenge TB deployed two mobile TB diagnostic units known as Wellness on Wheels (WOW) to provide TB diagnostic services to at-risk populations in hard to reach locations. This led to the diagnosis of 639 TB patients 94 percent of which were started on treatment.



#### TB/HIV

Challenge TB, did a rapid assessment on the implementation of TB preventive treatment (TPT) in supported districts. The team reviewed the patient care booklets of 2,145 PLHIV. The assessment facilitated the immediate updating of records and on-site mentoring of HCWs and the findings contributed to making preventive treatment a key focus of the Namibia Linkage, Viral load and End TB (NamLiVE) quality improvement collaboration. The project also provided technical support to NamLiVE in the planning and implementation of the SOP and developed stickers for the patient booklet reminding the healthcare worker to initiate TPT on the next visit.

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#### New Drugs and Regimens

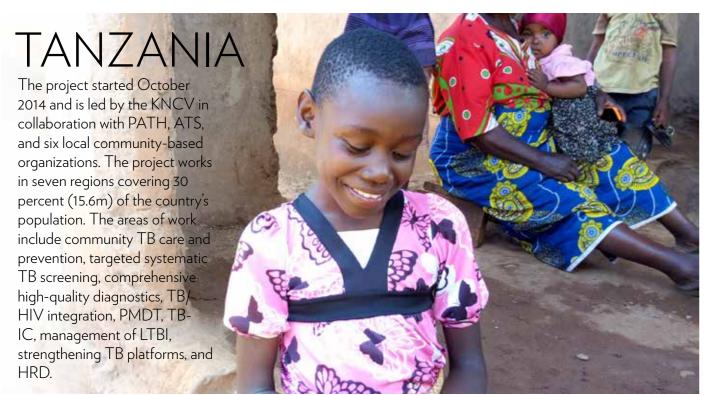
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#### Prevalence Survey

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Jamilya has had TB no fewer than three times, in 2017 she was diagnosed with XDR-TB and the only ray of hope was it coincided with Challenge TB introducing the new TB drugs Bedaquiline and Delamanid. These drugs are offering hope to XDR-TB patients who up until now had very little chance of being cured.

"I fought I B for so long," said Jamilya, "Sometimes I got depressed and wondered why can't my body fight this disease? Will I ever be free and start feeling and breathing better? When Delamanid was added to my treatment I immediately started to feel better, I was stronger, and my breathing improved."



For more than a year Gloria had no proper diagnosis, but fortunately she was taken to Mawenzi hospital, where she met Adam Mlonganile and Martha Lema. Adam is a clinician who works as a field coordinator and oversees all the project activities implemented in Kilimanjaro region. Martha is a dedicated nurse who works in the TB clinic.

When they did a thorough examination they found a large lump in her lower back, testing revealed she actually had TB of the spine. This is a sort of TB which invades the backbone and cause severe pain and deformation of the backbone.

"Gloria is one of those TB patients who slip through the net. It requires someone with a lot of experience to spot this sort of TB. So, we still need to train doctors to always think of TB," says Adam.

#### Case Notification

The project contributed 29,514/73,164 (40%) of the total national TB case notification in Year 4, including 202/315 (64%) RR-/MDR-TB cases. Contact investigation and active TB case-finding contributed 5,016/29,514 (17%).

#### Specimen Transportation

10,685 specimens were transported using motorcycles. Out of those, 648 (6%) specimens were MTB+, and 35 (5.4%) were rifampicin resistant. Specimen transportation started with four motorcycles/riders in four districts and scaled up to 17 in 16 districts.

#### MDR-TB Care and Treatment

Across the country 315 DR-TB cases were detected, compared to 183 cases in Year 3 (72% increase) and 295 (94%) patients were enrolled on treatment, compared to 158 (86%) in Year 3. In Year 4, 165 (56%) patients were initiated on DR-TB treatment in decentralized sites.

#### New Drugs and Regimens

ND&Rs were introduced with the support of Challenge TB. Thirty patients started on bedaquiline, 1 on delamanid and 149 on the shorter regimen. The project provided both technical and financial support in the mentoring of new PMDT sites, e.g. training of health care workers, conducting technical working group meetings, patient monitoring tests, patient transport stipends, and the procurement of supplies, and the implementation of aDSM.

#### TB/HIV

Ninety-nine percent of TB patients knew their HIV status and 98 percent among those who are HIV positive were on ART. Integrated HIV services within the TB clinic are now available in 70 percent of health facilities.



#### New Drugs and Regimens

The project developed training modules on MDR/XDR-TB and trained 182 specialists from the regions so that they could share their knowledge to the regional TB specialists and primary health care workers through cascade trainings in six regions of the country. To support the introduction of the shorter regimen, Challenge TB also provided organizational and technical support and conducted a study tour to the National Center for Tuberculosis and Lung Disease of Georgia in July 2018. This tour was attended by five representatives of the NTP of Turkmenistan.

#### Infection Control

Challenge TB conducted a course on IC measures in TB facilities for 14 TB specialists at both central and regional levels. The main focus was on preventing DR-TB transmission and enhancing IC measures in TB facilities. Laboratory technical staff and engineers responsible for the safety and maintenance of equipment were trained in basic IC measures. Challenge TB trained laboratory workers on standards and requirements of testing for laboratory biosafety equipment and maintenance, principles of natural and mechanical ventilation design and effective airborne IC.

Procurement and Supply Chain Management CTB trained 28 staff on drug forecasting and calculations by using of QuanTB tool in order to prevent drug stockouts.

#### Supportive Supervision and M&E

Challenge TB provided technical assistance to the TB national working group on the updating of the national MDR-TB and M&E guidelines with an emphasis on the programmatic and clinical management of M/XDR-TB including the implementation of new drugs and regimens.

Maya Egendurdiyeva - is the chief doctor at the laboratory in Mary Regional TB Center.

"We constantly use respirators in our daily work. There have been a number of theoretical courses on how to fit them properly, but I was never taught how to do it. Challenge TB specialists taught my colleagues and me how to do it right, and we also made a video. I now have an opportunity to share it with my colleagues. It is very important to keep doctors safe especially the ones who work in laboratories. Good infection control is a critical part of a patient's recovery."



doctors didn't know what to fighting. I knew I had only one and the first patient in Ukraine

#### New Drugs and Regimens

The project provided guidance and technical assistance to the Ukrainian Center for Public Health for the countrywide scale-up of new drugs and regimens. Challenge TB staff supported regional leaders and technical focal points during the implementation. Between June 2017 and September 2018 a total of 144 patients were enrolled on treatment with bedaquiline. The project has supported the adjustment of the national online system for pharmacovigilance.

#### Increasing ART Coverage

In Challenge TB supported areas, clinicians placed an increasing proportion of TB/HIV co-infected patients on ART, coverage increased from 49% in the first quarter of Year 4 to 83% at the end of Year 4. The average time to enroll patients on ART decreased from 2-3 months to 3-4 weeks.



#### New Drugs and Regimens

Challenge TB supported the scale-up ND and STR countrywide by facilitating the development of a national clinical protocol, standard operating procedures, training 168 clinical experts and relevant health care providers, and the updating the existing data recording and reporting formats and the establishment of a pharmacovigilance mechanism through the creation of a national technical working group. In June 2018, the first patients were initiated on new drugs and regimens in the pilot districts in Tashkent city, and by the end of Year 4, 114 patients were enrolled, including 52 on the shorter regimen, 55 on bedaquiline, and 7 on delamanid.

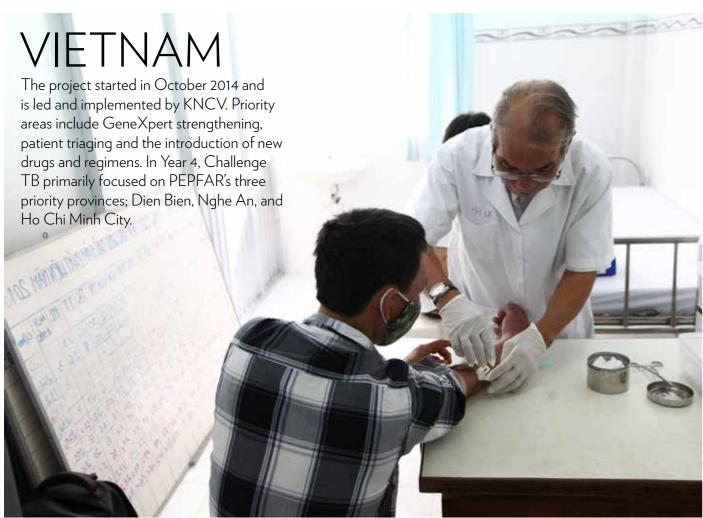
#### Strengthened Human Resources

The project developed two online TB "Distance Learning" modules. One for nurses on DOT and patient management, and for the other laboratory staff on TB detection. The distance learning platform is currently under beta-testing.

#### GeneXpert Scale-up

Challenge TB invested in the national TB diagnostic network, by procuring four GeneXpert machines. These were installed in pilot laboratories in the Tashkent city, Andijan, and Namangan regions, giving increased access to rapid TB diagnosis to around 1.5 million people. The project and the national reference laboratory organized training for 22 laboratory staff on the updated TB diagnostic algorithm including referral of TB presumptive patients for TB rapid molecular testing. An additional 3,000 Xpert MTB/Rif testing cartridges were also procured for pilot laboratories. Following the procurement, Challenge TB organized hands-on training for 76 healthcare workers from government programs and hospitals, including clinicians, nurses, and laboratory technicians.

"I am indebted to the team, care of me. I am so lucky to be just be patient and follow the doctors' advice, don't let Uzbekistan to be enrolled on a



I will never forget how tough those days were when I suffered from the side effects of the TB drugs, but every cloud has a silver lining though. God put me in a difficult situation, but God sent me this angel to help me through. I was so lucky to have my doctor by my side every step of the way. He became a true friend to me."

Pham Van Nghia – 1B patient in Vietnam

#### GeneXpert Strengthening

Between October 2014 and June 2017, a total of 254,389 presumptive TB patients were tested with GeneXpert, of which 108,060 (43.5%) were diagnosed with MTB and 12,314 (11.4%) with RR-TB. Challenge TB supported the NTRL in developing a country plan for the transition to GeneXpert MTB/RIF Ultra cartridges.

#### Case-Finding Among PLHIV

Challenge TB developed an approach for increasing TB case-finding in high risk groups, in particular among PLHIV. The preliminary results showed high prevalence/case detection rates of 541/100,000 (all forms of TB) among the PLHIV. Between January and June 2018, 1,444 MDR-TB patients were diagnosed, 1,151 (80%) patients started on a conventional regimen, with a treatment success rate of 75 percent for both the 2014 and 2015 cohorts.

#### New Drugs and Regimens

In Year 4, 40 patients were enrolled on individualized treatment with bedaquiline and 607 patients were enrolled on the shorter treatment regimen.

#### TB Prevalence Survey

The project provided technical assistance in the development and implementation of the second National TB Prevalence Survey. The survey data analysis is expected to be finalized in October 2018.



Improved DR-TB Diagnosis and Management Challenge TB has completed the installation of diagnostic connectivity system in 68 sites in supported areas. Between April and September 2018, a total of 23,165 Xpert test results were electronically transmitted in real time to the MoH server and to 1,806 clinicians via SMS and/or email. Of these, 2,611 (11.3%) were drug-sensitive TB while 128 (4.9%) were rifampicin-resistant TB. All the patients were started on treatment. Previously, GeneXpert data reporting to the national TB program took between 3-6 months.

#### New Drugs and Regimens

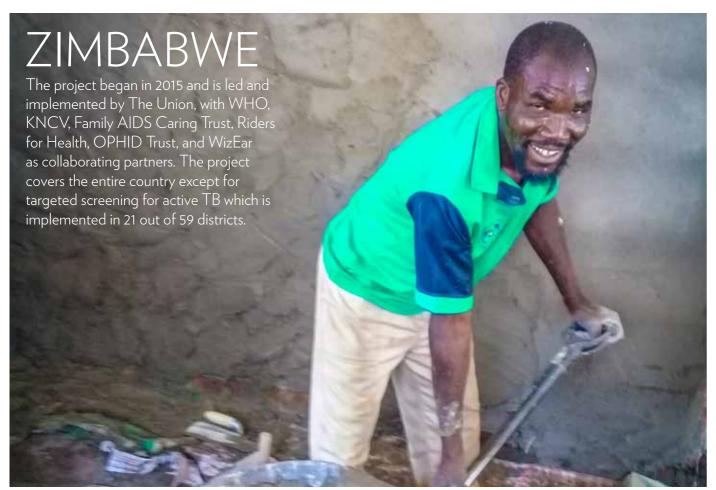
The introduction of ND&Rs began in October 2017 at four hospitals in Lusaka, Central, Copperbelt, and Southern provinces. Between October 2017 and September 2018, 271 patients started on the shorter treatment regimen. The number of sites implementing ND&Rs increased from four in 2017 to eleven in 2018. By the end of September 2018, a total of 10 patients were on bedaquiline, and 10 were on both bedaquiline and delamanid. Challenge TB also supported the introduction of ND&R by procuring medical equipment such as seven ECG machines for patient monitoring in seven provincial hospitals and providing on-the-job training of the staff on patient monitoring and the management of adverse events.

#### Renovation of MDR-TB Ward at UTH

The project supported the scale-up of DR-TB management and treatment by renovating some old buildings at UTH, Kabwe and Mansa hospitals as well as the National TB reference laboratory in Lusaka. The new MDR-TB ward at UTH is a major step forward. It provides a safe and clean environment to care for patients with drug-resistant TB. It will minimize cross-infection in the hospital and hopefully will also reduce the numbers of patients giving up on treatment.

Margaret is one of the patients being treated in the newly opened MDR-TB ward at UTH. She has multidrugresistant TB, and she moved to the new ward as soon as it was opened in August 2018. Though seriously ill, she is very happy to be in an environment that is not only clean and spacious but has water that is fit to drink. She knows this will help her recover faster.

about leaving because the conditions were so poor, but now I feel very well cared for."



"My wife and I were relieved to discover the cause of my illness. Both she and my children were also screened, but fortunately none of them had the disease.

I'm grateful to the health workers who helped save my life and Charles the specimen transport rider in particular. It was his watchful eye that helped me to get screened in the first place."

Elisha from Zimbabwe

#### Specimen Transportation

The specimen transportation system contributed to the diagnosis of 8,135 TB patients, accounting for 69 percent of all bacteriologically confirmed patients diagnosed nationwide in the same period. A total of 36,117 TB samples were transported, an 18 percent improvement over the 30,537 TB samples transported in the previous year.

#### Targeted Screening

Targeted screening for TB, HIV, and diabetes yielded 438 TB patients (all forms), 9 patients with RR-TB, 408 HIV patients, and 100 with diabetes; 99 percent of the patients were enrolled into care.

#### Contact Investigation

One-hundred-seventy-seven TB patients were identified through contact investigation, among whom 123 (70%) were bacteriologically confirmed. A total of 5,950 contacts were identified of which 5,770 (97%) were screened. Out of the contacts, 637 children under the age of 5 were identified, and 584 (92%) were screened for TB. Eighty-three (14%) had TB signs and symptoms, and 14 (16%) were ultimately diagnosed with TB.

Programmatic Management of Drug-resistant TB Seven-hundred and twenty-five patients were diagnosed with MDR-TB, of which 660 started on second-line treatment (91%). Of those who started treatment, 46 patients were enrolled on new drugs and regimens (bedaquiline: 29, delamanid: 7, shorter regimen: 10) after they were rolled-out in June 2018.



Improved Access to Quality Patient-Centered Care
The project supported the development of the TB component of
the IGAD HIV/AIDS, TB, and Malaria Strategic Plan that covers the
period 2018-2025. The strategic plan which was finalized, endorsed,
and adopted by the member states in March 2018 and it formed
the basis of IGADs successful application to the Global Fund for
a US\$10m regional grant on interventions among refugees in East
Africa.

#### Cross-Border Assessment

An assessment on cross-border and mobile populations and TB health services was conducted to provide the background for cross-border TB control planning. The main finding was that there is little investment in the border facilities for TB diagnosis and management and that there is no referral system in place. The findings will provide baseline values and will inform evidence-based planning and implementation of activities going forward.

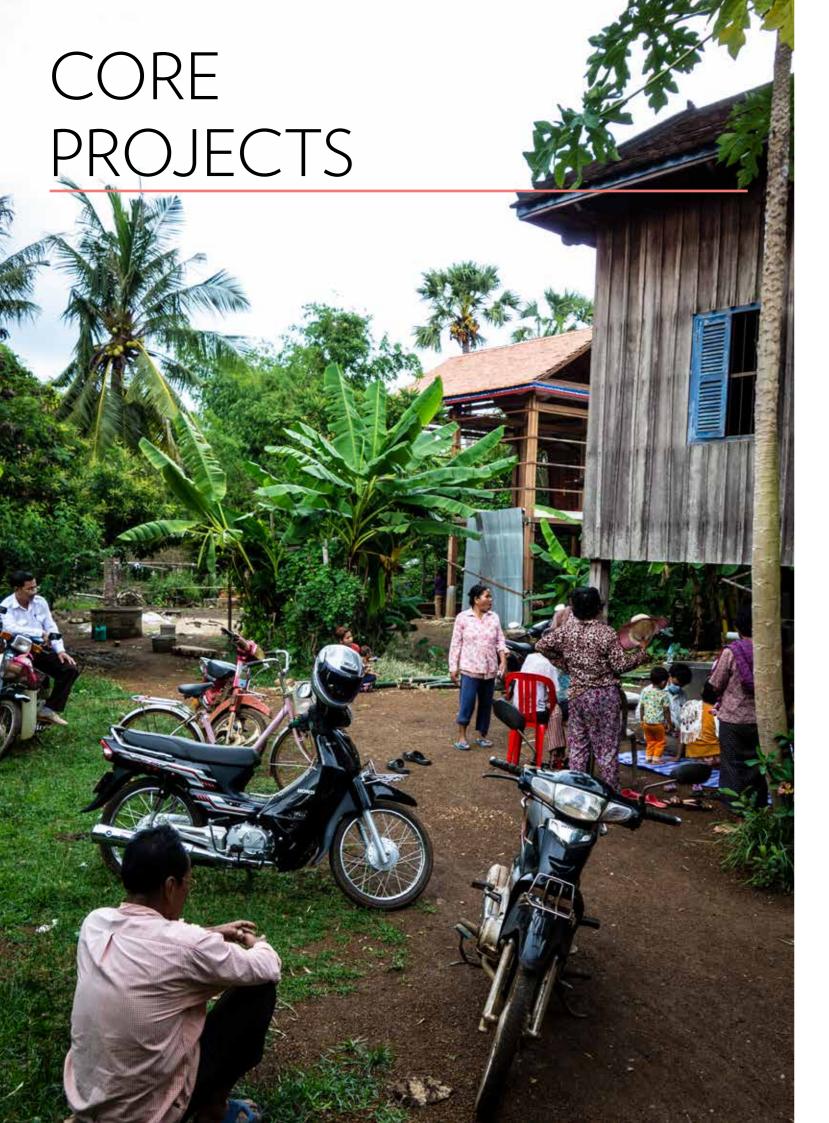
#### Strengthened TB Platforms

The ECSA TB Supply Chain Portal was handed over to ECSA-HC for hosting. The portal is being used to capture, collate, and create reports to disseminate TB commodities supply chain information). The relevant staff from the Uganda, Tanzania, Rwanda, and the ECSA-HC secretariat were trained on its use and maintenance. This will facilitate timely identification of countries with surplus or short expiry TB medicines especially second-line drugs and enable them to be borrowed/redistributed in the region. The portal is now live at: <a href="http://ecsascportal.org">http://ecsascportal.org</a>

Support to the Supra-National Reference Lab Uganda
The curriculum on new diagnostics (Xpert and line probe Assay)
with an emphasis on SL-LPA was finalized and has been used to train
14 international participants from nine countries (Burundi, Eritrea,
Ethiopia, Kenya, Somalia, Sudan, South Sudan, Tanzania, and Uganda)
and 6 local participants.

The Strategic plan has had an impact on IGAD operations.
Dr. Mohamed Elduma, Health Specialist at the IGAD
Regional Health Program said:

"We now have a tool with which to engage partners who would like to collaborate with IGAD. We have also used the Strategic plan to successfully apply to Global Fund for the support of interventions that address TB/HIV among refugees."



#### UN SPECIAL ENVOY FOR TB

This is the third year that Dr. Goosby has served as the UN Special Envoy for TB (UNSE). Despite all the challenges that remain, it is good to reflect on the progress that has been made in raising the profile of TB and preparing a pathway for accelerated progress. The impact of Dr. Goosby's work is evident both in technical forums and broader political spheres.

#### The UN High-Level Meeting (UN HLM) on TB

On September 26, 2018, the leaders of 194 nations endorsed a declaration that has strong operational targets in a politically relevant time frame, financial targets, recognition of the need for research and development, and a commitment to revisit TB in 2020 and 2023. The Office of the UN Special Envoy had a unique role to play in supporting the preparation of this meeting. In all, as a representative of the UN Secretary-General the UNSE strove to play a bridging role between the community, the member states of the general assembly, and the office of the Secretary-General. Dr. Goosby made five trips to New York to engage bilaterally with countries and to participate in TB briefings to member states. Jane Coyne spent approximately one week per month in New York to support missions and liaise with the TB partners.

In addition to the work focused on the UN HLM on TB additional efforts were made in the following themes:

- Ensuring integration of TB into the UHC and AMR agendas from both a technical and political perspective
- Urging countries, their ministries and implementing partners to focus on data-driven decision-making and putting the science of TB care in front of those that need it
- Encouraging donor countries to make stronger commitments to TB
- Raising general awareness about TB.

Dr. Goosby paid visits to specific countries, as a follow-up on existing relationships: India, Australia, United States, Indonesia, and Nigeria.

The efforts the UNSE has made in education and awareness is organized along themes that translate into work-streams. These themes reflect what are the best opportunities to use the Office of the Special Envoy to push the TB agenda forward. The speaking engagements of Dr. Goosby took place in:

- January New York, NY Bilateral meetings with UN agencies and country representatives
- February Wilton Park, UK focus on HIV/ HCV included TB in discussion and participated in March – Geneva, CH - WHO Accountability Framework workshop
- AMR related book launch
- March New Delhi, IN India TB Summit with PM Modi, Stop TB Board Meeting, Lancet Commission Meeting #3
- March New York, NY WHO World TB Day Luncheon at the UN + bilateral meetings with Ambassadors
- April San Francisco, CA Memorial Global Health Lecture
- April London, UK IACG AMR Governance discussion
- April New York, NY Parliamentary
   Consultation organized by Global TB Caucus
- May Palm Springs, CA keynote address to U.S. National TB controller meeting
- June- New York, NY UN Interactive Civil Society Hearing - Address to New York Public Health Department on Tuberculosis and participation in WHO TB STAG
- June- Geneva, CH UNAIDS PCB discussion
- July Amsterdam, NL Address at TB 2018 and organized TB/ HIV panel for IAS plenary
- August Durban, ZA African Health Education meeting on HIV/TB

CORE PROJECTS CORE PROJECTS

#### INDIA

The Core funded India project was a two-year project, implemented by PATH between October 2016 – September 2018. The aim of the project was to establish a test-and-refer model of care for the private sector patients in Mumbai, India.

The project engaged 137 providers in the implementation area who catered to a more than 80 percent of TB patients. This allowed the project to access a higher number of DR-TB presumptive cases. All the presumptive cases tested on GeneXpert and diagnosed RR-TB were included under the project leading to an improvement in the number of bacteriologically diagnosed DR-TB cases.

By providing the diagnosed RR-TB patients with all pre-treatment tests under a single roof as well as individualized follow up, the total time required to initiate the RR-TB patients on treatment significantly reduced, averaging to 13 days from the date of diagnosis as compared to 20 days in the non-intervention geographies.

By providing the RR-TB diagnosed patients with DST and linking them to the public sector for treatment, the project ensured access to standardized, high-quality treatment. This invariably decreased the patients' out-of-pocket expenditures which encourages their adherence.

The adherence provided by the project staff ensured that the patients continue the treatment, linked to the nearby treatment centers on migrating to nearer geographies as well as to different states though coordinating with the Revised National TB Control Program (RNTCP). The information on the TB burden, especially the DR- TB burden, in the implementation geography aided the public sector in understanding the actual burden in the community.

The patient support activities undertaken through this project also improved treatment adherence. The peer group support meetings conducted for all the patients were well received by the public sector, leading to the government including these activities in their annual budget for TB programs, thus ensuring sustainability of the intervention.

During the transition of the Private Provider Interface Agency (PPIA) to the Patient Provider Support Agency (PPSA), the project supported the forecasting of the required logistics for the inclusion of the private sector patient testing and treatment in the public sector. Technical assistance was provided through the project to the public sector for transitioning the services as well as optimizing the uptake of the services in the public sector.

At the conclusion of the project, the test-andrefer model was established for the private sector patients and transitioned to the Global Health Security Agenda project where it is currently being implemented.

#### **PREVENTION**

In Year 4 the following progress was made:

Participant enrollment (completed in November 2017):

A total of 4,027 participants were enrolled; 2,548 in South Africa (5 sites), 601 in Mozambique (1 site), and 878 in Ethiopia (2 sites).

The original eight sites actively continue to follow participants on the study:

#### South Africa

- 1. The Winnie Mandela Clinic, an Aurum site, has been enrolling since late 2016. In total, 895 participants were enrolled at this site.
- 2. Tsehpong Hospital, a PHRU site, has been enrolling since half March 2017. In total, 406 participants were enrolled at this site.
- 3. Tembisa Clinic (Aurum) has been enrolling since half April 2017 and enrolled 669 participants.
- 4. Empilisweni Clinic (PHRU) initiated enrolling participants at the end of April 2017, and enrolled 345 participants.
- 5. Rustenburg Clinic (Aurum) started enrolling participant in early June 2017, and enrolled 233 participants.

#### Ethiopia

- 1. Zewditu Hospital, an OSU site, began enrolling in mid-June 2017, and enrolled 367 participants.
- 2. ALERT (OSU) initiated enrollment in late June 2017, enrolling a total of 511 participants.

#### Mozambique

CISM was the last site to initiate enrollment, beginning in mid-July 2017. In total, 601 participants were enrolled at this site.

Enrollment across all sites continued into mid-November 2017. As a result, all sites are expected to complete the full 24 months of follow-up in September 2019 (24 months of follow-up, with 28 days marking a study month = 672 days).

Eligible participants in the pulsed 3HP arm at all sites have initiated their second round of treatment.

A small number of enrollees at the Winnie Mandela

Clinic site in South Africa (the first site to enroll) have been followed-up for the full 24 study months as of 30 September 2018.

There are 319 6H arm participants who have completed their participation in the study.

Completion rates at the Month 1, 2, and 3 visits are 95.3, 92.8, and 90.9 percent respectively. Visit completion rates at the Month 4, 6, 8, and 10 telephonic visits are 81.5, 83.6, 83.1, and 87.0 percent respectively.

As of the end of Year 4, 103 participants have withdrawn from the study. Of these, 24 are due to the death of the participant, 28 were the participants' decision, and the remaining 51 are due to other reasons (e.g., study clinician decision, unable to locate, moved from study area, erroneously randomized).

At the end of Year 4, the total number of SAEs is 118, of which 39 are study defined SAEs. The most common study defined SAE is drug-induced liver injury. The most common non-study defined SAEs are trauma and anemia.

Monitoring visits are occurring on a 6-weekly basis. A total of 111 site monitoring visits (across all sites) have been completed. No findings have warranted recommending a temporary pause.

Protocol amendment version 4 was approved by regulatory authorities and ethics boards in each participating country. Key amendments are: inclusion of language describing increased isoniazid risk during pregnancy, allowance for home visits, DAIDS toxicity table updated, expansion of M12 and M24 visit windows to -28/+14 days, hepatitis modified to hepatotoxicity, clarification that fixed dose combination tablets will not be available in this study, and incorporation of QFT test schedule in accordance with reduced quantities of donated assays.

The second Data Safety and Monitoring Board (DSMB) meeting occurred via teleconference on 6 October 2017. The main query was around the

preliminary low retention rates at month 2 and 3 visits. It was recognized that this may, in part, be an artifact of the delay between visits and data being entered into the database, resulting in underreporting. A follow-up report based on an up-to-date database was developed in January 2018, and shared with the DSMB in March 2018.

The fifth trial steering committee meeting was held during the Union conference in Guadalajara, Mexico, (12 October 2017) and the sixth trial steering committee meeting is scheduled to take place during the Union conference in The Hague (25 October 2018).

Retention has been and will continue to be closely monitored and evaluated. Patient-centered practices are being implemented to keep participants in the study: individual approaches, spending enough time with each patient during clinic visits, and home visits.

The agreement with Qiagen was amended to

increase the number of interferon-gamma release assays (IGRA) donated from 4,000 to 5,200. This will allow for retesting at month 12 and month 24 for all participants who test QFT-positive/CD8 signal-positive at baseline plus a sample of participants who test QFT-positive/CD8 signal-negative at baseline as a comparator group.

A second face-to-face meeting of key site research staff took place in Johannesburg in the first week of July 2018. Meeting attendance exceeded expectations with over 50 global site staff in attendance. The focus of the meeting was retention. In addition, the amended protocol was reviewed in detail, and data entry and management was reviewed.

The clinical trial insurance policy for Ethiopia has been renewed until the end of the study. The policies for Mozambique and South Africa are not set to expire until the end of the study.

#### MEASURING STIGMA

The TB Stigma Measurement Guidance was finalized and released during this year. The companion curriculum PowerPoint presentation and exercises are in draft form and are expected to be released in the first quarter of Year 5.

Phase 1 of the CTB Core Stigma Measurement funded pilot of the measurement tool among health care workers in Ethiopia concluded during this year; with 70 interviews being conducted. The outcomes of these interviews were assessed. A draft code book of emerging themes was developed, but this requires validation, fidelity and translation checks from the Ethiopian team and the NTP. Once the

themes are agreed, further analysis along the agreed themes can take place. A feasibility analysis and mitigation plan will be developed in the first quarter of Year 5.

KNCV continues providing support to the Stop TB Partnership on the development of a country assessment tool. Initially, support was to be provided through CTB funded workshops. Such workshops are no longer required, and instead, a remote support is provided through regular calls and review of documents. A proposed budget modification to support this revised course of action will be submitted in the coming weeks.

#### BEDAQUILINE COORDINATION

In Year 4, the core project on BDQ Coordination project initiated the implementation of a monthly mechanism of monitoring progress in the introduction/expansion of ND&R that includes monitoring of patient enrollment, identification of bottlenecks and challenges, and the necessary actions to overcome them. This strengthened monitoring mechanism includes:

- A monthly online questionnaire that is completed by the country offices and collects mainly qualitative information from the 23 CTB supported countries;
- b. A monthly "ND&R Country Follow-Up" call between the respective KNCV HQ PMDT Consultant and CTB country office counterparts (61 calls in total were held); and
- c. Collection and review of quarterly quantitative data reported by countries on the CTB M&E Framework database through their respective Quarterly Monitoring Reports.

Two countries have been identified for additional targeted short term technical assistance (STTA) missions supported by the core project based on various criteria – importantly, through the information yielded by the strengthened monitoring activities. Namibia is planned for November 2018 and Vietnam for January 2019. The terms of reference of these missions have been finalized by the respective PMDT consultants in coordination with the CTB Country Directors and USAID. Three other countries (DR Congo, Malawi, and Zimbabwe) were also identified for additional STTA missions – these missions will be funded from the respective Year 4 country budgets.

To showcase the work achieved under CTB and assist similar efforts, the project worked on production of printed materials that highlight the success and challenges of introducing and implementing ND&R. These materials include a scientific journal article and fact sheets on related themes (e.g., ECG and audiometry monitoring, aDSM, and contact investigation). These will be utilized for global advocacy and awareness raising of the achievements under the CTB project at global forums, such as several symposia and workshops at the Union conference in The Haque in October

2018. Core project team members were actively involved in the Global Drug-Resistant TB Initiative (GDI) Core Group, the GDI's Triage Task Force and DR STAT group, and regional Green Light Committees (rGLCs for the European, South-East Asia and the Western Pacific) – including participation in rGLC missions (e.g. to Vietnam in July 2018).

In addition, an updated version of the "Generic programmatic and clinical guide for the introduction of new drugs and regimens for the treatment of multi/extensively drug-resistant TB" and "Generic training modules for new drugs and regimens" were finalized and/or disseminated via the CTB website, in April and June 2018 respectively.

The "Patient management quality improvement checklist" was developed and widely disseminated during the reporting period. The quality improvement (QI) tool was adapted from those of the European Respiratory Society, the European Centre for Disease Prevention and Control, and CTB Indonesia. The draft tool was pilot-tested in countries in the WHO European Region, South-East Asia and Africa at both district and facility levels. The QI tool is targeted at supervisors and M&E specialists from both NTPs and partner organizations. It was finalized (in English, Russian, and Ukrainian) and disseminated in May/June 2018, including posting on the CTB website.

Based on current needs and challenges of CTB countries, the project developed a number of guidance/technical documents, tools and supporting job aids to enhance ND&R implementation. To date. two technical documents and one job aid are available on the CTB website. In addition to these activities, the project has continued to update existing documents that were produced by the core project in previous years as new evidence and policies emerge, particularly the recent WHO "Rapid Communication on key changes to DR-TB treatment" (e.g. updated versions of the "ND&R Planning" tool and relevant modules of the "Generic ND&R training package" are available to align with WHO's "Rapid Communication on key changes to DR-TB Treatment").

#### **CORE PROJECTS**

Although the introduction of ND&R has proved to be complex, requiring careful revision and review of the overall management of DR-TB patients, the core project has complemented the efforts of the Challenge TB country office teams and their workplans. As a result, steady progress has occurred. By early October 2018, all 23 Challenge

TB countries had introduced ITRs containing BDQ. Twenty-one countries have introduced the STR, with Botswana planning to introduce the STR in the coming months. Nineteen countries have introduced an ITR containing DLM, with Botswana planning to introduce the ITR-DLM in the coming months.

#### **OPERATIONS RESEARCH**

To date, eleven Challenge TB countries have planned a total of 46 operations research (OR) activities, of which 26 (54%) had been completed by the end of Year 4. Six OR studies were completed in Year 4, all of which were from Ethiopia.

All of those completed were presented at the national TRAC conference as well as the Union conference 2018 in The Hague. The ten ongoing ORs are planned to be completed in Year 5 of the project.

#### CONTRIBUTION TO SCIENCE

Over sixty abstracts (posters and oral presentations) were presented at the 2017 Union Conference in Mexico.

Several guidelines and publication on ND&Rs were also completed and shared through the Challenge TB website: Generic ND&R Training Modules, Generic programmatic and clinical guide for the introduction of new drugs and shorter regimens for the treatment of Multi/Extensively Drug-Resistant TB, and the New Drugs and Shorter Regimen Implementation Planning Tool.

Under the core-funded Stigma project, Challenge TB also published 11 open access research articles on stigma in the *International Journal of TB and Lung Disease*, as well as three editorials during the Union Conference:

http://www.ingentaconnect.com/content/iuatld/ijtld/2017/0000021/a00111s1

#### **SUB-AWARDS**

From Year 1-4, Challenge TB signed 326 sub-awards with different partners (290 sub-awards with local organizations and 36 sub-awards with international organizations) in 21 countries.

The number of local sub-awardees has increased three-fold from 31 in Year 1 to 92 in Year 4. During the same period the number of international sub-awardees increased from six to eleven.

The top three sub-objectives with major investment during the last four years are patient-centered care and treatment, enabling environment, and comprehensive high-quality diagnostics.



The project performance on critical indicators is generally in the right direction. Especially looking at areas of laboratory network strengthening, scalingup and optimization of new technologies; using the core package approach (multiple complementary interventions) to improve case-finding; scaling-up PMDT (including the STR/ND&Rs) activities with emphasis on case-finding, closing the treatment enrollment gap, and providing quality of care to ensure adherence and treatment success; and lastly ensuring data quality and utilization of data for planning at all levels, including digital health, connectivity, and the use of electronic TB reporting systems.

In Year 5 the focus will be on overall project results, documentation, effective dissemination of results, and lessons learned. This includes the development of best practices and implementation guides to hand over to the NTP for scale-up of interventions using other resources.

Immediate and urgent key interventions are:

- 1. Provide coordinated technical assistance to NTPs (with other stakeholders) on the implementation of new WHO PMDT guidelines.
- 2. Facilitate the application of a two-pronged approach to GeneXpert roll-out using access and optimization.
- 3. Develop a core package (including indicators) for the implementation of connectivity and assess the current status of each country to facilitate targeted support.
- 4. Conduct monthly monitoring of the project finances, sub-awards, as well as STTAs and communicate progress to both the USAID missions and the USAID AOR.
- 5. Monitor the closeout activities at country level: identify, document, and communicate any potential risks to the USAID missions, the USAID AOR, and NTPs.

#### **PHOTOS**



Poster Advertising TB Self-screening App, Tanzania Photo: Eunice Motur



Girl with MDR-TB, Bangladesh Photo: Tristan Bayly



Cured TB Patient Bipangu, DR Congo Photo: The Union



Patient Room Ukraine Photo: Volodymyr Shukatka



Raising, Afghanistan Photo: Ahmad Gul



TB Drug Bedaquiline Photo: Tristan Bayly



Worknesh Receiving Audiometry, Ethiopia Photo: Berhan Teklehaimanot



TB Patient Svetlana, Uzbekistan Photo: WHO



Women's MDR-TB Ward, Bangladesh Photo: Tristan Bayly



TB Drug Cycloserine Photo: Tristan Bayly



TB Patient Keerti and her Mother, India Photo: Dvanesh Waman

ormer TB Patient

Anjar, Indonesia

Sulistiawan

Photo: Rembrandt



TB Doctor Vo Van Photo: Tran Ngoc

Renovated MDR-TB

Ward, Zambia

Photo: Marcel



Children, Tajikistan Photo: Sayora Ziyoyeva

TB Waiting Area,

Photo: Tran Ngoc

Vietnam



Patient Hand With TB

Photo: Tristan Bayly

Cured TB Patient

Photo: Paidamoyo

Faustina, Zimbabwe



Guliya MDR-TB Patient on STR, Kazakhstan Photo: KNCV



Former TB Patient Charles, Zimbabwe Photo: Paidmoyo Magaya

Cross Border



MDR-TB Clinic Staff, Indonesia - Photo: Tristan Bayly



Dotto receiving his TB drugs, Tanzania Photo: Viocena Mlaki

Ashraf Ally With His

Treatment Supporter,



Former TB Patient Kyzygul, Kyrgyzstan Photo: Marion



Photo: Victor Ombeka Contact Investigation,

Cambodia

Meeting, East Africa



Community TB Awareness Raising, Mvanmar

Cured TB Patient,



Photo: Peter Kasabaja, ormer Drug-users Engaged by CTB,

Tanzania

Tanzania



Photo: Akuzike TB Patient Zita

Paulino, Mozambique

Photo: FHI 360

Cured Fisherman,

Malawi



WoW Truck, Nigeria Photo: Habiba Bello

Photo: Tristan Bayly



Cured TB patient Esther, Nigeria Photo: Alu Azege



Mobile TB Screening Truck. Zimbabwe Photo: S Dube



Volunteer Ma Kyu Kyu Win, Myanmar Photo: FHI 360



Treatment Support, Photo: FHI 360



Former TB patient Rabi Umar, Nigeria Photo: Alu Azege

GeneXpert Cartridge

Photo: Tristan Bayly

ndonesia

Refurbished

laboratory, Malaw

Photo: KNCV

Mozambique

Photo: FHI 360



TB Screening, Malawi Photo: Marcela Tommasi

Contact Investigation,

Afghanistan Photo: Farid Bakhtani



Patient Support, Namibia Photo: Harriet Kagoya



WoW Truck, Nigeria Photo: Habiba Bello

Jamilya XDT-TB

Patient, Tajikistan







Rahat and His Mother, Bangladesh Photo: Samuel Murmu



Lab Technologist, Botswana Photo: Vuyani Dlamini



Photo: Sayora Ziyoyeva Former TB patient

Gloria, Tanzania

Photo: A.Mlonganile



Laboratory Worker, Turkmenistan Photo: WHO



Specimen Transport

Woman TB Patient, Cambodia Photo: Tristan Bayly



We would like to acknowledge all the people across the world who make Challenge TB possible; our gratitude and thanks go out to all our partners and everyone in the field.

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