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CHALLENGE TB



Challenge TB - Kyrgyz Republic

Year 2

Quarterly Monitoring Report

April-June 2016

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*Cover photo: The Challenge TB Director Bakyt Myrzaliev presents last CTB updates on Coordination partners meeting on introduction of the new TB drugs and short regimens
Credit: Gulzat Sultanidinova 30 May 2016*

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1. Quarterly Overview

Country	Kyrgyz Republic
Lead Partner	KNCV Tuberculosis Foundation (KNCV)
Other partners	N/A
Work plan timeframe	October 2015 – September 2016
Reporting period	April-June 2016

Most significant achievements: *(Max 5 achievements)*

Challenge TB (CTB) project facilitated the partners' meeting held on May 30th, 2016 with participation of the National partners: MoH, Department of drug provision, Karabalta MDR TB hospital, Bishkek and Chui oblast TB centers and international Partners: WHO, UNDP, MSF, Defeat TB project and UNION representatives. This helped to move on preparation for implementation of new drugs and short regimens. Important issues have been raised, solutions discussed and decisions made during those meetings. As most important issue was determined that the drugs not ordered yet, because GDF request additional information and clarifications for this order. Partners agreed to joint efforts to address all comments and prepare justification for this order and made this meeting regular on monthly basis with involvement of NGO representatives. CTB provided support to working group on preparation of this information and UNDP submitted it to GDF in short time. The lack of accreditation of the TB facilities to providing TB diagnosis and treatment was also identified as a risk. Another problem was the halt of clinical trial of FC-1 pharmaceutical product produced in Kazakhstan, by Department of drug provision. This will affect to introduction of the Bedaquiline and short regimens. In this regards CTB met with Medical Accreditation Committee and agreed on future collaboration for development standards for accreditation of TB facilities. For reducing risks from the side of Department of drug provision CTB conducted a series of meetings with Department of drug provision and clarify that all drugs need to be registered, except Bedaquiline and Delamanid, which can be supplied with approval of MoH as humanitarian assistance.

CTB helped to prepare justification for anti-TB drugs order requested by GDF that was submitted. Another issue was related to the local regulations that oblige accreditation for tuberculosis (TB) facilities that are planning to use the new drugs. CTB agreed to support the Medical Accreditation Committee in development of accreditation standards for TB facilities.

During the following partners' meeting held on June 30th, it was agreed that new drugs (Bedaquiline and Delamanid) will be procured upon the Ministry of Health's (MoH) waiver as humanitarian assistance and will be supplied in November 2016.

Operational research (OR) protocol on introduction of the new TB drugs and short regimens was updated in accordance with the last WHO updates announced in May 2016. Based on this protocol CTB consultants will train National TB Program (NTP) TB specialists, lab specialist, M&E specialists, drug management specialists and nurses in July 2016. The protocol will be adjusted in accordance to participants' feedback, then submitted to the Ethics committee with the endorsement by MoH in August 2016 as a final step.

Technical/administrative challenges and actions to overcome them:

The new agreement between the Government of the Kyrgyz Republic and the United States (denunciated in August 2015) has not been signed yet. It remains challenging to implement CTB project activities due to the national requirement to pay VAT which USAID projects were previously exempted from. Revision and approval of documents by the NTP and MoH takes more time which may delay implementation.

Because of the official letter of the Council of Trustees at the MoH to the President of the Kyrgyz Republic on situation around anti-TB drugs, including clinical trial with use of FC-1 pharmaceutical product (produced in Kazakhstan), the Department of drug provision keeps strict control on following the national regulations related to the use of new drugs. It will require close collaboration with the Department of drug provision and additional technical support to meet the national regulations.

2. Year 2 activity progress

Sub-objective 3. Patient-centered care and treatment								
Planned Key Activities for the Current Year	Activity #	Planned Milestones				Milestone status	Milestone met? (Met, partially, not met)	Remarks (reason for not meeting milestone, actions to address challenges, etc.)
		Oct-Dec 2015	Jan-Mar 2016	Apr-Jun 2016	Year end	Oct 2015-Jun 2016		
Development of operational research protocols for introduction of shortened MDR-TB treatment regimens and regimens containing new drugs	3.2.1.	<ul style="list-style-type: none"> Optimized diagnostic algorithm for early diagnosis of M/XDR-TB developed SOPs for patient selection and management developed 	OR protocol submitted to the Ethics committee	OR protocol on shorter regimen and new TB drugs approved by MoH and Ethics committee		OR protocol updated in accordance with the last WHO updates announced in May 2016. Will be translated in RU, agreed with ethic committee and approved by MoH in August – September 2016	Partially met	Last WHO updates announced in May 2016 were included in OR protocol which resulted in a delay of the OR protocol.
Development of system for link between laboratory, clinicians, register and SES in pilot sites	3.2.2.			SOPs for link between laboratory, clinic and SES developed		Draft SOP on links between laboratory, clinicians and SES developed.	Partially met	Draft SOP on links between laboratory, clinicians and SES will be discussed with clinicians, laboratory and SES specialists in the training in July and will be updated in accordance with the feedback of participants.
Development data base for patient registration and monitoring in CTB pilot sites	3.2.3.		Interim data base for pilot sites and laboratory developed			Interim database for pilot sites developed. During the visit of the HQ consultants, data base will be installed and operators will be trained on work with database.	Met	
Development of system for clinical monitoring and active pharmacovigilance	3.2.4.		Guidelines for adverse effect management	<ul style="list-style-type: none"> AEs reporting forms adjusted. 		SOPs for aDSM developed, AE reporting forms adjusted.	Partially met	SOPs for aDSM and AE reporting forms were developed and with Generic WHO guideline on

			t developed	• SOPs for PV developed				aDSM will be discussed with clinicians and Department of drug provision specialists in the training and adjusted in accordance with the country feedback in July 2016.
Coordination partners' meetings	3.2.5.	Partners meeting conducted		Partners meeting conducted		Partners meeting with NTP, MSF, UNDP and other partners conducted on monthly base on 30 May and 30 June.	Met	
Trainings for clinical, laboratory, PV and SES personnel in pilot sites	3.2.6.				25 key specialists from pilot sites trained		N/A	
Patient selection, enrolment and monitoring	3.2.7.				KNCV consultants visited, TA to local partner provided, trainings conducted, TB patients selected and enrolled to treatment		N/A	

3. Challenge TB's support to Global Fund implementation in Year 2

Current Global Fund TB Grants

Name of grant & principal recipient (i.e., TB NFM - MoH)	Average Rating*	Current Rating	Total Approved/Signed Amount**	Total Committed Amount	Total Disbursed to Date
KGZ-S10-G08-T, UNDP	A2	A1	\$ 25.7 m	\$ 24.7 m	N/A
KGZ-910-G07-T, HOPE	A2	A2	\$ 5,9 m	\$ 5,6 m	N/A

* Since January 2010

** Current NFM grant not cumulative amount; this information can be found on GF website or ask in country if possible

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

GF grant implemented by UNDP on sufficient level. UNDP is working with MoH and NTP on transition plan and growing capacity of local specialist for transition of responsibilities on implementation grant to the MoH. USIAD hire GMS team for assisting MoH on assessment capacity of newly hired implementation team and determination of limits for follow up implementation of GF grant by MoH implementation team.

Despite the well general implementation of GF grant. Country have some delays of Bedaquiline and companion drugs, the delivery postponed from June 2016 to November 2016. It is related with difficulties in calculation of number of DR TB patients (especially PDR) and limitations of M&E teams of NTP and UNDP in data analysis and coming to consensus on final data. For solving this issue NTP invite all related partners including CTB for data analysis and making conclusion on this issue, finally partners and NTP come to consensus on number of DR TB patients getting treatment, calculation of SLD was done in Quant TB tool with taking to account of all stocks, SLD was ordered in June 2016.

Challenge TB & Global Fund collaboration this quarter – Describe Challenge TB involvement in GF support/implementation

Per NTP and UNDP request KNCV specialist, Merkinai Sulaimanova, funded by the Elli Lilly project 'Strengthening Country MDR-TB Drug Management and Quantification' provided assistance in calculation the number of SLD drugs in Quant TB tool and addressing the GDF comments on number of patients per treatment regimen. Assistance was needed because NTP and UNDP staff were not very familiar with Quant TB tool and previous calculations differences with GDF calculations. GDF comment was about MDR TB treatment regimens, differences between treatment regimens in national clinical protocol and requested drugs. The consultancy work was successful, SDL drugs finally calculated with Quant TB tool and ordered in June 2016.

CTB assists the NTP to coordinate partners' activities on introduction of the new TB drugs and short regimens, by facilitating the monthly coordination meetings. As a follow up of these meetings, CTB connected with Medical accreditation committee and Department of drug provision for discussion of accreditation and SLD registration issues.

4. Success Stories – Planning and Development

Planned success story title:	Preparation of introduction of the new TB drugs
Sub-objective of story:	7. Political commitment and leadership
Intervention area of story:	7.1. Endorsed, responsive, prioritized and costed strategic plan available
Brief description of story idea:	Political support and commitment help to introduce new TB drugs and save lives of M/XDR TB patients in Kyrgyz Republic
<p>Status update: Preparation in progress: the topic has been chosen, sub-objective and intervention area of the story are selected as well. For personalization of this success story we need a patient who will sign release agreement. The success story will be finalized after the endorsement of the Strategic plan and OR protocol, when drugs will be supplied and treatment has started (in September 2016).</p>	

5. Quarterly reporting on key mandatory indicators

Table 5.1 MDR-TB cases detected and initiating second line treatment in country (national data)

Quarter	Number of RR-TB or MDR-TB cases detected (3.1.4)	Number of MDR-TB cases initiating second-line treatment (3.2.4)	Comments:
Total 2011	679	804	
Total 2012	958	958	
Total 2013	1590	1160	
Total 2014	1285	1219	
Total 2015	1158	1200	
Jan-Mar 2016	350	350	
Apr-Jun 2016	371	371	
Jul-Aug 2016			
To date in 2016	721	721	

Table 5.2 Number of pre-/XDR-TB cases started on bedaquiline (BDQ) or delamanid (DLM) (national data)

Quarter	Number of pre-/XDR-TB cases started on BDQ nationwide	Number of pre-/XDR-TB cases started on DLM nationwide	Comments:
Total 2014	0	0	First patients are expected to start treatment with Bedaquiline in November 2016, when the GF/UNDP will supply the drugs.
Total 2015	0	0	
Jan-Mar 2016	0	0	
Apr-Jun 2016	0	0	
Jul-Aug 2016	0	0	
To date in 2016			

Table 5.3 Number and percent of cases notified by setting (i.e. private sector, prisons, etc.) and/or population (i.e. gender, children, miners, urban slums, etc.) and/or case finding approach (CI/ACF/ICF) (3.1.1)

		Reporting period					Comments
		Oct-Dec 2015	Jan-Mar 2016	Apr-Jun 2016	Jul-Sept 2016	Cumulative Year 2	
Overall CTB geographic areas	TB cases (all forms) notified per CTB geographic area (<i>List each CTB area below - i.e. Province name</i>)						CTB KG has not yet started implementation of activities in geographic areas. Now CTB is working on development plan,

							protocol and regulations on the national level for implementation in geographic areas included in APA3 WP. Only national data is available.
	TB cases (all forms) notified for all CTB areas						
	All TB cases (all forms) notified nationwide (denominator)	1356 and for full 2015 year 5,853	1471	Will available in August 2016			
	% of national cases notified in CTB geographic areas						
Intervention (setting/population/approach)							
Choose an item.	CTB geographic focus for this intervention						
	TB cases (all forms) notified from this intervention						
	All TB cases notified in this CTB area (denominator)						
	% of cases notified from this intervention						
Choose an item.	CTB geographic focus for this intervention						
	TB cases (all forms) notified from this intervention						
	All TB cases notified in this CTB area (denominator)						
	% of cases notified from this intervention						
Choose an item.	CTB geographic focus for this intervention						
	TB cases (all forms) notified from this intervention						
	All TB cases notified in this CTB area (denominator)						
	% of cases notified from this intervention						

6. Challenge TB-supported international visits (technical and management-related trips)

#	Partner	Name of consultant	Planned quarter				Specific mission objectives	Status (cancelled, pending, completed)	Dates completed	Duration of visit (# of days)	Additional Remarks (Optional)
			Q 1	Q 2	Q 3	Q 4					
1	KNCV	Susan v/d Hof		x			OR protocol development	Complete	1-5 March	3 days	
2	KNCV	Job van Rest		x			Data base	Complete		3 days	
3	KNCV	Susan v/d Hof				x	Training	Pending		7 days	Moved from Q3 to Q4 (beginning of July 2016)
4	KNCV	Maria Idrissova		x			OR protocol development	Complete	1-5 March	3 days	Trip is completed, just a few days deskwork need to finalize protocol, finalization expected in July-August 2016
5	KNCV	Gunta Dravniece		x			OR protocol development	Complete	1-5 March	3 days	Trip is completed, just a few days deskwork need to finalize protocol, finalization expected in July-August 2016
6	KNCV	Maria Idrissova				x	Training	Pending		7 days	Moved from Q3 to Q4 (beginning of July 2016)
7	KNCV	Svetlana Pak			x		Development Plan	Cancelled		7 days	
8	KNCV	Gunta Dravniece				x	Training	Pending		7 days	Moved from Q3 to Q4 (beginning of July 2016)
9	KNCV	HQ PM or PO			x		Monitoring visit	Pending		6 days	Preliminary dates for PM set for 9-15 October.
10	KNCV	RO FO			x		Internal audit	Pending		6 days	to be planned in Q4
11	KNCV	CD		x			International meeting week KNCV HQ	Complete	1-5 February	6 days	
12	KNCV	CD				x	CD meeting	Complete	20-24 June 2016	6 days	APA3 planning
13	KNCV	FO				x	Financial training	Pending	1-5 August 2016	6 days	

14	KNCV	Maria Idrissova				x	Patient enrolment	Pending		12 days	End of August 2016
15	KNCV	Gunta Dravniece				x	Patient enrolment	Pending		12 days	End of August 2016
16	KNCV	Maria Idrissova				x	Patient enrolment	Pending		5 days	End of August 2016
17	KNCV	CD	x				Conference	Complete	1 - 9 Dec 2015	7 days	UNION conference, poster and oral presentations of OR: Poster: <i>Reasons of lost to follow up among MDR TB patients</i> , and Oral session: <i>Reasons late diagnosis and treatment initiation of TB patients</i>
18	KNCV	CD		x			Symposium on the Introduction of new TB drugs - Tbilisi	Complete	22-23 March 2016	5 days	Preapproved by USAID mission will be included in MOT
Total number of visits conducted (cumulative for fiscal year)								8			
Total number of visits planned in approved work plan								18			
Percent of planned international consultant visits conducted								44%			

7. Quarterly Indicator Reporting

Sub-objective:	2. Comprehensive, high quality diagnostics					
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
2.1.2. A current national TB laboratory operational plan exists and is used to prioritize, plan and implement interventions.		annually	0	N/A	N/A	Measured annually
2.2.6. Number and percent of TB reference laboratories (national and intermediate) within the country implementing a TB-specific quality improvement program i.e. Laboratory Quality Management System (LQMS).		annually	50% (one from two laboratories)	N/A	N/A	Measured annually
2.2.7. Number of GLI-approved TB microscopy network standards met		annually	N/A	N/A	N/A	Measured annually
2.3.1. Percent of bacteriologically confirmed TB cases who are tested for drug resistance with a recorded result.		Every six months	2014 – 33.3%	65% in CTB pilot sites	2015 – 52% (883/1707)	

Sub-objective:	3. Patient-centered care and treatment					
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
3.1.1. Number and percent of cases notified by setting (i.e. private sector, pharmacies, prisons, etc.) and/or population (i.e. gender, children, miners, urban slums, etc.) and/or case finding approach		annually	Civil sector: all forms 7,221; Penitentiary sector: all forms 202	N/A	N/A	Measured annually
3.1.4. Number of MDR-TB cases detected		Quarterly and annually	1,285 MDR TB (data NTP 2014)	N/A	1,158 in 2015 721 Jan-June 2016	Jan-Mar - 350, Apr-June - 371
3.2.1. Number and percent of TB cases successfully treated (all forms) by setting (i.e. private sector, pharmacies, prisons, etc.) and/or by population (i.e. gender, children, miners, urban slums, etc.).		annually	Civil sector 1,096/1,349 - 81.2%; penitentiary sector 22/26, 84.6% (data NTP-2014)	N/A	N/A	Measured annually
3.2.4. Number of MDR-TB cases initiating second-line treatment		Quarterly and annually	1,219 MDR TB, 43 XDR TB with standard regimens, 0 initiated short regimens (2014) and none of the XDR cases received adequate Tx regimen	5 XDR TB (new regimens) and 20 MDR TB cases for short regimens	1,200 – 2015, 1Q 2016 – 350 2Q 2016 - 371	MDRT TB patients will start treatment with the new TB drugs and shorter regimen in November 2016
3.2.7. Number and percent of MDR-TB cases successfully		annually	General 62.7%, in civil sector 63.6%; penal	N/A	58% (2015)	Measured annually

Sub-objective:		3. Patient-centered care and treatment				
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
treated			sector 50.9% (NTP data for 2012)			

Sub-objective:		5. Infection control				
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
5.2.3. Number and % of health care workers diagnosed with TB during reporting period	gender	annually	24 (MoH, 2014)	N/A	N/A	Measured annually

Sub-objective:		6. Management of latent TB infection				
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
6.1.11. Number of children under the age of 5 years who initiate IPT		annually	550 children in 2014	N/A	N/A	Measured annually

Sub-objective:		7. Political commitment and leadership				
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
7.2.3. % of activity budget covered by private sector cost share, by specific activity		annually	N/A	N/A	N/A	Measured annually

Sub-objective: 8. Comprehensive partnerships and informed community involvement						
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
8.1.3. Status of National Stop TB Partnership		annually	0	N/A	N/A	Measured annually
8.1.4. % of local partners' operating budget covered by diverse non-USG funding sources		annually	N/A	N/A	N/A	Measured annually
8.2.1. Global Fund grant rating		annually	A1 in 2014		N/A	Measured annually

Sub-objective: 9. Drug and commodity management systems						
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
9.1.1. Number of stock outs of anti-TB drugs, by type (first and second line) and level (ex, national, provincial, district)	gender	annually	363 (2013)	N/A	N/A	Measured annually

Sub-objective: 10. Quality data, surveillance and M&E						
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
10.1.4. Status of electronic recording and reporting system		annually	1 in 2015	N/A	N/A	Measured annually
10.2.1. Standards and benchmarks to certify surveillance systems and vital		annually	N/A	N/A	N/A	Measured annually

Sub-objective:	10. Quality data, surveillance and M&E					
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
registration for direct measurement of TB burden have been implemented						
10.2.6. % of operations research project funding provided to local partner (provide % for each OR project)		annually	N/A	N/A	N/A	Measured annually
10.2.7. Operational research findings are used to change policy or practices (ex, change guidelines or implementation approach)		annually	N/A	N/A	N/A	Measured annually

Sub-objective:	11. Human resource development					
Performance indicator	Disaggregated by	Frequency of collection	Baseline (timeframe)	End of year target	Results to date	Comments
11.1.3. # of healthcare workers trained,	gender and technical area	Quarterly and annually	0	25	0	HCWs will be trained in Q4, 11-14 July 2016
11.1.5. % of USAID TB funding directed to local partners		annually	N/A	0	N/A	Measured annually