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Report No: PAD1716

INTERNATIONAL DEVELOPMENT ASSOCIATION

PROJECT APPRAISAL DOCUMENT

ON

PROPOSED CREDITS

TO

THE KINGDOM OF LESOTHO
IN THE AMOUNT OF SDR 10.7 MILLION (US\$15 MILLION EQUIVALENT)

THE REPUBLIC OF ZAMBIA
IN THE AMOUNT OF SDR 32 MILLION (US\$45 MILLION EQUIVALENT)

AND PROPOSED GRANTS AND CREDITS TO

THE REPUBLIC OF MALAWI
IN THE AMOUNT OF SDR 6.76 MILLION IN GRANTS
(US\$9.5 MILLION EQUIVALENT) AND SDR 5.34 MILLION IN CREDITS (US\$7.5
MILLION EQUIVALENT)

THE REPUBLIC OF MOZAMBIQUE
IN THE AMOUNT OF SDR 16 MILLION IN GRANTS
(US\$22.5 MILLION EQUIVALENT) AND SDR 16 MILLION IN CREDITS (US\$22.5
MILLION EQUIVALENT)

FOR A

SOUTHERN AFRICA TUBERCULOSIS AND HEALTH SYSTEMS SUPPORT PROJECT

May 20, 2016

Health, Nutrition & Population Global Practice
Africa Region

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CURRENCY EQUIVALENTS

(Exchange Rate Effective March 31, 2016)

Currency Unit = US\$1
US\$ = SDR 0.70981389

FISCAL YEAR

January 1 – December 31

ABBREVIATIONS AND ACRONYMS

ASLM	African Society for Laboratory Medicine
ASM	Artisanal Small-scale Mining
DALYs	Disability-Adjusted Life Years
DOTS	Directly Observed Treatment, Short Course
FM	Financial Management
GDP	Gross Domestic Product
EAPHLNP	East Africa Public Health Laboratory Networking Project
ECSA-HC	East, Central and Southern Africa Health Community
HRQoL	Health-Related Quality of Life
ICB	International Competitive Bidding
ICER	Incremental Cost-Effectiveness Ratio
ICWM	Infection Control and Waste Management
ICT	Information and Communications Technology
IDA	International Development Association
IFC	International Finance Corporation
IOM	International Organization for Migration
IPC	Internal Procurement Committee
IPR	Independent Post Review
LYs	Life Years
M&E	Monitoring and Evaluation
MDR-TB	Multidrug-resistant Tuberculosis
MOH	Ministry of Health
NCB	National Competitive Bidding
NPCA	New Partnership for African Development Planning and Coordinating Agency
NGO	Nongovernmental Organization
NTC	National Technical Committee
PAU	Project Accounting Unit
PIM	Project Implementation Manual
PIU	Project Implementation Unit
PDO	Project Development Objective
PPA	Project Preparation Advance
PPAD	Procurement Policy Advisory Division
PPP	Public-Private Partnership
PPRs	Procurement Post Reviews

QALYs	Quality-Adjusted Life Years
RAC	Regional Advisory Committee
RCO	Regional Coordinating Organization
SADC	Southern African Development Community
SBD	Standard Bidding Document
SLAMTA	Strengthening Laboratory Management Towards Accreditation
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
TB	Tuberculosis
UGEA	Unidade Gestora e Executora das Aquisições
UNDP	United Nations Development Programme
XDR-TB	Extensively Drug-resistant Tuberculosis

Regional Vice President:	Makhtar Diop
Country Directors:	Ahmadou Moustapha Ndiaye (Regional Integration, Central, Eastern and Southern Africa)
Senior Global Practice Director:	Timothy G. Evans
Practice Manager	Magnus Lindelow
Task Team Leader	Ronald U. Mutasa

Southern Africa Tuberculosis and Health Systems Support Project

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PAD DATA SHEET

Africa

AFCC2/RI-Southern Africa Tuberculosis and Health Systems Support Project (P155658)

PROJECT APPRAISAL DOCUMENT

AFRICA

Report No.: PAD1716

Basic Information			
Project ID P155658	EA Category B - Partial Assessment	Team Leader(s) Ronald Upenyu Mutasa	
Lending Instrument Investment Project Financing	Fragile and/or Capacity Constraints []		
	Financial Intermediaries []		
	Series of Projects []		
Project Implementation Start Date 26-May-2016	Project Implementation End Date 31-Dec-2021		
Expected Effectiveness Date 30-Sep-2016	Expected Closing Date 31-Dec-2021		
Joint IFC No			
Practice Manager/Manager	Senior Global Practice Director	Country Director	Regional Vice President
Magnus Lindelow	Timothy Grant Evans	Ahmadou Moustapha Ndiaye	Makhtar Diop
Borrower: Republic of Mozambique, Kingdom of Lesotho, Republic of Zambia, Republic of Malawi			
Responsible Agency: Ministry of Health			
Contact:	Sua Excelencia Nazira Abdula	Title:	Minister
Telephone No.:	258-1-427131	Email:	fsouto@misau.gov.mz
Responsible Agency: Ministry of Health			
Contact:	Dr. Peter Mwaba	Title:	Permanent Secretary
Telephone No.:	(260-211) 252-989	Email:	dps@moh.gov.zm
Responsible Agency: Ministry of Health			
Contact:	Mamoruti Tiheli	Title:	Acting PS Health
Telephone No.:	2665814396	Email:	mtiheli@hotmail.com
Responsible Agency: Ministry of Health			

Contact:	Dr. Jean Kalilani				Title:	Minister				
Telephone No.:	2657789408				Email:	ja.kalilani@gmail.com				
Project Financing Data (in USD Million)										
<input type="checkbox"/>	Loan	<input checked="" type="checkbox"/>	IDA Grant	<input type="checkbox"/>	Guarantee					
<input checked="" type="checkbox"/>	Credit	<input type="checkbox"/>	Grant	<input type="checkbox"/>	Other					
Total Project Cost:		122.00			Total Bank Financing:		122.00			
Financing Gap:		0.00								
Financing Source						Amount				
BORROWER/RECIPIENT						0.00				
International Development Association (IDA)						90.00				
IDA Grant						32.00				
Total						122.00				
Expected Disbursements (in USD Million)										
Fiscal Year	2017	2018	2019	2020	2021	2022				
Annual	20.00	25.00	35.00	20.00	15.00	7.00				
Cumulative	20.00	45.00	80.00	100.00	115.00	122.00				
Institutional Data										
Practice Area (Lead)										
Health, Nutrition & Population										
Contributing Practice Areas										
Energy & Extractives, Gender										
Cross Cutting Topics										
<input type="checkbox"/> Climate Change										
<input type="checkbox"/> Fragile, Conflict & Violence										
<input checked="" type="checkbox"/> Gender										
<input type="checkbox"/> Jobs										
<input checked="" type="checkbox"/> Public Private Partnership										
Sectors / Climate Change										
Sector (Maximum 5 and total % must equal 100)										
Major Sector				Sector		%	Adaptation Co-benefits %		Mitigation Co-benefits %	
Health and other social services				Health		75				

Energy and mining	Other Mining and Extractive Industries	25		
Total		100		
<input checked="" type="checkbox"/> I certify that there is no Adaptation and Mitigation Climate Change Co-benefits information applicable to this project.				
Themes				
Theme (Maximum 5 and total % must equal 100)				
Major theme	Theme	%		
Human development	Health system performance	40		
Human development	Tuberculosis	40		
Social dev/gender/inclusion	Participation and civic engagement	10		
Human development	HIV/AIDS	10		
Total		100		
Proposed Development Objective(s)				
A. Proposed Development Objective(s)				
The overall objectives of the project are to: (i) improve coverage and quality of TB control and occupational lung disease services in targeted geographic areas of the participating countries; and (ii) strengthen regional capacity to manage the burden of TB and occupational diseases.				
Components				
Component Name		Cost (USD Millions)		
Innovative Prevention, Detection and Treatment of TB		45.49		
Regional Capacity for Disease Surveillance, and Diagnostics and Management of TB and Occupational Lung Diseases		43.19		
Regional Learning and Innovation, and Project Management		33.32		
Systematic Operations Risk- Rating Tool (SORT)				
Risk Category			Rating	
1. Political and Governance			Moderate	
2. Macroeconomic			Moderate	
3. Sector Strategies and Policies			Moderate	
4. Technical Design of Project or Program			Substantial	
5. Institutional Capacity for Implementation and Sustainability			Substantial	
6. Fiduciary			Substantial	
7. Environment and Social			Moderate	
8. Stakeholders			Substantial	

9. Duplication of activities between the Bank-financed project and other major or related initiatives in the sub-region		Moderate	
OVERALL		Substantial	
Compliance			
Policy			
Does the project depart from the CAS in content or in other significant respects?		Yes []	No [X]
Does the project require any waivers of Bank policies?		Yes []	No [X]
Have these been approved by Bank management?		Yes []	No []
Is approval for any policy waiver sought from the Board?		Yes []	No [X]
Does the project meet the Regional criteria for readiness for implementation?		Yes [X]	No []
Safeguard Policies Triggered by the Project		Yes	No
Environmental Assessment OP/BP 4.01		X	
Natural Habitats OP/BP 4.04			X
Forests OP/BP 4.36			X
Pest Management OP 4.09			X
Physical Cultural Resources OP/BP 4.11			X
Indigenous Peoples OP/BP 4.10			X
Involuntary Resettlement OP/BP 4.12			X
Safety of Dams OP/BP 4.37			X
Projects on International Waterways OP/BP 7.50			X
Projects in Disputed Areas OP/BP 7.60			X
Legal Covenants			
Name	Recurrent	Due Date	Frequency
Regional Advisory Committee (RAC)	X		Ongoing
Description of Covenant			
The Recipient shall maintain throughout the period of Project Implementation its representative or representatives in the RAC			
Name	Recurrent	Due Date	Frequency
National Technical Committee	X		Ongoing
Description of Covenant			
The Recipient shall maintain throughout the period of Project Implementation the National Technical Committee, to be responsible for oversight and technical guidance of Project Implementation at the national level, as further set forth in the PIM			

Name	Recurrent	Due Date	Frequency
National TB Program unit	X		Ongoing
Description of Covenant			
The Recipient shall maintain throughout the period of Project Implementation the National TB Program unit, to be responsible for technical leadership of the Project, as further set forth in the PIM			
Name	Recurrent	Due Date	Frequency
Project Implementation Unit (PIU)	X		Ongoing
Description of Covenant			
The Recipient shall maintain throughout the period of Project Implementation the PIU to run the day-to-day management for the Project (including all fiduciary responsibilities for the Project at the national level), and provide secretariat services to the National Technical Committee			
Name	Recurrent	Due Date	Frequency
Annual Work Program	X		Yearly
Description of Covenant			
The Recipient shall not later than November 15 in each calendar year during Project implementation, prepare in cooperation with the National Technical Committee, MOH and other relevant ministries and furnish to the Association, a program of activities for inclusion in the Project during the following calendar year, including: (a) a detailed timetable for the sequencing and implementation of said activities; (b) the types of expenditures required for such activities; and (c) the planned procurement methods for the expenditures ("Annual Work Program")			
Name	Recurrent	Due Date	Frequency
ECSCA-HC: Regional Level Consolidated Annual	X		Yearly
Description of Covenant			
The Project Implementing Entity shall: (a) no later than November 15 in each calendar year during Project Implementation, prepare and to furnish to the Association a program of activities for its respective part of the Project, proposed for inclusion in the Project during the following calendar year, including: (i) a detailed timetable for the sequencing and implementation of said activities; (ii) the types of expenditures required for such activities; and (iii) the planned procurement methods for the expenditures ("Annual Work Program"); and (b) no later than December 15 in each calendar year during Project Implementation, prepare and furnish to the Association a consolidated program of activities at the regional level, consisting of the Annual Work Program and the annual work program submitted by NPCA to the Project Implementing Entity, endorsed by the RAC and proposed for inclusion in the Project during the following calendar year, including: (i) a detailed timetable for the sequencing and implementation of said activities; (ii) the types of expenditures required for such activities; and (iii) the planned procurement methods for the expenditures ("Consolidated Regional Annual Work Program")			
Name	Recurrent	Due Date	Frequency
NPCA: Annual Work Program	X		Yearly
Description of Covenant			
The Project Implementing Entity shall, no later than November 15 in each calendar year during Project Implementation, prepare and furnish to the Association and to ECSCA-HC (for incorporation and forwarding by ECSCA-HC to the Association of the regional annual work program ("Consolidated Regional Annual Work Program"), a program of activities for its respective part of the Project, proposed for inclusion in the Project during the following calendar year, including: (a) a detailed timetable for the			

sequencing and implementation of said activities; (b) the types of expenditures required for such activities: and (c) the planned procurement methods for the expenditures (“Annual Work Program”)			
Name	Recurrent	Due Date	Frequency
Adoption of Cooperation Protocol with other Participating Countries		30-Sep-2017	
Description of Covenant			
Adoption of Cooperation Protocol with other Participating Countries, in form and substance satisfactory to the Association, no later than twelve (12) months after the First Effective Date, or such later date as the Association may agree			
Name	Recurrent	Due Date	Frequency
Establishment of complaint handling mechanism		31-Mar-2017	
Description of Covenant			
The Recipient shall no later than six (6) months after the Effective Date, or such later date as the Association may agree, establish a complaint handling mechanism to enhance service delivery, satisfactory to the Association			
Name	Recurrent	Due Date	Frequency
Subsidiary Agreements		31-Oct-2016	
Description of Covenant			
To facilitate the carrying out of Parts 3.3 (a) and 3.3 (b) of the Project, the Recipient shall no later than one (1) month after the Effective Date or such later date as the Association may agree: (a) make the proceeds of the Financing allocated from time to time to Category (4) of the table set forth in Section IV.A.2 of this Schedule available to ECSA-HC; and (b) make the proceeds of the Financing allocated from time to time to Category (5) of the table set forth in Section IV.A.2 of this Schedule available to NPCA each under a Subsidiary Agreement between Recipient and ECSA-HC and NPCA, respectively, under terms and conditions approved by the Association			
Name	Recurrent	Due Date	Frequency
ECSA-HC: Establishment of Regional Secretariat		30-Nov-2016	
Description of Covenant			
The Project Implementing Entity shall, no later than two (2) months after the First Effective Date or such later date as the Association may agree, establish and thereafter maintain throughout project Implementation, its team for the Regional Secretariat, in a form and with functions, composition, mandate, and staffing (under terms of reference, qualifications, and scope of responsibilities) and adequate resources, including a Project coordinator, a finance officer, procurement specialist, monitoring and evaluation specialist, and other technical specialists, as further set forth in the PIM, all satisfactory to the Association; the Regional Secretariat to be responsible for running the day-to-day management of the Project at the regional level, and provide secretariat services to the RAC			
Name	Recurrent	Due Date	Frequency
NPCA: Establishment of Regional Secretariat		30-Nov-2016	

Description of Covenant			
The Project Implementing Entity shall establish, no later than two (2) months after the First Effective Date or such later date as the Association may agree, establish and thereafter maintain throughout Project Implementation, its team for the Regional Secretariat, in a form and with functions, composition, mandate, and staffing (under terms of reference, qualifications and scope of responsibilities) and adequate resources, including a policy specialist, an occupational health specialist, a finance officer, and other technical specialists, as further set forth in the PIM, all satisfactory to the Association; the Regional Secretariat to be responsible for running the day-to-day management of the Project at the regional level, and provide secretariat services to the RAC			
Name	Recurrent	Due Date	Frequency
Cooperation Agreement between ECSA-HC and NPCA		31-Dec-2016	
Description of Covenant			
The Project Implementing Entities (ECSA-HC and NPCA) shall, no later than three (3) months after the First Effective Date or such later date as the Association may agree, enter into a Cooperation Agreement in form and substance satisfactory to the Association, and shall carry out its Respective Part of the Project in accordance with the Cooperation Agreement			
Name	Recurrent	Due Date	Frequency
ECSA-HC and NPCA: Adoption of Project Implementation Manual (PIM)		31-Oct-2016	
Description of Covenant			
Project Implementing Entities (ECSA-HC and NPCA) shall, no later than one (1) month after First Effective Date or such later date as the Association may agree, adopt the PIM, in form and substance satisfactory to the Association			
Name	Recurrent	Due Date	Frequency
ECSA-HC and NPCA: Hiring of External Auditor		31-Mar-2017	
Description of Covenant			
The Project Implementing Entities (ECSA-HC and NPCA) shall, no later than six (6) months after First Effective Date or such later date as the Association may agree, hire an external auditor satisfactory to the Association			
Name	Recurrent	Due Date	Frequency
ECSA-HC and NPCA: Project Completion Report		31-Mar-2022	
Description of Covenant			
The Project Implementing Entities (ECSA-HC and NPCA) shall provide to the Recipients no later than three (3) months after the Closing Date, for incorporation in the report referred to in Section 4.08 (c) of the General Conditions, all such information as the Recipient or the Association shall reasonably request for purposes of report preparation			
Name	Recurrent	Due Date	Frequency
ECSA-HC: Hiring of Finance Officer		31-Dec-2016	
Description of Covenant			

The Project Implementing Entity shall, no later than three (3) months after the First Effective Date, or such later date as the Association may agree, hire a finance officer for the Project, with qualifications and under terms of reference satisfactory to the Association,			
Name	Recurrent	Due Date	Frequency
Kingdom of Lesotho: Hiring of Internal Auditor		31-Dec-2016	
Description of Covenant			
The Recipient shall hire, no later than three (3) months after the Effective Date or such later date as the Association may agree, an internal auditor for the Project, with qualifications and under terms of reference satisfactory to the Association			
Name	Recurrent	Due Date	Frequency
Kingdom of Lesotho: Hiring of Procurement Officer		31-Oct-2016	
Description of Covenant			
The Recipient shall hire, no later than one (1) month after the Effective Date or such later date as the Association may agree, a procurement officer for the PIU, with qualifications and under terms of reference satisfactory to the Association			
Name	Recurrent	Due Date	Frequency
Republic of Malawi: Hiring of Assistant Accountant		31-Dec-2016	
Description of Covenant			
The Recipient shall, no later than three (3) months after the Effective Date or such later date as the Association may agree, hire an assistant account for the PIU, with qualifications and under terms of reference satisfactory to the Association			
Name	Recurrent	Due Date	Frequency
Republic of Malawi: Computerized accounting software and training		31-Dec-2016	
Description of Covenant			
The Recipient shall no later than three (3) months after Effective Date or such later date as the Association may agree, have in place a computerized accounting software and have conducted initial training PIU staff to effectively use such software			
Name	Recurrent	Due Date	Frequency
Republic of Mozambique: Hiring of Procurement Officer		31-Dec-2016	
Description of Covenant			
The Recipient shall hire, no later than 90 days after the Effective Date or such later date as the Association may agree, a procurement officer for the PIU with qualifications and under terms of reference acceptable to the Association			
Name	Recurrent	Due Date	Frequency
Republic of Mozambique: Memorandum of Understanding		31-Oct-2016	

Description of Covenant			
To facilitate co-ordination with ECSA-HC and the Recipient's participation in ECSA-HC for the purposes of the Project, the Recipient shall enter into a Memorandum of Understanding with ECSA-HC, in form and substance satisfactory to the Association, no later than one (1) month after the Effective Date			
Name	Recurrent	Due Date	Frequency
Republic of Zambia: Accounting software		31-Mar-2017	
Description of Covenant			
The Recipient shall ensure that no later than six (6) months after the Effective Date or such later date as the Association may agree, an accounting software is fully functional, acceptable to the Association			
Name	Recurrent	Due Date	Frequency
Republic of Zambia: Hiring of Internal Auditor		31-Dec-2016	
Description of Covenant			
The Recipient shall hire or assign no later than three (3) months after Effective Date, or such later date as the Association may agree, an internal auditor for the Project, with qualifications and under terms of reference satisfactory to the Association			
Conditions			
Source Of Fund	Name	Type	
IDA/IDAT	Regional Advisory Committee	Effectiveness	
Description of Condition			
The Recipient has assigned its representatives to the RAC.			
Source Of Fund	Name	Type	
IDA/IDAT	Establishment of National Technical Committee	Effectiveness	
Description of Condition			
The Recipient has established the National Technical Committee, in a form and with functions and membership satisfactory to the Association			
Source Of Fund	Name	Type	
IDA/IDAT	Adoption of Project Implementation Manual	Effectiveness	
Description of Condition			
The PIM has been adopted by the Recipient in form and substance satisfactory to the Association			
Source Of Fund	Name	Type	
IDA	Kingdom of Lesotho: Hiring of Project coordinator and Project accountant to the PIU	Effectiveness	
Description of Condition			
The Recipient has hired a Project coordinator and Project accountant for the PIU, each with qualifications and under terms of reference satisfactory to the Association			
IDAT	Republic of Malawi: Establishment of Project Implementation Unit	Effectiveness	

Description of Condition				
The Recipient has established the PIU, in form and with functions, staffing (under terms of reference, qualifications and scope of responsibilities, including, at a minimum, a Project accountant, a procurement specialist, and a monitoring and evaluation specialist) and adequate resources satisfactory to the Association				
Source Of Fund	Name			Type
IDA	Republic of Zambia: Hire or assign an accountant for the PIU			Effectiveness
Description of Condition				
The recipient has hired or assigned an accountant for the PIU, with qualifications and under terms of reference satisfactory to the Association				
Source Of Fund	Name			Type
IDAT	ECSA-HC and NPCA			Effectiveness
Description of Condition				
Agreement shall become effective once: (a) it has been duly authorized, executed and delivered on behalf of the Project Implementing Entity; and (b) the first Participating Country Financing Agreement for the Project has been declared effective				
Source Of Fund	Name			Type
IDA/IDAT	Withdrawals under Category (4)			Disbursement
Description of Condition				
For the Republic of Mozambique, no withdrawal under Category (4) until Memorandum of Understanding and Subsidiary Agreement, each between Recipient and ECSA-HC, has been executed, in form and substance satisfactory to the Association. For all other countries, no withdrawal under Category (4) until the Subsidiary Agreement between Recipient and ECSA-HC has been executed, in form and substance satisfactory to the Association.				
Source Of Fund	Name			Type
IDA/IDAT	Withdrawals under Category (5)			Disbursement
Description of Condition				
No withdrawals under Category (5) until the Subsidiary Agreement between the Recipient and NPCA has been executed, in form and substance satisfactory to the Association				
Team Composition				
Bank Staff				
Name	Role	Title	Specialization	Unit
Ronald Upenyu Mutasa	Team Leader (ADM Responsible)	Senior Health Specialist	Task Team Leader	GHN01
Miriam Schneidman	Team Member	Lead Health Specialist	Public health, health systems, TB	GHN01

Son Nam Nguyen	Team Member	Lead Health Specialist	Health systems, quality improvement	GHN01
Abdo Yazbeck	Team Member	Lead (Health) Economist	Health systems	GHN01
Patrick Lumumba Osewe	Team Member	Global Lead	Public Health, TB	GHN03
Humberto Albino Cossa	Team Member	Senior Health Specialist	TTL, Mozambique Health	GHN01
Julie Rieger	Counsel	Senior Counsel	Legal	LEGAM
Musonda Rosemary Sunkutu	Team Member	Senior PHN Specialist	Health systems, HIV/AIDS	GHN01
John Bosco Makumba	Team Member	Senior Operations Officer	Pharmaceutical supply chain	GHN01
Yvonne Nkrumah	Team Member	Senior Operations Officer	Health Policy, Occupational Health	GHN01
Brigitte Marie Khadidja Bocoum	Team Member	Senior Mining Specialist	Mining	GEEX2
Carolyn J. Shelton	Team Member	Senior Operations Officer	TTL Lesotho HIV/AIDS, Operations	GHN01
Paula F. Lytle	Safeguards Specialist	Senior Social Development Specialist	Social Scientist, Gender and Mining	GSU07
Ruma Tavorath	Safeguards Specialist	Senior Environmental Specialist	Environment, Mining	GEN06
Patrick Piker Umah Tete	Financial Management Specialist	Senior Financial Management Specialist	Financial Management	GGO25
Wedex Ilunga	Procurement Specialist (ADM Responsible)	Senior Procurement Specialist	Procurement	GGO01
Maiada Mahmoud Kassem	Finance Officer	Finance Officer	Finance, Disbursements	WFALA
Jose Janeiro	Senior Finance Officer	Finance Officer	Finance, Disbursements	WFALA
Saba Nabeel Gheshan	Counsel	Legal Analyst	Legal	LEGAM
Peter Boere	Team Member	Industry Specialist	IFC public-private partnerships transactions advisor	CASPA

Omer Ramses Zang Sidjou	Team Member	Economist (Health)	Health Financing	GHNDR
Precious Zikhali	Team Member	Economist (Poverty)	Poverty Economics	GPVDR
Collins Chansa	Team Member	Health Specialist	Economic Analysis	GHN01
Thulani Clement Matsebula	Team Member	Economist	Economic Analysis	GHN01
Lori A. Geurts	Team Member	Operations Analyst	Operations, implementation arrangements	GHN06
Christopher Masila	Team Member	Health Specialist/consultant	Public Health	GHN01
Jaime Nicolas Bayona Garcia	Team Member	E T Consultant	Multidrug resistant TB	GHN05
Fernanda Da Gloria Mause	Team Member	E T Consultant	Public Health	GHN01
Lingson Chikoti	Team Member	Consultant	Financial Management	GGO25
Jonathan Aspin	Team Member	Knowledge Management Advisor/Consultant	Knowledge Management	GHN01
Cassandra De Souza	Team Member	Operations Officer/Consultant	Operations	GHN01
Chitambala John Sikazwe	Procurement Specialist	Senior Procurement Specialist	Procurement	GGO01
Amos Martinho Malate	Procurement Specialist	Procurement Specialist	Procurement	GGO07
Antonio L. Chamuco	Procurement Specialist	Senior Procurement Specialist	Procurement	GGO07
Elvis Teodoro Bernado Langa	Procurement Specialist	Financial Management Specialist	Procurement	GGO13
Steven Maclean Mhone	Procurement Specialist	Senior Procurement Specialist	Procurement	GGO01
Tandile Gugu Zizile Msiwa	Team Member	Financial Management Specialist	Financial Management	GGO13
Trust Chamukuwa Chimaliro	Team Member	Financial Management Specialist	Financial Management	GGO31
Diana Jimena Arango	Team Member	Sr. Gender-Based Violence and Development Specialist	Gender	GCGDR

Charity Inonge Mbangweta	Team Member	Team Assistant	Administrative support	AFMZM
Esther Angellah Lozo	Team Member	Executive Assistant	Operational support	AFMMW
Ethel Chipeta	Team Member	Temporary	Administrative support	AFCE1
Keneuoe Françoise Mofolo	Team Member	Program Assistant	Administrative support	AFMLS
Salma Chande	Team Member	Program Assistant	Administrative support	AFCS2
Yvette M. Atkins	Team Member	Senior Program Assistant	Administrative support	GHN01

Extended Team

Name	Title	Office Phone	Location
Karen F. Brudney	Advisor for Global TB		Centers for Disease Control and Prevention, Atlanta
Susan Maloney	Manager, Global TB/HIV Division		Centers for Disease Control and Prevention, Atlanta
Laura Podewils	Epidemiologist		Centers for Disease Control and Prevention, Atlanta
Peter Boere	Industry Specialist	27-11-731-3211	IFC

Locations

Country	First Administrative Division	Location	Planned	Actual	Comments

Consultants (Will be disclosed in the Monthly Operational Summary)

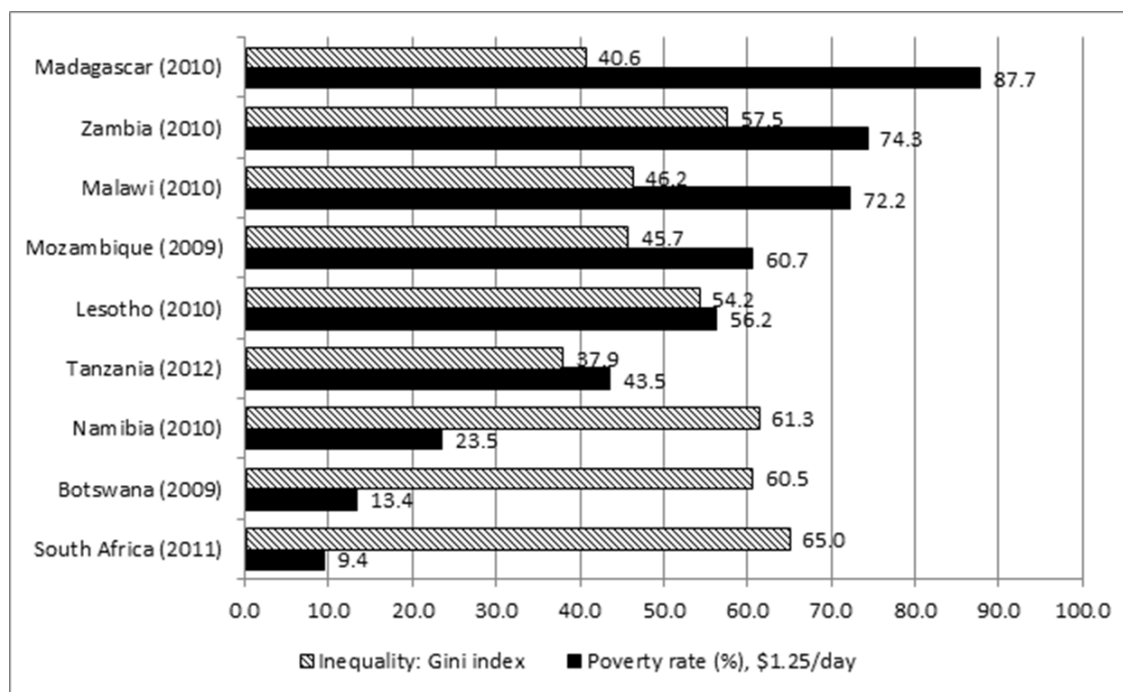
Consultants Required ? Yes.

I. INTRODUCTION AND STRATEGIC CONTEXT

A. Regional Context

1. **Despite steady economic growth over the past decade, the Southern Africa subregion¹ grapples with high levels of poverty combined with some of the worst income inequality in the world (Figure 1).** Annual gross domestic product (GDP) growth in the subregion has generally hovered above 4 percent since 2005. Rising income inequality, however, has dampened the effect of growth on poverty and constrained human development outcomes.² This inequality and low levels of human development create fertile ground for the spread of communicable diseases such as tuberculosis (TB) and HIV/AIDS. The Southern Africa subregion has some of the highest TB case rates on the continent and has been at the epicenter of the global HIV/AIDS epidemic with elevated TB/HIV coinfection rates.

Figure 1: Poverty and Inequality in Selected SADC Countries



Source: PovCalNet, World Bank, accessed May 27, 2015.

2. **High levels of intraregional economic activity in Southern Africa have also created fertile ground for the spread of diseases across porous borders, underscoring the regional nature of the problem and the need for coordinated action.** Informal cross-border trade in the subregion, while an important source of livelihood for populations residing in these areas, can contribute to the spread of infectious diseases (e.g. cholera, hemorrhagic fevers), underscoring the

¹ Angola, Botswana, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mozambique, Namibia, Swaziland, Tanzania, Zambia, and Zimbabwe.

² Member states of the Southern African Development Community (SADC) generally rank low on the human development index of the United Nations Development Programme (UNDP): for example, in 2014 life expectancy at birth of countries in the region ranged from 48.8 to 73.6 years.

importance of putting in place robust health systems and cross-border health programs. Likewise, the historical patterns of migration in the subregion, from labor-sending countries to South Africa, have generated important economic opportunities but have exacerbated communicable disease control efforts. With a rapidly growing regional economic integration agenda and policies to reduce trade barriers and facilitate the movement of goods and people across the subregion, these issues will take on greater importance, requiring countries to put in place appropriate public health measures.

3. **The mining sector is a prominent example of how labor mobility is contributing to disease spread in the subregion.** South Africa’s vibrant mining sector has traditionally attracted large numbers of workers from neighboring countries. While its mines employ about 500,000 miners, there are an estimated 3 million ex-miners living in South Africa, Lesotho, Mozambique, Malawi, and Swaziland. The persistently high rates of TB in the gold mines in South Africa (3,000–7,000 per 100,000) place miners among the highest risk groups in the region. Many migrant miners live in dwellings with severe overcrowding and poor ventilation, and work under difficult conditions, placing them at greater risk of developing TB and other occupational health diseases. With high mobility, mining communities and labor-sending zones in neighboring countries are also disproportionately affected by TB and related occupational diseases.³

4. **Internal migration from impoverished rural areas to mining areas also increases the risk of TB transmission to family members and labor-sending communities while hindering prevention and control efforts.** Countries with large (Zambia) or growing (Lesotho, Malawi, Mozambique) mining sectors face similar communicable disease control and occupational health challenges, and need to redouble efforts to deal with these complex interrelated health and economic issues.⁴ Countries with emerging mining sectors have an opportunity to invest early in systems that will protect the health and productivity of their workforce.

5. **Regional organizations have been proactive in galvanizing political support and developing strategies and plans for tackling TB as a regional public health issue, which threatens to undermine economic gains.** The *East, Central and Southern Africa Health Community* (ECSA-HC) aims to support countries in strengthening their health systems and to enhance cross-country collaboration on a number of health issues, including TB control, laboratory strengthening and networking, and disease surveillance and outbreak preparedness. The *New Partnership for African Development Planning and Coordinating Agency* (NPCA)—an African Union agency with growing involvement in policy and health systems—is becoming increasingly important in improving public health policy. The *Southern African Development Community* (SADC) supports regional collaboration in seven areas⁵ and, recognizing the significance of the mineral industry for the region, launched the Protocol on Mining in September 1997.⁶ The SADC

³ “The Mining Sector, Tuberculosis and Migrant Labour in Southern Africa.” AIDS and Rights Alliance for Southern Africa. July 2008.

⁴ The mining sector is estimated to represent roughly 8 percent of GDP (and 30 percent of government revenues) in Zambia, and 2 percent in Mozambique (where it is rapidly expanding). It is estimated to have risen to about 8.5 percent of GDP in Lesotho by 2015; and is projected to rise to up to 20 percent in Malawi over the next five years.

⁵ Trade and economic liberalization; infrastructure development; food security, environment, and transboundary natural resources; social and human development; gender and development; statistics; and science and technology.

⁶ “Protocol on Mining in SADC.” SADC 1997.

Health Policy promotes regional collaboration on pharmaceuticals and communicable disease control.⁷

6. **Building on plans and ongoing initiatives in the subregion, the proposed regional project will initially focus on four of the countries in the SADC bloc: Lesotho, Malawi, Mozambique, and Zambia.** While effective communicable disease control efforts require coordinated action across a large number of countries, this group represents some of the hardest hit in the region. The countries have been selected based on the following criteria: (i) *burden of disease* using estimated incidence rates as provided by the World Health Organization (WHO) which, for the four, are high and above the WHO threshold for a TB emergency; high levels of TB/HIV coinfection; and increased risk of multidrug-resistant TB (MDR-TB); (ii) *a large-scale or growing mining sector*, associated with domestic and/or regional migration; and (iii) *strong government commitment* to work collaboratively at the regional level. The project has been designed to complement other regional and national activities. Depending on successful implementation of the project, neighboring countries may consider joining the project later, subject to availability of funding.

7. **The proposed regional project involves multiple collaborative efforts, internally and externally, and is a major piece of a wider regional effort to control TB while strengthening critical dimensions of health systems.** Internally, project preparation was led by a multisectoral team from the Health, Nutrition and Population (HNP) Global Practice and specialists from the Mining, Social Development, and Environment Global Practices. Collaboration is also ongoing with the International Finance Corporation (IFC) to explore opportunities for tapping private sector potential. Externally, the Bank team has mobilized support from the United States Centers for Disease Control and Prevention (CDC) to leverage global knowledge and expertise in TB control.⁸ Likewise, partnerships to support project implementation are being established with other specialized institutions, such as the African Society for Laboratory Medicine (ASLM), WHO, and the International Labour Organization (ILO). The proposed project builds on selected pilots and innovations supported by TB Reach and the World Bank's South Africa Knowledge Hub, and will be coordinated with ongoing activities of regional organizations such as SADC, ECSA-HC, and NPCA as well as regional projects, including those funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria.

B. Sectoral and Institutional Context

8. **The year 2015 marked a crossroads in the fight against TB—now officially the leading global cause of death from an infectious disease, ahead of HIV/AIDS.** TB is a highly preventable and curable condition. Although the Millennium Development Goal to reduce the incidence of TB has been met, the world was still confronted with 9.6 million new cases and 1.5 million deaths from TB in 2014.⁹ Nearly all (99 percent) cases are in low-income countries and inflict a tremendous burden on poor households.¹⁰ A 2015 survey of diagnostic and treatment practices by Médecins Sans Frontières (MSF) and the Stop TB Partnership in 24 countries, including Mozambique, found huge gaps between current TB control policies and the best

⁷ <http://www.sadc.int/themes/health/>

⁸ The technical collaboration with CDC will not entail financial contracting to implement project activities.

⁹ WHO. 2015. *Global Tuberculosis Report 2015*. Geneva.

¹⁰ Zignol M, M.S. Hosseini et al. 2006. "Global Incidence of Multi-drug Resistant Tuberculosis." *J Infect Dis*. Aug 15; 194(4):479-85.

practices critical to meet a global target of 90 percent reduction in TB incidence and 95 percent reduction in TB mortality by 2035.¹¹ To meet the recently endorsed Sustainable Development Goals by 2030, countries need to adopt and scale up implementation of such best practices.

9. **Sub-Saharan Africa has the highest rates of TB and the worst treatment outcomes in the world.** The continent accounts for 13 percent of the world's population but a disproportionate 28 percent of the world's burden of TB and 34 percent of deaths from TB. Sub-Saharan Africa has about 281 new cases per 100,000 population (incidence), more than double the global average of 133. Although TB incidence decreased globally by 45 percent between 1990 and 2014, rates in the Africa region have continued to rise.

10. **Southern Africa contributes substantially to the global TB burden.** Around a third of the world's 22 high-burden TB countries are in Southern Africa, and most countries in the subregion are above the WHO threshold for a TB emergency (250 cases per 100,000). Eight of the 14 countries in the world with the highest TB incidence (at least 400 cases per 100,000) are in Southern Africa. While the unprecedented rise in TB cases in Southern Africa has been largely driven by the HIV epidemic, mining has been historically associated with some of the highest TB incidence. In South Africa, TB incidence is four to seven times higher among miners and ex-miners than among the general population.¹² In Zambia, a recent population-based national TB prevalence survey found that TB prevalence in mining areas such as Ndola, Kitwe, and Solwezi was three to five times higher than the national TB average.¹³ Regionally, 33 percent of new TB cases in Sub-Saharan Africa are attributed to mining.¹⁴ The burden of TB is also high along the region's transport corridors, in mining and peri-mining areas, cross-border areas, and labor-sending communities.

11. **TB figures prominently in the overall burden of disease on the continent.** Despite reductions in global TB deaths between 1990 and 2013, TB remains among the top five causes of death in Sub-Saharan Africa (2013). In terms of the years-of-life-lost to TB, in Botswana, Lesotho, and Namibia it was number two; in South Africa number three; in Swaziland and Zimbabwe number four; in Malawi and Mozambique number five; and in Zambia number six.¹⁵

12. **MDR-TB is becoming an increasing threat to health and development gains.** Inadequate treatment of TB creates resistance to first-line drugs, and leads to MDR-TB. Inadequate treatment of MDR-TB can lead to a highly lethal form of extensively drug-resistant TB (XDR-TB). Resistant forms of TB require the use of much more expensive drugs, with higher levels of toxicity and higher case fatality and treatment failure rates (Figure 2). Individuals who are treated inappropriately continue to transmit TB, but countries are ill equipped to identify and respond efficiently. With growth in regional migration, global travel, and the emergence of lethal forms of the disease, early detection and effective treatment are paramount.

¹¹ Stop TB Partnership and Médecins Sans Frontières. 2015. *Out of Step. TB Policies in 24 Countries.*

¹² World Bank. 2014. "Economic Benefits and Costs of Tuberculosis Prevention and Control in the Mining Industry in Lesotho, Mozambique, South Africa, and Swaziland."

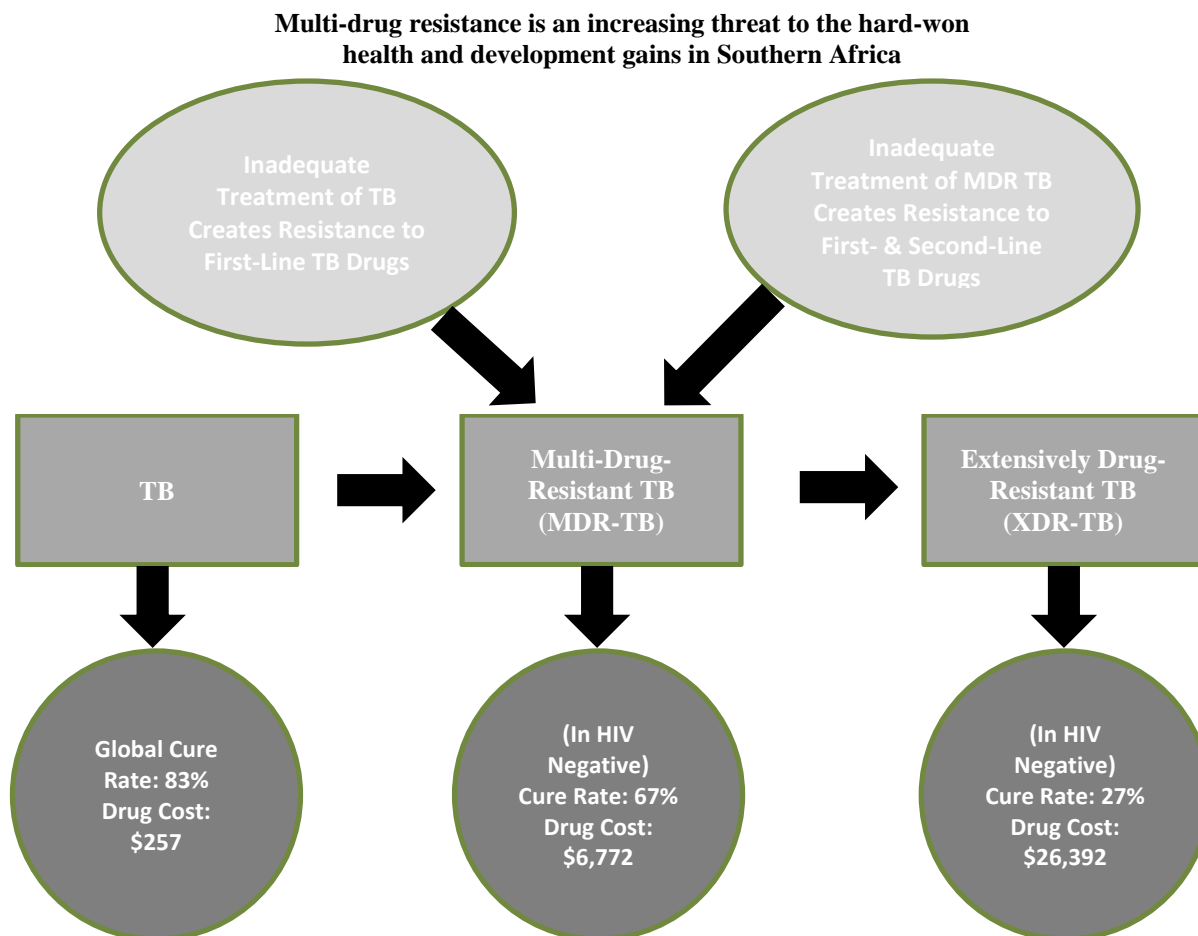
¹³ Zambia National TB Prevalence Survey Preliminary Report 2014.

¹⁴ Fitzpatrick, S. et al. 2013. "Tuberculosis in South Africa's Gold Mines: A United Call to Action." Results UK.

¹⁵ Global Burden of Disease 2013 Mortality and Causes Collaborators. 2014. "Global, Regional and National Age-sex Specific All-cause Specific Mortality for 240 Causes of Deaths, 1990-2013: A Systematic Analysis of the Global Burden Study 2013." *Lancet* 2015: 385:117-71.

13. **Putting in place systems for early detection, diagnosis, and surveillance of MDR-TB will have multiple benefits for tackling the growing problem of antimicrobial drug resistance (AMR).** AMR is a global problem associated with inappropriate use of antibiotics in human and veterinary medicine. Diseases such as TB that were once easily treatable are becoming more difficult to cure, resulting in rising health care costs, elevated morbidity and mortality, and higher risk of disease transmission within countries and across the subregion. The capacity of health systems in Southern Africa to monitor, track, and share information on the scope and scale of AMR is limited. Detection, monitoring, and responding to AMR will rely on strengthened and coordinated laboratory and surveillance capacities.

Figure 2: The High Cost of MDR-TB



Source: Cost data from A. Pooran, E. Pieterse, M. Davids, G. Theron, and K. Dheda. 2013. “What is the Cost of Diagnosis and Management of Drug-resistant Tuberculosis in South Africa?” *PLoS One* 8(1):e54587.

14. **Southern Africa has the highest TB/HIV coinfection¹⁶ rates in the world, ranging from 50 percent to 77 percent.¹⁷** Trends in TB incidence closely mirror trends in HIV/AIDS,

¹⁶ TB and HIV coinfection is when an individual has both HIV infection, and latent or active TB disease. Each disease speeds up the progress of the other.

¹⁷ WHO. 2014. *Global Tuberculosis Report 2014*.

with the bulk of the TB burden driven by the high HIV/AIDS rates. This dual epidemic is challenging to manage. Africa's experience suggests that even well-managed TB programs cannot easily control the rise in TB in settings with high HIV prevalence *without concurrent robust responses to the HIV epidemic*. For all individuals with TB there is a need for rapid diagnosis, as infectiousness and risk of TB transmission are most serious before initiation of treatment.

15. **In mining operations and communities, several factors combine to create a “perfect storm” for TB infection and transmission.** Working conditions inside mines constitute a high-risk environment for TB transmission, resulting from poor ventilation and exposure to silica dust, which is inadequately controlled and regulated. Prolonged exposure to silica dust damages the lungs and creates susceptibility to silicosis, a high-risk factor for TB. Health-seeking behavior of miners is not conducive to early diagnosis and treatment as a result of the high opportunity cost of accessing care, persistent stigma, and fears over losing their jobs. Annex 5 provides a more detailed discussion of the key risk factors associated with small-scale and large-scale mining in Southern Africa.

Health System Challenges

16. **TB response, detection, and monitoring are constrained by multiple weaknesses.** They comprise:

17. ***Weak and non-standardized TB prevention and treatment strategies and protocols across countries.*** Many TB cases are not diagnosed and many cases are detected late, with the continual risk of disease transmission. For mobile populations working in mining, the absence of robust processes to support continuum of care can lead to a discontinuation of treatment as they move from one country to another.

18. ***Gaps in occupational health systems and services.*** These include inadequate policies; absent and/or non-standardized service delivery models within and across borders; and a limited number of occupational health services.

19. ***Inadequate mine-health regulatory capacity in most countries in the subregion.*** Many mining companies are left to self-report on health issues, and legislation on mining operations lags behind international standards and practices.¹⁸ There are large gaps between the principles of the African Union and actual practices in most countries in Southern Africa, including those participating in this regional project (Lesotho, Malawi, Mozambique, and Zambia). Mine dust control policies and standards vary from country to country and enforcement of those policies and standards by government agencies is weak.

20. ***Weak laboratory diagnostic capacity, laboratory networking, and quality assurance.*** Laboratories are among the weakest aspects of regional health systems. Unreliable and inaccurate testing and misdiagnosis can lead to higher costs and compromised patient care,¹⁹ forcing many cases to be diagnosed on clinical symptoms alone. Most countries in the region do not have the

¹⁸ Some countries have regressive laws on TB and the mining sector, which discourages health-seeking behavior. For instance in Zambia, the Workmen's Compensation Act, 1999 provides for the termination of employment for any miner diagnosed with pulmonary TB.

¹⁹ Petti, C., et al. 2006. "Laboratory Medicine in Africa: A Barrier to Effective Health Care." *Clinical Infectious Diseases* 42.

capacity to do drug-sensitivity testing or to conduct drug resistance surveys, which are critical to effective TB control. Most national reference and public health laboratories need physical upgrading and new technologies capable of diagnosing complex forms of TB (i.e. HIV-related TB and multidrug-resistant strains). A reliable lab-sample transport system across the four target project countries is missing, and feedback of results is slow. The limited capacity of the national reference laboratories is another major gap: the participating countries rely on sending samples to South Africa or to other reference laboratories in developed countries, at a higher cost and with the risk of delays.

21. ***Human resources for health below WHO-recommended density per population.*** Shortages of human resources hamper disease surveillance, TB control efforts, quality of health care, and laboratory testing. Poorer rural areas, mining and peri-mining areas, transport corridors, and cross-border areas are particularly affected by these gaps and require special focus.

22. ***Financing gaps.*** Inadequate government expenditure and high direct and indirect costs of care limit access to TB treatment and contribute to poor outcomes.²⁰ The four countries are low income and depend heavily on donor funding, with external resources ranging from roughly 50 percent in Malawi to nearly 70 percent in Mozambique. Annex 5 provides a summary of the health sector context and main issues for each.

23. ***Households' demand-side barriers to access TB care.*** In the subregion, TB care utilization is constrained by economic, behavioral, and structural barriers. Total household TB-related spending is high, ranging from 39 percent to 58 percent of reported annual household incomes. Sixty percent of these costs usually lead to income loss, particularly among poor people and those with MDR-TB. In addition, lack of awareness of TB, stigma, weak or absent community health systems, and socioeconomic factors such as household poverty, negatively affect health-seeking behavior and treatment outcomes.

24. ***Modest involvement of private mining companies in TB and related disease control efforts.*** In some segments of the mining sector, the response to TB and other occupational lung diseases has been limited. The costs of TB and silicosis cases fall disproportionately on the public sector, as most miners opt for using public health facilities either due to ease of access, lower cost, or fear associated with disclosing their illness to their employers.

Strong Regional Justification

25. ***TB control has potential positive spillover effects and benefits for neighboring countries.*** Conversely, ineffective management of TB can have adverse effects on other countries. The project promotes strategic and complementary investments to help contain cross-border spillovers, beyond what countries can achieve acting alone.²¹ The regional rationale is based on the need to:

²⁰ Lonnroth K, P. Glaziou, D. Weil, K. Floyd, M. Uplekar, et al. 2014. "Beyond UHC: Monitoring Health and Social Protection Coverage in the Context of Tuberculosis Care and Prevention." *PLoS Med* 11(9): e1001693. doi:10.1371/journal.pmed.1001693.

²¹ Independent Evaluation Group. 2007. "The Development Potential of Regional Programs: An Evaluation of World Bank Support of Multi-country Operations." Washington, DC.

- ***Avoid negative spillover effects and maximize positive externalities:*** The project addresses the substantial transboundary economic and public health costs of TB and occupational lung diseases and strengthens critical health system functions such as disease surveillance in cross-border areas. Improving screening and occupational health systems and services will enable ex-miners from Lesotho and Mozambique to better access compensation services from the South African Medical Bureau for Occupational Diseases.
- ***Support the delivery of public goods:*** The project will contribute to generating knowledge of what works and at what cost through investments in centers of excellence, piloting of innovative TB control efforts, and support to countries in designing and evaluating their own efforts. Other public goods include the development of common tools, guidelines, and protocols based on international best practices in TB control. Analytic work to be supported under the project will be helpful in better understanding the drivers of the TB epidemic and identifying strategies for engaging the private sector to assume greater responsibility.
- ***Promote economies of scale:*** A regional approach will allow countries to reap economies of scale through coordinated and harmonized efforts, standardization of a package of occupational health services, pooling of resources, and specialization in service delivery. Notable examples include joint strengthening of laboratories toward accreditation; introduction of regional peer review mechanisms; coordinated training of personnel; rollout of regional quality assurance and accreditation schemes; and promotion of centers of excellence with each country leading in different areas.
- ***Foster regional-level accountability:*** The project will serve as a platform for advancing the SADC Declaration on TB and maintaining high-level political commitment. It will also serve as a vehicle for deepening regional cooperation, creating mechanisms for increased accountability, and promoting South–South learning.

C. Higher-level Objectives to which the Project Contributes

26. **The proposed project is fully in line with the World Bank Group’s twin goals to reduce poverty and promote shared prosperity.** The project reflects the institutional commitment to address regional public goods, including communicable diseases, which have a disproportionate impact on the poor with serious impoverishing effects. The project was initiated during Dr. Jim Yong Kim’s first visit to Southern Africa to support countries to tackle TB more forcefully. The project is also aligned with the Bank’s Health, Nutrition and Population Strategy by supporting clients to combat communicable diseases and strengthen health systems.

27. **The project is fully in line with the Regional Integration Assistance Strategy (approved by the Board in April 2008), the Africa Strategy (approved in March 2011), and the Country Partnership Strategies.** Implementation of Pillar III of the Regional Integration Assistance Strategy—Coordinated Interventions to Provide Regional Public Goods—is directly

supported by the project, given the project's aim to strengthen regional capacity to manage the burden of TB and occupational lung diseases with cross-border dimensions.

28. **The proposed project comes at a critical juncture in TB control efforts** given the recently endorsed Sustainable Development Goal target to end TB by 2030,²² the most ambitious goal ever. The project provides critical support to advance progress toward milestones and targets laid out in WHO's End TB Strategy. In addition, it directly contributes to meeting the International Health Regulations 2005.²³ At the subregional level, the project directly advances the implementation of the SADC Declaration on TB and the 2008 Maputo Declaration on Health Laboratory Systems, which emphasizes strengthening diagnostic capacity and systems for better disease control outcomes.

29. **Governments recognize that they must work with global partners to address the epidemic's multisectoral and multicountry dimensions.** The 1997 Protocol on Mining in SADC provides a framework for regional cooperation in regulating the mining sector and addressing occupational health and safety issues. In August 2012, heads of SADC member states signed the SADC Declaration on TB, one of the bases for World Bank support to strengthen regional and national efforts by participating countries, private sector mining stakeholders, and development partners. In March 2014, Lesotho, Mozambique, South Africa, and Swaziland led the regional adoption of a framework for the harmonized management of TB in mining. The framework seeks to introduce common clinical standards and processes. In addition, SADC health ministers approved a TB Code of Conduct in October 2014. At a wider level, the proposed project is a timely investment to strengthen efforts toward implementation of WHO's End TB Strategy, which has bold TB control targets and aims to directly address the social protection and poverty dimensions of TB.

30. **The proposed project is also consistent with other activities at regional and country levels.** These include health sector strategies of the participating countries, which place emphasis on addressing the burden of communicable diseases, mainly TB and HIV/AIDS; activities by other partners financing TB control and health systems strengthening work focused on diagnostics and surveillance; and Bank-funded projects in health and mining sectors (Annex 6).

D. Partnerships

31. **The project serves as a platform for coordination of TB control and health systems strengthening in the subregion (Box 1).**

32. **The project aims to ensure complementarity and synergy with other key regional initiatives, including those funded by the Global Fund.** The main differences between the proposed project and two regional Global Fund TB grants²⁴ are: (i) *geographic coverage*, with the two Global Fund grants supporting a broad group of countries, while the proposed operation focuses on four countries; (ii) *budgetary envelope*, with relatively modest amounts per country

²² The Sustainable Development target for TB is to reduce number of TB related deaths by 90 percent in 2030 from 2015.

²³ The regulations require governments to develop, maintain, and strengthen core capacities of national public health systems to detect, assess, notify, and respond promptly and effectively to health risks and public health emergencies of international concern.

²⁴ The two Global Fund grants are: (i) a US\$30 million grant managed by Wits Health Consortium to 10 countries in Southern Africa focused on addressing the burden of TB in the mining sector; and (ii) a US\$6 million grant managed by ECSA-HC to 18 countries in Eastern and Southern Africa to strengthen the Uganda Supra National Reference Laboratory.

(i.e. less than US\$3 million over three years) under the Global Fund grants related to this project; and (iii) *nature and scope* of proposed activities, with the US\$30 million Global Fund grant for TB focused primarily on TB in the mining sector, while the proposed project design targets support for vulnerable groups more broadly and for high transmission areas in line with WHO's End TB Global Strategy.

Box 1: Platform for TB Control Coordination

The project presents a unique platform for coordination in the subregion on TB control and health systems strengthening.

First, the project builds on the cooperation platforms provided by the SADC Protocol on Health. The project will deepen collaboration between the four participating countries, ECSA-HC, NPCA, and SADC on the broader regional response to TB and efforts to address underlying health system issues.

Second, the project presents an opportunity for countries participating in the Bank-financed East Africa Public Health Laboratory Networking Project (EAPHLNP) to share experiences and lessons learned in areas such as strengthening diagnostic capacity, disease surveillance, TB control, and project management. Given that EAPHLNP has well-established technical working groups/communities of practice in key areas such as diagnostics and disease surveillance, similar technical working groups under the project will be networked and, to the extent possible, will work with those in East Africa. EAPHLNP and other partners such as CDC successfully supported the establishment of the Uganda Supranational Reference Laboratory, which is serving countries like Lesotho. The project will support a facility for participating countries to be mentored by experts from that laboratory.

Third, the proposed project presents a platform for participating countries to further strengthen coordination in TB control with the Government of South Africa, which is already cooperating with other countries in the subregion to scale up TB control efforts. A key area for potential collaboration relates to the availability of occupational health services and compensation packages. Migrant workers from labor-sending areas in Lesotho, Malawi, and Mozambique are adversely affected by weaknesses in occupational health policies, and poor access to compensation in South Africa. Main barriers include: (i) occupational health services for target populations are largely centralized in Johannesburg; (ii) weak health facilities in the labor-sending areas are unable to provide the required medical examinations; (iii) undue financial burdens associated with accessing services in Johannesburg (travel and accommodation); and (iv) lack of awareness of the importance and benefits of medical examinations.

The South Africa National Department of Health, through the Medical Bureau for Occupational Diseases and Compensation Commissioner for Occupational Diseases, is undergoing reforms to improve the efficiency and utility of occupational health services and compensation services to miners, ex-miners, their families, and peri-mining communities. The Bureau has begun discussions with public sector health, social protection, and labor agencies in labor-sending countries to expand occupational services to labor-sending communities. The proposed project will support interventions to strengthen linkages of occupational health services across participating countries and South Africa.

33. **The project will ensure close coordination with the recipients—ECSA-HC and Wits Health Consortium—of the two regional Global Fund grants.** The grant managed by ECSA-HC to operationalize the Uganda Supranational Reference Laboratory (SRL) to serve other countries in the region will be complemented by activities under this project to strengthen diagnostic capacity and networking of national reference laboratories in the participating countries. Moreover, some of the participating countries (e.g. Lesotho) have established a Memorandum of Understanding with the Uganda SRL or have expressed interest to do so in order to benefit from

regional technical expertise. As ECSA-HC provides oversight for the Bank-funded East Africa Public Health Laboratory Networking Project (EAPHLNP; in Burundi, Kenya, Rwanda, Tanzania, and Uganda)—which helped establish the Uganda SRL and is expected to coordinate this project—there will be strong synergies between ongoing and proposed activities.

34. **Likewise, there will be strong continued collaboration with the Wits Health Consortium, which is managing the Global Fund grant** to bolster regional support for improving TB control in the mining sector in all SADC countries. The grant is financing complementary activities, such as mapping and development of databases for miners and examiners from the 10 countries in the subregion, including the four target project countries. The Bank-funded project will finance complementary health information systems and record-management systems to improve patient care and referral between and within countries. Pilot TB active case-finding activities, initiated by countries under the Global Fund Grant, will be considered for scale-up under the project. At the governance level, there will be a representative from the Global Fund Regional Coordinating Mechanism on the Regional Advisory Committee (RAC) for the Bank project to ensure that activities remain well coordinated. Annex 6 provides further details on related initiatives and projects in the region.

35. **The South Africa Knowledge Hub (“the Hub”) will continue to play an important complementary role.** Key areas include undertaking analytical work and convening stakeholders to address regional challenges in TB control, with a specific focus on the mining sector.

II. PROJECT DEVELOPMENT OBJECTIVES

A. Project Development Objectives

36. **The overall objectives of the project are to:** (i) improve coverage and quality of TB control and occupational lung disease services in targeted geographic areas of the participating countries; and (ii) strengthen regional capacity to manage the burden of TB and occupational diseases.

B. Project Beneficiaries

37. **The primary beneficiaries of the project will be TB-affected individuals and households.** The project will target mining communities, high TB burden regions, high HIV/AIDS burden regions, transport corridors, and cross-border areas of the four target countries. Miners, examiners, their families, labor-sending areas, and health workers will be direct beneficiaries. The project will directly benefit women, particularly in the small-scale mining sector.

C. Community of Practice

38. **Following broad-based consultations, representatives from the four participating countries agreed to function as a community of practice²⁵ for TB and occupational lung disease control,** fostering cross-country knowledge generation, learning, and sharing. The

²⁵ “Community of practice” is loosely defined as a group of practitioners who are bound together by a shared learning objective.

community of practice will include key themes and technical areas that present regional and cross-country challenges. Key areas identified include:

- Economics of TB control and sustainable financing
- Service delivery: continuum of TB care across and within national boundaries
- Research, and monitoring and evaluation (M&E)
- Mine health regulation and occupational health
- Diagnostics and surveillance of diseases.

39. **Emerging areas of technical leadership proposed by the countries are highly innovative** and present opportunities for the subregion to learn from “best buys” in TB control. Examples of areas for learning in the subregion and beyond include use of laboratory-based information and communications technology (ICT) to strengthen TB diagnosis; transmission of results and patient monitoring; and follow-up within and across borders. Collaboration with well-established communities of practice under EAPHLNP will be supported by ECSA-HC, which has been selected as the Regional Coordinating Organization (RCO) for the project. Furthermore, there is strong demand from all participating countries for the project to support learning, mentorship, and research.

D. Project Development Objective–level Results Indicators

40. **To monitor progress toward the project development objective, project stakeholders have agreed upon a core set of indicators:**

- TB case notification in target geographic areas (number)
- TB treatment success rate in target geographic areas: (i) new and (ii) relapse TB cases (percentage)
- TB cases identified through active TB case finding (screening) among TB vulnerable populations in targeted geographic areas (number)
- Project-supported laboratories compliant with regionally harmonized standard operating procedures for surveillance of MDR-TB (number)
- Direct beneficiaries (number), and the share of females among them (percentage).

III. PROJECT DESCRIPTION

A. Project Components

41. **Although the operation started out with a focus on TB in the mining sector, based on consultations with clients and key stakeholders, the design has been refined to:** (i) tailor investments to the epidemiologic context in each country; and (ii) promote a health systems approach to maximize the impact of investments and reap potential synergies. The project is designed to respond to the key constraints in the control of TB and other occupational lung diseases described above. It will support countries to implement international best practices and to scale up promising interventions in a complementary manner to government and other ongoing World Bank and partner investments.

42. **The project includes three mutually reinforcing components that will assist participating countries to mount an effective regional response to TB and occupational lung diseases.** The project will support a paradigm shift in how the subregion prevents and treats TB by: (i) introducing a multisectoral platform for regionally coordinated actions led by ministries of health; (ii) supporting the implementation of the latest WHO TB Strategy, including the 90-90-90 targets²⁶ by strengthening demand- and supply-side interventions for effective management of TB and other communicable diseases; and (iii) improving use of the latest diagnostic methods for TB and occupational lung diseases. Annex 2 provides a detailed description of the project as well as a summary of best practices, key lessons, and best buy interventions in TB control.

Component 1: Innovative Prevention, Detection, and Treatment of TB (US\$45.49 million)

43. **Component 1 will improve the demand for and availability of high-quality TB, TB-HIV/AIDS, and occupational lung disease services in targeted geographic areas of the four participating countries.** WHO's End TB Strategy, the Harmonized Framework for the Management of TB in the Mining Sector, the SADC Code of Conduct for the Management of TB, and national plans provide a sound framework for Bank support.

44. ***Subcomponent 1.1: Enhancing case detection and treatment success (US\$37.52 million).*** The subcomponent will finance demand- and supply-side interventions to enhance early case detection and improve treatment success rates through the rollout of a package of standardized TB prevention and treatment services across the four countries.

45. On the demand side, the project will finance interventions to address inadequate community knowledge and awareness, TB stigma, and weak or absent community health systems. These interventions will include *social and behavior change communication* tailored to communities, miners (predominantly male), and families and caregivers (predominantly female); and targeted community/population screening programs with appropriate community support. In addition, the project will finance *nutritional support* for MDR-TB patients to simultaneously minimize out-of-pocket expenditures and to enhance the effectiveness of the TB treatment. These activities will be implemented by appropriately qualified and experienced nongovernmental organizations (NGOs), community-based organizations, private for-profit organizations, and labor unions to be selected using quality-based selection or selection based on consultants' qualifications, as will be provided for in the specific procurement plan and Project Implementation Manual (PIM).²⁷

46. On the supply side, the project supports two main strategies: (i) improving the clinical quality of services to ensure International Standards for Tuberculosis Care are met across countries; (ii) strengthening specimen transportation and management. To improve the *clinical quality of services*, the project will finance:

²⁶ 90 percent of vulnerable groups screened; 90 percent diagnosed and started on treatment; and 90 percent treatment success.

²⁷ The responsibilities will be outlined in the Project Implementation Manual and further articulated in the Terms of Reference (TORs) satisfactory to the Bank, which will be included in the specific Requests for Proposals and ensuing specific contracts during the selection process.

- In-service training and mentorship for front-line health workers in the management of TB and integrated TB-HIV services²⁸
- Facility-based TB screening using improved protocols and tools
- Improving patient referral, and follow-up (including through the use of ICT)
- Scaling-up community TB-related activities²⁹, including targeted community screening/contact investigation and patient/community support systems to enhance adherence.

47. To strengthen *sample specimen transportation and management*—critical for the effective management of TB—the project will support: (i) establishment and maintenance of *community sputum collection points*; (ii) *sample transport systems* using motorcycles and other means for transporting sputum specimens from such collection points to health facilities for microscopy, Xpert testing or culture, and drug-sensitivity testing; and (iii) more efficient and rapid transmission of laboratory results to clinicians and patients. The project will contract with private courier services to transport samples on the basis of existing successful pilots such as Riders-For-Health. To the extent possible, the project will also support the use of Global Positioning System and barcode capabilities in sputum sample management. The aim is to shorten the diagnosis time, especially for rural, mining, peri-mining and cross-border populations.

48. ***Subcomponent 1.2: Rolling out a standardized package of occupational health services and mining safety standards across the four countries (US\$7.97 million)***. Three main activities will be funded under this subcomponent: (i) *strengthening the capacity of public sector agencies* responsible for mine safety to undertake inspection of mines with an emphasis on determining mine dust levels; (ii) *expanding periodic screening and referral* for occupational lung diseases and other diseases³⁰ in line with standards set within the subregion and international best practices; and (iii) *developing/strengthening care programs* for occupational lung diseases.

49. The subcomponent will enable countries with established mining sectors—like Zambia—to strengthen their occupational health services with a focus on the package³¹ provided by the Occupational Health and Safety Institute. For countries with nascent domestic mining sectors like Lesotho, Malawi, and Mozambique, the subcomponent will finance the development and rollout of *occupational health services databases and electronic record systems* to strengthen referral for compensation services.

50. Ministries of labor or agencies mandated with occupational health and safety issues will implement screening for occupational lung diseases. Ministries of mines (mine safety or regulation departments) will support mine health safety inspection. The project will complement existing government programs and other related initiatives, as well as the Global Fund Grant on TB in the

²⁸ The project will finance the rollout of integrated TB-HIV services in targeted areas by scaling up one-stop shop TB-HIV service centers at existing health facilities.

²⁹ Scaling up community-based outreach TB services will help minimize transportation, financial, and other opportunity costs related to traveling to health facilities to access TB care.

³⁰ Screening of miners and ex-miners will include other co-morbidities in the region, such as diabetes.

³¹ The Occupational Health and Safety Institute provides pre-employment screening, periodic screening during employment, and post-employment screening for ex-miners for occupational health and safety.

mining sector to finance models for occupational health service delivery, such as the pilot one-stop center model in South Africa, which will be supported across the participating countries.³²

51. Under this component, the project will finance goods, training, equipment, technical assistance, and operational expenses. While governments and partners will finance first-line drugs for TB treatment, the project will fund *second- and third-line anti-TB drugs* as a backup to minimize stock outs.

Component 2: Regional Capacity for Disease Surveillance, Diagnostics, and Management of TB and Occupational Lung Diseases (US\$43.19 million)

52. **Component 2 will strengthen selective aspects of health systems to position the subregion to better manage the TB epidemic and other infectious diseases.** This component will prioritize activities via the following subcomponents.

53. ***Subcomponent 2.1: Improving quality and availability of human resources in the targeted areas (US\$15.24 million).*** This subcomponent aims to support the *development of a skilled health workforce* related to project activities based on a regionally defined curriculum, mentoring, and knowledge sharing in three critical areas: (i) case detection and management of TB; (ii) mine health regulation and occupational services; and (iii) disease surveillance. The subcomponent will finance both *pre- and in-service training*. It will seek to achieve economies of scale and promote intercountry learning and exchanges through regionally coordinated training and skills development. This subcomponent will finance training, consultancy, technical support, and operational costs.

54. ***Subcomponent 2.2: Strengthening diagnostic capacity and disease surveillance (US\$23.02 million).*** The subcomponent will: (i) strengthen regional diagnostic capacity and networking; (ii) enhance access to diagnostics for TB and occupational health in the targeted intervention areas; and (iii) enable participating countries to strategically revamp surveillance systems.

55. The project will strengthen diagnostic capacity by: (i) expanding microscopy networks in targeted intervention areas; (ii) rolling out newer and more accurate diagnostic technologies such as *Xpert MTB/RIF (GeneXpert) and Line Probe (Hain test) assays* for HIV-related TB and MDR-TB and for digital imaging for occupational lung diseases; (iii) scaling up the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) and the companion training and mentorship program (Strengthening Laboratory Management Towards Accreditation—SLAMTA) for at least 43 laboratories³³; and (iv) strengthening the networking of national TB laboratories. National TB reference laboratories will be upgraded to support their national networks of laboratories and link them to other key laboratories in the subregion.

56. To strengthen surveillance capacity in the subregion, the subcomponent will finance the establishment of a mechanism for regional disease intelligence sharing among the target countries.

³² The one-stop center model provides comprehensive occupational health services—medical, rehabilitation, social, and financial support; assistance with compensation, pension, and provident funds; and health promotion—under “one roof” for miners, ex-miners, and their families.

³³ SLIPTA is a mechanism used to strengthen and measure the quality and capacity of laboratories through a certification system linked to stars, with five stars being the highest possible level to be achieved by laboratories.

The focus will be selective and include financing to: (i) upgrade surveillance capacity for drug resistance with a focus on MDR-TB and improvements to laboratory-based monitoring of antimicrobial resistance; (ii) establish joint cross-border committees that will carry out joint outbreak investigations, responding to disasters and other public health events, and conducting tabletop simulations, building on experiences and emerging lessons from EAPHLNP and other related public health programs; and (iii) establish/reinforce information and reporting systems across satellite/project districts and border areas. The above activities will be supported in collaboration with key partners, such as ASLM, CDC, and WHO Africa Region. Under this subcomponent, the project will finance civil works, goods, training, technical assistance, operational expenses, and equipment.

57. ***Subcomponent 2.3: Strengthening mine health regulation (US\$4.93 million)***. This subcomponent will support countries to update or draft *occupational health and safety legislation*; review and/or develop *guidelines* for mine health inspections, occupational health screening protocols, and compensation systems and guidelines; develop *information technology (IT) systems* for compliance monitoring and mine health surveillance; and provide *equipment for mine health inspection*. While strengthening the supply side of regulatory services, the subcomponent will remove policy and service delivery barriers that negatively impact health seeking behaviors of miners, ex-miners, and households in peri-mining areas. The project will finance technical assistance, equipment, minor civil works related to the use or installation of equipment for mine health inspection, and operational expenses.

Component 3: Regional Learning and Innovation, and Project Management (US\$33.32 million)

58. **Component 3 will fund technical support to strengthen regional capacity and promote regional innovation through sharing of knowledge and evidence from interventions implemented under Components 1 and 2.** In addition, Component 3 will support advocacy for policy reforms and for greater accountability by mining companies on enforcement of occupational and mine health standards. While the activities financed under this component will primarily benefit the participating countries, they will contribute more broadly to strengthen the regional response to TB and TB/HIV by generating new knowledge.

59. **The knowledge activities and products generated will be in the form of:** (i) *regional baseline assessment reports* that bring evidence to better define the context and to inform policy and project interventions; (ii) *in-depth case studies* capturing the innovative activities and outputs funded under the project; (iii) *joint operational/implementation research*; (iv) *South–South learning exchanges* between policy makers and practitioners from the participating countries as well as between representatives of the project countries and other key stakeholders in the region; and (v) *rigorous evaluations* of interventions where feasible. A joint annual review and planning meeting bringing together representatives of the participating countries will be used as a platform to strengthen cross-country learning and promote innovative approaches.

60. ***Subcomponent 3.1: Operational research and knowledge sharing (US\$3.61 million).*** This will include key baseline assessments³⁴ with technical support of CDC and IFC. ECSA-HC³⁵ will coordinate the major studies related to activities under the project (Annex 2).

61. ***Subcomponent 3.2: Centers of excellence in TB and occupational lung disease control (US\$5.76 million).*** The participating countries have a shared vision to innovate and learn in different technical areas. Each country has agreed to provide regional leadership in key technical areas where each has a comparative advantage and will serve as a center of excellence. There is emerging consensus that the countries' centers of excellence will be in the following strategic areas: Lesotho—*community-based management of TB*; Malawi—*community TB care and integrated disease surveillance*; Mozambique—*MDR-TB and childhood TB management*; and Zambia—*occupational health and safety*.

62. ***Subcomponent 3.3: Regional coordination, policy advocacy, and harmonization (US\$13.42 million).*** The project will support ECSA-HC to undertake regional activities that generate economies of scale and deepen learning and knowledge exchange. Building on its activities under EAPHLNP, ECSA-HC will be well placed to support project activities and leverage existing platforms to promote South–South knowledge sharing. ECSA-HC will:

- Convene technical experts and policy makers
- Support research on TB control and health systems strengthening
- Support knowledge sharing
- Provide implementation support
- Facilitate capacity building and training
- Support cross-border surveillance efforts.

63. ***NPCA will complement ECSA-HC and participating countries' activities through regional policy advocacy*** and coordination of action on mine health regulation and occupational health. More specifically NPCA will:³⁶

- Support regional baseline research work on: (i) opportunities for private sector participation in TB control; and (ii) the state of mine health regulation
- Undertake policy level dissemination of key findings, including engaging policy makers on mining and health
- Support countries to strengthen policy level reforms and political level commitment to tackling TB (domestic financing for TB)
- Coordinate regional level policy advocacy to sustain commitment toward tackling TB including holding the mining sector accountable for its contribution to the burden of TB and occupational lung diseases
- Coordinate with SADC on regional aspects that require policy level harmonization e.g. standards for dust exposure levels in mines.

³⁴ The project will coordinate with the Global Fund and other key stakeholders to finance joint studies and minimize duplication.

³⁵ ECSA-HC will coordinate with well-positioned institutions to undertake research in the subregion, including Wits Health Consortium, the principal recipient of the Global Fund Grant for TB in the mining sector.

³⁶ NPCA's work program will be reviewed and modified during project implementation to ensure continued relevance to the project's objectives.

64. **Subcomponent 3.4: Project management (US\$10.53 million).** The project will support the work of the project implementation units (PIUs), including financial management, procurement, risk-based auditing, and M&E. Funding will be provided to facilitate meetings of inter-ministerial National Technical Committees and the RAC. Joint annual review meetings will be supported at national level and interim reviews in participating districts, as needed.

65. The project will fund operating costs for all project activities including learning, advocacy, and research work relevant to the project and to the needs of the participating countries.

B. Project Cost and Financing

66. **The project will be financed through IDA grants and credits (Malawi and Mozambique) and credits (Lesotho and Zambia).** The lending instrument will be an Investment Project Financing allocated among each of the participating countries and the RCO (Table 1).

Table 1: Overall Project Cost and Financing (US\$ million)

Project Cost by Component and Subcomponent Activity	Project cost (US\$ m)	IDA financing (US\$ m)	% financing
Component 1: Innovative Prevention, Detection, and Treatment of TB			
<i>1.1. Enhancing case detection and treatment success</i>	37.52	37.52	100
<i>1.2. Rolling out a standardized package of occupational health services and mining safety standards across the participating countries</i>	7.97	7.97	100
Total Component 1	45.49	45.49	100
Component 2: Regional Capacity for Disease Surveillance, Diagnostics, and Management of TB and Occupational Lung Diseases			
<i>2.1. Improving quality and availability of human resources in the targeted areas</i>	15.24	15.24	100
<i>2.2. Strengthening disease surveillance and diagnostic capacity</i>	23.02	23.02	100
<i>2.3. Strengthening mine health regulation</i>	4.93	4.93	100
Total Component 2	43.19	43.19	100
Component 3: Regional Learning and Innovation, and Project Management			
<i>3.1. Operational research and knowledge sharing</i>	3.61	3.61	100
<i>3.2. Centers of excellence in TB and occupational lung disease control</i>	5.76	5.76	100
<i>3.3. Regional coordination, policy advocacy, and harmonization</i>	13.42	13.42	100
<i>3.4 Project management</i>	10.53	10.53	100
Total Component 3	33.32	33.32	100
Total Project Financing (US\$ million)	122.00	122.00	100

C. Lessons Learned and Reflected in the Project Design

67. **The project design has been informed by lessons learned from the Bank’s experience in managing regional health projects and from its technical assistance in mining and related sectors.** Lessons have been derived from regional operations such as EAPHLNP, Great Lakes Emergency Sexual and Gender Based Violence & Women's Health Project (P147489), and the Sahel Women’s Empowerment and Demographics Project (P150080); regional public–private collaborations focusing on communicable disease control such as the African Program for Onchocerciasis Control in West Africa; and the Lubombo Spatial Development Initiative, which focuses on malaria control in southeast Africa. The recently completed Intergovernmental Authority on Development (IGAD) HIV/AIDS Partnership Program (IRAPP) Support Project (P104523) provided lessons, as did the Bank’s mining sector projects, technical assistance, and regional flagship initiatives. Key lessons and approaches learned and applied from the above regional operations and the Independent Evaluation Group’s evaluation of regional projects include:

- **Use a simple monitoring framework** and avoid relying on complex surveys to monitor outcome indicators. Former overreliance on complex surveys, especially those beyond the control of the project for the majority of project development objective–level indicators, resulted in large gaps of data for many years in some Bank regional projects and significant difficulty in assessing project impact. Similarly, reliance on developing a complex regional M&E framework to collect information also led to monitoring delays. Thus this project will rely mainly on data routinely collected by countries and will invest in strengthening the quality of these data. The project will also finance baseline surveys using Project Preparation Advance resources to supplement baseline data needs, and this step will be completed before or during the project’s first year. The RCO will be staffed by M&E specialists to ensure robust project evaluation. The project will set up and support a community of practice on M&E and impact evaluation, to build subregional evaluation capacity.
- **Simplify implementation arrangements.** This is critical. The project will have one lead ministry at national level, which will lead and coordinate multisectoral activities and account for resources and results. Performance-based contracting and funding arrangements will be used for service delivery through private sector entities, where possible, to strengthen the link between implementation of key activities and funding from the project. All key entities engaged to implement the project at regional and national levels will have well-defined performance milestones built into their work plans. The project has minimized layers of accountability and is structured to allow direct accountability between the lead entity and other stakeholders.
- **Carefully assign project implementation roles based on comparative advantages.** Evidence from the Independent Evaluation Group’s review of regional projects found that best practice is to rely on national institutions for execution and implementation of program interventions at the country level, and on regional institutions for supportive services that cannot be performed efficiently by national

agencies, such as coordination, data gathering, technical assistance, dispute resolution, and M&E.³⁷

- **Conduct analytical work to inform design.** Project design has benefited immensely from earlier analytical work supported by the Bank and other agencies in the region. WHO and CDC’s analytical work and assessments, including drug-resistance surveys in particular, informed project design. The project will support an ambitious learning agenda on topics of strategic relevance to the subregion, including MDR-TB, occupational health, and mine-health surveillance. Resources for impact evaluations for highly innovative interventions will be set aside and coordinated regionally.
- **Ensure ownership.** Project preparation has benefited from high-level support from ministers of health and finance and permanent secretaries who have provided strong leadership to moving the design forward and bringing together key actors at regional and national levels. The project builds on the leadership and ownership of the subregion through the SADC Declaration on TB and follow-up efforts since 2012.
- **Promote partnerships.** Within the Bank, the project is a multisectoral effort supported by Health, Mining, Social Development and Environment Global Practices and the IFC Public–Private Partnerships for Health team. Outside the Bank, the project is being prepared with CDC and other key partners involved in TB control and strategic multisectoral initiatives in Southern Africa. The project has already catalyzed high-level intersectoral technical working groups and steering committees in the participating countries drawn from health, mining, labor, civil society, and private sectors. These partnerships augur well for project implementation when cross-sectoral collaboration will be even more critical.

IV. IMPLEMENTATION

A. Institutional and Implementation Arrangements

68. Proposed implementation arrangements are adapted to the country and regional contexts and draw on evidence of best practices and lessons from past and ongoing Bank-financed regional projects. The proposed implementation arrangements were also informed by the Bank Independent Evaluation Group’s recommendations on regional projects. The institutional and implementation arrangements will be further elaborated and spelled out in the PIM to be finalized by September 2016.

Regional Level

69. **ECSA-HC was selected competitively to serve as the RCO.** Established in 1974, it has a clear mandate to work on regional public health issues; a solid track record managing similar regional health projects for the Bank and other partners; and substantial experience and knowledge

³⁷ Independent Evaluation Group. 2007. “The Development Potential of Regional Programs: An Evaluation of World Bank Support of Multi-country Operations.” Washington, DC.

in the core, project-supported areas (TB control, laboratory systems, cross-border disease surveillance, and outbreak preparedness).³⁸ The institution plays a pivotal role regionally to support harmonization of policies and strategies and to share best practices. ECSA-HC's core competencies and performance are summarized in Annex 3.

70. ECSA-HC will provide technical and regional coordination support, facilitate knowledge sharing, and advocate for policy and institutional change, as agreed with key project stakeholders. Specific roles and responsibilities are to: (i) facilitate regional dialogue and efforts to harmonize systems and standards for managing TB and to develop and roll out standardized best practices in mine health; (ii) coordinate specialized technical inputs as may be needed; (iii) foster networking and knowledge sharing; (iv) provide implementation support to participating countries, as required; (v) support policy-oriented research and dissemination; (vi) support countries to disseminate evidence at national, regional, and international platforms; (vii) facilitate strategic discussions and collaboration between international and regional organizations and project teams on technical and policy issues of mutual interest; and (viii) advocate for policy change and sustained political commitment.

71. ECSA-HC will establish a dedicated secretariat to coordinate project activities at the regional level. The core team will be small and selective, including specialists in laboratory strengthening, disease surveillance, TB control, and M&E. Such personnel will be recruited within the first three months of project effectiveness. ECSA-HC will prepare consolidated annual project status reports on progress in implementing national and regional activities; organize annual meetings of the participating countries to discuss achievements, issues, and lessons learned; support the regional technical working groups that will serve as the main vehicle for regional activities; and follow up on intergovernmental issues.

72. ECSA-HC will facilitate the establishment of an RAC and serve as its secretariat by the time the project becomes effective. The goal of the RAC will be to bring together stakeholders working on the project, review implementation progress, provide strategic guidance and oversight, explore opportunities for partnerships, and ensure coordination with other key initiatives. The RAC will include three members from each country;³⁹ one member from the Global Fund Regional Coordinating Mechanism; and one representative from SADC. Five members from outside government—preferably from the chamber or association of mines or a mining company, an NGO, a research institution, ex-miners' association, and a labor union—will be nominated on a rotating basis by the participating countries. The RAC chair will be selected from a regional organization with expertise in policy and technical issues related to the project's scope. In line with this, a senior official from NPCA will chair the RAC during the first year of the project. Participating countries will decide on a chair in subsequent years based on a process to be outlined in the PIM. The RAC will meet semi-annually in the first year of the project and annually thereafter.

73. ECSA-HC will work closely with NPCA to sustain high-level political and economic support for critical activities under the project. ECSA-HC will enter into a cooperative

³⁸ Member countries are Kenya, Lesotho, Malawi, Mauritius, Seychelles, Swaziland, United Republic of Tanzania, Uganda, Zambia, and Zimbabwe.

³⁹ One a senior policy maker at permanent secretary level; one a senior technical specialist from the Ministry of Health with project-area expertise; and one a senior technical specialist from either the Ministry of Labor or Ministry of Mines to be rotated annually.

agreement with NPCA outlining specific roles, responsibilities, and deliverables within three months of the project becoming effective. As the technical arm of the African Union, NPCA has a strong comparative advantage in several critical areas, such as mine health regulation, occupational health policy, and advocacy for sustaining momentum on TB control. The scope of work and deliverables for NPCA will be reviewed during project implementation to ensure continued relevance. To adequately provide technical support to the participating countries and execute regional level policy and advocacy, some key technical staff will be hired or designated to support the project within NPCA, including a Health and Regulatory Policy Specialist, Mining and Occupational Health Specialist, and a private sector advisor.

74. **The funding of regional-level activities will come from the participating countries.** Each country will sign a Subsidiary Agreement with ECSA-HC. In addition, Mozambique (which is not a member of ECSA-HC) will sign a Memorandum of Understanding with it, under terms and conditions acceptable to the Bank, as detailed in the project's Financing Agreement. Roughly 11 percent of the IDA credits/grants for each country will finance regional activities based on an annual work plan approved by the participating countries through the RAC. Direct disbursements will be made from the Bank to ECSA-HC and NPCA based on approved annual work plans. (Annex 8 provides detailed information on the flow of funds.) Regional coordination and implementation arrangements will be reviewed at an interim 18-month review by the Bank, and modifications will be made as needed in consultation with the participating countries.

75. While there are existing subregional cooperation agreements between countries—e.g. the SADC Health Protocol of September 1998 and cooperation frameworks for intergovernmental activities for ECSA-HC and NPCA to enable cross-border activities to be rolled out—the project will develop a project cooperative agreement within 12 months of becoming effective, to provide a project-specific framework to facilitate cross-border activities.

76. To enhance the impact of the project, there will be technical coordination between the participating countries and selected agencies of the government of South Africa such as the Medical Bureau for Occupational Diseases. This is in line with existing agreements between South Africa and its neighboring countries and with the Occupational Diseases in Mines and Works Act of South Africa.⁴⁰ In addition, partnerships to train the health workforce will be forged with strategic institutions such as the South Africa WHO/ILO Collaboration Center on Occupational Health and South Africa's National Institute of Occupational Health to improve availability of occupational health staff across the region.

National Level

77. The institutional framework for project implementation, to vary by country, is based on the following principles: (i) building upon country systems and relying on national structures with targeted technical assistance where appropriate; (ii) using implementing entities based on comparative advantages, for example, community-based activities that are best suited to NGOs will be contracted out while core public health functions or mining sector functions that require government agencies will be implemented by these entities; (iii) relying on simple performance-

⁴⁰ Coordination with the Medical Bureau for Occupational Diseases will be primarily with (i) Lesotho, Malawi, and Mozambique (labor-sending countries) and entails sharing of information and databases on cross-border miners and ex-miners and use of occupational health facilities and equipment funded by the project to facilitate cross-border occupational health services such as compensation for lung diseases; and with (ii) Zambia to facilitate knowledge exchange.

based agreements to strengthen accountability between the lead ministry and other stakeholders; and (iv) streamlining arrangements and avoiding parallel structures or processes.

78. The project will promote multisectoral collaboration between implementing ministries (ministries of health, mines, finance, and labor). In each country, the national TB program—with the support of the Policy and Planning Department of the Ministry of Health (MOH)—will coordinate project implementation. The MOH as the lead implementing agency will coordinate multisectoral activities implemented by the ministries of mines and labor as well as competitively selected NGOs and private sector stakeholders.

79. At country level, an inter-ministerial National Technical Committee (NTC) will be established before effectiveness to oversee the project. The NTC will be responsible for reviewing and approving consolidated annual work plans and budgets submitted by the technical departments and providing technical guidance to implementing agencies.

80. Implementing agencies will develop annual work plans with measureable outputs and budget resources. The plans will be submitted to the MOH as the lead implementing agency and will be consolidated by the national TB program, which will provide technical leadership to the project. PIUs and other MOH departments will provide overall support for project implementation and be responsible for day-to-day coordination of the project, including fiduciary aspects and preparation of quarterly and annual consolidated technical and financial reports.

81. In *Lesotho*, overall implementation will rest with the MOH and overall oversight with the Principal Secretary. The MOH will serve as the lead implementing agency and will work with the Ministry of Mining, Ministry of Finance, Ministry of Development Planning, Ministry of Labour and Employment, and the Ministry of Justice and Correctional Services. The national TB program will oversee a team of technical and fiduciary staff in a Project Accounting Unit established to support the project. The TB program will also coordinate other implementing entities. With private entities such as NGOs and private-for-profit companies, the government will use simple performance-based contracts to ensure accountability for results.

82. In *Malawi*, the Principal Secretary for Health will be responsible for overall project oversight. The key implementing agencies will be the MOH; the Ministry of Natural Resources, Energy and Mining; and the Ministry of Labour and Manpower Development. Overall responsibility for coordination will rest with the national TB program, which will house a small core PIU to be established before the project becomes effective with technical and fiduciary staff who meet the Bank's requirements. Where private entities have comparative advantage to execute key project activities, they will be engaged through competitive selection. To minimize teething problems, the PIU for the ongoing Nutrition and HIV/AIDS Project (P125237) will provide fiduciary support during the start-up phase.

83. In *Mozambique*, the key implementing agencies will be the MOH (lead agency), Ministry of Mineral Resources and Energy, and Ministry of Labor, Employment and Social Security. The existing PIU in the MOH will lead project coordination and fiduciary oversight. The national TB program will be the lead technical program reporting to the Director for Public Health.

84. In *Zambia*, the key implementing agencies will be the MOH, Ministry of Mines and Mineral Development, Ministry of Labour and Social Security, and the Occupational Health and

Safety Institute. The MOH will be the lead entity with a central coordinating role. In the MOH, the national TB program will serve as the lead technical program and will be supported by the Directorate of Policy and Planning as per the arrangements of the ongoing Bank-funded health project (P145335). The Directorate of Policy and Planning in the MOH will be responsible for fund management and day-to-day project operations.

85. National implementation arrangements will be monitored during Bank supervision missions and assessed during the project's mid-term review.

B. Results Monitoring and Evaluation

86. The project will emphasize generation and use of data for decision making at various levels. A community of practice on M&E—comprising M&E officers from the participating countries and the RCO—will be set up in the subregion to strengthen skills and integrate a culture of data analysis and dissemination. Operations research to document process aspects of the project will be finalized. Countries will lead M&E activities, but the RCO will be mandated to collect and aggregate project-monitoring data. Most data for the results framework (Annex 1) will be generated by the project and routinely captured in the countries' health information systems. The project will therefore provide funding to strengthen these systems and, where needed, conduct baseline surveys. Contracted by the RCO with Bank technical support, qualified entities will conduct impact evaluations. The Bank will review the results framework during implementation to assess the pace of progress toward key targets. The results chain (Annex 1, Figure 1) will be scrutinized during the mid-term review for continued relevance and to confirm the overall logic of the project design. The project will support activities to improve availability and quality of data, including surveillance systems in cross-border areas and laboratories to produce data that countries cannot generate at present.

C. Sustainability

87. The project will be implemented primarily through existing public sector structures such as national TB programs, and government financial and procurement systems in each country, enabling the participating-country governments to maintain activities with their current institutions and resource environment after the project closes. On the recurrent cost implications of the project, a financial sustainability analysis shows that the project is viable (Annex 8): the annual project budget as a share of the 2015 government (domestic) health budget in the participating countries ranged from 1.6 percent to 2.1 percent, which is a sustainable investment. Further analysis shows that the annual project funding in target areas ranged from US\$0.5 to US\$1.6 per capita, which is below the government (domestic) budget per capita and GDP per capita of US\$13-98 and US\$250-1,680, respectively. This means that the cost per patient treated for drug-susceptible TB will be less than GDP per capita in each of the participating countries, and that economies of scale will be realized. The potential added costs from scaling up MDR-TB services will be assessed during implementation.

88. The project's multisectoral, multicountry approach will have greater impact on TB control programs and enhance prospects for sustainability. Previous initiatives to address TB in the region have not been effective in reducing the TB burden as they did not fully consider the multisectoral and multicountry dimensions in mining areas, peri-mining areas, and high-burden regions. A multicountry focus enables economies of scale, especially in: (i) expertise and resources for MDR-

TB management; (ii) accreditation and development of laboratory capacity to manage TB and provide continued training in laboratory management; (iii) training of new and in-service health personnel to further strengthen knowledge and skills; and (iv) delivery of a standardized package of occupational health services and safety standards. Furthermore, the project will also take stock of opportunities for public–private partnerships in TB control. While not guaranteed, the approach is expected to boost chances of sustainability as ownership is enhanced, accountability improved, economies of scale achieved, and collaboration expanded.

V. KEY RISKS

A. Overall Risk Rating and Explanation of Key Risks

Table 2: Risk Rating Summary

Risk Category	Rating
1. Political and Governance	Moderate
2. Macroeconomic	Moderate
3. Sector Strategies and Policies	Moderate
4. Technical Design of Project or Program	Substantial
5. Institutional Capacity for Implementation and Sustainability	Substantial
6. Fiduciary	Substantial
7. Environment and Social	Moderate
8. Stakeholders	Substantial
9. Other: Risk of duplication of activities between the Bank-financed project and other major or related initiatives in the subregion	Moderate
Overall	Substantial

89. The overall risk to the project relates to three main elements: (i) complexity of working with multisectoral entities across participating countries; (ii) capacity constraints within national systems; and (iii) coordination challenges between national and regional stakeholders. Specific substantial risks during implementation, and possible impact and mitigation measures, are as follows:

- (i) The proposed project is both *regional and multisectoral*. Hence the key implementing ministries (health, mines, and labor) may have insufficient understanding and commitment to a shared regional strategy, and there may be lack of clarity on their roles and responsibilities. To mitigate this risk, the implementation arrangements (through the RAC and ECSA-HC as RCO), buttressed by close Bank engagement, will ensure a clear and common vision shared and understood by all target country agencies. Every year, joint detailed planning will be carried out with all countries.
- (ii) *Institutional capacity for implementation and sustainability*. Some of the implementing entities in the participating countries have limited technical and project implementation capacity. To counter this risk, the Bank will continue working closely with CDC to ensure sound design of technical components. For its part, ECSA-HC will support the participating countries in capacity building and skills development at

regional level; and provide technical support to the overall implementation of the project and supervision of M&E. NPCA will provide specialized policy development and harmonization support with a focus on mine regulation and occupational health policies. In addition, a multisectoral team from the Bank will adopt an intensive and proactive supervision approach for technical and fiduciary aspects of the project with strong technical backstopping from international and local offices. The Bank will also collaborate with WHO experts in the region and globally.

- (iii) ***Fiduciary issues (Annex 8):*** The project’s fiduciary risk stems from having multiple countries and implementing entities. Related factors have been addressed during preparation and will continue to be addressed during the first year of the project in the participating countries.⁴¹ These include limited fiduciary personnel and limited staff with training in Bank procedures; lack of good manuals; inadequate accounting information systems; and weaknesses in internal control systems. The Bank’s fiduciary team will provide oversight, training, and hands-on implementation support, particularly in the first year of the project.
- (iv) ***Stakeholders:*** Because expectations of multiple stakeholders may not always be consistent, the task team will manage these expectations through proactive engagement with national and regional stakeholders, and by sharing information as widely as possible. The project will enhance engagement of all stakeholders, in mining, labor, and health sectors. In addition, given the political economy there is a risk that some mining lobby groups or professional associations may not be fully on board with the project’s envisaged activities. The project is designed to promote win-win outcomes from controlling TB and other diseases in participating countries via key national coordination platforms such as the NTCs, which will have representatives from the private sector and miners’ associations. At regional level, NPCA will provide high-level policy advocacy to galvanize national and regional stakeholders to act on the core objectives of the proposed project. The project will support analytical work on the economic and social benefits for TB control by governments and mining companies, and disseminate the findings widely.
- (v) ***Other:*** There is a risk of duplication of activities between the Bank-financed project and other major or related initiatives in the subregion. To mitigate this, key stakeholders implementing these other initiatives, including those financed by the Global Fund, will be represented on the RAC. To ensure coordination with broader regional activities in the region, SADC will be represented on the RAC. In addition, ECSA-HC and NPCA may face challenges coordinating the regional work program. However, in practice this risk is expected to be minimal. ECSA-HC and NPCA have a demonstrated track record of working together in health and multisectoral initiatives. Both have participated in steering committees in Africa on key public health issues, including the African Platform for Human Resources for Health, where NPCA served as chair of the steering committee.

⁴¹ Each country will receive Project Preparation Advance funding, which will finance activities to address fiduciary and technical capacity gaps identified during project preparation.

VI. APPRAISAL SUMMARY

A. Economic and Financial Analysis

90. The proposed project was appraised from both an economic and financial perspective. The analyses were informed by administrative data and past studies in the targeted countries, in the region, and around the globe.

Economic Analysis

91. Health benefits of investing in cost-effective TB control and treatment services are well documented. The project will contribute to saving health care costs related to disease treatment by focusing on cost-effective measures such as the Directly Observed Treatment, Short Course (DOTS), and save on the socioeconomic burden related to the extra care necessary for TB patients. Studies show that over 90 percent of TB cases can be cured with proper monitoring and high adherence to taking the full course of medicines with reductions in deaths of about 60–70 percent.⁴² In the participating countries we estimated the current DOTS treatment success rate at 83 percent, implying that there is room for further improvement. Treating TB is highly cost-effective, as observed by Goodchild et al. (2011)⁴³ who concluded that scaling up TB control in India resulted in a total health benefit of 29 million disability-adjusted life years (DALYs), 1.3 million deaths averted, and economic well-being valued at US\$88 billion over a decade. Apart from averting normal TB, the proposed project also presents benefits of increased investments in MDR–TB surveillance and treatment.

92. The project will facilitate improvements in technical and allocative efficiency by rolling out a harmonized package of services for TB prevention, control, and treatment in line with the post-2015 global TB strategy and the SADC Declaration on TB. The harmonized package will improve access to high-impact, cost-effective services across the participating countries, and it will be delivered using both input- and results-based financing mechanisms. Supply- and demand-side interventions will strengthen basic health systems and promote regional-level accountability aimed at increasing the ability of the participating countries in managing the complex TB epidemic and associated diseases. The approach will improve technical efficiency by pushing implementing units closer to the highest production possibility frontier, where the units will be able to deliver better services at least cost. Allocative efficiency will be improved by allocation of resources to where marginal benefits and utility are highest via a focus on targeted geographic areas and vulnerable populations, in line with the 90-90-90 global and regional TB goals. To achieve the desired impact, this regional TB project will benefit from the Bank’s diverse network, and regional and national collaboration at technical and policy levels. The Bank is particularly suited to implement this project given its comparative advantage in institutional and systems strengthening, innovation, brokering partnerships with development partners and regional institutions, policy dialogue and analytic work across multiple sectors.

⁴² Vassall, A. 2014. “Benefits and Costs of the TB Targets for the Post-2015 Development Agenda.” Working paper produced for the Copenhagen Consensus Centre for the Post-2012 Consensus.

⁴³ Goodchild M., S. Sahu, F. Wares, P. Dewan, R.S. Shukla, L.S. Chauhan, and K. Floyd. 2011. “A Cost-benefit analysis of scaling up tuberculosis control in India”. *International Journal Tuberculosis Lung Disease* 15(3):358–362. <http://www.ingentaconnect.com/content/iatld/ijtld/2011/00000015/00000003/art00011?crawler=true>, accessed December 10, 2015.

93. To assess the value of the investment, a cost-benefit analysis for the project was conducted (Annex 7).⁴⁴ The total present value of benefits is estimated at US\$776.1 million while the present value of costs is estimated at US\$111.7 million, giving a net present value of benefits of US\$664.4 million. Therefore, the benefit-cost ratio is estimated at 6.95:1—i.e. for every US\$1 invested through the project, there is a yield of US\$6.95. Sensitivity tests show that the minimum benefit-cost ratio will be 1.75:1 even if certain assumptions do not, or only partly, occur (see Annex 7 for assumptions, methods, data, and results). However, the benefit-cost ratio may have been underestimated (per the following paragraph).

94. Very conservative assumptions were used to estimate the impact of the project, leading to underestimation of the total economic and social benefits. Vassall (2014) shows that the benefit-cost ratio for diagnosis and treatment of TB based on current screening practices is in the range of 11-192:1.⁴⁵ Therefore, given the additional investments in intensified diagnosis and treatment through the proposed project, the benefit-cost ratio should be higher. Furthermore, minimum rather than average wages were used while economic benefits of increased life-years of children saved before they become active in the labor force were not included. In addition, income gained from deaths averted in the 45-64 age group were excluded. Likewise, welfare gains from reduced poverty or improved equity were not included even though the relationship between TB and poverty is well established. The analysis also assumes that there will be no new advances in TB diagnosis and treatment during the duration of the TB project. However, new technologies may be discovered (such as a vaccine), which could further shorten diagnosis and treatment with positive benefits. Many other benefits, such as efficiency improvements, were also excluded because they cannot be measured or translated to monetary value easily. Therefore, the result of this analysis should be interpreted as an underestimation of the return of this project, given that it does not include all expected benefits.

Financial Analysis

95. According to World Bank projections, economic growth in Sub-Saharan Africa countries is estimated to have fallen to 3.7 percent in 2015 from 4.6 percent in 2014. Nonetheless, overall growth for the Sub-Saharan Africa region is expected to rebound to 4.3 percent in 2016 and improve further to 5 percent in 2017, albeit with mixed recovery across countries on domestic factors (Annex 7). Based on evidence from several countries, the expectation is that government health expenditure will increase with stronger GDP growth.

96. For the four countries, general government health expenditure as a share of general government expenditure was estimated at 8-19 percent on average over 2011-2013.⁴⁶ Further analysis showed that the per capita project funding (target areas) per year, which ranged from US\$0.5 to US\$1.6, was below the government (domestic) budget per capita and GDP per capita (US\$13 to US\$98 and US\$250 to US\$1,680, respectively). Thus, the financing situation in each

⁴⁴ Benefits are presented in life years rather than quality-adjusted life years or disability adjusted life years. Justification is provided in Annex 7.

⁴⁵ Benefits and Costs of the TB Targets for the Post-2015 Development Agenda. A Working Paper produced for the Copenhagen Consensus Centre for the Post-2015 Consensus. http://www.copenhagenconsensus.com/sites/default/files/health_perspective_tb_-_vassall.pdf, accessed December 10, 2015.

⁴⁶ WHO, Global Health Expenditure Database. 2011-2013 period averages are: 8 percent Mozambique, 13 percent Zambia, 14 percent Lesotho, and 19 percent Malawi.

of the four is positive, given that annual project financing as a share of the total government (domestic) budget for health is expected to diminish over time as government (domestic) financing increases. However, while general government health expenditure is expected to grow, there is no guarantee that part of the extra financial resources will be allocated to the TB programs in the four countries. Our analysis finds that the 4 countries give low priority to TB programs through domestic resources. The governments therefore have to allocate considerable domestic funding over the project implementation period in order to reduce reliance on donor support for the TB program, and to sustain the project's benefits.

B. Technical

97. There is a sound rationale for supporting the subregion to tackle TB while strengthening critical dimensions of health systems. The prioritized interventions are important in light of evidence from India, Tanzania, Thailand, and Vietnam, suggesting that advances in disease control and health systems strengthening are complementary.⁴⁷ The multisectoral approach is critical to strengthening overall impact. National TB programs have shown weaknesses in addressing TB in the mining sector. The proposed approach, which combines countries' efforts and engages multisectoral actors, potentially yields high rewards.

98. The targeting approach prioritizes those groups most affected by TB and TB-HIV/AIDS. There is substantial evidence that TB impacts the poor the most and the proposed targeting criteria will contribute to improved access to high-quality TB control interventions by the poor and vulnerable, some of who are missed by conventional and country-focused TB control programs. New diagnostics will help detect complex cases of TB and TB-HIV.

99. There is a strong merit in promoting improved laboratory-based surveillance to raise countries' understanding of the size and public health and economic impacts of drug resistance to TB and other antimicrobial agents. Limited capacity in participating countries to monitor and mitigate drug-resistance in TB presents a huge risk given the transboundary effects of TB and the documented growing risks of MDR-TB and XDR-TB that the subregion faces.

100. The technical support from IFC will contribute to assessing opportunities for public-private partnerships for TB control and occupational health. The engagement of experts from CDC, WHO, ASLM, and the South Africa WHO/ILO Collaboration Center on Occupational Health will be fundamental to increasing the technical capacity of health staff across the participating countries and to creating innovative models for delivering occupational health services, not just TB control.

101. The proposed project is based on global evidence of high-impact TB control interventions that improve demand for TB services and improve TB control outcomes. A combination of demand-side (household and community-based) and supply-side (health facility-based) TB control interventions has been shown to improve both TB and health systems strengthening outcomes, as evidenced by impact evaluations.

C. Financial Management

102. The World Bank conducted a financial management assessment of the national-level coordinating implementing entities, which include the Ministries of Health in Lesotho (using a

⁴⁷ Atun R., et al. 2010. "Health Systems Strengthening and TB Control." *Lancet*.

PIU known as the Project Accounting Unit), Malawi and Mozambique (both using a PIU), Zambia, as well as two regional-level institutions: NPCA of NEPAD and ECSA-HC (as RCO). The assessment's objective was to determine whether the implementing entities have in place acceptable financial management arrangements that satisfy the Bank's Operation Policy/Bank Procedure (OP/BP) 10.00. These arrangements are designed to ensure that the implementing entities: (i) use project funds only for the intended purposes in an efficient and economical way; (ii) prepare accurate and reliable accounts as well as timely periodic interim financial reports; (iii) safeguard assets of the project; and (iv) have acceptable auditing arrangements. The assessment followed the Financial Management Manual for World Bank Investment Project Financing Operations, which became effective on March 1, 2010, but was issued (retrofitted) on February 4, 2015.

103. There are adequate financial management arrangements in all implementing entities. However, the following improvements will be important for the project.

104. **Malawi:** The PIU at the MOH needs to: prepare a Financial Management Manual acceptable to the Bank by effectiveness (this will be part of the PIM); acquire an accounting information system to prepare the project's accounts within three months after effectiveness; and recruit two qualified and experienced accountants, of whom one has to be recruited by effectiveness and the other within three months after effectiveness.

105. **Zambia:** The MOH needs to hire or assign a qualified and experienced accountant by effectiveness. The ministry also needs to hire or assign a qualified and experienced internal auditor for the project within three months after effectiveness, given the inadequate capacity of the existing internal audit unit and its inability to conduct regular project audits. There is also a need to address internal control and accountability issues raised in the ministry's external audit report of December 31, 2014 (FY14) during implementation. The non-functionality of the project module of the Integrated Financial Management Information System (IFMIS) at the ministry, which is causing delays in producing financial statements according to the Auditor General's FY13 audit report, needs to be addressed within six months after effectiveness. If this is not possible, MOH will use Excel or the previously used NAVISION accounting software that needs to be activated within six months after project effectiveness. The audit committee needs strengthening to carry out its mandate to address audit issues.

106. **Lesotho:** The MOH's Project Accounting Unit needs to recruit an internal auditor for the project within three months after effectiveness given that the current internal audit unit does not have the capacity to conduct regular project audits. There is also need to recruit a Project Accountant to account for the project funds by effectiveness.

107. **ECSA-HC:** This institution will need to recruit a Finance Officer to adequately account for project funds within three months after effectiveness given that the current workload of existing staff will not allow them to efficiently handle this duty.

108. All implementing entities will require a PIM acceptable to the Bank. It should cover project financial management aspects not covered in the existing Financial Management Manuals. A complaint handling mechanism will need to be put in place by the MOH in Zambia, Malawi, Lesotho, and Mozambique such that project beneficiaries can have a mechanism of raising any of

their concerns that need to be addressed. With regard to disbursements, a report-based method will be used by all the implementing entities.

109. The conclusion of the assessment is that the financial management arrangements in place meet the World Bank's (IDA) minimum requirements under OP/BP10.00, and therefore are adequate to provide, with reasonable assurance, accurate and timely information on the status of the project required by World Bank (IDA). The overall financial management residual risk rating is substantial for the MOHs in the participating countries and moderate for ECSA-HC and NPCA.

110. Detailed financial management assessments and summary outline of funds flow and reporting arrangements are in Annex 8.

D. Procurement

111. Procurement capacity assessments for the MOHs for the participating countries, which will be in charge of implementing the project at national level, were undertaken. Assessments of the RCO (ECSA-HC) and of NPCA were also undertaken. Preliminary findings suggest that the overall risk for procurement (prior to mitigation measures) is substantial. The key issues are:

- **Lesotho:** (i) The need for the MOH Procurement Unit to contract a dedicated Procurement Officer to the regional project within three months of effectiveness; and (ii) limited capacity of the implementing partners under the regional project to assure adherence to World Bank Procurement and Consultant Selection Guidelines.
- **Malawi:** (i) The need for the regional project to have its own fully dedicated Procurement Specialist; (ii) weak record management system; (iii) limited capacity of the implementing partners under the TB project to assure adherence to World Bank Procurement and Consultant Selection Guidelines; (iv) inefficiencies and delays in procurement processes; (v) weak contract management; (vi) fraud and corruption risks; and (vii) a weak complaint-redress system.
- **Mozambique:** (i) Current capacity of the Executive Management Procurement Unit below requirements; (ii) overstretched internal units contributing to inefficient procurement and weak contract management, and a response time longer than it should be; (iii) weak record management system; and (iv) insufficient documentation to guide the procurement process.
- **Zambia:** (i) Weak record management system; (ii) insufficiently detailed evaluation and contract award recommendation reports; and (iii) weak contract management.
- **ECSA-HC:** (i) Procurement treated as a clerical function and not positioned strategically; and (ii) weak record management system.
- **NPCA:** (i) Weak record management system; and (ii) insufficiently detailed evaluation and contract award recommendation reports.

112. The risk mitigation actions and implementation schedules are provided in Annex 8 in the various "Procurement Risk Assessment and Mitigation Measures" tables.

113. Procurement activities for the proposed project will be carried out in accordance with the World Bank's "Guidelines: Procurement of Goods, Works and Non-consulting Services under IBRD Loans and IDA Credits and Grants by World Bank Borrowers," dated January 2011, revised in July 2014; with the "Guidelines: Selection and Employment of Consultants under IBRD Loans and IDA Credits and Grants by World Bank Borrowers," dated January 2011, revised in July 2014; and with the provisions stipulated in the Financing Agreements for the Project.

114. The "Guidelines on Preventing and Combating Fraud and Corruption in Projects Financed by IBRD Loans and IDA Credits and Grants," dated October 15, 2006 and revised in January 2011, will apply.

E. Social (including Safeguards)

115. Fluctuating mining expansions have a significant impact on the social context in which the project operates. In Zambia, the shift in mining is from the traditional Copperbelt province to other regions, particularly to North-West province, while sharp growth in contract mining has implications for the spread of TB beyond well-defined areas. Similarly, miners in Mozambique with experience in South African mines well may be some of the first employed as the Mozambique and Lesotho mining sectors grow. The changing and somewhat circular migration patterns in the region underscore the need to provide information and encourage follow-up at multiple interfaces. As many current migrant miners may have had TB exposure, sensitization campaigns need to have short- and longer-term time horizons and address miners, their families, and the communities they migrate to and from. More generally, living conditions among miners in the subregion tend to increase the risk of exposure, but are difficult to change as migrant workers' incentives are to minimize costs.

116. TB is associated with stigma, which discourages positive health-seeking behaviors and worsens the spread of the disease, particularly among vulnerable populations. Women in mining face added challenges due to underlying gender inequality and other social factors, especially in small-scale mining. The other major social dimension of TB exposure relates to the families of migrant miners, who are predominantly male, and the common pattern is for men to migrate for mine labor while families remain in labor-sending areas. This pattern tends to exclude women from diagnosis and medical treatment available through employers, even though women (and children) are at risk for disease transmission.

117. Meetings with stakeholders during preparation underscored findings from other analyses on the extent to which families of migrant miners may have little information and options about TB treatment. Poor information sharing is a particular concern. Yet there are opportunities to use women's waiting times at provincial and local health clinics for routine maternal and child health to provide information on exposure and symptoms, and to encourage testing. Through facilitating a broader approach, the project is intended to ensure that TB screening will be available beyond the traditional focus on the (usually male) employee. Union officials in Zambia noted their interest in such an approach, and could facilitate events outside health clinics as well.

118. On safeguards, separate country-level Environmental and Social Management Frameworks have been prepared to outline procedures for managing social impacts and social risks, and were cleared by the Bank and disclosed on March 16, 2016. Social risks in the project include failure of

interventions to reach target populations, particularly those with insecure legal status in mining in other countries, and those engaged in informal mining.

F. Environment (including Safeguards)

119. TB in mining is associated with environmental and infection control issues in three ways:

- *Occupational health and safety*, including environmental health. This includes: (i) preventive requirements within the mines; (ii) curative requirements for patients; and (iii) preventive measures for health care workers. The project activities under Components 1 and 2 are expected to address these issues from a policy angle and through interventions on the ground.
- *Infectious waste management*. This is related to: (i) clinical and infectious waste materials (primarily sharps including needles and slides and sputum cups) generated from service delivery and treatment centers; (ii) biosafety and occupational safety of health care staff and workers and laboratory technicians; and (iii) infection control measures for patients and health facilities.
- *Civil works*. The project intends to finance construction and upgrading of laboratory facilities, including national TB reference laboratories under Component 2. Safeguards issues on construction management are related to siting, solid and liquid waste treatment infrastructure, and construction waste. Envisaged construction or renovations under the project will be undertaken on already designated sites, in most cases in premises where public health facilities are already located. As such, no land acquisition is foreseen under the Project.

120. While all the above issues are well defined, site specific, and manageable, inadequate attention and poor management can result in severe public health risks due to the infectious, communicable, and opportunistic nature of the disease. Good occupational infection control and safety practices reduce this risk substantially, if implemented in a systematic and sustained manner. Each country has prepared its own Infection Control and Waste Management (ICWM) Plan, and conducted a rapid assessment of representative samples of TB clinics to assess current practices on testing and on prevention and control activities, which will provide a basis for recommendations of improved measures. Each country has also prepared an Environmental and Social Management Framework to address the environmental issues related to construction and upgrading of laboratories. These and the ICWM Plans were consulted by key stakeholders, approved, and disclosed by the countries and the Bank.

121. All participating countries have health programs funded by the World Bank. They are therefore familiar with World Bank Operational Policies and due diligence requirements for environment and social safeguards; however, capacity building and institutional strengthening measures will need to be undertaken for successful implementation and monitoring of the ICWM Plans and Environmental and Social Management Frameworks.

G. World Bank Grievance Redress

122. Communities and individuals who believe that they are adversely affected by a World Bank–supported project may submit complaints to existing project-level grievance redress mechanisms or the World Bank’s Grievance Redress Service (GRS). The GRS ensures that complaints received are promptly reviewed in order to address project-related concerns. Project affected communities and individuals may submit their complaint to the World Bank’s independent Inspection Panel, which determines whether harm occurred, or could occur, as a result of World Bank non-compliance with its policies and procedures. Complaints may be submitted at any time after concerns have been brought directly to the World Bank’s attention, and Bank Management has been given an opportunity to respond. For information on how to submit complaints to the World Bank’s corporate GRS, please visit <http://www.worldbank.org/GRS>. For information on how to submit complaints to the World Bank’s Inspection Panel, please visit www.inspectionpanel.org.

ANNEX 1: RESULTS FRAMEWORK AND MONITORING

1. The Results Framework for this project, grounded in accountability for results, moves beyond the usual tracking of inputs and outputs to emphasize intermediate and final outcomes. This Results Framework applies best practices from the World Bank, Centers for Disease Control and Prevention (CDC), Stop TB Partnership, and World Health Organization (WHO) monitoring and evaluation (M&E) approaches.

M&E Design

2. *Selection of indicators.* In support of the project objectives, five project outcome indicators (POIs) and 15 intermediate outcome indicators (IOIs) have been identified and constitute the project's Results Framework (Tables 2 and 3, below), to which the project will be accountable. Table 2 presents selected project outcome indicators, while Table 3 presents intermediate outcome indicators.

3. *Consistency with sector core indicators.* The project directly supports service delivery. Core indicators relevant to service delivery include: (i) number of laboratories renovated and/or equipped; (ii) number of health personnel receiving training; and (iii) direct beneficiaries (number), and the share of females among them (percentage).

4. In addition to tracking indicators formally part of the Results Framework (i.e. to which the project will be accountable), the project will track additional indicators to inform decision-making and course correction. The project will also track indicators dependent on inputs beyond the control of the project and in areas to which the project aims to contribute. As seen in Table 4, there are two types of these additional indicators: (i) lower-level complementary inputs on which the project success is dependent, but over which the project has limited control; and (ii) higher-level indicators to which the project aims to contribute, but which are again dependent on other inputs over which the project has limited control. The motivation for these indicators is that:

- There are uncertainties and risks that even the best project preparation and design cannot resolve. These uncertainties can only be mitigated by early and good quality data collection to inform necessary course corrections. The additional lower level indicators will serve this function.
- It is important to keep sight of why the project is working to improve health systems, i.e. to improve health outcomes. For this reason, the project will also monitor higher-level outcome indicators, such as TB success rates.

5. Together, the Results Framework indicators and the additional indicators constitute the results chain that underpin the line of reasoning for the expected changes, i.e. the theory of change. Identifying this theory of change ensures keeping sight of impacts to which the project ultimately aims to contribute, but which may not be fully within the project's control.

6. *Definition of indicators and data sources.* Table 5 specifies the denominator, numerator, and source of data for each indicator, and provides notes on variation by country. The data sources are mainly laboratory information systems, and data are primarily collected by national TB programs (NTPs) for WHO evaluation. Data quality varies across the participating countries, thus the project will consistently work to enhance data quality. Through technical support led by the

East Africa Public Health Laboratory Networking Project (ECSA-HC), the project will strengthen data collection, analysis, and quality assurance capacity of participating countries. ECSA-HC annual reports will contribute to operational research.

7. *Disaggregation of data.* Within each participating country, financed activities will likely have both national-level results and subnational-level results. For this reason, identified indicators will account for national averages and allow for regional and subnational disaggregation to more closely link with subnational activities. Thus, three levels of indicators will be collected: regional, national, and subnational.

8. *Use of existing data collection mechanisms.* The proposed Results Framework uses existing indicators and data to measure the progress of both the project and its contribution to the overall national program, not only for efficiency, but also to build on and strengthen existing data collection mechanisms.

9. *Targets for the indicators.* Table 6 identifies end-of-project targets. Close attention has been paid to ensure that the targets are feasible.

Planning for M&E Implementation

10. A determinant of successful M&E implementation is the quality of data planning during project preparation and the resources and responsibility for data collection and analysis. To this end, as part of each country's implementation plan, a detailed M&E plan identifies the following information for each indicator:

- Source of the data or data collection mechanism
- Frequency of data collection
- Assessment of the quality of the data collection mechanism
- Comment on any concerns about data collection methodology, especially where a non-standardized data collection mechanism is used
- Responsibility for data collection and analysis (where an external source has been identified, the contact within the respective ministry of health is listed)
- Level and source of resources available for data collection and the project costs allocated to facilitate successful implementation of M&E.

11. Sources of data are mainly NTP program data, laboratory information systems, and surveillance systems. Most data for the Results Framework will be generated by the project, since data will be routinely captured in countries' information systems. There will be ad hoc funding to strengthen country data systems. Baseline studies will be conducted where needed. Standardized WHO TB data collection methods will be used to the extent possible.

12. M&E human resources in each country will have continuous training and mentorship by ECSA-HC, and specialized personnel will be recruited if needed.

13. *Responsibility for M&E.* Responsibility will be both country and regional level.

- *Country*. In each country, an M&E specialist will be responsible for coordinating data collection processes and procurement, including defining TORs, participating in technical reviews, and reviewing consultant reports or analytical products for M&E. The M&E specialist will also serve a quality assurance role for the project, and solicit expert input as necessary. The M&E specialist will work closely with the project leader in each country; the success of data use will ultimately depend on the extent to which it feeds into decision-making processes.
- *Regional*. Regional-level responsibility will be in the Regional Advisory Committee (RAC). There are two dimensions to the regional role: coordination and data quality assurance (Table 1).

Table 1: Regional-level coordination of M&E

Coordination	Data quality assurance
<ul style="list-style-type: none"> • Jointly establish common project reporting requirements. • Establish a community of practice of M&E officers. • Agree on reporting tools, formats (including IT system formats), frequency, and channels, etc. • Develop a common database and system that can collate reporting from countries in a timely and accurate manner, produce analytic reports, and provide feedback to countries on multicountry performance. 	<ul style="list-style-type: none"> • The regional M&E office will serve an M&E quality assurance function complementary to the inputs from the country-level M&E specialists. Annually and especially at mid-term review (MTR), the regional M&E office with inputs from country-level M&E specialists will review the quarterly and annual reports with definition of indicators, data collection systems, analysis, and other methodological aspects.
<ul style="list-style-type: none"> • Regional M&E officer will track and facilitate timely flow of monthly, quarterly and annual data reporting. • Prepare for quarterly and annual reporting. • Consolidate baseline data. • Quarterly reports will be submitted to the regional M&E office. • Based on quarterly reports submitted, the regional M&E office will compile a consolidated Annual Report, which is one of the inputs into the Annual Joint Review. At the Annual Review countries will present and defend their own progress and performance. 	<ul style="list-style-type: none"> • Coordinate MTR preparation. • Coordinate and facilitate implementation of the end-of-project evaluation. • Contribute to the process of learning and knowledge sharing. This will be in part through linkages with the communities of practice/ technical working groups.

14. *Resources for M&E*. Resources reserved for M&E as agreed at appraisal are summarized in the project costs. The Implementation Support Plan reflects resources that will finance M&E-related activities, although not all are distinctly identified as such. Examples include: procurement of information and communications technology (ICT—hardware and software); hiring of technical advisors for process monitoring; and ICT operational costs (web-page, internet access, etc.).

15. At the regional level, ECSA-HC and NPCA will establish a small team of experts to: provide technical oversight; monitor and support the lead implementing team at national level; and ensure coordinated and standardized execution of project activities. However, critical positions—

e.g. TB advisor, laboratory strengthening specialist, mine health specialist, and M&E advisor—will be hired after the project has been approved by the Board.

Planning for M&E Use

16. The implementation of the Results Framework will be tracked during project implementation and will be a central focus of project supervision. The MTR will provide an opportunity to assess some fundamental M&E design issues and make requisite adjustments. Supervision will be results oriented, with adequate attention devoted to progress in data collection, data quality, and the actual use of data in tracking project implementation. This progress will be documented and shared through Aide Memoires and Implementation Status Reports.

17. Annual review meetings, organized under the auspices of ECSA-HC and the New Partnership for African Development Planning and Coordinating Agency (NPCA), will provide a forum for sharing implementation experiences, proposing recommendations on programmatic changes, and generating additional demands for information and analysis. The MTR will enable: (i) assessment of progress to date and of continued relevance/realism of the targets; and (ii) review of the project's experience with definition of indicators, data collection systems, analysis, and other methodological aspects.

Country-level M&E Systems and Capacity-building Strategies

18. *M&E capacity.* The institutional framework for M&E is based on: use of country systems, reliance on national structures—with targeted technical assistance, where appropriate—and use of implementing entities based on comparative advantages. An inter-ministerial National Technical Committee (NTC) will be constituted to oversee project implementation. The NTC will be responsible for reviewing and approving consolidated annual work plans and budgets submitted by technical departments and for providing technical guidance to implementing agencies.

19. The project will emphasize generation and use of data for decision making at various levels. An M&E community of practice, comprising M&E officers from the participating countries and ECSA-HC, will be set up to strengthen skills and integrate a culture of data analysis and dissemination. Countries will lead M&E activities, but ECSA-HC will be mandated to collect and aggregate project-monitoring data. The project will provide funding to strengthen these systems and, where needed, to conduct baseline surveys.

20. ECSA-HC, with Bank approval, will contract qualified entities to carry out impact evaluations. The project will support activities to improve availability and quality of data, including surveillance systems in cross-border areas and laboratories, to produce data that countries cannot generate at present.

Operational Research

21. The proposed project offers substantial opportunities for operational research, which by its very nature will have a strong evaluation dimension. Given the local experiences over recent years in tackling TB and occupational health and risks in the mining sector, with different outcomes, there is a need to create and share regional knowledge on what works, what does not, and why. Investment in centers of excellence in the management of TB will enable the production of the necessary knowledge. Annual review meetings, organized under the auspices of ECSA-HC,

provide a forum for sharing findings from the operational research. The intention is to build local capacity to carry out operational research and evaluation, and involve not only NTP staff, but also stakeholders beyond the national laboratories, such as research and academic institutions, mining companies, etc.

22. Representatives from the participating countries agree to function as a broad community of practice for TB and occupational lung disease control, which will foster regional knowledge generation, learning, and sharing. The community of practice will identify themes and areas that present regional and cross-country challenges, including best practices in mine health surveillance and safety, laboratory management and networking, surveillance and management of drug resistance, and occupational health and communicable diseases.

Table 2: Results Framework

Project Development Objective (PDO)	Project Outcome Indicator (POI)	Use of Project Outcome Information
i) Improve coverage and quality of TB control and occupational lung disease services in targeted geographic areas of the participating countries ii) Strengthen regional capacity to manage the burden of TB and occupational diseases	POI#1: TB case notification in target geographic areas (number)	PDO indicator
	POI#2: TB treatment success rate in target geographic areas (i) new and (ii) relapse TB cases (percentage)	PDO indicator
	POI#3: TB cases identified through active TB case finding (screening) among TB vulnerable populations in targeted geographic areas (number)	PDO indicator
	POI#4: Project-supported laboratories compliant with regionally harmonized standard operating procedures for surveillance of MDR-TB (number)	PDO indicator
	POI#5: Direct beneficiaries (number), and share of females among them (percentage)	PDO indicator

Table 3: Results Framework (continued)

Intermediate Outcomes	Intermediate Outcome Indicator (IOI)	Use of Intermediate Outcome Monitoring Information
Component 1:		
Enhanced treatment success of MDR-TB treatment	IOI#1. Proportion of MDR-TB patients in target geographic areas benefiting from psychosocial and nutritional support during the treatment period	To track quality of MDR-TB case management
Increased compliance with compensation policies	IOI#2. Proportion of miners eligible for compensation due to occupational diseases actually receiving it	To track the implementation of compensation policies

Intermediate Outcomes	Intermediate Outcome Indicator (IOI)	Use of Intermediate Outcome Monitoring Information
Improved quality of TB services	IOI#3. Proportion of TB patients satisfied with TB services as per patient exit survey or feedback in target geographic areas	To track client satisfaction, which is a dimension of quality of TB services
Improved quality of TB case management	IOI#4. Percentage of HIV patients routinely screened for TB in targeted geographic areas in the four participating countries.	To track quality of TB case management
Component 2:		
Improved equipment of laboratory facilities	IOI#5. Proportion of health facilities with TB Smear microscopy	To track coverage of laboratory services
Improved quality of laboratory services	IOI#6. Outbreak for infectious diseases for which cross-border investigation undertaken (number)	To track quality of laboratory services
Improved infrastructure	IOI#7. Health facilities renovated and/or equipped (number)	To track quality of laboratory services
Improved infrastructure	IOI#8 Number of countries scaling up Electronic Health Systems for TB case management or laboratory management (number)	To track implementation of IT health applications in improving TB and laboratory management
Improved quality of laboratory services	IOI#9. Number of laboratories rated 2 stars and above in SLIPTA assessment	To track quality of laboratory services
Increased compliance with mine health regulations	IOI#10. Proportion of mines inspected at least twice a year for compliance with national mine health regulations	To track the implementation of mine health regulations
Component 3:		
Improved availability of skilled labor	IOI#11. Number of health personnel receiving training (number)	To track coverage of training.

Intermediate Outcomes	Intermediate Outcome Indicator (IOI)	Use of Intermediate Outcome Monitoring Information
Draft legislation in compliance with international best practice	IOI#12. Number of countries in which new legislation or amendment to existing mine health and safety legislation are drafted	To track the implementation of mine health and safety legislations
Improved reference and contra-reference system among participating countries	IOI#13. Number of miners and ex-miners successfully referred and screened for TB and occupational health services between participating countries and within participating countries.	To track quality of TB case management and occupational lung diseases
Improved quality of care for occupational health	IOI#14. Number of countries with harmonized clinical protocols for occupational health in compliance with international best practices	To track quality of TB case management and occupational lung diseases
Increased joint operational research	IOI#15. Regional operational research studies commissioned, and findings and lessons learned disseminated through national and regional platforms	To reflect the contributions from the proposed project to enhance regional knowledge about TB and occupational lung diseases

Table 4: Project Outcome Indicators and Intermediate Outcome Indicators (Results Chain)

Level IV: Output	Level III: (Intermediate Outcome Indicators)	Level II: Coverage (Outcome Indicators)	Level I: Health and Development Outcomes (Impact Indicators)
Regional quality improvement framework for management of TB introduced	Improve availability of quality standardized TB treatment and care services.	<p>Improved coverage of quality TB control interventions and occupational health services</p> <p>PDO: (i) improve coverage and quality of TB control and occupational lung disease services in targeted geographic areas of the participating countries; and (ii) strengthen regional capacity to manage the burden of TB and occupational diseases</p>	<p>Contribution to improved health and development outcomes in the participating countries</p>
Laboratories entered in quality improvement process toward accreditation to provide quality and timely diagnostics services for TB	Improved availability of timely diagnostic/laboratory services.		
Regional health work force expanded through training on: (i) lab. management; (ii) disease surveillance; (iii) MDR-TB management; and (iv) occupational health	Improved availability of skilled labor for: (i) lab services; (ii) disease surveillance; (iii) MDR-TB; and (iv) occupational health		
Regional mine health regulatory environment strengthened	Improved prevention of TB and other lung diseases in the mining sector		
Regional, standardized occupational health services developed and rolled out	Improved availability of a minimum package of occupational health services for the mining sector		
Evidence informed innovative TB and occupational health service delivery documented	Improved effectiveness of TB and occupational health services		

Table 5: Definition of Project Outcome Indicators and Intermediate Outcome Indicators

Project Outcome Indicator (POI)	Numerator	Denominator	Source of Data	Comments (pertaining to methods—measurement, collection and analysis)
POI#1. TB case notification in target geographic areas (number)	Number of notified TB cases in target geographic areas		National NTP reports	
POI#2. TB treatment success rate in target geographic areas: (i) new and (ii) relapse TB cases (percentage)	Number of TB patients successfully treated and having negative sputum	Number of sputum positive patients beginning TB treatment	National NTP reports	
POI#3. TB cases identified through active TB case finding (screening) among TB vulnerable populations in targeted geographic areas (number)	Number of TB vulnerable population in target geographic areas screened for TB and occupational lung diseases	Not applicable	NTP screening reporting and recording tools	
POI#4. Project-supported laboratories compliant with regionally harmonized standard operating procedures for surveillance of MDR-TB (number)	Number of project-supported laboratories compliant with SOPs for MDR-TB surveillance	Total number of project supported laboratories	Laboratory information system and support supervision reports	A checklist that will be used in supportive supervision should be developed
POI#5. Direct beneficiaries (number), and the share of females among them (percentage)	Number of direct beneficiaries (of whom x% female)	Not applicable	HIMS data/Project data documentation and laboratory information system	
Intermediate Outcome Indicator				
Component 1:				
IOI#1. Proportion of MDR-TB patients in target geographic areas benefiting from psychological and	Number of MDR-TB patients in target geographic areas benefiting from psychological and	Total MDR-TB patients	National TB reports	Some countries offer nutritional support already to MDR-TB patients through other partners, the

Project Outcome Indicator (POI)	Numerator	Denominator	Source of Data	Comments (pertaining to methods—measurement, collection and analysis)
nutritional support during the treatment period	nutritional support during the treatment period			attribution only by this project should reported
IOI#2. Proportion of miners eligible for compensation due to occupational diseases actually receiving it	Number of miners eligible for compensation due to occupational diseases actually receiving it	Total number of miners	National registry for miners with TB and/or occupational lung diseases (to be established)	Baseline assessment to be done under the Project Preparation Advance (PPA) to provide indicator values
IOI#3. Proportion of TB patients satisfied with TB services as per patient exit surveys or “drop box” feedback in target geographic areas	Number of TB patients satisfied with TB services as per patient exit surveys or feedback in target geographic areas	Total number of TB patients	Patient exit surveys or feedback mechanisms at the point of care in target geographic areas	A regional harmonized client satisfaction tool should be developed and used across all the participating countries
IOI#4. Percentage of HIV patients routinely screened for TB in targeted geographic areas in the participating countries	Number of HIV patients routinely screened for TB in targeted geographic areas	Total number of HIV patients in country	National TB and HIV reports	
Component 2:				
IOI#5. Proportion of health facilities with TB smear microscopy	Number of health facilities with TB microscopy	Total number of health facilities	Laboratory information system and support supervision reports	
IOI#6. Outbreaks for infectious diseases for which cross-border investigations undertaken (number)	Number of infectious disease outbreaks for which cross-border investigations were undertaken	Number of outbreaks reported in cross-border districts served by project laboratories	Disease surveillance program reports and regional entity surveillance report	Prompt sharing of information on outbreaks in border districts by participating countries will be critical in achieving this indicator
IOI#7. Health facilities renovated and/or equipped (number)	Sum of the number of health facilities renovated and equipped	Not applicable	Project documentation	

Project Outcome Indicator (POI)	Numerator	Denominator	Source of Data	Comments (pertaining to methods—measurement, collection and analysis)
IOI#8. Number of countries scaling up Electronic Health Systems for TB case management or laboratory management (number)	Number of countries scaling up Electronic Health Systems for TB case management or laboratory management	Not applicable	Project documentation	
IOI#9. Number of target labs rated 2 stars and above in SLIPTA assessment	Number of target labs rated 2 stars and above in SLIPTA assessment	Total number of target laboratories within country network	Country progress reports and project documentation	Independent assessors approved by the regional entity or regional accreditation program will undertake assessment.
IOI#10. Proportion of mines inspected at least twice a year for compliance with national mine health regulations	Number of mines inspected and compliant at least twice a year with national mine health regulations	Total number of mines in-country	National mining inspection reports	
Component 3:				
IOI#11. Number of health personnel receiving training	Number of health personnel receiving training	Not applicable	Project documentation	
IOI#12. Number of countries in which new legislation or amendment to existing mine health and safety legislation are drafted	Number of countries in which new legislation or amendment to existing mine health and safety legislation are drafted	Not applicable	Regional project documentation	
IOI#13. Number of miners and ex-miners successfully referred and screened for TB and occupational health services between participating countries and within participating countries	Number of miners and ex-miners successfully referred and screened for TB and occupational health services between participating countries and within participating countries	Not applicable	Regional project documentation and annual reports	

Project Outcome Indicator (POI)	Numerator	Denominator	Source of Data	Comments (pertaining to methods—measurement, collection and analysis)
IOI#14. Number of countries with harmonized clinical protocols for occupational health in compliance with international best practices	Number of countries with harmonized clinical protocols for occupational health in compliance with international best practices	Not applicable	Regional project documentation and annual reports	
IOI#15. Regional operational research studies commissioned and findings, lessons learned disseminated through national and regional platforms	Number of operational research studies completed and effectively disseminated	Number of operational research studies approved or commissioned by the project and research institutions	Regional project documentation and annual reports	

Table 6: Results Framework^{48, 49}

Project Development Objectives

The project aims to: (i) improve coverage and quality of TB control and occupational lung disease⁵⁰ services in targeted geographic areas of the participating countries; and (ii) strengthen regional capacity to manage the burden of TB and occupational diseases.

Project Outcome Indicators

Data collection and reporting												
Indicator name	Core	Unit of measure	Country/ regional	Base-line	Target values					Fre-quency and reports	Data collection instruments	Responsibility for data collection
					2017	2018	2019	2020	2021			
POI#1. TB case notification in target geographic areas	<input type="checkbox"/>	Number	Regional	85,391	90,640	95,107	96,657	98,657	100,758	Annual	National TB control reports. Target area specific data from each district or province will be aggregated for each country and then consolidated for the region. (Malawi used NSP projections ending up to 2017/18. For 2017-2020, Zambia will develop new estimates)	MOH in each country
			Lesotho	9,854	10,135	9,894	9,777	10,400	10,900			
			Malawi	9,726	13,130	14,783	14,783	14,783	14,783			
			Mozambique	40,059	41,261	42,705	44,200	45,747	47,348			
			Zambia	25,752	26,114	27,727	27,727	27,727	27,727			

⁴⁸ The definitions of the numerator and denominator for each of the indicators is provided in table 2.

⁴⁹ For regional indicators, aggregation on proportion requires overall population or numerator/denominator figures at country level, but country proportions can be used for comparison using trend graph analysis.

⁵⁰ Priority occupational lung diseases include diseases like silicosis, pneumoconiosis, COPD, and asbestosis.

Project Outcome Indicators

Data collection and reporting

Indicator name	Core	Unit of measure	Country/ regional	Base-line	Target values					Fre-quency and reports	Data collection instruments	Responsibility for data collection
					2017	2018	2019	2020	2021			
POI#2. ⁵¹ TB treatment success rate in target geographic areas: (i) new and (ii) relapse TB cases (percentage)	<input type="checkbox"/>	Percent	Regional	83	87	88	89	90	90	Annual	National TB control reports. Based on the data from the target areas, treatment success rates will be calculated for each country, and then a simple average for the region.	MOH in each country
			Lesotho	71	86	87	90	90				
			Malawi	83.4	85	86	87	88				
			Mozambique	87	87	88	89	90				
			Zambia	85	88	89	90	90				
POI#3. ⁵² TB cases identified through active TB case finding (screening) among TB vulnerable populations in targeted geographic areas (number)	<input type="checkbox"/>	Number	Regional	5,239	18,825	20,290	21,461	23,197	22,557	Annual	NTP screening reporting and recording tools - Target district health reports. <i>To be reviewed after baseline assessment is finalized with PPA financing</i>	MOH in each country
			Lesotho	4,676	7,500	7,322	7,235	7,696				
			Malawi	N/A	2,500	2,900	2,900	2,900				
			Mozambique	563	825	1,068	1,326	1,601				
			Zambia	N/A	8,000	9,000	10,000	11,000				

⁵¹ Treatment success rate is for new smear positive, smear negative, and relapse TB cases in target geographic areas.

⁵² Vulnerable population is defined as consisting of miners, ex-miners, healthcare workers and prisoners **HIV positive patients not included

Project Outcome Indicators
Data collection and reporting

Indicator name	Core	Unit of measure	Country/ regional	Base-line	Target values					Fre-quency and reports	Data collection instruments	Responsibility for data collection
					2017	2018	2019	2020	2021			
POI#4. Project-supported laboratories compliant ⁵³ with regionally harmonized standardized operating procedures for surveillance of MDR-TB (number)	<input type="checkbox"/>	Number	Regional Lesotho Malawi Mozambique Zambia	58 3 21 14 20	65 3 24 15 23	74 3 26 20 25	84 3 28 25 28	93 3 30 30 30	100 3 32 35 30	Annual	Laboratory information system and support supervision reports (for Mozambique 14 labs have GeneXpert but only 10 are functional under baseline)	MOH in each country
POI#5. ⁵⁴ Direct beneficiaries (number), and the share of females among them (percentage) – (all diseases within health facilities including TB)	<input type="checkbox"/>	Number	Regional Lesotho Malawi Mozambique	695,903 (37%) 0 9,276 (39%) 660,875	810,165 (35%) 28,000 (20%) 33,130 (39%) 713,745 (50%)	889,456 (35%) 34,000 (20%) 39,783 (39%) 770,845 (50%)	965,661 (35%) 34,000 (20%) 44,783 (39%) 832,512 (50%)	1,037,262 (35%) 34,000 (20%) 49,783 (39%) 899,113 (50%)	1,109,191 (35%) 34,000 (20%) 49,783 (39%) 971,042 (50%)	Annual	HIMS data/Project data documentation	MOH in each country

⁵³ The markers for “compliant” laboratories include turnaround time, quality, documentation, and proficiency based on standards of SLIPTA checklist and ISO 15189.

⁵⁴ Beneficiaries include HIV positive or PLWHA; direct beneficiaries are those primarily receiving direct health services from the project; and indirect beneficiaries are those having received positive spillovers or are indirectly linked to project implementation, for instance, contact tracing.

Project Outcome Indicators

Data collection and reporting

Indicator name	Core	Unit of measure	Country/ regional	Base- line	Target values					Fre- quency and reports	Data collection instruments	Responsibility for data collection
					2017	2018	2019	2020	2021			
			Zambia	25,752 (35%)	35,290 (35%)	44,828 (35%)	54,366 (35%)	54,366 (35%)	54,366 (35%)			

	Intermediate Outcome Indicators	Country/ regional	Baseline	2017	2018	2019	2020	2021	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
Component 1	IOI#1. Proportion of MDR-TB patients in target geographic areas benefiting from psychosocial OR nutritional support during the treatment period	Regional Lesotho Malawi Mozambique Zambia	95% N/A 0% 49%	95% 15% 20% 55%	95% 25% 30% 60%	96% 30% 40% 65%	96% 30% 50% 70%	97% 40% 60% 75%	Annual	Target district (or province) TB reports. Target area-specific data first aggregated for each country and then for the region	MOH
	IOI#2. Proportion of miners eligible for compensation due to occupational diseases actually receiving it <i>**To be updated based on baseline assessment to be conducted within six months of achieving effectiveness.</i>	Regional Lesotho Malawi Mozambique Zambia	N/A N/A N/A N/A N/A	10% 10%	20% 20%	30% 30%	40% 40%	50% 50%	Annual	National registry for miners with TB and/or occupational lung diseases (to be established)	MOH
	IOI#3. Proportion of TB patients satisfied with TB services as per	Regional Lesotho Malawi Mozambique	N/A N/A N/A N/A	65% 50% 50%	70% 55% 55%	70% 60% 60%	70% 65% 65%	70% 65% 65%	75% 65% 65%	Annual	Patient exit surveys or feedback mechanisms at

	Intermediate Outcome Indicators	Country/ regional	Baseline	2017	2018	2019	2020	2021	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
	patient exit surveys or feedback in target geographic areas **To be updated based on baseline assessment to be conducted within six months of achieving effectiveness.	Zambia	N/A	60%	60%	65%	65%	70%		the point of care in target geographic areas. Requires harmonized client satisfaction assessment/citizen feedback tool	
	IOI#4. Percentage of HIV patients routinely screened for TB in targeted geographic areas in the four participating countries	Regional Lesotho Malawi Mozambique Zambia	94% 95% 98% 90% 91%	94% 95% 98% 90% 93%	95% 95% 98% 90% 95%	95% 95% 98% 90% 95%	95% 95% 98% 90% 95%	95% 95% 98% 90% 95%	Quarterly	National TB and HIV reports Target district (or province) TB reports. Target area-specific data first aggregated for each country and then for the region	MOH
	IOI#5. Proportion of health facilities with TB smear microscopy <i>Zambia has 364 facilities offering smear microscopy</i>	Regional Lesotho Malawi Mozambique Zambia	17% 21% 28% 23%	30% 32% 29% 30%	30% 43% 31% 40%	30% 54% 33% 50%	30% 63% 37% 60%	30% 63% 40% 60%	Annual	Target district (or province) TB reports. Target area-specific data first aggregated for each country and then for the region	MOH

	Intermediate Outcome Indicators	Country/ regional	Baseline	2017	2018	2019	2020	2021	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
Component 2	IOI#6. ⁵⁵ Outbreaks for infectious diseases for which cross-border investigation undertaken (number)	Regional Lesotho Malawi Mozambique Zambia	2 2 0 0 0	5 2 1 1 1	9 4 2 1 2	10 4 2 2 2	10 4 2 2 2	10 4 2 2 2	Annual	Target cross-border district report prepared with support from regional entity cross-border report	MOH
	IOI#7. Health facilities renovated and/or equipped (number)	Regional Lesotho Malawi Mozambique Zambia	0 0 0 0 0	36 8 10 10 8	37 7 10 10 10	40 0 10 15 15	45 0 15 15 15	45 0 15 15 15	Annual	Project documentation	Ministries of health, labor, and mining
	IOI#8. Number of countries scaling up Electronic Health Systems for TB case management or laboratory management (number)	Regional	0	0	1	2	2	0	Annual	Project documentation	MOH
	IOI#9. Number of target labs rated 2 stars and above in SLIPTA assessment	Regional Lesotho Malawi Mozambique Zambia	0 0 0 0 0	7 3 2 1 1	9 3 3 2 1	11 3 3 3 2	13 3 4 3 3	13 3 4 3 3	Annual	National SLIPTA assessment report	MOH
	IOI#10. Proportion of mines inspected at least twice a year	Regional Lesotho Malawi Mozambique	0% 0% 0% 0%	70% 20% 20% 20%	80% 30% 30% 30%	90% 35% 40% 40%	90% 50% 50% 50%	90% 60% 50% 50%	Annual	National mine health inspection report	Ministries of health, labor, and mining

⁵⁵ Example of the outbreaks include cholera, malaria, hepatitis, salmonella, typhoid, etc.

	Intermediate Outcome Indicators	Country/ regional	Baseline	2017	2018	2019	2020	2021	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
	for compliance with national mine health regulations	Zambia	0%	20%	25%	30%	35%	40%			
	IOI#11. ⁵⁶ Number of health personnel receiving training (number)	Regional Lesotho Malawi Mozambique Zambia	0 0 0 0 0	2,163 128 595 840 600	2,075 80 395 900 700	2,429 134 395 1,000 800	4,824 100 395 1,100 800	2,539 144 395 1,200 800	Annual	Admin data	Ministries of health, labor, and mining
	IOI#12. Number of countries in which new legislation or amendment to existing mine health and safety legislation are drafted	Regional	0	0	1	2	2		Annual	Admin data	Regional entity

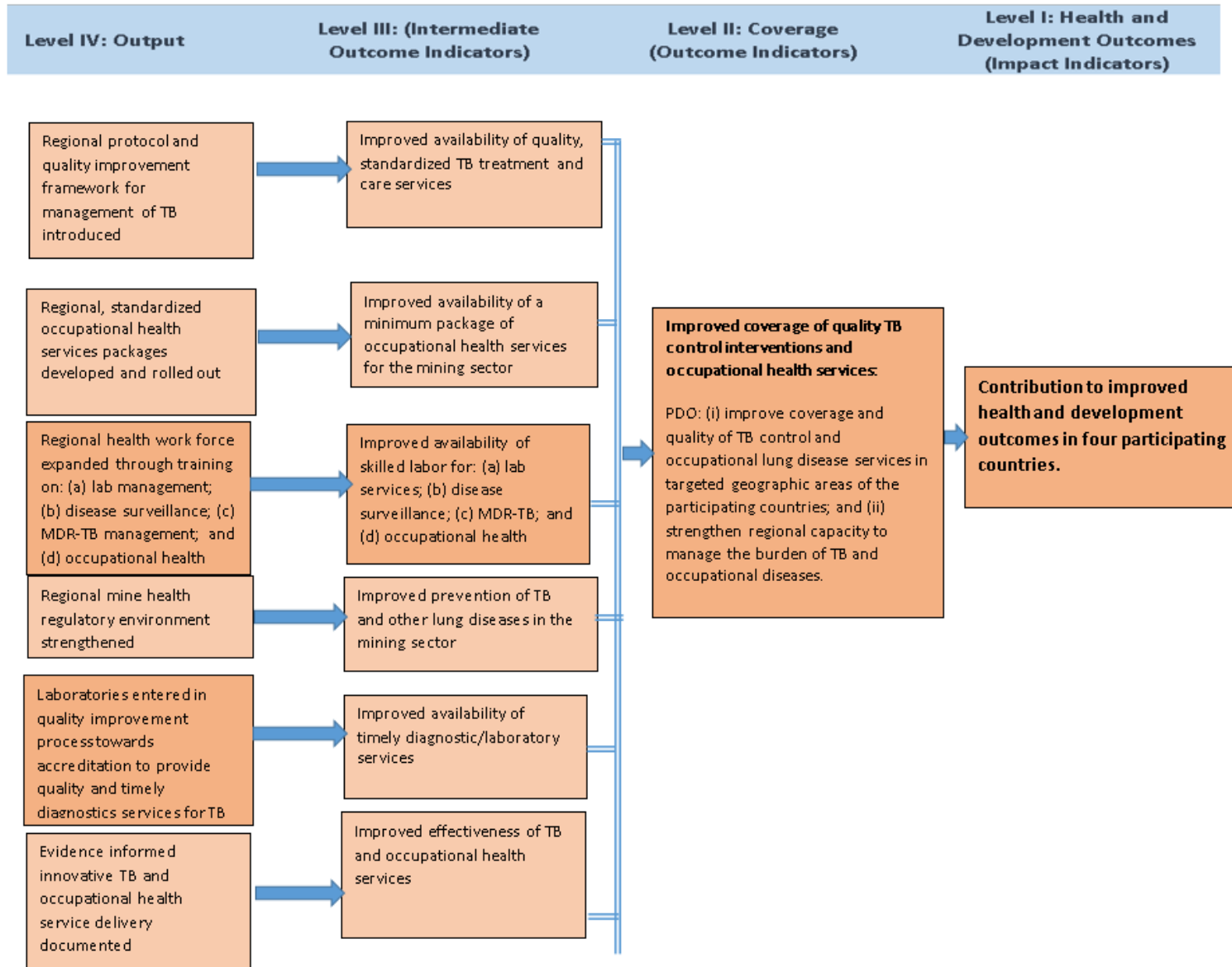
⁵⁶ Health personnel receiving training refers to both frontline health workers and health management staff in target areas receiving relevant training financed by the project.

	Intermediate Outcome Indicators	Country/ regional	Baseline	2017	2018	2019	2020	2021	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
Component 3	IOI#13. Number of miners and ex-miners successfully referred and screened for TB and occupational health services between participating countries and within participating countries	Regional	0						Annual To be updated after baseline is finalized in September 2016 through PPA financing	Admin data	Regional entity
	IOI#14. Number of countries with harmonized clinical protocols for occupational health in compliance with International best practices	Regional	0	1	2	2	3	4	Annual	Admin data	Regional entity

	Intermediate Outcome Indicators	Country/ regional	Baseline	2017	2018	2019	2020	2021	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
	IOI#15. Regional operational research studies commissioned and findings, lessons learned disseminated effectively through national and regional platforms	Regional Lesotho Malawi Mozambique Zambia	0 0 0 0 0	4 1 1 1 1	7 2 1 2 2	6 1 1 2 2	5 0 1 2 2	5 0 1 2 2	Annual	Admin data	Regional entity

N/A = not available.

Figure 1: Results Chain (Graphic Depiction)



ANNEX 2: DETAILED PROJECT DESCRIPTION

1. The project builds on the commitment of the participating countries to work together and of ECSA-HC and NPCA to tackle the regional dimensions of TB. The project supports mining and peri-mining communities, labor sending areas, high TB–burden regions, high HIV burden regions, transport corridors and cross-border areas of the participating countries. Overall, this project will prioritize two aspects: full implementation of the latest WHO TB Strategy, including the 90-90-90 targets in strengthening demand and supply sides of public health systems for effective management of TB and other communicable diseases; and improved use of the latest diagnostic methods for TB and occupational lung diseases. The project builds on best practices in TB control and promotes best buy interventions (Box 1).
2. The project has three components:
3. ***Component 1: Innovative Prevention, Detection, and Treatment of TB:*** Will improve the demand and availability of high quality TB, TB-HIV/AIDS, and occupational lung disease prevention and treatment services in targeted geographic areas of the participating countries.
4. ***Component 2: Regional Capacity for Disease Surveillance, Diagnostics, and Management of TB and Occupational Lung Diseases:*** Will strengthen basic health systems to position the subregion to better manage TB and other infectious diseases. Component 2 will prioritize: (i) improving quality and availability of skilled human resources for disease surveillance, management of MDR-TB, and occupational health services; (ii) strengthening diagnostic capacity; and (iii) strengthening mine health regulation.
5. ***Component 3: Regional Learning and Innovation, and Project Management:*** With evidence generated from interventions implemented under Components and 1 and 2, Component 3 will finance activities on regional knowledge sharing in selected areas of significant interest.
6. At the regional level, the East, Central and Southern Africa Health Community (ECSA-HC) has been selected competitively to serve as the Regional Coordinating Organization (RCO). NPCA will provide specialized technical support on policy issues as described in earlier sections of the PAD. The scope of NPCA’s support was finalized during appraisal and will be reviewed annually to ensure continued relevance and need.
7. At the country level, implementation of activities will rely on national institutions to the extent possible, using country-specific existing coordination mechanisms. This would ensure broad based ownership at national level, and stakeholder empowerment and resourcing to carry out the various activities.
8. The Project will be implemented over five years from 2016 to 2021.

Box 1: Best Practices and Best Buy Interventions in TB Control

The project design draws on lessons learned from TB control programs globally and promotes use of best buy interventions. The main lessons applied are as follows:

- **Targeting is critical for reaching the most vulnerable groups and ensuring effective use of scarce resources.** The project is in line with the 90-90-90 targets articulated in the new Global Plan to Stop TB (2016-2020) which urges countries to find at least 90 percent of people with TB and place them on treatment; reach at least 90 percent of the most vulnerable, underserved at risk populations; and strive to reach at least 90 percent treatment success.
- **Knowing the nature and scope of epidemic is critical for good planning.** Understanding the main drivers of the TB epidemic in each country is important for targeting key geographic areas and identifying appropriate interventions. To this end, the project has been designed drawing on information from recent TB prevalence surveys and from other recent evaluations; and countries have been supported to tailor the design to their specific contexts.
- **Investing early and smartly will avert future high costs.** The project will provide support for enhancing case detection (focusing on “missing cases”); strengthening quality of basic TB treatment (DOTS) to avoid multi-drug resistant forms which are costly to treat; and piloting demand side interventions to ensure TB patients remain adherent to treatment. The combination of supply and demand side interventions have been shown to yield better results.
- **Promoting a health systems approach to TB control will maximize impact.** In line with the Bank’s comparative advantage in health systems the project focuses on critical pillars to effective TB management (i.e. strengthening human resources, diagnostics, and information systems). Investing in these systems will have multiple benefits for both TB control and broader health service delivery.
- **Rolling out new technologies is essential for dealing with HIV related TB and multi-drug resistant forms.** Rapid molecular tests have the potential to improve case detection, decrease the turnaround time compared to conventional methods, and interrupt disease transmission. Some technologies have multi-platform applications, implying they can be used for diagnosing both TB and other public health problems. Point of care diagnostics are critical for reaching patients in remote areas, tapping the potential of community and civil society groups.
- **Adopting a multi-sectoral approach will enable participating countries to respond more effectively to TB and occupational health issues.** By supporting active engagement of ministries of labor, private sector, and other key regulatory bodies the project will partly address some of the underlying factors contributing to the elevated TB rates and related occupational health problems.
- **Leveraging global expertise and promoting partnerships.** The project has been designed with support of the United States Centers for Disease Control and Prevention (CDC) and aims to expand collaboration with other key stakeholders in the region involved in TB control and laboratory systems strengthening (i.e. WHO, ASLM, Wits Health Consortium)

Component 1: Innovative Prevention, Detection, and Treatment of TB (US\$45.49 million)

9. Component 1 will support interventions to strengthen case detection and treatment success rates in different geographic areas and among vulnerable population groups. The overarching thrust of the component is to improve the demand and availability of high quality TB, TB-HIV/AIDS, and occupational lung disease prevention and treatment services in targeted geographic areas of the participating countries. WHO's End TB Strategy, the Harmonized Framework for the Management of TB in the Mining Sector, the SADC Code of Conduct for the Management of TB, and national plans in each of the participating countries provide a sound framework for Bank support, and will underpin the proposed investment.

10. More specifically, Component 1 will support: (i) rollout of a harmonized package of TB services—with a focus on active screening of TB suspects, miners, ex-miners, and mining communities, active contact tracing, and strengthened capacity for diagnosis of TB; (ii) strengthening of occupational health services; and (iii) strengthening of national TB programs to manage MDR-TB. Priority interventions and activities under each subcomponent include:

Subcomponent 1.1: Enhancing Case Detection and Treatment Success

11. This subcomponent will finance interventions to improve prevention of TB infection and enhance case detection and treatment in the identified areas and target populations on the supply side. National TB programs within each country's ministry of health will lead implementation of this subcomponent. Primary activities to be financed under this component will include: (i) active screening of miners, ex-miners, and mining communities, including establishing a system of symptom screening and digital X-rays with active household contact tracing to optimize TB diagnosis; (ii) conducting Xpert MTB/RIF and culture tests—which have high sensitivity and specificity—to ensure early and accurate diagnosis of presumptive TB patients; (iii) ensuring all TB patients are tested for HIV to facilitate a comprehensive package of care for those found to be co-infected. To that effect, the project will carry out HIV testing among target groups, including provider-initiated counseling and testing for patients found to have TB; and (iv) scaling-up community TB-related activities including community screening/contact investigation for high risk groups by community health workers affiliated with health facilities.

12. The project will finance the rollout of integrated TB-HIV services in targeted areas by setting up one-stop shop service centers at existing health facilities serviced by an improved sample transportation system. A variety of transport modes for specimen will be considered, including public-private partnership (PPP) arrangements using appropriate transport such as motorcycles for transporting sputum specimens to district collection points, and picking up these samples at the collection point for each district and transport them for Xpert testing or culture and drug-sensitivity testing. This same system will also be used to relay results back to the referral health center. (The Sample transportation system by Riders for Health is a successful program across various countries in the subregion.) The project will build on these and expand the coverage and tracking of this critical service. Similarly, the project will finance the expansion of community sputum collection points and delivery of samples to microscopy sites closer to patients, shortening time for diagnosis, especially for rural, mining, peri-mining, and cross-border populations. The PPP on sputum-sample collection offers strong learning opportunities for the participating countries and the wider subregion. To the extent possible, the project will support integration of

Global Positioning System and bar-code capabilities into sample collection to strengthen overall management of sputum samples.

13. Other innovative approaches include strengthening facility-based quality improvement initiatives to guarantee a minimum level of clinical quality of TB services, which are: (i) developing and rolling out an in-service training and mentorship for front-line health workers in the management of TB and TB-HIV; (ii) developing tools for systematically screening for TB in facilities; (iii) improving patient adherence to treatment through community based support; (iv) strengthening patient referrals and follow-up (including through the use of ICT; and (v) strengthening contact tracing for current and former TB patients. Community health workers affiliated with health facilities will be contracted to screen and test TB contacts and to closely monitor the cohort of patients under treatment for adherence and possible signs of complications due to drug toxicities during treatment.

14. Further, strategic behavioral and household community-based TB interventions to address demand-side challenges will be financed. First, the subcomponent will support behavior change TB interventions in the targeted districts mainly focusing on services to reduce stigma, and to improve knowledge and early health-seeking behavior to promote early screening for TB in the targeted areas. Resources will be made available to promote adherence to treatment as well as patient tracing in communities, where required. The possibility of using results-based approaches in these activities will be explored. Such services will reflect a differentiated approach designed for outreach to mine workers (predominantly male), families and caregivers (predominantly female). Second, the project will finance nutritional support to MDR-TB patients. The subcomponent will be implemented through subcontracts with NGOs, community-based organizations, and labor unions that meet defined criteria and are selected competitively.⁵⁷

15. The subcomponent will further support strategic approaches that maximize the comparative advantages of stakeholders. They include use of government structures, i.e. national TB programs and ministries of labor where feasible, but most importantly, identifying strategic opportunities to partner with the private sector, NGOs, and CBOs. Examples are use of ex-TB patients and labor unions for health education at community level; use of performance-based contracting mechanisms within and outside government for delivery of specific packages of high-impact TB control interventions; and scaling up innovative service-delivery approaches in nontraditional health service delivery settings, such as border areas. In line with efforts to improve diagnosis and treatment services for TB and other infectious diseases, patient referrals within and across countries will be strengthened through the public health systems.

16. The threat of MDR-TB looms over the SADC countries, especially in light of the deepening regional integration, greater cross-border movements of the population, weak surveillance systems, and inadequate programmatic management of drug-resistant TB. In most of these countries, patient support and clinical monitoring are a major challenge; it is expected that many cases will be detected during the implementation period, requiring provision of adequate quality of service and patient care. Thus, this subcomponent will support MDR-TB patient holistic management and should complement overall health system strengthening, as outlined in the respective national health strategic and TB plans. MDR-TB patients will be provided with

⁵⁷ A PIM, to be developed before the project becomes effective, will set out criteria for selecting and contracting NGOs and other nongovernmental providers.

psychosocial and nutritional support while health facilities will be supported to improve their capacity to diagnose and treat MDR-TB patients. The introduction of new TB molecular diagnostics is shared across the participating countries and with newer DST and culture technologies like GeneXpert and Hain to be introduced and scaled up in order to increase MDR-TB case detection.

Subcomponent 1.2: Rolling Out a Standardized Package of Occupational Health Services and Mining Safety Standards across the Participating Countries

17. With varying levels of expansion of mining activities within the participating countries, stakeholders have recognized the urgent need to increase efforts to strengthen occupational health and safety standards in the mining industry. This is necessary to reduce work related hazards, improve working conditions, and reduce the burden of TB and other occupational lung diseases associated with mining. This subcomponent will be implemented by ministries of mining and labor within the participating countries.

18. Prioritized activities include financing periodic screening⁵⁸ of miners and ex-miners for TB and other occupational lung diseases in line with international best practices and protocols adopted by the subregion. The project will also finance mine health safety inspection and monitoring, including dust control by mandated entities based on standards agreed to by participating countries and in line with international best practices. Specifically, resources will be made available to procure equipment for screening and diagnosis; a strong maintenance and user training component is expected to ensure sustainability and prolonged working life of the equipment. The objective is to ensure that the participating countries achieve international best practices in these two areas and that they enforce preventive practices with a focus on dust control. The standards will include, for small-scale mining, disease monitoring, and documentation and enforcement of controls.

19. The project will support the development of a minimum standard package of occupational health services, i.e. pre-employment, periodic, exit and post-employment health screening and safety standards. The project will finance efforts to improve the human resource and diagnostic capacity of the respective occupational health and safety authorities to scale up their services to miners working in the formal and informal mining sectors, as well as to ex-mine workers and communities in close proximity to the mines. Specific interventions will include: (i) intensifying screening, active TB and other occupational lung diseases case finding, and contact tracing among miners, ex-miners, and mining communities; (ii) screening and treatment of other occupational lung diseases (e.g. asthma, bronchitis, asbestosis, and pneumoconiosis) through an enhanced system; (iii) upgrading equipment for diagnosing silicosis through procurement of modern equipment to ensure accurate and early diagnosis and personal protective equipment (PPEs) for care providers in TB and MDR wards in order to minimize the risk of infection; and (iv) conducting behavior change and communication (BCC) activities for TB and occupational health diseases for miners, ex miners, senior management, and labor unions, including surrounding communities, training of ex-miners and community health workers to conduct BCC activities to improve knowledge of TB control among the affected target populations. The project will also finance a baseline environmental risk assessment; train environment health officers in industrial hygiene in the target districts; and ensure monitoring of environmental health in mines, quarry areas and hospitals. The project may support occupational health and safety authorities to scale up outreach

⁵⁸ Screening of miners and ex-miners will include other co-morbidities in the region, such as diabetes.

services to track exposure to occupational diseases in the informal mining sector and strengthen disease surveillance systems in mining districts. This support will include establishment of an electronic management information system to bring efficiency and accountability in this area. The support will also include developing/strengthening care program for occupational lung diseases.

20. This subcomponent will not fund compensation of occupational diseases; however, it will facilitate linkages and establishment of referral systems between agencies involved in compensation for occupational lung diseases. These linkages—within and across government agencies and across labor sending and receiving countries—will be through enhanced electronic records systems.

21. The subcomponent will be coordinated with the Medical Bureau for Occupational Diseases in South Africa in line with agreements between South Africa and its neighboring countries and with the Occupational Diseases in Mines and Works Act of South Africa.⁵⁹ Box 1 describes potential synergies between the project activities and related reforms being undertaken by South African government agencies.

22. Under this component, the project will finance goods, training, equipment, technical assistance, and operational expenses. While governments and partners will finance first-line drugs for TB treatment, the project will fund *second and third line drugs* as a backup to minimize stock outs.

Component 2: Regional Capacity for Disease Surveillance, Diagnostics, and Management of TB and Occupational Lung Diseases (US\$43.19 million)

23. This component will help strengthen selective aspects of health systems to position the subregion to better manage the TB epidemic and other infectious diseases. It will prioritize activities via the following subcomponents.

Subcomponent 2.1: Improving Quality and Availability of Human Resources in the Targeted Areas

24. This subcomponent primarily promotes the development of a skilled health workforce based on defined curricula and mentoring, knowledge sharing for disease control across countries and achieving economies of scale. The project will address public health human resources gaps through provision of high quality, regionally recognized training to strengthen clinical skills in: MDR-TB, diagnostics, and laboratories (auditors, assessors, mentors, trainers); disease surveillance; occupational health (nurses, doctors, inspectors); and basic training for health surveillance, community volunteers, and civil society groups. Both long- and short-term training are proposed in the above areas within national and regional training institutions in the participating countries of the regional project and SADC region. The project will finance continued education and further training of laboratory and other health care staff, which will be important for career progression and retention of skilled personnel and contribute to sustaining the health system gains that the project achieves. Innovative e-learning training modules will expand training opportunities and improve learning access to remote districts and allow piloting of cost-effective

⁵⁹ Coordination with the Medical Bureau for Occupational Diseases will be primarily with Lesotho, Malawi, and Mozambique (labor-sending countries) to facilitate cross-border occupational health services

training tools and cascading training materials (with minimal interruption of health service delivery).

25. The project will introduce and support the Field Epidemiology Leadership and Training Program (FELTP), a flagship field epidemiology program designed and supported by CDC. Participating countries will scale up this program with CDC support and financing from the project. The project will also support advanced training in epidemiology in participating countries—for example, short courses in advanced research and epidemiology to build operational research capacity at national and district levels within the Southern Africa region.

26. Regional training in culture and DST for drug-resistant TB in established institutions is encouraged to share learning and scale up better management of drug-resistant TB patients. The regional laboratory accreditation—using SLAMTA and SLIPTA—will be critical in improving laboratory services and quality or accuracy of laboratory testing at subnational laboratories.

27. The project will support selected training institutions in target countries to increase the quality and quantity of professionals managing TB and occupational lung diseases (and broader disease surveillance efforts). Priority will be given to developing a cadre of: mycobacterial laboratory and disease surveillance experts who can strengthen diagnostic and disease management capacity at subnational, national, and regional levels; and occupational health professionals. Partnerships will be forged with the South Africa WHO/ILO Collaboration Center on Occupational Health and the South Africa National Institute for Occupational Health to improve availability of occupational health staff across the region.

Subcomponent 2.2: Strengthening Disease Surveillance and Diagnostic Capacity

28. The project will complement ongoing national, regional, and global initiatives to improve Integrated Disease Surveillance and Response country systems.

29. The project will support the development of mechanisms and processes for sharing information on public health threats within the participating countries to contain disease outbreaks more quickly and minimize the risk of high case fatality rates. Particular attention will be given to cross-border areas with higher risks of disease transmission. This includes: strengthening laboratory-based IT surveillance systems, establishing cross-border committees, and conducting joint investigations and carrying out joint tabletop simulations. Given the project's focus on TB control, a special effort will be given to strengthening TB surveillance in targeted geographic areas and among priority vulnerable groups within the cross-border areas. Box 2 summarizes lessons learned on cross-border disease surveillance.

Box 2: Lessons learned from East Africa Public Health Laboratory Networking Project on cross-border disease surveillance and response

The following elements are required for an effective regional response to communicable diseases:

1. Common standard operating procedures for coordinating joint regional response to public health emergencies
2. A register of regional experts who can ensure emergency disease response
3. A solid mechanism for secure and rapid exchange of data and information among disease surveillance national programs
4. Solid, country-disease surveillance structures (to achieve cross-border programming and disease control)
5. An interoperable mobile or web-based reporting system with capacity to synchronize national and regional data with automation alert/notification ability (for efficient and fast response)

30. The focus will be selective and will include: (i) upgrading surveillance capacity for drug resistance with a focus on MDR-TB; (ii) improving laboratory-based monitoring of antimicrobial resistance, building on pilot initiatives and lessons learned from the East Africa Public Health Laboratory Networking Project and regional surveillance projects (Box 1); (iii) supporting establishment of joint cross-border committees that will carry out joint outbreak investigations, responding to disasters and other public health events, and to conduct table-top simulations; and (iv) purchasing ICT and mobile health software to strengthen surveillance reporting across satellite/project districts and border areas.

31. The project will: support local, regional, and international meetings on disease surveillance to share best practices in disease surveillance and cost-effective community surveillance activities; strengthen laboratory based surveillance systems; establish cross-border committees; and conduct joint investigations.

32. ECSA-HC will play a big role in coordinating regional surveillance efforts in partnership with other development partners like WHO, ASLM, ILO, the International Organization for Migration (IOM) and CDC. Support to border districts by individual countries in terms of cross-border meetings, capacity building, and innovative ways of sharing outbreak information will achieve the project mission of having a robust network of laboratory surveillance and early detection of infectious diseases.

33. A network of functional laboratories will be supported across the participating countries in terms of strengthening laboratory infrastructure, equipping laboratories with the latest diagnostic technologies, and accrediting laboratories with the global WHO, ASLM and CDC supported SLAMTA process. This subcomponent is critical in strengthening the value chain of TB diagnosis at national and regional tuberculosis laboratory levels within the region. There has been a significant expansion of laboratory services including the introduction of Xpert MTB/RIF assay and Line Probe (Hain test) and other molecular-type technologies, which is likely to improve TB case finding, reduce the proportion of patients treated for TB without bacteriologic confirmation,

and reduce delays in TB diagnosis. The recent Ebola outbreaks in West Africa reaffirmed the critical importance of strengthening laboratory systems for reliable and faster diagnosis.

34. National TB Reference Laboratories will be strengthened to support a functional network of laboratories in the country and to link them with the regional cohort of laboratories. The project will install and utilize a gene-sequencing machine to genotype TB strains in several laboratories across the participating countries, which will enable identification of areas with high transmission and assist in understanding the nature of MDR-TB development. This subcomponent will also strengthen the capacity of TB reference laboratories outside capital cities so that culture and drug sensitivity can be performed closer to where patients live and closer to the mining and cross-border areas and transportation corridors. The reference laboratories will undergo renovations based on technical assessments by CDC expert TB laboratory engineers at the start of the project.

Subcomponent 2.3: Strengthening Mine Health Regulation

35. This subcomponent will strengthen the regulatory capacity for occupational health and mine inspections. Surveillance, documentation and follow-up of miners' occupational lung diseases will be implemented, via regional electronic databases, informing a regional registry of silicosis, impaired lung function and lung cancers. This component overlaps and interfaces with the training of new occupational health workers and the creation of national and decentralized occupational health centers.

36. Regulatory capacity strengthening will include review of existing legislation, review of mine regulations in other SADC countries, and development of regional policies and methods for implementation and enforcement. The policy will include mine health inspection as well as safety inspection, and the strengthening of compensation guidelines and mechanisms to ensure that recipients receive payments. In addition, the project will also fund consultancies to support the development of harmonized mine inspection guidelines, standards and codes of practices, occupational health screening protocols, and updated compensation guidelines for mining communities.

37. The project will support the procurement of innovative common ICT regional systems for compliance monitoring and mine health surveillance, including strengthening mapping of miners, ex-miners, and their communities through cost-effective mapping tools.

Component 3: Regional Learning and Innovation, and Project Management (US\$33.32 million)

38. Component 3 will support learning and knowledge sharing and focus on innovative evidence generation to inform national and regional health policies and practices. The countries have a strong interest in embedding an effective learning and evaluation agenda into the regional project. This component promotes regional innovation through sharing of knowledge and evidence from interventions implemented under Components 1 and 2. Knowledge and technical research partners will play a crucial role in this component. A good knowledge sharing strategy will enable the project to gather, store, and share information, lessons, and knowledge to all relevant stakeholders using knowledge sharing platforms such as widely used websites/web portal or online media, documentation centers, workshops, and conferences. The use of short publications for, e.g.

case studies, policy briefs, and implementation note series provides high-level summaries for practical sharing of lessons and documentation of best practices from the project activities.

39. The aim of a learning and knowledge sharing project focuses on:

- Improving internal knowledge capture and utilization
- Promoting knowledge exchange and continuous learning to position the project as a knowledge source for TB, occupational health, and mine health in the subregion
- Sharing and disseminating information internally and externally with partners and stakeholders
- Enabling evidence-based decision making and more targeted use of resources
- Improving use and application of knowledge
- Supporting effective monitoring and reporting on program outcomes
- Opportunities of private sector involvement in TB control in the subregion.

40. **The knowledge activities and products generated will be in the form of:** (i) regional baseline assessment reports that bring evidence to better define the context and to inform policy and project interventions; (ii) in-depth case studies capturing the innovative activities and outputs funded under the project; (iii) joint operational research; (iv) South–South learning exchanges between policy makers and practitioners from the participating countries as well as between representatives of the project countries and other key stakeholders in the region (i.e. implementers from the East Africa Public Health Laboratory Networking Project in Burundi, Kenya, Rwanda, Tanzania, and Uganda with a solid five-year track record of rolling out similar activities) and globally (i.e. countries with important successes in TB control, such as Peru, and those with a solid experience in mine health regulations, such as Chile); and (v) rigorous evaluations of interventions (process and impact), subject to the feasibility of the intervention design. A joint annual review and planning meeting bringing together representatives of the participating countries will be used as a platform to strengthen cross-country learning and promote innovative approaches. Annual reviews and monitoring and evaluation (M&E) activities will document the gender-related dimensions of the TB burden in the participating countries.

41. **Policy advocacy:** The advocacy for this project targets: (i) holding mining companies accountable for TB and occupational health safety standards; (ii) regional level advocacy to galvanize action for sustained reforms to address disease risk factors in mining; and (iii) national level advocacy for policy level attention to the burden and effects of TB in the subregion. NPCA will provide technical support to implement this component and will lead regional level policy advocacy.

42. Numerous national and regional policy advocacy platforms exist that provide an opportunity to give both direct and indirect input into the dialogue and policy making process for TB and occupational lung health; the guiding factor is ensuring active engagement with such policy advocacy platforms to get research into policy and exploring relevant policy points, evidence, and appropriate mediums.

Subcomponent 3.1: Operational Research and Knowledge Sharing

43. ***This includes key baseline assessments⁶⁰ with technical support of the IFC and CDC.*** The project will support relevant operational research and use this research to inform policy and practice through innovative knowledge sharing approaches. Some of the priority operational research proposed includes:

- Impact evaluation of new diagnostics tools on health outcomes
- Mapping of mining activities within the participating countries
- In-depth case studies capturing the mechanism and effects of innovations funded by the project
- South–South learning exchanges between policy makers and practitioners from the participating countries and between them and other parts of the developing world with successes in TB, such as Peru
- Rigorous random control evaluations of interventions (process and impact), subject to the feasibility of the design of the interventions.
- Comparative analysis of interventions proposed by participating countries

44. The outcomes of the baseline assessments will inform key interventions during the life of the project. Communicating the results of the baseline assessment is key, with particular note to policy makers and key influencers in the policy-making process. It is important to ensure that the results are presented in ways appropriate to the forum or platform.

Subcomponent 3.2: Centers of Excellence in TB and Occupational Lung Disease Control

45. Centers of Excellence facilitate knowledge generation and sharing; build capacity of participating countries; and lead the demonstration of excellence in the management of TB, occupational lung diseases, and other specific health intervention areas for broader impact. Each country will serve as a center of excellence in a technical area of its choice and in which it enjoys comparative advantage.

46. The following proposals were put forward by the participating countries:

Lesotho—community-based management of TB

Malawi—community TB care and integrated disease surveillance

Mozambique—MDR-TB and childhood TB Management

Zambia—occupational health and safety.

Subcomponent 3.3: Regional Coordination, Policy Advocacy, and Harmonization

47. The project will support ECSA-HC as the RCO to undertake regional activities that generate economies of scale and deepen learning and knowledge exchange (see below). Building

⁶⁰ The project will coordinate with Global Fund and other key stakeholders to finance joint studies and to minimize duplication.

on its activities under the East Africa laboratory project, ECSA-HC will be well positioned to support critical regional activities and promote South–South knowledge sharing, leveraging existing platforms. ECSA-HC’s main roles are to:

- **Convene technical experts and policy makers.** ECSA-HC will support regional technical learning and exchanges between specialists from the participating countries. ECSA-HC will serve as a host and facilitator of regional community of practices defined by the countries. Examples of community of practice under the project include surveillance and diagnostics; drug-resistance and TB control; and mine health and regulation.
- **Provide implementation support.** ECSA-HC will support countries in specialized technical areas where there is need, such as management of MDR-TB, cross-border disease surveillance, laboratory strengthening and networking, occupational health, etc.
- **Facilitate capacity building and training.** ECSA-HC will facilitate training in partnership with specialized technical agencies such as CDC and ASLM based on demand from the participating countries. It will also support capacity building.
- **Facilitate cross-border surveillance efforts.** ECSA-HC will support the participating countries to develop and rollout surveillance of TB and other infectious diseases in cross-border areas, and to facilitate intelligence sharing on disease outbreaks between countries. ECSA-HC will support the convening of subregional events on surveillance.

48. **NPCA will complement the above regional activities by ECSA-HC and participating countries through high level regional policy advocacy** and coordination of action on mine health regulation and occupational health. High-level policy advocacy will enhance the impact of technical efforts under the project and galvanize political support and policy action to address multisectoral challenges in mine health regulation.

Subcomponent 3.4: Project Management

49. The project will support training and skills building for staff at the project implementation units (PIUs) and at key sectors in management of IDA operations, including training in financial management, procurement, risk-based auditing, and M&E. Funding will be provided to facilitate meetings of inter-ministerial National Technical Committees (NTCs) and the Regional Advisory Committee (RAC). Joint annual review meetings will be supported at national level and interim reviews in participating districts, as needed. Finally, the project will fund routine M&E activities.

50. **The project will fund operating costs for all learning and research work** and establish a team of technical and management experts relevant to the project and to the needs of the participating countries. In addition, the project will finance video conferencing and other virtual learning facilities as well as a website for the project to disseminate knowledge. It will also finance technical assistance as defined in annual work plans.

PROJECT FINANCING: Categories/Types of Expenditures

51. The summary below outlines the project activities and categories/types of expenditures for various subcomponents organized by country. In some cases, countries have already identified detailed activities under specific subcomponents. These are outlined below where applicable.

LESOTHO

1. Component 1: Innovative Prevention, Detection and Treatment of TB

1.1. Enhancing Case Detection and Treatment Success

Project activities	US\$ m	Type of expenditure
<i>1.1.</i> Roll out a harmonized standardized package of TB services based on regionally defined standards and international best practices	4.64	Operational costs, goods and services
Subtotal	4.64	

1.2. Rolling out a standardized package of occupational health services and mining safety standards across the participating countries

52. This subcomponent 1.2 will fund occupational health services:

Project activities	US\$ m	Detailed activities	Type of expenditure
Prioritized activities include financing <i>periodic screening</i> of miners and ex-miners for TB and other occupational lung diseases in line with international best practices and protocols adopted by the subregion.	0.43	Procuring occupational health equipment	Goods
		Infrastructural renovations	Works
		Capacity building	Consulting services
		Occupational health safety policy and guidelines, mine health safety inspection and dust control monitoring	Consulting services Operational expenses
Subtotal	0.43		

2. Component 2: Regional Capacity for Disease Surveillance, Diagnostics, and Management of TB and Occupational Lung Diseases

2.1. Improving quality and availability of human resources

53. This subcomponent 2.1 will support capacity-building efforts:

Project activities	US\$ m	Detailed activities	Type of expenditure
Regional strengthening of human resources for health	3.58	Capacity building for health cadres, mining and labor/occupational health specialists	Training related costs and operational expenses
Subtotal	3.58		

2.2. Strengthening disease surveillance and diagnostic capacity

54. Several activities will be funded through this subcomponent:

Project activities	US\$ m	Types of expenditures
The subcomponent intends to strengthen cross-border disease surveillance and conduct joint outbreak investigations and mechanisms for regional disease intelligence sharing. Regional laboratory accreditation through WHO and ASLM Strengthening Laboratory Management Toward Accreditation (SLMTA) Processes will be adopted	1.69	Goods, works, consulting and non-consulting services
Subtotal	1.69	

2.3. Strengthening mine health regulation

55. This subcomponent will support mine health activities:

Project activities	US\$ m	Types of expenditures
This subcomponent will finance updating or drafting occupational health and safety legislation; reviewing and/or developing guidelines for mine health inspections, occupational health screening protocols, and compensation systems and guidelines	1.06	Consulting services, goods and operating costs
Subtotal	1.06	

3. Component 3: Regional Learning and Innovation, and Project Management

3.1. Operational Research and Knowledge Sharing

Project activities	US\$ m	Types of expenditures
Supports baseline and operational research for TB, Occupational lung disease and mining issues including advocacy and knowledge sharing platforms	0.29	Consulting services and goods
Subtotal	0.29	

3.2. Centers of Excellence in TB and Occupational Lung Disease Control

56. This subcomponent will support the following activities:

Project activities	US\$ m	Types of expenditures
Centers for Excellence approach which will generate services and knowledge for the subregion	0.47	Consulting services and goods
Subtotal	0.47	

3.3. Regional coordination, policy advocacy, and M&E

Project activities	US\$ m	Types of expenditures
Regional coordination, policy advocacy learning and research	1.65	Consultants, IT and office equipment, vehicles, workshops, operating costs
Subtotal	1.65	

3.4. Project Management

Project activities	US\$ m	Types of expenditures
Strengthen project implementation capacity	1.19	Consultants, IT and office equipment, vehicles, workshops, operating costs
Subtotal	1.19	

MALAWI

1. Component 1: Innovative Prevention, Detection and Treatment of TB

1.1. Enhancing Case Detection and Treatment Success

Project activities	US\$ m	Type of expenditure
<i>1.1.</i> Roll out a harmonized standardized package of TB services	4.31	Operational costs, goods and services
Subtotal	4.31	

1.2. Rolling out a standardized package of occupational health services and mining safety standards across the participating countries

57. This subcomponent 1.2 will fund occupational health services:

Project activities	US\$ m	Detailed activities	Type of expenditure
Prioritized activities include financing periodic screening of miners and ex-miners for TB and other occupational lung diseases in line with international best practices and protocols adopted by the subregion.	0.35	Procuring occupational health equipment	Goods
		Infrastructural renovations	Works
		Capacity building	Consulting services
		Occupational health safety policy and guidelines, mine health safety inspection and dust control monitoring	Consulting services and operational expenses
Subtotal	0.35		

2. Component 2: Regional Capacity for Disease Surveillance, Diagnostics, and Management of TB and Occupational Lung Diseases

2.1. Improving quality and availability of human resources

58. This subcomponent 2.1 will support capacity-building efforts:

Project activities	US\$ m	Detailed activities	Type of expenditure
Regional strengthening of human resources for health	1.21	Capacity building for health cadres, mining and labor Ministry officials	Training related costs and operational expenses
Subtotal	1.21		

2.2. Strengthening disease surveillance and diagnostic capacity

59. Several activities will be funded through this subcomponent:

Project activities	US\$ m	Types of expenditures
The subcomponent intends to strengthen cross-border disease surveillance and conduct joint outbreak investigations and mechanisms for regional disease intelligence sharing. Regional laboratory accreditation through WHO and ASLM/ SLMTA. Processes will be adopted	3.75	Goods, works, consulting and non-consulting services
Subtotal	3.75	

2.3. Strengthening mine health regulation

60. This subcomponent will support mine health activities:

Project activities	US\$ m	Types of expenditures
This subcomponent will finance updating or drafting occupational health and safety legislation; reviewing and/or developing guidelines for mine health inspections, occupational health screening protocols, and compensation systems and guidelines	0.44	Consulting services, Goods and operating costs
Subtotal	0.44	

3. Component 3: Regional Learning and Innovation, and Project Management

3.1. Operational research and knowledge sharing

Project activities	US\$ m	Types of expenditures
Supports baseline and operational research for TB, Occupational lung disease and mining issues including advocacy and knowledge sharing platforms	1.00	Consulting services and Goods
Subtotal	1.00	

3.2. Centers of Excellence in TB and Occupational Lung Disease Control

61. This subcomponent will support the following activities:

Project activities	US\$ m	Types of expenditures
Centers for Excellence approach which will generate services and knowledge for the subregion	1.80	Consulting services, operating costs and goods
Subtotal	1.80	

3.3. Regional coordination, policy advocacy, and harmonization

Project activities	US\$ m	Types of expenditures
Regional coordination, learning and policy advocacy	1.87	Consultants, IT and office equipment, vehicles, workshops, operating costs
Subtotal	1.87	

3.4. Project Management

Project activities	US\$ m	Types of expenditures
Strengthen project implementation capacity	2.44	Consultants, IT and office equipment, vehicles, workshops, operating costs
Subtotal	2.44	

MOZAMBIQUE

1. Component 1: Innovative Prevention, Detection and Treatment of TB

1.1. Enhancing Case Detection and Treatment Success

Project activities	US\$ m	Type of expenditure
1.1. Roll out a harmonized standardized package of TB services based on regionally defined standards and international best practices	15.07	Operational costs, goods and services
Subtotal	15.07	

1.2. Rolling out a standardized package of occupational health services and mining safety standards across the participating countries

62. This subcomponent 1.2 will fund occupational health services:

Project activities	US\$ m	Detailed activities	Type of expenditure
Prioritized activities include financing <i>periodic screening</i> of miners and ex-miners for TB and other occupational lung diseases in line with international best practices and protocols adopted by the subregion.	2.69	Procuring occupational health equipment	Goods
		Infrastructural renovations	Works
		Capacity building	Consulting services
		Occupational health safety policy and guidelines, mine health safety inspection and dust control monitoring	Consulting services and operational expenses
Subtotal	2.69		

2. Component 2: Regional Capacity for Disease Surveillance, Diagnostics, and Management of TB and Occupational Lung Diseases

2.1. Improving quality and availability of human resources

63. This subcomponent 2.1 will support capacity-building efforts:

Project activities	US\$ m	Detailed activities	Type of expenditure
Regional strengthening of human resources for health	7.45	Capacity building for health cadres, mining and labor Ministry officials	Training related costs and operational expenses
Subtotal	7.45		

2.2. Strengthening disease surveillance and diagnostic capacity

64. Several activities will be funded through this subcomponent:

Project activities	US\$ m	Types of expenditures
The subcomponent intends to strengthen cross-border disease surveillance and conduct joint outbreak investigations and mechanisms for regional disease intelligence sharing. Regional laboratory accreditation through WHO and ASLM SLMTA.	6.33	Goods, works, consulting and non-consulting services
Subtotal	6.33	

2.3. Strengthening mine health regulation

65. This subcomponent will support mine health activities:

Project activities	US\$ m	Types of expenditures
This subcomponent will finance updating or drafting occupational health and safety legislation; reviewing and/or developing guidelines for mine health inspections, occupational health screening protocols, and compensation systems and guidelines	1.73	Consulting services, Goods and operating costs
Subtotal	1.73	

3. Component 3: Regional Learning and Innovation, and Project Management

3.1. Operational research and knowledge sharing

Project activities	US\$ m	Types of expenditures
Supports baseline and operational research for TB, Occupational lung disease and mining issues including advocacy and knowledge sharing platforms	1.52	Consulting services and Goods
Subtotal	1.52	

3.2. Centers of Excellence in TB and occupational lung disease control

66. This subcomponent will support the following activities:

Project activities	US\$ m	Types of expenditures
Centers for Excellence approach which will generate services and knowledge for the subregion	1.19	Consulting services, goods, and civil works
Subtotal	1.19	

3.3. Regional coordination, policy advocacy, and harmonization

Project activities	US\$ m	Types of expenditures
Regional coordination, learning and policy advocacy	4.95	Consultants, IT and office equipment, vehicles, workshops, operating costs
Subtotal	4.95	

3.4. Project Management

Project activities	US\$ m	Types of expenditures
Strengthen project implementation capacity	3.99	Consultants, IT and office equipment, vehicles, workshops, operating costs
Subtotal	3.99	

ZAMBIA

1. Component 1: Innovative Prevention, Detection and Treatment of TB

1.1 Enhancing Case Detection and Treatment Success

Project activities	US\$ m	Type of expenditure
Roll out a harmonized standardized package of TB services based on regionally defined standards and international best practices	13.50	Operational costs, goods and services
Subtotal	13.50	

1.2. Rolling out a standardized package of occupational health services and mining safety standards across the participating countries

67. This subcomponent 1.2 will fund occupational health services:

Project activities	US\$ m	Detailed activities	Type of expenditure
Prioritized activities include financing <i>periodic screening</i> of miners and ex-miners for TB and other occupational lung diseases in line with international best practices and protocols adopted by the subregion.	4.50	Procuring occupational health equipment	Goods
		Infrastructural renovations	Works
		Capacity building	Consulting services
		Occupational health safety policy and guidelines, mine health safety inspection and dust control monitoring	Consulting services and operational expenses
Subtotal	4.50		

2. Component 2: Regional Capacity for Disease Surveillance, Diagnostics, and Management of TB and Occupational Lung Diseases

2.1. Improving quality and availability of human resources

68. This subcomponent 2.1 will support capacity-building efforts:

Project activities	US\$ m	Detailed activities	Type of expenditure
Regional strengthening of human resources for health	3.00	Capacity building for health cadres, mining and labor Ministry officials	Training related costs and operational expenses
Subtotal	3.00		

2.2. Strengthening disease surveillance and diagnostic capacity

69. Several activities will be funded through this subcomponent:

Project activities	US\$ m	Types of expenditures
The subcomponent intends to strengthen cross-border disease surveillance and conduct joint outbreak investigations and mechanisms for regional disease intelligence sharing. Regional laboratory accreditation through WHO and ASLM SLMTA. Processes will be adopted	11.25	Goods, works, consulting and non-consulting services
Subtotal	11.25	

2.3. Strengthening mine health regulation

70. This subcomponent will support mine health activities:

Project activities	US\$ m	Types of expenditures
This subcomponent will finance updating or drafting occupational health and safety legislation; reviewing and/or developing guidelines for mine health inspections, occupational health screening protocols, and compensation systems and guidelines	1.70	Consulting services, Goods and operating costs
Subtotal	1.70	

3. Component 3: Regional Learning and Innovation, and Project Management

3.1. Operational research and knowledge sharing

Project activities	US\$ m	Types of expenditures
Supports baseline and operational research for TB, Occupational lung disease and mining issues including advocacy and knowledge sharing platforms	0.80	Consulting services and Goods
Subtotal	0.80	

3.2. Centers of Excellence in TB and Occupational Lung Disease Control

71. This subcomponent will support the following activities:

Project activities	US\$ m	Types of expenditures
Centers for Excellence approach which will generate services and knowledge for the subregion	2.30	Consulting services and goods
Subtotal	2.30	

3.3. Regional coordination, policy advocacy, and harmonization

Project activities	US\$ m	Types of expenditures
Regional coordination, learning and policy advocacy	4.95	Consultants, IT and office equipment, vehicles, workshops, operating costs
Subtotal	4.95	

3.4. Project Management

Project activities	US\$ m	Types of expenditures
Strengthen project implementation capacity	2.91	Consultants, IT and office equipment, vehicles, workshops, operating costs
Subtotal	2.91	

ANNEX 3: IMPLEMENTATION ARRANGEMENTS

Overview

1. Proposed implementation arrangements are adapted to the country and regional contexts and draw on evidence of best practices and lessons from past and ongoing Bank-financed regional projects. The proposed implementation arrangements were also informed by the Independent Evaluation Group's recommendations on regional projects.
2. The project will promote multisectoral collaboration between the key implementing sectors (ministries of health, mines, and labor). In each country, the national TB program with the support of the Policy and Planning Department of the Ministry of Health (MOH) will coordinate project implementation. The MOH as lead ministry will be responsible for coordinating multisectoral activities implemented by the key implementing sectors as well as by competitively selected NGOs and private sector stakeholders.
3. At regional level, implementation arrangements include the following: (i) the East, Central and Southern Africa Health Community (ECSA-HC) will serve as the Regional Coordinating Organization (RCO), will coordinate project activities at the regional level, and will provide project implementation support to participating countries and specialized technical assistance on health systems strengthening; and (ii) a Regional Advisory Committee (RAC) will provide strategic guidance and governance functions. Detailed procedures for regional-level implementation arrangements will be outlined in the Project Implementation Manual to be prepared for the project.
4. ECSA-HC and NPCA were selected through a competitive due diligence assessment of four regional organizations,⁶¹ identified as RCO candidates by the Bank in consultation with project stakeholders. The assessment, conducted in October-December 2015, found that ECSA-HC and NPCA meet the Bank's eligibility criteria for supporting regional projects and offer complementary expertise and experience, with ECSA-HC being more of a technical institution focused on health and NPCA having a broader economic and political mandate that will be useful in facilitating multisectoral work. Both institutions have expressed a commitment to working together with the specific arrangements to be finalized during the first month of implementation.
5. At country level, implementation arrangements include: (i) annual work plans prepared by the key implementing agencies; (ii) inter-ministerial National Technical Committees (NTCs) that will review and approve the consolidated work plans submitted by the lead technical ministry and endorsed by the RAC, in addition to providing technical guidance to implementing agencies at national level; and (iii) project implementation units (PIUs) and other MOH structures that will provide overall support for project implementation and be responsible for day-to-day coordination of the project, including fiduciary aspects and preparation of quarterly and annual consolidated technical and financial reports.

⁶¹ ECSA-HC; NPCA; Southern African Development Community (SADC); and Wits Health Consortium, South Africa.

6. The Bank will assess regional coordination and implementation arrangements during an interim 18-month review and modifications will be made as needed in consultation with participating countries. National implementation arrangements will be monitored during Bank supervision missions and assessed during the project's mid-term review.

Regional Level

7. In line with the Independent Evaluation Group's recommendation on regional projects,⁶² the RCO will coordinate project activities, beginning by bringing together representatives of the participating countries and key regional stakeholders to develop a common vision and clarify respective roles and responsibilities of all players.

8. ECSA-HC and NPCA will: (i) provide implementation support to participating countries, as required; (ii) foster networking and knowledge sharing; (iii) coordinate specialized technical inputs in areas identified by the countries and the Bank; (iv) support policy-oriented research case studies and dissemination; (v) facilitate regional dialogue and efforts to harmonize systems and standards for managing TB and to develop and roll out standardized best practices in mine health in line with global standards and evidence; (vi) facilitate strategic discussions between international and regional organizations and project teams on technical and policy issues of mutual interest; and (vii) advocate for policy change and sustained political commitment.

Regional Advisory Committee

9. Regional oversight of the project will be the responsibility of the RAC comprising three members of the NTCs⁶³ from each country; one member from the mining-sector Global Fund Regional Coordinating Mechanism (Wits Health Consortium); and one representative from SADC. A representative from ECSA-HC will serve as the secretariat. Five members will be from outside government, preferably from the chamber or association of mines or a mining company; an NGO; a research institution; and a labor union. The entities will be nominated on a rotational basis by the countries. The Chair of the RAC will be selected from a regional organization, with expertise in policy and technical issues related to the project's scope. The Committee will meet semi-annually in the first year of the project and annually thereafter. A senior official from NPCA will chair the RAC during the first year of the project. Participating countries will decide on a chair in subsequent years based on a process to be outlined in the Project Implementation Manual. For each Permanent Secretary nominated to the RAC and NTC, an alternate member will be officially designated by the relevant ministry.

10. The goal of the RAC will be to bring together the stakeholders working on the regional project to provide strategic guidance and governance functions, review implementation progress, and strengthen working relationships in order to achieve the expected deliverables of the project.

⁶² "What has generally worked best is reliance on national institutions for execution and implementation of program interventions at the country level, and on regional institutions for supportive services that cannot be performed efficiently by national agencies, such as coordination, data gathering, technical assistance, dispute resolution, and monitoring and evaluation" (Independent Evaluation Group 2007).

⁶³ One senior policy maker at permanent secretary level; one senior technical specialist from MOH with project area expertise; and one senior technical specialist from either Ministry of Labor or Ministry of Mines to be rotated annually.

11. It is envisaged that the RAC will have the following responsibilities:

- Endorse consolidated work plans and budgets submitted by the inter-ministerial National Technical Committees
- Approve regional work plan and deliverables submitted by ECSA-HC and NPCA
- Follow up on key research findings
- Review Community of Practice annual work plans
- Harmonize cross-cutting regional activities
- Review country implementation and support each other in seeking solutions to common challenges
- Advise on coordination and management of project activities at regional level
- Provide actionable reports and coordinate implementation of agreed actions with member countries
- Provide regional M&E of regional project activities
- Identify opportunities for new partnerships and advocacy for the project
- Review and endorse the final reports from regional project experts and consultants

East, Central and Southern African Health Community (ECSA-HC)

12. ECSA-HC was established in 1974 to strengthen regional cooperation and capacity to address its member states' health needs.⁶⁴ It is the only regional organization that exclusively focuses on supporting member states on health-related matters. Accountable to the Conference of Health Ministers of its member countries, ECSA-HC has a strong, clearly defined regional public health mandate. Its experience is long standing and significant, with a good track record in successful regional policy dialogue, coordination, technical assistance, and advocacy. The due diligence assessment found ECSA-HC's policy dialogue and regional harmonization approach systematic and thoughtful. On TB and health system strengthening, ECSA-HC has ample practical experience supporting member states, including an ongoing USAID-funded TB control initiative targeting East Africa. Its capacity in health is reflected in its health portfolio, which is funded by member states and development partners and financed by grants ranging from US\$3.5 million to US\$6 million a year. As the implementer of the World Bank-financed East Africa Public Health Laboratory Networking Project (EAPHLNP), and an Institutional Development Fund (IDF) grant on nutrition, ECSA-HC is familiar with World Bank processes and the Bank's approach to regional initiatives.

New Partnership for African Development Planning and Coordinating Agency (NPCA)

13. As the technical arm of the African Union, NPCA also has a strong regional mandate. Its Health Unit was responsible for spearheading the Africa Health Strategy (2007-2015), which was adopted at the First Conference of Health Ministers of the African Union and at the 2003 AU Summit in Maputo. In addition, NPCA's political clout and access to senior government officials beyond health is critical for policy reform and in sync with the project's multisectoral focus. Its Southern African location is close to participating countries and major regional stakeholders. NPCA's Health Division is currently working with the African Union Commission on the review

⁶⁴ Member countries include Kenya, Lesotho, Malawi, Mauritius, Seychelles, Swaziland, United Republic of Tanzania, Uganda, Zambia and Zimbabwe.

of the Africa Health Strategy. In addition, NPCA’s regional pharmaceutical harmonization work has demonstrated the organization’s strategic role in coordinating regional policy harmonization and reforms. NPCA has a strong track record of coordinating with the African Union’s “Regional Economic Communities”—including SADC, specialized intergovernmental organizations such as ECSA-HC—as well as with UN Agencies and other pan-African organizations on policy reform and harmonization in implementing AU policy instruments on health.

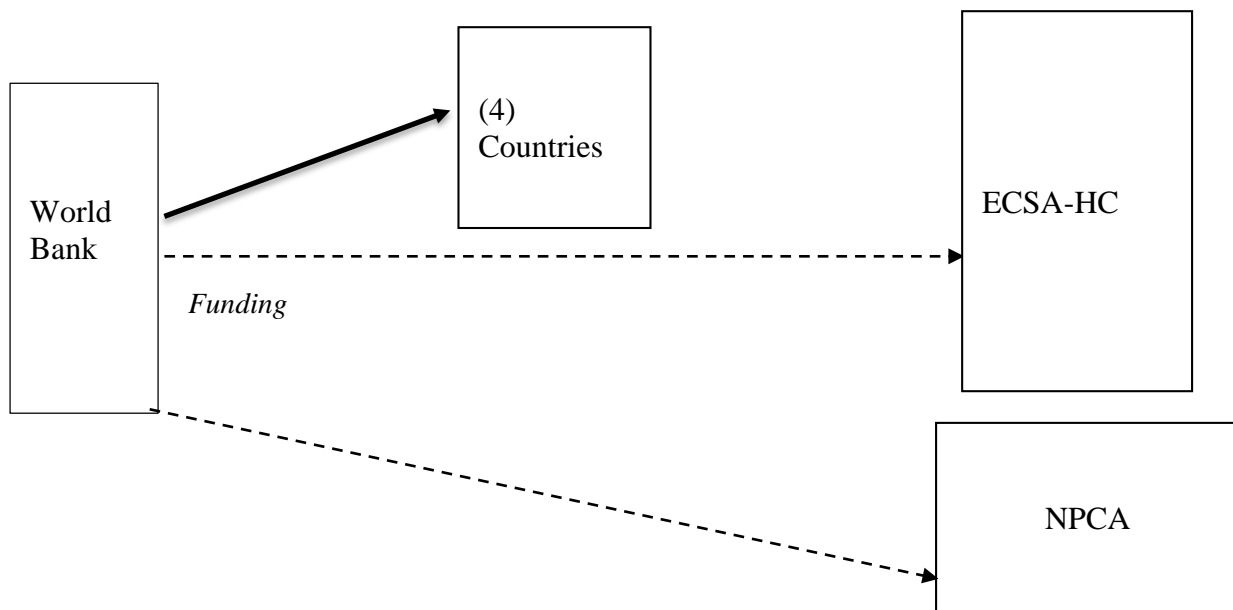
Financing of Regional Activities

14. The funding of regional level activities will come from the participating countries. Out of the IDA credits/grants for the countries (US\$122 million), countries will use roughly 11.0 percent (US\$13.42 million) to contract with ECSA-HC and NPCA through subsidiary agreements for implementing regional-level activities. The rest of the IDA credits/grants (89 percent or about US\$108.58 million) will be managed directly by countries.

15. Each country will sign a subsidiary agreement with ECSA-HC. In addition, Mozambique (which is not a member of ECSA-HC) will sign a Memorandum of Understanding with the institution, under terms and conditions acceptable to the Bank, as detailed in the Financing Agreement.

16. Direct disbursements from the Bank to ECSA-HC and NPCA will be made based on the approved annual regional work plan. NPCA, in line with the cooperation agreement with ECSA-HC, will submit its annual work plan to ECSA-HC for consolidation of regional activities and subsequent approval by the RAC. The flow of funds is depicted in Figure 1.

Figure 1: Flow of funds



Note: The bold solid arrow to the countries represents disbursements to borrowers. The dashed lines to the regional organizations represent direct disbursement on behalf of borrowers by IDA.

National Level

17. The institutional framework for project implementation, to vary by country, is based on the following principles: (i) use of country systems; (ii) reliance on national structures with targeted technical assistance where appropriate; (iii) use of implementing entities based on comparative advantages, for example, community-based activities that are best suited to NGOs will be contracted out while core public health functions or mining sector functions that require government agencies will be implemented directly; (iv) use of simple performance-based agreements to strengthen accountability between the lead ministry and other stakeholders; and (v) streamlined arrangements and avoidance of parallel structures or processes. The framework will build on existing national structures and country systems.

18. Implementing agencies will develop annual work plans with measureable outputs and budget resources. The plans will be submitted to the MOH as the lead implementing agency and will be consolidated by the national TB program (NTP), which will provide technical leadership to the project. PIUs and other MOH structures will provide overall support for project implementation and be responsible for day-to-day coordination of the project, including fiduciary aspects and preparation of quarterly and annual consolidated technical and financial reports.

19. In **Lesotho**, overall implementation will rest with the MOH, and overall oversight with the Principal Secretary. The MOH will serve as the lead implementing agency and will work with the Ministry of Mining and the Ministry of Labour and Employment (MoLE). The MOH has a TB Program that will oversee a team of technical and fiduciary staff in a Project Accounting Unit (PAU) established to support the project. The MOH's TB Program will also coordinate other implementing entities. With private entities, the government will use simple performance-based contracting to ensure accountability for results.

20. Technical Departments: The key technical departments that will be involved in project implementation include the NTP under the Disease Control Directorate (MOH); Department of Mine Safety and the Policy and Planning Department (Ministry of Mining); the Department of Occupational Health and Safety and the Migration Liaison Unit (MoLE); and the Ministry of Justice and Correctional Services.

21. An inter-ministerial NTC will be constituted for providing oversight and technical guidance to project implementation across the participating ministries. It will be responsible for reviewing and approving consolidated annual work plans and budgets submitted by the technical departments. The committee chairmanship will be rotated annually among the Principal Secretaries from the three technical participating ministries. Membership of the NTC will include the directors from key implementing ministries (e.g. MOH, Ministry of Mining; and MoLE) and the head of the NTP. The NTC will meet at a minimum three times during the first year of implementation and semi-annually thereafter.

22. The NTP will be responsible for overall support to project implementation and coordination of project activities among the implementing agencies. The NTP will oversee a team of technical and fiduciary staff in the PAU housed in MOH, which will be responsible for day-to-

day management of the project. The PAU currently supports the Bank-financed HIV/AIDS and Technical Assistance (HTAP) Project.

23. The proposed composition of the PAU team will include a Project Coordinator, Project Accountant, Procurement Specialist, Monitoring and Evaluation Specialist; and technical specialists from key implementing ministries. The need to recruit additional technical and fiduciary personnel (e.g. procurement, financial management, etc.) for the PAU is based on the outcomes of the fiduciary assessments to be conducted by the World Bank.

24. In addition, technical assistance from an agency with a strong track record of working with MOH and the NTP may support project implementation while building MOH capacity. Strategic partnerships between government and NGOs or private sector entities may be utilized to support specific components of the project. With private entities, the government will use performance-based contracting to ensure accountability for results.

25. In **Malawi**, the Principal Secretary for Health will be responsible for overall project oversight. The key implementing agencies will be the MOH; Ministry of Natural Resources, Energy and Mining; and Ministry of Labour and Manpower Development. Overall responsibility for project coordination will rest with the MOH's NTP, which will house a small core PIU to be established before the project becomes effective with technical and fiduciary staff who meet the Bank's requirements. Where private entities have comparative advantage to execute key project activities, they will be engaged through competitive selection.

26. Technical Departments: The key technical departments which will be involved in project implementation include Preventive Health Services, Clinical Health Services, Diagnostics, TB and HIV/AIDS, and Planning (MOH); Occupational Health (Ministry of Labour and Manpower Development) and Mines (Ministry of Natural Resources, Energy and Mines).

27. An inter-ministerial NTC, led by the Secretary to the Treasury, will be constituted for providing oversight of project implementation across the participating ministries. The NTC will meet a minimum of three times during the first year of implementation and thereafter twice a year to review and approve the consolidated annual work plans and budgets. It will also provide technical guidance to implementing agencies at national level. Members will include the Principal Secretaries from key implementing ministries (e.g. MOH; Ministry of Natural Resources, Energy and Mines; and Ministry of Labour and Manpower Development), Directors of key ministry departments and the head of the National TB Control Program (NTP). The chairmanship will be rotated annually among the three Principal Secretaries.

28. As the lead technical program, the NTP will provide overall support for project implementation and coordination of project activities among implementing agencies. The NTP will be supported by a PIU which will be responsible for day-to-day management of the project, including procurement and financial management functions, M&E, and preparation of technical and financing reporting. The proposed composition of the PIU team will include a Project Coordinator, Project Accountant, Procurement Officer, ICT Officer, and Monitoring and Evaluation Specialist. The Director of NTP will serve as Project Manager. The PIU structure is based on the outcomes of the fiduciary assessments conducted the World Bank.

29. In **Mozambique**, the key implementing agencies will be the MOH; Ministry of Mineral Resources and Energy; and Ministry of Labour, Employment and Social Security. Overall responsibility for project coordination will rest with the MOH as the lead technical agency for the project. The National TB Control Program (NTP) will be the lead technical program reporting to the Director of Public Health. The existing PIU in the MOH for the Health Sector Development Project will lead project coordination and fiduciary oversight.

30. Technical Departments: The key technical departments to be involved in project implementation include the NTP, the General Inspectorate and Directorate of Migratory Work in the Ministry of Labour, Employment and Social Security; and the General Inspectorate for Mining in the Ministry of Mineral Resources and Energy.

31. An inter-ministerial NTC on Health and Mining (CONSAMI) will be constituted for providing oversight to project implementation across the participating ministries. It will be responsible for reviewing and approving consolidated annual work plans and budgets, and providing technical guidance to implementing agencies. On a rotational basis, the committee will be led by a Permanent Secretary of each of the participating ministries. Members will include the Permanent Secretaries from key implementing ministries; senior official representatives of key ministry inspectorates, directorates, and departments; and the head of the NTP. In the MOH, this would comprise the Director of Public Health and the Deputy Director of Planning and Cooperation. In the Ministry of Labour, Employment and Social Security, this will comprise a representative from the General Inspectorate and a representative from the Directorate of Migratory Work. In the Ministry of Mineral Resources and Energy, this would comprise a representative from the General Inspectorate for Mining.

32. The existing PIU in the MOH will lead project coordination and fiduciary oversight. The project will utilize the PIU arrangements already in place for managing the World Bank–financed Health Service Delivery Project. The PIU, which is housed in the Department of Investments of the Directorate of Planning and Cooperation, will provide support to the NTP in the day-to-day management of the project, including procurement and financial management functions, M&E, and preparation of technical and financing reporting.

33. The composition of the PIU team will include a project manager, project coordinator, operations assistant, financial management specialist, project accountant, procurement specialist, and a procurement assistant. The NTP Director will be the Project Manager of the PIU. The Project Manager will ensure the overall coordination of implementation of project activities at central level and will ensure that information related to project activities is shared across key central and provincial level units. The Project Manager will report to the National Director of Public Health who will provide technical and strategic oversight of the Project.

34. In **Zambia**, the key implementing agencies will be the MOH; Ministry of Mines, Energy and Water Development (MMEWD); and the Occupational Health and Safety Institute. The MOH will be the lead entity for the project and will have a central coordinating role through its Directorate of Policy and Planning (DPP). The NTP will serve as the lead technical program and will be supported by the Directorate of Policy and Planning as per the arrangements of the ongoing

Bank-funded health project. The Directorate of Policy and Planning in the MOH will be responsible for fund management and day-to-day operations of the project.

35. Technical Departments: Under the guidance of the Director for Disease Surveillance, Control and Research, the NTP will be the lead technical program for the project. It will provide overall support to project implementation and the coordination of project activities among other implementing ministries and partners. Other key technical departments which will be involved in project implementation include the Mine Safety Directorate and the Policy and Planning Directorate (MMEWD).

36. An inter-ministerial NTC will be constituted for providing oversight to project implementation across the participating ministries. It will be responsible for reviewing and approving consolidated annual work plans and budgets submitted by the technical departments, and providing technical guidance to implementing agencies. The Permanent Secretary of one of the participating ministries will lead the committee. Members will include the Permanent Secretaries from key implementing ministries, senior official representatives of key ministry inspectorates, directorates, and departments; and the head of the NTP.

37. The Department of Policy and Planning (DPP) in MOH will provide support to the project, and will be responsible for fund management and day-to-day operations of the project. The DPP already provides support to the ongoing Bank-financed Health Service Improvement Project. The following staff are proposed to be recruited to support project management: Program Coordinator, Epidemiologist, Monitoring & Evaluation Officer, Occupational Health and Safety Officer, Logistics Manager, Public Private Liaison Officer, Data Manager, Procurement Officer, Accounts Officer, and Administrative Assistant. This proposed structure is based on the outcomes of the fiduciary assessments conducted by the Bank.

38. National implementation arrangements will be monitored during Bank supervision missions and subject to review during the mid-term review of the project.

Financial Management

39. Further details of the financial management capacity assessment of ECSA-HC and NPCA, national level assessments and proposed financial management are summarized in Annex 8.

Procurement

40. Procurement assessments and proposed arrangements are summarized in Annex 8.

Legal Arrangements

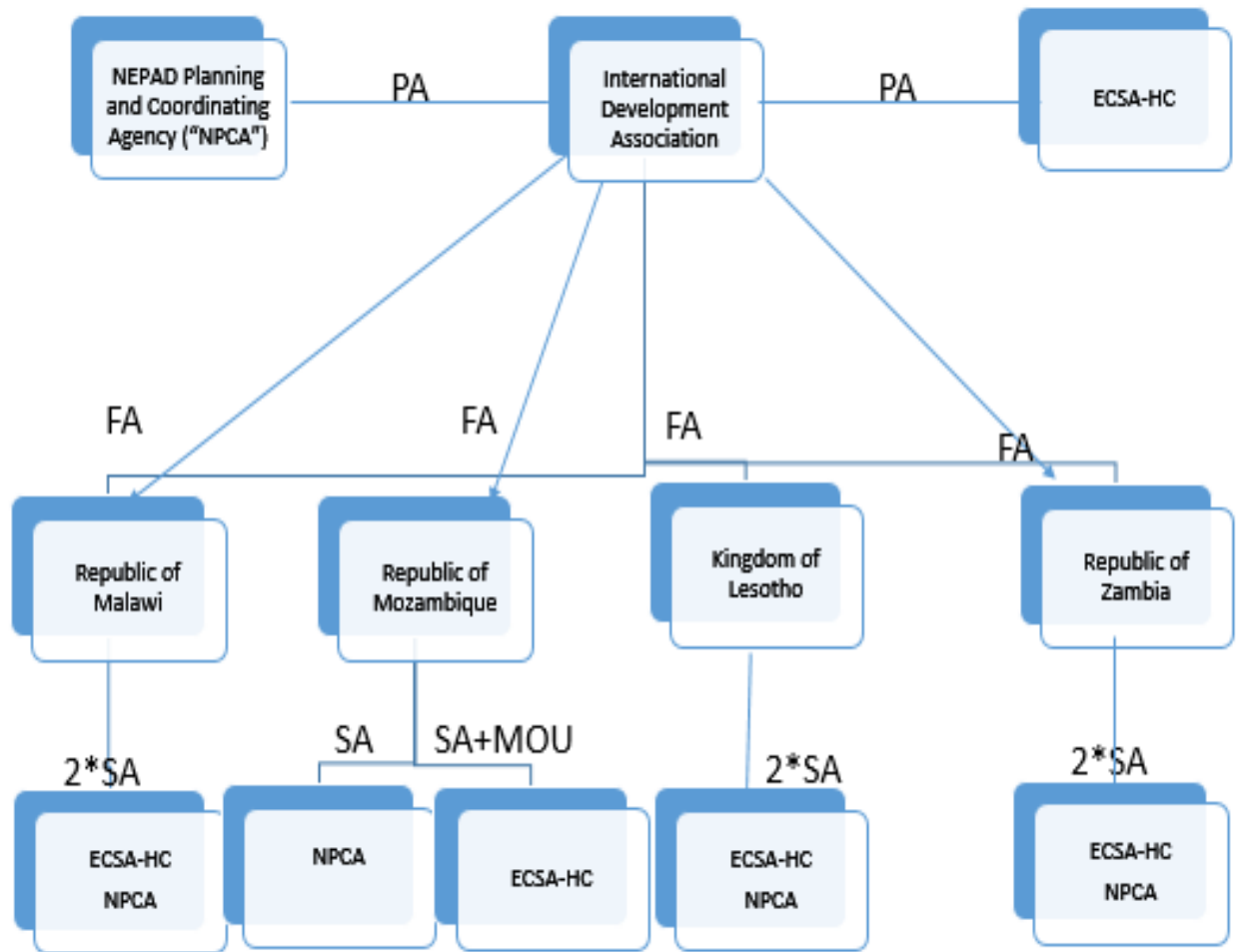
41. There are several legal layers for the project that govern the relations between IDA, the participating countries, and the regional entities (ECSA-HC and NPCA). The legal arrangements are summarized below:

- Each participating country will sign a Financing Agreement with IDA.

- Each participating country will also sign two Subsidiary Agreements: one with ECSA-HC and one with NPCA. Under these Subsidiary Agreements, each participating country will pass on a proportional part of their project funds to these two regional entities, because the two regional entities will each be implementing part of the project. In the case of Mozambique, it will also sign an MOU with ECSA-HC in addition to the Subsidiary Agreement because Mozambique is not a signatory member of ECSA-HC; such MOU will govern their mutual coordination relationship and Mozambique's participation in ECSA-HC for the purposes of the project.

42. IDA will sign two Project Agreements, one with ECSA-HC and one with NPCA, to establish a direct legal relationship between IDA and these two regional entities. Figure 2 outlines the legal arrangements.

Figure 2: Legal Arrangements



Note: PA: Project Agreement; FA: Financing Agreement; SA: Subsidiary Agreement; MOU: Memorandum of Understanding.

Participating countries will sign among themselves a cooperation protocol. NPCA and ECSA-HC will sign among themselves a cooperation agreement.

ANNEX 4: IMPLEMENTATION SUPPORT PLAN

Strategy and Approach

1. The implementation support plan for the project has been developed based on the project activities, on lessons learned from past operations in the sector, in response to the demands for multisectoral activities, and on the project's risk profile as described in this Project Appraisal Document. The plan will be reviewed regularly and revised when required.

2. The plan includes regular, thorough reviews of implementation performance and progress to be carried out by a team of Bank specialists with the Project Implementation Units (PIUs, in participating countries) and with the Regional Coordinating Organization (RCO). In addition to these formal implementation support missions and field visits, which will be carried out at least semi-annually given project urgency and complexity, special workshops will be held at key decision points in the project. Midway during the project, the Bank team will undertake a mid-term review mission to take stock of project implementation and to take any corrective actions. That mission is expected by March 2019. Prior to that mission (by end-February 2019), the RCO, with input from the countries, will prepare and send to the Bank a report summarizing project progress, highlighting any particular issues that require special attention. At the end of the project, the Bank team will prepare an Implementation Completion Report (ICR), which will summarize achievements made under the project. This report will also include an assessment of the project by the PIUs. This process will also be guided and coordinated by the RCO.

Implementation Support Plan

3. The Bank team will monitor progress on several fronts including: (i) key performance indicators as identified in the Results Framework; (ii) project components; (iii) compliance with key legal conditions and covenants; (iv) progress made against the project implementation plan and the procurement plan; (v) whether estimated project costs are sufficient to cover planned activities and whether reallocations of the Grant/Credit funds are required; (vi) compliance with the Bank's financial management and disbursement provisions; and (vii) compliance with environmental and social safeguards. In addition, the Bank will also review the findings and results of third-party assessments, community-based monitoring, and social audits, which will be undertaken during the course of project implementation. The Bank team will also closely monitor the completion of the baseline, mid-term, and other surveys that will be used to evaluate the impact of key activities supported by the project, including user-satisfaction assessments.

4. In addition to monitoring project progress, the Bank team will work closely with all implementing agencies. The implementation support team will include health specialists, a mining specialist, occupational health specialist, health economists, laboratory specialists, and private sector and partnership specialists. The Centers for Disease Control and Prevention (CDC) will continue to second TB control experts and other specialists to provide technical and implementation support in areas mutually defined with the Bank. This will leverage global expertise in TB control and other strategic technical areas of the project.

5. Implementation support to the countries will most likely be challenging, given the number of countries in the project (Lesotho, Malawi, Mozambique, and Zambia), the combination of national and regional activities, and limitations in countries' implementation capacities. Within the country, this is further compounded by the multisectoral approach of the project, which requires working across at least three sectors (health, mining, and labor) and engaging a number of stakeholders (public and private sectors, civil society organizations, and development partners). The project will require significant technical support, given the complex nature of the activities to be financed and relatively limited in-country experience with some of the components.

Supervision Objectives and Strategy

6. The objectives of the implementation support for this project are to:

- Ensure that country and regional agencies implement the project with due diligence to achieve the development objectives;
- Identify implementation challenges quickly and support the implementing agencies to resolve them;
- Adjust the project—as necessary—based on lessons learned during implementation and other pertinent changes in order to accelerate the attainment of the project objectives; and
- Facilitate collaboration among development partners already involved in addressing the burden of TB and occupational diseases.

7. Implementation support missions will concentrate on the overall implementation of the project activities at all levels. These missions will be carried out in close coordination with all development partners as well as regional agencies as relevant.

8. To assure timely implementation support, the project team will maximize electronic communication, and audio and videoconferencing in between country visits. To the extent possible, some mission members will provide virtual support from Washington, DC during supervision missions. This arrangement will result in substantial cost savings of supervising a project of this nature that draws on expertise from a number of Global Practices in the Bank. Furthermore, as much as possible, the project will draw on regional technical expertise such as consultants to ensure that the necessary technical leadership is available in close proximity to the clients.

9. The main elements of the implementation support for the countries will be as follows:

- The designated national agencies in charge of project implementation in each of the countries will coordinate project activities across agencies in government, NGOs, and local communities and submit a progress report to the project team periodically.
- The project team, development partners, and regional agencies involved in the project will provide technical advice to the project countries; and
- To the extent possible, there will be joint implementation support missions with other key agencies. Furthermore, several members of the project team are based in the field and will be able to provide ongoing implementation support, with additional inputs from team members based in Washington, DC and elsewhere, in between scheduled missions.

10. **Composition of missions.** The implementation support missions will include, as appropriate at the time, a multidisciplinary team comprised of specialists in the following areas: public health, occupational health, mining, epidemiology, laboratory, procurement, and financial management. Additional technical staff from international agencies involved in the response will participate as part of the implementation support missions.

11. **Supervision outputs/outcome.** On the basis of project monitoring and evaluation, the supervision missions would be geared toward ensuring that implementation of the project is progressing as planned and to anticipate or detect any implementation bottlenecks. These missions would also gauge the degree of progress in meeting set goals on the basis of evaluation of inputs (human and capital resources available for project implementation) and project operation variables (who is to do what, where, when, and how), as well on assessments of impacts and outcomes that may include changes in knowledge, attitudes, behavior, risk factors, and socioeconomic impacts.

12. The specific support in implementation during the project period is in Table 1.

Table 1: Implementation support during the project

Time	Focus	Skills Needed	Staff weeks	Number of trips
	Overall coordination	Task Team Leader (TTL)		
Year 1 (resource estimate: US\$350,000)⁶⁵				
	Project launch (September 2016)	Task team: total TTL – Health Specialist Senior Mining Specialist Economist (2) Lead Health Specialist (2) Social Development Specialist Environmental Specialist Industry Specialist (PPP) Epidemiologist (Global Lead) M&E Specialist Senior Operations Officer/ Occupational Health Policy Operations Officer FM Specialist Procurement Specialist Consultants on specialized areas (M&E, occupational health – clinical, health policy)	90 18 5 6 8 4 4 1 1 4 8 10 3 8 10	1 for each specialist listed
	Regular implementation	Task team: total TTL – Health Specialist	78 18	1 for each specialist listed

⁶⁵ Estimated budget includes fixed and variable costs, including staff travel.

Time	Focus	Skills Needed	Staff weeks	Number of trips
	Overall coordination	Task Team Leader (TTL)		
	support mission (February 2017)	Senior Mining Specialist Economist (2) Lead Health Specialist (2) Social Development Specialist Environmental Specialist Industry Specialist Epidemiologist (Global Lead) M&E Specialist Senior Operations Officer/ Occupational Health Policy Operations Officer FM Specialist Procurement Specialist Consultants on specialized areas	4 4 6 2 3 1 1 4 6 8 8 3 10	
	Regular implementation support mission (May 2017)	Task team: total TTL – Health Specialist Senior Mining Specialist Economist (2) Lead Health Specialist (2) Social Development Specialist Environmental Specialist Industry Specialist Epidemiologist (Global Lead) M&E Specialist Senior Operations Officer Operations Officer FM Specialist Procurement Specialist Consultants on specialized areas	53.5 16 2 2 3 2 1 1 0.5 3 4 3 3 3 10	1 for each specialist listed
Years 2-5 (resource estimate: US\$1,000,000)				
	Bi-annual implementation support missions ⁶⁶ (technical and fiduciary reviews)	Task team: total TTL – Health Specialist Senior Mining Specialist Economist (2) Lead Health Specialist (2) Social Development Specialist Environmental Specialist Industry Specialist Epidemiologist (Global Lead) M&E Specialist	49.5 x 2 12 2 2 3 2 1 1 0.5 3	1 for each specialist listed

⁶⁶ Bi-annual missions will be complemented by half missions by team members supporting other projects in the region.

Time	Focus	Skills Needed	Staff weeks	Number of trips
	Overall coordination	Task Team Leader (TTL)		
		Senior Operations Officer	4	
		Operations Officer	3	
		FM Specialist	3	
		Procurement Specialist	3	
		Consultants on specialized areas	10	
	Mid-Term Review (March 2019)	Task team: total	50	1 for each specialist listed
		TTL – Health Specialist	12	
		Senior Mining Specialist	2	
		Economist (2)	2	
		Lead Health Specialist (2)	3	
		Social Development Specialist	2	
		Environmental Specialist	1	
		Industry Specialist	1	
		Epidemiologist (Global Lead)	1	
		M&E Specialist	3	
		Senior Operations Officer	4	
		Operations Officer	3	
		FM Specialist	3	
		Procurement Specialist	3	
		Consultants on specialized areas	10	
	Implementation Completion Review Mission (March 2021) ICR preparation	Task team: total	54	1 for each specialist listed
		TTL – health specialist	5	
		Lead Health specialist	2	
		M&E Specialist	2	
		Operations Officer	5	
		ICR Author	40	

13. As a collaborating partner, CDC will provide technical support on management of TB/MDR TB and on strengthening epidemiology, disease surveillance systems, and laboratory networks.

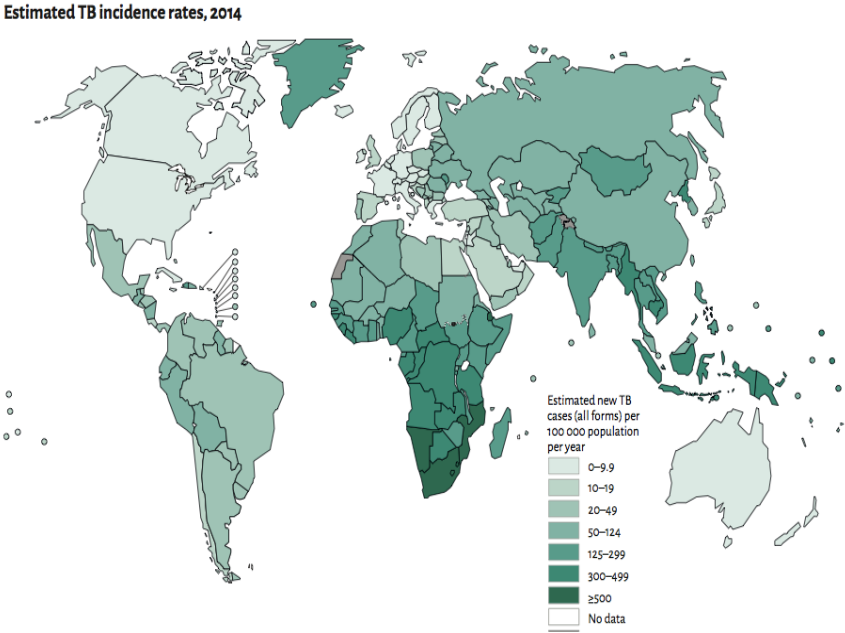
ANNEX 5: REGIONAL AND SECTOR BACKGROUND—TUBERCULOSIS CONTROL CONTEXT

Overview

1. *Tuberculosis (TB) is a major global health problem and the leading cause of death worldwide, surpassing mortality from the human immunodeficiency virus (HIV).* In 2014, there were an estimated 9.6 million new TB cases, broken down into 5.4 million men, 3.2 million women, and 1.0 million children. There were also 1.5 million TB deaths, of which 1.1 million were among HIV-infected people, underscoring the dual nature of the epidemic and high rates of coinfection (Figure 1).

2. *Southern Africa has some of the highest TB rates on the continent, mirroring the HIV/AIDS epidemic.* Incidence rates are highest in *Lesotho (852/100,000), South Africa (834/100,000), Swaziland (733/100,000), and Mozambique (551/100,000).* *Zambia and Malawi* appear to have slightly lower rates (i.e. 300-500 per 100,000 population) but these figures underestimate the true magnitude of the problem due to significant under-reporting, as discussed below.

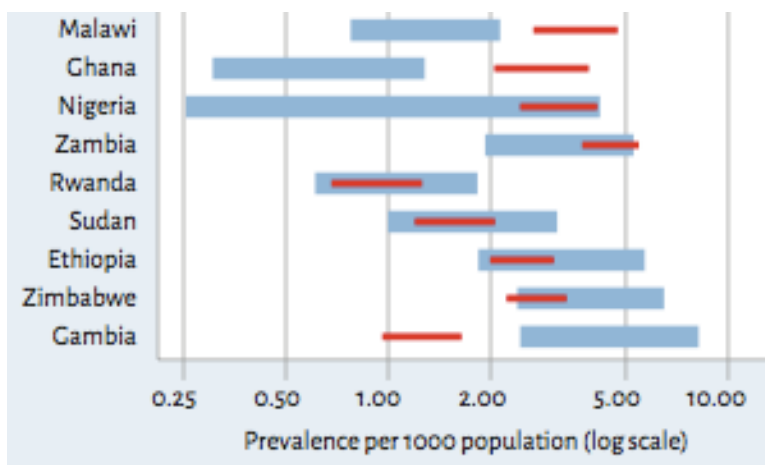
Figure 1: Estimated TB Incidence Rates, 2014



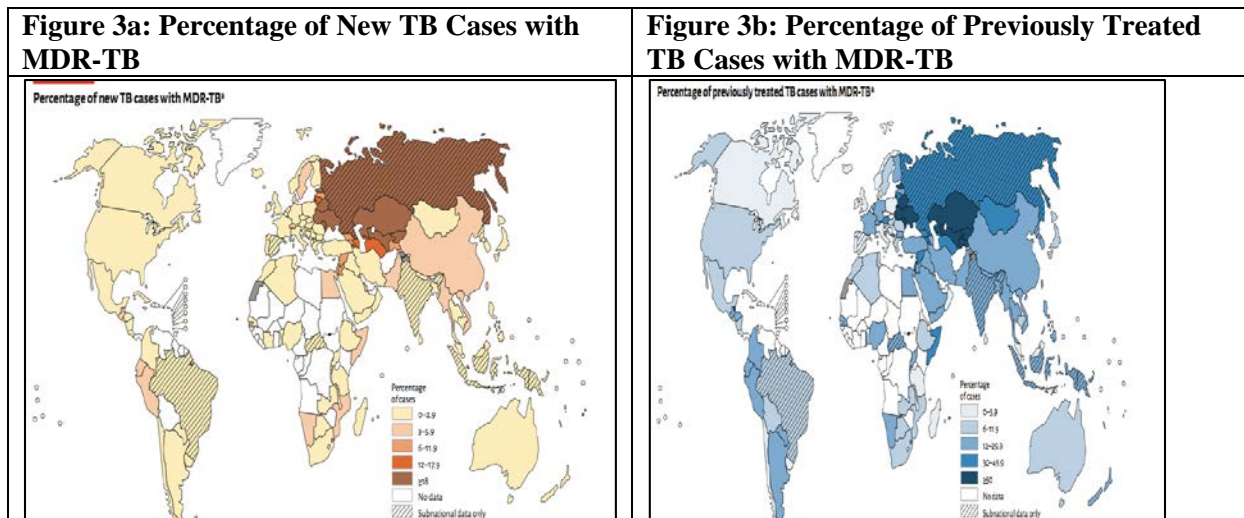
3. *Within the past two years, major strides have been made to improve estimates of the true burden of TB.* Many countries in Africa, including Malawi and Zambia, have conducted TB prevalence surveys, which provide more reliable and comprehensive estimates of the true TB burden than case notification data, which rely on weak surveillance systems. The prevalence surveys completed in Malawi and Zambia between October 2014 and August 2015 found that more than 50 percent of actual TB cases are not being diagnosed and reported in national notification statistics. These missing cases are a major concern and an impediment to effective TB

control. As can be seen in Figure 2, the incidence reported to the World Health Organization (WHO) based on case notifications to national TB programs (light blue bars) is generally lower than the true number of cases based on the recent national prevalence surveys (red bars). The situation is broadly similar in Mozambique where only an estimated 39 percent of actual TB cases are diagnosed and reported annually. The two main reasons why a significant number of cases are being missed are: (i) patients not seeking care; and (ii) weak capacity of health systems to diagnose TB cases in a timely manner. In order to diagnose and treat the actual TB cases in these countries, countries need to adopt a combination of measures, including behavior change interventions to raise awareness on TB, strengthened surveillance; better quantification of underreporting (i.e. the number of cases that are missed by surveillance systems); enhanced sputum collection and processing systems; and improved general access to quality health care, so that once diagnosed, patients can receive treatment.

Figure 2: Prevalence per 1,000 Population (log scale)



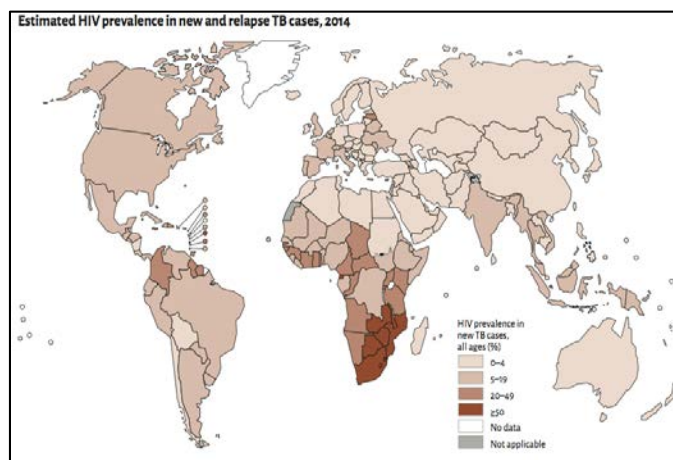
4. ***Multidrug-resistant TB represents a growing problem both globally and regionally, reflecting poor adherence to basic TB treatment.*** Globally, an estimated 480,000 people developed MDR-TB, of whom 3.3 percent are new TB cases and 20 percent represent previously treated cases; and roughly 190,000 died of MDR-TB (2014, Figures 3a and 3b). Most MDR-TB cases are in India, the Russian Federation, and the former Soviet republics. While estimates of MDR-TB in Sub-Saharan Africa are not available, there are growing concerns with drug resistance in many countries. In the participating countries, an estimated 3-6 percent of newly diagnosed TB patients and 7-10 percent of patients who have discontinued treatment have been afflicted with MDR-TB.



5. **Treatment for MDR-TB is longer, requires more expensive drugs, and has higher levels of toxicity and side effects.** Treatment can take up to 24 months in comparison with six months for drug-sensitive TB; and costs per patient are US\$5,000-10,000 against US\$100-500 for drug-susceptible TB. Treatment success rates are relatively low (i.e. less than 50 percent) as patients struggle to cope with the medical, financial, and social impediments associated with treatment.

6. **High rates of TB/HIV coinfection reflect the historical nature of the dual epidemic on the continent.** The HIV epidemic of the 1980s and 1990s set off a chain reaction that sent TB rates spiking to unprecedented levels. HIV prevalence rates in the participating countries are among the highest in the world, ranging from 10 percent in Malawi to 23 percent in Lesotho. Once infected with HIV, a person is 20 to 30 times more likely to develop active TB. TB/HIV coinfection rates are relatively high, ranging from 52-54 percent in Mozambique and Malawi; 61 percent in Zambia; and 72 percent in Lesotho. TB remains the leading cause of death among people living with HIV in Africa.

Figure 4: Estimated HIV Prevalence in New and Relapse TB cases, 2014



TB in Mining

7. ***The historical patterns of migration in the subregion, from labor-sending countries to South Africa, underscore the regional nature of the problem and the need for coordinated, collective action.*** There are 500,000 miners working in South Africa's mines, and an estimated 3 million ex-miners in South Africa, Mozambique, Lesotho, and Swaziland. The mining sector in Southern Africa has skyrocketing rates of TB infection (Box 1). TB also adversely affects mining communities and labor-sending zones domestically and in neighboring countries. The risk of transmission of TB to other household members and to the mining and source communities is high.

8. ***Miners are one of the most vulnerable groups that need to be targeted by TB control programs, in line with the new global TB strategy (90-90-90).*** The myriad issues that miners face in their daily lives increase the likelihood that they will develop active TB. Many migrant miners live in single-sex company-owned compounds or hostels built as barracks supplied by the mining companies with *severe crowding* (16 men per room) and *poor ventilation*, facilitating transmission of TB. Once they develop TB, *continuity and completion of treatment* have proven to be extremely problematic among migrant miners. For those migrating across borders, from Lesotho or Mozambique into South Africa, *entitlement to free TB medications* is problematic as they are foreign nationals. They return to their own countries ill, begin treatment and their health improves, but as mining remains one of the better jobs available, they return to the mines before completing treatment and work until they become ill once again, setting in place a vicious cycle of infection, reinfection, and transmission. For miners traveling within Zambia, although they are entitled to continue both anti-TB treatment as well as antiretroviral therapy (ART), there is no mechanism for medical records or medications transfer from one province to another. Furthermore, *stigma* is rampant in many countries, and in Zambia, the acknowledgment of having TB as a miner leads to *job termination* and prohibition of future employment, as legislation remains outdated.

9. ***Many miners are also at risk of HIV/AIDS and face difficulties in remaining compliant with AIDS treatment.*** Most miners have no families on site so commercial sex workers have been brought in to the mining sites. As a result, and because miners earn higher incomes, an active sex industry has arisen in the areas surrounding the South African mines. Although there are no data on HIV prevalence among miners with TB, the high rates of TB/HIV coinfection in all participating countries are broadly similar for miners facing multiple risks. As with TB treatment, although miners from Lesotho and Mozambique are started on ART in their own countries, the treatment is not available to them in South Africa and they often discontinue or interrupt treatment with risks of increased HIV transmission, and emergence of drug resistance.

Box 1: Tuberculosis in Mining Communities

Mozambique: Nearly 70,000 workers migrate annually to South Africa's gold mines.⁶⁷ Although the adult HIV prevalence rate in Mozambique is approximately 11.5 percent, in the two provinces from which most miners are recruited, the prevalence rates are dramatically higher (i.e. 20 and 25 percent in Maputo and Gaza, respectively). TB has increased rapidly in both provinces in the past 15 years, with 75 percent of TB patients co-infected with HIV, compared with 58 percent nationwide.⁶⁸ The International Organization for Migration estimated that the cost to Mozambique of migration-related health spending was US\$800 million.

Lesotho: Lesotho has the highest TB incidence in the world, the second-highest HIV coinfection rate of adult TB cases in the world, as well as one of the highest MDR-TB rates. Lesotho has sent massive numbers of migrant workers into South African mines during the past century but these numbers have dropped significantly in recent years. During the 1980s and 1990s, according to The Employment Bureau of Africa Limited (TEBA), nearly 100,000 men from Lesotho worked as miners in the South African gold mines. As of 2012, this number was estimated at 35,000. There are also an estimated 2,300 miners working domestically. While the actual number of miners from Lesotho working in the South African gold mines may be higher, it is clear that these individuals and their families are at greater risk of both TB and HIV. Given their high levels of mobility and the limited coordination among countries, there are concerns with both missing cases and adherence to treatment.

Zambia: The Zambian mining sector is disproportionately hit by the incidence of TB as well. While Lusaka province, once regarded as Zambia's TB hub, has seen important drops in TB prevalence, the traditional mining provinces continue to lag behind significantly. The Copperbelt province now has the highest TB prevalence in the country. The transportation corridor and other urban areas also have significantly high TB rates.

Malawi: The nascent mining sector in Malawi presents an opportunity to intervene early and establish necessary systems and services to manage the burden of disease from mining. However, Malawi has ex-miners and active miners who worked in Zimbabwe and South Africa. Preliminary analysis of MDR-TB cases shows that at least 50 percent of drug-resistant cases in Malawi can be traced to South Africa. Just like regional peers, Malawi has a high TB-HIV coinfection rate, which makes its TB burden complex to manage.

Occupational Health

10. ***Silica dust is a significant risk factor to contracting TB.*** Silica dust produced by gold mining in particular is a facilitator of the TB bacillus and enhances the ability of the bacillus to

⁶⁷ Approximately 34,000 active migrant mine workers are recruited by TEBA, and an additional 34,000 are recruited by smaller brokers (Barwise et al. 2013. *Int J health Serv* 43:699-719; and CDC Maputo).

⁶⁸ Provincial Health Offices, Maputo and Gaza Provinces, Mozambique 2012; WHO TB Report 2013.

establish infection and disease in the lungs, even without fully developed silicosis.⁶⁹ One of the more compelling studies attempted to quantify dust exposure by occupational category within the mining industry and documented that drillers and winchers had statistically significant higher rates of TB than other miners.⁷⁰ While there is little which can be done to improve ventilation in deep narrow shafts, *control of silica dust* levels may contribute to decreased TB incidence, as documented in several studies that have demonstrated the efficacy of dust reduction in reducing TB rates among exposed workers.⁷¹

11. ***Given the huge social and economic implications of occupational diseases for individuals, their families, and their communities, there is significant value in addressing occupational health systematically to ensure that the economic benefits of mining are not eroded.*** In the subregion, respirable dust levels—an underlying cause of occupational lung diseases—are well documented to be relatively high in the mines. This issue is further compounded by the lack of capacity to monitor a growing artisanal and small-scale mining (ASM) industry. While ASM contributes to poverty alleviation by creating job opportunities, certain types of ASM practices involve higher levels of exposure to silica dust.

12. ***The gold mining industry has a poor track record of compliance with health and safety standards relating to the prevention of exposure to silica dust.*** Moreover, the current *outdated legal levels of silica dust* in mines ($0.1\text{mg}/\text{m}^3$) are derived from ineffective recommendations that do not prevent the development of the disease.⁷² There are several ways to accomplish a reduction, including exhaust ventilation and diluting contaminated air with uncontaminated air. Given the significantly increased risk of contracting TB once one has developed actual silicosis, reducing silica dust levels would reduce silicosis and thereby cut TB even further.

13. ***Trends in silicosis in gold miners at autopsy provide additional evidence of the inadequate efforts of the mines to control dust and prevent occupational respiratory disease.*** In an autopsy study of miners in South Africa between 1975 and 2007, the proportions of white and black gold-mine workers with silicosis increased from 18 to 22 percent and from 3 to 32 percent, respectively. Cases of diamond and platinum miners with asbestos-related diseases and silicosis, respectively, were also identified. The two case series of diamond and platinum mine workers contribute to the evidence for the risk of asbestos-related diseases in diamond mine workers and silicosis in platinum mine workers, respectively. The *absence of reliable environmental dust measurements* and *incomplete work history records* impede occupational health monitoring and care in all participating countries.

14. ***Most policies and regulatory instruments governing occupational health and safety regulation in mining in the participating countries for this project—Lesotho, Mozambique,***

⁶⁹ There is ample literature on this connection in the occupational health and industrial hygiene journals, but it largely focuses on macro-epidemiologic relationships. (Reid et al. *Occup. Environ. Med.* 53:11-16, 1996; Hnizdo and Murray, *Occup. Environ. Med.* 55:496-502, 1998; Churchyard et al. *Occup. Environ. Med.* 61:811-16, 2004.)

⁷⁰ Tewatermaude, JM. et al. *Occup. Environ. Med.* 63:187-92, 2006.

⁷¹ In a 1937 publication from South Africa, a progressive fall in average dust levels coincided with a drop in the incidence of TB, and a cohort study of Vermont (United States) granite workers showed that the reduction of dust levels over time was effective in eliminating TB in this population.

⁷² The American Conference of Governmental Industrial Hygienists, for example, recommends that silica dust levels in mines be reduced to $0.025\text{mg}/\text{m}^3$ as a way of preventing over-exposure.

Malawi, and Zambia—are outdated and urgently need to be updated in line with international conventions and protocols as well as international best practices. Most of the countries are not signatories to core ILO Conventions on Occupational Safety and Health. The few countries that have ratified them have not translated them into national policies, legislation, and standards. For example, Zambia became a member of the ILO in 1964 immediately after independence. The country has ratified 39 ILO conventions; however, within the context of health and safety, it has only ratified the Safety and Health in Mines Convention of 1995. It has not ratified the main conventions relating to occupational safety and health. In Lesotho, compensation for TB and other occupational lung diseases has not been reviewed in over 15 years. Moreover, some of the countries have regressive laws on TB and the mining sector that discourage health-seeking behavior. For instance, in Zambia, the Workmen’s Compensation Act, 1999 provides for the termination of employment for any miner diagnosed with pulmonary TB. Thus few miners report for screening out of fear of losing their jobs if diagnosed with TB.

15. ***South Africa’s occupational health and safety policies directly affect migrant workers from labor-sending areas—Lesotho, Malawi, and Mozambique.*** For example, the law requires miners who exit South African mines to undergo post-employment screening every other year. Those who have a compensable occupational disease are eligible for compensation. The key challenge associated with this is that these services are only available in South Africa and miners are expected to travel to South Africa for post-employment screening and to access their compensation. For many ex-miners the journey to South Africa—especially when suffering from TB and related occupational diseases—poses an undue burden, including creating concerns about the financial resources to cover the journey and length of stay. This has typically been one of the barriers impeding ex-miners—who worked in the South African mining sector—from complying with the law.

16. ***There are limited activities and measures in the participating countries to assist miners with preventing occupational lung diseases,*** including silicosis, chronic lung disease and respiratory failure even without silicosis, and the multiple forms of cancer associated with long years of mineral mining. Although Zambia has a long tradition of occupational safety and health because of its copper mining history, even in Zambia standards of mine dust control, prevention of dust inhalation, monitoring and evaluation of miners who become ill, and provision of adequate compensation need to be improved. In the other three countries, these systems are virtually nonexistent and need to be established.

17. ***The combination of human, equipment, and financial constraints make it difficult to provide comprehensive occupational health services to the mining workforce within and across borders.*** These constraints also affect the scope and coverage of services. In both established and emerging producer countries, services are centralized, often located in major mining communities or capital cities, which poses a problem for ex-miners living in remote areas.

18. ***Certain demand-side barriers limit the use of occupational health services by miners and ex-miners, including: stigma; cultural beliefs; risk of wage reduction; contract termination; and for migrant workers, forced repatriation.*** In Lesotho, qualitative evidence confirms that when some miners do not want families to know of their medical condition, they often interrupt their treatment, thereby increasing incidence of drug resistance. Routine supply-side efforts to

strengthen traditional health systems do not fully address personal behavioral or corporate practices, impeding diagnosis and treatment.

Diagnostics and Laboratory Capacity

19. ***The basic microscopy capacity for diagnosing drug sensitive TB needs to be expanded and strengthened in all participating countries.*** While all countries have networks of health facilities that perform sputum-smear microscopy, the geographic coverage is insufficient and the quality of these services needs to be improved through more intensive training of laboratory personnel and enhanced provision of reagents and supplies.

20. ***New molecular technologies for diagnosing HIV-related TB and drug-resistant TB need to be scaled up to enhance accuracy of testing and to improve coverage.*** All countries are beginning to take advantage of the rapid, more sensitive molecular tests that pick up cases missed by smear microscopy.⁷³ For example, the increasingly popular Gene Xpert technology identifies TB's genetic material and will be positive even when far fewer TB bacteria are present. Gene Xpert can also identify TB bacilli that are resistant to rifampicin. It is relatively expensive in comparison to smear microscopy but has become increasingly necessary to deal with more complex TB cases and is available at pre-negotiated prices for all participating countries. Utilization of the Gene Xpert technology has been on the rise globally and regionally, including in the participating countries. Much more needs to be done to take advantage of this new technology, particularly to reach remote districts and vulnerable groups.⁷⁴

21. ***For cases identified as drug resistant by the newer molecular methods, there is a need to ensure there is capacity to perform culture methods in line with WHO recommendations.*** The reason this is critical is that treatment will vary depending on how many and which drugs the TB bacillus is resistant to. If culture and sensitivity are not performed, and treatment of resistant TB is guessed at, extensively drug-resistant TB (XDR-TB) may be created, and this remains largely untreatable and fatal.

22. ***Quality laboratory systems need to be put in place and replicated more widely in order to ensure the quality and accuracy of testing, and ultimately contribute to clinical care and improved disease outbreak capacity.*** A number of laboratories in the participating countries have been enrolled in the *Stepwise Laboratory Improvement Process Towards Accreditation* (SLIPTA) with support of other partners. The SLIPTA process has proven to be an effective tool for measuring the performance of laboratories and identifying gaps; instilling a culture of continual quality improvements; and tracking and benchmarking performance within and across countries. The companion training program—*Strengthening Laboratory Management Towards Accreditation* (SLAMTA)—has been used effectively in several of the participating countries, to provide hands-on training and support to laboratory personnel. Both SLIPTA and SLAMTA have not yet become widespread in the participating countries. Likewise, there has been a shortage of

⁷³ These molecular tests are critical for patients with advanced HIV disease, who often develop active TB with far fewer bacteria in their lungs so that there are not enough organisms to show up on a sputum microscopy smear.

⁷⁴ The use of GeneXpert has expanded substantially since 2010, when WHO first recommended its use. In all, 4.8 million test cartridges were procured in 2014 by 116 low- and middle-income countries at concessional prices, up from 550,000 in 2011. By 2015, 69 percent of countries recommended using this technology as the initial diagnostic test for people at risk of MDR-TB.

mentors, who are critical for the hands on training. Greater collaboration with the African Society for Laboratory Medicine (ASLM) and other technical partners is needed to scale up mentorship, introduce regular SLIPTA audits, and mainstream the SLAMTA process.

ANNEX 6: WORLD BANK GROUP REGIONAL PROJECT VALUE ADDED TO CURRENT RELATED FUNDING STREAMS

1. The proposed project will complement ongoing investments by the World Bank and from other development partners supporting country responses to their TB/HIV co-epidemics. The Bank’s regional project will ensure coordination between regional and national initiatives, both at technical and governance levels, to avoid duplication of efforts, and strengthen synergies in order to maximize impact for clients. The Bank’s comparative advantage in institutional and systems strengthening, innovation, brokering partnerships with regional institutions, policy dialogue and analytic work across multiple sectors will contribute significantly to the efforts to address the burden of TB in the subregion. Table 1 outlines Bank support in the participating countries as well as from other major donors supporting anti-TB/HIV measures.

Table 1

Funding Source	Countries Covered	Strategic Focus	Objectives	Funding Amount	WBG Regional Project Value Proposition
World Bank: Southern Africa TB and Health Systems Strengthening Project (P155658)	Lesotho, Malawi, Mozambique, and Zambia	Aims to advance implementation of the subregion’s End TB Strategy through strengthening the health sector response to TB and implementing strategic, selective multisectoral activities to enhance impact. Finances a targeted approach in line with the 90-90-90 TB targets (90 percent of vulnerable groups screened; 90 percent	(i) Improve coverage and quality of TB control and occupational lung disease services in targeted geographic areas of the participating countries; and (ii) Strengthen regional capacity to manage the burden of TB and occupational diseases.	US\$122 million. Project will span 2016-2021	Building on the Bank’s comparative advantage in institutional and systems strengthening, supporting innovations, brokering partnerships with regional institutions, policy dialogue, and multisectoral approaches to disease control and analytic work, the regional project will support countries in the subregion to tackle TB while strengthening critical dimensions of health systems, including laboratory surveillance and diagnostic capacity, cross-border

Funding Source	Countries Covered	Strategic Focus	Objectives	Funding Amount	WBG Regional Project Value Proposition
		<p>diagnosed and started on treatment; and 90 percent treatment success) approach focusing on vulnerable populations, including those in the mining sector.</p> <p>The WB regional project has a broader focus that harmonizes with individual country, policy and epidemiological contexts.</p>			<p>surveillance, and human resources for health.</p> <p>In line with the Bank’s approach to multisectoral disease control, the regional project will support selected high-impact, multisectoral interventions in mining and labor to maximize impact.</p> <p>The project will complement other existing subregional resources—Development Grant Fund (DGF), Global Fund and country-specific WB health projects—in the participating countries. Overall, the WB regional project will build on analytic work and some innovations supported by the DGF, such as the one stop service center pilots for integrated occupational health services.</p> <p>Given limited resources from the Bank’s DGF and from the Global Fund grant for TB in the mining sector, the Bank</p>
<p>Global Fund: TB in the mining sector regional grant for Southern Africa</p> <p>Supranational Reference Laboratory Grant</p>	<p>Lesotho, Mozambique, Zambia, Namibia, South Africa, Malawi, Botswana, Zimbabwe, Tanzania and Swaziland</p>	<p><i>Focuses on the mining sector</i> and funds regional interventions that cannot be implemented by one country.</p> <p>Examples of innovations: the Global Fund grant for TB in the mining sector will include development of databases and cross-border patient referral</p>	<p>(i) Increase TB case notification through TB screening and active case finding among key target population. (ii) Improve treatment success rate through ensuring treatment adherence among the key populations on TB treatment.</p>	<p>US\$30 million in 2 years. Project spans 2015-2017 (approximately US\$1.5 million per year per country)</p>	<p>Given limited resources from the Bank’s DGF and from the Global Fund grant for TB in the mining sector, the Bank</p>

Funding Source	Countries Covered	Strategic Focus	Objectives	Funding Amount	WBG Regional Project Value Proposition
		<p>systems for miners. The second Global Fund grant to operationalize the Uganda <i>TB Supranational Reference Laboratory</i> (SRL) will be fully compatible with the Bank regional project, which will support countries to acquire specialized technical services and support from the SRL.</p>	<p>(iii) Increase proportion of key population with TB who are tested for HIV and enrolled for anti-retroviral therapy.</p>		<p>regional project will scale up promising pilot TB prevention activities initiated under the Global Fund grant in the participating countries where the two overlap.</p> <p>The Global Fund grant to strengthen the regional reference lab for TB in Uganda complements investments to strengthen regional diagnostic and laboratory-based surveillance capacity in the subregion. Economies of scale will be achieved in countries like Lesotho that work directly with the Uganda Supranational Reference Laboratory.</p>
DGF	Lesotho, Swaziland, Mozambique, and South Africa	The project initiates harmonized subregional action to address TB in the mining sector.	<p>(i) Strengthen partnerships to tackle TB in miners, ex-miners, local mining communities and labor supply areas in Southern Africa</p> <p>(ii) Improve TB treatment outcomes in selected hotspots in two countries</p> <p>(iii) Improve access to occupational health services in a selected labor-sending area</p>	US\$6 million, project spans 2014-2017	<p>The Bank regional project will strengthen capacity of key institutions to monitor, track and enforce mine dust control levels and strengthen disease monitoring, sample specimen transportation systems and use of performance-based financing mechanisms. Moreover, the “center for</p>

Funding Source	Countries Covered	Strategic Focus	Objectives	Funding Amount	WBG Regional Project Value Proposition
Global Fund: Investing for Impact Against Tuberculosis and HIV	Lesotho			US\$62.15; spans 2016-2018	excellence” approach will enable the subregion to generate best practices for TB control while learning from each other.
PEPFAR: HIV Treatment and Prevention (COP 14)	Lesotho		<ul style="list-style-type: none"> • HIV prevention focused on treatment retention & TB/HIV coinfection • Scaling up HIV testing and counseling, VMMC, and PMTCT • HMIS, SCM, HIV/AIDS surveillance, & laboratory systems 	US\$32.4 million; spans 2014-2016	
World Bank: HIV and AIDS Technical Assistance Project (P107375)	Lesotho	Health systems strengthening decentralization, HIV/AIDS	Build capacity of government agencies and civil society organizations at national and local levels to address the identified key gaps in implementing the National HIV and	US\$5 million, project spans 2009-2016	

Funding Source	Countries Covered	Strategic Focus	Objectives	Funding Amount	WBG Regional Project Value Proposition
			AIDS Strategic Plan in an effort to contain and reverse the epidemic.		
Global Fund: Toward TB/HIV Epidemic Control in Malawi: Bringing Innovations to Scale	Malawi			US\$285.2 million	
PEPFAR: HIV Treatment and Prevention COP 14	Malawi		<ul style="list-style-type: none"> • HIV treatment, care and support with focus on TB/HIV coinfection in urban areas • Strengthening health systems, including HRH • MCH-HIV/AIDS services 	US\$80 million	
World Bank: Nutrition and HIV/AIDS Project (P125237)	Malawi	Project themes include: Population and Reproductive Health; Nutrition and Food Security; Child Health; and HIV/AIDS	Increase access to and utilization of selected services known to: contribute to the reduction of child stunting and	US\$80 million; project spans 2012-2017.	

Funding Source	Countries Covered	Strategic Focus	Objectives	Funding Amount	WBG Regional Project Value Proposition
			maternal and child anemia; and prevent HIV and AIDS in children and sexually active adults.		
World Bank: Mining Governance and Growth Support Project (P120825)	Malawi		To improve the efficiency, transparency and sustainability of mining sector management	US\$28.2 million (US\$25 million IDA plus US\$3.2 million EU); spans 2011-2016	
Global Fund: Investing for Impact Against TB and HIV	Mozambique		Increase TB and MDR-TB case detection, improve treatment outcomes, provide universal integrated TB/HIV care to co-infected patients	US\$40.8 million; spans 2015-2017	
World Bank: Health Service Delivery (P099930)	Mozambique	Project themes include: Health System Performance; Child Health; Population and Reproductive Health; HIV/AIDS; and Malaria.	Increase access to and utilization of maternal and child health and nutrition services in target areas in the Recipient's territory.	US\$81.6 million; spans 2009-2016	
World Bank: Mining and Gas Technical	Mozambique		To strengthen the capacity and governance systems	US\$57.8 million (US\$50 million IDA)	

Funding Source	Countries Covered	Strategic Focus	Objectives	Funding Amount	WBG Regional Project Value Proposition
Assistance Project (P129847)			of key institutions to manage the mining and hydrocarbon sectors in Mozambique.	plus US\$7.8 DFID TF); spans 2013-2020	
USAID: Eradicate TB	Zambia	Based on the TB Strategic plan, DOTS Expansion and enhancement, TB/HIV collaborative activities, Programmatic management of drug-resistant TB and community social mobilization	Support the National TB Control Program in implementing the End TB strategy in Selected districts in six Provinces in Zambia	US\$19-25 million; spans 2015-2020	
Global Fund: CCM Country Grant: Joint TB/HIV Concept Note	Zambia	Strengthen TB/HIV activities, drug and medical commodity SCM and M&E	Enhance and strengthen TB/HIV activities and strengthen the Programmatic Management of Drug-Resistant TB	US\$14.5 million; spans 2015-2017	
World Bank: Health Services Improvement Project (P145335)	Zambia	Project themes include: Population and Reproductive Health; Health System Strengthening; Child Health; and Communicable Diseases	Improve health delivery systems and utilization of maternal, newborn and child health and nutrition services in project areas.	US\$52 million; spans 2014-2019	

ANNEX 7: ECONOMIC AND FINANCIAL ANALYSIS

1. This project focuses on strengthening tuberculosis (TB) control in four Southern African countries: Lesotho, Malawi, Mozambique, and Zambia. It is being designed at a time when TB is ranked as a leading cause of disease in Africa, particularly in the four targeted countries. For example, at 528 incident cases per 100,000 people, TB cases in the participating countries are almost twice (88 percent) the African average of 281 cases for every 100,000 people (WHO 2015a). And despite the progress that has been made in TB control in these participating countries, the annual rates of reduction are insufficient to meet all the three 2015 targets for reductions in TB disease burden (incidence, prevalence, and mortality). As a result of the high prevalence and incidence of TB in the participating countries, the burden of disease attributable to TB is among the leading causes of years of life lost. For instance in 2013, TB was the second-highest cause of years of life lost in Lesotho, fifth in Malawi and Mozambique, and sixth in Zambia. Compounding the problem are the co-epidemics of TB and HIV, poor diagnosis of TB and HIV, drug-resistant TB, exposure to TB and other occupational diseases in the mines, and ineffective mechanisms to address in-country and multicountry dimensions of TB in the mining sector.

Project Development Impact

2. The overall project objectives are: (i) to improve coverage and quality of TB control and occupational lung disease services in targeted geographic areas of the participating countries; and (ii) strengthen regional capacity to manage the burden of TB and occupational diseases. The project aims to target underserved populations with a high TB and/or TB/HIV burden, including mining communities, transport corridors, and cross-border areas. While the main focus of the proposed project is on strengthening the health sector response to TB, there will be selective support for joint multisectoral activities to enhance the overall impact. The main project components are: (i) prevention, detection, and treatment of TB; (ii) strengthening of regional capacity for enhanced disease surveillance, diagnostics and management of TB and occupational lung diseases; and (iii) strengthening of learning, knowledge sharing, and innovation at national and regional levels.

3. Though the components are similar across the participating countries, each country is expected to adapt the design to its own context by: (i) identifying priority geographic areas and vulnerable groups; (ii) scaling up interventions which have shown promising results; and (iii) proposing innovative activities that can be rigorously evaluated with the potential for scale up. Activities that will be supported will be strategic and selective, with a keen eye on sustainability. Therefore, the proposed project will contribute to economic development in the targeted countries through reduced morbidity and mortality that will translate into: (i) decreased health costs associated with TB treatment for the various governments, mining companies and other employers, communities, and family members; (ii) increased labor productivity and, therefore, an increase in revenue for mining companies and other employers; and (iii) steady income for the family of mine workers and others, which could be forfeited during illness or death. By focusing on the most disadvantaged populations within the countries, the project will also promote shared prosperity and equity.

4. The project will contribute to the reduction of morbidity and mortality by increasing access to and utilization of TB control services especially in mining areas, peri-mining areas, and high-burden regions of the targeted countries. As highlighted in the Global End TB Strategy (2015-2035), the international community has developed targets for TB prevention, care, and control, which includes epidemic-ending approaches through an increased focus on local strategies such as systematic reporting of every case and identification of disease clusters or hotspots (WHO 2015d). In the targeted participating countries, we estimated that 41 percent of new TB cases are undiagnosed (missed) and, therefore, one of the main key interventions in the proposed project will be to improve case detection in order to increase the number and quality of treatment. This will be achieved through a variety of methods including the use of community-based interventions targeted at households, miners, and ex-miners. A study in Tanzania found that community-based interventions contributed to the identification of 38–70 percent new smear-positive cases (Colvin et al. 2014).

5. The project will invest in strengthening regional and national health systems to prepare them to better manage a complex burden of TB, HIV/AIDS, and other occupational lung diseases. As such, the project prioritizes three key health systems areas critical for communicable disease control: (i) diagnostic capacity; (ii) human resources for health to improve the quality of patient care and treatment outcomes; and (iii) information systems to enable better patient care. With a mass of trained health workers, a good information system, and state-of-the-art diagnostic equipment, the project will be in a position to strengthen disease surveillance. For instance, large-scale rollout of the Xpert MTB/RIF rapid diagnostic technology for TB as recommended by the World Health Organization (WHO) is one of the cost-effective interventions that will be implemented under the project. One study shows that Xpert MTB/RIF is a more cost-effective method of TB diagnosis than a base case of smear microscopy and clinical diagnosis of smear-negative TB in low- and middle-income settings (Vassall et al. 2011). The incremental cost-effectiveness ratio (ICER) for using Xpert MTB/RIF “as a replacement of” smear-microscopy ranges from US\$52 to US\$138 per disability-adjusted life year (DALY) averted (ibid). This ICER is below the WHO willingness to pay threshold (ibid).

6. The project will contribute to saving health care costs related to disease treatment by focusing on cost-effective measures such as DOTS and save on the socioeconomic burden related to the extra care necessary for TB patients. Studies show that over 90 percent of TB cases can be cured with proper monitoring and high adherence to taking the full course of medicines with reductions in deaths of about 60–70 percent (Vassall, n.d.). In the targeted participating countries we estimated the current DOTS treatment success rate at 83 percent on average, implying that there is room for further improvement. Treating TB is highly cost effective, as observed by Goodchild et al. (2011) who examined the economic costs and benefits of scaling up TB control in India between 1997 and 2006. They concluded that scaling up TB control resulted in a total health benefit of 29 million DALYs over the 10-year period, and 1.3 million deaths were averted. The overall increase in economic well-being was valued at US\$88 billion for the 10 years, and each dollar spent generated US\$115 worth of benefits. Laxminarayan et al. (2007) estimate the cost of TB control in high-burden TB countries in Africa at US\$7.70 billion over the period 2006-2015, compared to the economic benefit of US\$81.06 billion. Furthermore, approximately one-seventh of the total global economic benefits of sustained DOTS programs accrue to the high-burden countries in Africa.

7. Reducing the burden of TB in the mining sector will bring significant long-term economic benefits to the targeted countries by increasing the active and productive labor force that can potentially contribute to economic growth and poverty eradication. The project will have a dual focus: (i) addressing the burden of TB and TB-HIV/AIDS associated with cross-border migrant population; and (ii) supporting countries to develop systems to improve occupational health and safety services in the domestic mining sector, which includes large and small-scale artisanal mining. By addressing factors fueling TB infections in the mines and labor-sending areas in the participating countries, economic growth would be guaranteed through export earnings from mining activities and transfer payments. Mine workers in Southern Africa generally have a higher risk of contracting TB than the general population and studies show that about 33 percent of TB infections in southern Africa are attributable to the mining industry. Addressing TB in the mining sector can significantly reduce economic and social losses as shown by a study in South Africa, which concluded that every US\$1 invested in the universal testing and treatment of TB in the mining sector yields more than US\$12 in economic benefits within South Africa and labor-sending countries (Laxminarayan et al. 2015). These benefits include savings from reduced expenditure on treatment due to new cases averted, productivity gains from healthier mine workers, and other economic benefits due to reduced early mortality associated with TB. Under the Global Plan, reaching the 90-90-90 global targets using the accelerated scenario yields a return of US\$85 for each dollar invested (Stop TB Partnership 2015).

8. Besides affecting health, TB leads to income loss which forces many people deeper into poverty. The burden of TB is generally associated with the poor and this makes it a major public health concern. By focusing on the most disadvantaged populations within the countries, this project will facilitate financial risk protection by reducing the incidence of catastrophic health expenditure among TB patients. Lonroth et al. (2014) show that high direct and indirect costs of care for TB patients limits access to treatment leading to poor TB treatment outcomes, unrelenting TB transmission, and exacerbated poverty. This is confirmed by another study which found that 77 percent of TB patients were from households with a per capita income of less than US\$1 per day while the average cost to the patient of being treated for TB was US\$145—around 50 percent of the annual per capita income (Pantoja et al. 2009). A systematic review of the financial burden⁷⁵ of TB faced by patients and affected families further shows that the mean total costs⁷⁶ range from US\$55 to US\$8,198 across 40 studies which had been conducted in low- and middle-income countries, with an unweighted average of US\$847 and a median of US\$379 (Tanimura et al. 2014). Furthermore, total TB costs on average, are equivalent to 58 percent and 39 percent of reported annual individual and household incomes, respectively; 60 percent of these costs usually lead to income loss, particularly among poor people and those with multidrug-resistant TB who incur a higher cost as a percentage of their income. Coping mechanisms include selling of household items and taking a loan (ibid). Considering that the total cost of TB can be catastrophic, health care services should minimize financial risk while at the same time provide suitable income replacement and other social protection interventions (Lonroth et al. 2014; Tanimura et al. 2014).

⁷⁵ The financial burden varied widely between individuals within and across different settings. This suggests that the burden is determined by a number of factors which includes socioeconomic status, clinical needs, health system structure, TB service delivery model, distance to health services, insurance coverage, capacity to work, and existence of formal and informal social support networks.

⁷⁶ The costs include direct medical costs (20 percent) direct non-medical costs (20 percent), and income loss (60 percent).

9. This project will promote equity and shared prosperity by targeting geographic areas with high burden of TB in the participating countries to address service utilization barriers which have traditionally hindered TB prevention and treatment outcomes. The selection criteria were based on: (i) mining/peri-mining regions; (ii) underserved populations with a high burden of TB; (iii) high incidence of poverty and TB; (iv) high incidence of TB-HIV and of MDR-TB; (v) cross-border areas and transportation corridors; (vi) labor-sending areas; and (vii) areas with weak laboratory networks.

10. The project will facilitate improvements in technical and allocative efficiency by rolling out a harmonized package of services for TB prevention, control, and treatment in line with the post-2015 global TB strategy and the SADC Declaration on TB. The harmonized package will improve access to high-impact but cost-effective services across the participating countries, and this package will be delivered using both input-based and results-based financing mechanisms. This will include use of both supply- and demand-side interventions to strengthen basic health systems and promote regional-level accountability aimed at increasing the ability of the participating countries in managing the complex TB epidemic and associated diseases. This will improve technical efficiency by pushing implementing units closer to the highest production possibilities frontier, where they will be able to deliver better quality services at the least cost. On the other hand, allocative efficiency will be improved by allocating resources to where marginal benefits and utility are highest by focusing on geographic areas and underserved populations.

Cost-benefit Analysis for the Project

11. A cost-benefit analysis was conducted focusing on selected benefits to determine whether the expected benefits outweigh the costs of the project. To estimate the benefits, life years (LYs) rather than quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs) were used. This means that the analysis only takes care of mortality and does not consider the quality of life of patients living with TB that can be measured through QALYs and DALYs. Furthermore, the analysis does not take into consideration the Copenhagen consensus approach to assigning a monetary value of economic benefits to DALYs. LYs saved rather than QALYs and DALYs were chosen because: (i) LYs saved is a transparent method for measuring population health and there are few value choices involved; and (ii) QALYs and DALYs are complex metrics which are much harder to measure and track over time. They require definition and assignment of weights to take into account the Health-Related Quality of Life (HRQoL) after the intervention. For the TB project, which will support the implementation of various interventions in several geographic areas in participating different countries, the process of defining and assigning HRQoLs was difficult due to varying interpretations and subjectivity. Our emphasis on mortality is also justified by empirical evidence, which shows that the burden of disability and suffering captured in a DALY is relatively smaller than mortality in low-income countries (Jha et al. 2015).

12. The analysis uses population data (some of which are presented in Table 1), incidence per 100,000 population, number of reported TB cases, age distribution of TB cases, missed cases, and number of deaths for both HIV negative and positive TB cases. Using age-distributed data was key in quantifying TB cases according to the target population and in-depth analysis of trends in mortality, deaths averted, and other measures by different age groups.

Table 1: Number of beneficiaries in targeted areas in each country⁷⁷

Province	Population	Incidence per 100,000 Population	No. reported TB cases	Age distribution of TB cases				Missed cases	TB- related deaths all ages
				Children 0-14 years	15-44 years	45-64 years	≥ 65 years		
Lesotho	1,894,194	852	9,854	525	6,266	2,330	734	147	3,125
Malawi	6,701,989	227	9,726	1,264	6,322	1,653	486	25,661	11,058
Mozambique	6,109,549	551	18,404	2,945	11,042	3,681	736	13,854	10,081
Zambia	5,649,002	482	25,752	1,817	18,327	4,415	1,193	4,075	9,321
TOTAL	20,354,734	528	63,736	6,551	41,957	12,079	3,149	43,737	33,585

Data Sources: National TB Programs and Statistics Offices – Lesotho, Malawi, Mozambique, Zambia; 2015 Global TB Report.

13. As shown in Table 1, the targeted population in the project areas of Lesotho, Malawi, Mozambique, and Zambia is estimated at 20,354,734. The incidence is 528 cases per 100,000 people while the reported number of TB cases (excluding MDR and XDR TB) is 63,736. The number of missed TB cases and deaths are estimated at 43,737 and 33,585, respectively. To calculate the costs and expected benefits from the project, a number of assumptions and empirical evidence were used to estimate the effect on TB morbidity and mortality across the different age groups. This includes the prevalence of TB-HIV coinfection, MDR and XDR TB; and case detection and treatment rates, days lost at work, and wage information. The assumptions are as follows:

- The percentage of TB cases coinfecting with HIV across the participating countries was 60 percent. Applying this percentage shows 38,082 HIV coinfecting TB cases among reported TB cases, and 26,133 among the missed cases. If left untreated, 45 percent of the infected TB cases who are HIV-negative would die and 100 percent of those who are HIV positive would die (WHO 2015c);
- The targeted DOTS treatment success rate by the end of the project is 90 percent. This is based on empirical studies that show that over 90 percent of TB cases can be cured with proper monitoring and high adherence to taking the full course of medicines with reductions in deaths of about 60–70 percent (Vassall 2014). Thus, it is assumed that the proposed project will lead to an extra decline of mortality (Table 2) in addition to the counterfactual decline over time;
- MDR TB rate (as percentage of total TB) is estimated at 1.9 percent; XDR TB rate (as percentage of MDR TB) at 9.7 percent; and missed MDR TB at 75 percent (WHO 2015b);
- Successful MDR treatment is estimated at 50 percent; and successful treatment of XDR at 26 percent (WHO 2015b);
- Increase in case detection due to use of Xpert MTB/RIF is estimated at 19 percent (Vassall et al. 2011), and GeneXpert by 30 percent (UNITAID 2014);
- Work days lost before and after treatment are estimated at 48 and 35, respectively. This is derived from Rajeswari et al. (1999) who found that 83 work days are lost due to TB in

⁷⁷ Population covers the project intervention areas. The number of TB cases exclude MDR and XDR-TB. TB deaths include both HIV negative and positive TB patients.

India. Of these 83 days, 48 precede treatment while 35 days are lost after the treatment is started; and

- The minimum wage per day is estimated at US\$3.6. This is an average of the minimum wages in the participating countries. Minimum wages were used so that the worker and the cost of living could be captured. Average wages, medium wages, or wages in the mining sectors from each of the participating countries could also have been used but we found minimum wages more conservative and welfare reflective. GDP per capita in each of the participating countries is presented in Figure 2.

Table 2: Predicted impact on case detection, and income gained from mortality averted and previously untreated cases

Current cases - All forms of TB	Number
Current reported cases of normal TB	63,736
No. MDR TB cases	1,179
No. XDR TB cases	114
New MDR cases found due to GeneXpert	354
Total current reported cases - all forms of TB	65,383
No. of deaths in current reported cases - all forms of TB, pre-intervention	33,585
Total MDR TB deaths, pre-intervention	766
Total XDR TB deaths, pre-intervention	85
Total normal TB deaths (less MDR and XDR), pre-intervention	32,734
Normal TB deaths averted after intervention at 90% treatment success	29,461
MDR and XDR TB deaths averted after intervention, at 50% and 26% treatment success, respectively	405
Total TB deaths averted from current cases - All forms of TB	29,866
New cases - All forms of TB	
Missed normal TB cases	43,737
Increase in TB notifications due to use of Xpert MTB/RIF, GeneXpert	8,091
MDR TB cases	150
Increase in detection of MDR TB due to GeneXpert	45
XDR TB cases	15
Total - New cases (All forms of TB)	52,037
No. of normal TB deaths HIV-positive, pre-intervention	26,133
No. of normal TB deaths HIV-negative, pre-intervention	19,682
Total normal TB deaths (less MDR and XDR), pre-intervention	45,815
Total MDR TB deaths, pre-intervention	97
Total XDR TB deaths, pre-intervention	11
Total TB deaths, pre-intervention	45,923
Normal TB deaths averted after intervention at 90% treatment success	41,233

MDR and XDR TB deaths averted after intervention, at 50% and 26% treatment success, respectively	51
Total TB deaths averted from new cases - All forms of TB	41,284
Mortality averted due to intervention (current plus new cases)	
All age groups	71,151
No. adult, working age, 15-44	46,204
Income gain from mortality averted, 15-44 (US\$)	60,885,487
No. adult, working age, 45-64	13,836
Income gain from mortality averted, 45-64 (US\$)	18,232,542
Wage gained from previously untreated cases	
Workdays lost due to being sick	48
No. adults not treated	60,040
Wages that would otherwise have been lost (US\$)	10,404,563

14. Using the assumptions above, we calculated the benefits of the proposed TB project in terms of deaths averted from both reported and missed cases to come up with the income gained from mortality averted and previously untreated cases (Table 2). Deaths averted are the difference between the deaths pre-intervention and deaths after intervention, all other things being equal, assuming a treatment success rate of 90 percent for normal TB cases, and 50 percent and 26 percent for MDR and XDR TB, respectively. Among the currently reported 65,383 cases of TB (all forms) in the participating countries, the deaths without the intervention are 33,585 but 29,866 of the deaths would be averted after the intervention. Since the project will use intensified diagnosis and treatment of all forms of TB including latent TB for those living with HIV, MDR-TB, and XDR-TB, a total of 52,037 new TB cases (all forms) will be recorded. For the 52,037 new TB cases, the deaths without the intervention are 45,923 but 41,284 of the deaths would be averted after the intervention. The total number of TB-related deaths that will be averted (current plus new cases) due to the project interventions is 71,151.

15. To calculate income gained, we use only the productive age group of 15-44 years over a period of 15 years starting in year 3. We apply a minimum wage loss of US\$3.6 per day, as discussed above. The income gained from mortality averted in the 15-44 age group is US\$61 million a year. This is a conservative approach as income gain from mortality averted in the 45-64 age group could also have been included. The number of adults among missed cases who would not have been treated without the intervention are likely to be severely morbid. We assume a loss of 48 work days for this group at US\$3.6 per day. The wages gained which should otherwise have been lost is US\$10.4 million per year. This is calculated for the first two years before the treatment is initiated (year 0 and year 1).

16. The overall economic analysis for the regional TB project (Table 3) shows high benefits relative to costs. The total present value of benefits is estimated at US\$776.1 million while the present value of cost based on expected disbursements is estimated at US\$111.7 million, giving a net present value of benefits of US\$664.4 million. Therefore, the benefit-cost ratio is estimated at 6.95:1 which implies that for every US\$1 invested through the project, there is a yield of US\$6.95. The present value of the benefits and costs are calculated at a 3 percent discount rate, the standard

rate used in cost-benefit analysis in the health sector (WHO, 2003). The analysis uses a five-year time frame that is consistent with the project implementation period. However, understanding that investments in human development produce long-term economic benefit, it is assumed that income gains from lives saved in the 15-44 age group start accruing from the age of 18, for 15 years. It should also be understood that costs and benefits represent total entities and not incremental benefits of TB control from baseline.

Table 3: Cost-benefit analysis results

	Benefit/ Cost US\$	2015	2016	2017	2018	2019	2020
<i>Discounting years</i>		0	1	2	3	4	5
Income gains from lives saved, 15-44 age group (income accrues from age 18 for 15 years)							
Income gain from deaths averted					60,885,487	60,885,487	60,885,487
Discount factor		1.00	0.97	0.94	0.92	0.89	0.86
Discounted stream of income gains					55,718,845	54,095,966	52,520,356
PV benefits - Income gains from lives saved (US\$) (A)	755,608,946						
Income gains from wages loss averted							
Wage loss averted		10,404,563	10,404,563				
Discount factor		1.00	0.97				
Discounted stream		10,404,563	10,101,517				
PV benefits - Income gains from wage loss averted (US\$) (B)	20,506,080						
Total PV benefits due to project interventions (US\$) (A+B)	776,115,025⁷⁸						
Monetary costs							
Project cost (US\$)	122,000,000		24,400,000	24,400,000	24,400,000	24,400,000	24,400,000
Discount factor			0.97	0.94	0.92	0.89	0.86
PV of cost (US\$)	111,744,855		23,689,320	22,999,340	22,329,456	21,679,084	21,047,654
Net present value	664,370,170						
Benefit-cost ratio	6.95						

Note: The table only shows the analysis over a five-year time frame that is consistent with the project implementation period. However, benefits are expected to accrue over 15 years.

17. Considering that the project will use intensified diagnosis and treatment of all forms of TB including latent TB for those living with HIV and MDR-TB, it is presumed that this project will be very beneficial but the estimated benefit-cost ratio of 6.95:1 seems to have been underestimated.

⁷⁸The total PV of benefits (US\$776,115,025) is a summation of the discounted stream of income gains from lives saved which start accruing after 3 years of project investments, for a period of 15 years; and income gains from wage loss averted for the first two years before the treatment is initiated (year 0 and year 1). This is with an understanding that investments in human development produces long term economic benefit which take time to start accruing benefits. Table 3 only shows partial analysis for a five-year time frame that is consistent with the project implementation period. The full discounted stream of income gains for the 15 years period is not fully shown in the table.

For example, Vassall (2014) show that the benefit-cost ratio for diagnosis and treatment of TB based on current screening practices is in the range of 11-192:1. With additional investments in intensified diagnosis and treatment, the benefit-cost ratio can be higher. Very conservative assumptions were used to estimate the impact of this regional TB project leading to underestimation of the total economic and social benefits. For example, only minimum wages were used while economic benefits of increased life-years of saved children before they become active in the labor force are not included. In addition, income gained from deaths averted in the 45-64 age group are not included.

18. Furthermore, welfare gains from reduced poverty or improved equity are not included even though the relationship between TB and poverty is well established. TB deaths averted can contribute to restoring physical capacity to work, while the costs of seeking and accessing care during illness can be reduced. The analysis also assumes that there are no new advances in TB diagnosis and treatment. However, during the duration of the TB project, new technologies may be discovered (such as a vaccine) which could further shorten diagnosis and treatment with positive benefits. On the other hand, the analysis may have underestimated the costs of strengthening and expanding TB services through a broader health systems approach. Most studies used in the analysis tackle TB control interventions from a disease perspective but rapid scale-up of TB control may require broader health system investments. Many other benefits are also excluded because they cannot be measured or translated to monetary value easily, e.g. efficiency improvement. Therefore, the result of this analysis should be interpreted as an underestimation of the return of this project given the fact that it does not include all expected benefits.

19. Though the values of the variables used to calculate the benefit-cost ratio were based on the most probable forecast, these variables can be influenced by a number of factors during project implementation. Therefore, a sensitivity analysis (Table 4), was used to assess the risks that the project may face during its tenure. The first step was to identifying variables that could influence the project's aggregate costs and net benefits. Sensitivity tests were then conducted on a range of individual parameters that are critical to the project, and quantifying the effects of variations on the project's costs and benefits, and ultimately on the benefit-cost ratio. Based on a one-way sensitivity analysis, the model was sensitive to variations in the following parameters on morbidity, coverage, costs, and benefits: (i) discount rate; (ii) DOTS treatment success rate; (iii) TB incidence rate per 100,000 population; (iv) TB cases in the 15-44 age group; (v) project costs (funding); and (vi) minimum vs average wages. The sensitivity tests show strong benefits relative to costs of the overall TB project, and that project objectives will still be achieved if certain assumptions do not, or only partly, occur. The large economic benefits (benefit-cost ratios ranging from 1.75-11.90:1) are mainly due to the value of life lost, using the plausible assumption that each death averted provides considerable welfare gains (discounted at either 3 percent or 5 percent).

Table 4: One-way sensitivity analysis on variations on morbidity, coverage, costs, and benefits

Variable/Scenario	Mortality averted, 15-44 age group	Cost/benefit ratio at 3% discount rate	Cost/benefit ratio at 5% discount rate
1. 90% DOTS treatment success rate (most probable and preferred outcome)	46,204	6.95	6.09
2. No change in DOTS treatment success rate	41,919	6.30	5.52
3. Incidence at half of current value (264 per 100,000)	13,265	1.99	1.75
4. Incidence at 50% more than the current value (792 per 100,000)	79,143	11.90	10.42
5. TB cases in 15-44 age group at 22% (one third of current value)	15,653	2.38	2.09
6. 50% increase in project costs (funding)	46,204	4.63	4.06
7. Minimum wage at US\$1.25 per day		6.83	5.96
8. Average wage for low income economies in SSA (US\$12.27 per day)		7.39	6.55

Rationale for Working with the Public Sector and Value-Added of Bank's Support

20. The project will use a multisectoral approach in order to have greater impact on TB control programs in the targeted countries. Previous initiatives to address TB in the region have not been effective in reducing the burden of TB as they did not consider the multisectoral and multicountry dimension of TB in mining areas, peri-mining areas and high-burden regions of the targeted countries. A multicountry focus enables economies of scale especially in specialized areas that would otherwise be costly for individual low-income countries. Key areas where economies of scale will be achieved include: (i) expertise and resources for the management of MDR-TB; (ii) development of supranational laboratory capacity to manage TB and provide continued training in laboratory management; (iii) training of new and in-service health personnel to further strengthen knowledge and skills; and (iv) delivery of a standardized package of occupational health services and safety standards.

21. In each of the targeted countries, the project will primarily be implemented through the public sector, because evidence shows that the public sector is the main source of health care for the majority of people in these countries. However, studies show that early diagnosis and treatment of TB can be much more effective through a public-private mix. Thus the project will take stock of opportunities for public-private partnerships (PPPs) in TB control by: (i) supporting a study on private sector involvement in TB control in Sub-Saharan Africa; (ii) training private practitioners in TB diagnosis and management; and (iii) consulting with policy makers and partners to reach agreement on the main elements of a PPP in TB control.

22. The Bank is particularly suited to implement this project given its comparative advantage in institutional and systems strengthening, innovation, brokering partnerships with development partners and

regional institutions, policy dialogue and analytic work across multiple sectors. For example, the World Bank Group has experience in managing regional projects in the health sector such as the East Africa public health laboratory project, the regional public–private African programme for onchocerciasis control program in West Africa covering 19 countries, and the Lubombo spatial development initiative in Southeast Africa. For the proposed regional TB project, the Bank will be supported by a team from two Global Practices (Energy and Extractives and Poverty), the IFC, and the Centre for Disease Control. Furthermore, the project will complement ongoing investments by the World Bank and other development partners on TB/HIV and the health sector as a whole (Annex 6). Through the Bank’s diverse network, this regional TB project will benefit from holistic regional and national collaboration at technical and policy levels to achieve the desired impact.

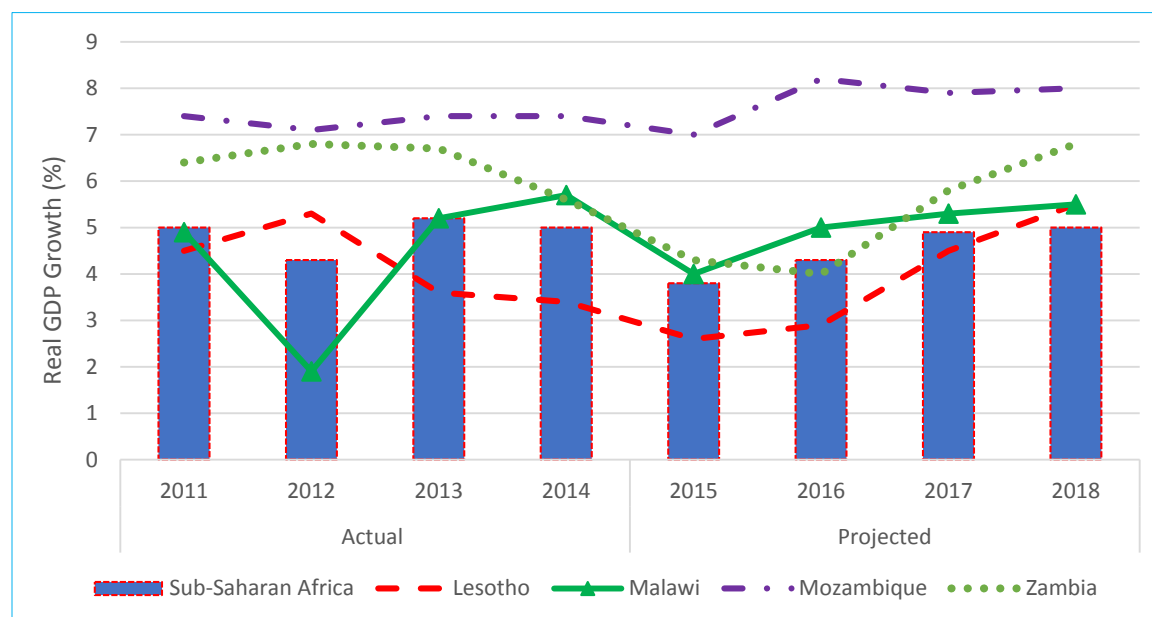
Financial Sustainability Analysis

Economic growth outlook

23. According to World Bank projections, economic growth in Sub-Saharan Africa countries is predicted to drop to 3.7 percent in 2015 from 4.6 percent in 2014 (World Bank 2015). The decline is a combination of global and domestic factors including a drastic drop in the commodity prices for oil, copper, and iron ore; a slowdown of the Chinese economy; and tightening global financial conditions (World Bank 2015). On the domestic front, fiscal imbalances have been worsened by rising wage bills, large expenditure on infrastructure and subsidies, adverse weather, electricity deficits, and depreciation in most resource-dependent currencies, which has in turn exposed economies to inflation through imported inputs and consumables (ibid). Financing fiscal deficits by borrowing from the domestic and international markets in countries such as Malawi and Zambia has also contributed to huge increases in debt-to-GDP ratios.

24. Despite the negative economic outlook highlighted above, overall growth for Sub-Saharan Africa in the medium term is expected to rebound to 4.3 percent in 2016 and improve further to 5 percent in 2017, albeit with mixed recovery across countries due to domestic factors. For example, among the targeted countries in the TB project, medium-term growth recovery is expected to be much quicker in Malawi and Mozambique, but by the end of 2018 it is expected that economic growth in all the participating countries will be above the Sub-Saharan Africa average of 5 percent (Figure 1).

Figure 1: Economic Growth in Project Countries and Sub-Saharan Africa



Source: World Economic Outlook available from <http://www.imf.org/external/datamapper/index.php>

Financial sustainability analysis

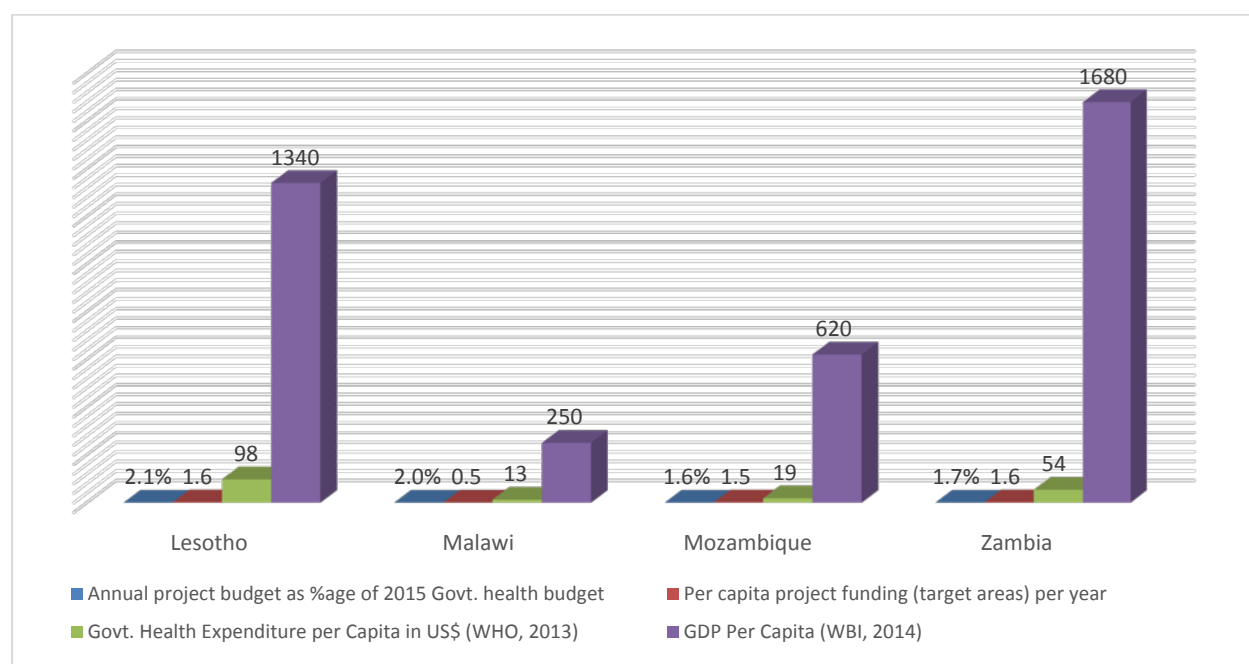
25. A financial sustainability analysis was conducted to determine the ability of the recipient countries to sustain the project when it comes to an end. The was done by analyzing the total project investment of US\$122 million over a period of five years in relation to the GDP per capita and annual government (domestic) health budgets (Figure 2). The results show that the annual project budget as a percentage of the 2015 government (domestic) health budget in each of the participating countries ranged from 1.6 percent to 2.1 percent. Further analysis also show that the per capita project funding (target areas) per year which ranged from US\$0.5 to US\$1.6 was below the annual government (domestic) budget per capita and the GDP per capita which ranged from US\$13 to US\$98 and from US\$250 to US\$1,680, respectively. Furthermore, while the level of GDP per capita has an influence on the cost of TB treatment, WHO (2015a) suggests that the size of the total patient caseload is also an important factor. For example, in all of the 22 high-burden countries, the cost per patient treated for drug-susceptible TB was less than the GDP per capita, which implies that economies of scale can be realized when large numbers of patients are treated (ibid).

26. The above assumptions are very conservative considering that the government health budgets in the targeted countries have been growing each year over the past decade. Between 2011 and 2015, the nominal government domestic health budget grew by 71 percent on average: 1 percent in Lesotho, 25 percent in Malawi, 46 percent in Zambia, and 213 percent in Mozambique. General government health expenditure as a proportion of general government expenditure was estimated at 8-19 percent on average over 2011-2013⁷⁹ in the four countries. Our expectation is

⁷⁹ WHO, Global Health Expenditure Database. 2011-2013 period averages are: 8 percent Mozambique, 13 percent Zambia, 14 percent Lesotho, and 19 percent Malawi.

that government health expenditure will rise with increased GDP growth. For example, in Zambia, empirical evidence⁸⁰ shows that for a 1 percent increase in GDP, government health expenditure grew by 2.3 percent during 2009-2012. Therefore, in each country, the annual project financing as a proportion of the total government (domestic) budget for health is expected to diminish over time as government (domestic) financing increases. However, while general government health expenditure is expected to grow, there is no guarantee that some of the extra financial resources will be allocated to the TB programs in the four recipient countries. Our analysis finds very low prioritization of the TB program from domestic resources in the four countries. Therefore, the governments have to address the situation in order to reduce reliance on donor support for the TB program, and to enable the project's benefits to be sustained.

Figure 2: Project Financing vs. Historical Government Budgets



Data sources: National Health Budgets, World Bank NHP Project Data, WHO Global Health Expenditure Database, World Bank Development Indicators

Apart from financial sustainability, the project design allows for institutional and impact sustainability. This is because the project will make use of existing structures such as the national TB programs, local and regional experts, and government financial and procurement systems in each of the participating countries. This will make it possible for the participating countries' governments to maintain and scale up project activities within the prevailing institutions and resource environment after the project expires. Furthermore, by strengthening regional capacities for disease surveillance, diagnostics, and management of TB and occupational lung diseases, it is

⁸⁰ Chansa C., C. Chama, and E.V. Velenyi. 2015. Zambia Health Sector Mid-term Review Health Financing Thematic Report.

envisaged that the project will have lasting impact. Therefore, all expectations of sustainability (financial, institutional, and impact) will be addressed in the project.

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ANNEX 8: FIDUCIARY ISSUES

1. This annex summarizes the outcome of financial management and procurement assessments of regional organizations and national-level agencies involved in the implementation of the project.

A. Financial Management

Financial Management, Disbursement, and Procurement

2. A Financial Management (FM) assessment was conducted on the FM arrangements for the Southern Africa Tuberculosis and Health Systems Support Project. The assessment was done on the coordinating implementing entities at national level, which are the Ministries of Health in Lesotho (using a PIU known as the Project Accounting Unit [PAU]), Malawi and Mozambique (both using a PIU), Zambia, as well as two regional-level institutions, which are NPCA of NEPAD and ECSA-HC—which will be the RCO.

3. The objective of the assessment was to determine whether the implementing entities have acceptable financial management arrangements in place that satisfy the Bank's Operation Policy/Bank Procedure (OP/BP) 10.00. These arrangements would ensure that the implementing entities: (i) use project funds only for the intended purposes in an efficient and economical way; (ii) prepare accurate and reliable accounts as well as timely periodic interim financial reports (IFRs); (iii) safeguard assets of the project; and (iv) have acceptable auditing arrangements. The FM assessment was carried out in accordance with the Financial Management Manual for World Bank Investment Project Financing Operations that became effective on March 1, 2010 but was issued (retrofitted) on February 4, 2015.

Institutional and Implementation Arrangements

4. Component 1 will have its implementation coordinated by the Ministry of Health (MOH) in the participating countries (Lesotho, Malawi, Mozambique, and Zambia). Other sub-implementing entities that will implement the project under the coordination of MOH are the ministries responsible for mines and labor.⁸¹ These three ministries (health, mines, and labor) will form an inter-ministerial National Technical Committee that will, among other activities, approve work plans and budgets for the project. The other sub-implementing entities will include NGOs and private institutions that are competitively selected and will operate under performance-based agreements to strengthen accountability with the MOH. Under component 1, community health workers affiliated to the health facilities will be contracted to perform their duties under the project. The Project Implementation Manual (PIM) should ensure that these workers are properly identified with identification cards preferably with their biometrics captured, and they should be paid through a formal system either through their bank account or using a mobile money system (where there is a reliable registration system of mobile numbers in the country). The accounting officers for

⁸¹ *Lesotho*: Ministry of Mining; and Ministry of Labor and Employment; *Malawi*: Ministry of Natural Resources, Energy and Mining; and the Ministry of Labor and Manpower Development; *Mozambique*: Ministry of Mineral Resources and Energy; and the Ministry of Labor, Employment and Social Security; *Zambia*: Ministry of Mines, Energy and Water Development; and the Occupational Health and Safety Institute.

component 1, whose implementation is coordinated by the MOH, will be the Principal Secretary (Lesotho and Malawi) and the Permanent Secretary (Mozambique and Zambia).

5. Components 2 and 3 will be implemented by participating countries, NPCA, whose accounting officer will be its Chief Executive Officer, and by ECSA-HC, whose accounting officer will be its Director General. NPCA will remit its work plans to ECSA-HC for consolidation in its capacity as the RCO. ECSA-HC has a membership of 10 countries that include Lesotho, Malawi, and Zambia. Mozambique is not a member and in order to ensure effective implementation of the project with ECSA-HC, both parties will have a Memorandum of Understanding that includes having acceptable FM arrangements.

6. The MOHs of the four countries, ECSA-HC, and NPCA will be responsible for maintaining satisfactory FM arrangements throughout the life of the project. These institutions will constitute the operational links with the World Bank (IDA) on matters related to the implementation of the project.

Budgeting Arrangements

7. The ECSA-HC, NPCA, and the MOHs will prepare annual budgets based on their work plans and thereafter submit them to the Bank at least two months before the beginning of the project's fiscal year. The budgets will follow budgeting guidelines in the respective entity's FM Manual and PIM. The details of each entity's FM Manual are in Table 1. Implementing entities under component 1 (ministries of mines and labor in the participating countries, NGOs, health facilities, etc.) will submit their budgets to the MOHs for consolidation. All budgets should be approved before the financial year they relate to begins. During the financial year, budgets will be monitored on a quarterly basis using IFRs. The IFRs will compare the budget and actual expenditure, and significant variances will need to be explained. These IFRs will be expected to be submitted within 45 days after the end of the calendar quarterly period to the Bank.

Accounting Arrangements

8. **Accounting Policies and Procedures.** These are adequate for ECSA-HC, NPCA, and the MOHs in Lesotho, Mozambique, and Zambia. The PIU in the MOH of Malawi will need to prepare an FM Manual for the project that documents the accounting policies and procedures that will be used. This FM Manual will be part of the PIM. The PIM will also be prepared by all the other implementing entities as it will cover any gaps in their manuals/regulations to ensure that project FM arrangements are in line with the Financing Agreement. The FM Manuals to be used are outlined in Table 1.

9. **Accounting Staff.** ECSA-HC and NPCA have adequate accounting staff. The following needs to be done to strengthen accounting-staff arrangements in the MOHs:

- **Mozambique:** The MOH needs to maintain the current accounting staff in the PIU in order to have adequate accounting staff for this project.
- **Lesotho:** The PAU of the MOH will need to recruit a Project Accountant before effectiveness using the Project Preparation Advance (PPA) in order to account for project funds.

- **Malawi:** The MOH PIU needs to recruit a qualified and experienced Project Accountant before effectiveness using the PPA and a second accountant within three months after effectiveness (dated covenant).
- **Zambia:** The MOH needs to assign a qualified and experienced accountant among its current staff to account for the project funds and this will need to be done by sending a letter to the Bank confirming the assigned accountant before the project becomes effective. Should this not be possible, the MOH will need to recruit a qualified and experienced accountant using the PPA.
- **ECSA-HC:** It needs to recruit an additional Finance Officer who will account for the project funds within three months after effectiveness. This is because the workload of the current staff will not enable them to effectively provide accountability related to the project.

All accounting staff will, where necessary, be trained in World Bank FM and Disbursement guidelines.

10. **Accounting Information Systems.** These are adequate for ECSA-HC, NPCA, and the MOHs in Lesotho and Mozambique. The MOH PIU in Malawi will need to acquire an accounting information system using the PPA. In Zambia, the MOH is using the Integrated Financial Management Information System (IFMIS), but its project module is not functional and leads to delays in preparing financial statements, as noted in the Auditor General’s Report for December 31, 2013. While the Government of Zambia addresses these challenges, this project will use Microsoft Excel to prepare its accounts or the NAVISION accounting software, which was used previously, and will need to be activated and used to prepare the project’s accounts.

11. **Accounting Standards.** ECSA-HC, NPCA, and the MOHs will use International Public Sector Accounting Standards to prepare the project’s accounts.

12. **Accounting Basis:** ECSA-HC and the MOHs will use the cash basis⁸² of accounting while NPCA will use the accrual basis.⁸³

⁸² The cash basis recognizes transactions and events only when cash (including cash equivalents) are received or paid by the entity. Financial statements prepared under the cash basis provide information about the sources of cash raised during the period, the purposes for which cash was used, and the cash balance at the reporting date.

⁸³ Under the accrual basis, transactions and other events are recognized when they occur (and not only when cash or its equivalent is received or paid). Therefore, the transactions and events are recorded in the accounting records and recognized in the financial statements of the periods to which they relate. The elements recognized under accrual accounting are assets, liabilities, net assets/equity, revenues, and expenses.

Table 1: Accounting Arrangements

Institution	Accounting Staff	FM Manual	Accounting Information System
RCO: ECSA-HC	The Directorate of Finance has six qualified and experienced accounting staff who are adequate for the project, considering their other duties.	Financial Rules and Procedures Manual (2013)	Advanced Accounting Version 7
NPCA	The FM Unit led by a Head of Finance supported by Senior Finance Officers will be adequate for the project.	Financial Procedures Manual	SAP ERP
Lesotho: MOH (using PAU)	The PAU needs to recruit two accounting staff to prepare accounts for the project in order to have adequate staffing.	The PAU internal control framework (combines government policies and procedures and PIM to be developed) that manages all donor funded projects in the MOH.	TOMPRO
Malawi: MOH (using PIU)	The PIU needs to recruit two accounting staff to prepare accounts for the project in order to have adequate staffing.	The PIU will need to prepare an FM Manual agreeable to the Bank as part of the PIM to document accounting policies and procedures to be used for the project.	The MOH is using an IFMIS that has very weak internal controls that need to be addressed. The PIU will need to acquire an accounting information system to be used for this project.
Mozambique: MOH aka MISAU (using PIU)	MISAU Finance Department staff are adequate to account for the project's funds.	MISAU Internal Control and Procedures Manual complemented by the Manual of Financial Administration issued by the Ministry of Economy and Finance.	MISAU is using e-SISTAFE.
Zambia: MOH	To have adequate staff for this project, MOH should assign one accountant from its existing staff or recruit an accountant.	Finance Act 2004 and Financial Regulations 2006.	The MOH is using IFMIS but the project module is not functional. As the government improves the system, MOH will use Excel or the previously used NAVISION accounting software.

Internal Control and Internal Audit Arrangements

13. **Internal Controls:** The internal control procedures will be documented in the FM Manual (Table 1) for each of the implementing entities and their PIM, which will take into consideration gaps in their existing FM Manuals/Regulations to ensure that project FM arrangements are in line with the Financing Agreement. These will ensure that the project has an effective internal control system. A review of the internal control systems was conducted and the following was noted:

- **Zambia:** The MOH was last audited on December 31, 2014 and a number of accountability and internal control issues were raised that included: not following procurement guidelines; failure to produce activity reports; holding workshops without authority; unaccounted-for drugs and medical supplies; unaccounted-for store items with no receipts or disposal details in line with Public Stores Regulation No. 16; not identifying/marketing MOH assets; poor workmanship and incomplete works; failure to recover loans and advances; failure to dispose of obsolete equipment; failure to insure government buildings; misapplication of funds; payments for equipment not delivered; unaccounted staff advances and irregular payments of salary advance; and unsupported expenditure. While the MOH is working to address some of the findings of the audit, there will be need for a dedicated internal auditor to regularly monitor the internal control systems and to ensure they are functioning as planned. The internal audit will produce reports that will reflect whether action is being taken, which will be reviewed during the Bank's supervision of the project.
- **Malawi:** The MOH has a weak internal control environment with audit backlogs given that the last audit conducted was for the period ending June 30, 2012. Audit issues raised under the MOH included unsupported expenditure; weak authorization and approval of expenditure; and lack of registers for stock and fuel expenses. These issues will be mitigated by using the PIU to implement the project and ensuring it has robust accountability systems in place.
- **MOH (PAU) of Lesotho, MOH (PIU) of Mozambique, ECSA-HC, and NPCA:** No major internal control or accountability issues were noted.

14. **Internal Audit.** ECSA-HC, NPCA,⁸⁴ and MOH in Mozambique have adequate internal audit functions while those at the MOHs in Lesotho, Malawi, and Zambia are weak, as most of the projects are not audited. In Zambia, pre-audits of payment transactions are done instead of risk-based audits. Despite the ongoing reforms to strengthen internal audit in Lesotho and Zambia, it will be essential for each of the MOHs to recruit a qualified and experienced internal auditor for this project to monitor compliance with internal control and accountability systems put in place. The internal auditor will produce at least quarterly reports that shall be reviewed by the Bank during the supervision of the project. With regard to Malawi, the project will use the MOH internal auditor. Internal auditors in each of the implementing entities should ensure that the project's audit is included in their work plan and the audit conducted using a risk-based approach.

⁸⁴ NPCA being part of the African Union will use the internal auditors of the African Union Commission, who conduct audits at least semi-annually.

15. **Audit Committees.** ECSA-HC is using its Advisory Committee as its audit committee while MOH Mozambique is using the Department of Internal Control to conduct the role of an audit committee which is to follow up and ensure management is addressing issues raised in the external and internal audit reports. The MOH in Malawi has an independent audit committee made of non-governmental staff while in Zambia there is an audit committee but it is weak as it does not effectively follow up audit issues. This audit committee in Zambia will need training to conduct its role, which has been planned to be undertaken by the government (Ministry of Finance) under its Public Financial Management (PFM) reforms. At the MOH in Lesotho, there is no audit committee but there are ongoing PFM reforms supported by the African Development Bank, which should eventually establish the committee. In the interim, the National Technical Committee of Lesotho can as part of its duties add the role of being an audit committee of the project. This will mean that its staff will need to be trained. NPCA, as part of the African Union, will use the audit committee of the African Union Commission.

Governance and Anti-corruption arrangements

16. All implementing entities will use the World Bank Anti-Corruption Guidelines. FM arrangements will ensure that there are internal control systems in place and audits conducted to prevent and detect fraud and corruption. Transparency and accountability is highly encouraged by putting the project's budget and audited financial statements on the implementing entity's websites. Complaint-handling mechanisms should also be set up, especially by the MOHs, such that beneficiaries who are not receiving services as planned can have a mechanism to raise their complaints such that they are followed up and addressed. This will involve putting in place a system to record all complaints received, direct them to the responsible person to be addressed, and record when a response is sent to the complainant.

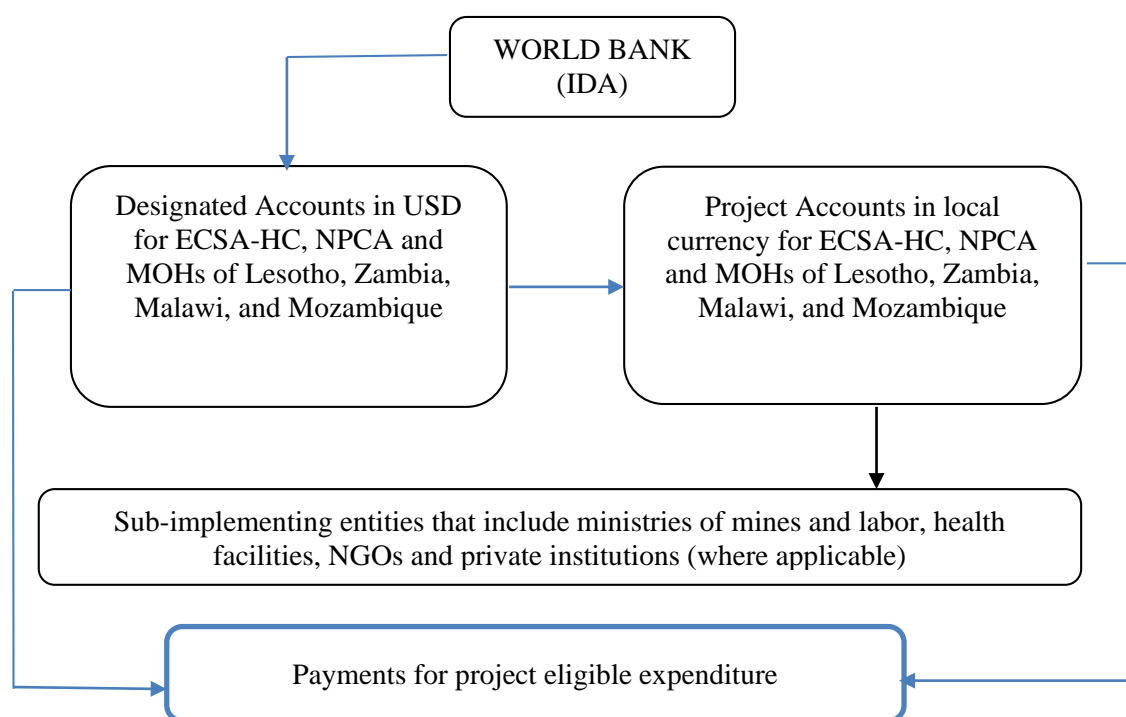
Funds Flow Arrangements

17. **Designated and Project Accounts.** ECSA-HC and NPCA will each have a pooled designated account from the four participating countries. The MOHs will have to open a Designated Account denominated in United States Dollars and a Project Account denominated in local currency. These will be maintained in either the central bank or a commercial bank acceptable to the Bank. The specific banking details for each implementing entity is shown in Table 2. The signatories to these accounts should be in line with the FM Manual of the implementing entities and they should be submitted to the Bank between the signing of the project and its effectiveness. Payments to eligible expenditure can be made from either the Designated or Project Accounts.

Table 2: Designated and Project Bank Accounts

Institution	Designated Account	Project Account
RCO: ECSA-HC	Commercial Bank (Standard Chartered)	Commercial Bank (Standard Chartered)
NPCA	Commercial Bank (Ned Bank)	Commercial Bank (Ned Bank)
Lesotho: MOH (PAU)	Central Bank (Central Bank of Lesotho)	Commercial Bank
Malawi: MOH (PIU)	Central Bank (Reserve Bank of Malawi)	Central Bank (Reserve Bank of Malawi)
Mozambique: MOH aka MISAU (PIU)	Central Bank (Bank of Mozambique)	Central Bank (Bank of Mozambique)
Zambia: MOH	Central Bank (Bank of Zambia)	MOH Project Operational Account held at Central Bank (Bank of Zambia) ⁸⁵

Figure 1: Funds Flow Diagram



Disbursements

18. ECSA-HC, NPCA, and the MOHs will access funding from the Bank using the report-based method of disbursement. Under this method, the first withdrawal applications should be

⁸⁵ Funds from the Designated Account to the MOH Project Operational Account will be transferred through the Control 99 (Treasury Account) and MOH Sub Control account, both in Zambia Kwacha currency. Payments made from the MOH Project Operational Account at the central bank will be made through the mirror account (zero balance) held at a commercial bank.

prepared within one month after project effectiveness supported with a six-month cash-flow projection based on agreed work plans. Subsequently, each implementing entity can access funds from the Bank on a calendar year quarterly basis by accounting for funds received using IFRs and submitting withdrawal applications with the next six-month cash flow projections. Other methods of disbursement that can be used by all the implementing entities include direct payments, reimbursements, and special commitments (letters of credit). If ineligible expenditures are found to have been made from the Designated and/or Project Accounts, the borrower may be obligated to refund the same. If the Designated Account remains inactive for more than six months, the Bank may reduce the amount advanced. The Bank will have the right, as reflected in the terms of the Financing Agreement, to suspend disbursement of the funds if significant conditions, including reporting requirements, are not complied with. Additional details regarding disbursement will be provided in the disbursement letters.

Financial Reporting Arrangements

19. ECSA-HC, NPCA, and the MOHs will prepare separate quarterly unaudited IFRs in form and content satisfactory to the Bank, which will be submitted to the Bank within 45 days after the end of the quarter to which they relate. The format and content of the IFR was agreed between the Bank and the national implementing entities during negotiations. The contents of the IFR for all implementing entities will include the following information to account for project funds:

- Statement of Sources and Uses of Funds;
- Statement of Uses of Funds by Project Activity/Component;
- Designated Account Activity Statement;
- Bank statements for both the Designated and Project Account and related bank reconciliation statements;
- Summary statement of Designated Account expenditures for contracts subject to prior review; and
- Summary statement of Designated Account expenditures not subject to prior review.

20. ECSA-HC, NPCA, and the MOHs will also prepare the project's annual financial statements within three months after the end of the accounting year in accordance with International Public Sector Accounting Standards. The financial statements will be required to be submitted to the Bank within six months after the end of the fiscal year.

External Audit Arrangements

21. The external audit of the project's funds that are implemented by the MOH of the four countries will be done by the Supreme Audit Institutions who can contract private audit firms acceptable to the Bank to conduct the audit on their behalf. ECSA-HC and NPCA will use private audit firms that are acceptable to the Bank. The cost of hiring a private audit firm will be met by the project. All audits should be carried out in accordance with International Standards on Auditing or International Standards for Supreme Audit Institutions issued by the International Organization for Supreme Audit Institutions. All external audit Terms of Reference for each implementing entity were agreed with the Bank during negotiations. The external auditors should be appointed within six months after effectiveness. Audit reports together with management letters should be submitted

to the World Bank within six months after the end of the government’s fiscal year with respect to the four countries and for ECSA-HC and NPCA, in accordance with their fiscal year. Audit reports will be publically disclosed by the World Bank Group in accordance with the Bank’s disclosure policy. A review of audit reports of each of the entities was done and, as documented under “Internal Controls” above, accountability and internal control issues in the MOHs of Malawi and Zambia need to be addressed.

Table 3: Financial Management Action Plan

Implementing Entity	Action	Responsibility	Due Date
All implementing entities	Agree on IFR Formats and External Audit Terms of Reference	ECSA-HC, NPCA, MOHs of Zambia, Malawi, Lesotho and Mozambique	Completed
Malawi	Prepare a Project Financial Management Manual that is acceptable to the Bank. This will be part of the PIM.	Malawi MOH (PIU)	By effectiveness using PPA
All implementing entities except Malawi	Prepare a PIM that is acceptable to the Bank. The PIM will address gaps in the existing FM Manuals to reflect project specific requirements.	ECSA-HC, NPCA, MOHs of Zambia, Lesotho and Mozambique	By effectiveness using PPA
Zambia	Designate/assign an accountant among existing staff to account for project funds by effectiveness or recruit an accountant by effectiveness.	Zambia MOH	By effectiveness using PPA (for recruitment)
Malawi	Recruit two qualified and experienced accountants. The first (Project Accountant) before effectiveness and the second within three months after effectiveness.	Malawi MOH (PIU)	The first by effectiveness using PPA and the second within three months after effectiveness
ECSA-HC	Recruit a qualified and experienced Finance Officer.	ECSA-HC	Within three months after effectiveness
Lesotho	Recruit a qualified and experienced Project Accountant.	Lesotho MOH (PAU)	By effectiveness using PPA
Malawi	Acquire a computerized accounting software and train staff of the MOH (PIU) to effectively use the software.	Malawi MOH (PIU)	Within three months after effectiveness
Zambia	Address project functionality concerns related to the IFMIS project module or activate the NAVISION accounting	Zambia MOH	Within six months after effectiveness

Implementing Entity	Action	Responsibility	Due Date
	software to account for project funds.		
Lesotho and Zambia	Recruit a qualified and experienced internal auditor to strengthen internal control systems.	Zambia MOH; and Lesotho MOH (PAU)	Within three months after effectiveness (use of PPA recommended)
ECSA and NPCA	Appoint an external auditor for the Project	ECSA-HC, NPCA	Within six months after effectiveness
Malawi and Zambia	Address internal control and accountability issues raised in the external audit reports of June 30, 2012 for Malawi and December 31, 2014 for Zambia (see “Internal Controls” section for details).	MOH of Malawi and Zambia	Monitored during project implementation
Zambia and Lesotho	Zambia: Government under PFM program to strengthen internal audit committee through training. Lesotho: Government to set up audit committees under PFM reforms such that MOH has this committee to follow up and ensure audit issues are addressed.	Zambia: MOH and Ministry of Finance Lesotho: Ministry of Finance	Monitored during project implementation
Malawi, Lesotho, Mozambique, and Zambia	Put in place a complaint-handling mechanisms to enhance service delivery.	Malawi MOH (PIU); Zambia MOH; Mozambique MOH (PIU) and Lesotho MOH (PAU)	Within six months after effectiveness

Financial Covenants

22. Financial covenants are the standard ones as stated in the Financing Agreement Schedule 2, Section II (B) on Financial Management, Financial Reports and Audits and Section 4.09 of the General Conditions.

Implementation Support Plan

23. Financial Management implementation support missions will be carried out twice a year for the four MOHs based on the substantial FM residual risk rating and once a year for ECSA-HC and NPCA based on the moderate FM residual risk rating. Implementation support will also include desk reviews such as the review of the IFRs and audit reports. The FM implementation support will be an integrated part of the project’s implementation reviews.

Conclusion

24. The conclusion of the assessment is that the financial management arrangements in place meet the World Bank's (IDA's) minimum requirements under OP/BP10.00, and therefore are adequate to provide, with reasonable assurance, accurate and timely information on the status of the project required by World Bank (IDA). The overall Financial Management residual risk rating is substantial for the MOHs (Zambia, Malawi, Lesotho, and Mozambique) and moderate for ECSA-HC and NPCA.

B. Procurement

25. For all four countries and ECSA-HC and NPCA, all procurement to be financed under the proposed project will be carried out in accordance with the World Bank's "Guidelines: Procurement under the International Bank for Reconstruction and Development (IBRD) Loans and IDA Credits" dated January 2011, revised July 2014 (Procurement Guidelines) and "Guidelines: Selection and Employment of Consultants by World Bank Borrowers" dated January 2011, revised July 2014 (Consultant Guidelines), as well as the provisions stipulated in the Legal Agreement. For international competitive bidding (ICB) and national competitive bidding (NCB), all procurement of goods, works, and non-consultant services will be done using the Bank's Standard Bidding Documents (SBDs). All consultant selection undertaken for firms will be done using the Bank's Standard Requests for Proposals. The project will also carry out implementation in accordance with the "Guidelines on Preventing and Combating Fraud and Corruption in Projects Financed by IBRD and IDA and Grants" dated October 15, 2006 and revised in January 2011 (the Anti-Corruption Guidelines).

ECSA-HC

26. **General.** Procurement activities under the project will be undertaken in accordance with the Guidelines: "Procurement of Goods, Works and Non Consulting Services under IBRD Loans and IDA Credits and Grants by World Bank Borrowers" dated January 2011, revised July 2014 (Procurement Guidelines); "Guidelines: Selection and Employment of Consultants under IBRD Loans and IDA Credits and Grants by World Bank Borrowers" dated January 2011, revised July 2014 (Consultant Guidelines); "Guidelines on Preventing and Combating Fraud and Corruption in Projects Financed by IBRD Loans and IDA Credits and Grants" dated October 15, 2006 and revised in January 2011; and the provisions stipulated in the Financing Agreement.

27. **Procurement of Goods.** Goods to be procured under the project will include computers and office equipment for staff, etc. Procurement will be done under ICB using the World Bank's Guidelines and SBDs. Small-value goods may be procured under shopping procedures. Direct contracting may be used where necessary if agreed in the procurement plan in accordance with the provisions of paragraphs 3.7 to 3.8 of the Procurement Guidelines.

28. **Selection and Employment of Consultants.** Consultancy services would include those for development of policy notes and guidelines for TB treatment management, etc. The selection method will mainly be based on consultant's qualification selection (CQS). The following additional methods may be used where appropriate: quality and cost-based selection (QCBS), quality-based selection, selection under fixed budget (FB), and least-cost selection (LCS). Single-

source selection may be employed with prior approval of the World Bank and will be in accordance with paragraphs 3.8 to 3.11 of the Consultant Guidelines. All services of Individual Consultants will be procured under contracts in accordance with the provisions of paragraphs 5.1 to 5.6 of the Guidelines.

29. **Operating Costs.** Operating costs shall consist of operations and maintenance costs for vehicles, office supplies, communication charges, utility charges, travel expenses, per diem and travels costs, office rental, training costs, workshops and seminar and associated costs, among others. Operating costs will not include salaries of civil servants.

30. **Training and Workshops.** Training and workshops will include those for advocacy in policy change, facilitating networking and knowledge exchanges, etc. Detailed training plans and workshops activities will be developed during project implementation and included in the project annual plan and budget for World Bank's review and approval.

31. **Risk Assessment.** The procurement capacity assessment for ECSA-HC was carried out in order to get an understanding of the overall institutional set-up of ECSA-HC and the organizational set-up of the procurement function. The assessment also looked at staffing numbers and qualifications; procurement cycle management; record keeping; and presence of controls in procurement processes.

32. ECSA-HC is finalizing a new organization structure, which has a procurement staff position (i.e., Procurement Officer) placed under the Director of Finance and Administration with the position having been filled with a qualified and experienced staff member. However, that person is yet to carry out procurement under World Bank projects and hence would require training in procurement under World Bank procedures. Furthermore, the position of the Procurement Officer would need to be elevated to report directly to the Director instead of the proposed arrangement whereby the position reports to the Senior Administration Officer under the Director.

33. ECSA-HC has been conducting most of its procurement through the shopping methods and selection of individual consultants. The staff have limited skills in procurement planning, preparation of bidding documents, and processing of procurement through methods other than shopping and selection of individual consultants. Therefore, the staff will require training in procurement of goods and consultancy services through method other than shopping and selection of individual consultants.

34. **Risk Rating.** Considering the organizational set-up of the procurement function within the organization structure of ECSA-HC and the limited knowledge in procurement of large value contracts under World Bank procedures, the procurement risk for ECSA-HC is considered Substantial. With the implementation of the proposed mitigation measures, the risk is expected to be reduced to Moderate.

35. Action Plan to Mitigate Procurement Risks. A summary plan is in Table 4.

Table 4: Procurement Risk Assessment and Mitigation Measures, ECSA-HC

Risk	Action	Time frame	Responsibility
Procurement function placed very low in ECSA-HC structure	Elevate the procurement function so as to make it report directly to the Director of Finance and Administration	As part of organization structure finalizing	ECSA-HC
Inadequate knowledge in procurement of World Bank procedures	Provide basic procurement training in goods and consultancy services to procurement staff	During project implementation	ECSA-HC
Inadequate record keeping and filing system	Improve procurement record keeping and filing system	During project implementation	ECSA-HC

36. Training of specific staff charged with implementation responsibilities in procurement and contract management will be carried out by the Bank and the Borrower within the first six months of project implementation, ideally under financing from the PPA.

37. **Frequency of Procurement Supervision.** In addition to the prior review supervision to be carried out from Bank offices, one supervision mission every six months to visit the field to carry out post review of procurement actions is recommended.

38. **Procurement Plan.** ECSA-HC has prepared a Procurement Plan for the first 18 months of project implementation, which provides the basis for procurement activities. The Procurement Plan was agreed between ECSA-HC and the World Bank during negotiations. It will also be available in the project’s database and on the World Bank’s external website. The Procurement Plan will be updated in agreement with the Project Team annually or as required to reflect the actual project implementation needs and improvements in institutional capacity.

39. **Details of Procurement Arrangements Involving ICB and Other Methods.** These appear in Table 5.

Table 5: Thresholds for Procurement/Selection Methods and Prior Review

Expenditure Category	Contract Value Threshold (US\$)	Procurement/ Selection Method	Contracts Subject to Prior Review
Goods	≥3,000,000	ICB	All
	<100,000	Shopping	None (Post review)
	All	Procurement from UN Agencies	None
	All values	Direct Contracting	All
Consulting Services—Firms¹	≥ 300,000	QCBS/ Other ² (QBS/FBS/ LCS)	All
	< 300,000 ≥200,000	QCBS/ Other ² (CQS/QBS/ FBS/LCS)	None (Post Review)
	< 200,000	CQS/ Other ² (QCBS/QBS/ FBS/LCS)	None (Post Review)

Expenditure Category	Contract Value Threshold (US\$)	Procurement/ Selection Method	Contracts Subject to Prior Review
	All values	SSS	All
Consulting Services— Individuals (IC)	≥200,000	IC – Qualification	All
	<200,000	IC – Qualification	None (Post review)
	All Values	IC – SSS	All

Notes:

1. General – Terms of Reference for all contracts shall be cleared with the Bank: (i) Shortlists for consultancy services for contracts estimated to cost less than US\$300,000 equivalent per contract may be composed entirely of national consultants in accordance with the provisions of paragraph 2.7 of the Consultant Guidelines. (ii) Consultancy services for contracts estimated to cost US\$300,000 and above equivalent per contract shall be advertised in UNDB online in addition to advertising in national newspaper(s) in accordance with the provisions of paragraph 2.5 of the Consultants Guidelines.
2. QBS, FBS, and LCS for assignments meeting requirements of paragraphs 3.2, 3.5, and 3.6 respectively of the Consultant Guidelines.
3. Clearance of a Procurement Plan that lists Direct Contracting (DC) or Single Source (SS) contract packages does not constitute a clearance of the SS/DC method for such contracts. The justification for the DC or SS contracts if any in the Procurement Plan will have to be provided and cleared by the Bank at the time of the procurement.

New Partnership for African Development Planning and Coordinating Agency (NPCA)

40. The key issues identified in procurement for project implementation are: (i) a weak record management system; and (ii) insufficiently detailed evaluation and contract award recommendation reports.

41. Proposed corrective measures to mitigate the overall risks include: (i) clearly describe what records should be kept in the contract file, preferably in Project Operations Manual (POM) or PIM; and (ii) training of project staff in good evaluation practices. An acceptable Procurement Plan covering the first 18 months of the project and Procurement Manual has been prepared.

42. The Risk Assessment is rated as Moderate, taking into account the mitigation measures proposed below

43. **Risk Mitigation Action Plan.** The following actions are required to mitigate the procurement risk and facilitate the implementation of the project (Table 6).

Table 6: Procurement Risk Assessment and Mitigation Measures, NPCA

Risk	Mitigation/Action	Responsibility
Weak record management system	Clearly describe what records should be kept in the contract file, preferably in POM/PIM	Project staff
Insufficiently detailed evaluation and contract award recommendation reports	In-country training of project staff in good evaluation practices.	Bank / project staff

44. Training of specific staff charged with implementation responsibilities in procurement and contract management will be carried out by the Bank and the Borrower within the first six months of project implementation ideally under financing from the PPA.

45. NCB is not applicable for NPCA.

Goods, Works, and Non-consulting Services

46. The project will finance about US\$2.0 million of procurement activities, which will include goods and consulting services assignments.

Procurement of Services (other than consulting services)

47. No services (other than consulting services) to be procured under the project have been identified during project preparation. Should any be identified during project implementation, the procurement plan will be revised and submitted to the Bank for its review and no objection before any procurement activities can be undertaken.

Selection of Consultants

48. Consultant services required from firms and individuals are estimated in aggregate at not more than US\$1,903,000 to cover various consulting assignments including some individual consultant staff positions.

Other

49. **Operating Costs.** Incremental operating costs relate to the project implementation services to be provided to the project. These will be procured using the Borrower's administrative procedures, acceptable to the World Bank.

50. **Procurement Manual.** The procurement procedures and SBDs to be used for World Bank-funded procurement will be presented in the Procurement Manual to be developed in line with the guidelines of the World Bank. The Procurement Manual will include component descriptions, institutional arrangements, regulatory framework for procurement, approval systems, activities to be financed, procurement and selection methods, thresholds, prior- and post-review arrangements and provisions, filing and data management, and the procurement plan for the first 18 months for all project components. The Procurement Manual, once developed, will be updated from time to time by the NPCA.

51. **Assessment of NPCA Capacity to Implement Procurement.** The NPCA procurement unit comprises a Procurement Supervisor assisted by two full-time Procurement Officers who have the relevant qualifications and experience with Bank procurement. Considering the type and quantum of procurements expected over the life of the TB project, additional staffing is not required.

52. **Procurement Supervision.** Given the project context and the project risk indicated above, an annual Post Procurement Review will be conducted in addition to the semi-annual supervision missions by the World Bank. The Review will be carried out either by the World Bank or World

Bank-appointed consultants. The frequency of procurement supervision missions will be once every six months and special procurement supervision for post-procurement reviews will be carried out at least once every 12 months.

53. To enhance the transparency of the procurement process, the Recipient shall publish the award of Contracts selected under the QCBS method, generally within two weeks of receiving the World Bank no-objection to the recommendation of award of Contract, in accordance with the Procurement and Consultant’s Guidelines. Additional procedures, as elaborated in the procurement manual, will govern the disclosure under other procurement and selection methods.

54. **Procurement Plan.** The Borrower has developed a draft Procurement Plan for project implementation. The Procurement Plan will be updated annually or as required to reflect the actual project implementation needs and improvements in institutional capacity.

Goods, Works, and Non-consulting Services

55. **Prior review threshold.** Table 7 outlines procurement decisions that are subject to prior review by the Bank (Appendix 1 to the Guidelines for Procurement)

Table 7: Prior Review Threshold: Goods, Works and Non-consulting services, NPCA

	Procurement Method	Prior Review Threshold (US\$)	Comments
Works			
1.	ICB	≥20,000,000	All
2.	NCB	>200,000 - <20,000,000	As per procurement plan
3.	Shopping (Small contracts)	<200,000	As per procurement plan
4.	Direct Contracting	N/A	All
Goods and Non-consulting Services (excluding consulting services)			
1.	ICB	>5,000,000	All
2.	Shopping	<100,000	None
3.	Procurement from UN Agencies	All	None
4.	Direct Contracting	N/A	All

56. **Procurement Packages Subject to Bank Prior and Post Review.** The procurement packages for supply and installation contracts and non-consulting services that will be subject to Bank prior and post review were provided in the procurement plan that was approved during negotiations

Selection of Consultants

57. **Prior Review Threshold.** Table 8 outlines consultant selection decisions subject to prior review by the Bank (Appendix 1 to the Guidelines Selection and Employment of Consultants)

Table 8: Prior Review Threshold: Consultants, NPCA

	Selection Method	Prior Review Threshold (US\$)	Comments
1.	QCBS and QBS	≥300,000	All
2.	FBS, QBS, LCS and CQS	<300,000	As per procurement plan
3.	Single Source (Firms)	N/A	All
4.	Individual Consultants	≥100,000	All
5.	Individual Consultants	<100,000	As per procurement plan
6.	Single Source (Individual Consultants)	N/A	All

Note:

QCBS = Quality- and Cost-Based Selection (Section II of the Consultants' Guidelines)

LCS = Least Cost Selection (Para 3.6, of the Guidelines)

CQS = Selection based on Consultants' Qualifications (Para 3.7 of the Guidelines)

FBS= Fixed Budget Selection (Para 3.5 of the Guidelines)

QBS = Quality Based Selection (Para 3.2 of the Guidelines)

58. **Short List Comprising Entirely National Consultants.** A short list of consultants estimated to cost less than US\$300,000 equivalent per contract may comprise entirely of national consultants in accordance with the provisions of paragraph 2.7 of the Consultant Guidelines. All terms of reference, irrespective of the value of the consultancy assignment, are subject to prior review.

59. **Consultant Procurement Packages.** The procurement packages for consulting services that will be subject to Bank prior and post review were provided in the procurement plan that was approved during negotiations.

Lesotho

60. The key issues identified regarding procurement for project implementation are: (i) the need for the MOH PAU to hire a new Procurement Officer; and (ii) limited capacity of new project staff to construct, procure, and manage several procurement contracts while adhering to World Bank Procurement and Consultant Selection Guidelines.

61. Proposed corrective measures to mitigate the overall risks include: (i) the MOH PU to hire a Procurement Officer; (ii) training of project staff on World Bank Procurement and Consultant Selection Methods and Procedures; and (iii) selected contracts to be subject to prior review. An acceptable Procurement Plan covering the first 18 months of the project and Procurement Manual are to be developed.

62. The Risk Assessment is rated as Moderate, taking into account the mitigation measures proposed below

63. **Risk Mitigation Action Plan.** The following actions are required to mitigate the procurement risk and facilitate the implementation of the project (Table 9).

Table 9: Procurement Risk Assessment and Mitigation Measures, Lesotho

Risk	Mitigation/Action	Responsibility
Procurement Officer not in place leading to inability to manage major procurements and consultant selections	<p>The MOH PU to hire an additional Procurement Officer</p> <p>The recruitment of this staff will be carried out within the PPA implementation period.</p>	Project staff
Limited capacity of project staff to assure adherence to World Bank Procurement and Consultant Selection Guidelines	<p>a) In-country training of project staff on World Bank Procurement and Consultant Selection Methods and Procedures. Training of specific staff charged with implementation responsibilities in procurement and contract management will be carried out by the Bank and the Borrower within the first six months of project implementation ideally under financing from the PPA.</p> <p>b) Selected contracts to be subject to prior review</p> <p>c) Completion of Procurement Manual</p>	Bank / project staff

64. A Country Procurement Assessment Report (CPAR) for Lesotho was conducted in 2008. Public procurement in Lesotho is regulated by the 2007 Public Procurement Regulations. The CPAR noted the considerable progress made in adopting a modern legislation to regulate public procurement. The CPAR also noted areas requiring improvement including (i) allowing for the use of different procurement procedures for projects financed by development partners; (ii) harmonizing the conflict between the 2007 Public Procurement Regulations, the 1973 Financial Regulations and the 2007 Local Government Act; (iii) reviewing the provision for domestic preference so that it relates to the content of the goods being provided and not to the nationality of the provider; and (iv) developing a procurement manual and accompanying bidding documents.

65. The 2008 CPAR further highlighted limited capacity of the regulator—the Procurement Policy Advisory Division (PPAD)—under the Ministry of Finance, and of the Procurement Units at central and district levels. Lack of specific training and experience in public procurement and weak contract management capacity were noted. The private sector perceived public procurement as having limited competition, inadequate information, and lengthy payment arrangements, and viewed public procurement practices as detrimental to its interest and prone to corruption. Robust procurement oversight systems are still being developed with the 2008 Post Procurement Review providing for a dispute resolution process managed by an Appeals Panel appointed by the PPAD, which may limit its independence.

66. The government has started implementing some of the CPAR recommendations: the redrafting of the 2007 Public Procurement Regulations; the finalization of the Procurement Manual and the SBDs; a review of the current Center for International Policy Studies program to consider the introduction of a public procurement module; the recent introduction of the Procurement Tribunal under the PFMA bill to handle procurement disputes; and the implementation of the IFMIS. Other matters remain to be addressed.

67. NCB shall follow the government's procurement procedures provided that the following provisions apply: (i) use of the Bank's SBD; (ii) registration/ classification of bidders by PPAD, the Ministry of Public Works and Transport, or any other body shall not be used as a condition of bidding; (iii) preferences will not be granted based on citizen degree of ownership and local content; (iv) bracketing to provide for the rejection of bids which are in excess of 15 percent of the cost estimate will not be used; (v) award of contracts must be made to the lowest evaluated tender; and (vi) award of contracts shall be publicly disclosed in the media for wide circulation.

Goods, Works, and Non-consulting services

68. The project will finance procurement activities with an aggregate estimate of US\$3,100,000 for works, goods, and consulting services assignments.

69. Procurement of services (other than consulting services): US\$185,600 for works procurement and US\$2,200,000 for procurement of goods.

70. No services (other than consulting services) to be procured under the project have been identified during project preparation. Should any be identified during project implementation the procurement plan will be revised and submitted to the Bank for its review and no objection before any procurement activities can be undertaken.

Selection of Consultants

71. Consultant services required from firms and individuals are estimated in aggregate at about US\$886,000 for both selection of firms and individual consultants. Other consulting assignments may be identified during the life of the project. Should any be identified during project implementation, the procurement plan will be revised and submitted to the Bank for its review, and no objection before any procurement activities can be undertaken.

Other

72. **Training.** This category will cover all costs related to carrying out study tours, training courses, and workshops, i.e., hiring of venues and related expenses, stationery, and resources required to deliver the workshops as well as costs associated with financing the participation of community organization in short-courses, seminars, and conferences, including associated per diem and travel costs. Training projects will be part of the Annual Work Plan and Budget and will be included in the procurement plan. Prior review of training plans, including proposed budget, agenda, participants, location of training, and other relevant details, will be required only on an annual basis.

73. **Operating Costs.** Incremental operating costs related to the project's implementation services are to be provided to the project. These will be procured using the Borrower's administrative procedures, acceptable to the World Bank.

74. **Procurement Manual.** The procurement procedures and SBDs to be used for World Bank-funded procurement will be presented in the Procurement Manual to be developed in line with the guidelines of the World Bank. The Procurement Manual will include component descriptions, institutional arrangements, regulatory framework for procurement, approval systems, activities to be financed, procurement and selection methods, thresholds, prior- and post-review arrangements and provisions, filing and data management, and the procurement plan for the first 18 months for all project components. The Procurement Manual, once developed, will be updated from time to time by the MOH.

75. **Assessment of MOH PAU Capacity to Implement Procurement.** A full-time Procurement Officer will be assigned to the MOH Procurement Unit, with relevant experience in national government and Bank procurement.

76. As per the Public Procurement Regulations of Lesotho (2007), procurement has been decentralized to procuring entities, and all procurement decisions will therefore be made at Ministry of Finance level. Delays in obtaining procurement clearances are therefore not envisaged.

77. **Procurement Supervision.** Given the country context and the project risk indicated above, an annual Post Procurement Review will be conducted in addition to the semi-annual supervision missions by the World Bank. The annual Post Procurement Review will be carried out either by the World Bank or World Bank-appointed consultants. The frequency of procurement supervision missions will be once every six months and special procurement supervision for post-procurement reviews will be carried out at least once every 12 months.

78. To enhance the transparency of the procurement process, the Recipient shall publish the award of contracts procured under NCB procedures or selected under the QCBS method, generally within two weeks of receiving the World Bank's no-objection to the recommendation of award of contract, in accordance with the Procurement and Consultant's Guidelines. Additional procedures, as elaborated in the Procurement Manual, will govern the disclosure under other procurement and selection methods.

79. **Procurement Plan.** The Borrower has developed a draft Procurement Plan for project implementation. The Procurement Plan will be updated annually or as required to reflect the actual project implementation needs and improvements in institutional capacity.

Malawi

80. The key issues identified regarding procurement for project implementation are: (i) the TB project needs to have its own fully dedicated Procurement Specialist; (ii) a weak record management system; (iii) limited capacity of the implementing partners under the TB project to assure adherence to World Bank Procurement and Consultant Selection Guidelines; (iv) inefficiencies and delays in procurement process; (v) weak contract management; (vi) fraud and corruption risks; and (vii) a weak complaint-redress system.

81. Proposed corrective measures to mitigate the overall risks include: (i) attending short procurement courses within the region at a later stage by key personnel handling procurement; (ii) strengthening of complaint handling mechanism; (iii) annual audits by external procurement auditors and national audit office; and (iv) post review by the Bank as per the risk rating.

82. The Risk Assessment is rated as Substantial taking into account the mitigation measures proposed below.

83. **Risk Mitigation Action Plan.** The following actions are required to mitigate the procurement risk and facilitate the implementation of the project (Table 10).

84. Public procurement in Malawi is governed by the Malawi Public Procurement Act (No. 8) of August 2003. The Act requires procurement Regulations to provide, among other things, thresholds for use of various procurement methods, bidding and bid evaluation procedures, and contract management. The Law further established the Office of Director of Public Procurement (ODPP) with oversight for public procurement. The Office became operational in 2005 with the appointment of the Director and other substantive officers. The Government also established Internal Procurement Committees (IPC) and Specialized Procurement Units in all Ministries and Departments as the responsible bodies for procurement and award of contracts in the Ministries and Departments. Procurement Regulations and Desk Instructions have been distributed to all procuring entities. The Office of Director of Public Procurement has also established a dedicated website for sharing of information, placing of adverts and notification of awards to the general public.

85. The Office of Director of Public Procurement issued a number of SBDs, the use of which is mandatory, covering works, goods, and services. The Office further issued desk instructions, Request for Proposal and forms of contract for Consulting Services as well as request for quotations for goods, works and services. The Bank had reviewed the documents and they were found to be generally consistent with Bank Guidelines and may be used under NCB procedures.

86. The Malawi Public Procurement Act of August 2003, Regulations and Desk Instructions will be used for all procurements below Bank prior review thresholds as agreed in the Procurement Plan.

Table 10: Procurement Risk Assessment and Mitigation Measures, Malawi

Risk Factor	Initial Risk	Mitigation Measure	Residual Risk
Record keeping and documentation	Substantial	<ul style="list-style-type: none"> • MOH and PIU will maintain all procurement records duly catalogued and indexed that will facilitate easy access to information. Mitigation actions will be implemented throughout the life of the project 	Low
Fiduciary Risk relating to main principles of the Bank Procurement Guidelines	Substantial	<ul style="list-style-type: none"> • Experienced procurement staff/consultant shall be positioned to guide implementing activities • Attend training in Bank procurement procedures • Regular supervision support and monitoring • Training of specific staff charged with implementation responsibilities in procurement and contract management will be carried out by the Bank and the Borrower within the first six months of project implementation ideally as under financing from the PPA 	Low
Inefficiencies and delays in procurement process	Substantial	<ul style="list-style-type: none"> • Regular monitoring through procurement plan. Mitigation actions will be implemented throughout the life of the project 	Low
Contract Management	Substantial	<ul style="list-style-type: none"> • Disclosure of all contract awards in UNDB Magazine for prior contracts and post review contracts in local newspapers and website of Office of Director of Public Procurement. Mitigation actions will be implemented throughout the life of the project 	Low
Probability of staff handling procurements being transferred or resigning	Substantial	<ul style="list-style-type: none"> • Dialogue with government to retain trained staff of TB Unit and MOH. 	Substantial
Fraud and corruption risks [including collusion and outside interference] in contracting process	Substantial	<ul style="list-style-type: none"> • Disclosure of procurement plan • Disclosure of contract awards • Creating awareness on effects of fraud and corruption • Regular reviews such as PPR, internal Audit, external audit etc. 	Low
Weak complaint-redress system	Substantial	<ul style="list-style-type: none"> • Disclosure of complaint-redress procedure through ODPP • Bi-annual report of all complaints received and action taken. 	Low
Overall Risk	Substantial		Low

National Competitive Bidding (NCB)

87. Any contract exceeding shopping threshold will be subject to NCB. The model bidding documents for NCB as agreed with Office of Director of Public Procurement, Malawi Public Procurement Act, Regulations and Desk Instructions (and as amended from time to time), shall be used for bidding. The following NCB exceptions shall apply:

- No bidder or potential bidder shall be declared ineligible to bid for reasons other than those provided in Section I of the Bank Procurement Guidelines.
- Bidding documents acceptable to the IDA shall be used.
- The bidding documents and contract shall include provisions reflecting the Bank's policy relating to firms or individuals found to have engaged in fraud and corruption as defined in the Procurement Guidelines.
- Each bidding document and contract shall provide that bidders, suppliers and contractors, and their subcontractors, agents, personnel, consultants, service providers, or suppliers, shall permit the Bank to inspect all accounts, records, and other documents relating to the submission of bids and contract performance, and to have them audited by auditors appointed by the Association. Acts intended to materially impede the exercise of the Association's inspection and audit rights provided for in the Procurement Guidelines constitute an obstructive practice as defined in the Procurement Guidelines.
- Unquantifiable criteria, such as local content, technology transfer, and managerial, scientific, and operational skills development, shall not be used in the evaluation of bids; and
- Contracts may not be split into small lots, and their award may not be restricted to small enterprises for purposes of promotion of the participation of small enterprises.

Procurement of Works, Goods, and Non-consulting Services

88. The project will finance procurement activities with an aggregate estimate of US\$1,211,000 for works, goods, non-consulting services and consulting services assignments.

89. The aggregate amount for works contracts is estimated at US\$339,000. The aggregate estimate amount for goods contracts is estimated at US\$282,000 whilst the aggregate estimated amount for procurement of non-consulting services is estimated at US\$160,000.

Selection of Consultants

90. Consultant services required from firms and individuals are estimated in aggregate amount of approximately US\$430,000.

Other

91. **Force Account:** When contractors/suppliers are unlikely to bid at reasonable prices because of the location and risk associated with the project or a certain government agency has a sole right in certain type of works/supply, borrowers may use their own government departments' personnel and equipment or government owned construction unit may be the only practical method, provided that the government agency has sufficient managerial capacity and possesses the

required technical and financial controls to report to the Bank on expenditure as per paragraph 3.9 of the Procurement Guidelines.

92. **Framework Agreements (FAs):** Such agreements shall be used as alternatives to NCB or shopping for goods that can be procured off the shelf or are commonly used with standard specifications, non-consulting services of a simple and non-complex nature that are required from time to time, or small works under emergency. Agreement amount for the FA shall be set in the Procurement Plan and agreed with the Bank.

93. **Use of Government Institutions and Parastatals:** Government-owned institutions or parastatal organizations in Malawi may be hired for their unique and exceptional nature if their participation is considered critical to project implementation. In such cases, the conditions given in clause 1.13 of Consultant Guidelines shall be satisfied and each case will be subject to prior review by the Bank.

94. **Operational Cost.** Any operational expenses to be financed by the project are to be procured using the implementing agency's administrative procedures, as reviewed and found acceptable to the Bank.

95. **Other Conditions.** The Bank will also consider further simplification of procedures if so requested by the implementing agency and if such simplification is within the overall framework of Bank Guidelines

Implementation Arrangements and Capacity Assessment of the Implementing Agencies under the TB and Health Sector Support Project

96. MOH will be the lead agency responsible for implementation of the Project and a PIU will be established at the TB Unit. The other agencies in the project, Mining and Environment, will be submitting their requests to the MOH for processing requests with the Bank. The PIU will be responsible for procurement of all goods, works, and services under the project and once it has processed the requests, these will be submitted to the MOH's Internal Procurement Committee for its review and award of the contract or recommendation for submission to the Bank for its review and no objection.

97. **Capacity Assessment of MOH.** As part of project preparation process, a capacity assessment of the MOH and the TB Unit was carried out using the Procurement Risk Assessment System (PRAMS) on November 17, 2015. The assessment found that staff were not familiar with procurement procedures of the World Bank, including IDA guidelines and procedures. It was pleasing to note the MOH has an Internal Procurement Committee (IPC) responsible for award of contracts. The IPC is composed of the Secretary for Health, Director of Finance, Director of Clinical Services, Director of Administration, Deputy Director Diagnostics, Director of Nursing Services. The Director of Infrastructure and Procurement Section is secretariat to the Committee. The TB Unit does not undertake its own procurement as it is a satellite office of the MOH headquarters, which procures all its requirements.

98. In terms of staffing, the Procurement Unit in the MOH has seven officers and is headed by a Chief Procurement Officer with a Master's degree in Strategy and Procurement Management from the University of Birmingham, United Kingdom, and who has over 20 years' procurement

experience. The Chief Procurement Officer is supported by two Principal Procurement Officers, both of whom have Master's degrees in Supply Chain Management from Malawi Institute of Management in association with Bolton University, United Kingdom. Both have over eight years' experience. The two Principal Procurement Officers are supported by two Procurement Officers; one has a Master's degree in Supply Chain Management while the other has an MCIPS from the Chartered Institute of Purchasing and Supply, United Kingdom. Below the Procurement Officers are two Assistant Procurement Officers, one with an MCIPS from the Chartered Institute of Purchasing and Supply, United Kingdom while the other has a certificate in purchasing but is studying for a degree in Business Administration. The TB Unit does not have its own procurement staff as it relies on central MOH staff.

99. In terms of procurement capacity, the Ministry staff have adequate qualifications and experience to undertake procurements for the TB provided they undergo refresher courses in World Bank procedures. The staff are undertaking procurements for other donors such as African Development Bank, BADEA & Saudi Fund, Global Fund, CDC, and the Department for International Development (DFID), which are supporting similar operations as those that will be financed by the IDA/Trust Fund. The Chief Procurement Officer and one of the Principal Procurement Officers was understudying a procurement TA under the IDA-financed Health Sector Support Project before it closed in 2008. Ministry procurement staff are overloaded with ministry activities and the addition of the TB project will lead to overloading and inefficiencies. To make TB project procurement effective, it is recommended that the project have its own fully dedicated procurement specialist who will undertake all procurement under the project.

100. **Office Facilities and Space.** Procurement staff in the ministry have adequate facilities for their use and they are also connected to a LAN. However, the TB Unit will have to provide an office, including computer equipment, for the Procurement Specialist.

101. **Risk of Fraud and Corruption.** The project risk is Substantial because staff are not familiar with IDA guidelines.

102. **Procurement Plan.** The MOH, with the support of the World Bank, developed a procurement plan for the first 18 months of project implementation. The World Bank reviewed and approved this plan during negotiations. The procurement plan includes all the procurement packages identified for the first 18 months of project implementation. The procurement plan will be updated as required at least once a year throughout the life of the project.

Goods, Works, and Non-consulting Services

103. **Prior Review Threshold.** Table 11 outlines procurement decisions that are subject to prior review by the Bank (Appendix 1 to the Guidelines for Procurement).

Table 11: Prior Review Threshold: Goods, Works, and Non-consulting Services, Malawi

	Procurement Method	Prior Review Threshold (US\$)	Comments
Works			
1.	ICB	≥\$5,000,000	All
2.	NCB	>\$1,000,000 - <\$5,000,000	As per procurement plan
3.	Shopping (Small contracts)	<\$1,000,000	As per procurement plan
4.	Direct Contracting	N/A	All
Goods and Non-consulting Services (excluding consulting services)			
1.	ICB	>\$1,000,000	All
2.	NCB	>\$200,000 - <\$1,000,000	As per procurement plan
3.	Shopping	<\$200,000	As per procurement plan
4.	Procurement from UN Agencies	All	None
5.	Direct Contracting	N/A	All

104. **Procurement Packages Subject to Bank Prior and Post review.** The procurement packages for supply and installation contracts and non-consulting services that will be subject to Bank prior and post review were provided in the procurement plan that was reviewed and approved during negotiations.

Selection of Consultants

105. **Prior Review Threshold.** Table 12 outlines consultant selection decisions subject to prior review by the Bank (Appendix 1 to the Guidelines Selection and Employment of Consultants).

Table 12: Prior Review Threshold: Consultants, Malawi

	Selection Method	Prior Review Threshold	Comments
1.	QCBS and QBS	≥\$200,000	All
2.	FBS, QBS, LCS and CQS	<\$200,000	As per procurement plan
3.	Single Source (Firms)	N/A	All
4.	Individual Consultants	≥\$100,000	All
5.	Individual Consultants	<\$100,000	As per procurement plan
6.	Single Source (Individual Consultants)	N/A	All
<i>Note:</i> QCBS = Quality- and Cost-Based Selection (Section II of the Consultants' Guidelines) LCS = Least Cost Selection (Para 3.6, of the Guidelines) CQS = Selection based on Consultants' Qualifications (Para 3.7 of the Guidelines) FBS= Fixed Budget Selection (Para 3.5 of the Guidelines) QBS = Quality Based Selection (Para 3.2 of the Guidelines)			

106. **Short List Comprising National Consultants.** Short list of consultants estimated to cost less than US\$200,000 equivalent per contract, may comprise entirely of national consultants in

accordance with the provisions of paragraph 2.7 of the Consultant Guidelines. All terms of reference, irrespective of the value of the consultancy assignment, are subject to prior review.

107. **Consultant Procurement Packages.** The procurement packages for consulting services that will be subject to Bank prior and post review were provided in the procurement plan that was reviewed and approved during negotiations.

Mozambique

108. **The key issues identified regarding procurement for project implementation are:** (i) The current capacity of the MOH Procurement Unit (UGEA) is below requirements and has weaknesses that need attention; (ii) other internal units that contribute to efficient procurement are overstretched, contract management is weak, and their response time is longer than anticipated; (iii) a weak record management system; and (iv) insufficient documentation to guide the procurement process.

109. Proposed corrective measures to mitigate the overall risks include: (i) hire an experienced procurement consultant; (ii) improve procurement record keeping; and (iii) improve the Procurement Manual.

110. Based on the procurement capacity assessment and by the fact that the team does not possess relevant experience under Bank fiduciary requirements, the overall project risk for procurement is **High**.

111. **Risk Mitigation Action Plan.** The following actions are required to mitigate the procurement risk and facilitate the implementation of the project.

Table 13: Procurement Risk Assessment and Mitigation Measures, Mozambique

Risk	Mitigation Measures	When
1. The Project Implementation team is familiar with Bank operations. The Procurement Unit of the MOH (UGEA) has been strengthened through the contracting of a procurement specialist, but this is not enough to manage a larger operation. Capacity of UGEA is below requirements. Other internal units that contribute to efficient procurement are overstretched (contract management) and their response time is longer than anticipated.	<ul style="list-style-type: none"> • An experienced procurement consultant with skills in systems strengthening and organization should be hired for up to 12 months to help organize the workflow and procurement functions at the level of UGEA and to provide on-the-job training to UGEA staff. • Training of the UGEA staff in government and World Bank Procurement and Consultant Selection Methods and Procedures. 	<p>In Progress using PPA funds</p> <p>In Progress using PPA funds</p>

Risk	Mitigation Measures	When
2. Improvement of Procurement record keeping.	Keep proper records in a filing system, records labeled and numbered in chronological order.	Ongoing throughout the life of the project
3. Improvement of Procurement Manual.	Develop, on the basis of the Health Service Delivery Project Procurement Manual, as part of a specific chapter in the PIM, a procurement manual for the Southern Africa Tuberculosis and Health Systems Support Project, as part of the Operations Manual	In progress using PPA funds

112. The Government and the World Bank, with the support of the Kreditanstalt für Wiederaufbau and the African Development Bank, carried out in 2008 an update of the Country Procurement Assessment Report (CPAR). The 2008 CPAR highlights that the country made considerable progress from the 2002 CPAR, and the government has adopted a new Procurement Regulation which makes progress toward meeting the requirement of OECD-DAC indicators. Bank and partners will continue to engage with government and aid the implementation of the 2008 CPAR which will aim to strengthen, among others, the availability of reliable procurement information to enable effective procurement management and public monitoring; an effective complaint mechanism to disclose abuse of the systems and allow for effective remedies while maintaining the efficiency of the process; effective internal control and audit mechanisms sensitive to “red flags” on fraud and corruption to ensure enforcement; and limit abuse and a capacity-building system for public procurement mainstreamed into the national systems.

113. On September 8, 2006, the government issued by decree in the *Gazette* a number of SBDs for works, goods, and non-consulting services; drugs and medical supplies; and consulting services. These SBDs are generally consistent with Bank guidelines and may be used under NCB. However, with regards to national preference, the Bank will ensure that (i) domestic preference applies only for the ICB procedure, and that under NCB domestic preference shall not apply, even when foreigners show interest; (ii) domestic preference for locally manufactured goods shall be applied only for ICB without limitation to the nationality of the goods’ manufacturer; and (iii) when it is an ICB, the bidding documents as well as the advertisement shall also be made available in the English language, using Bank SBDs. Additional provisions to mitigate the departure from Bank Guidelines on the national SBDs will be included in the NCB Letter below.

NCB Letter

114. **General.** The procedures to be followed for NCB shall be those set forth in the “*Regulamento de Contratação de Empreitada de Obras Públicas, Fornecimento de Bens e Prestação de Serviços ao Estado*” of the Republic of Mozambique of May 24, 2010 (“the Regulation”), as per Decree No. 15/2010, with the modifications described in the following paragraphs.

115. **Eligibility.** No restriction based on nationality of bidders and/or origin of goods shall apply. Foreign bidders shall be allowed to participate in NCB without restriction and shall not be

subject to any unjustified requirement which will affect their ability to participate in the bidding process such as, but not limited to, the proof that they are not under bankruptcy proceedings in the Recipient's territory; have a local representative; have an attorney resident and domiciled in the Recipient's territory; form a joint venture with a local firm. In cases of joint ventures, they shall confirm joint and several liability.

116. **Prior Registration.** Obtaining a license or agreement shall not be a requirement for any bidder to participate in the bidding process.

117. The Recipient's government-owned enterprises or institutions shall be eligible to participate in the bidding process only if they can establish that they are legally and financially autonomous, operate under commercial law, and are not dependent agencies of the Recipient.

118. **Bidding Documents.** SBDs acceptable to the Association shall be used for any procurement process under NCB.

119. **Preferences.** No domestic preference shall be given for domestic bidders and/or for domestically manufactured goods.

Applicable Procurement Method under the Regulation

120. Subject to these NCB exceptions, procurement under NCB shall be carried out in accordance with the Regulation's public competition (*Concurso Público*) method.

121. **Bid Preparation Time.** Bidders shall be given at least 28 days from the date of the invitation to bid or the date of availability of bidding documents, whichever is later, to prepare and submit bids.

122. **Bid Opening.** Bids shall be opened in public, immediately after the deadline for their submission in accordance with the procedures stated in the bidding documents.

123. **Bid Evaluation.** Qualification criteria shall be clearly specified in the bidding documents, and all criteria so specified, and only such criteria so specified shall be used to determine whether a bidder is qualified; the evaluation of the bidder's qualifications should be conducted separately from the technical and commercial evaluation of the bid. Qualification criteria shall be applied on a pass or fail basis. Evaluation of bids shall be made in strict adherence to the criteria declared in the bidding documents; criteria other than price shall be quantified in monetary terms. A contract shall be awarded to the qualified bidder offering the lowest-evaluated and substantially responsive bid. Bidders shall not be eliminated on the basis of minor, non-substantial deviations.

124. **Rejection of All Bids and Re-bidding.** All bids shall not be rejected and new bids solicited without the Association's prior concurrence.

125. **Complaints by Bidders and Handling of Complaints.** The Recipient shall establish an effective and independent complaint mechanism allowing bidders to complain and to have their complaint handled in a timely manner.

126. **Right to Inspect/Audit.** In accordance with paragraph 1.16(e) of the Procurement Guidelines, each bidding document and contract financed from the proceeds of the financing shall provide that: (i) the bidders, suppliers, and contractors and their subcontractors, agents, personnel, consultants, service providers or suppliers, shall permit the Association, at its request, to inspect their accounts, records and other documents relating to the submission of bids and contract performance, and to have them audited by auditors appointed by the Association; and (ii) the deliberate and material violation by the bidder, supplier, contractor or subcontractor of such provision may amount to obstructive practice as defined in paragraph 1.16(a)(v) of the Procurement Guidelines.

127. **Fraud and Corruption.** Each bidding document and contract financed from the proceeds of the financing shall include provisions on matters pertaining to fraud and corruption as defined in paragraph 1.16(a) of the Procurement Guidelines. The Association may sanction a firm or individual, at any time, in accordance with prevailing Association sanctions procedures, including by publicly declaring such firm or individual ineligible, either indefinitely or for a stated period of time: (i) to be awarded an Association-financed contract; and (ii) to be a nominated subcontractor, consultant, supplier or service provider of an otherwise eligible firm being awarded an Association-financed contract.

128. **Debarment under the National System.** The Association may recognize, if requested by the Recipient, exclusion from participation as a result of debarment under the national system, provided that the debarment is for offenses involving fraud, corruption or similar misconduct, and further provided that the Association confirms that the particular debarment procedure afforded due process and the debarment decision is final.

Procurement of Works

129. Works procured will include infrastructure improvements; rehabilitation or construction and equipping of three clinical centers of excellence for TB/MDR/XDR-TB diagnosis, treatment and management; rehabilitation and upgrading of national reference laboratories and standardizing Laboratory Information Systems; adding LPA capacity; and rehabilitation and establishment of smear microscopy points or conditions for Xpert. The procurement will be done using the World Bank's Standard Bidding Documents (SBD) for all International Competitive Bidding (ICB) contracts. National Competitive Bidding (NCB) documents in Portuguese, in accordance with the Mozambican Procurement Regulations as per Decree Number 54/2005 of December 13, 2005, with the exceptions elaborated in the NCB Letter, will be used as agreed upon by the World Bank. For contracts estimated to cost less than US\$15,000,000 equivalent per contract, NCB procedures will apply. The small minor works estimated to cost less than \$100,000 per contract may be procured by requesting at least three written quotations from qualified and reputable contractors.

Procurement of Goods and Non-consulting services

130. Goods and non-consulting services procured under this project would include: vehicles, motorcycles, laboratory equipment, televisions, mobile clinics, IEC material, publicity/marketing or advocacy, office equipment, communication equipment, procurement of refrigerators, procurement of transport coolers, and community radio spots in local language, and digital X-ray equipment. Procurement will be done using the World Bank's SBDs for all ICB contracts. NCB

documents in the Portuguese language, in accordance with the Mozambican Procurement Regulations as per Decree Number 54/2005 of December 13, 2005, with the exceptions elaborated in the NCB Letter, will be used as agreed upon by the World Bank. For contracts estimated to cost less than US\$500,000 equivalent per contract NCB procedures will apply. Off the shelf goods and non-consulting services estimated to cost less than \$75,000 per contract may be procured under the shopping method, by requesting at least three written quotations from the qualified and reputable suppliers.

Selection of Consultants

131. Consulting services include consultants to design, develop, train staff, and maintain a cloud-based database of health care worker screening. They also include a consultant to write scripts for radio and television spots, Occupational Health specialist, Landscape analysis of current capacity and development of 5-year strategic plan for growth and others.

Training

132. This category will cover all costs related to carrying out training and workshops, i.e. hiring of venues and related expenses, stationery, resources required to deliver the workshops, and per diem and travel costs of participants. Training programs will be part of the project's annual work plan and budget and will be included in the procurement plan. Prior review of all activities will be required, only on annual basis, including proposed budget, agenda, participants, location of training and other relevant details.

Operating Costs

133. Operating costs shall include office supplies; operation and maintenance costs for vehicles and equipment; utility costs; travel expenses and subsistence expenditures; costs related to carrying out of training and workshops; and costs related to implementing unit staff but excluding government civil service personnel.

134. The procurement procedures and SBDs to be used for each procurement method, as well as model contracts for works and goods procured, are presented in the Operation Manual prepared by the Borrower. The Procurement section of the Operations Manual will be an update on the Health Service Delivery Project (HSDP) manual, incorporating the features of the Southern Africa Tuberculosis and Health Systems Support Project submitted for Bank review and approval prior to negotiations.

Assessment of the Agency's Capacity to Implement Procurement

135. Procurement activities will be carried out by the MOH Procurement Unit (UGEA). The UGEA was created under the framework of the Government's New Procurement Regulation, Decree 54/2005, enacted on December 13, 2005 will provide support to the project. The Government updated this Procurement Regulation, effective August 20, 2010.

136. A procurement capacity assessment was conducted at the procurement unit (UGEA) on December 11, 2015. It reviewed the institutional arrangements for the project, with an emphasis on capacity building of existing structures.

137. UGEA is within the Department of Administration and Finance (DAF) and reports to the Deputy National Director of Logistics. The Permanent Secretary acts as the Competent Authority, with power to take decisions and sign on behalf of the MOH, as defined in Procurement Regulation Decree 54/2005.

138. Eight staff, including the head of UGEA, five technicians, and two procurement specialists make up UGEA, which is physically housed and equipped with the basic requirements. All technicians, including the head of UGEA, have no experience in procurement using World Bank procedures. No procurement manual (other than the government procurement regulations) is in place. The two procurement specialists are responsible for the projects financed by the Global Fund and the World Bank. Coordination between staff allocated to the project (consultants) and staff of UGEA (civil servants) is limited.

139. The unit has a dedicated room for record keeping; nevertheless, the filing system needs to be improved, including labeling and numbering in chronological order. The unit has an internal control system. One technician and one assistant are assigned for planning and monitoring activities. The team is to monitor and follow up the procurement plan and track all activities.

140. The procurement assessment found that the procurement unit's overall capacity to efficiently handle procurement, in particular Bank-financed procurement, is limited.

141. The ongoing Bank-financed operation (HSDP) has many delays in the activities due to weak coordination during the procurement process and weak capacity of the unit. To mitigate this risk, the procurement section of the Operations Manual should detail the coordination and approval requirements during the procurement process, particularly the government's mandatory clearances by the MOH and Administrative Tribunal, including the time required for review. The review time for these institutions should be considered in the procurement planning. Furthermore, the HSDP procurement manual should be updated to incorporate the issues of the Southern Africa Tuberculosis and Health Systems Support Project prior to effectiveness.

142. The frequency of procurement supervision missions will be once every six months, and special procurement supervision for post-procurement reviews at least once every 12 months.

Procurement Plan

143. The MOH, with the support of the World Bank, developed a procurement plan for at least the first 18 months of project implementation. The World Bank reviewed and approved this plan during negotiations. The procurement plan includes all the procurement packages identified for the first 18 months (and if possible beyond) of project implementation. The procurement plan will be updated as required at least once a year throughout the life of the project.

Goods, Works, and Non-consulting Services

144. **Prior Review Threshold.** Table 14 outlines procurement decisions that are subject to prior review by the Bank (Appendix 1 to the Guidelines for Procurement).

Table 14: Prior Review Threshold: Goods, Works, and Non-consulting Services, Mozambique

	Procurement Method	Contract Value Threshold (US\$)	Contracts Subject to Prior Review
Works			
1.	ICB	≥\$15,000,000	All
2.	NCB	≥5,000,000 - < 15,000,000	All
		< 5,000,000	None (Post Review)
3.	Shopping (Small contracts)	<\$100,000	None (Post Review)
4.	Direct Contracting	N/A	All
Goods and Non-consulting Services (excluding consulting services)			
1.	ICB	>\$3,000,000	All
2.	NCB	>\$500,000 - <\$3,000,000	As in Procurement Plan
	NCB	< 500,000	None (Post Review)
3.	Shopping	<\$75,000	None (Post Review)
4.	Procurement from UN Agencies	All	None
5.	Direct Contracting	All	All

145. **Procurement Packages Subject to Bank Prior and Post Review.** The procurement packages for supply and installation contracts and non-consulting services that will be subject to Bank prior and post review were provided in the procurement plan that was reviewed and approved during negotiations.

Selection of Consultants

146. **Prior review threshold.** Table 15 outlines consultant selection decisions subject to prior review by the Bank (Appendix 1 to the Guidelines Selection and Employment of Consultants)

Table 15: Prior Review Threshold: Consultants, Mozambique

Procurement Method	Prior Review Threshold (US\$)	Selection Method	Comments
Consulting Services - Firms	≥ 300,000	QCBS/ Other (QBS/FBS/LCS)	All
	≥ 200,000 - < 300,000	CQS/ Other (QCBS/QBS/FBS/LCS)	All
	< 200,000	CQS/ Other (QCBS/QBS/FBS/LCS)	None (Post Review)
	All values	Single Source Selection (SSS)	All
Consulting Services – Individuals (IC)	≥ 100,000	IC – Competitive Selection (CS)	All
	< 100,000	IC – Competitive Selection (CS)	None (Post review)
	All Values	IC – SSS	All
<p>Note: QCBS = Quality- and Cost-Based Selection (Section II of the Consultants’ Guidelines) LCS = Least Cost Selection (Para 3.6, of the Guidelines) CQS = Selection based on Consultants’ Qualifications (Para 3.7 of the Guidelines) FBS = Fixed Budget Selection (Para 3.5 of the Guidelines) QBS = Quality Based Selection (Para 3.2 of the Guidelines)</p>			

147. **Short List Comprising Entirely National Consultants.** Short list of consultants estimated to cost less than US\$200,000 equivalent per contract, may comprise entirely national consultants in accordance with the provisions of paragraph 2.7 of the Consultant Guidelines. All terms of reference, irrespective of the value of the consultancy assignment, are subject to prior review.

148. **Consultant Procurement Packages.** The procurement packages for consulting services that will be subject to Bank prior and post review were provided in the procurement plan that was reviewed and approved during negotiations.

Zambia

149. The key issues identified regarding procurement for project implementation are: (i) a weak record management system; (ii) insufficiently detailed evaluation and contract award recommendation reports; and (iii) weak contract management.

150. Proposed corrective measures to mitigate the overall risks include: (i) improve the record keeping and management system; (ii) train staff in good evaluation practices; and (iii) build skills in contract management.

151. A Procurement Risk Assessment (P-RAMS) of the Ministry of Health (MOH) was undertaken on December 16, 2015 in accordance with the World Bank’s Procurement Risk Management System. The Implementation Agency Procurement Risk for the MOH was assessed as Moderate. Implementation of the following risk mitigation actions would reduce it to Low.

152. **Risk Mitigation Action Plan.** The following actions are required to mitigate the procurement risk and facilitate project implementation (Table 16).

Table 16: Procurement Risk Assessment and Mitigation Measures, Zambia

Issues and Risks	Mitigation Measures	Action Undertaken By	Period
Record keeping and management system: There is inadequate space for good and orderly filing, making it hard to audit, review, and resolve disputes	<ul style="list-style-type: none"> - Clearly describe what records should be kept in the contract file, preferably in POM/PIM, and for how long. - Agree and include as part of the project funding possible improvements to safe keeping of and retrieval of records 	Procurement Supplies Unit (PSU)	December 16 2015 to March 2017
Evaluations and awards of contracts: Reports do not always contain all essential information necessary for approvals, including adequate justification for decisions taken during evaluation, such as rejection of bids Wrong award decision may be made because of inadequate information, and due diligence is not routinely carried out	<ul style="list-style-type: none"> - Quality of evaluations and awards of contracts must be enhanced. - Staff to be trained in good evaluation practices that base decisions on pre-disclosed criteria and include due diligence verifications of bidders recommended for award of contract 	PSU	December 16 2015 to September 30 2016
Contract management and administration: Experience from other projects in Zambia and MOH has shown: <ul style="list-style-type: none"> - Inadequate mechanisms in place for procurement and/or contract monitoring - Invoices from vendors not always paid within the contractual terms - At times, contracts not implemented per contract terms 	MOH PSU to build skills in contract management: <ul style="list-style-type: none"> - Training in contract management for selected key staff may be appropriate - For every contract, MOH should appoint a contract manager in line with the Zambia public procurement Act No 12 of 2008 - Hire consultants to enhance capacity 	MOH PSU MOH PSU MOH	Upon availability of trainer(s), and continuously thereafter By the time of contract effectiveness As required

153. **Procurement Manual and Procurement Plan.** The procurement arrangements to be used under the Project, including packaging of procurement, maintaining clarity of accountability over procurement, record keeping, and frequency and scope of prior and post review, will be elaborated in the procurement module of the PIM (“the procurement manual”) and in the procurement plans. There is an existing procurement plan for the Zambia Health Services Improvement Project (Project ID No. P145335). This procurement manual will be amended to include a section on the specific requirements for the project. The procurement manual will address the needs of the implementation agencies, including the needs and procedures for procurement at community level.

The manual will outline the identified risks and provide risk mitigation actions. It will cover the legal and regulatory framework, roles and responsibilities of the institutions and staff involved in procurement, internal and external controls and quality assurance checks or systems, approval systems and accountability, and a contracts register. It will spell out the roles and responsibilities of various players in contract management, based on government regulations and as required for prior review of IDA contracts.

154. **Procurement Decentralization.** As of January 1, 2013, all procuring entities carried out procurement in a fully decentralized environment. This means that the Zambia Public Procurement Agency (ZPPA) has not been involved in reviewing bidding documents, bid evaluation, review and approval, nor contract award recommendations. All procurement activities will be carried out internally by the MOH using its own institutional arrangements, controls, and quality checks. Since January 2013, the ZPPA has been transformed into a regulatory and oversight body for public procurement in Zambia.

155. **Procurement Post Reviews (PPRs) and Independent Post Reviews (IPRs) by the World Bank.** Based on the assessed agency implementation risk for procurement, which is Moderate, the World Bank will carry out PPRs or IPRs for all contracts that will be based on the procurement plan not having been subject to prior review by the World Bank using a sample of 10 percent. Based on continuing assessment of risk and the success of risk-mitigation measures implemented, the sample size will be reduced as risk-mitigation measures are successfully implemented. High risk represents a sample size of 20 percent, Substantial risk 15 percent, Moderate risk 10 percent, and Low risk 5 percent. Changes in risk levels will be communicated to the MOH as outcomes of the PPR/IPR exercise, which also result in revisions to the prior review and NCB thresholds.

156. **Prequalification.** N/A.

157. **Proposed Procedures for CDD Components** (as per paragraph. 3.17 of the Guidelines). N/A.

158. **Reference To (if any) Project Operational/Procurement Manual.** The components will be undertaken in accordance with the provisions of the World Bank's Guidelines for Selection and Employment of Consultants under IBRD Loans and IDA Credits & Grants by World Bank Borrowers, dated January 2011, revised April 2014; the World Bank's Guidelines Procurement of Goods, works, and Non-Consulting Services under IBRD Loans and IDA Credits & Grants by World bank Borrowers, dated January 2011, revised July 2014; the World Bank's "Guidelines on Preventing and Combating Fraud and Corruption in Projects Financed by IBRD Loans and IDA Credits and Grants", dated October 15, 2006 and revised in January 2011; and the provisions stipulated in the Financing Agreement. The project will also make use of the additional information and guidance provided in the manual "Guidance for Procurement of Small Contracts; World Bank Africa Region Procurement February 2011, revised July 2014", and in the case of all small contracts entered into below the use of NCB. Procurement under NCB will be based on use of national SBDs subject to the application of additional provisions contained in the attachments and standard clauses of the Bank's Policy – Corrupt and Fraudulent Practices, whose text may not be modified and will be used in both the bidding documents and the ensuing contracts.

159. **Applicable legal and regulatory framework for NCB.** The procurement procedure to be followed for NCB shall be the open international bidding procedure set forth in the Public Procurement Act, 2008, Act No.12 of 2008, as amended by the Public Procurement (Amendment) Act, 2011, Act No. 15 of 2011 (the “PPA”), and the Public Procurement Regulations, 2011, Statutory Instrument No. 63 of 2011 (the “Regulations”); provided, however, that such procedure shall be subject to the provisions of Section I and Paragraphs 3.3 and 3.4 of Section III, and Appendix 1 of the “Guidelines for Procurement of Goods, Works, and Non-Consulting Services under IBRD Loans and IDA Credits & Grants by World Bank Borrowers” (January 2011, revised July 2014; the “Procurement Guidelines”), and subject to the additional provisions in the following paragraphs:

160. **Eligibility:** Eligibility to participate in a procurement process and to be awarded an IDA-financed contract shall be as defined under Section I of the Procurement Guidelines; accordingly, no bidder or potential bidder shall be declared ineligible for contracts financed by IDA for reasons other than those provided in Section I of the Procurement Guidelines. No restriction based on nationality of bidders and/or origin of goods shall apply, and foreign bidders shall be allowed to participate in NCB without application of restrictive conditions, such as, but not limited to, mandatory partnering or subcontracting with national entities.

161. **Domestic Preference:** No margins of preference of any sort shall be applied in the bid evaluation.

162. **Bidding Documents:** Procuring entities shall use bidding documents acceptable to IDA.

163. **Bid Validity:** An extension of bid validity, if justified by exceptional circumstances, may be requested in accordance with Appendix 1 of the Procurement Guidelines. A corresponding extension of any bid guarantee shall be required in all cases of extension of bid validity. A bidder may refuse a request for extension of bid validity without forfeiting its bid guarantee.

164. **Qualification:** Qualification criteria shall be clearly specified in the bidding documents. All criteria so specified, and only such specified criteria, shall be used to determine whether a bidder is qualified. Qualification shall be assessed on a “pass or fail” basis, and merit points shall not be used. Such assessment shall be based entirely upon the bidder’s or prospective bidder’s capability and resources to effectively perform the contract, taking into account objective and measurable factors, including: (i) relevant general and specific experience, and satisfactory past performance and successful completion of similar contracts over a given period; (ii) financial position; and where relevant (iii) capability of construction and/or manufacturing facilities.

165. Prequalification procedures and documents acceptable to IDA shall be used for large, complex, and/or specialized works. Verification of the information upon which a bidder was prequalified, including current commitments, shall be carried out at the time of contract award, along with the bidder’s capability with respect to personnel and equipment. Where pre-qualification is not used, the qualification of the bidder who is recommended for award of contract shall be assessed by post-qualification, applying the qualification criteria stated in the bidding documents.

166. **Bid Evaluation:** All bid evaluation criteria other than price shall be quantifiable in monetary terms. Merit points shall not be used, and no minimum point or percentage value shall be assigned to the evaluation criteria or significance of price in bid evaluation. No negotiations shall be permitted.

167. **Guarantees:** Guarantees shall be in the format, shall have the period of validity, and shall be submitted when and as specified, in the bidding documents.

168. **Cost Estimates:** Detailed cost estimates shall be confidential and shall not be disclosed to prospective bidders. No bids shall be rejected on the basis of comparison with the cost estimates without IDA's prior written concurrence.

169. **Rejection of Bids and Re-bidding:** No bid shall be rejected solely because it falls outside of a predetermined price range or exceeds the estimated cost. All bids (or the sole bid if only one bid is received) shall not be rejected, the procurement process shall not be cancelled, and new bids shall not be solicited without IDA's prior written concurrence.

170. **Fraud and Corruption:** In accordance with the Procurement Guidelines, each bidding document and contract shall include provisions stating IDA's policy to sanction firms or individuals found to have engaged in fraud and corruption as set forth in the Procurement Guidelines.

171. **Inspection and Audit Rights:** In accordance with the Procurement Guidelines, each bidding document and contract shall include provisions stating IDA's policy with respect to inspection and audit of accounts, records, and other documents relating to the submission of bids and contract performance.

Procurement Plan

172. The MOH, with the support of the World Bank, developed a procurement plan for at least the first 18 months of project implementation. The World Bank reviewed and approved this plan by negotiations. The procurement plan includes all the procurement packages identified for the first 18 months and if possible beyond project implementation. The procurement plan will be updated as required at least once a year throughout the life of the project.

Goods, Works, and Non-consulting Services

173. **Prior Review Threshold.** Table 17 outlines procurement decisions that are subject to prior review by the Bank (Appendix 1 to the Guidelines for Procurement).

Table 17: Prior Review Threshold: Goods, Works, and Non-consulting Services, Zambia

	Procurement Method	Prior Review Threshold (US\$)	Contracts Subject to Prior Review
Works			
1.	ICB	≥10,000,000	All
2.	NCB	>300,000 - <10,000,000	As per procurement plan
3.	Shopping (Small contracts)	<300,000	As per procurement plan
4.	Direct Contracting	N/A	All
Goods and Non-consulting Services (excluding consulting services)			
1.	ICB	>2,000,000	All
2.	NCB	>100,000 - <2,000,000	As per procurement plan
	Shopping (motor vehicles only)	<300,000	None
3.	Shopping (all other goods / non-consultant services, supply and installation)	<100,000	None
4.	Procurement from UN Agencies	All	None
5.	Direct Contracting	N/A	All

174. **Procurement Packages Subject to Bank Prior and Post Review.** The procurement packages for supply and installation contracts and non-consulting services that will be subject to Bank prior and post review were provided in the procurement plan that was reviewed and approved during negotiations.

Selection of Consultants

175. **Prior Review Threshold.** Table 18 outlines consultant selection decisions subject to prior review by the Bank (Appendix 1 to the Guidelines Selection and Employment of Consultants).

Table 18: Prior Review Threshold: Consultants

	Selection Method	Prior Review Threshold (US\$)	Comments
1.	QCBS and QBS	≥200,000	All except for engineering and contract management only whose threshold will be ≥\$200,000
2.	FBS, QBS, LCS and CQS	<200,000	As per procurement plan
3.	Single Source (Firms)	N/A	All
4.	Individual Consultants	≥100,000	All
5.	Individual Consultants	<100,000	As per procurement plan
6.	Single Source (Individual Consultants)	N/A	All
<p><i>Note:</i> QCBS = Quality- and Cost-Based Selection (Section II of the Consultants' Guidelines) LCS = Least Cost Selection (Para 3.6, of the Guidelines) CQS = Selection based on Consultants' Qualifications (Para 3.7 of the Guidelines) FBS= Fixed Budget Selection (Para 3.5 of the Guidelines) QBS = Quality Based Selection (Para 3.2 of the Guidelines)</p>			

176. **Short List Comprising Entirely National Consultants.** Short list of consultants estimated to cost less than US\$200,000 equivalent per contract, except in cases of selection of engineering, contract management, environmental assessments and studies with cost estimates below US\$300,000 may comprise entirely of national consultants in accordance with the provisions of paragraph 2.7 of the Consultant Guidelines. All terms of reference, irrespective of the value of the consultancy assignment, are subject to prior review.

177. **Consultant Procurement Packages.** The procurement packages for consulting services that will be subject to Bank prior and post review were provided in the procurement plan that was reviewed and approved during negotiations.

Other

178. **Training.** This category will cover all costs related to the carrying out of study tours, training courses and workshops, i.e., hiring of venues and related expenses, stationery, and resources required to deliver the workshops as well as costs associated with financing the participation of community organization in short courses, seminars, and conferences, including associated per diem and travel costs. Training projects will be part of the Annual Work Plan and Budget and are included in the procurement plan. Prior review of training plans, including proposed budget, agenda, participants, location of training, and other relevant details, will be required only on an annual basis.

179. **Operating Costs.** Incremental operating costs relate to the project implementation services to be provided to the project. These will be procured using the Borrower's administrative procedures, acceptable to the World Bank. Lists of eligible expenditures applicable to each

participating borrower country or beneficiary institution will be spelt out in the specific Financing Agreement and PIM. The PIM will elaborate the applicable administrative procedures.

