REPUBLIC OF RWANDA

MINISTRY OF HEALTH

Tuberculosis National Strategic Plan 2013-2018 Extension 2018-2020

RWANDA BIOMEDICAL CENTER

A Healthy People. A Wealthy Nation

INSTITUTE OF HIV/AIDS, DISEASE PREVENTION&CONTROL (IHDPC)
TUBERCULOSIS & OTHER RESPIRATORY COMMUNICABLE DISEASES DIVISION

Kigali, February 2017

Table of Contents

ABBREVIATIONS

ACF	Active case finding
ACSM	Advocacy, communication and social mobilization
ADSM	Active drug safety monitoring
ART	Antiretroviral therapy
BCC	Behavior change communication
CDT	Centre of diagnostic and treatment of TB
CFR	Case fatality rate
CHU	University Teaching Hospital
CHW	Community Health Workers
CNR	Case notification rate
CPT	Cotrimoxazole preventive therapy
CSO	Civil Society organization
CT	Centre of treatment of TB
CXR	Chest radiography
DH	District Hospital
DHS	Demographic and Health Survey
DP	District Pharmacy
DQA	Data quality audit
DRS	Drug Resistance Survey
DR-TB	Drug-resistant TB
DS-TB	Drug-susceptible TB
DST	Drug susceptibility testing
ECSAHC	East, Central and Southern Africa Health community
e-LMIS	Electronic Logistics Management Information System
e-TB	Electronic case-based TB register
EQA	External quality assurance
FLD	First Line drugs
FNA	Fine Needle Aspiration
FY	Fiscal year
GFATM or GF	Global Fund against TB, AIDS-HIV and malaria (GFTAM)
GLI	Global laboratory initiative
GoR	Government of Rwanda
HC	Health centre
HF	Health facilities
HFU	Health financing unit
HIV	Human immunodeficiency virus
HR	Human resources
HRG	High-risk group
HSSP	Health Sector Strategic Plan
ICCM	Integrated community case management
IC	Infection control
IHDPC	
IMCI	Integrated Management of Children Illnesses
IPT	Isoniazid preventive therapy
KAP	Knowledge, attitude and practices
LIS	Laboratory information system
LMIS	Logistic management information system
LPA	Line Probe Assay
LQMS	Laboratory quality management system
LTBI	Latent TB infection
MCH	Mother and Child Health
MCCH	Mother Child and Community Health
MDG	Millennium Development Goal
MDR-TB	Multidrug-resistant tuberculosis
M&E	Monitoring and evaluation

MOH	Ministry of Health
MOTT	Mycobacteria other than tuberculosis
MPPD	Medical Production and Procurement Division (RBC)
MTR	Mid-term Review
MYICT	Ministry of Youth, information & communication
NGO	Non-governmental organization
MTR	Mid Term Review
NCD	Non-communicable diseases
NGO	Non-governmental organization
NISR	National Institute of Statistics of Rwanda
NRL	National Referral Laboratory
NSP	National Strategic Plan
NTP	National Tuberculosis Program
OPD	Out-patient department
OSDV	On-site data verification
PAL	Practical Approach to Lung Health
PBF	Performance Based Financing
PEPFAR	President's Emergency Plan for AIDS Relief
PLWH /PLHIV	People living with HIV
PMEBS	Planning, M&E, and business strategy / RBC
QA	Quality assurance
QC	Quality control
QMS	Quality management system
RBC	Rwanda Biomedical Center
RDB	Rwanda development board
RH	Referral hospital
RHMIS	Rwanda Health information system.
RMNCH	Reproductive, maternal, new born and child health
RRP+	Rwanda network of People living with HIV
RR-TB	Rifampicin resistant TB case
R&R	Recording and reporting
RSB	Rwanda standards board for drug quality assurance
RSQA	Rapid service quality assessment
SDG	Sustainable Development Goal
SLD	Second Line drugs
SOP	Standard Operating Procedures
SPH	School of Public Health
SPIU	Single Project Implementation Unit
SWOT	Strengths, weaknesses, opportunities and threats
TAT	Turnaround time
TB	Tuberculosis
TB&ORD Division	Tuberculosis and other respiratory diseases Division
The Union	International Union against Tuberculosis and Lung Diseases
TWG	Technical working group
TST	Tuberculin Skin Test
UHC	Universal Health coverage
UNAIDS	Joint United Nations Programme on HIV/AIDS
USG	United States Government
VRS	Vital registration system
WHO	World Health Organization
Xpert MTB/RIF	Rapid TB and MDR-TB diagnostic test based on nucleic acid amplification

Executive Summary

The extended TB National Strategic Plan (TB-NSP) 2018-2020 has been developed by the TB&ORD division of RBC, referred as National TB program (NTP) throughout this document. It is a comprehensive update of the 2013-2018 TB-NSP aimed at implementing recommendations of NSP Mid-Term Review (MTR) conducted in November 2016 and to align to the global End TB Strategy of the World Health Organization. Rwanda's vision is to eliminate TB and attain the Sustainable Development Goals (SDGs) by 2030 and to eliminate TB in Rwanda by 2035.

Tuberculosis remains a public health concern in Rwanda. According to WHO estimates, incidence and TB mortality rates are on steady decline which suggest decreased transmission of the disease. Treatment coverage is estimated at 84% indicating that significant numbers of prevalent TB cases are missed. For the 2013-2018 period, the National TB program (NTP) invested a lot of interventions aimed at increasing early TB case finding through active TB screening among prioritized High-Risk Groups and scaling up more sensitive diagnostic methods (Xpert MTB/RIF) in all DH. Rwanda NTP has maintained high performance with regard to treatment success rates and ART coverage among TB patients co-infected with HIV. In addition, the country has implemented the shorter 9-months regimen recently endorsed by WHO for MDR-TB treatment. Significant progress has been made in monitoring and evaluation (M&E), including the rollout of electronic reports using the RHMIS and the introduction of an electronic patient based register (e-TB) in all health facilities.

Main program gaps highlighted by the MTR include the under-utilization of Xpert and radiography in the TB diagnostic process, sub-optimal biosafety and lack of maintenance of laboratory equipment, insufficient efficiency of the national sample transportation system, low detection of childhood TB, insufficient coverage of drug susceptibility testing especially among previously treated patients, absence of a pharmacovigilance system and lack of nutritional support for drug-susceptible TB patients, declining participation of Community Health Workers (CHWs) coupled with gaps in their TB knowledge. Those gaps will be addressed by introducing new proper strategic interventions, while maintaining and/or improving interventions that have proven successful.

Main strategic changes in this extended NSP aim at increasing sensitivity of the case finding strategy. XPert MTB/RIF will be adopted as initial diagnostic test for all presumptive TB cases in a phased manner, first optimizing and later increasing the capacity of the laboratory network. Radiological screening, currently used for active case finding campaigns in prisons and for PLHIV at high HIV prevalence health centers (HC) will become systematic for all new PLHIV and all TB contacts at the beginning of treatment of the index case. Both interventions will ensure accurate diagnosis, universal access to DST and proper treatment based on drug susceptibility. Key interventions to support this new strategy are the introduction of connectivity systems within the laboratory networks, strengthening the sample transportation system, regular maintenance of laboratory equipment, efficient procurement of cartridges, training on new guidelines and chest radiography (CXR) interpretation, supervision and continuous monitoring to detect implementation bottlenecks in a timely manner. Additional laboratory and radiography equipment will be needed.

In addition to this, the TB-NSP 2018-2020 foresees new interventions such as the introduction of mentorship program on childhood TB, the establishment of an active drug safety monitoring and management system (aDSM), the provision of nutritional support for the moderate and severely malnourished drug-susceptible patients, the introduction of new drugs for defined category of MDR-TB patients, and the transition to individual case-based electronic reporting system.

This plan requires stronger engagement of the CHWs, CSOs, NGOs and private clinics as well as sustained coordination across MoH divisions, government institutions and with NTP external partners to advocate for universal health coverage and social protection in benefit of all TB patients.

The top-10 indicators of the END-TB strategy have been incorporated in the M&E plan. NSP main targets are to achieve 89% treatment coverage and at least 87% treatment success rate for all patients diagnosed with TB by end of 2020.

The estimated total budget for the 3-year plan is US$ 22 million of which 22% are already committed by the Government of Rwanda and 64% by the Global Fund.

I. OVERACHING GOAL AND NSP DEVELOPMENT PROCESS

I.1. Overarching goal

This TB-NSP is guided by the Government's overall vision of development in the health sector, as set out in Vision 2020, the Economic Development and Poverty Reduction Strategy (EDPRS II 2013-2018), the Rwandan Health Policy of 2014 and the Health Sector Strategic Plan III July 2012 – June 2018. The overall objective of the health sector is to ensure universal accessibility (in geographical and financial terms) of equitable and affordable quality health services (preventative, curative, rehabilitative and promotional services) for all Rwandans. Extension of EDPRS II 2013-2018 and the HSSPIII are expected by end 2017 and new orientations will be taken into consideration.

At international level, the most important policies and commitments providing direction to this NSP are the Sustainable Development goals (SDGs), the End TB strategy and the Africa Health Strategy 2016-2030.

Rwanda's vision is to eliminate TB and attain the Sustainable Development Goals (SDGs) of reducing TB incidence and TB deaths by 80% and 90% respectively by 2030 compared to 2015. This extended plan aims at achieving the End TB milestones set up for 2020 of reducing TB incidence by 20%, TB deaths by 35% and eliminating catastrophic costs for TB affected patients and families. Therefore, NTP intends to approach the TB Global plan targets of ensuring 90% treatment coverage and 90% treatment success rate for all TB patients by 2025 the latest.

I.2. NSP development process

The extended TB National Strategic Plan (TB-NSP) 2018-2020 was developed following the external mid-term review (MTR) of the TB-NSP 2013-2018 conducted in November 2016. It is a comprehensive update of the current 2013-2018 TB-NSP aimed at implementing recommendations of the review and align to the End TB Strategy of the World Health Organization (WHO). It has been developed with active participation of the TB stakeholders including civil society, national and international partners and the Government of Rwanda, through a series of workshops and consultative meetings under the lead of the NTP.

This extended NSP gives a general vision of where Rwanda is now in terms of TB control, where we want to be by the end of this three year extended plan and how we plan to get there. The chapter on situation analysis provides the key elements of the current situation; the policy environment, guiding principles and result framework give us indications of where we want to go, and the remainder of the document describes how we plan to get there (detailed interventions, M&E plan and costing, prioritization and implementers).

Costing estimates were adapted to the projected decrease in external funding, with prioritization of the most cost-effective interventions.

II. SITUATION ANALYSIS

II.1. Context and Health sector policies

II.1.1. Demographic and politico-administrative environment

Rwanda is an East African country, bordered to the north by Uganda, to the south by Burundi, to the west by the Democratic Republic of Congo and to the east by Tanzania. Rwanda has a total surface area of 26,338 km^2 and is divided in five provinces which are divided in 30 districts which are divided into 416 sectors, which are further divided into 2,148 cells then into 14,837 villages (Umudugudu).

Based on the August 2012 national census, the population as of 2016 is estimated at 11,533,446 inhabitants [1], giving a population density of 437.9 inhabitants per km² and a population growth rate of 2.6% per year since the 2002 census. The majority, 83% of the population lives in rural areas; 51.8% are women and 48.2% are less than 15 years of age. The poverty rate has declined from 77.8% in 1994 to 44.9% in 2010-2011 fiscal year (FY)[2] and to 39.1% in 2013/14[3]. In 2014, the Gross Domestic Product per head was 718$, compared to 572$ in 2010. Life expectancy in 2015 was 66.7 years.

II.1.2. Health policy environment

The larger vision for the Government of Rwanda (GoR) is to guarantee the wellbeing of the entire population by increasing production while decreasing poverty through good governance. In this context, the mission of the health sector is to guarantee and improve the health status of the Rwandan population through the provision of good quality services in terms of prevention, rehabilitation and curative medicine in an efficient health system.

II.1.2.1. End TB strategy

In May 2014, the Sixty-seventh World Health Assembly adopted the End TB Strategy that aims at ending the global TB epidemic by 2035. This means reducing the TB burden in the whole world to levels achieved in high-income countries. The End TB Strategy builds on and significantly expands the scope of efforts in the context of the United Nations Sustainable Development Goal 3.3.
The Global Strategy comprises three pillars, namely:

(1) Integrated, people-centred care and prevention – aimed at early and universal access to diagnosis and treatment of all forms of tuberculosis;
(2) Bold policies and supportive systems – aimed at strengthened government leadership, civil society and private sector engagement, as well as universal health coverage, social protection, poverty alleviation and action on the social determinants of TB;
(3) Intensified research and innovation – aimed at accelerating discovery, development and rapid uptake of new tools, interventions and strategies.

The strategy has specific indicators, milestones and targets for 2020, 2025, 2030 and 2035.

II.1.2.2. The Sustainable Development goals and TB

The GoR has committed itself to achieving the Sustainable Development Goals (SDGs) by 2030, which were adopted in 2015 by the United Nations (UN). The SDGs[4] have set the target of ending the TB epidemic by 2030. They are fully aligned with the WHO End TB Strategy.

The specific target on TB (Target 3C) stipulates to end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases. Other SDGs targets related to health and/or social determinants of health which have potential impact on TB: End poverty in all its forms everywhere; End hunger (malnutrition); Reduce maternal mortality; End preventable deaths of newborns and children under 5 years of age; reduce premature mortality from non-communicable diseases (diabetes); Achieve universal health coverage; reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination (household and ambient air pollution, unsafe water, unsafe sanitation and lack of hygiene).

---

[1] *2012 Population and Housing Census,* **Population size, structure and distribution**, Novembe*r 2012*. 2012, National Institute of Statistics of Rwanda: Kigali-Rwanda.
[2] *Rwanda Statistical Year Book, 2012 Edition, N.I.o.S.o. Rwanda, Editor. 2012, National Institute of Statistics of Rwanda: Kigali-Rwanda.*
[3] *Rwanda Statistical Year Book, 2015 Edition, N.I.o.S.o. Rwanda, Editor. 2015, National Institute of Statistics of Rwanda: Kigali-Rwanda.*
[4] Report of the Inter-Agency and Expert Group on Sustainable Development Goal Indicators (E/CN.3/2016/2/Rev.1), Annex IV

II.1.2.3. The Africa Health Strategy 2016-2030

The goal of the Africa Health Strategy (AHS) 2016-2030 is to ensure healthy lives and promote the well -being for all in Africa in the context of "Agenda 2063: The Africa We Want" and the Sustainable Development Goals. The overall objective is to strengthen health systems performance, increase investments in health, improve equity and address social determinants of health to reduce priority diseases by 2030.

II.1.2.4. The Rwanda 2020 Vision

Developed in 2000, the Rwanda Vision 2020 sets out the long term vision for the country in terms of goals and objectives by the year 2020. The goal is for Rwanda to become a middle-income country, halving the percentage of people living in poverty, raising life expectancy to 55 years and reducing its aid dependency. It expects to reach these goals by means of 7 strategies/pillars, to be attained by decreasing population growth, increasing education and improving the health of people. The GoR considers good health for its population a valuable asset in itself, contributing to greater general welfare, as well as a means to reduce poverty and increase economic productivity through a healthy workforce. Inversely, illness is related to poverty: illness and injuries can result in high health care costs, which can steep families further into poverty. Also, poverty can prevent people from seeking necessary health care. Good health care services, provision of clean drinking water and good hygiene, effective waste disposal and sanitation systems are all important measures to attain health. Vision 2020 also pursues gender equity to be integrated into all development policies and strategies. The document serves as the basis for the national and sector plans for the medium term.

II.1.2.5. The Health Sector Strategic Plan III July 2012 – June 2018

The five overall priorities of HSSP III are[5]: 1) achieve MDGs: 1 (nutrition), 4 (child), 5 (MCH) and 6 (Disease control) by 2015; 2) Improve accessibility to health services (financial, geographical, community health); 3) Improve quality of health provision (quality assurance, training, medical equipment, supervision); 4) Reinforce institutional strengthening (especially towards district health services); And 5) Improve quantity and quality of Human Resources for Health (planning, quality, management). The first objective of the HSSP III includes the reduction of TB-related morbidity and mortality as well as interrupting its transmission through the improvement of case detection and management of both drug susceptible and drug resistant TB; improved TB prevention with community involvement; strengthened TB/HIV integrated interventions; and strengthened TB M&E. In addition, the HSSP III aims to expand appropriate diagnostic services, based on the most recent technology in laboratory and imaging sciences, to encourage the introduction of electronic health systems, including for TB. and to improve monitoring of drug resistance pathogens (HIV, TB and other bacterial infections). In line with the Rwanda Health Sector Research Policy (2012), HSSP III intends to build HR research capacity; to strengthen coordination among research institutions; to initiate new research activities and to provide financial resources. Identified main challenges that could impede the HSSP III are[6]: Still limited technical performance of the staff in health centers and district hospitals; less than 100% coverage of the health infrastructure; old equipment in the hospitals and HCs; limited maintenance facilities; challenge to sustain (external) funding; Implement the decentralization process, strengthen district planning, budgeting and reporting by DHU / DH[7].

II.1.2.6. The National Tuberculosis Control Strategic Plan July 2013 - June 2018

With the 2013-2018 TB NSP, TB control strategy was clearly reformulated: while maintaining TB control activities in general population, new and more sensitive screening and diagnostic strategies were introduced to target prioritized high risk groups and maintaining the level of involvement of community health workers to ensure equity in TB control activities. It has four objectives: 1) Provide early TB detection in general population and intensify case-finding in prioritized high-risk groups so

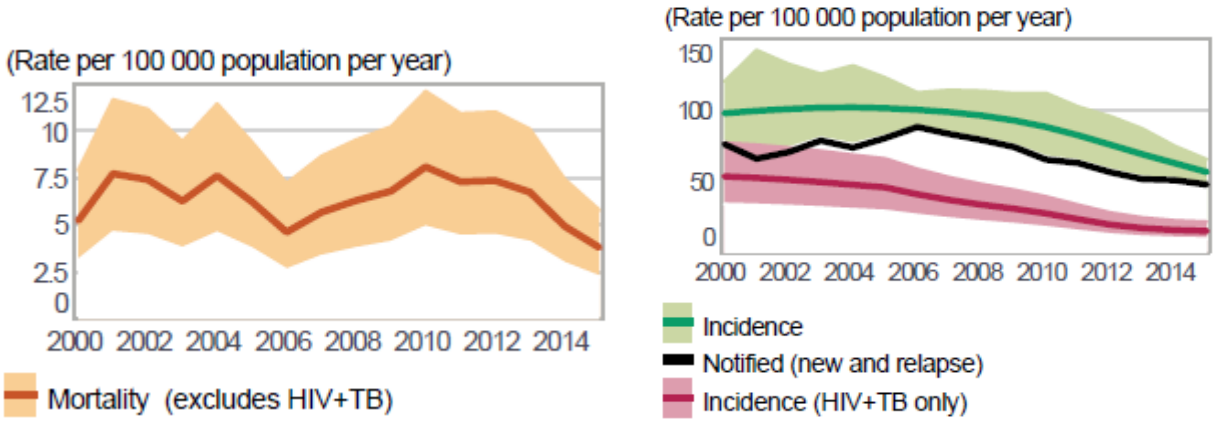
[5] Rwanda Health System Strategic Plan III.
[6] Rwanda Health System Strategic Plan III.
[7] Rwanda Health System Strategic Plan III.

that the proportion of TB cases all forms identified among HRG increases from 14% to at least 24% by mid-2018, 2) Increase treatment success rate from 88% to 90% for bacteriologically confirmed TB cases and maintain it at 87% for MDR-TB, 5) Improve TB prevention (TB infection control in health facilities, behavioral change in the general population and prevention by medication) so that the percentage of population with adequate knowledge on TB increase from 56% to 75% by 2018, 4) Improve managerial capacities of the TB program; enhance the monitoring, evaluation system and operational research, by implementing and make functional* an electronic TB register in all CDTs.

II.2. TB epidemiology in Rwanda

WHO estimates of Rwanda TB burden were reduced in 2014 after the national TB prevalence survey found a lower TB prevalence than had been previously estimated[8]. Estimated TB incidence rates in Rwanda are lower than the Global and AFRO Regional average, but remains high with 56 (48-65) incident TB cases -new and relapse- per 100,000 habitants in Rwanda in 2015 vs. 142 and 275 respectively at global and AFRO Region level[9]. Rwanda achieved the MDG target of halting the TB incidence in 2006. Incidence has since then been on a steady decline at an average rate of 8% per year between 2010 and 2015[10] (Figure 1). Similarly, after an initial increase between 2006 and 2010, mortality has been on a consistent decline thereafter to the current level of 6.2 per 100,000 population.

Figure 1 : Trends of WHO estimates of mortality and incidence rates, 1990 to 2015 in Rwanda



Source: WHO Global TB report 2016.

TB burden in Rwanda's neighbouring countries is high, 3 of them being among the 22 high TB burden countries (table 1).

Table 1 : TB burden in Rwanda and neighbouring countries, WHO data 2015

	DRC	Uganda	Tanzania	Burundi	Kenya	Rwanda
Incidence rate per 100,000	324	202	306	122	233	56
Notification All-forms Numbers	120,508	43,736	62180	6,966	81,518	5,637
TB Mortality rate (HIV- and HIV+ TB cases) per 100,000	87	30	103	30	35	6.2
Is the country among the 22 high burden countries?	Yes	Yes	Yes	No	Yes	No

[8] The prevalence of all forms of TB in the total population of Rwanda was re-estimated by WHO to be 95 (95% CI 69-125) for 2012.

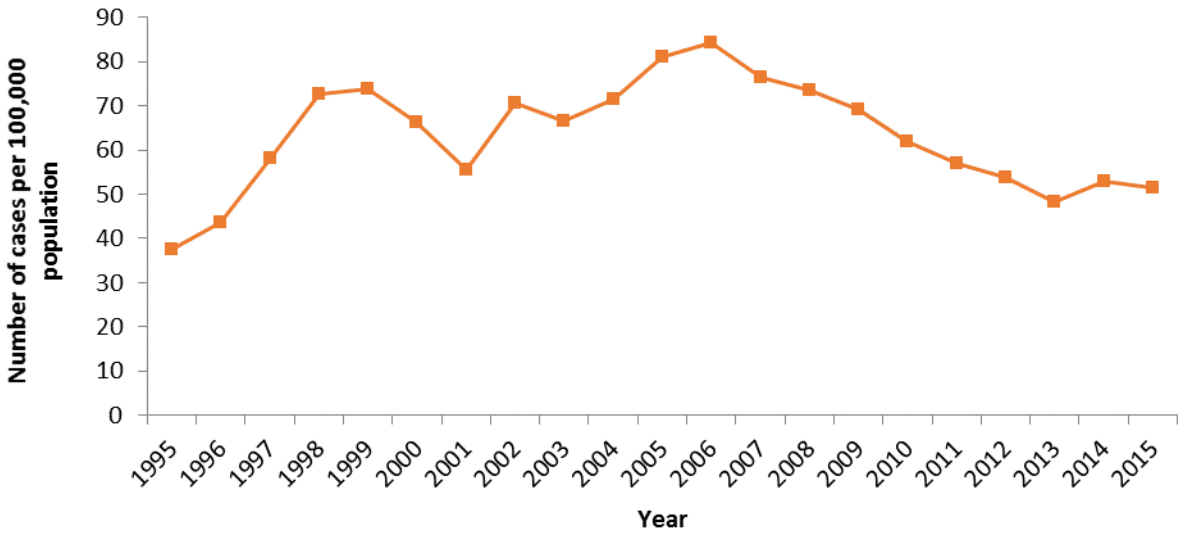
[9] World Health Organization. Global tuberculosis report 2016

[10] Population of 11,357,730 based on Rwanda national Statistics Institute estimates

Source: WHO Global TB report 2016.

The case notification rate (CNR) decreased between 2006 and 2013, and then increased slightly in 2014 and 2015; with a CNR of 50 per 100,000 in 2015 (figure 2). This increase is attributed to increased screening activities, in part due to active case finding (ACF).

Figure 2: Trend in TB case notification rate, 1995-2015



In 2015/16 FY, a total of 5,763 TB cases were notified. The proportion of TB patients infected with HIV remains stable each year at about 25%. The highest proportion of TB cases were aged between 25 and 44 (47.6%) while children (<15) and elderly (> 55) represented 6% and 15.5% respectively with majority of the cases being males (male to female ratio of 2.0) (table 2).

Table 2: TB notifications by case category, age and sex, July 2015-June 16

Cases Types	0-14 years		15-24 years		25-34 years		35-44 years		45-54 years		55-64 years		>=65 years		TOTAL		
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	TOTAL
NTPB+	28	36	368	311	799	373	654	221	400	137	284	98	155	59	2,688	1,235	3,923
Relapses	0	1	9	8	69	26	73	26	51	17	44	8	14	3	260	89	349
TAF	0	0	4	1	10	4	15	7	10	0	6	1	4	1	49	14	63
TALTFU	0	0	3	4	17	3	4	0	2	0	3	0	0	0	29	7	36
NTPB-	14	12	11	15	29	20	29	17	33	20	36	15	23	23	175	122	297
NTPB0	71	65	7	12	14	13	18	3	8	4	8	5	8	11	134	113	247
NEPTB	49	22	100	41	114	83	67	51	55	28	37	29	32	24	454	278	732
Others	5	2	5	9	10	10	15	12	12	11	9	2	10	4	66	50	116
TOTAL	**167**	**138**	**507**	**401**	**1062**	**532**	**875**	**337**	**571**	**217**	**427**	**158**	**246**	**125**	**3,855**	**1,908**	**5,763**

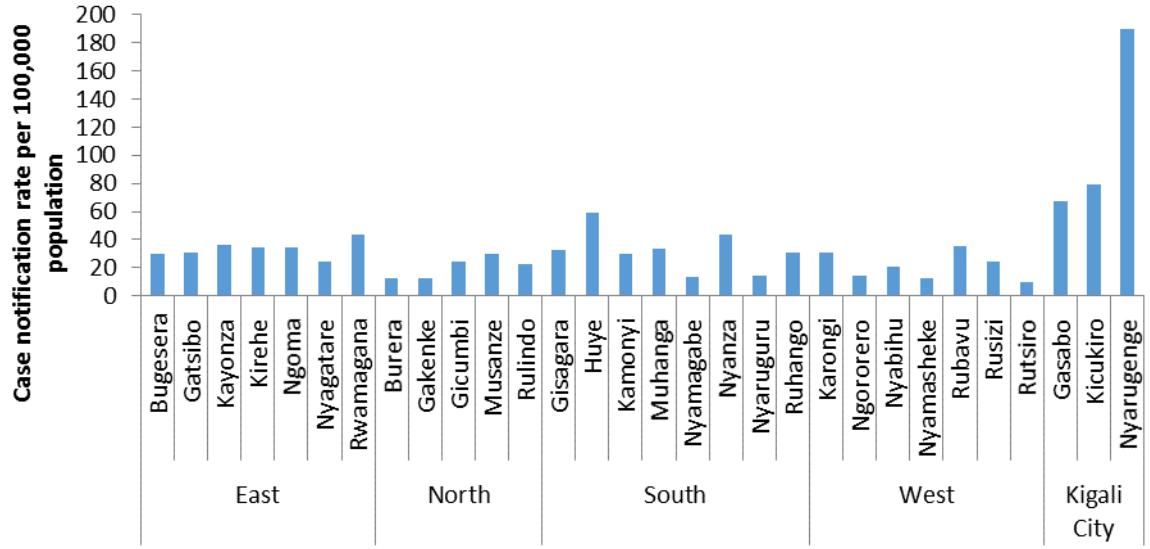
NTPB+ = new pulmonary TB case bacteriological confirmed.
TAF: Treatment after Failures.
TALTFU: Treatment after lost to follow up.
NEPTB=Extra pulmonary TB.
NTPB-: sputum smear negative.
NTPB0: sputum smear not done.
M: male.
F: female.

Source: TB&ORD annual report July 2015-June 16

For the same year, 167,941 presumptive TB cases were tested by microscopy or Xpert; the positivity rate was 2.6%, against 2.1% in the previous year, which is attributed to higher use of Xpert MTB/RIF. The positivity rate was higher in Kigali districts (8.6% at Nyarugenge, 7,9% at Kicikiru and 4.7% at Gasabo). These districts accounted for 33% of cases in 2015 and, like every year, they report the highest case notification rates (Figure 3).

Figure 3. TB case notification rate for new and relapse bacteriologically confirmed TB cases by district, 2015 Rwanda.

(a)



43% of all presumptive cases and 44% of all TB cases (2,534/5,763) were notified among the five prioritized high risk-groups (table 3). CHWs contributed to 44.5% of all presumptive cases and to 19.4% of all TB cases.

Table 3: Screening, number of presumptive and diagnosed TB cases among high risk groups, 2015/16

High-risk groups	Screened N	Presumptive TB N (%*)	TB cases N (%**)
HIV+ persons (exclude prisoners, contacts, children & elderly)	531,485	15,000 (8%)	1,195 (8%)
Contacts (of pulmonary bacteriologically confirmed case)	16,953	3,278 (19%)	77 (2%)
Prisoners	70,083	5,915 (10%)	159 (3%)
Elderly ≥55 years (excludes prisoners & contacts)	978,930	33,329 (3%)	828 (2%)
Children <15 years (excludes prisoners and contacts)	1,633,287	19,690 (1%)	275 (1%)
Total from high risk groups	**3,230,738**	**77,212 (3%)**	**2,534 (3%)**

*Proportion with presumptive TB out of those screened

**Proportion diagnosed with TB out of those with presumptive TB

II.3. Drug-resistant Tuberculosis in Rwanda

Rwanda has a relatively low MDR-TB burden. Findings from the recent TB Drug Resistance Survey conducted in 2015/2016 revealed low levels of drug resistance to first line drugs (1.5% in new cases; 10.7% in previously treated cases) and no established resistance to any second line TB agent. In 2015/16 FY, Rwanda notified 95 confirmed and 1 empiric cases of MDR/RR-TB compared to the 120 (95% CI 78-180) estimated by WHO, of which 59 (63%) were new cases and 47 (49%) were HIV positive. The main factor driving MDR-TB appears to be transmission by infected individuals not yet detected. The programme has been successful in eliminating the diagnosis versus treatment gap, such that all of the 95 notified cases (97%) were initiated on the shorter 9-month MDR-TB treatment while one was initiated on the longer standard 20-month regimen because a failure of the shorter treatment. In July 2014, Rwanda participated at the multicountry study led by the UNION with the aim to evaluate the “effectiveness and tolerance to a short course MDR-TB treatment”. Study results

revealed higher cure rate with the shorter (9 months) regimen compared to the conventional one (20-24 months). Based on these findings, WHO recommends the use of this regimen under specific conditions and Rwanda has adopted the shorter treatment regimen in line with WHO recommendations.

Table 4: DR-TB WHO estimate and Rwanda notification*. 2015 (calendar year)

	New cases	Previously treated cases	Total number
Estimated number TB cases with MDR/RR-TB			120 (73-180)
Estimated % of TB cases with MDR/RR-TB	1.5% (0.77–2.2)	11% (3.3–18)	
Notified Laboratory-confirmed cases			94
Patients started on treatment			93

Source. WHO Rwanda Country profile 2016.

There have been consistently less than 100 patients on annual basis over the last 8 years and no XDR-TB was diagnosed.

Table 5: Trend of DR-TB notification (number of cases). 2005-2015

MDR-TB notification	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Notified TB	7,680	8283	8014	7841	7644	7065	6784	6208	6091	5706	5637
Notified MDR-TB	35		102	79	78	90	76	57	42	80	94

Source: national data

II.4. National response

II.4.1. TB case finding

The National TB program (NTP) has invested a lot of interventions towards increasing early and accurate TB case finding among prioritized High-Risk Groups (HRGs) including active case finding among prisoners, intensification of TB screening among PLHIV, TB contacts at the beginning and end of treatment of the index case, children and elderly patients of the health facilities. The TB diagnostic algorithm was revised to include XPert MTB/RIF in addition to microscopy for HRGs. The capacity for rapid molecular test has been expanded and by the end of 2016, Xpert was accessible in 46 hospitals laboratories including 7 sites in Kigali City. As a result, in 2015-16, 42% of all TB presumptive cases and 44% of TB cases were detected among HRGs. However, according to WHO Global Report 2016, the TB treatment coverage[11] was 84% in 2015 indicating that about one thousand active TB cases were not diagnosed. Laboratory tests for TB diagnosis are free of charge.

Treatment coverage among children was estimated much lower at 40%. During the fiscal 2015-2016 year, 78% of the cases were aged 15-54 years while children under 15 years and elderly aged 55 and more represented 5.3% and 16.6% respectively for all TB cases. The proportion of children is below the expected norms of 10%, which may be a reflection of low detection levels for childhood TB. In order to improve TB detection and management in children, the NTP in collaboration with stakeholders developed childhood TB guidelines and a TB diagnostic algorithm specific to children including Xpert MTB/RIF as initial diagnostic test for all children presumed of TB. Systematic TB screening has been incorporated in IMCI clinics.

[11] Treatment coverage is the proportion of notified cases among the estimated incident cases

II.4.2. TB treatment outcome

Over the past 20 years, the NTP has demonstrated increasing success on treatment outcomes reaching respectively 90% for new bacteriologically-confirmed and 79% for clinically diagnosed cases enrolled in the 2014/15 cohort. The treatment success rate for all-forms cases of the same cohort was 86.5%. Excellent treatment outcomes (95%) have been noted especially for TB patients managed by CHWs. Overall treatment death rate was 7.9% for the same cohort, but it remains high at 15-20% for all sputum smear negative, smear status unknown and extra-pulmonary forms of TB, this may be due to late case finding and high HIV co-infection rate.

II.4.3. TB/HIV collaborative activities

Rwanda was one of the first African countries implementing TB/HIV collaborative activities. The country rapidly reached impressive results on HIV testing among TB cases (99% since 2012) and TB presumptive cases (99% in 2015/16), on CPT (99%) and ART among TB/HIV+ cases (93.9% for the cohort 2014/15). Integrated care and treatment is offered in all 200 CDT through the "One-stop TB/HIV service". Since July 2016, Rwanda implemented the "Treat all" policy, meaning that all PLHIV are enrolled on ART whatever their CD4 count or clinical stage in less than two weeks of testing. This policy is expected to introduce early treatment to healthier individuals and reduce TB morbidity and mortality associated to TB/HIV coinfection.

In 2016, Rwanda decided to stop the IPT pilot phase implemented in three sites; this decision was taken considering the low sensitivity of the screening questionnaire and microscopy. This was reflected through data collected in active case-finding campaigns conducted in 6 HC continuously reporting high TB/HIV prevalence in Kigali. All PLHIV had radiological and symptomatic screening and all screened positive had XPert test; 45% of the confirmed TB cases had no sign suggestive of TB but only abnormal CXR. Considering that excluding active TB by the absence of TB signs, as recommended in WHO guidelines, is not adequate in Rwanda, the TWG decided to stop IPT.

II.4.4. Drug resistant TB management

Rwanda started programmatic management of drug resistant TB using 20 month-treatment regimen in July 2005. The country operates a mixed model of care. All RR and MDR patients are hospitalized to initiate treatment at in one of the two MDR-TB centers (Kabutare and Kibagabaga) until they convert to culture negative and once stable, they are transported to a health centre near area of residence for ambulatory care. Patients receive psychological, nutritional and transportation support during the treatment to attend the Health Centre daily for supervised treatment administered by nurses.

Number of eligible groups for drug resistance test increased with inception of Xpert and includes all retreatment cases (failures, relapses, after interruption), contacts of MDR-TB, smear positive at month 2, HIV+ TB cases, smear positive TB among health staff, smear-positive TB in Kigali. In 2015/16 FY, 59% of new and 70% of previously treated cases bacteriologically confirmed TB cases had a drug susceptibility test (Xpert or phenotypic test), below targets (respectively 65% and 88%). Reliable DR-TB diagnosis capacity is available in 3 reference laboratories in Rwanda (National Reference Laboratory, Kigali and Butare University Teaching Hospitals), which are providing Xpert, LPAs, culture (on solid and liquid media) and DST for all eligible patients.
All patients diagnosed with MDR-TB are linked to care; no waiting lists exist. Rwanda has fully implemented the 9-month MDR treatment regimen in July 2014 and collaborated with The Union study. Treatment outcome are very high; 85.1% for patients enrolled on 20-month treatment in 2013/2014 and 84.8% for those enrolled on 9-month regimen in 2014/15 and the death rate was 13.5% and 12.1% respectively.

II.4.5. TB monitoring and evaluation

During the past years, the following main activities have been implemented in the area of TB monitoring and evaluation, to ensure quality of TB surveillance data. Those are: development and update of TB M&E policies/guidelines/tools and SOPs (using standardized reporting tools and WHO

definitions), related capacity building of concerned staff involved in TB data management at all levels of the health system, quarterly or biannual DQA and RSQA visits to intermediate and peripheral levels and regular evaluation meetings (quarterly and annual) with HFs and Districts to discuss TB program performance and TB program periodic reviews (WHO surveillance checklist and Epi-assessment) and annual data verification by LFA. In 2013, the WHO mandated a consultant to evaluate the TB surveillance system in Rwanda, completed in 2014 by a full "TB Epi-assessment". The conclusion of those external evaluations was that "in general the TB surveillance system in Rwanda seems to accurately capture TB cases detected and TB control program efforts"[12,13].

Significant progress has been done in monitoring and evaluation since the development of the NSP 2013-2018. The country is progressively transitioning from a paper-based to an electronic M&E system. Since January 2014, all HF are reporting quarterly aggregated data to RHMIS. The electronic patient based register (e-TB) is already incorporated in RHMIS. Active TB cases and all presumptive TB cases have to be recorded in e-TB, including their lab results. NTP trained the staff supposed to use the e-TB (TB nurses, M&E focal points and data managers).

II.4.6. Community management of TB

Community DOTS was initiated in 2005 and reached national coverage in 2010. The roles of CHWs are: a) sensitization of their communities on tuberculosis; b) identification and early orientation of people with cough to the HC; c) administration of DOT to patients; d) orientation of household contacts with cough to the HC; e) home visit and recuperation of TB patients who do not show for treatment. Currently, CHWs play a crucial role in bringing TB care close to the people. In 2015/16 FY, CHWs contributed to 44.5% of all presumptive cases and to 19.4% of all TB cases whereas 56% all TB patients were receiving DOT close to their home under observation of the CHWs. Treatment success for patients receiving community DOT is excellent at 95%.

II.4.7 TB prevention and infection control

Strong emphasis was put on TB infection control within the last NSP, the focus being on administrative, environmental and personnel protection measures. A minimum package of IC measures was defined which includes the existence of the IC plan and appointment of the TB focal point, regular training of health workers on IC, triage system and separation of coughers in the waiting areas, fast investigation of presumptive TB cases, IEC on cough hygiene and optimization of natural ventilation by maintaining opened doors and windows in services at higher risk for TB. According to the 2015-16 annual report, 80.1% (448/559) of the Health facilities are applying all six basic measures.

Surveillance of TB among health facilities workers (HFWs) was initiated in July 2015 and is done once a year. Specific register has been developed and distributed in all health facilities. Twenty-four thousand four hundred and forty-seven (24,447) health facility workers were sensitized on the importance of in 2015-2016. Among these 14,508 (59.3%) were screened and 19 were diagnosed as TB cases (1.3 per 1000).

With regard to Isoniazid preventive therapy, in 2015/16 fiscal year, 95.5% (2,289/2,397) of all children under 5 years who were contacts of tuberculosis bacteriologically-confirmed cases were screened for TB. Of these 12% (276/2,289) were presumptive TB cases and 6% (16/276) were TB cases. Among 2,273 children who screened negative, 78% (1,767/2,273) were enrolled on IPT. As explained above (section II.4.3 on TB/HIV collaborative activities) IPT for PLHIV was piloted in 3 HIV clinics but stopped in August 2016 based on evidences from active case finding activities indicating that clinical screening is not accurate to select eligible PLHIV.

[12] 2013 Evaluation of the Rwanda TB surveillance system using the WHO Checklist for standards and benchmarks for tuberculosis surveillance and vital registration systems

[13] Eveline Klinkenberg. Epidemiological review and impact analysis of tuberculosis in Rwanda. Rwanda 21-25 July 2014

II.4.8. Knowledge and health seeking behavior

The KAP study conducted in 2012[14] showed that comprehensive knowledge of TB improved from 40% in 2009 to 56% by end 2012. Updated information on TB knowledge was collected in the last DHS (2014), but the results have not yet been analyzed.

The TB prevalence survey[15] revealed that the health seeking behavior was poor. Only 40% of the survey participants reporting cough > 2 weeks sought care. Among them, only 48% were asked to provide a sputum sample while 15% were asked to conduct an X-ray. Although men are more prone to have TB, women showed higher health seeking behaviors. A previous study[16] suggest that late health seeking behavior might be due to stigma or self-stigmatisation since TB is perceived as an HIV-related disease..

II.4.9. TB control program coordination/management and financing in Rwanda

Country's vision includes ending priority SDG targeted diseases with well-established and focused structure to coordinate an integrated national response (RBC);

There is a longstanding history of partnership and support available to the TB Programme from international and national non-governmental organizations (INGOs and NGOs), bilateral and multilateral agencies, research institutes and universities for TB control in Rwanda. This collaboration includes financial assistance, technical assistance, materials in kind, diagnostic and treatment services, research, and management support. External partners firmly line up their aid behind the priorities outlined in the National Strategic Plan. Indeed, activities of donors have since the initiation of the program been guided by the National Strategy, and the vast majority of aid for tuberculosis is channeled through the government account.

In order to increase ownership over programs, Rwanda is using the performance based financing (PBF) mechanism aiming to improve the involvement of the health providers in implementation of the TB program at all levels of the health system. The 2013-2018 NSP was funded at a level of around 17.9 million annually. However, funding of the TB interventions is declining, which drive a very effective prioritization process of interventions planned in the new NSP to meet the resources that have projected to be available.

In line with MOH policy, the PBF for TB control activities was introduced in 2010. The system includes more than 20 TB-related indicators and it led to substantial improvements such as wide awareness on TB in community, increase easy access to TB services by involvement of CHWs (about 40% of all presumptive TB cases are brought by CHWs and half of TB cases managed through community DOT), better TB treatment success rate (especially for patients managed by CHWs). The TB suspicion, success rate and quality of services improved as a result of PBF towards HFs. The PBF scheme is also applied as a part of salary and as policy of MoH, aiming at improving staff performance; its payment is based on achievement of fixed targets set in contract between the two parts.

Capacity building for personnel involved in TB control activities has been one of the key interventions in the context of changes in different policies and guidelines, as well as for the new enrolled staff (introductory TB course). Examples of training provided include TB and TB/HIV, MDR-TB, TB infection control, TB laboratory, TB data management, CXR interpretation for MDs and radiology technicians, etc.

PAL was introduced during the 2009-2012 NSP with the objective to increase TB detection and improve the quality of TB suspicion and diagnosis investigation by the health services, in particular follow-up of sputum smear-negative HIV-positive TB presumptive cases; and to improve the

[14] National University of Rwanda, School of public health. Knowledge, Attitude and Practices study on Tuberculosis in Rwanda

[15] The first national tuberculosis prevalence survey 2012 in Rwanda.

[16] Ngang, P. N., Ntaganira, J., Kalk, a, Wolter, S. & Ecks, S. Perceptions and beliefs about cough and tuberculosis and implications for TB control in rural Rwanda. Int. J. Tuberc. Lung Dis. 11, 1108–13 (2007).

management of patients with chronic respiratory diseases. Guidelines for the practical approach to lung health (PAL) were developed both for Health centers and District Hospitals. PAL materials (Peak flow meters for all health centers, pulse oxymetres, hand held portable spirometers for all District hospitals, Oxygen concentrators for some hospitals) and products (Salbutamol and beclomethazone for all HF) have been procured and distributed. This approach has been implemented in all health facilities. The TB and ORD Division has continued to expand the PAL strategy through training to strengthen health care provider capacity, procurement of essential equipment and medicine and printing information material for health care staff. An assessment to evaluate the relevance, effectiveness, efficiency and sustainability of the PAL approach in primary health will be carried out in 2017.

In Rwanda, there is a policy and a legal framework including registration and limiting use/sale of TB drugs only by approved TB programs, which is in place since 1990. The procurement system for TB drugs, consumables and laboratory reagents is centralized where the Medical Production and Procurement Division (MPPD) conducts all health commodity procurement through WHO pre-qualified suppliers. The MPPD is responsible to storage and distribution of health commodities to all health facilities through the district pharmacies. A robust drug management system through paper based and an Electronic Logistics Management Information System (e-LMIS) has been implemented at different levels of the supply chain. Currently, the management of the drug information system is fully computer-based at central level (MPPD). District Pharmacies (DP) and health facilities (HF) are using e-LMIS mostly for ordering and distribution but warehouse management is still using paper based in (DP) and HF.

II.5. Current gaps in TB control activities in Rwanda

In this section, we describe programmatic gaps and other bottlenecks as highlighted in both internal and external evaluations and program assessments such as the epidemiological review conducted in 2014 and updated in 2016, the 2016 TB NSP mid-term review, the 2016 GLC evaluation, and the annual GLI evaluation of the laboratory network.

Although TB control in Rwanda has made substantial progress over the last decade, there are still gaps and significant challenges to the program. Nonetheless, there are also new opportunities to improve control. The main gaps are described in the following section.

II.5.1. The TB treatment coverage hasn't reached the desired level (about 16% of the estimated incident cases are not detected nor treated) despite ongoing efforts to increase TB detection among HRGs and to increase diagnostic capacities.

According to WHO Global Report 2016, the treatment coverage[17] in 2015 was 84% meaning that about 1000 active TB cases were not diagnosed. The 2016 mid-term review of the 2013-2018 TB NSP highlighted several weaknesses that may lead to under-detection of TB cases. These include the following: a) sub-optimal quality of TB screening and inadequate screening tools that do not capture all the 5 screening signs and do not allow analysis of the complete diagnosis cascade; b) under-utilization of Xpert and CXR in the diagnostic process; c) constraints related to the sample transportation system from peripheral HF to DH; d) delayed transmission of culture/Xpert results back to the requesting HF due to the lack of connectivity systems; e) lack of well-defined maintenance system of laboratory equipment (particularly Xpert machines) beyond their respective manufacturer's initial warranty periods, f) insufficient biosafety measures at the laboratories; d) insufficient mentorship and supervision of the health care providers and lab technicians; e) stagnating contribution to TB detection using CHWs resulting from the reduction of their stipend; f) insufficient awareness on TB and lack of an ACSM plan inspired on the ENGAGE-TB strategy. Low health seeking behavior was also highlighted through the national TB prevalence survey conducted in 2012.

[17] Treatment coverage is the proportion of notified cases among the estimated incident cases

There is insufficient detection of resistance. According to the July 2015-June 2016 TB&ORD annual report 59% of new bacteriologically confirmed TB cases and 70% (315/448) of previously treated TB cases had rapid test against NSP targets of 65% and 90% respectively. This sub-optimal performance is attributed to constraints for sample transportation from HCs to hospitals for Xpert testing, insufficient documentation of DST results in the TB registers, inadequate system for transmission of results from NRL and DH back to HC; and insufficient on-site support through supervision and mentorship.

II.5.2. Low detection of Childhood TB

In 2015-2016, the number of TB cases aged 0-14 accounts for only 5.3% of all TB cases that is similar to the proportion reported in previous years. TB treatment coverage among children is estimated at 40% that is lower than the 84% among adults. Possible low detection of children with TB may be due to limited health worker knowledge, skills, and confidence to suspect or establish clinical diagnosis; compounded by absence of mentorship and high staff turnover. Sample collection techniques (sputum induction, naso-gastric aspiration, fine needle aspirate) are not routinely used which may be limiting bacteriological confirmation of diagnosis in children. There are no SOP for such procedures and Pediatric guidelines are not yet published. Although childhood TB has been introduced in MCCH division activities; there are missed opportunity of using a family-centered approach and limited inter program collaboration. Children affected with TB do not yet benefit from the new pediatric formulations and may not receive adequate dosages and drug intake may be challenging in young children.

II.5.3. Gaps related to TB laboratory network

The national reference laboratory for TB (NRL) is mandated to provide leadership and expert guidance in order to strengthen the national tuberculosis laboratory diagnostic network to provide quality laboratory services and contribute to the reduction of the burden of tuberculosis and leprosy in the country**. However, the laboratory** has only 11 technical personnel in place of which 4 are supported from the recent DRS survey until June 2017, therefore this will leave a huge gap in terms of workload and distribution of labour to the remaining staff at NTRL, since the same personnel are involved in technical work on bench, preparation of reagents, quality control and quality assurance for the network, and EQA blinded rechecking as second controllers, at the same time conducting mentorship and support supervision for other intermediate laboratories in the country.

The NTRL is not ISO 15189:2012 accredited. ISO 15189:2012 for medical laboratories provides policies and guidelines on the stratified organizational structure (organogram) for a laboratory with key positions that ensures compliance of the ISO standard and LQMS implementation. Some of these key positions are currently not fulfilled (LQMS, biosafety, EQA coordinator, data manager).
The laboratory is geared towards accreditation by 2019 and become a supranational TB lab SRL candidate in the WHO AFRO. For this to be achieved, more staff is needed to support implementation of quality management system (LQMS) activities towards accreditation.

The laboratory has diagnostic equipment including Xpert, iLED microscopes for the network however the capacity to service, calibrate and maintain their functionality in the network is limited, thus there is need to plan for training personnel as superusers with capacity to maintain this equipment.

Specimen referral system especially sending samples from the peripheral sites to the District hospital is a challenge as well as delays in sending of results back to the clinician's, however with exploring other courier companies to transport samples and introduction of data connectivity solution this problem could be minimized.

II.5.4. The TB treatment success rate for all forms of TB is at 86.5%, below the 90% global target; no aDSM system is in place for both drug-susceptible and resistant TB cases; and no support is provided to vulnerable drug-susceptible patients (malnourished, diabetics, hospitalized...)

Although the treatment success rate for bacteriologically confirmed TB patients reaches 90%, it was 86.5% for all forms of TB, which is associated to a high fatality rate among clinically diagnosed (16%)

and HIV+ TB cases (15%). These deaths are attributed to late diagnosis (due to use of less sensitive screening and diagnosis strategies), low awareness on TB and HIV management, limited access to XPert test and radiography, insufficient human resources' capacity strengthening. Some deaths may also be attributed to other diseases/ comorbidities, such as malnutrition, diabetes etc. However, the real causes are not well identified due to the lack a functional vital registration system and a TB death audit reporting system.

Drug-susceptible patients with nutritional difficulties do not receive nutritional support, even if they are hospitalized, which may impede or slow recovery. Payment is required for the management of co-morbidities like diabetes and others; therefore, these comorbidities may not be treated and hamper TB cure. TB treatment educative materials and pamphlets for the patient and their families are not available to foster adherence, regular control and general awareness during treatment.

Following the MTR recommendation, the streptomycin-based regimen is being removed; it is necessary to ensure that DST is done for all previously treated TB case in order to provide them the proper treatment regimen based on sensitivity.

There is no active drug safety monitoring (aDSM) during treatment for both drug-susceptible and resistant TB cases, especially during ambulatory care of MDR-TB patients. There is no regular audiology monitoring during second-line treatment. Staff is not trained on aDSM nor on the interpretation of the audiology screening results. Knowledge and skills are not sufficient at peripheral HFs to effectively manage patients on ambulatory treatment, which is not adequately addressed by the current annual MDR-TB training. PMDT guidelines are not yet updated and do not incorporate the 9-months MDR-TB regimen nor the new TB drugs.

II.5.5. Gaps related to TB prevention and infection control

According to the Mid Term Review (MTR) of the TB NSP 2013-2018, infection control was recognized as a priority intervention in both policy and practices. A broad range of infection control (IC) measures including managerial, environmental measures and personal protection are implemented in all facilities in line with NTP and international recommendations. The MTR highlighted several weaknesses to IC including lack of Standard Operating Procedures (SOPs) on IC in most HF, implementation gaps of the IC policy and programme coordination due to high staff turnover, proper use of the personal protective equipment is not ensured, insufficient TB surveillance coverage among health workers, no TB screening for CHWs; lack of IC intervention at community level, infrastructure limitations hindering effective TB IC measures in a number of HFs especially poorly aerated waiting rooms in HIV clinics and other areas due to old and outdated infrastructure.
On the other hand, IPT coverage for contacts 0-5 years is at 78% and should be increased to 90%. The MTR team called attention to the fact that the discontinuation of preventive therapy for PLHIV was an area of challenge that requires reconsideration.

II.5.6. Monitoring and Evaluation (M&E) system and operational research not yet meeting all program information needs

The rollout of the electronic aggregate and patient based reporting (e-TB) systems in RHMIS, through systems development and staff training at all level (data managers, TB focal nurses, TB supervisors and M&E officers), were recognized as key achievements by the 2016 MTR. Despite that, there are remaining challenges, in particular advancing the M&E engagement through all levels (facility-district-national), which has particularly come to light with the low use of e-TB (only 30% of all presumptive and active TB cases are being registered in e-TB). The national M&E team might have insufficient staff resources to provide support to facility data managers in the use of e-TB or routinely clean, manage and analyse the data obtained from the system. Restricted access to the e-TB may slow down its use at HF level and it is not possible to enter the cases that do not have the required ID. On the other hand, the NTP doesn't have reliable data allowing the analysis of causes of death since the vital registration system implementation is still at an early stage.

II.5.7. Gaps related to TB Program coordination and financial capacity

The financial support for the TB program in Rwanda is declining whereas the achievements in TB control need to be maintained or scaled up with innovative interventions. The funding landscape is uncertain given that TB funding is mostly received through external sources. There is a need to identify and lobby for new funding sources aside the traditional funding development partners to support NSP implementation. Although the new technology such as Xpert and digital Xray has proven to be cost effective, it often increases the unit cost of TB case, calling for better synergies between programs and Health systems.

Rwanda faces a challenge of maintaining a complex strategy at lower cost with sufficient skilled human resources. While capacity building for personnel involved in TB control activities has been strengthened, the NTP still faces three main challenges in this area. These are high turnover of trained personnel (calling for repetitive refresher trainings), the need for integrated training (for cost-effectiveness) and the lack of an online interactive training system. Following MoH orientations, the NTP has strengthened on-site training and mentorship. However, TB is insufficiently covered in the Infectious disease mentoring initiative at the district level, which calls for providing clear guidelines and regular update training for mentors to maintain adequate implementation capacity at all levels.

There is particular threat to the community based TB care due to potential demotivation of CHWs resulting from the reduction in CHWs stipend in the last 2 years as evidenced by the stagnation of the CHWs case detection performance. This is coupled with gaps in their TB knowledge which are not addressed since there was no refresher training nor sensitization for CHWs in recent years. As a consequence, it is difficult to ascertain the quality of messages they are transmitting to the community and the quality of TB follow up in DOT patients.

The NTP has not elaborated an ACSM plan and doesn't produce adequate IEC/BCC materials on TB for the TB patients, their families, close contacts, and the overall public. However, findings of the TB prevalence survey[18] call for new strategies to raise awareness on the need to seek care when experiencing ≥ 2 weeks' cough.

Few private clinics are engaged in TB diagnosis and treatment; there is no guidance to assist NGOs/CSOs to engage on TB prevention, treatment and care at their workplace.

The PAL strategy introduced during the past NSP needs to be strengthened in all health facilities, and track of its outcome improved. Standardized M&E indicators and tools are not yet defined and a program evaluation is necessary to identify bottlenecks in the implementation process as well as results. The collaboration between the NTP, NCD Division and other health partners with regard to respiratory diseases should be strengthened.

[18] The first national tuberculosis prevalence survey 2012 in Rwanda.

III. The 2018-2020 extension of Tuberculosis National Strategic Plan 2013-2018 in Rwanda

III.1. VISION

Rwanda free of tuberculosis, with zero deaths, disease and suffering due to TB.

III.2. MISSION

To contribute to the end of global tuberculosis epidemic by promoting universal and equitable access to quality diagnosis and appropriate treatment of TB, MDR-TB, and TB/HIV patients and by enhancing prevention of the disease.

III.3. GOALS

NTP goal is to end the TB epidemic in Rwanda by 2035 which means to have 10 incident cases per 100 000 population or less per year (new and relapses).

The following goals are set up for end 2020 as compared to 2015:

- 20% reduction of TB incidence rate from 56/100,000 to 45/100,000 population
- 35% reduction of TB deaths
- 0% TB-affected families facing catastrophic costs due to TB

III.4. GUIDING PRINCIPLES

- Governance stewardship and accountability with adequate resources use as well as monitoring and evaluation.
- Strong coalition with civil society organizations and communities
- Health system strengthening
- Protection and promotion of human rights, ethics, equity and gender equality
- Adaptation of the strategy and targets to Rwanda context, with global collaboration

III.5. OBJECTIVES AND TARGETS FOR 2020

Objective 1: Improve early and accurate diagnosis of TB including universal DST through progressive adoption of WHO-recommended rapid tests for all presumptive cases so that TB treatment coverage[19] increase from 84% in 2015 to 89 % by mid-2021.

Objective 2: Provide patient-centered treatment for all forms of TB so that the treatment success rate be maintained at least at 90% for bacteriologically-confirmed tuberculosis and at least at 87% for drug resistant tuberculosis.

Objective 3: Improve TB prevention (TB infection control and prevention by medication) so that LTBI[20] treatment coverage among TB contacts $\leq$ 5 years increases from 78 % to 90 % by mid-2021.

Objective 4: Improve managerial capacities of the TB program; enhance the performance of the TB surveillance to achieve concordance between aggregate and case-based systems; and develop research.

Objective 5: Strengthen the coordination across MoH divisions and other government ministries as well as the collaboration with communities, civil society, private care providers and local administrations so that zero TB-affected families are facing catastrophic costs[21] due to TB.

[19] Treatment coverage = Number of notified and treated cases / Estimated number of incident cases (new and relapses)
[20] LTBI: latent tuberculosis infection
[21] The operational definition of "catastrophic costs" refers to medical and non-medical out-of-pocket payments and indirect costs exceeding a given threshold (e.g. 20%) of the household's income.

IV. COMPREHENSIVE STRATEGIC FRAMEWORK

This extensive chapter describes the strategic interventions selected for each of the objectives as well as expected ouputs and main activities to be implemented to achieve these results. A detailed logframe table is presented in annex 3.

IV.1. Objective 1: Improve early and accurate diagnosis of TB including universal DST through progressive adoption of WHO-recommended rapid tests for all presumptive cases so that TB treatment coverage increase from 84% in 2015 to 89 % by mid-2021.

This first objective aims to detect as many cases of TB as possible, as early as possible. This requires a comprehensive set of activities that include improving the quality of screening, conduct systematic screening among prioritized HRGs, and improving the capacity and quality of TB diagnosis services.

IV.1.1. Improve active case finding in prioritized HRGs so that at least 90% of contacts of TB bacteriologically confirmed cases are investigated for TB.

Systematic TB screening among people with higher risk of developing TB has three main objectives: a) to ensure early detection and initiation of treatment for people with active TB, b) to reduce the risk of poor treatment outcomes, health sequelae and the adverse social and economic consequences of TB; and c) to reduce transmission of TB, with the ultimate goal of reducing future incidence. Therefore, it is necessary to prioritize the groups to be screened and to select proper screening approaches for each risk group, taking into consideration their yield, cost, and operationalization.

Rwanda NTP prioritized five high-risk groups to be systematically screened: PLHIV, TB contacts, prisoners, children and elderly. Two screening approaches are used: a) symptom screening followed by Xpert MTB/RIF as initial diagnostic for those who screen positive; b) radiological and symptom screening followed by Xpert MTB/RIF for those who have abnormal chest X-ray (CXR) and/or symptoms suggestive of TB. The second approach is used during active campaigns in prisons and in some HC attending high numbers of PLHIV in Kigali. These campaigns are carried out by a specific team including one MD and radiology technician using the mobile CXR equipment from the prevalence survey.

During this planning process, we used WHO guidelines and web-based screening tool to revise our screening and diagnostic algorithms and analyze the efficiency and feasibility of alternative approaches. This exercise shows two important considerations: a) systematic CXR screening would significantly increase the sensitivity of the strategy allowing to detect about 90% of all prevalent cases, but it would also considerably increase costs; b) efficiency of the symptomatic screening would increase by using CXR before Xpert resulting in similar yield of positive cases with a cost reduced by approximately 30%. Current challenges for adopting such a strategy are the limited access to digital CXR, limited capacity for CXR interpretation and patients' transportation costs from HC to DH.

This exercise led us to define the following case finding approaches to be used during this extended plan:

<u>Active case finding among high risk groups</u> will be enhanced by modifying our screening approach as follows:

a) Systematic CXR screening will be expanded to all new PLHIV (about 14,000 per year) and TB contacts at the beginning of treatment of the index case (about 16,000 contacts per year). As previously, active case finding campaigns with systematic radiological screening will be conducted in prisons and some high HIV prevalence health centers using mobile radiography equipment. This is justified since these three groups have the highest risk for developing TB and this algorithm has the highest yield of cases.

b) For the other HRGs, including PLHIV attending ART clinics for follow up, elderly and children, the symptomatic s

c) screening approach will be maintained. For PLHIV, positive screening is defined by the presence of any of the following signs: cough of any duration, fever, loss of weigh, night sweats and/or TB contacts. For the other HRGs groups, criteria remain a cough of 2 weeks' duration.

   XPert MTB/RIF will be done as initial diagnostic test for all HRGs patients who screened positive (abnormal CXR and/or symptoms of TB).

Diabetes triples the risk of developing TB and its burden is likely increasing with Rwanda economic growth. Its current prevalence among the population aged 15-64 is estimated at 3%.[22] During this extended NSP, the NTP plans to develop the TB-diabetes collaborative framework in collaboration with RBC/NCD Division and implement systematic TB screening among diabetics in a limited number of HF with proper monitoring to evaluate the yield of the strategy before scale-up.

On the other hand, urban districts are continuously reporting high case notification and high positivity among the presumptive cases. The NTP is willing to map all these cases in order to identify high TB spots where active case finding activities will be conducted.

Passive case finding will continue to be done among people attending the HF with symptoms suggestive of TB (cough ≥ 2weeks) and not having higher risk for TB. During this 2018-2020 NSP, the use of Xpert MTB/RIF as initial test will be extended for all presumptive cases detected within Kigali districts. Further scale-up to all HCs will depend on funding availability. The release of new point of care diagnostic tools (mobile) expected by end 2017 would facilitate the use of molecular diagnostic technique countrywide and solve the sample transportation issue. If this becomes available, it should be an option for the program.

The revised screening algorithm is presented in annex 4.

Strengthening the collaboration with CHWs, CSOs and private clinics will be paramount to find additional cases and achieve SDGs. The NTP will enhance its current partnerships with the PLHIV Network (RRP+), Youth Association and NGOs, engage more private clinics in TB management and mobilize additional actors from CSOs.

The Rwanda network of People living with HIV (RRP+) is an umbrella organization that coordinates a project developed to increase TB case finding in PLHIV. This approach is currently implemented in 22 districts with the participation of 1,320 Peer educators (PE) whose tasks include sensitization on TB during PLHIV association meetings, promotion of TB screening and referral of presumptive TB cases to the HFs. Since this approach is effective to find TB cases, RRP+ is willing to extend the project to the most HIV prevalent sectors countrywide.

M&E screening tools will be revised to capture all screening information and enable proper and continuous monitoring of the whole screening/diagnosis cascade and annual evaluation of screening strategies' yield. This will allow periodic reassessment of the screening strategy including HRGs prioritization and screening algorithms; and to decide the appropriate time when a TB screening approach should be discontinued.

IV.1.2. Strengthen diagnosis capacities for childhood TB so that the proportion of TB cases among children increases from 5% in 2015 to 8% by mid-2021

In this extended plan, the NTP has set up an ambitious target related to childhood TB detection. Increasing the coverage and the sensitivity of screening among TB contacts, as mentioned in intervention IV.1.1., is essential to ensure early identification of childhood TB. In addition, the NTP will put strong effort on all activities aimed at building knowledge, skills and confidence of health workers to screen and diagnose TB in children. First, childhood TB guidelines will be finalized, published and disseminated. Medical doctors and nurses will be trained on these guidelines and also, on specimen collection procedures (naso-gastric aspiration, sputum induction) which should allow to

[22] Rwanda STEPS Survey 2012, 2013. RBC

detect additional cases. Secondly, the NTP will implement a paediatric mentorship program to DH with support of the Rwanda Pediatric Association (RPA). The content and methodology of the program will be elaborated during an initial joint workshop (NTP and RPA), including the task description of mentors and the reporting tool. Each DH should receive a mentorship visit once per year, where mentoring paediatricians will work together with DH medical doctors and nurses in charge of the paediatric ward, OPD, TB and HIV clinics, and nutritional service. DH mentors will be invited to participate so they will gain additional competencies for mentoring childhood TB in HCs. Moreover, the NTP will collaborate with the MCCH division in order to incorporate TB in the curriculum of management of malnourished children. DH nutritionists will be involved in the supervision to the HC. Both activities aim to increase TB knowledge of the staff managing malnourished children at the HC. The NTP will also collaborate with MCCH and its partners to incorporate TB in the management of sick children at community level (ICCM). The latter aims to raise awareness of CHWs on the signs suggestive of TB that require referral to the health facilities. Finally, the NTP will explore the use of on-line training modules on the clinical management of childhood TB.

IV.1.3. Improve TB diagnosis across the laboratory network and ensure universal DST coverage for all bacteriologically confirmed TB patients.

The NTRL will build human resource capacity through training, development of training materials, programs and plans, manuals and standard operating procedures as well as assessment of human resource capacity and development of human resource strategies and plans including supportive supervisory through a comprehensive training plan that is adhered too (Annex 8, tables 1 and 2).

The TB diagnosis will be done across all levels of TB laboratories in the country. Surveillance of resistance will be enhanced among previously treated cases but also among new cases. Based on MTR recommendation, Rwanda has adopted the policy of using Xpert MTB RIF as initial diagnostic test for all presumptive TB cases, which is paramount to achieve SDGs and End-TB goals. The policy is appropriate given the additional accuracy of the test and simultaneous detection of rifampicin resistance at the onset, which will ensure that patient receive proper treatment regimen based on sensitivity. Operationalization of the policy will be done in two phases, starting with health facilities in Kigali where all TB presumptive cases will be tested with Xpert. Other health centers will be using Light Emitting Diode Fluorescence Microscopy (LED-FM) for most of their TB presumptive patients except those classified as HRGs to whom Xpert test will be used as unique initial diagnostic test at the closest Xpert site. Scale-up of the policy countrywide will not be done during this extended-NSP period since it is too expensive compared to available funds. Performance indicators will be monitored monthly but reported on quarterly basis using appropriate data connectivity software that will be adopted.

During the past years mycobacterial culture laboratories were built and equipped in two referral hospitals (CHUK and CHUB) to improve TB diagnosis and increase the DST coverage as well as to support the NRL in ensuring the quality assurance of TFB diagnosis across the laboratory network. Though the capacity of these laboratories was able to perform at least 1/3 of routine mycobacterial cultures and molecular as well as phenotypic DST since their initiation, these laboratories are being used to perform culture for a small number of patients attending these hospitals. The NRL therefore is developing a new referral plan for the 2 culture laboratories (NRL and CHUB) for both MGIT and LJ culture methods, as a result of CHUB having received training on first line DST. The CHUK will technically be involved to support implementation of external quality assurance in the TB laboratories located in Eastern province; the CHUB will provide mycobacterial cultures and DST (LPA 1st and 2nd line) and will support to strengthen the implementation of quality management system in TB laboratories located in Southern and some districts of the Western provinces and the NRL will cover the remaining districts. Xpert test and culture will also be used to diagnose extrapulmonary TB. The culture network will be established, with standardized EQA and control MTB strains (*M fortutum and H37Rv).*

To ensure competence of these laboratories to carry out their roles, NRL will be conducting onsite mentorship and periodic support supervision especially for error laboratories and in case of new staff recruited at the intermediate lab. There is need to plan for competence evaluation of CHUB laboratory as well as plan for training of the same laboratory to perform second line DT on both MGIT and LJ culture respectively.

At the NRL and CHUB, liquid mycobacterial culture and rapid molecular assays such as Line Probe Assay (LPA) will be used for first and second line TB DST (annex 7, LPA, culture, and DST algorithm). The culture will be used mostly to get susceptibility to all TB drugs in samples resistant to rifampicin and also where there is no detection on Xpert; culture will also be used for follow up of TB patients on second line regimen. Second line LPA is under implementation which will enable to exclude resistance to fluoroquinolones and second line injectable agents before starting shorter second line treatment for MDR-TB patients.

Quality assurance of culture results shall be ensured through a culture network of the two culture labs through interlaboratory comparison using PT panels from SRL that have characterized strains in addition to support supervision and mentorship of CHUB laboratory by NRL. This will be done as well for LPA and Xpert test to ensure quality results and ascertain personnel competence with harmonized recording and reporting of test culture results both at regional lab and NRL respectively.

The capacity to prepare PT for Xpert and LPA is vital that will need comprehensive training of selected team of individuals from NRL to ensure integrity and quality of results from Xpert and or LPA sites.

The NRL will be provided with sequencing machine which will help in genotyping of Mycobacteria strains, and Mycobacteria other than tuberculosis (MOTT) and resolving discrepancies arising from Xpert, Hain test and conventional DST.

IV.1.3.1 Sample referral systems for the TB laboratory network

The NRL has established an integrated specimen transportation system where vehicles collect samples from DHs, RHs and provincial hospitals once a week, and HCs sent their samples to DHs using motorbikes. The system is used for any specimen requiring to be tested at NRL or CHUB and to send results. The purchase of new sample transportation vehicles and motor bikes will be shared between the benefiting programs, including TB, HIV, and other programs.
The SOPs and guide for specimen referral and transport and for returning results are available, where the presumptive TB or patient delivers samples for smear microscopy to the clinic and/or laboratory.
The culture and DST referral and transport system involves use of NRL designated vehicles for transportation of original sputum samples both preserved in cetyl pyridium chloride (cpc) and fresh/ without additive from DHs, RHs and provincial hospitals once a week to the NRL; the sputum is triple packaged in cotton wool and Ziplock bag to minimize leakage and aerosols then packaged in a shipping box (cool box).
The use of other means of transport like engaging the public service vehicles (Bus courier services) is an avenue to be explored through forming a memorandum of understanding between NRL and respective bus companies for timely delivery of samples to NRL to minimize the cost and time. However, this needs planning for training of personnel from the bus courier services on packaging, labelling and handling of sputum samples, at the same time identify a shipping coordinator to monitor the functionality of the specimen referral network followed by piloting of the system before implementation.

IV.1.3.2 Improve Laboratory information and data management systems through diagnostics connectivity solutions

The conventional diagnostic systems in Rwanda inclusive of smear microscopy, and solid culture has widely been used however faced with challenges of data quality, prolonged turnaround time (TAT), limited information sharing and tedious paper work that has led to persistent human errors.
However, the WRD Newer diagnostics including Xpert® MTB/RIF (using the GeneXpert® platform), liquid culture (e.g., Bactec MGITTM), line probe assays (LPA) with automated readers are in use for appropriate early diagnosis of TB and MDR TB, due to their highly sensitive and limited error results that need connectivity solutions.

Though the Xpert MTB RIF has improved the rapid diagnosis of susceptible and rifampicin resistance tuberculosis, the logistics of data reporting has been challenging for the past years. The NRL plans to implement a connectivity software as a solution for capturing and analyzing data linked to Xpert but also other TB lab results including mycobacterial culture, LPA and phenotypic DST. The software would permit to capture data directly from the laptop of the GeneXpert machine, such as the test results, including precise information such as cycle threshold (Ct) and individual probe results, basic epidemiological information and basic clinical data. This information would be sent by internet to a central server at NRL, which allows consultation, analysis and exportation of data using a web interface. The prescriber would receive results through sms or email and the connectivity solutions should allow data capture and transmission of future novel tests.

The data to care Connectivity software platforms developed by third-party Company is adopted, with a central server at NTRL/NTP where data from the diagnostic device to the server will be sent using internet and a modem.
The current data to care connectivity platform has been integrated to timely report Xpert, LPA, mycobacterial culture and phenotypic DST results but microscopy is yet to be uploaded as one of the crucial test for reporting to clinicians and notifying respective patients of their results.

The NTP/NTRL planned diagnostics connectivity solution will be able to capture some quality indicators in laboratory and clinical management of TB and MDR TB by:
i) **Monitor and remotely ensure quality assurance by establishing the number** of tests performed nature of results, and status of facility performance i.e underperforming or experiencing abnormal results or errors as well as contamination, which may highlight a need for troubleshooting, device repairs, targeted site supervision, or retraining of technicians.
ii) send results automatically to clinicians, where test results (or a subset of them; for example, rifampicin-resistant test results) will automatically and instantly upon result availability be sent to a clinician's phone or email, SMS printer or other clinical results reporting mechanism, allowing for faster patient follow-up.
iii) Send results automatically to laboratory information management systems or electronic registers, where results will automatically be integrated into laboratory information management systems or electronic registers, reducing the chance of transcription errors, and greatly facilitating M&E processes. Configuration could be done to allow for additional patient information to be entered; for example, a patient's HIV status or prior TB treatment history could be captured, aiding a programme to measure testing coverage and implementation of diagnostic algorithms.
iv) Inventory management; the data on stock availability and forecasting needs of supplies at the site level could be achieved using the data connectivity software, based on consumption rates through the number of tests run, results reported and errors /contaminations leading to repeating of tests can be captured from the sites as a result of entering initial stocks in the platform.
This is very helpful in tracking the service and calibration needs of particular machines at the site as well as tracking renewal of service contracts if necessary.
V) Access to patient information: with data to care connectivity in place, confidentiality of patient information will be assured, quality and timely data will be availed to respective personnel especially those who need it more like the implementing partners, clinicians and NTP and minimizing bulk of data from those who don't need it, thus ensuring maximum utilization of data.
vi) Disease surveillance; the data to care connectivity will help in timely remote monitoring of critical result outcome (Rif resistance) from respective sites and analyze the resistant patterns with

minimized duplication of patient resistance status helpful for determining prevalence with relevant agency in the country for proper planning of future essential diagnostic platforms needed for managing the disease burden by NTP.
Facilities that will require modems will be provided with a 3G/2G modem that contain SIM cards and access to the internet is provided by a cellular provider and require the desktop or laptop computer accompanying a GeneXpert. Facilities with Wi-Fi connection capabilities will have direct uploading of data to the central unit server. Although they are relatively inexpensive, dongles carry a risk of being removed, misplaced and misused, and therefore needs close monitoring through integrated data collection by M&E personnel.
A role out plan for data to care will be developed that is inclusive of the stratified activities necessary for capturing Xpert, LPA liquid culture and microscopy data, for example installation of the data to care software on all Xpert, LPA and liquid culture as well as microscopy sites, procurement of modems, servicing/loading of modems, training of personnel on its use, and monitoring data utilization respectively. (Annex 8, table 4)

IV.1.4. Strengthen the implementation of quality management system in the TB lab network

Ensuring the competence of technical personnel and quality of service at all levels of the TB laboratory network is challenging for NRL and requires continuous monitoring of the different laboratory activities and an adequate quality assurance system (Annex 8, table 5). The external quality assurance (EQA) system of microscopy through quarterly blinded rechecking will be maintained and strengthened. This is organised in 2 levels (NRL performing rechecking for DHs and RHs, and DHs perform rechecking for HCs in their catchment area). Discordant slides are sent to NRL for a second control to confirm whether it's a discrepancy before doing corrective action. CHUB and CHUK will be involved as controllers according to the new referral plan however they need training and competence before decentralization of the second controlling. In addition, NRL will prepare and distribute twice per year panel testing (PT) for microscopy to CDTs with discrepancies on blind rechecking and these panel will also be used for training. EQA proficiency panels for Xpert MTB RIF will be procured to enroll GeneXpert and LPA sites in the EQA program in order to ensure the accuracy of the results and this will be done once a year. For the international EQA, the NRL will receive slides smears for microscopy three times per year and panels for culture and DST once a year from Supranational Reference Laboratory (SRL) on the other hand through a culture network CHUB and CHUK technical competence will be assured through interlaboratory comparison of culture isolates as well as support supervision and mentorship from NRL respectively. To strengthen the implementation of new diagnostic tools, the NRL plans to conduct intensive onsite training, mentorship and supervision to improve the quality and gain the real benefit expected from the new tools. In this regards the NRL supported by CHUK and CHUB will conduct the training at provincial and district TB laboratories and subsequently the districts and provincial TB laboratories will train their respective health center laboratories. At least each TB laboratory will be visited once a year. This is done at two levels, NRL will do supervision and mentorship for DHs and RHs and the same will be done by DHs to their HCs (CDTs and CTs).

IV.1.4.1 Equipment maintenance

In order to limit the interruption of services due to equipment breakdown, the NRL plans to provide proper maintenance of TB laboratory equipment by ensuring an up to date service schedule is available and adhered too. Service contracts that include replaceable spares for each specific equipment is procured. Except biosafety cabinet and TB BSL3 lab that require special service twice a year; the BSC shall be serviced and certified by a locally trained and certified bioengineer at NRL while the BSLIII shall be certified by AFMS from South Africa where the service contract shall need to be planned for since currently the BSLIII is still under warranty until April 2017; other laboratory equipment require one special service maintenance per year. For GeneXpert machines, NRL will procure a one-year service contract for all machines and will develop capacity in servicing and maintenance through provision of advanced training of staff as super users; 2 from NRL and 2 from

MTI technical division on GeneXpert maintenance machine to timely trouble shooting, calibration and servicing of the machines as well as ensure long term sustainability.
With regard to human resources; it is needed to appoint a staff at the NRL to coordinate the laboratory network and the proper scale up of GeneXpert, monitoring and optimizing their use, ensuring timely procurement of cartridges and maintenance of equipment. To ensure uninterrupted GeneXpert test service, we plan to enroll four staff on advanced training on maintenance of GeneXpert and train at least one laboratory technologist for each GeneXpert site as GeneXpert super user for better track the optimal utilization of this technology. We foresee appointing a monitoring officer at the NRL to improve the quality of data and facilitate the information flow of lab data who will also liaise with NTP M&E unit.

IV.1.4.2 Strengthen the implementation of quality management system in the TB lab network towards accreditation

The TB lab, a section within microbiology unit has planned to have all its tests inclusive of Microscopy (FM), GeneXpert, LPA first and second line, liquid and solid culture and liquid and solid culture DST, and rapid identification test accredited by **2019.** However, this process needs intense mentorship, technical assistance and a comprehensive integrated plan with stratified activities budgeted within specified period of time in the accreditation roadmap.

The main activities involved for fulfilment of this accreditation process include, conducting a baseline assessment of the laboratory's quality management system using a recognized checklist based on ISO 15189:2012, developing an action plan for quality improvements followed by implementation of the recommendations. The checklist used will specify requirements for quality and competency aimed at developing and improving TB laboratory services to raise the quality to ISO standard 15189:2012 services for patient care. Identification of key focal personnel inclusive of the Quality officer for NTRL under the quality assurance directorate of NRL and the safety officer. Development of the TB lab quality manual policies/ procedures specified for NTRL as well as document control SOP; formation of quality improvement team within the TB laboratory is key to ensure essential LQMS activities are done like; conduct internal audit, risk management and identification of occurrences as well as ensure management review is done respectively. Technical assistance in terms of mentorship for the identified quality improvement projects need to be planned at defined intervals. (Annex 8, tables 6 and 7)

This plan will support the cost of accreditation of NRL TB lab while the technical assistance during this accreditation process should be provided by ECSAHC/GF project.

IV.1.5. Enhance the use of CXR and other diagnostic techniques for extrapulmonary and bacteriologically negative TB.

Adding radiography to complement symptomatic screening significantly increases the sensitivity of the screening algorithm. CXR is also useful for diagnosis of extrapulmonary and bacteriologically negative forms of TB. Digital radiology is preferable to conventional CXR for easier use, lower cost, better image quality, better safety (decreased radiation dose) and easy transmission of the images allowing off-site interpretation. As exposed in objective 1, systematic CXR screening will be incorporated in the screening algorithm for new PLHIV and TB contacts at the beginning of treatment of index case and it will continue to be used in active case finding campaigns in prisons and in high TB/HIV prevalence HCs for all PLHIV. All hospitals in Rwanda have a functional radiology equipment, among them 32 have digital machines of which 8 need to be replaced. This plan includes the purchase of digital RX machines, which will increase access to digital CXR and contribute to strengthen the health system. The NTP will continue to organize an annual training course on CXR interpretation for MDs, in partnership with the radiologist association. This activity remains crucial since there is a high turnover of MDs at DH level. NTP will also implement a quality control system of digital CXR in close collaboration with the radiologist association. In addition to this, we also train

radiology technicians on preventive maintenance of radiology machines, radiation safety, as well as basic knowledge on chest-Xray interpretation.

This NSP will strive to strengthen the capacities for diagnosis and management of extrapulmonary TB with the aim to reduce diagnostic delays which might be amongst factors leading to high death rate observed in this category of patients. Standard operating procedures (SOP) will be developed for techniques such as Fine Needle Aspiration (FNA), biopsies, gastric aspiration and sputum induction methods. Practical training on these techniques will be conducted by both CHUs. Use of FNA will be encouraged for patients with presumption of lymph nodes TB. Extrapulmonary specimens will be sent to NRL or CHUs laboratories for bacteriological investigation (liquid culture, DST) and to CHUK and Rwanda Military Hospital for anatomopathology. Necessary materials and reagents will be provided for these tests.

With the aim to strengthen TB management capacities, NTP will maintain the mentorship program provided to DH by referral/provincial hospital specialists. Mentors provide on-site training on diagnosis (including radiography and ultrasound) and on clinical management of complicated cases; they will put emphasis on investigating death causes. To better evaluate the added value of this mentorship program, NTP in collaboration with participating referral/provincial hospitals will have to agree on clear task description and reporting tool.

IV.2. Objective 2: Provide patient-centered treatment for all forms of TB so that the treatment success rate be maintained at ≥90% for bacteriologically confirmed tuberculosis and at ≥ 87% for drug resistant tuberculosis.

In Rwanda TB treatment is available in all health facilities under direct observation by health staff or community health workers. High success rates in both sensitive and drug resistant TB have been achieved. This has been a result from joint efforts from both central, decentralized and community levels. Priorities for this NSP extension are to maintain an efficient drug management system, initiate an active drug safety monitoring and management system, improve treatment outcome for all patients and reduce the mortality rate in HIV-infected TB patients and clinically diagnosed TB cases. Xpert or DST is mandatory for all previously TB cases which will ensure the selection of proper treatment regimen based on sensitivity. Therefore, Category II TB treatment with Streptomycin has been removed from the treatment guidelines as recommended during the MTR and by the WHO. The new child-friendly drug formulations will be introduced since they provide better dosage and are easier to take.

IV.2.1. Ensure no stock out of first-line and second-line drugs in all CDT

Ensuring an uninterrupted supply of high-quality and affordable, first and second-line anti-TB drugs for all TB people diagnosed with TB, is critical for sustaining treatment success and prevention of resistances.

Management of TB commodities is ensured by MPPD at central and intermediate level and is supported by NTP. This plan will contribute to strengthening skills of district pharmacies (DP) in accurate stock forecasting and appropriate use of the electronic logistic management information system (e-LMIS) for stock management through training and on-site supervision of staff. Rwanda has a plan to use fully e-LMIS and switch off paper based system nationwide for management of health commodities. This requires strong capacity building of users, mentorship and strengthening internet capacity by availing 4 G internet in remote area with network problem, which goes beyond funding available for this plan.

IV.2.2. Improve treatment success rate for all forms of TB, specifically maintain it at least at 90% for bacteriologically confirmed TB cases

Our priorities are to reduce the death rate, especially in HIV-positive patients and clinically diagnosed patients. Therefore, we will first intend to get better understanding of TB death causes through analysis of death audit data which are reported quarterly and introduced in a specific database. This

should help us to identify specific interventions likely to reduce the causal factors. Among them, malnutrition is likely to contribute significantly to deaths since it impedes the absorption of drugs. This plan foresees the provision of nutritional support not only for drug-resistant, as currently done, but also for drug-susceptible TB patients who are moderately or severely malnourished (strategic intervention 2.7). HIV is a leading cause of deaths and contributes for about 50% of all deaths reported through the death audit system. As exposed in objective 1, systematic radiological screening for all new PLHIV should improve early detection, early treatment and result in reduced mortality. In addition, the new policy of universal access to ART implemented since August 2016 is expected to reduce TB/HIV morbidity and mortality. Interventions aimed at improving diagnosis capacities of extrapulmonary and bacteriologically negative TB (strategic intervention 1.5) should contribute to the reduction of deaths associated with long diagnostic delay. This plan will also focus on strengthening the quality of treatment follow-up; increasing the cure rate in bacteriologically confirmed TB cases and the treatment success rate in all patients through training (theoretical and practical), supervision, and mentorship. This will be ensured at two levels: from Referral/provincial hospitals to DHs, and from DHs to HCs. Emphasis will be put on comorbidities that increase the risk of death (diabetes, malnutrition, etc.) and require referral to the upper level for their adequate management.

IV.2.3. Maintain treatment success rate at ≥ 87% for MDR-TB patients

Shorter course treatment regimen (9 months) for MDR-TB patients has been introduced in Rwanda through a multi-country study led by the UNION to evaluate its effectiveness and tolerance within field conditions. Shorter regimen has potential of higher acceptability and lower toxicity for patients, less workload at facility level with potential cost savings at programmatic level. This regimen has been endorsed by WHO in May 2016 and adopted by Rwanda NTP since July 2014. In line with last WHO recommendations, NTP will ensure that RR/MDR-TB patients have second line LPA test before initiation of the shorter regimen. This test is being implemented at NRL and CHUs.

Equipment for audiogram and electrocardiogram has been purchased for the MDR-TB centres, provincial and referral hospitals and this extended NSP will consider ensuring referral facilitation to MDR-TB patients to access follow up tests during ambulatory phase including regular audiology controls. Trainings will be carried out specifically for MDR-TB management and interpretation of specific tests coupled with mentorship sessions by the MDR-TB centres and the central level. Specific follow-up tests will be performed in order to adhere to the national DR-TB guidelines requirements. Post-treatment follow-up should be ensured during 24 months in order to detect potential relapses. New regimens including new TB drugs (Bedaquiline, Linezolid, etc.) will be introduced for MDR-TB relapse and pre and/or XDR-TB cases, children, pregnant women and contra-indications of injectable. Hospitalisation for treatment initiation will be maintained because it ensures close follow-up and adequate management of potential adverse effects as well as nutritional rehabilitation. Nutrition and transportation support will continue to enhance the treatment adherence during ambulatory phase. The partnership with CHUs through consultancy contract in managing complicated MDR-TB patients will help in maintaining high treatment success rate. The quality of follow up during ambulatory treatment will be improved by involving medical doctors and nurses of both specialized MDR-TB centers in the quarterly supervision of HF in charge of ambulatory MDR-TB treatment.

Additional GeneXpert machines, coupled with improved sample transportation system are expected to provide universal access to DST, ensure early detection of resistance, increase number of MDR-TB cases as it is observed in other countries. Early treatment should also lead to better treatment outcome and reduced fatality rate.

IV.2.4. Implement active drug-safety monitoring and management (aDSM)

The NTP is taking steps to introduce active drug-safety monitoring and management (aDSM) as standard practice as part of the recommendation of the MTR of the 2013-2018 TB NSP to reduce risks from drug-related harm in patients. Both MDR-TB and DS-TB will be the benefactors of the aDSM, They should undergo active monthly clinical assessment during treatment to detect adverse events (AEs). In addition, RR/MDR-TB patients should have specific follow-up tests as stipulated in DR-TB

guidelines. ADSM is absolutely required for all patients on treatment with new anti-TB drugs, novel MDR-TB regimens or XDR-TB regimens to detect, manage and report suspected or confirmed drug toxicities. Patients should be encouraged to report to the attending health worker any adverse event that occurs during treatment. All AEs detected should be managed in a timely manner in order to deliver the best possible patient care.
The TB treatment card has been revised to record information on AEs or their absence. This revised TB card will be introduced by July 2017 and a new variable will be collected through RHMIS to know the proportion of TB patients for whom adverse effects have been investigated regularly during treatment. In addition, severe AEs should be reported within 48 hours to the national pharmacovigilance center at MoH using MoH standardized form for all kind of medicines with copy to NTP. NTP will develop and implement SOP on ADSM practice. ADSM will be incorporated within the training package of health care providers, including the classification in mild, moderate and severe reactions and their management.

IV.2.5. Maintain ART coverage among co-infected patients at least at 90%.

One of NSP goals is to reduce the mortality among HIV-infected TB patients and the overall TB case fatality by ensuring early diagnosis and early treatment of TB/HIV coinfection. As explained in objective 1, radiological screening algorithm will be used for new PLHIV since it has higher sensitivity. Symptomatic screening will be maintained for all PLHIV at each follow up visit. Those who screen positive, either on radiological or symptomatic screening, will have an Xpert test. PLHIV suspected of extrapulmonary TB, will undergo specific tests including FNA, biopsy, anatomopathlogy, XPert, ultrasound, X-ray, etc. All presumptive and confirmed TB cases will have HIV counselling and testing and HIV positive TB patients will be enrolled into HIV care and treatment.

All TB/HIV co-infected patients will be adequately treated for both diseases in an integrated way through the “one-stop TB/HIV service” and with a patient centred approach. They will be enrolled on ART according to NTP and HIV program guidelines, within 2 to 8 weeks after TB treatment initiation. Rifabutine will be provided instead of Rifampicine for HIV/TB co-infected patients receiving an ART second-line regimen with Atazanavir. We will also strengthen TB-HIV integration and linkages with the HIV services for better follow-up of HIV infected patients during TB treatment and continuation of care and treatment after completing TB treatment.

To maintain high performance with regard to TB/HIV targets, it will be necessary to strengthen the collaboration between TB and HIV programs and services and hold regular meetings of the TB-HIV technical working group which is responsible for updating TB/HIV policy and guidelines, ensuring joint planning, monitoring and evaluation of policy implementation and building capacities of the health providers. The infectious disease clinical mentorship program at district hospitals will be involved to improve the quality of TB/HIV services by ensuring early initiation of ART, application of TB infection control measures in the one-stop TB/HIV services and HIV prevention among TB patients.

IV.2.6. Maintain at ≥ 95% the treatment success rate for patients managed in the community.

Community PBF will be maintained for CHWs in order to sustain their contribution to community TB activities. Capacity building of CWHs will be strengthened through trainings/refresher and supervisions by health centres. Coordination meetings with MOH/CHD, and District supervisors will continue to occur, biannually, to review performance of TB indicators, including the indicator related to TB treatment success.

IV.2.7. Provide patient-centered treatment including nutritional support for moderately and severely malnourished patients

Psychological counselling and support is an integral part of the treatment process for all patients who need long terms follow up for treatment. Usually, patients have family, friends and colleagues (social structures) who provide moral support to them. Even then, sometimes patients go through social isolation, stigmatization, and depression because of the long process of treatment. Patients could get

tired and lose their motivation to become healthy. Some patients might be lonely, or because of their personality features might be in conflict with their support structures, leading to a low motivation to get cured. Those patients require correction of their mental and emotional condition to help improve their discipline and create positive thinking regarding the treatment. The NTP in collaboration with mental health division will look towards setting up psychological counselling and support for DS-TB as this activity was already part of the follow up process for MDR-TB. We aim to develop a quick and easy to use depression index to be used by health care providers.

Adequate nutritional intake is essential to ensure adequate absorption of TB drugs and contribute to patients' recovery. This plan includes the provision of nutritional support to TB patients who present moderate and severe malnutrition at the beginning of treatment (BMI below 18.5). We estimate that 15-20% of all TB cases should benefit of such support, taking into consideration findings among PLHIV.

IV.3. Objective 3: Improve TB prevention so that LTBI treatment coverage among contacts < 5 years increases from 78 % to 90 % by mid-2021.

TB prevention includes TB infection control and prevention by medication. In Rwanda isoniazid preventive treatment (IPT) is administered to children under 5 years who live in close contact with a TB index case. WHO also recommends IPT for PLHIV but Rwanda has decided not to apply this strategy due to the lack of a sensitive screening and diagnosis strategy for adequately excluding active TB.

IV.3.1. Ensure that basic infection control measures are applied in at least 85% of all Health Facilities and that at least 70% of the health providers are screened for TB.

TB infection control (IC) practices have been implemented in CDTs since 2009 and in all health facilities since July 2013. In this extended plan we will continue to foster application of basic IC measures in the HF, with emphasis on administrative measures, triage, separation and fast tracking of TB presumptive and confirmed cases, cough hygiene, and maximisation of the natural ventilation. This will be done through supervision, RSQA and trainings and we will provide personal protective equipment to the health providers highly exposed to TB.

Surveillance of TB among health facilities workers (HFWs) started in July 2015 and should be done once a year. Specific register has been developed and distributed in all health facilities. During this plan, we will encourage HF to conduct this surveillance for all HFWs and we will initiate TB screening among CHWs. CHWs should also receive more information on the essential infection control measures to apply in the community including cough hygiene and natural ventilation within the houses.

IV.3.2. Increase treatment coverage of latent TB infection (LTBI) among TB contacts ≤ 5 years of age from 78 % to 90 % by mid-2021.

TB case finding and treatment are crucial to progress towards elimination of the disease. It is also necessary to prevent the evolution of infection to active disease through preventive treatment. During this extended plan, we will strengthen active screening among TB contacts using systematic CXR and symptom screening at diagnosis of the index case (objective 1) and provide INH preventive therapy for 6 months to contacts under 5 years of age who screened negative.

WHO also recommends IPT for PLHIV but Rwanda has decided not to apply this strategy due to the lack of a sensitive screening and diagnosis strategy for adequately excluding active TB. Indeed results of researches[23], studies and routine active case finding activities showed the low sensitivity of the symptomatic screening approach. As a result, several HIV+ persons may be put on IPT while having active TB without presenting symptoms. Although we will implement systematic radiological

[23] Operating characteristic of a tuberculosis screening tool for people living with HIV in out-patients HIV care and treatment services, Rwanda. Kenneth Kurinawe and all. PLOS. September 2016

screening for all new PLHIV in July 2018, we will first evaluate results of this new screening approach, before reconsidering IPT for PLHIV.

IV.3.3. Intensify communication and social mobilization

During this three-year extension plan, the NTP will develop its ACSM plan, produce structured guidance on community sensitization on TB to ensure correct information is passed on the community members and enhance CHWs knowledge on TB signs, transmission, prevention and management. CHWs will continue to be remunerated through the PBF scheme. The CHWs training materials will be revised and refresher trainings will be conducted in collaboration with MCCH and the health facilities. IEC materials for patients and their families will be produced as well as IEC materials to support sensitization of the population, reduce stigma linked to TB and HIV and foster early health seeking behavior. In addition, radio programs related to TB will be broadcast.

IV.4. Objective 4: Improve managerial capacities of the TB program; enhance the performance of the TB surveillance to achieve concordance between aggregate and case-based systems; and develop research.

Proper data management associated with strong monitoring and evaluation are needed to help improve program interventions, achieve goals and sustain funding. Significant progress has been made since the beginning of this NSP with the implementation of an electronic recording and reporting system. Considering current achievements and challenges, the NTP will continue developing and consolidating the system and enhance the quality of TB data management.

IV.4.1. Strengthening routine use of TB individual record (e-TB) at Health Facilities and Central level so that by 2020 TB aggregated electronic reports are generated from e-TB system.

Current priorities are to improve data completeness and accuracy into e-register (e-TB) which will allow to transition from aggregated quarterly reports (RHMIS) to case-based data and phase out the aggregating reporting. The e-TB register provides information on TB presumptive and TB active cases which is paramount to assess the effectiveness of intensified case finding strategy used among HRGs and make decision for further planning. As mentioned in objective 1, the NRL will establish connectivity system with interfaces allowing for automatic recording of laboratory results in e-TB, which will save time and ensure quality of data. Therefore, the NTP will monitor the system completes and accuracy and provide feedback to monitoring teams at peripheral level.

A new assessment of the TB surveillance system will be conducted by end 2018 to reach WHO certification and measure if TB indicators are on track with NSP targets and END-TB strategy milestones for 2020.

IV.4.2. Collaborate to the establishment of a national vital registration system (VRS) that includes TB death data

The NTP will collaborate with the NISR to the development of the VRS system and ensure that it includes TB information. We will monitor if all TB deaths occurring during TB treatment are reported in the VRS and we will promote its use for deaths in the community. We expect that the VRS will not yet provide reliable data on TB deaths within the period covered by this plan since its implementation may require up 3 to 5 years. Therefore, it will not be possible to report case fatality rate (CFR) during the period of this plan from VRS. As a consequence, NTP will inform CFR indicator through WHO estimates of mortality and incidence (Annual WHO Global TB Reports). CFR is currently at 11% and it should decline to 7,8% by end 2020 if we achieve our targets of reducing TB deaths and TB incidence by 35% and 20% respectively.

IV.4.3. Conduct research to inform program strategies

This NSP encourages programme-based operational research as a core component to improve programme implementation locally through the identification of problems, evaluation of

interventions and monitoring of activities, in order to adjust policy along evidence-based recommendations. For this two years' extension period, the NTP is willing to conduct a survey on the "catastrophic costs associated with TB"; a research on the "Long term outcomes of former MDR TB patients who have been successfully treated with second line TB Drugs in Rwanda." NRL has already developed a protocol with the aim "To assess the prevalence of mutations associated with Rifampicin resistance outside the RRDR and of "disputed" mutations in the rpoB gene". NTP research capacity at different levels will be developed and a research team will be set up to work on identified research topics, including people from different Institutions. Technical assistance may also be needed in many of those steps to carry out better research for better strategy.

IV.4.4. Strengthen the implementation of Practical approach for lung diseases (PAL) at health facilities

The PAL strategy is at different stage of programme development and implementation in Rwanda. Initial results show the approach is consistent with ongoing health sector development and continues to empower health care workers to make appropriate decisions and develop a strong patient-centred approach with regard to respiratory conditions.

Current priorities in this intervention area are to regularly update clinical guidelines for respiratory conditions in primary health care facilities, develop data collection and reporting tools for PAL in the HMIS system, continue training for health care workers to build skills in this nascent strategy, conduct a program evaluation of PAL focusing on the implementation process and reassess progress done in 2020 compared to 2017, strengthen collaboration between the NTP, NCD and other health programs with regard to respiratory diseases.

IV.4.5. Build capacities of human resources

Lately changes have been coming rapidly and health care providers need to know what are the latest findings, the new tools and new strategies. For the matter of cost-effectiveness, TB training of health providers is organized in cascade including training of trainers of national and district levels and secondly, training of peripheral staff by district' trainers. On the other hand, some specific TB related documents and training modules will be uploaded to RHMIS website for use by health providers.

This extended plan addresses training needs related to dissemination of updated guidelines and national scale-up of new interventions such as Xpert, Xray interpretation, implementation of connectivity system for the laboratory network, new diagnosis algorithm among risk groups, shorter treatment regimen of MDR-TB, surveillance of adverse effects of TB drugs, childhood TB management, generation of quarterly report from e-TB register, etc. In addition, initial training is conducted for new staff, focusing on practical competencies and covering all TB control components. Also, NTP conducts initial training for post-graduate medical students and nurses.

NTP will also explore multimedia and interactive training opportunities; and seek the support of partners to develop a training plan and interactive on-line training modules.

Trainings related to TB control activities will be compiled in NTP training database in order to evaluate the training coverage among key TB staff and to determine training needs.

Capacities of the TB & ORD Division at central level will be strengthened, through short courses on specific topics or during technical assistance missions or attendance in national, regional and international conferences.

With regard to staffing, the PBF scheme will continue to be applied as a part of salary and as policy of MoH, and will aim at improving staff performance; its payment will continue to be based on achievement of fixed targets set in contract between the two parts. To respond to current implementation challenges, the performance based financing scheme (PBF) for TB control activities will be maintained. PBF indicators will be reviewed and revised periodically to boost achievement of new interventions or those with suboptimal results.

Technical assistance with capacity building focus will be required for program evaluation (NSP end review), for periodic evaluation of defined program component (such as the laboratory network, MDR-TB, M&E, PAL), for special surveys (catastrophic costs) and for laboratory accreditation.

IV.4.6. Ensure proper program management, planning and evaluation

During this extended plan, we will maintain the current frequency of planning and evaluation activities including quarterly meetings at DH, national evaluation with districts and partners. We will continue ensuring quality of data reported to RHMIS through routine data quality audit (RDQA), rapid service quality assessment (RSQA) and integrated supervision by levels. We will also conduct evaluations of program components implementation and results at different levels, for decision making and feed-back to all stakeholders and implementers.

IV.4.7. Ensure logistics for TB control activities

This plan includes the purchase of medical and non-medical equipment necessary for the execution of activities. Some of them will strengthen the health system such as radiography and laboratory equipment.

IV.5. Objective 5. Strengthen the coordination across MoH divisions and other government ministries as well as the collaboration with communities, civil society, private care providers and local administrations so that zero TB-affected families are facing catastrophic costs due to TB.

This objective contributes to health system strengthening for all core TB managerial functions and includes all these interventions beyond free diagnosis and treatment for which the NTP will play a catalytic role. Main strategic interventions for this objective are as follow:

IV.5.1. Sustain political commitment with adequate resources for tuberculosis care and prevention

Tuberculosis as a public health concern remains a priority for the Government of Rwanda and the Ministry of Health and Rwanda Biomedical Centre aim to continue to respond effectively to this disease and to sustain the current progress through activities of the National TB program. Successful implementation of the End TB strategy will depend on effective execution of key responsibilities by Ministry of health in close collaboration with all stakeholders. The main intervention will be advocating for increased domestic and external financial support, implementation of activities, accountability and transparency. The aim is to accomplish the efficient and effective management of funds to reach targets of the TB program. Financial management of TB control activities includes monitoring resource allocation and purchasing of services related to TB. It is under the responsibility of RBC, in collaboration with different MOH departments including SPIU, MPPD, HFU, CHD, etc.

Integrated approaches will continue to be enhanced, for rational use of resources. This will concern areas like supply chain management, sample transportation across the lab network, supervision, data reporting and human resource management. Districts Pharmacies will distribute TB drugs to Health Facilities using the active distribution method.

Supervisions, aimed at improving quality of TB services and TB data, will be conducted at different levels of the health system, including the central, intermediate and peripheral levels. At central level, they will be integrated and conducted under coordination of the RBC/PME Division (biannual integrated supportive supervision). At intermediate and peripheral level, district hospitals will supervise health centers (HCs) and the latter will supervise the community level, using the integrated approach. Even though, depending on specific issues identified, specific supervisions or mentorship may be conducted in districts presenting low performance. TB data will be collected and introduced into the R-HMIS, where a TB reporting tool has been integrated since 2014. For human capacity building, TB has been integrated in trainings of HIV program and MCCH/IMCI. This plan foresees integration of TB in training module of ICCM and nutrition management.

In summary; the main intervention will be for advocating for domestic and external financial support, implementation of activities, accountability and transparency. The aim is to accomplish the efficient and effective management of funds to reach our targets.

IV.5.2. Improve collaboration across MoH and other government institutions

Inter-ministerial social cluster groups allow different ministries to align priorities and closely work together towards a common goal. The Rwanda Biomedical centre also brings the different disease areas and national programs together under a single umbrella to allow for a shared vision and mission in terms of service provision for health to all Rwandans. The NTP will under a single strategic plan of RBC work closely with other disease areas to accomplish partnered interventions to provide services.

Financial management of TB control activities includes monitoring resource allocation and purchasing of services related to TB. This is under the responsibility of RBC, in collaboration with different MOH departments including, MPPD, HFU (health financing unit), CHD, etc. Using the new financial structures in place, the MoH will also have to closely collaborate with MINICOFIN through which all financial mechanisms are arranged. The NTP through the MoH will also collaborate with peer ministries like MINALOC for decentralized activities in districts, MINEDUC, MYICT (Ministry of Youth, information & communication), MINIJUST and other ministries for public awareness. The NTP will also partner with other government parastatals like RSB (Rwanda standards board for drug quality assurance), RDB (Rwanda development board for ICT related matters) to engage the public to provide them with quality products and service delivery.

IV.5.3. Strengthen collaboration with communities, CSO and NGOs, private associations and national pharmacy council

Country's vision includes ending priority SDG targeted diseases with well-established and focused structure to coordinate an integrated national response through the Rwanda Biomedical Center (RBC).

There is a longstanding history of partnership and support available to the TB Programme from international and national nongovernment organizations (INGOs and NGOs), bilateral and multilateral agencies, research institutes and universities for TB control in Rwanda. This collaboration includes financial assistance, technical assistance, materials in kind, diagnostic and treatment services, research, and management support. External partners firmly line up their aid behind the priorities outlined in the National Strategic Plan. Indeed, activities of donors have since the initiation of the program been guided by the National Strategy, and the vast majority of aid for tuberculosis is channelled through the government account.

There are different umbrella Organizations in the country including the umbrella for PLHIV, Faith based Organizations and NGOs/CSOs. We also have 10 NGOs working on TB through the GF support to sensitize the population and improve case finding among the high risk groups like elderly, contact persons, and diabetics.

The NTP will closely involve these institutions in Technical Working Groups, planning activities and in the implementation of interventions for the programs. Regular meetings will be held to assess progress of the partnership between the NTP and the umbrella organizations for NGOs and CSOs.

The NTP will engage former TB patients as opinion leaders at district level to share experience within HCWs meetings, local administrative meetings, special events such as the world TB day, and to contribute to raise awareness and reduce stigma surrounding TB and HIV.

IV.5.4. Enhance the engagement of private health care providers

There is a strong collaboration between the government institutions and Faith based institutions in the provision of services for TB care in terms of human resources capacity building, materials and

equipment, financial partnerships, infrastructure etc. Out of 200 CDTs, 79 (40%) are Faith based health facilities -. There is further collaboration with private health facilities using the public private partnership mechanism. There are about 200 private clinics in the country (>90% residing in Kigali) that engage on presumptive TB identification and referral, of these 3 private clinics are providing TB diagnosis and treatment.

The NTP will review, strengthen and expand the current framework for partnerships with private health facilities to engage them in TB diagnosis, care and treatment, patient follow up and reporting systems through increasing number of CDTs among private facilities. The NTP will organize meetings with private facilities to plan and monitor activities of these facilities. We will also improve capacity building through trainings, mentorship, and supervision of private health facilities involved in TB control.

IV.5.5. Advocate for Universal health coverage for all TB patients and legal frameworks

Rwanda's Vision 2020 and the Economic Development and Poverty Reduction Strategy (EDPRS) provide for a health-care system that is based on health equity and has been developed using a people-centred, inclusive, and social cohesion-driven approach. In Rwanda, this is modelled around a human rights-based approach to health with practical policies, programmes and strategies to address and rectify inequalities, which include gender inequalities causing inequitable health outcomes for poor or marginalized parts of the population. Poverty is recognized as a risk factor for acquiring TB, in our bid to reduce TB incidence and mortality in Rwanda, an all-inclusive model is paramount with strategies aimed at the poorest and the most vulnerable. According to the WHO, TB is the third leading cause of death for women worldwide. This TB NSP recognises that and takes into account the need for gender equity and the removal of any gender based barriers in its endeavours to eliminate TB as major cause of morbidity and mortality in women.

Health service delivery is based on the principles of Universal health coverage (UHC) with interventions in conformity with WHO's definition complimented by 5% solidarity contributions from private health insurance providers; there is Mandatory CBHI programme (Mutuelle de Santé) to all people living in Rwanda. The NTP is willing to assess the proportion of TB patients who are not covered by health insurance and advocate to get support on behalf of local authorities, partners and individuals.

With regards to regulatory frameworks, the NTP has developed and expanded appropriate strategies for ensuring mandatory notification of tuberculosis cases, care and control through inter-ministerial and inter-sectorial collaboration. Procurement and distribution of TB drugs is done through the MoH/MPPD division in collaboration with the district pharmacies. This ensures that the supply chain management of free TB medicines reaches the lowest health facilities to avoid stock outs. In Rwanda TB medicines are procured and distributed through public sector mechanisms. The NTP has set up policies and interventions in health facilities to ensure adequate TB infection control measures to avoid transmission of disease. The NTP will advocate for the inclusion of this policy in IC guidelines produced by the MoH/clinical services department. Although the vital registration system in Rwanda is still in its early phases of development, the program will coordinate with institutions charged with vital registration system to ensure that relevant health statistics are available for use by the program.

IV.5.6. Advocate for the extension of social protection schemes for all TB patients

Rwanda's community-based health insurance programme (Mutuelle de Santé) which has been reformed into comprehensive insurance through an enactment in mid-2011 transformed Mutuelle de Santé to a system of tiered premiums to make it more financially progressive and sustainable and also mandatory to all people living in Rwanda. A wealth categorisation programme (Ubudehe) was adopted to enable communities to assess the socioeconomic status of each citizen to provide a more progressive tiered premium collection system that includes full subsidies for members of the two poorest sub-categories.

TB treatment is not handled as a special case under UHC, except for that the patient may benefit if the person is registered under Category one of the tiered premiums classification where the premium and co-payment of 200FRW and 10% of cost of care is paid by the Social Security Board at health centre levels and at referral facilities respectively. For the case of MDR TB patients, all costs for treatment and social support (nutrition and transport) are covered by the NTP.

During this plan, the NTP will assess TB patients' health insurance coverage as well as nutritional by collecting routinely this information through HMIS; this assessment will be the basis to advocate to local authorities, local partners and private institutions for the expansion of social protection schemes in order to cover needs associated with Tuberculosis beyond free diagnosis and treatment, with particular emphasis on the provision of nutritional support.

V. ESTIMATED BUDGET COST FOR THE 2018-2020 TB NSP IN RWANDA

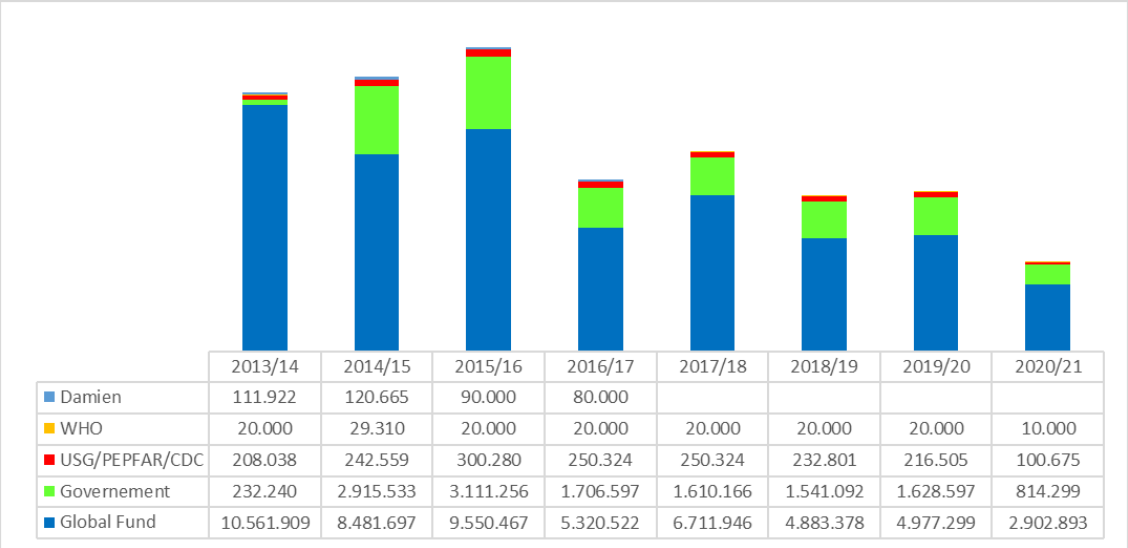
V.1. Costing methodology

After many consultations, discussions, workshops with different TB control activities implementers, partners and decision-makers, and after having consulted the End TB strategy, we have determined goals and objectives of TB control in Rwanda for 2018-2020. From these objectives, we have generated strategic interventions, for which we have then defined activities. Those new objectives, strategic interventions and their specific activities were then transferred in the excel sheet template provided by the Planning Unit/RBC for costing. For each activity, we determined quantities by quarter, unit cost per year and frequency per year, and then the total budget per year. We used unified unit costs provided by the Planning Unit/RBC and then we calculated the total budget of each activity and finally, the total detailed budget for the entire NSP, and disaggregated by NSP objectives, strategic interventions, cost categories, and sources of funding. Several revisions of the budget were carried out to ensure the relevance and feasibility of each activity in terms of quantity, frequency and unit cost, and to ensure the best cost-effectiveness.

V.2. Funding landscape

Three main funding sources were considered in the forecast calculations: Government funding projections (USD 4.8 million for NSP period), Global Fund allocation (USD 14,154,944) and USG funding. The latter has been estimated on projections of the first 2 year commitments, while for the last year according to historical data and an exponential regression analysis. Figure 4 presents the results of this analysis.

Figure 4. Forecasted TB funding. USD



	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Damien	111.922	120.665	90.000	80.000				
WHO	20.000	29.310	20.000	20.000	20.000	20.000	20.000	10.000
USG/PEPFAR/CDC	208.038	242.559	300.280	250.324	250.324	232.801	216.505	100.675
Governement	232.240	2.915.533	3.111.256	1.706.597	1.610.166	1.541.092	1.628.597	814.299
Global Fund	10.561.909	8.481.697	9.550.467	5.320.522	6.711.946	4.883.378	4.977.299	2.902.893

This forecast is meant to provide high level guidance to the development of realistic scenarios; however, it shouldn't be considered a fully accurate picture of future funding since past funding levels are not always indicative of what future funding levels will look like, and on the other hand, the regression analysis was done with limited historical data.

V.3. Costing results, gap analysis and scenario development

NSP cost was first calculated with the aim to expand the use of Xpert MTB/RIF as initial test for all TB presumptive cases countrywide. This first scenario implies the purchase of 393,208 cartridges over NSP lifespan and 19 additional geneXpert machines in the first year. The total cost is US$ 24.5 million and requires US$ 16.5 million on behalf of the Global Fund, which is not realistic in view of anticipated funding. A second scenario was developed in which Xpert is done only for all HRGs countrywide and all presumptive TB cases in Kigali districts where more cases are expected. The need of cartridges is reduced to less than half and only 5 additional geneXpert machines will be needed.

Table 6. Comparison of two NSP costing scenarios.

	july-Dec 17	*2018/2019*	*2019/2020*	*Jan-June 2021*	*Total*
Number of cartriges					
scenario 1		118.255	134.337	140.616	393.208
scenario 2		56.500	66.199	70.409	193.108
Number of additional Xpert machines					
scenario 1		19			
scenario 2		5			
Cost of geneXpert commodities and equipment					***USD Total***
scenario 1		1.576.804	1.415.490	1.536.705	4.528.999
scenario 2		672.515	688.052	787.172	2.147.740
Difference		904.288	727.438	749.532	2.381.259
NSP Cost					
scenario 1	3.210.952	8.915.263	8.655.880	3.672.500	24.454.595
scenario 2	3.210.952	8.010.975	7.928.442	2.922.968	22.073.336
Difference	**-**	**904.288**	**727.438**	**749.532**	**2.381.259**

Scenario 1: Xpert as initial test for all presumptive TB cases countrywide
Scenario 2: Xpert as initial test for all HRG presumptive TB cases countrywide and all presumptive TB cases in Kigali districts.

Given the anticipated funding's, only the second scenario can be realistically implemented during this extended NSP. Total NSP implementation will require US$ 22 million of which US$ 14.1 million (64%) are committed on behalf of GF, US$ 4.8 million (21.7%) by the government of Rwanda and 3% by the USG/UN. There will still be a remaining gap of about USD 2.4 million (11%).

Table 7. TB-NSP 2018-2020 costing by TB program and funding source.

NTP program	*july-Dec 17*	*2018/2019*	*2019/2020*	*Jan-June 2021*	*USD Total*	*%*
TB Care and Prevention	1.434.239,9	3.749.326,8	4.484.329,9	2.002.878,4	11.670.775,0	53%
MDR TB	1.415.531,3	2.456.314,5	2.492.483,6	443.835,3	6.808.164,6	31%
TB/HIV	56.536,9	689.629,9	116.563,6	20.108,3	882.838,6	4%
Coordination/Program management	292.408,8	805.985,7	772.381,2	455.200,8	2.325.976,6	11%
RSSH	12.235,0	309.717,9	62.683,3	945,3	385.581,5	2%
Total	**3.210.952**	**8.010.975**	**7.928.442**	**2.922.968**	**22.073.336**	

Funding source	*july-Dec 17*	*2018/2019*	*2019/2020*	*Jan-June 2021*	*USD Total*	*%*
GVT of Rwanda	1.610.166	1.541.092	1.628.597	-	4.779.855,4	21,7%
GF	1.491.424	4.990.658	4.823.473	2.849.440	14.154.994,0	64,1%
COAG	71.930	156.703	346.579	42.133	617.345,2	2,8%
WHO	500	57.977	51.000	-	109.477,4	0,5%
Gap	36.931	1.264.545	1.078.793	31.395	2.411.664,2	10,9%
Total	**3.210.952**	**8.010.975**	**7.928.442**	**2.922.968**	**22.073.336**	

VI. IMPLEMENTATION PLAN

VI.1. Governance, coordination and implementation arrangement

VI.1.1. Coordination of TB control activities by the central level

At central, the TB and other respiratory communicable diseases Division (Rwanda NTP), under the IHDPC/RBC/MoH, will be responsible for coordinating all partners' activities of the NSP. This will include strategic and operational planning, advocacy, fund mobilization, policies, guidelines and curricula development and their dissemination, trainings of trainers, monitoring of implementation and reporting of national level information. The National Referral Laboratory (NRL) together with TB & ORD Division determine all TB laboratory related activities and policies. The NRL will also ensure the quantification of laboratory products, training of laboratory technicians and conduct laboratory quality control activities at DH level and in some selected HCs. In collaboration with the Medical procurement and Production Division (MPPD) of RBC, NTP will ensure quantification of TB medicines and health equipment according to the targets described in the performance framework. Procurement of all medicines, reagents, consumables and health equipment are endorsed by MPPD. Second line medicines are procured from GDF, first line medicines are procured from prequalified manufacturers. For the procurement method for other products, MPPD is using an international open tender. To reduce long administrative procedures and mitigate external factors affecting procurement of TB medicine, MPPD signed contract framework for two years with suppliers. The distribution of TB medicines is based on number of TB cases and stock on hand reported in the requisition forms from district pharmacies with validation of NTP. MPPD is ensuring transport of all medicines from central level to district pharmacies.

Supervisions of TB services and TB data will be performed on an integrated approach in coordination with other MoH departments, specifically the Division of Planning and M&E of RBC. Since January 2013, TB & ORD Division initiated the integration of reports to electronic reporting through R-HMIS. Starting January 2014, quarterly reporting of TB surveillance aggregated data is done only through R-HMIS[24]. Concomitantly, in 2013 an electronic TB register, with individual data, was developed and has been hosted on R-HMIS and, the latter will provide technical assistance to central and decentralized levels for trainings and data management.

Several departments within the MoH/RBC will be involved in NSP implementation. The Community Health Desk of MCCH/RBC will ensure organization of Community health workers CHWs and set Community DOT related indicators. The Health Financing Unit of the MoH will coordinate verification process of indicators to be paid to Health Facilities and CHWs. NTP will collaborate with MCCH/RBC to reinforce integration of TB into IMCI clinics (Integrated Management of Children illnesses) and antenatal care and to integrate childhood TB into management of children at community level (MCCH) .

The Rwanda Health Communication Centre will coordinate development and dissemination of IEC/BCC messages and policies/guidelines/tools related to TB awareness and BCC.

With regards to TB/HIV collaboration at central level, the TB/HIV technical working group (TWG) includes partners and implementers involved in TB/HIV activities, and meet quarterly to discuss related issues. Its main mission is to coordinate TB/HIV activities and develop policies/guidelines/tools related.

[24] hmis.moh.gov.rw/hmis

The RBC Medical Research Center (MRC) will intervene in TB operational research(OR) protocols, scientific reviews and in capacity building. CHUs and the Rwanda Paediatric Association will provide mentorship to DH on TB/HIV management and childhood TB respectively.

The University of Rwanda School of Public Health (SPH) hosts the Centre of MDR-TB programmatic management of drug resistant TB (PMDT). The latter will, in collaboration with TB & ORD Division, play a role of a regional (eastern and southern Africa) centre for capacity building in MDR-TB program management and laboratory diagnosis of DR-TB, childhood TB, TB/HIV, TB IC and TB drug management. In addition, they will collaborate in research activities (training in operational research and collaboration in implementation of TB related surveys/operational research).

NTP is fully integrated in health sector using the existing infrastructure. Renovation is done for some health facilities which don't meet with standards required for infection control.

VI.1.2. TB control activities by the decentralized level

The number of CDT (centres for TB diagnosis and Treatment) is now 201, including 47 hospitals CDTs, 143 health centres CDTs, 8 prisons CDTs and 3 private clinics CDTs. Remaining health centres (entitled CT or TB treatment centres) don't perform TB microscopy but will participate in TB case finding through the following activities: identification of presumptive TB cases, sputum collection, smear preparation, slide transmission to the nearest CDT for staining and reading and DOT (Directly observed treatment), and perform HIV infection testing for both presumptive and TB cases. In addition to above responsibilities, CDTs will perform microscopy of sputum samples and they will register TB cases, as unit of surveillance. Some of CDTs are hospitals; the latter will provide supervision, mentorship and quality control of all TB technical work done at health centers (laboratory related activities at CDT/CT and quality of TB case management as well as quality of surveillance data).

For each health facilities, there is a focal point for tuberculosis and in some HF, staff like laboratory technician, IT specialist and doctors are recruited to meet increasing demand for high quality care. To build the capacity of staff and institution, training and on job training for laboratory technician, radiography chest x-ray, TB/HIV, infection control and others specific subjects are conducted at national and districts level to improve knowledge and skills of health providers and civil society with aim to strengthen organizational and institutional capacities and ensure continuity of service in spite of the frequent problem of turnover of staff.

CHWs will play role in mass sensitizations, searching of potential presumptive TB cases in villages and giving TB drugs through the community DOT. Health centers will oversee activities of CHWs of their catchment area (quality of TB case finding and management). TB/HIV integration at health facilities level is ensured through the "One stop TB/HIV services", where HIV+ TB patients initiate their TB treatment, receive CPT/ARTs and HIV related exams. HIV Mentors are in charge of mentoring of TB integration into HIV services (like regular TB screening among PLHIV, etc).

Supply chain of TB medicines at decentralized level is fully integrated within health sector by using an electronic logistic management information system for reporting, requisition and monitoring of medicines at all levels. The electronic system has alert mechanism to notify risk of stock out or expiry of medicines. District pharmacies ensure transport of medicines at health facilities of its catchment area.

VI.1.3. TB/HIV collaborative activities

TB/HIV collaborative activities are under the leadership of both TB and HIV programs. At central level, the TB/HIV technical working group composed by representatives of TB and HIV programs, NRL, MPPD, PMEBS, health facilities, partners and CSOs, is responsible for coordinating TB/HIV collaborative activities. TB/HIV TWG has the following tasks: update TB/HIV policy and guidelines, ensure joint strategic programme planning including joint M&E plan, develop annual work plans, implement operational activities at health services delivery, establish joint capacity building activities

such as training, supervision and mentorship. The TB/HIV TWG will also assure that different operational research questions are addressed to inform and improve program implementation.

Delivery of integrated care and treatment is ensured through the existing "One stop TB/HIV services" which are available in all CDT and CT. These are responsible for providing HIV counselling and testing to all TB patients, provision of cotrimoxazole preventive therapy (CPT), ART initiation and follow up during the TB treatment, referral to ART clinics for ART continuation after successful completion of TB treatment. On the side of HIV services, TB screening and diagnosis is systematically conducted among HIV patients. HIV patients diagnosed with TB are referred to TB services for TB and HIV treatment in accordance with infection control standards.

VI.1.4. Role of the civil society in TB control activities

Community health workers will actively participate in community DOTS, through BCC and social mobilization, referral of chronic coughing patients, and support to patients on treatment. They will play a key role in raising awareness, improving health seeking behavior and reducing stigma associated to TB and HIV.

Almost one third of CDT and CTs are property of faith-based and private organizations. They will play the same role as for other CDT and CTs.

Some activities related to mass sensitization in specific groups will be conducted by national organizations (NGOs/CSOs) in charge of those groups and in collaboration with national and decentralized levels. This may include organizations of PLHIV, diabetics, youth, etc.

The NTP will support NG0s/CSOs to be able to mobilize additional funding through recommendations towards application for grants, and other sources of funding.

The NTP is also willing to engage more private clinics attending large numbers of patients in TB detection and management and to engage private pharmacists as they are at the forefront to inform their clients on TB signs which require to seek adequate care.

VI.1.5. Partnership for the extended TB NSP 2018-2020

The Rwanda MoH/RBC will advocate for maintaining partnership that have been established during previous NSP and, will of course work to involve new partners (from national, regional and international). Some of current partners in TB control efforts are: The Government of Rwanda, the Damien Foundation, the World Health Organization (WHO), the GFTAM, the PEPFAR, the UNION, the KNCV, 5% initiative of the French Embassy, TEAM. All provide technical and/or financial support.

VI.2. MONITORING AND EVALUATION PLAN FOR THE 2018-2020 TB NSP IN RWANDA

VI.2.1. Process of development of the 2018-2020 TB NSP M&E Plan

This M&E plan has been developed to measure progress made in the implementation of activities of the 2018-2020 TB NSP, as well as to measure progress made to achieve the intended goal(s), objectives and targets.

For each indicator, the following elements must be specified:

- The purpose of the indicator (impact, outcome, output or process);
- The procedure of calculation (absolute figure, proportion, ratio, rate, index, others);
- The source(s) of information that will be used; if it is a rate, ratio or proportion, the sources of information of the numerator and denominator need to be specified;
- The periodicity (and timeliness) of data collection;
- The entity that will collect the information;

- The levels where the information will be collected, compiled and analyzed;
- The values of the indicator at the baseline and expected values at the end of each fiscal year covered by the NSP.

This monitoring and evaluation plan contains 36 indicators, representing the goals and objectives of the plan as well as the Top-ten indicators of the End TB strategy. These indicators assess the goals (impact), operational objectives (outcome) and strategic interventions (output), as defined in the core plan. The process indicators need to be considered only for the most important activities. IV.2. The 2018-2020 TB NSP M&E system

VI.2.2. M&E Coordination

The TB control M&E system is fully integrated in the national RHMIS system. The NTP will coordinate all stakeholders involved in TB control activities at national and decentralized levels, to ensure optimum utilization of available M&E resources. This coordinating structure will oversee resources mobilization for M&E, capacity development, data quality assurance and data analysis, reporting and archiving.

IV.2.3. Data flow, validation and use

The reporting system is organized from community level to health centers, compiled for hospital catchment area and for national level. This includes public and private health facilities (CTs and CDTs). Data are entered from health centers and hospitals (for their own patients), compiled for Hospitals catchment area, and then for the district and the national level[25].

For data from community, a transfer form is used when transferring a presumptive TB cases to health center for microscopy, the patient is then recorded in the health center (HC) TB laboratory register if the HC has confirmed its "TB presumption" status. For TB cases managed by CHWs in community DOT (cDOT), a specific treatment card for cDOT is used, and is brought to health center each month, where its data are recorded on the TB treatment card and TB cases register of the health center.

During this extension period, the TB & ORD Division will continue the substitution of the paper-based TB surveillance system by an electronic system, under RHMIS, with the purpose of better data quality, easy availability, use and feedback. The aggregated paper report has already been replaced by an aggregated electronic report, which is completed quarterly by the health facilities (DHs, Districts and National)[26]. The 2nd step is ongoing and aims to transition from the paper-based register to a web-based electronic register (e-TB) with individual data. This electronic register has two objectives, to improve data quality and to improve quality of case management. The latter will involve a reminders system (SMS) towards TB patients, to recall on among others treatment compliance (avoid lost to follow up patients, tracking transferred patients, decrease in number of doses not taken on time) and better identification of patients requiring special management, such as HIV-positive TB patients, eligibility to special lab techniques, etc.. Presumptive TB cases are also recorded in e-TB, including their lab results. Confirmed TB case are recorded in a new module of TB cases management. Data has to be entered at health facilities level (by the data manager in collaboration with the TB Focal Point) and is visible at higher hierarchic level, in real time. The process of transitioning from aggregated report to automatically generated reports is underway and during this plan both systems will be running in parallel, the paper-based being the reference. The e-TB captures information on TB notification, TB/HIV, TB laboratory, TB in HRGs, TB treatment outcome, MDR-TB and TB infection control[27].

The electronic reporting system contains validation rules, which allow to measure timeliness (fixed on 05th of each month following the evaluated quarter). The system is also designed to not permit any submission of incomplete report.

[25] 2013 Procedural Manual for M&E of TB in Rwanda
[26] 2014 Policy of TB electronic surveillance system
[27] 2014 Policy of TB electronic surveillance system

Each quarter, Evaluation and performance assessment (quarterly evaluation meetings) are held at district hospital (DH) level. Before these assessments, health facilities have to upload their report in the system. During evaluation meetings, the last quarter's TB data are reviewed and cross-checked with the data from source documents and agreed upon in case of discrepancies. Then after feedback is provided, through data analysis and interpretation for selected indicators, using a standardized tool. The validated national report is uploaded into the system as part of the feedback.

Bi annually, the national level conducts data quality assurance in selected health facilities and on selected indicators. Supervisions oriented to quality of TB services are conducted, community level being supervised by health centers and health centers by district hospitals. Districts hospitals are supervised by the national level through an integrated approach.

Electronic TB data in HMIS and e-TB will be archived in the National Data Center.

VI.2.4. NSP Reviews.

An end-of-term TB NSP review will be conducted (April-June 2020) with the purpose of evaluating NSP achievements, implementation gaps and to provide recommendations which will serve for the next strategy. A TB epidemiological review including TB surveillance checklist review will be conducted in partnership with WHO and other partners (2018-2019). However specific programs evaluations will also be conducted during the implementation period of this plan.

VI.2.5. M&E plan

Assumptions:

Impact targets are based on current estimates published in the WHO 2016 Global TB report and are expected to continue declining in line with the End TB strategy milestones for 2020, by about 4.3% annually for TB incidence and by 8.3 % annually for TB mortality, as a result of good program design and implementation of all key recommended TB activities with high performance levels and synergistic efforts in HIV control.

As regard TB notification (all forms), active case-finding in HRGs should detect additional cases so that the Treatment coverage is expected to increase from 84% in 2015 up to 87% by mid-2020 (1% increase per year). The number of additional cases will not be sufficient to invert the declining overall notification but the total number of cases is expected to decline with a slower pace, approximately by 0.6% per year against 3.6% in 2010-2015 period.

The proportion of TB cases among HRGs should remain high. A reduction of TB cases detected through ACF activities in prisons is already seen but it should not affect significantly the indicator since it concerns a small number of cases.

The top-10 indicators of the End TB strategy have been incorporated in the M&E plan and new targets have been set up for all indicators based on recent achievements (2015-2016 FY). Most of these will be collected through the routine surveillance but some will still rely on WHO estimates like the treatment coverage and the case fatality rate. In addition, technical and financial resources are not ensured for conducting the survey on catastrophic costs. LTBI coverage indicator is limited to contacts $\leq$ 5 since Rwanda has not adopted IPT policy for PLHIV.

Compared to TB NSP 2013-2018, targets were reduced only for the indicator related to intermediate outcome of MDR-TB treatment. Indeed, lessons learned show that they were over ambitious taking into consideration proportions of deaths before 6 months and contaminated cultures. However, NTP will do much effort to improve the collection of sputum samples at the 6th month of treatment so as to decrease the number of "not done" controls. This will be done through supervision/ mentorship and PBF.

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
GOALS for 2020 as compared to 2015: • 20% reduction of TB incidence rate from 56.0/100,000 to 45/100,000 population • 35% reduction of TB deaths • 0% TB-affected families facing catastrophic costs due to TB .													
Goal	1. Incidence rate (per 100,000 hab)	**Impact**	Measured by WHO estimations by modeling	WHO annual TB Report	Annually	WHO		56	54	51	49	47	45
									4.3% annual decrease				
Goal	2. Percentage of reduction in number of TB Deaths	**Impact**	Measured by WHO estimations by modeling	WHO annual TB Report	Annually	WHO		720	661	607	557	511	468
									8.2 % annual decrease				
Goal	3. Percentage of TB-affected families facing catastrophic costs due to TB ***(End TB Top-ten indicator N°3)***	**Impact**	Numerator: Proportion of TB patients (and their households) who incur catastrophic costs Denominator: all patients treated	Survey results							Survey		0%
Objective 1: Improve early and accurate diagnosis of TB including universal DST through progressive adoption of WHO-recommended rapid tests for all presumptive cases so that the treatment coverage increase from 84% in 2015 to 89 % by mid-2021.													
1.	4. TB notification rate new and relapses (per 100,000)	Outcome	Numerator: Number of TB cases notified (new and relapses) Denominator: Population/100,000	RHMIS report	Annually	NTP	National level	5534	5501	5468	5434	5400	5333
								48.7	47.2	45.7	44.3	42.9	41.3
	5. Notification rate of new pulmonary bacteriologically confirmed TB cases	Outcome	Numerator: Number of new bacteriologically confirmed TB cases notified (new and relapses) Denominator: population/100,000	RHMIS report	Annually	NTP	National level	3762	3740	3718	3696	3674	3652
								33.1	32.1	31.1	30.1	29.2	28.3
	6. TB treatment coverage ***(End TB Top-ten indicator N° 1)***	Outcome	Numerator: Number of new and relapses cases that were notified and treated Denominator: estimated number of incident cases in the same year (%)	RHMIS report WHO incidence estimates	Annually	WHO	National level	84%	85	86%	87%	88%	89%
1.1. Improve active case finding in prioritized HRGs so that at least 90% of contacts of TB bacteriologically confirmed cases are investigated for TB.													
1.1.	7. Contact investigation coverage ***(End TB Top-Ten N°6)***	Coverage	Numerator: Number of contacts of bacteriologically confirmed TB cases who were investigated for TB Denominator: Number of contacts of bacteriologically	RHMIS report	Annually	NTP	National level	81%	83%	85%	87%	88%	90%

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
			confirmed TB cases										
1.1.	8. Proportion of TB cases notified among high-risk groups (HRGs (Number and Percentage)	Process	Numerator: Number of TB cases (new & relapses)) notified in HRGs Denominator: Total number of TB cases notified during the period of assessment	RHMIS	Quarterly and annually	NTP	National	43.9	≥ 40%	≥ 40%	≥ 40%	≥ 40%	≥ 40%
1.2. Strengthen diagnosis capacities for childhood TB so that the proportion of TB cases among children increase from 5% in 2015 to 10% by mid-2021													
1.2.	9. Proportion of TB cases among children 0-14	Output	Numerator: Number of TB cases aged 0-14 (new & relapses) Denominator: Total number of TB cases notified (new and relapses)	RHMIS	Quarterly and annually	NTP	National District HF	5%	5.5%	6%	7%	7.5%	8%
1.3. Improve TB diagnosis across the laboratory network and ensure universal DST coverage for all bacteriologically confirmed TB patients.													
1.3.	10. Percentage of newly notified TB+ patients diagnosed using WHO recommended rapid tests ***(End TB Top-Ten N°4)***	Output	Numerator: Number of new and relapses cases diagnosed using WHO recommended rapid tests Denominator: Number of new and relapses case notified	RHMIS	Quarterly and annually	NTP	National District HF	NA	28%	31%	37%	43%	49%
1.3.	11. DST Coverage for TB patients ***(End TB Top-Ten indicator N° 7)***	Coverage	Numerator: Number of TB patients with a drug susceptibility result for at least Rifampicin (Xpert MTB/RIF or phenotypic DST) Denominator: Number of bacteriologically confirmed notified cases in the same year. Disaggregation for New TPB+ and previously treated cases	RHMIS	Quarterly and annually	NTP	All	60%	72%	75%	83%	86%	86%
							New B+	59%	70%	73%	82%	85%	85%
							All previously treated	70%	89%	95%	95%	97%	98%

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
1.4. Strengthen the implementation of quality management system in the TB lab network													
1.4	12. Laboratories showing adequate performance in external quality assurance for smear microscopy	Output	Numerator: Laboratories showing adequate performance in external quality assurance for smear microscopy (No major error in at least 3 controls) Denominator: Total number of TB microscopy laboratories that undertake smear microscopy during the reporting period (number and percentage)	NRL EQA reports	Annually	NRL-Division	National level	75.5%	96%	96%	96%	96%	96%
1.4.	13. Xpert laboratories showing adequate performance in EQA	Output	Numerator: Laboratories showing adequate performance on panel testing for Xpert (once per year) Denominator: Total number of Xpert laboratories (number and percentage)	NRL EQA reports	Annually	NRL-Division	National level	NA	NA	NA	98%	98%	98%
1.4	14. Culture laboratories showing acceptable performance in culture DST proficiency testing	Output	Numerator: Total number of laboratories showing acceptable performance results on culture DST panel (once per year) Denominator: Total number of functional culture laboratories	SRL and NRL culture DST PT report	Annually	NRL-Division	National	NA	90	90	90	95	95
1.6. Intensify communication and social mobilization for early TB detection													
1.6.	15. Percentage of population with adequate knowledge* on TB symptoms, transmission and prevention	Outcome	Numerator: Number of people with adequate knowledge* on TB symptoms, transmission and prevention Denominator: Number of people interviewed through the survey.	Survey (integrated in RDHS)	Once during the extended NSP	NTP	National level	56% (2012)			75%		
1.6.	16. Proportion of TB cases (all forms) referred by CHW during the evaluated year.	Output	Numerator Number of TB cases (all forms) referred by CHW during the evaluated period Denominator:	RHMIS	Quarterly, Annually	NTP	Health facilities	19.4%	21%	21%	≥21%	≥21%	≥21%

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
			The total number of notified TB cases (all forms).										
Objective 2: Provide patient-centered treatment for all forms of TB so that the treatment success rate be maintained at least at 90% for bacteriologically confirmed tuberculosis and at least at 87% for drug resistant tuberculosis.													
2	17. Treatment success rate (TSR) for all forms of TB cases (DS & DR-TB cases) ***(End TB Top-ten 2)***	Outcome	Numerator: TB cases (DS- and DR-TB cases) successfully treated (cured plus completed treatment) Denominator: total number of TB cases (DS- and DR-TB cases) registered during the year	RHMIS	Annually	NTP	National District CDT	86,5%	≥ 87%	≥ 87%	≥ 87%	≥ 87%	≥ 87%
2.1. Ensure no stock out of first-line and second-line drugs in all CDT													
2.1.	18. Percentage of CDT with no stock out of FSL of experienced in the last 12 months	coverage	Numerator: Percentage of CDT with no stock out of First-Line TB drugs (R150H75ZE&R150H75) Denominator Total number of CDT	RHMIS reports	Annually	NTP	CDT	>97%	>97%	>97%	100%	100%	100%
2.1.	19. Percentage of RR/MDR TB patients with no interruption of treatment due to stock out of SLD in the last 12 months	coverage	Numerator: Percentage of RR/MDR TB patients with no interruption of treatment due to stock out of SLD in the last 12 months Denominator Total number of RR/MDR TB patients under second-line treatment during the last 12 months	Supervision reports of MDR-TB centers to CDT giving ambulatory DOT	Annually	NTP	MDR-TB centers and CDT giving ambulatory DOT	100%	100%	100%	100%	100%	100%
2.2. Improve treatment success rate for all forms of TB, specifically maintain it at least at 90% for bacteriologically confirmed TB cases													
2.2.	20. Treatment success rate for bacteriologically confirmed new and relapse TB cases	Outcome	Numerator: Bacteriologically confirmed new and relapse TB cases successfully treated (cured plus completed treatment) Denominator: total number of bacteriologically confirmed new and relapse TB cases registered during the year of assessment	RHMIS report,	Quarterly and	NTP	National District Hospital CDT	90%	> 90%	> 90%	> 90%	> 90%	> 90%

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
2.2	21. Treatment success rate for clinically diagnosed TB cases (SS-, SS0, EPTB and others)	Outcome To know if treatment success improved for forms other than bacterio confirmed	Numerator: number of clinically diagnosed TB case with completed treatment during the year of assessment Denominator: number of clinically diagnosed TB case during the year of assessment	RHMIS report,	Quarterly and	NTP	National District Hospital CDT	79%	79%	80%	80%	81%	82%
2.2.3.	22. Cure rate bacteriologically confirmed new and relapse TB cases	Outcome	Numerator: Bacteriologically confirmed pulmonary TB cases who were smear- or culture-negative in the last month of treatment and on at least one previous occasion Denominator: All pulmonary bacteriologically confirmed TB patients registered the evaluated period of time.	RHMIS	Quarterly, Annually	NTP	National, District CDT	83%	83%	84%	84%	85%	85%
2.3. Maintain treatment success rate at ≥ 87% for MDR-TB patients													
2.3	23. Proportion of confirmed RR/MDR-TB cases enrolled on second-line treatment (number and percentage)	Output	Numerator: Number of bacteriologically confirmed RR/MDR-TB cases enrolled on second-line anti-TB treatment Denominator: Number of bacteriologically confirmed RR/MDR-TB cases during the period of assessment	Numerator: RHMIS Denominator LIS / Connectivity laboratory system	Quarterly, Annually	MDR-TB unit NTP	National, District CDT	99%	100%	100%	100%	100%	100%
2.3	24. Treatment success rate, confirmed RR/MDR-TB	Outcome	Numerator: Rifampicin resistant (RR)/MDR-TB cases successfully treated (cured plus completed treatment) Denominator: RR/MDR-TB cases enrolled on second-line anti-TB treatment (shorter regimen: patients enrolled in the previous 12 to 24 months; conventional regimen; patients enrolled in the previous 24 to 36 months)	RHMIS	Quarterly and annually	NTP	National	85%	86%	≥ 87%	≥ 87%	≥ 87%	≥ 87%

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
2.3	25. Interim results: culture conversion at six months	Output	Numerator: Bacteriologically confirmed RR/MDR-TB cases who have a negative culture at the end of six month Denominator: Total number of RR/MDR-TB cases initiated on a second-line anti-TB treatment during the period of assessment.	RHMIS	Annually	MDR-TB unit NTP	National	78%	79%	80%	82%	84%	85%
2.3	26. Treatment coverage new drugs ***(End TB Top-ten indicator N°8)***	Coverage	Numerator: Number of TB patients treated with regimens that include new TB drugs Denominator: Number of notified TB patients eligible for treatment with new drugs	RHMIS	Annually	MDR-TB unit NTP	National	NA	NA	NA	≥85%	90%	95%
2.4. Implement active drug safety monitoring and management (aDSM)													
2.5.	27. Proportion of TB treatment cards where ADSM section is completed	Output	Numerator: Number of TB patients whose TB treatment card section on AE was completed adequately (every month for MDR-TB and at least 3 times for DS-TB) Denominator: Total number of registered TB cases during the period of assessment.	RHMIS (variable to be added)	Quarterly and annually	NTP	National, District Hospital, CDT	NA	NA	NA	40%	60%	80%
2.5. Maintain ART coverage among co-infected patients at least at 90%.													
2.5.	28. Proportion of diagnosed TB cases tested for HIV infection ***(End TB Top-ten indicator N°9)***	Output	Numerator: Number of TB patients who had an HIV test result recorded in the TB register Denominator: Total number of registered TB cases during the period of assessment.	RHMIS	Quarterly and annually	NTP	National, District Hospital, CDT	99%	99%	99%	99%	99%	99%
2.5.	29. Proportion of HIV-positive TB cases given antiretroviral therapy during TB treatment	Output	Numerator: number of HIV-positive TB cases given antiretroviral therapy during TB treatment Denominator: number of HIV-positive TB cases registered during the evaluated period	RHMIS	Quarterly and annually	NTP	National, District Hospital, CDT	93.9%	> 90%	> 90%	> 90%	> 90%	> 90%

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
2.6. Maintain at ≥ 95% the treatment success rate for patients managed in the community.													
2.6.	30. Treatment success rate for TB patients (all forms) receiving DOT through community health workers (CHW)	Outcome	Numerator: TB patients receiving DOT by CHW who were successfully treated Denominator: all TB patients receiving DOT by CHW during the evaluated period	RHMIS	Quarterly and annually	NTP	CDT	95%	≥ 95%	≥ 95%	≥ 95%	≥ 95%	≥ 95%
Objective 3: Improve TB prevention (TB IC and prevention by medication) so that LTBI treatment coverage among contacts < 5 years increases from 78 % to 90 % by mid-2021.													
3.1. Ensure that basic infection control measures are applied in at least 85% of all HF and that at least 70% of the health providers undergo annual TB screening													
3.1.	31. Percentage of Health providers screened for TB at least once during the year.	Coverage	Numerator: number of Health providers screened for TB at least once during the year. Denominator: number of health providers	RHMIS	annually	NTP	All HF	59.3%	62%	64%	66%	68%	70%
3.1.	32. Percentage of CHWs screened for TB at least once during the year.	Coverage	Numerator: number of CHWs screened for TB at least once during the year. Denominator: number of CHWs	RHMIS (to be created)	annually	NTP	All HC	NA	3%	20%	30%	40%	50%
3.1. Increase LTBI treatment coverage among TB contacts < 5 years of age from 78 % to 90 % by mid-2021.													
3.2	33. LTBI treatment coverage among contacts < 5 ***(End TB Top-ten indicator N°5)***	Coverage	Numerator: number of children who are contacts of TB cases started on LTBI treatment Denominator: number of children eligible for LTBI treatment	RHMIS	Quarterly and annually	NTP	National, District Hospital, HF	78%	80%	82%	85%	87%	90%
Objective 4: Improve managerial capacities of the TB program; enhance the performance of the TB surveillance to achieve concordance between aggregate and case-based systems; and develop research.													
4.1. Improve the implementation of TB individual record (e-TB) so that by June 2020 TB aggregated electronic reports are generated from e-TB system.													
4.1.	34. Percentage of HF reporting concordant data in e-TB and RHMIS	outcome	Numerator: Reporting units (CDT and CT) submitting timely reports to RHMIS by the 5th day following the end of the evaluated quarter Denominator: Total number of reporting units (CDT and CT)	RHMIS	Quarterly	NTP	National, District Hospital, HF	30%	50%	80%	90%	95%	100%

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
4.1.	35. Timeliness of routine aggregated reports RHMIS	Process	Numerator: Reporting units (CDT and CT) submitting timely aggregated reports to RHMIS by the 5th day following the end of the evaluated quarter Denominator: Total number of reporting units (CDT and CT)	RHMIS	Quarterly	NTP	National, District Hospital, HF	81.2%	90%	95%	98%	98%	100%
4.2. Collaborate to the establishment of a national vital registration system that includes TB death data													
	36. Case fatality ratio (CFR) ***(End TB Top-ten indicator N° 10)***	Outcome	Numerator: Number of TB deaths (from VR system) Denominator: estimated number of incident cases in the same year	Numerator: VR system Denominator: WHO	annually	NTP WHO	National	NA	NA	NA	NA	NA	< 8%
4.3. Conduct research to optimize implementation and impact of new strategies and tools													
4.3.	37. Number of completed operational researches	Output	Number of completed operational researches (report disseminated)	Study report	annually	NTP	1					1	1
4.4. Strengthen the Practical approach for lung diseases (PAL)													
4.4	38. Percentage of health care facilities reporting integrated use of the PAL strategy for respiratory conditions	Output	Numerator: Number of health care facilities reporting full integration of the PAL strategy (have trained staff, PAL equipment and medicines available). Denominator: Number of health care facilities evaluated	RSQA reports	Quarterly	NTP	National, District Hospital, CDT	68%	68%	76%	84%	92%	100%

	Indicators	Purpose	Calculation	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline Jul.2015/2016	Jul 2016/ June 2017	Jul 2017/ June 2018	Jul 2018/ June 2019	jul 2019/ June 2020	Jul 2020 / June 2021
Objective 5. Strengthen the coordination across MoH divisions and other government ministries as well as the collaboration with communities, civil society, private care providers and local administrations so that zero TB-affected families are facing catastrophic costs[28] due to TB.													
5.5. Advocate for Universal health coverage for all TB patients													
Goal	39. Percentage of TB-affected families facing catastrophic costs due to TB ***(End TB Top-ten indicator N°3)***	**Impact**	Numerator: Proportion of TB patients (and their households) who incur catastrophic costs Denominator: all patients treated	Survey results	Survey results	NTP	National	NA	NA	NA	NA	NA	0%

* Indicator 29. **Adequate comprehensive knowledge on TB**:

- At least one airborne transmission mode: coughing, sneezing, or talking
- At least one of 2 important prevention ways (cover mouth when coughing or sneezing, open windows)
- At least 3 risk factors of TB disease: HIV infection, being in contact with an TB infectious patient and any other risk factor
- TB most important sign: cough $\geq$ 2 weeks
- Where patients go for health care seeking (HF)
- Curability of TB
- The RDHS survey will include questions on knowledge on TB and on behavioral changes

[28] The operational definition of "catastrophic costs as a result of TB" refers to medical and non-medical out-of-pocket payments and indirect costs exceeding a given threshold (e.g. 20%) of the household's income. Medical costs refer to the sum of out-pocket payments for TB diagnosis and treatment made by TB patients in a given household. Non-medical out-of-pocket costs are payments related to the use of TB health services, such as payments for transportation, accommodation or food. Both costs are net of any reimbursements to the individual who made the payments. Indirect costs refer to patient or guardian lost time, lost wages (net of welfare payments) and lost income due to TB health-care seeking and hospitalization during the TB episode.

VII. CONCLUSION

This extended NSP 2018-2020 is built on achievements and lessons learned of the current NSP 2013-2018 as well as recommendations of the 2016 mid-term review. It is inspired by the end TB strategy and sets ambitious targets in view of attaining the SDGs by 2030.

Rwanda NTP is willing to adopt Xpert instead of microscopy as initial test for all TB presumptive cases countrywide. This first scenario resulted too expensive as compared to anticipated funding. A second scenario was developed in which Xpert will be used as initial test for all HRG countrywide and all presumptive cases in Kigali districts. In addition, radiological screening will become systematic for define high-risk groups. This approach is more cost effective than the first one since effort is focused on populations which have higher burden of TB. Therefore, it should have high impact on TB burden and allow Rwanda to be in track with SDG. This extended NSP 2018-2020 will provide strong support the health system which underpins all interventions required for maintaining current achievements and enable successful implementation of this NSP.

REFERENCES

Document reviewed and international guidance

DIAGNOSIS

1) Guide for providing technical support to TB laboratories in low- and middle income countries. GLI / STOP TB partnership
2) WHO/HTM/TB/2015.11. Implementing tuberculosis diagnostics. Policy framework.
3) WHO/HTM/TB/2016.18. Framework of indicators and targets for laboratory strengthening under the End TB Strategy.
4) WHO_HTM_TB_2007.379. Improving the diagnosis and treatment of smear-negative pulmonary and extrapulmonary tuberculosis among adults and adolescents. Recommendations for HIV-prevalent and resource-constrained settings. World Health Organization 2007
5) WHO/HTM/TB/2011.4 Policy statement: Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF system
6) WHO/HTM/TB/2011.2 Rapid implementation of the Xpert MTB/RIF diagnostic test. Technical and operational 'How-to'. Practical consideration
7) Heidi Albert and al. Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons have we learnt and how can we do better? ERJ Express. Published on July 13, 2016
8) Zachary D et al. Changes in tuberculosis notifications and treatment delay in Zambia when introducing a digital X-ray service, IUATLD VOL 2 NO 3 PUBLISHED 21 SEPTEMBER 2012
9) Dye C, Williams B. Eliminating human tuberculosis in the twenty-first century. Journal of the Royal Society Interface, 2008, 5:653–662.

DS-TB and DR-TB TREATMENT

1) WHO/HTM/TB/2016.04. WHO treatment guidelines for drug-resistant tuberculosis. 2016 update.
2) WHO/HTM/TB/2014.23, WHO interim guidance on the use of delamanid in the treatment of multidrug-resistant tuberculosis. Geneva, WHO, 2014
3) WHO/HTM/TB/2013.6. The use of bedaquiline in the treatment of multidrug-resistant tuberculosis: interim policy guidance.

4) WHO/HTM/TB/2015.13. Guidelines for the surveillance of drug-resistance in tuberculosis.2015
5) WHO/HTM/TB/2011.3 Towards universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis by 2015. WHO progress report 2011
6) WHO/HTM/TB/2011.6 Guidelines for the programmatic management of drug-resistant tuberculosis - 2011 update
7) WHO/HTM/TB/2015.28 Active tuberculosis drug-safety monitoring and management (aDSM): Framework for implementation

HIGH-RISK GROUPS

1) Systematic screening for active tuberculosis: principles and recommendations (WHO/HTM/2013.4)
2) Systematic screening for active tuberculosis: an operational guideline (WHO/HTM/TB/2015.16)
3) WHO. Chest radiography in tuberculosis detection (WHO/HTM/TB/2016.20)
4) Recommendations for investigating contacts of persons with infectious tuberculosis in low- and middle-income countries. Geneva, World Health Organization, 2012 (WHO/HTM/2012.9)
5) Guidelines for control of tuberculosis in prisons. January 2009. USAID. TBCTA. ICRC
6) Guidelines for the control of tuberculosis in prisons. Geneva, World Health Organization, 1998 (WHO/TB/98.250).
7) WHO. Guideline: Nutritional care and support for patients with tuberculosis. Geneva: World Health Organization; 2013.
8) WHO/HTM/STB/PSI/2011.21 Early detection of tuberculosis: An overview of approaches, guidelines and tools
9) WHO Collaborative framework for care and control of Tuberculosis and Diabetes.
10) Lönnroth K et al. Drivers of tuberculosis epidemics: the role of risk factors and social determinants. Social Science & Medicine, 2009.
11) Tuberculosis care and control in refugee and displaced populations. Geneva, World Health Organization, 2007 (WHO/HTM/TB/2007.377).
12) Shah NS et al. Population-based chest X-ray screening for pulmonary tuberculosis in people living with HIV/AIDS, An Giang, Vietnam. International Journal of Tuberculosis and Lung Disease, 2008, 12:404–410.

CHILDHOOD TB

1) WHO HTM TB 2014.03 Guidance for NTP on management of TB in children. 2d edition.
2) WHO/HTM/TB/2013.12. Roadmap for childhood tuberculosis: towards zero deaths.
3) New fixed - dose combinations for the treatment of TB in children. World Health Organization. December 2016

TB/HIV

1) WHO/HTM/TB/2015.02. A guide to monitoring and evaluation for collaborative TB/HIV activities - 2015 revision.
2) WHO/HTM/TB/2012.1 WHO policy on collaborative TB/HIV activities: guidelines for national programmes and other stakeholders
3) WHO/HTM/TB/2011.11 Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings
4) WHO/HTM/TB/2012.3 Working together with businesses: Guidance on TB and TB/HIV prevention, diagnosis,treatment and care in the workplace

5) Kenneth Turinawe et al. Operating Characteristics of a Tuberculosis Screening Tool for People Living with HIV in Out-Patient HIV Care and Treatment Services, Rwanda. PLOS ONE. September 29, 2016

M&E

1) WHO/HTM/TB/2015.21. Digital health for the End TB strategy.
2) WHO/HTM/TB/2013.2 Definitions and reporting framework for TB - 2013 revision
3) WHO/HTM/TB/2011.22 Electronic reporting and recording for tuberculosis care and control

Human resources development

4) WHO/HTM/TB/2008.407. Planning the development of human resources for health for implementation of the Stop TB Strategy
1) http://www.theunion.org/what-we-do/courses/online-and-multimedia-training
2) mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings: Mental Health Gap Action Programme (mhGAP). World Health Organization 2010

Community DOTS

1) ENGAGE-TB. Integrating Community-based tuberculosis activities into the work of nongovernmental and other civil society organizations. Operational guidance
2) ENGAGE-TB. Integrating Community-based tuberculosis activities into the work of nongovernmental and other civil society organizations. Implementation manual.

Planning

1) Global Plan to End TB.2015. Stop TB Partnership
2) Implementing the end TB strategy: the essentials. WHO. 2015
3) Toolkit to Develop National Strategic Plan for TB Control

ANNEXES

Annex 1. Trend of TB financing

In US $	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	July-Dec 2020
NSP cost					9.585.687	8.263.397	8.174.318	2.988.640
Governement	232.240	2.915.533	3.111.256	1.706.597	1.610.166	1.541.092	1.628.597	814.299
Damien	111.922	120.665	90.000	80.000				
USG/PEPFAR/CDC	208.038	242.559	300.280	250.324	250.324	232.801	216.505	100.675
WHO	20.000	29.310	20.000	20.000	20.000	20.000	20.000	10.000
Global Fund	10.561.909	8.481.697	9.550.467	5.320.522	6.711.946	4.883.378	4.977.299	2.902.893
Total	11.134.109	11.789.764	13.072.003	7.377.443	8.592.436	6.677.271	6.842.401	3.827.867
GAP					993.251	1.586.126	1.331.916	- 839.228

Annex 2. Situation analysis: Strengths, weaknesses, opportunities and threats

Strengths	**Weaknesses**
• Strong political commitment at various levels of Government • Structured and adequately staffed NTP • Well-articulated TB NSP linked to the National Health Sector Strategy and aligned to international recommendations	• 14% of the estimated incident cases were missed in 2015 (WHO GR 2016). • Underutilization of XPert and CXR in the diagnostic process; lack of standardized screening tools • Low capacities for diagnosis of extrapulmonary

• Decreasing incidence in favour of decreasing transmission. • Robust health planning at Central and District levels, • Good collaboration with other MOH programs, • Availability of guidance documents in the field, • Robust management of TB commodities. • TB burden estimates based on 2014 prevalence survey results. • Access to Xpert and CXR in all DH • Sustained high treatment success rate for bacteriologically-confirmed TB cases. • Integrated care and treatment of TB-HIV coinfection and TB/HIV targets fully reached; universal access to ART. • Good PMDT with patient support and shorter regimen • Strong routine surveillance system integrated into RHMIS and transitioning to an electronic case-based system • Efficient community DOTS in the whole country • Application of infection control measures in health facilities dealing with TB and MDR-TB patients	and smear-negative TB forms • Sub-optimal efficiency and quality of the overall laboratory network (sample transportation system, EQA, lack of connectivity system for rapid transmission of results, biosafety concerns, lack of maintenance system of laboratory equipment) • Insufficient DST coverage • Low detection of childhood TB • Absence of a pharmacovigilance monitoring system (aDSM system) • Lack of nutritional support to drug-susceptible patients; • Treatment success rate target (90%) not achieved for all TB patients; elevated fatality rate among TB-HIV and clinically diagnosed forms of TB whose causes are not yet analysed • Overall quality of supervision needs to be improved; TB insufficiently covered in the mentorship program • Gaps in CHW knowledge related to TB; decreased motivation owing to decreased incentives • Lack of ACSM strategy and IEC materials for patients and their families • Low use of e-TB; low ownership of M&E activities • Limited capacities for research
Opportunities: **a) national** • Vision and political commitment to universal health coverage and to attain SDGs • High political commitment to poverty reduction and fighting against malnutrition. • High coverage of health insurance. • Various social protection schemes to address the wider determinants of TB • Existence of umbrella organization of willing NGOs, CSOs, and medical associations • Development of a vital registration system which will aid the estimation of TB-related deaths. • Integration of TB within other health programs; • Ongoing implementation of a nationwide Laboratory Information System (LIS) which has the potential to be linked with the e-TB register. **b) international** • Availability of global guidance on End-TB strategy and specific strategies • Existence of online training platforms • Willingness of partners to support the development of interactive training courses • Innovative diagnostics and new drugs • New drugs and vaccine in pipeline	**Threats** • Over-reliance on donor funding and uncertainty around the funding landscape while more funding is necessary to find the missing cases • Turnover of health care staff generating ongoing capacity building needs • Threat to the Community-based TB care due to potential lack of motivation of CHWs following reduction of TB community PBF stipends • Internet connectivity issue, which hinders input of data within RHMIS and other electronic systems used for TB management. • Higher TB burden in neighbouring countries

Annex 3. The 2018-2020 TB NSP LOGICAL FRAMEWORK

Objective 1: Improve early and accurate diagnosis of TB including universal DST through progressive adoption of WHO-recommended rapid tests for all presumptive cases so that TB treatment coverage increase from 84% in 2015 to 89% by mid-2021.	
Strategic interventions	**Activities**
1.1. Strengthening TB active case finding in prioritized HRGs	**1.1.1.** Update, print and disseminate TB screening /diagnostic tools **1.1.2.** Train health providers (all HF) on new TB screening guidance and use of sensitive diagnostic techniques (see 2.2.2) **1.1.3.** Intensify TB case finding among PLHIV (systematic CXR for all new PLHIV) **1.1.4.** Conduct ACF in prisons (sensitization, CXR screening) **1.1.5.** Conduct contact examination at beginning (systematic CXR) and at the end of treatment by Health providers **1.1.6.** Introduce TB-diabetes collaborative framework **1.1.7.** Conduct active case finding (ACF) of TB and TB-HIV in identified hotspots
1.2. Strengthening diagnosis capacities for childhood TB	**1.2.1.** Provide guidance on childhood TB (guidelines, SOP on tuberculin test and sputum collection techniques, TWG meetings) **1.2.2.** Build capacities of the health providers on childhood TB through: - training including practical training on sputum collection methods and TST; - mentorship at DH by the Rwanda pediatric association **1.2.3.** Increase the use of sputum collection methods (commodities for tuberculin test, sputum induction, nasogastric aspiration). **1.2.4.** Integrate TB in ICCM (workshop with MCCH and partners, training of trainers, integrate ICCM in the refresher training of CHWs on TB) **1.2.5.** Strengthen TB detection among malnourished children
1.3. Improving TB diagnosis capacity across the laboratory network	**1.3.1.** Perform Xpert test as initial diagnostic for all eligible TB presumptive cases (cartridges, ventilated work stations, new GeneXpert machine, functional backup) **1.3.2.** Appoint NRL staff to coordinate GeneXpert network **1.3.3. Carry out sample transportation** 1.3.3.1. Purchase required commodities 1.3.3.2. Engage other courier services (MOU, training of couriers personnel) 1.3.3.3. Pilot through evaluation of data usefulness of courier services (cost of shipping, shipping coordinator) **1.3.4.** Perform proper maintenance of GeneXpert machines (service contracts, warranty, training of super user at central level and new lab technicians) **1.3.5.** Develop and review TB lab guidance documents (specimens referral guidelines, TB laboratory manual, Clinician handbook, Quality manual, Safety manual and review SOPs) **1.3.6.** Finalize switching from ZN microscopy to iLED FM microscopy (Onsite training for lab technicians) **1.3.7.** Perform smear microscopy for TB diagnosis and follow up of TB patients (purchase LED-FM and ZN reagents and other commodities) **1.3.8.** Perform TB DST for all bacteriologically confirmed TB patients (commodities for mycobacterial culture on liquid (MGIT) or solid (LJ); LPA first line and second line, phenotypic DST **1.3.9.** Purchase laboratory equipment for NRL/CHUs **1.3.10.** Ensure maintenance of lab equipment (NRL and CHUs and P3 TB container laboratory)
1.4. Strengthening Laboratory Quality Management System.	**1.4.1.** Pursue TB laboratory accreditation (TA, ISO15189 accreditation fees) **1.4.2.** Establish connectivity system for prompt transmission of laboratory results and interfaces with existing data bases (software, training for

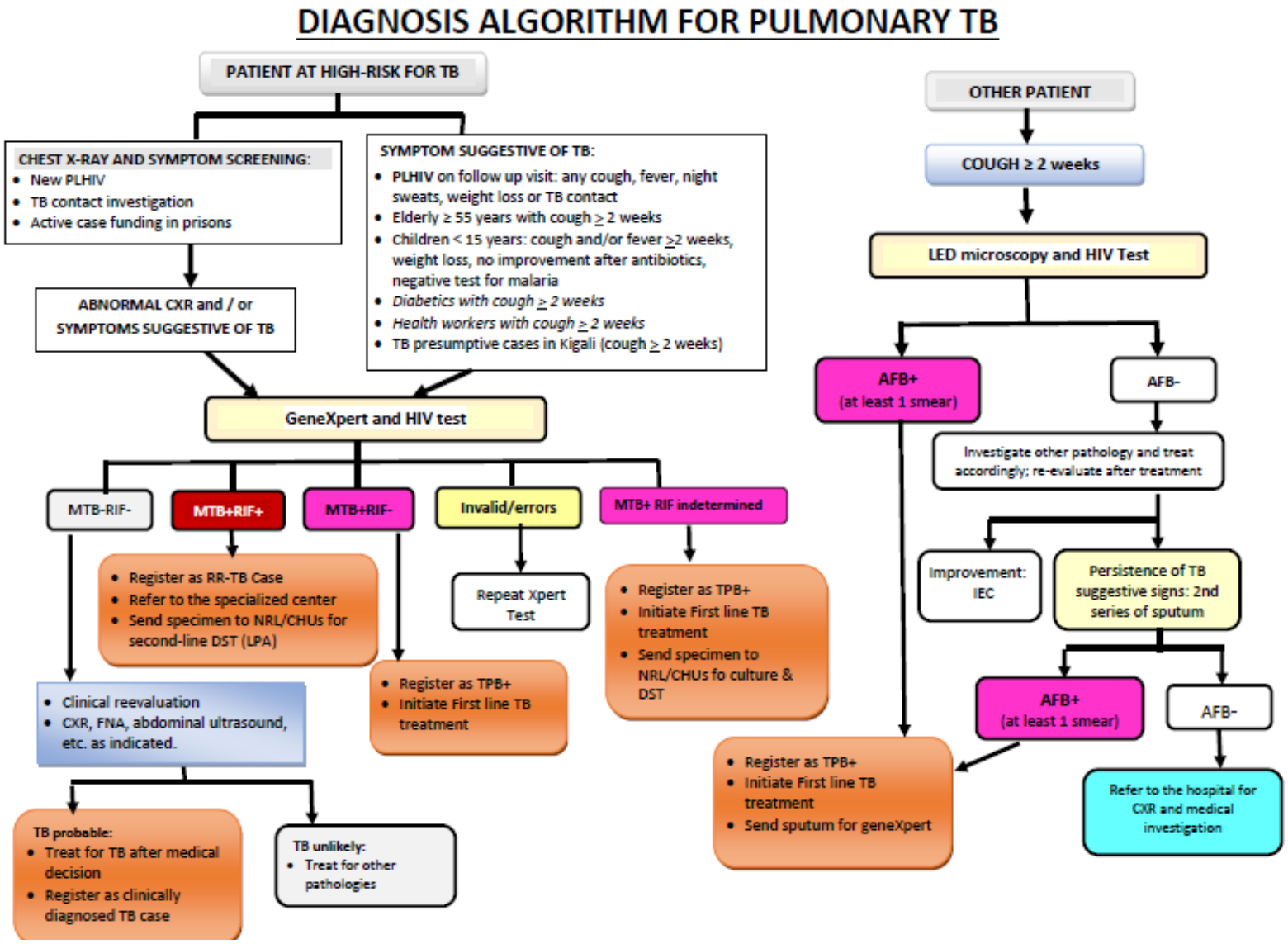
	users (central level and GeneXpert sites) **1.4.3.** Build capacities in the laboratory network (NRL and CHUB staff and on-site training of Xpert and iLED-FM sites). **1.4.4.** Conduct blind rechecking of smear microscopy to all CDTs **1.4.5.** Conduct inter-laboratory comparison of culture, LPA and GeneXpert laboratories **1.4.6.** Implement EQA for Xpert (preparation of panels) **1.4.7.** Print and distribute TB lab Manual and TB lab Handbook **1.4.8.** Implementation of laboratory quality management system **1.4.9.** Establish a proper data management system
1.5. Enhancing use of CXR and other diagnostic techniques for extrapulmonary and bacteriologically negative TB.	**1.5.1.** Strengthen capacities of CXR interpretation (training, purchase of digital CXR machines) and implement a quality control system of digital CXR **1.5.2.** Build capacities of MDs on diagnosis of EP TB (Training on specimen collection procedures, commodities, mentorship to DH by CHUK staff
Objective 2: Provide patient-centered treatment for all forms of TB so that the treatment success rate be maintained at least at 90% for bacteriologically confirmed TB and at least at 87% for drug resistant tuberculosis.	
Strategic interventions	**Activities**
2.1. Ensuring no stock out of first-line and second-line drugs in all CDT	2.1.1. Ensure availability of first-line TB drugs including child-friendly formulations 2.1.2. Ensure quality of TB drugs (QA and air conditioners) 2.1.3. Train DH pharmacists on TB drug management including e-LMIS 2.1.4. Ensure adequate management of TB commodities by MPPD
2.2. Improving treatment success rate for all forms of TB.	2.2.1. Develop/update TB policy/guidelines and tools 2.2.2. Train health providers (MD, nurses, private, etc.) 2.2.3. Conduct routine service quality assessment (RSQA). See 4.6.3. 2.2.4. Conduct specific activities to reduce death rate among TB patients
2.3. Maintaining high treatment success rate for MDR-TB patients.	2.3.1. Purchase second line TB drugs including new TB drugs 2.3.2. Provide financial support to MDR-TB centres (salaries, complementary exams, ancillary drugs, running costs, monthly mentorship to HF with MDR-TB patients on ambulatory phase) 2.3.3. Train health providers on DR-TB management. 2.3.4. Provide support to MDR-TB patients (nutritional support, transportation fees including for monthly audiology controls at provincial hospital, health insurance) 2.3.5. Conduct field visits by CHUs specialist MD to MDR-TB centres to review complicated MDR-TB cases 2.3.6. Conduct monthly supervision/mentorship by MDR-TB Unit to the MDR-TB centres.
2.4. Implementing active drug safety monitoring and management (aDSM)	2.4.1. Develop an implementation plan for aDSM 2.4.2. Adapt standard data collection tools 2.4.3. Train staff for data collection 2.4.4. Define schedules and routes for data collection 2.4.5. Consolidate aDSM electronically 2.4.6. Develop a robust response mechanism 2.4.7. Procure TDM (therapeutic drug monitoring) test for persistent positive cases
2.5. Maintaining ART coverage among co-infected TB-HIV patients	2.5.1. Hold TB-HIV technical working group meetings twice per year. 2.5.2. Update, print and distribute the new TB-HIV policy. 2.5.3. Support mentorship from central level to district hospital to ensure high quality integrated TB/HIV treatment 2.5.4. Provide regular update training for DH mentoring teams with relation to TB management 2.5.5. Support mentorship from District Hospitals level to 518 Health centers to ensure high quality integrated TB/HIV treatment.

	2.5.6. Conduct sensitization and/or supervision once per quarter per cell to reinforce DOT management and TB knowledge at community level.
2.6. Maintaining treatment success rate for patients managed in the community.	2.6.1. Develop/update and distribute TB policy/guidelines and tools 2.6.2. Organize and conduct refresher trainings for CHWs to update them on TB management. 2.6.3. Provide financial support to improve TB program coordination, integration and management (PBF, running costs of CHD and steering committees. 2.6.4. Conduct field visits from health centres to CHWs to improve monitoring of CHW by health care providers (supervisions from HC to CHWs, etc.)
2.7. Providing psycho-social and nutritional support	2.7.1. Develop psychosocial materials for patients (print the form) 2.7.2. Develop a chapter on psychosocial assessment guides for health care workers (to be done in the current revision) 2.7.3. Integrate psychosocial component in the TB training modules 2.7.4. Provide nutritional support to malnourished drug-susceptible TB patients (in objective 5)
Objective 3. Improve TB prevention (TB infection control and prevention by medication) so that LTBI treatment coverage among contacts ≤ 5 years increases from 78 % to 90 % by mid-2021.	
Strategic interventions	**Activities**
3.1. Ensuring implementation of TB infection control measures at Health Facilities and community levels.	3.1.1. Ensure application of the minimum package of infection control; 3.1.2. Conduct annual TB Screening of health providers; 3.1.3. Initiate annual TB screening of CHWs 3.1.4. Advocate for application of IC standards in the design of constructions and renovations of Health Facilities to MoH and others institutions; 3.1.4.1. Train engineers in collaboration with PMDT COE on architectural IC measures 3.1.4.2. Recruit facilitators 3.1.5. Provide PPE to staff highly exposed to TB and ensure proper use. 3.1.6. Sensitize the population on IC measures during the community works by CHWs 3.1.7. Print and distribute posters on IC measures
3.2. Improving LTBI treatment coverage among TB contacts ≤ 5 years of age	3.2.1. Ensure availability of INH 100 mg 3.2.2. Print and distribute register for IPT
3.3. Intensifying communication and social mobilization	3.3.1. Develop, print and distribute ACSM plan and guide 3.3.2. Disseminate messages on TB signs & prevention (radio, IEC materials) 3.3.3. Strengthen partnerships with NGOs/CSOs (guidelines, CHWs training and PBF, partnership with NGOs/CSOs).
Objective 4. Improve managerial capacities of the TB program; enhance the performance of the TB surveillance to achieve concordance between aggregate and case-based systems; and develop research.	
Strategic interventions	**Activities**
4.1 Strengthening routine use of TB individual record (e-TB) at Health Facilities and Central level.	4.1.1 Conduct workshop to customize automated standard report from e-TB system (14 central level staff/ 5 days). 4.1.2 Provide Technical Assistance for automated generation of quarterly reports from e-TB. 4.1.3 Conduct training of decentralized staff on use of automated standard report from e-TB system (21 staff from Central level staff, Provincial data managers, hospital M&E and data manager, health centers data manager and TB focal points). 4.1.4 Conduct Bi annual meetings between M&E staff from central level and Hospitals to reinforce TB data use and ownership at decentralized level. 4.1.5 Procure computers for e-TB system (To be updated based on available

	list of HFs with/without computers).
4.2 Collaborating to the establishment of a national vital registration system (VRS) that includes TB death data	4.2.1 Organize consultative meeting with the national vital registration system to assess its strengths and limitations for providing reliable data on TB deaths. 4.2.2 Organize joint session with national Institute of statistic of Rwanda to analyse TB deaths causes from using available data from national vital registration system..
4.3 Conducting research to inform program strategies.	4.3.1 Define TB&ORD research topics and agenda 4.3.2 Conduct operational research using existing databases (like e-TB, DHS, LIS, HMIS, etc) 4.3.3 Conduct studies for "Long term outcomes of former MDR TB patients who have been successfully treated with second line TB Drugs in Rwanda." and "To assess the prevalence of mutations associated with Rifampicin resistance outside the RRDR and of "disputed" mutations in the rpoB gene." 4.3.4 Conduct bi annual workshops for data analysis with routine data, which can be a basis for further studies. 4.3.5 Strengthen TB&ORD capacities on data analysis/research methods. 4.3.6 Set up a TB&ORD research team to work on identified research topics, including people from different Institutions (define ToRs).
4.4 Strengthening implementation of Practical approach for lung diseases (PAL) at Health Facilities.	4.4.1 Develop data collection and reporting tools for PAL in the HMIS system 4.4.2 Conduct trainings on PAL for District Hospitals and Health Centers by trainers having attended TOT 4.4.3 Develop common activity plans of PAL with other programs for cross cutting diseases. 4.4.4 Conduct assessment activities to map integration, scale up and progress of the PAL strategy.
4.5 Building capacities of human resource .	4.5.1 Provide Salary for Contractual staff 4.5.2 Provide PBF for civil servants' staff 4.5.3 Conduct biannual Rapid Service Quality Assessment in all CDTs. 4.5.4 Participate in international conferences, workshops and trainings. 4.5.5 Provide Technical Assistance to conduct WHO-GLC (Green Light Committee) annual evaluation. 4.5.6 Provide Technical Assistance to conduct End-Term Review of extended TB NSP 2013-2020
4.6 Ensuring program management, planning and evaluation	4.6.1 Conduct TB Quarterly Evaluation Meetings 4.6.2 Develop TB quarterly Narrative Reports 4.6.3 Organize a workshop to develop TB&ORD annual action plan 4.6.4 Conduct workshop to produce TB&ORD annual report 4.6.5 Conduct workshop to update TB M&E tools and SOPs. 4.6.6 Conduct End-Term Review of extended TB NSP 2013-2020. 4.6.7 Conduct TB Epidemiological Review including TB surveillance checklist in partnership with WHO and other partners. 4.6.8 Conduct annual national evaluation meetings with DH 4.6.9 Ensure national policies and strategies for tuberculosis response, and the delivery of tuberculosis care and prevention are clearly elaborated (with clear guidance and SOPs) 4.6.10 Develop a well costed national TB Strategic Plan (workshop)
4.7 Ensuring logistics for TB control activities	4.7.1 Purchase necessary medical and non-medical equipment 4.7.2 Ensure supplies related to medical equipment at central and peripheral level 4.7.3 Ensure logistics related to furniture and equipment including IT, communication 4.7.4 Provide running costs 4.7.5 Renovations (for laboratory, management and care services)

	4.7.6	Purchase one ambulance for MDR TB
	4.7.7	Provide fuel for cars in TB activities
	4.7.8	Ensure the maintenance of cars in TB activities
Objective 5. Strengthen the coordination across MoH divisions and other government ministries as well as the collaboration with communities, civil society, private care providers and local administrations so that zero TB-affected families are facing catastrophic costs due to TB.		
5.1 Sustaining political commitment with adequate resources for tuberculosis care and prevention	5.1.1	Advocate for continued domestic and external financial support
	5.1.2	Setting up collaborative agreements (CoPs and CoAgs) between funding partners.
	5.1.3	Ensure Technical assistance from program partners according to the needs of the program
	5.1.4	Set up mechanisms to ensure efficient and effective management of funds
5.2 Improving collaboration across MoH and other government institutions	5.2.1	Conduct annual meetings between the MoH and other government institutions and partners including create shared indicators and activity plans of progress for the concerned institutions, set up mechanisms of follow up and evaluation for activities agreed
5.3 Strengthening collaboration with communities, CSO and NGOs, private associations and national pharmacy council.	5.3.1	Conduct annual meetings between the TB&ORD and other CSOs, NGOs, private clinic associations, national pharmacy council, and other partners
	5.3.2	Engage formers TB patients as opinion leaders and peer educators for the TB program in the community
	5.3.3	Enable greater involvement of civil society and communities in policy development, planning and implementation
5.4 Enhancing the engagement of private health care providers	5.4.1	Strengthen and expand partnerships with private health providers; Increase number of CDTs in Private health facilities. No specific cost
	5.4.2	Involve private health care providers in program planning and design, service delivery and implementation No specific cost
5.5 Advocacy for Universal health coverage for all TB patients	5.5.1	Assess the proportion of TB patients not covered by health insurance by mapping and hold a consultative meeting between GOR and partners to address that issue. (not specific cost)
	5.5.2	Collaborate in the expansion, development, roll out and use of the vital statistics systems (see 4.2.1 and 4.2.2) (not specific cost)
	5.5.3	Collaborate with MoH/clinical services department to integrate TB in policy on infection control. (not specific cost)
	5.5.4	Advocate for application of IC standards in the design of constructions and renovations of Health Facilities to MoH and others institutions (not specific cost)
	5.5.5	Advocate for public health laws in relation to diseases and the greater benefit to health care workers and society
5.6 Advocacy for the extension of social protection schemes for TB patients	5.6.1	Ensure patient-centred mechanisms and systems for social and psychological support to patients
	5.6.2	Assess the nutritional status of TB patients by mapping and advocate to local authorities, local partners and private people for the expansion of Social protection schemes to cover needs associated with TB (no specific costs)
	5.6.3	Assess the wealth status of TB patients by mapping and advocate to local authorities, local partners and private people for inclusion of TB patients within Poverty reduction programs
	5.6.4	Carry out survey on catastrophic costs due to TB

Annex 4. TB Diagnosis algorithm

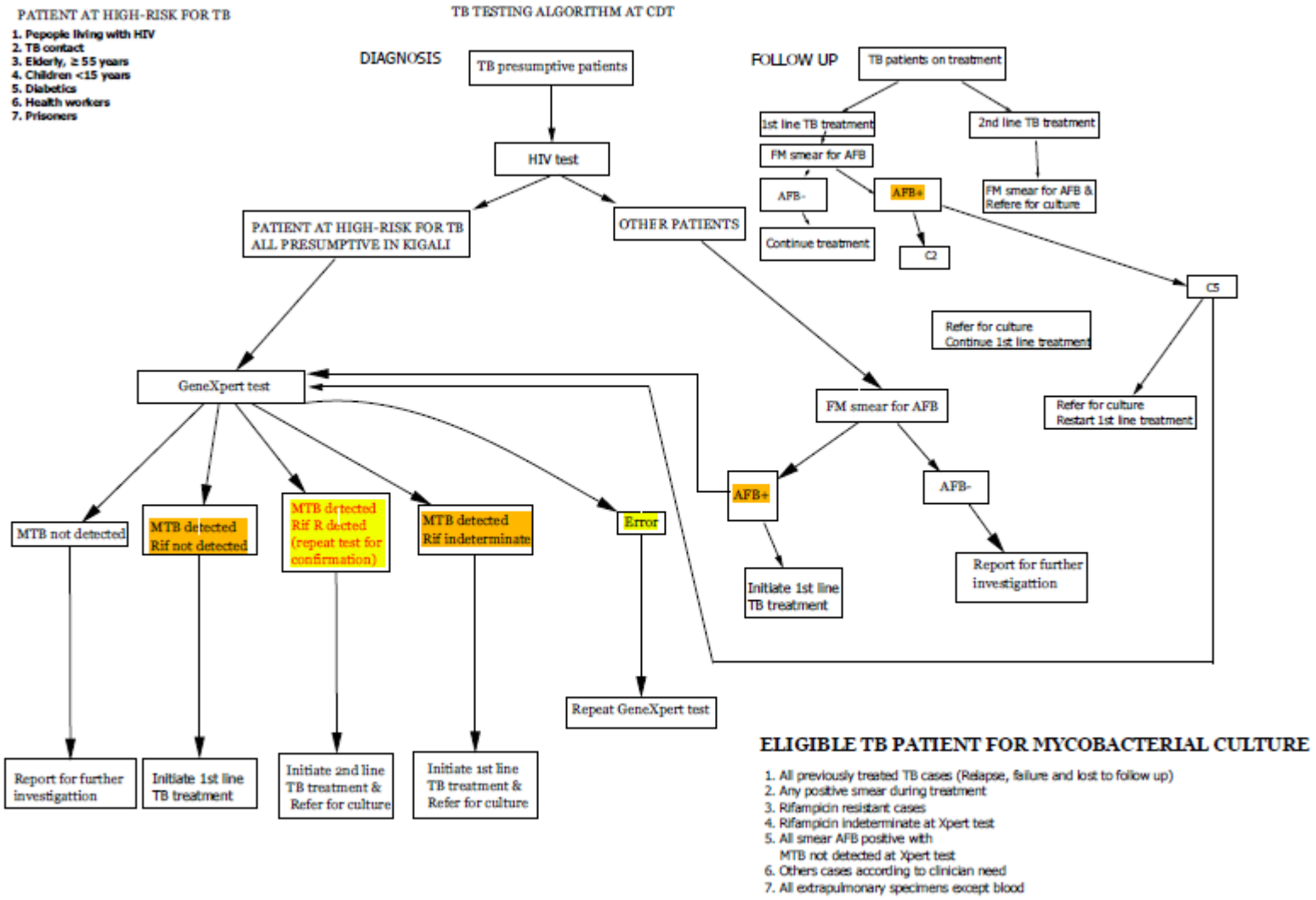


Annex 5. The 2018-2020 TB NSP OPERATIONAL RESEARCH AGENDA

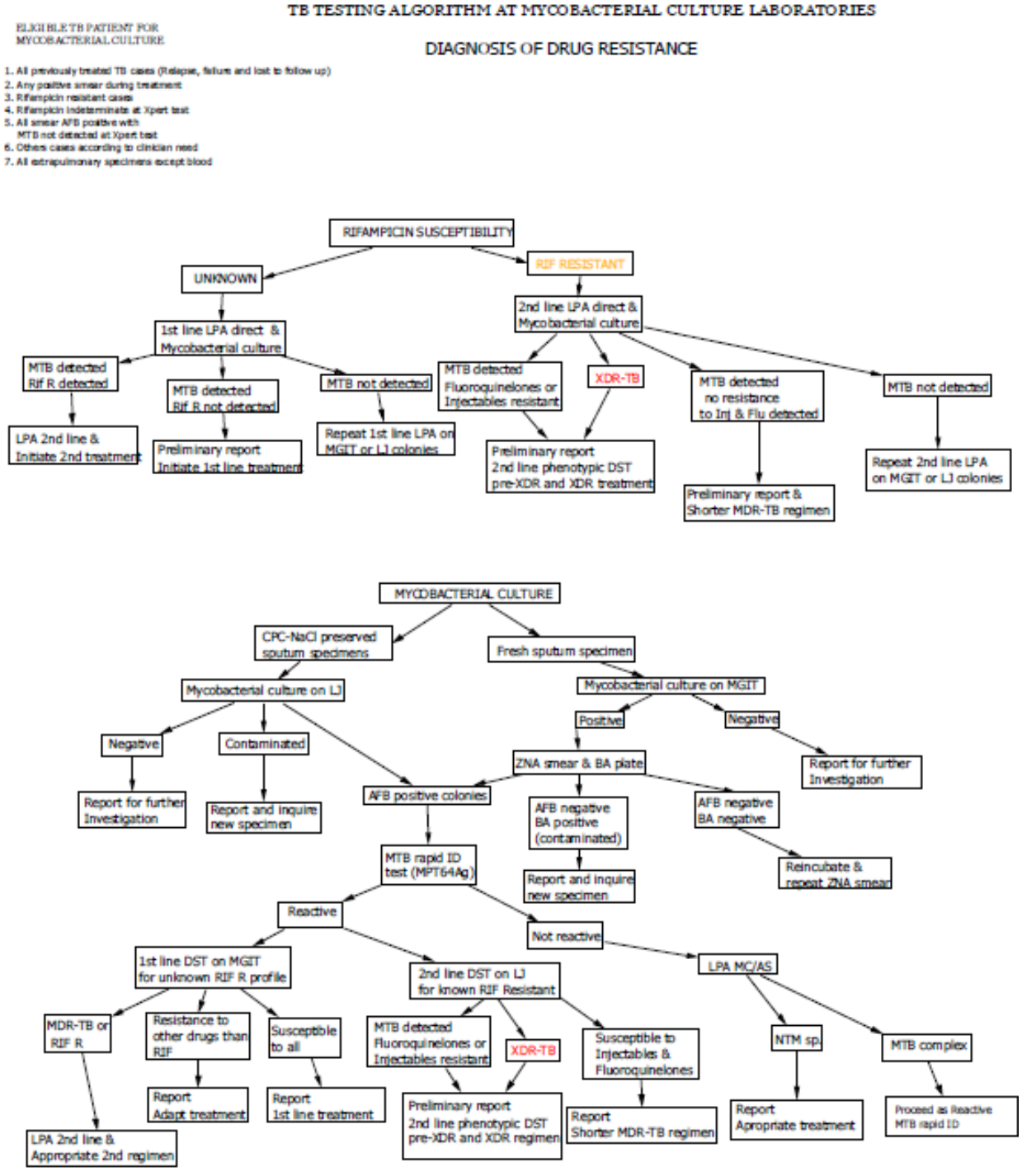
NSP Objective	Title	Rationale	Purpose/Objectives	Proposed methods	Timeline and possible partnership
Objective 1	Prevalence of mutations associated with Rifampicin resistance outside the rifampicin resistance-determining region (RRDR) and of "disputed" mutations in the rpoB gene	TB susceptibility testing tools such as Xpert MTbRif, Hain Line Probe Assay (MTBDRplus) have been successfully implemented in Rwanda and in others countries allowing early detection of rifampicin-/MDR-TB thus early initiation of appropriate regimen; however these are exclusively designed to detect rifampicin resistance associated with mutations inside 81bp rifampicin resistance-determining region (RRDR), and are therefore not designed to detect the rare resistance associated mutations outside the RRDR, such as Val146Phe and Ile572Phe. In addition, other rifampicin resistance associated mutations referred to as "disputed mutations", located within the RRDR, are commonly missed as resistant by the phenotypic DST methods, especially liquid based Bactec MGIT960 testing, unlike the common 'undisputed' mutations that are readily detected as resistant in phenotypic tests. In this study we aim to test whether the clonal expansion of rare mutations- conferring resistance to rifampicin yet not detected by the current rapid molecular tools- explains the persistent prevalence of rifampicin resistance among retreatment patients. The knowledge of the prevalence of such occult resistance would allow us to setup strategies for screening these resistance.	1. To assess the prevalence of mutations associated with rifampicin resistance outside the RRDR and of 'disputed' mutations in the rpoB gene among TB patients with relapse and failure to 1st line Anti-TB regimen. 2. To implement new strategy (algorithm) for screening occult resistance to rifampicin among TB patients with relapse and failure to 1st line Anti-TB regimen	Cross sectional study recruiting TB cases registered as relapse or failure that are rifampicin susceptible with either rapid molecular test (Xpert MTB Rif test and or LPA MTBDRplus) and or phenotypic testing. Entire rpoB gene sequence will be screened for mutations conferring rifampicin resistance (target gene sequencing or Deeplex).	2017-2019, this will be done in collaboration with the Institute of Tropical Medicine, Antwerp Belgium as part of a PhD candidate and the study will be embedded in a larger project "DIAMA", an observational study which aims to improve the diagnosis and management of multidrug resistant patients by validating novel molecular tools and approaches.
Objective 2	Long term outcomes of former MDR-TB patients who have been	In Rwanda, like in many other countries with MDR-TB programs, post-treatment outcomes have never been evaluated and remain uncertain. Better understanding of the outcomes of MDR-TB following successful treatment will help the	1. To determine the prevalence of different clinical symptoms (residual and new), after treatment outcome, chest radiological damages, lung	• A cross-sectional study on all MDR-TB patients who were successfully treated from 2005 to 2010	• 2018-2019 • Possible partners: RBC, CHUs and MDR-

NSP Objective	Title	Rationale	Purpose/Objectives	Proposed methods	Timeline and possible partnership
	successfully treated with second line TB Drugs in Rwanda	Rwandan TB control program to set up comprehensive MDR-TB program that takes into account the management of MDR-TB post-treatment phase, to reduce continued respiratory and radiological symptoms and reoccurrence of TB, as well as improve mental and social well-being. This will enable Rwandan to develop a successful health program for MDR-TB, which addresses both the clinical impact/aspects of the disease and the social impacts.	function patterns and effect of MDR-TB on hearing function, among former MDR-TB patients who successfully completed treatment in Rwanda MDR-TB program. 2. To determine the prevalence of different mental, psychological and social symptoms among former MDR-TB patients successfully completed treatment in Rwanda MDR-TB program.	• Patient interview on current health status (clinical and mental evaluation). • Retrospective review of MDR-TB medical records.	TB centres.
Objective 5	Catastrophic costs due to TB	• Rwanda NTP has no baseline to evaluate this high-level indicator of the End TB strategy • It will help to understand cost barriers for access and adherence to TB services • It will measure impact of Universal Health Coverage (UHC) and social protection specifically on TB	1. Evaluate direct and indirect costs due to TB as a percentage of annual individual income and identify main cost drivers 2. Monitor progress towards zero percent households with catastrophic costs Secondary 3. Subgroup analyses (MDR/DS, socioeconomic position, sex, urban/rural, etc) 4. Determine the association between cost and treatment outcome (using routine cohort data)	• WHO protocol • Facility-based survey: consecutive patients on TB treatment • National random sample (500-1000 patients, min. 20 clusters) • Cross sectional study with retrospective data collection and projections • Costs : $30,000 - $100,000	2018-2019 all survey time: 5-6 months Survey frequency: once every 5 years Possible partners: RBC/UR SPH/WHO/ KNCV

Annex 6 TB testing at CDTs



Annex 7. TB testing at culture laboratories



Annex 8. Laboratory situational analysis for improved diagnosis strengthening across the TB network and ensuring Laboratory accreditation.

Table 1 : Following a situational analysis below, various elements of human resource were identified with respective activities indicators and timelines/target identified

Improve NTRL capacity to carryout TB diagnosis across the laboratory network			
Situational Analysis Topic	**Activity**	**Indicators**	**Target**
NTRL Human resource structure	- Finalise the HR organogram for NTRL	-Organogram finalized	By end of March 2017
	- Lobby for approval for the new HR organogram for NTRL	-Organogram approved	By end of June 2017
	-Lobby Govt to take up more HR support for NTRL,	New staff recruited	By end of 2017
	Train laboratory personnel in biosafety measures and practices	Proportion of TB lab personnel trained in biosafety measures and practices	80% of TB personnel trained in biosafety practices
	Appoint quality officer Appoint safety officer Provide competence and job descriptions	quality officer and safety officer Identified competence and job descriptions Provided	quality officer and safety officer Identified competence and job descriptions Provided

Table 2: NTRL training plan for 2017 to 2020

Area of training	Type of training	Tearget group	Period	Responsible	remarks
iLED microscopy training	Regional	All microscopy sites	Jan to July	NTRL	
Basic Genexpert training	National	All genexpert sites		NTRL	
Training on liquid and solid culture assay	National	CHUB and CHUK		NTRL	Sites already trained
EQA blinded rechecking of intermediate labs	Regional	CHUB and CHUK		NTRL	
Advanced Genexpert Super user training	international	NTRL and IMT		Cepheid-Karoga	
Training on use of sequencer	international	NRL PI and one technical staff		DIAMA project	
Continuous Quality improvement process (root cause analysis, quality indicators)	National				
TB specimen referral training of couriers	National	Courier for buses and motor bikes		NTRL	

Training on PT panel preparation for GeneXpert	International	NTRL		SRL	
Internal audit training	international	NTRL		SRL	

Table 3: Situational analysis of activities and indicators to be monitored for laboratory network to ensure universal DST coverage for all bacteriologically confirmed TB patients

Improve TB diagnosis across the laboratory network and ensure universal DST coverage for all bacteriologically confirmed TB patients.			
Situational Analysis Topic	**Activity**	**Indicators**	**Target**
The TB-specific contextual analysis	-Develop a training plan for all new diagnostics and capacity building culture labs of CHUB and NTRL	-Training Plan developed including all WRDs	By December 2017
	Approval of the training plan and sharing with various stakeholders	Approved training plan with proportion of trainings having established budget line	80% of the training have budget line by 2018
	Implementation of the training plan	Proportion of trainings implemented	80% of the proposed trainings implemented by 2019
	-Provide PTs for interlaboratory comparison	-Number of rounds PTs are provided for WRD	One PT panel for xpert LPA and for culture
	- NTRL to hold culture network coordination meetings to guide quality of culture results	-Number of culture network meetings	Twice per year
	- NTRL to regularly monitor performance of all xpert, LPA machines, and MGIT/LJ culture tests	-Proportion of Xpert , LPA and culture centres with supervision reports at NTRL quarterly	80%
Structure of the Tb laboratory network	-Ensure new personnel especially in districts are trained in TB diagnostics	-Proportion of new personnel trained in TB diagnostics	All appropriate new personnel are trained in TB diagnostics
	-Define and document the roles of labs at various level in the network	-Working document defining roles of various levels of the network especially national, regional, provinces and districts produced	By end of 2017
	Review the xpert functional backup system at all xpert sites	Number of Xpert sites with functional backup system	95% of all GeneXpert sites have functional back up by end of 2018
Improve microscopy diagnostics and network	Finalize switching from ZN to iLED microscope for FM and training	Number of sites switched from ZN to iLED microscope for FM	100% of microscopy sites switched to iLED microscopy by June 2017
	Strengthen the use of iLED microscopy through onsite	Proportion of sites receiving onsite training on	100% of sites with major error in EQA blinded

	training	iLED microscopes	rechecking
	-Procure maintenace and spares for iLED microscopes)	Service contract and spares procured	By end of 2018
Laboratory quality management systems	-sustain coverage of blinded rechecking among all microscopy sites	Proportion of TB diagnostic sites with at least 3 EQA reports with no major errors at NRL and intermediate labs annually	95% of all diagnostic sites with at least 3 EQA reports at NRL annually
	-Send timely feedback reports, explore using courier mechanism	Proportion of diagnostic sites receiving EQA feedback reports	95% of all Diagnostic sites received feedback reports timely
	-Strengthen support supervision and mentorship	Proportion of TB diagnostic sites receiving supportive supervision/mentorship at least once a year	95% of all diagnostic sites receive supportive supervision at least once annually
	- Strengthen the EQA data acquisition and analysis by having a dedicated personnel to oversee the EQA implementation	appoint a dedicated personnel to oversee the EQA implementation	Dedicated personnel for EQA in place by end of 2018
Management of laboratory commodities and supplies	- Advocate the GF to provide an adequate budget for supplied and commodities	Number of stock out for microscopy supplies and commodities annually	No stock outs for microscopy supplies and commodities
	- Install a toll free line at NRL to improve communication between NRL and other laboratories	A toll free line installed at NRL and used for communicate to diagnostic sites	Toll free line installed by end of 2019 to improve communication between distribution sites, and NRL
	- Ensure the TB lab network needs are incorporated in the electronic LIS of Laboratory services	All TB lab work data needs are catered for in the electronic LIS of Laboratory services	The electronic LIS of Laboratory services is adequate for the TB lab network
	-appoint a data manager at NRL to assist in national data acquisition, aggregation and analysis.	Data manager appointed at NRL	Data manager appointed by 2019
Sample referral systems	Explore the use of courier buses to be involved in Tb Specimen Referral System (TSRS)	Number of courier companies identified	By end of 2019
	Evaluate data on the usefulness of courier buses in improving access to TB diagnostic services	Data on usefulness of courier buses available	By end of 2019
	Establish and approve MOUs with identified Courier bus company	Number of courier bus companies with approved MOU	By end of 2020

Legal and policy review	- Revision of TB lab network manual completed and distributed	Revised EQA manual distributed	By end of 2020

Table 4 Situational analysis of data connectivity solutions activities and indicators to be monitored

Improve Laboratory information and data management systems with diagnostics connectivity solutions			
Situational Analysis Topic	**Activity**	**Indicators**	**Target**
The TB-specific contextual analysis	-Develop a plan for expansion of data connectivity platform	-expansion Plan developed	By June 2017
	Finalization of the platform integration with all WRD test menue as well as iLED microscopy	Proportion of WRD uploaded on the connectivity platform	100% of WRD including iLED microscopy uploaded on the platform
	-assess the number of sites with WRDs that are ready for data connectivity	-proportion of WRD sites with necessary set up for data connectivity	90% of WRD sites with necessary set up for data connectivity by 2018
	- installation and onsite training on data connectivity solution	-proportion of WRDs sites with data connectivity	80% of WRDs sites with data connectivity by 2018
	- Procure adequate IT equipment to facilitate national data acquisition, storage, aggregation and analysis.	Adequate IT equipment procured to meet ISO 15189 requirements	By end of 2018
	- training of other stakeholders including clinicians on data connectivity operation data utilization	-Proportion of WRD centres with trained personnel on operation	80% of WRD sites with trained personnel
Structure of the Tb laboratory network	-Ensure new personnel especially in districts are trained in TB diagnostics connectivity	-Proportion of new personnel trained in TB diagnostics	All appropriate new personnel are trained in TB diagnostics
	-review the data utilization using the data connectivity solution	-proportion of data obtained by use of data connectivity solution	By end of June 2018
Laboratory quality management systems on information and data management	Reviewing the data collected from xpert sites	Proportion of TB diagnostic data received on quarterly basis	Quarterly review meetings to evaluate data accuracy
	-Strengthen support supervision and mentorship	Proportion of WRD sites receiving supportive supervision at least once a year	95% of all WRD sites receive supportive supervision at least once annually
	- Ensure the TB lab network needs are incorporated in the electronic LIS of Laboratory services	All TB lab work data needs are catered for in the electronic LIS of Laboratory services	The electronic LIS of Laboratory services is adequate for the TB lab network

Legal and policy review	- Revision of data connectivity solution guides completed and distributed	Revised data connectivity solution manual distributed	By end of 2020

Table: 5: Situational analysis with activities for NTRL quality management System towards accreditation

Quality assurance and quality control of laboratory technical procedures			
Situational Analysis Topic	**Activity**	**Indicators**	**Target**
	-Develop an integrated plan for blinded rechecking, interlaboratory comparison and PTs for microscopy, culture DST, Genexpert/LPA respectively to include, schedule, resources, location etc.	-intergrated plan developed	By December 2017
	Liase with equipment maintenance division to define the iLED microscope service	-Number of iLED microscopes serviced per schedule	90%
	- NTRL should hold stake holder coordination meetings to guide QC/QA and PTs for xpert, LPA, culture and microsocpy	-Number of meetings on QC/QA and PTs	Meet twice a year
	- NTRL should regularly monitor performance of all microscopes, genexpert and LPA	-Proportion of microscopy centres with supervision reports at NTRL quarterly	90%
	To establish the equipment service schedule and approve	Proportin of equipment serviced as per schedule	90% of equipment serviced per schedule
	Human resource development and capacity building for GeneXpert maintenence	Number of personnel trained on xpert maintenence as superusers	4 personnel trained

	Procurement of service and spare parts for GenXpert, LPA and iLED microscopy		

Table 6. Situational analysis of NTRL Laboratory Quality Management System (LQMS) activities and indicators to be monitored towards accreditation

Strengthen the implementation of quality management system at NTRL towards Accreditation			
Situational Analysis Topic	**Activity**	**Indicators**	**Target**
The NTRL -specific contextual analysis	Using ISO15189:2012 SANAS checklist to conduct baseline assessment developing an action plan for quality improvements followed by implementation of the recommendations	an action plan for quality improvements developed Proportion of the recommendations implemented	By October 2017
	Establish an NTRL organogram with key positions, level of authority and reporting mechanism	Number of key positions captured in the organogram	November 2017
	Sharing of the NTRL Organogram with NTP and NRL management and approval	Proportion of key positions approved on the organogram	October 2017
	Appoint quality officer Appoint safety officer Provide competence and job descriptions	quality officer and safety officer Identified competence and job descriptions Provided	quality officer and safety officer Identified competence and job descriptions Provided
	Revising of the current Quality manual, safety manual and clinician's handbook from NRL to capture NTRL specific activities	-Number of quality documents developed and authorized	100% of the NTRL specific quality documents developed by march 2018
	Harmonization and aligning of policies/Sops according to the ISO15189:2012 standard	-Proportion of policies/Sops harmonized according to the ISO15189:2012 standard	100%
Technical assistance and follow up of identified QIPs	Review the QM, BSM, clinician's handbook and SOPs for NTRL	-Proportion of reviewed quality documents e.g QM, BSM, clinician's	All appropriate new documents e.g QM, BSM, clinician's handbook and SOPs for

		handbook and SOPs for NTRL per visit	NTRL reviewed and authorized/approved by august 2018
	To develop competence checklist and provide technical competence	Proportion of technical personnel with competence	100% of technical personnel have up to date competence By end of 2017
LQMS main activities for compliance to ISO15189 :2012	Contact regional TB focal persons and respective laboratories on dissemination of clinician's handbook	Number of units with updated disseminated clinician's handbook	95% of the facilities have disseminated clinician's handbook by December 2018
	Training in internal audit using the ISO15189:2012	The number of personnel trained and competent in internal audit	Quality officer safety officer and one technical personnel trained by December 2018
	Conduct internal audits Perform root cause analysis	The proportion of audit findings with root causes done and appropriate corrective action taken	All audit findings have root causes done and appropriate corrective action taken
	Develop risk assessment tool and conduct the assessment from pre analytical, analytical to post analytical	Proportion of preventive actions generated monitored for effectiveness	All preventive actions monitored for their effectiveness by 2018
	Engage laboratory management inclusive of the director to hold management review with adopted agenda from the ISO15189:2012, develop actions and quality year plan	Number of management meetings conducted per year	At least one meeting conducted per year
Participation in proficiency testing	To identify PT scheme providers	Proportion of TB lab tests with a PT scheme	100% of all test with PT scheme by end of end of 2018
	To develop a PT scheme including all tests in the lab	- Proportion of TB lab tests with a PT scheme	100% of all test with PT scheme by end of May 2017
	To review the PT scheme	-reviewed and up to date PT scheme available	By end of end of 2018
	- To review the PT performance across all tests	Proportion of tests with acceptable PT performance	100% of all test with acceptable PT performance end of

			2018
Technical assistance and follow up of identified QIPs	Review the progress on identified QIPs from audits	Proportion of QIPs completed	95% of all QIPs addressed by 2018
Application for Accreditation	To identify the source of funding for accreditation To apply to SANAS for accreditation of all tests in the laboratory	Number of tests to be enrolled for accreditation	All tests enrolled for accreditation by june 2019
Pre accreditation visit	To conduct a mock assessment prior to SANAS visit	Proportion of nonconformities identified Quality improvement projects identified	All the nonconformities addressed by june 2019
	-mentorship and technical assistance	Number of completed nonconformities identified	All the nonconformities addressed by august 2019
NTRL accreditation	Carryout assessment by SANAS for ISO15189:2012 compliance	Proportion of major and minor nonconformities	Addressing all non-conformities Attain accreditation By end of February 2020

Table: 7: The work plan and road map of NTRL quality management System towards accreditation

Objective	Activity	responsible	Time frame
To conduct a baseline assessment	Using ISO15189:2012 SANAS checklist to conduct baseline assessment developing an action plan for quality improvements followed by implementation of the recommendations	SRL	May 2017
To develop an Organogram in compliance to ISO15189:2012	Establish an NTRL organogram with key positions, level of authority and reporting mechanism	NTRL	August 2017
	Sharing with NTP and NRL management and approval of the Organogram	NRL, NTP	September 2017
To identify key positions for LQMS implementation	Appoint quality officer Appoint safety officer Provide competence and job descriptions	NRL and NTRL	December 2017
To develop a TB quality manual, TB safety manual and clinician's handbook for TB lab tests	Revising of the current Quality manual, safety manual and clinician's handbook from NRL to capture NTRL specific activities	NTRL and SRL Uganda	October 2017
To harmonize all the policies/SOPs for NTRL with the ISO15189:2012 requirements	Harmonization and aligning of policies/Sops according to the ISO15189:2012 standard	NTRL	September 2017
Select and monitor quality indicators	Monitor the selected quality indicators on monthly basis		

Technical assistance and follow up of identified QIPs	Review the QM, BSM, clinician's handbook and SOPs for NTRL	ECSA/SRL	August 2018
To provide technical competence	To develop competence checklist and provide technical competence	SRL	August 2018
Dissemination of clinicians handbook for laboratory users	Contact regional TB focal persons and respective laboratories on dissemination of clinician's handbook	NTRL/NTP	December 2018
Conduct management review	Engage laboratory management inclusive of the director to hold management review with adopted agenda from the ISO15189:2012, develop actions and quality year plan	NTRL and NRL	December 2018
To train personnel in internal audit process	Training in internal audit using the ISO15189:2012	NRL	March 2018
To evaluate PT scheme	To develop a PT scheme including all tests in the lab To review the PT scheme To review the PT performance across all tests	NTRL	June 2017
Conduct risk assessment and internal audits	Develop risk assessment tool and conduct the assessment from pre analytical, analytical to post analytical Conduct internal audits Perform root cause analysis	NTRL	June 2018
Technical assistance and follow up of identified QIPs	Review and support the progress on identified QIPs from audits	ECSA/SRL	November 2018
Application for TB lab Accreditation	To apply to SANAS for accreditation of all tests in the laboratory	NTRL	January 2019
Pre accreditation visit	To conduct a mock assessment prior to SANAS visit	ECSA/SRL	September 2019
SANAS Assessment of NTRL	Carryout assessment by SANAS for ISO15189:2012 compliance	SANAS	December 2019
Clearance of identified Non conformities	NTRL to analyze the nonconformities and perform respective root cause analysis for clearence of NCs		February 2020