National Tuberculosis Programme

Strategic Plan: 2017-2021

THINK TANK

“We can't fight AIDS unless we do much more to fight TB as well.”

Nelson Mandela, July 2004

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Acronyms and Abbreviations

3HP	high-dose rifapentine plus high-dose isoniazid given weekly for 3 months
AIDS	acquired immunodeficiency syndrome
AMDS	AIDS Medicines and Diagnostics Services
ART	antiretroviral therapy/treatment
BCAP	Bedaquiline Clinical Access Programme
BIG	Bridge Implementation Gap
BMGF	Bill & Melinda Gates Foundation
CDW	Corporate Data Warehouse
CHAI	Clinton Health Access Initiative
CPT	co-trimoxazole preventive therapy
CSD	consultant systems developer
DCS	Department of Correctional Services
DHIS	District Health Information System
DHMT	District Health Management Team
DIP	District Implementation Plan
DOTS	directly observed treatment, short course
DR-TB	drug-resistant tuberculosis
DS-TB	drug-susceptible tuberculosis
EDR	Electronic Drug-Resistant TB Register
EML	Essential Medicines List
ETR	Electronic TB Register (drug-sensitive cases)
HAST	HIV/AIDS, STIs and TB
HCW	healthcare worker
HPRN	Health Patient Registration Number
ICF	intensified case-finding
ID	identification (number)
IHME	Institute for Health Metrics and Evaluation
ILTF	initial loss to follow-up

INH	isoniazid
IPT	isoniazid preventive therapy
KAP	knowledge, attitudes and practices
LIS	laboratory information system
LPA	line probe assay
M&E	monitoring and evaluation
MCC	Medicines Control Council
MCH	maternal and child health
MDG	Millennium Development Goals
MDR-TB	multidrug-resistant tuberculosis
NDoH	National Department of Health
NGO	nongovernmental organization
NHLS	National Health Laboratory Services
NICD	National Institute for Communicable Diseases
NSP	National Strategic Plan
NTP	National Tuberculosis Programme
PDoH	Provincial Department of Health
PHC	primary health clinic
PLWHIV	people living with human immunodeficiency virus
PMTCT	prevention of mother-to-child transmission (of HIV)
PZA	pyrazinamide
QI	quality improvement
RR- / RIF-R	rifampicin-resistant
SDG	Strategic Development Goal
SMS	short message service
SOP	standard operating procedure
TB	tuberculosis
WBOT	Ward-based outreach team
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

Acknowledgements

The South Africa National Department of Health (NDoH) National Tuberculosis Programme (NTP) is grounded in the principles and processes outlined in World Health Organization (WHO) Global Tuberculosis Report 2016[1] and the Stop TB Partnership, UNOPS – Paradigm Shift 2016-2020.[2] As such, this report has relied liberally on text and figures from those documents. The format of this report was informed by the WHO Toolkit to Develop a National Strategic Plan for TB Prevention, Care and Control.[3]

TB Think Tank

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Contributors to the meetings are shown in **Appendix 4.**

Foreword

To be written for the Minister

Executive Summary

South Africa has made considerable gains in its control of TB. The South African government has implemented many of the key elements of a successful TB control programme including significant resource allocation, a strong policy environment, rapid technology introduction, valuable research outputs, and bold political support. The country's government is heavily invested in its TB programme, demonstrated by its allocation of one of the highest proportions of domestic funding in developing countries.

As a result, South Africa is heading towards an 85% treatment success rate for drug-sensitive TB. The country is a leader in scaling up Xpert MTB/RIF as the first test for TB, implementing preventive therapy for people living with HIV, and using new drugs to treat drug-resistant TB.

However, TB still poses a significant threat to health in South Africa. South Africa ranks sixth and second among 30 high-burden TB countries in terms of absolute number of cases and number of cases per 100 000 population respectively, and is also one of the countries with the highest burden of HIV/TB co-infection and multi-drug resistant TB[1]. South Africa's drug-resistant TB situation is exacerbated by a large burden of extensively drug resistant TB.

Impediments to achieving success in South Africa's fight against TB have resulted from issues related to decentralisation, programme coordination and partnerships, clinical case management and outcomes, laboratory services and support, drugs management and rational use, data management, community support systems and patient perspectives of care. While a wealth of expertise and data exist to inform TB programme decision-making in South Africa, these resources have often been underutilized in terms of anticipating and responding to the needs of policy makers for quantitative analysis and improvements in TB control policy and implementation. There is a need for a more focused and more collaborative approach going forward.

The process of drafting the new National Tuberculosis Programme (NTP) Strategic Plan (2017-2021) offered an important opportunity to ensure that innovative approaches and evidence-based practices are identified and used to tackle specific challenges. Interventions for the NTP Strategic Plan were identified and discussed in a series of workshops and meetings that included input from key stakeholders representing government, programme staff, the academic/scientific community, advocacy groups, and civil society. The feedback reflected a wide spectrum of concerns and experiences, including the impact of TB, the degree to which TB is a social and political priority, the scientific and social challenges of working with TB, the progress that has been made in halting the spread and impact of TB, and some of the challenges in finding, treating and preventing TB.

Resulting from this process are seven strategic, evidence-based interventions; five of these are grounded in the Find-Treat-Prevent framework and two reflect cross-cutting issues. The following table introduces these seven interventions and describes key outcome indicators and targets.

NTP Strategic Plan: Interventions, Indicators and Targets

	Baseline 2016	Target 2021
NTP Interventions		
Facility-based TB screening		
Proportion of People living with HIV (PLWHIV) in care screened for TB	40%	>95%
Proportion of adult clinic attendees screened for chronic cough	40%	>90%
Active TB case-finding among select key populations		
Proportion of household contacts screened for TB	unknown	>90%
Proportion of informal settlements screened for TB	unknown	>90%
Scale up short-course MDR-TB treatment		
Proportion of eligible patients with rifampicin-resistant or MDR-TB treated with short-course MDR-TB regimen	unknown	>90%
Proportion of rifampicin-resistant or MDR-TB patients treated with the short-course MDR-TB regimen that successfully complete treatment	unknown	>70%
Reduce initial loss to follow up for DS-TB and DR-TB Patients		
Proportion of patients with confirmed DS-TB and DR-TB not started on treatment within 1 month of result	30%	<5%
Scale up 3HP for all household contacts and PLWHIV		
Proportion of household contacts >2 years of age started on 3HP	unknown	>90%
Proportion of eligible PLWHIV on ART started on 3HP	unknown	>90%
Cross-cutting Interventions		
Establish TB information system to improve patient management & health service delivery		
Proportion of patients with a unique identifier recorded in data systems	unknown	100%
Proportion of provinces with an integrated TB information system	unknown	>90%
Scale up QI to support successful implementation of NTP interventions		
Proportion of facilities implementing QI programme	unknown	>90%

Implementation strategies will vary with each specific intervention. During the 2017-2021 National Strategic Plan timeframe, it is likely that a number of new diagnostics for TB disease and infection will emerge, and that new TB drugs and regimens for DS-TB and DR-TB disease and infection will need to be scaled up. These new tools will be implemented either as new interventions or incorporated into the existing interventions.

The NDoH is committed to supporting the South African provinces and other partners to improve TB control, and has carefully considered the most strategic, cost-effective, easily scalable, and locally contextualized solutions to achieve progress towards the End TB goals over the next five years.

1 Background

1.1 Purpose

The World Health Organization (WHO) End TB Strategy aims to move the current global trend of a 2% reduction per year in new cases of tuberculosis (TB), to ending the global TB epidemic by 2035. This document presents the South Africa National Department of Health (NDoH) National Tuberculosis Programme (NTP) strategy for the next five years (2017-2021), with emphasis on implementation of interventions with evidence-based potential for population-level impact on TB incidence and mortality. These interventions are in addition to routine ongoing activities in South Africa to end the TB epidemic. South Africa is using a "Find-Treat-Prevent" approach to address the TB epidemic and it is anticipated that these additional interventions will be targeted to their specific settings.

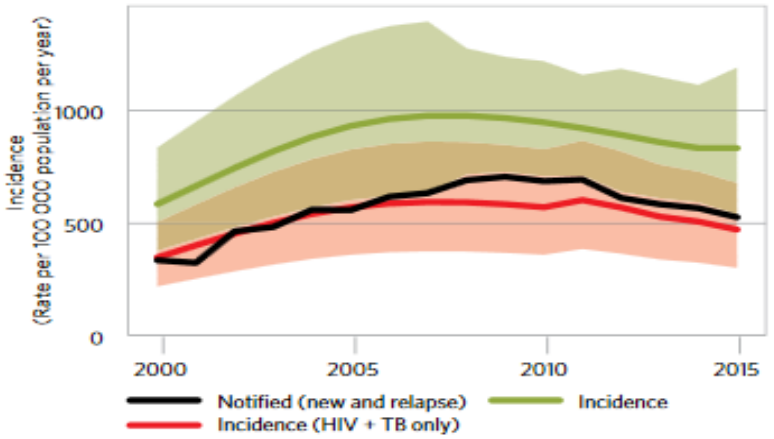
The purpose of South Africa's NTP Strategic Plan (2017-2021) is as follows:

- Note recent progress in TB control and prevention
- Highlight the WHO's End TB Strategy and Global Plan to End TB 2016-2020
- Describe evidence-based biomedical interventions that must be scaled up to meet the NTP targets of reducing TB deaths and incidence by 43% and 26% respectively by 2021 (relative to 2015), in keeping with the WHO End TB targets and Strategic Development Goals

1.2 Tuberculosis in South Africa

TB poses a significant threat to health in South Africa. With an estimated incidence of 834 cases per 100 000 population, South Africa ranks sixth among 30 high-burden TB countries in terms of absolute number of cases and highest in TB incidence . It is also one of the countries with the highest burden of human immunodeficiency virus (HIV)/TB co-infection and multi-drug resistant (MDR-)TB[1]. In 2015, 57% of new and relapse TB patients with known HIV status were HIV-positive, and an estimated and an estimated 2.1% and 4.6% of new and retreatment cases respectively were infected with MDR-TB[4]. South Africa's drug-resistant (DR) TB situation is exacerbated by a large burden of extensively drug resistant (XDR-)TB , low treatment success and high rates of loss to follow-up[1].

Figure 1: Estimated TB Incidence Rates in South Africa (2000–2015)[1]

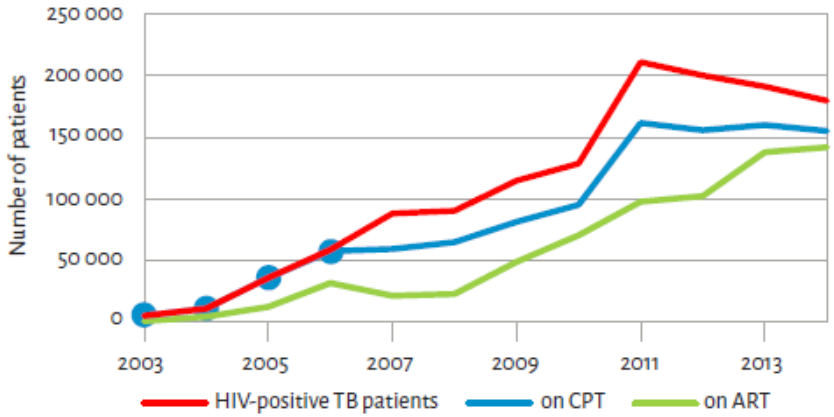


Shaded areas represent uncertainty bands.

1.3 Progress made and remaining challenges

South Africa has made considerable gains in its control of TB. The South African government has many of the key elements of a successful TB control programme in place, including significant resource allocation, rapid technology introduction, valuable research outputs, a strong policy environment and bold political support. South Africa has invested substantially in its TB programme, demonstrated by its allocation of one of the highest proportions of domestic funding in developing countries. As a result, South Africa is heading towards an 85% treatment success rate for drug-sensitive (DS-) TB. The country is a leader in scaling up Xpert MTB/RIF as the first test for TB, implementing preventive therapy for people living with HIV (**Figure 2**) – South Africa is the country in which the highest proportion of people living with HIV (PLWHIV) are receiving TB preventive treatment[1]– and using new drugs to treat DR-TB.

Figure 2: HIV-Positive TB Patients on CPT or ART in South Africa (2003-2014)[5]



CPT= Co-trimoxazole preventive therapy; ART= Antiretroviral therapy

Although South Africa has seen a laudable decline in TB notifications which has also been reflected in reduced WHO TB incidence estimates (**Figure 1**), it is insufficient to meet the 2030 Sustainable Development Goals (SDG) and 2035 End TB targets[6,7] Challenges in meeting these targets have resulted from issues related to decentralisation, programme coordination and partnerships, clinical case management and outcomes, laboratory services and support, drugs management and rational use, data management, community support systems and patient perspectives of care. While a wealth of expertise and data exist to inform TB programme decision-making in South Africa, these resources have often been underutilized in terms of anticipating and responding to the needs of policy makers for quantitative analysis and improvements in TB control policy and implementation. There is a need for a more focused and more collaborative approach going forward.

1.4 WHO's End TB Strategy and Global Plan to End TB 2016-2020: strategies and targets

According to the Global Plan to End TB – The Paradigm Shift,[2] there is vast potential to improve the scope and quality of current TB interventions. More than a third of individuals who develop TB disease each year are not properly diagnosed or treated, and among those who are treated, nearly 15% do not have a successful outcome. Further, close to half a million individuals develop drug-resistant disease annually, and more than 80% of these do not receive appropriate treatment. Consequently, the possibility of a cure is not available to approximately half of all individuals with TB disease[2].

The WHO's End TB Strategy outlines four barriers to realizing success in the fight against TB[2]:

1) Weak health systems, including those with large, unregulated non-state sectors
2) Underlying determinants of TB such as poverty, undernutrition, migration and aging populations; and risk factors such as diabetes, silicosis and smoking
3) Lack of effective tools
4) Continuous unmet funding needs

Illustrated in **Figure 3**, the End TB Strategy, endeavouring to address these barriers and end the TB epidemic, is centred around four principles and three pillars of action, and integrates health and social interventions[2]. This inclusive approach should contribute considerably to hastening the end of the epidemic, but in order for these efforts to be fully successful, new tools will also be required including point-of-care diagnostics; shorter and more effective treatment regimens; and an effective vaccine[2].

Priority indicators and targets for the End TB Strategy[2] are outlined in **Table 1**.

Table 1: Global Priority Indicators and Targets for Monitoring Implementation of WHO End TB Strategy

INDICATOR	TARGET
Treatment coverage Number of people that developed TB, and were notified and treated, out of the total estimated number of incident cases in the same year	≥90%
TB treatment success rate Number of TB patients who were successfully treated out of all notified TB cases	≥90%
Preventive treatment coverage Number of people living with HIV and children who are contacts of cases who were started on preventive treatment for latent TB infection, out of all those eligible	≥90%
TB affected households facing catastrophic costs Number of TB patients and their households that experienced catastrophic costs due to TB, out of all TB patients	0%
Uptake of new diagnostics and new drugs Number of TB patients who were diagnosed using WHO-recommended rapid tests, out of all TB patients Number of TB patients who were treated with regimens including new TB drugs, out of those eligible for treatment with such drugs	≥90% ≥90%

Figure 3: The WHO End TB Strategy: At A Glance[8]

VISION	A world free of TB: zero deaths, disease and suffering due to tuberculosis			
GOAL	End the global TB epidemic			
INDICATORS	**MILESTONES**		**TARGETS**	
	2020	2025	**2030***	**2035**
Reduction in number of TB deaths compared with 2015	35%	75%	**90%**	**95%**
Reduction in TB incidence rate compared with 2015	20% (<85/100 000)	50% (<55/100 000)	**80%** (<20/100 000)	**90%** (<10/100 000)
TB-affected families facing catastrophic costs due to TB (%)	0	0	**0**	**0**
PRINCIPLES	1. Government stewardship and accountability, with monitoring and evaluation 2. Strong coalition with civil society organizations and communities 3. Protection and promotion of human rights, ethics and equity 4. Adaptation of the strategy and targets at country level, with global collaboration			

PILLARS and COMPONENTS		
1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION A. Early diagnosis of TB, including universal drug-susceptibility testing and systematic screening of contacts and high-risk groups B. Treatment of all people with TB, including drug-resistant TB, and patient support C. Collaborative TB/HIV activities, and management of co-morbidities D. Preventive treatment of persons at high risk, and vaccination against TB	**2. BOLD POLICIES AND SUPPORTIVE SYSTEMS** A. Political commitment with adequate resources for TB care and prevention B. Engagement of communities, civil society organizations, and public and private care providers C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control D. Social protection, poverty alleviation and actions on other determinants of TB	**3. INTENSIFIED RESEARCH AND INNOVATION** A. Discovery, development and rapid uptake of new tools, interventions and strategies B. Research to optimize implementation and impact, and promote innovations

*Targets for the United Nations Sustainable Development Goals Source: Implementing the WHO End TB Strategy: The Essentials

The Global Plan to End TB 2016–2020 (the "Global Plan") is the implementation plan for the End TB Strategy's first five years[2]. The Global Plan introduces three people-centred targets called the 90-(90)-90 targets[2]**:**

- Reach at least 90% of all people who need TB treatment and place all of them on appropriate therapy — first-line, second-line and preventive therapy, as required
- As a part of this approach, reach at least including (90)% of people in key populations (see **Table 2**), and
- Achieve at least 90% treatment success for all people diagnosed with TB through affordable treatment services, adherence to complete and correct treatment, and social support.

Table 2: Key Populations for TB

People who have **INCREASED EXPOSURE** to TB **due to where they live or work**	Prisoners, sex workers, miners, hospital visitors, healthcare workers and community health workers
	PEOPLE WHO: ▪ Live in urban slums ▪ Live in poorly ventilated or dusty conditions ▪ Are contacts of TB patients, including children ▪ Work in environments that are overcrowded ▪ Work in hospitals or are healthcare professionals
People who have **LIMITED ACCESS TO QUALITY TB SERVICES**	Migrant workers, women in settings with gender disparity, children, refugees or internally displaced people, illegal miners, and undocumented migrants
	PEOPLE WHO: ▪ Are from tribal populations or indigenous groups ▪ Are homeless ▪ Live in hard-to-reach areas ▪ Live in homes for the elderly ▪ Have mental or physical disabilities ▪ Face legal barriers to access care ▪ Are lesbian, gay, bisexual or transgender
People at **INCREASED RISK** of TB because of **biological or behavioural factors** that compromise immune function	PEOPLE WHO: ▪ Live with HIV ▪ Have diabetes or silicosis ▪ Undergo immunosuppressive therapy ▪ Are undernourished ▪ Use tobacco ▪ Suffer from alcohol-use disorders ▪ Inject drugs

Source: Stop TB Partnership, Global Plan to End TB – Paradigm Shift, 2015, Table 3.1

1.5 Development process for 2017-2021 NTP Strategic Plan

The process of drafting the new NTP Strategic Plan (2017-2021) acknowledged the need for a more focused and more collaborative

approach going forward. It offered an important opportunity to ensure that innovative approaches and evidence-based practices are identified and used to tackle specific challenges. The South African government established the TB Think Tank in 2014 with financial support from the Bill and Melinda Gates Foundation (BMGF), which brought together government leaders, policymakers, academics, researchers, non-governmental organizations (NGO) and funders to identify primary gaps in the management of TB in South Africa. The TB Think Tank has played a major role in laying the foundation for recommending interventions for the NTP Strategic Plan. The TB Think Tank reviewed the evidence for and used mathematical impact and economic modelling to help inform TB policy (see **Appendix C**).

Interventions for the NTP Strategic Plan were identified and discussed in a series of workshops and meetings, starting with a NTP Strategic Plan kick-off workshop in April 2016, that included input from key stakeholders representing government, programme staff, the academic/scientific community, advocacy groups, and civil society from all over the country. The feedback reflected a wide spectrum of concerns and experiences, including the impact of TB, the degree to which TB is a social and political priority, the scientific and social challenges of working with TB, the progress that has been made in halting the spread and impact of TB, and some of the challenges in finding, treating and preventing TB. Themes that have emerged from this exercise are the need to strengthen strategies for case-finding, contract tracing, treatment adherence, TB prevention, MDR treatment and linkage to care.

Figure 4: Attendees at kick-off strategic plan workshop

A 2nd TB Think Tank meeting in July 2016 identified and prioritized the interventions for the NTP. The participants agreed to use the WHO End TB Strategy Framework for the NTP Strategic Plan and developed seven strategic interventions. Corresponding working groups met during the following month to determine the goals and impact of each proposed intervention, summarize the background and justification of the intervention, review the evidence and modelled impact, and identify outputs, indicators and activities.

The NDoH is committed financially to improving TB control, and has carefully considered the most strategic, cost-effective, easily scalable, and locally contextualized solutions to achieve progress towards End TB goals over the next five years. The strategy proposes five interventions plus two cross-cutting interventions which are leveraged for optimal national level impact.

2 Strategic Interventions

2.1 Overview of interventions

The main goals of the NTP Strategic Plan, and the five interventions under the Find-Treat-Prevent framework plus the two cross-cutting interventions, are summarized in **Table 3**. Key outcome indicators, milestones and targets are described for each intervention.

Table 3. NTP Strategic Plan 2017-2021: Goal, Interventions and Indicators

	Baseline	Milestones				Target
GOAL	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
To reduce estimated TB incidence and mortality (vs 2015)						
Estimated reduction in TB deaths (HIV-uninfected)*	7%	14%	21%	28%	35%	43%
Estimated reduction in TB deaths (HIV-infected)*	7%	14%	21%	28%	35%	43%
Estimated reduction in TB incidence*	4%	8%	12%	16%	20%	26%
NTP Interventions						
Facility-based TB screening						
Proportion of PLHIV in care screened for TB	40%	60%	80%	80%	90%	>95%
Proportion of clinic attendees screened for chronic cough	40%	50%	60%	70%	80%	>90%
Active TB case-finding among select key populations						
Proportion of household contacts screened for TB	unknown	18%	36%	54%	72%	>90%
Proportion of informal settlements where screening campaigns for TB have taken place	unknown	18%	36%	54%	72%	>90%
Scale up short-course MDR-TB treatment						
Proportion of eligible patients with rifampicin-resistant or MDR-TB treated with the short-course MDR-TB regimen	unknown	18%	36%	54%	72%	>90%
Proportion of rifampicin-resistant or MDR-TB patients treated with the short-course MDR-TB regimen that successfully complete treatment	unknown	14%	28%	42%	56%	>70%
Reduce initial loss to follow-up for DS-TB and DR-TB patients						
Proportion of patients with confirmed DS-TB and DR-TB not started on treatment within 1 month of test result being available	unknown	25%	20%	15%	10%	<5%
Scale up 3HP for all household contacts and PLWHIV						
Proportion of household contacts >2 years of age started on 3HP	unknown	18%	36%	54%	72%	>90%
Proportion of eligible PLWHIV on ART started on 3HP	unknown	18%	36%	54%	72%	>90%
Cross-cutting Interventions		**2017**	**2018**	**2019**	**2020**	**2021**
Establish an integrated, real-time TB information system to facilitate improved patient management and health service delivery						
Proportion of patients with a unique identifier recorded in data systems	<5%	20%	45%	70%	85%	100%
Proportion of provinces with an integrated and functional TB information system	~10%	18%	35%	65%	>90%	>90%
Scale up quality improvement to support successful implementation of NTP interventions						
Proportion of facilities implementing the QI programme to support NTP interventions	unknown	18%	36%	54%	72%	>90%

*Estimated reduction in TB mortality and incidence based on End TB milestones and targets

2.2 FIND: Increased facility-level TB screening

Intervention 1: Target facility-level screening or intensified case-finding (ICF)

OUTPUT 1: Increased annual number of adult clinic attendees who are screened for TB

ACTIVITIES:

- Offer screening to all new adult clinic attendees
- Offer TB screening to returning patients in all areas of the clinic
- Conduct TB information sessions in the waiting areas

OUTPUT 2: Increased annual number of symptomatic individuals who are tested for TB

ACTIVITIES:

- Train clinic staff on TB screening and sputum collection procedures
- Record all those with TB symptoms in the presumptive TB register
- Refer all those with TB symptoms for sputum collection
- Ensure that sputum samples are stored appropriately until collected

OUTPUT 3: Increased national utilisation of Xpert as the first-line diagnostic tool for TB cases

ACTIVITIES:

- Train clinic staff on Xpert
- Train clinic staff on National Health Laboratory Service (NHLS) requisition procedures

OUTPUT 4: Improved adherence to the Xpert-negative algorithm in HIV-positive patients

ACTIVITIES:

- Offer provider-initiated HIV counselling and testing to all those

Goal: Reduce TB incidence and mortality by improving TB case-finding

Anticipated outcomes:

1) An increase from 40% to 90% in the proportion of adult clinic attendees screened for presence of a chronic cough (lasting longer than 2 weeks)
2) An increase from 40% to >95% in the proportion of HIV-positive clinic attendees screened for presence of any cough
3) An increase from 80% to >95% in the proportion of all persons who present with symptoms suggestive of TB who are tested for TB
4) An increase from 14% to 90% in the proportion of HIV-positive persons who present with symptoms suggestive of TB with an initial negative Xpert test who are tested again using culture

Justification

TB detection remains a major public health problem in South Africa. Although approximately 300,000 new TB cases have been identified annually for the last three years, and TB notifications and incidence are estimated to be declining, TB case detection rates (estimated at 68%) are still below the WHO Global targets (≥70% case detection rate). Achieving the aims of the Global Plan to End TB (to identify and place on treatment 90% of all people with TB) will require new interventions to find and diagnose TB cases.

Goal: Reduce TB incidence and mortality by improving TB case-finding

Anticipated outcomes:

5) An increase from 40% to 90% in the proportion of adult clinic attendees screened for presence of a chronic cough (lasting longer than 2 weeks)
6) An increase from 40% to >95% in the proportion of HIV-positive clinic attendees screened for presence of any cough
7) An increase from 80% to >95% in the proportion of all persons who present with symptoms suggestive of TB who are tested for TB

8) An increase from 14% to 90% in the proportion of HIV-positive persons who present with symptoms suggestive of TB with an initial negative Xpert test who are tested again using culture

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TB detection remains a major public health problem in South Africa. Although approximately 300,000 new TB cases have been identified annually for the last three years, and TB notifications and incidence are estimated to be declining, TB case detection rates (estimated at 68%) are still below the WHO Global targets (≥70% case detection rate). Achieving the aims of the Global Plan to End TB (to identify and place on treatment 90% of all people with TB) will require new interventions to find and diagnose TB cases.

Table 4: Intervention 1: Target Facility-Level Screening Implementation, Monitoring and Evaluation of Outputs and Activities

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 1: **Increased annual number of adult clinic attendees who are screened for TB**	Facilities Districts	% adult primary health clinic (PHC) headcount screened for TB	Requires a consistent method for recording, must be accessible to all staff, tool must be easy to complete (i.e. No duplication of patient demographic information)
ACTIVITIES			
TB symptom screening of all new adult clinic attendees	Facilities	% adult PHC headcount offered/approached for TB screening	Ensure that all areas of the clinic are covered and consider a private space for confidentiality. Ensure that relevant recording tool is used to document screening.
TB symptom screening of returning patients in all areas of the clinic	Facilities		Ensure that relevant recording tool is used to document screening.
TB symptom screening of all new adult clinic attendees	Facilities	% adult PHC headcount offered/approached for TB screening	Ensure that all areas of the clinic are covered and consider a private space for confidentiality. Ensure that relevant recording tool is used to document screening.
OUTPUT 2: **Increased annual number of symptomatic individuals who are tested for TB**		% presumptive TB cases who have a laboratory TB result	
ACTIVITIES			
Train clinic staff on TB screening and sputum collection procedures	NDOH, Provincial Department of Health (PDOH)	% districts who have conducted TB screening workshops	This could be done as district-level workshops or as in-service training by HIV/AIDS, STIs and TB (HAST) managers. Workshops must cover completion of relevant recording tools.
Record all those with TB symptoms in the presumptive TB register	Facilities Districts	% presumptive TB cases entered into the presumptive TB register	
Refer all those with TB symptoms for sputum collection	Facilities Districts	% presumptive TB cases who have sputum collected	
Ensure that sputum samples are stored appropriately until collected	Facilities Districts	% sputum samples taken with result from NHLS	Any logistics or supply issues would be carefully monitored

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 3: **Increased national utilisation of Xpert as the first-line diagnostic tool for TB cases**	Districts, PDOH	% of presumptive TB cases who are tested using Xpert	
ACTIVITIES			
Train clinic managers and relevant NHLS staff on the TB conditional grant to highlight appropriate use of GeneXpert	NDOH, PDOH	% districts who have conducted TB screening workshops (same workshop as in Output 3)	This could be done as district-level workshops or as in-service training by HAST managers. Workshops must cover completion of relevant recording tools.
Train clinic staff on appropriate NHLS requisition procedures	As above	As above	As above
OUTPUT 4: **Improved adherence to the Xpert-negative algorithm in HIV-positive patients**	Facilities Districts	% HIV+ presumptive TB cases with initial negative Xpert result who receive a TB culture result	
ACTIVITIES			
Offer provider-initiated HIV counselling and testing to all those with TB symptoms		% of presumptive TB cases with HIV- or unknown HIV status referred for TB screening	
Train clinic staff on the TB screening and diagnostic algorithm	NDOH, PDOH	% districts who have conducted TB screening workshops (same workshop as in Output 2)	This could be done as district-level workshops or as in-service training by HAST managers. Workshops must cover completion of relevant recording tools

2.3 FIND: Improve active case-finding in special populations

Goal: Improve TB case-finding among special populations, including household contacts of patients with TB, residents of informal settlements, inmates in correctional facilities and health care workers (HCWs).

Outcome: Increased identification of undiagnosed cases of TB among special populations

Justification

The large difference between notification rates and the reported incidence of TB suggests that many TB cases are being missed. Infectious patients are often undiagnosed in our communities and this hinders efforts to control TB. Household contacts, individuals living in informal settlements, inmates in correctional facilities and HCWs are among the groups that been identified as contributing considerably to the overall TB epidemic in South Africa (**Table 5**; unpublished data).

Table 5 Risk Groups and Contribution to the Epidemic

	Size of Risk Group							
Risk Groups	**Risk Group (% of Population)**	**Size of Risk Group (Absolute Number)**	**Prevalence of TB (/100 000)***	**Relative Risk of TB ****	**% of Population Accepting Screening*****	**NNS †**	**Number of Cases (2014)‡**	**Overall Contribution to TB Epidemic#**
General population	100%	54 000 000[9,10]	696[11]	1.0	60%	144	450 360	100%
HCWs	0.4%	231 111[12]	1470[13]	2.1	85%	68	2618	1%
Prisoners	0.3%	162 000[14]	2482[15,16]	3.6	100%	40	8800	2.0%
Informal settlements	6.1%	3 306 697[9,17]	2703[18]	3.6	60%	37	162 689	36%
Household contacts	1.7%	1261 800****	3500[19]	5.0	95%	28	63 090	14%

Key: Shaded cells denote estimates that have been extrapolated from data:

*Information from a literature review

**Relative risk of TB calculated as:

$$RR = \frac{TB\ prevalence\ in\ risk\ group}{TB\ prevalence\ in\ general\ population}$$

*** % of population accepting screening calculated from a summation of the reported number of participants recruited and screened in selected studies

$$\%\ accepting\ screening = \frac{\Sigma(Number\ screened)}{\Sigma(Number\ recruited)} * 100$$

*** estimated at about 3 per TB case notified

$NNS = \frac{1}{TB\ prevalence\ in\ risk\ group}$ † Number to be screened to find one case calculated from the prevalence

‡ Number of TB cases reported calculated from the absolute population and the incidence of TB per 100 000

$$Number\ of\ cases = \frac{Total\ population\ of\ risk\ group}{Reported\ incidence\ from\ literature} * 100\ 000$$

#Overall contribution to TB epidemic calculated by the proportion of TB cases in each risk group over the cases in the general population

$$Overall\ contribution = \frac{Number\ of\ cases\ reported\ in\ risk\ group}{Total\ number\ of\ cases\ reported\ in\ general\ population} * 100$$

Intervention 2: Improve active case-finding in special populations

OUTPUT 1: Increased household contact tracing

ACTIVITIES:

Year 1: Pilot processes to determine model for implementation

- Define two sets of processes for household contact tracing
- For each set of processes, set target and define indicators
- Implement and compare the processes in two high-burden provinces

Year 2: Implementation of contact tracing

- Define intervention with national standard operating procedures (SOPs) and guidelines
- Staggered implementation across districts
- Implement monitoring and evaluation

OUTPUT 2: Continued screening in informal settlements

ACTIVITIES:

- Implement community screening
- Perform formal assessment to understand the yield of TB and maximise efficiency

OUTPUT 3: Continued screening in correctional facilities

ACTIVITIES:

- Continue activities at correctional facilities
- Improve contact tracing in cells when TB case identified
- Improve communication with district system for tracing back to homes
- Consider evaluation to determine:
  - Frequency of testing
  - Value of CXR screening, compared to symptom screening
  - Need for culture as well as Xpert testing

OUTPUT 4: Implement screening for HCWs

ACTIVITIES:

- Finalize policy for TB and HIV screening in HCWs
- Evaluate processes to encourage screening and tests needed to identify TB, evaluate the use of screening and treatment for latent TB infection (LTBI)
- Implement programme for HCW TB screening, including all cadres of HCWs

Table 6: Intervention 2: Improve Active Case-Finding in Special Populations
Implementation, Monitoring and Evaluation of Outputs and Activities

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 1: **Increased Household Contact Tracing**	NDoH	Contacts screened for TB per year	Assume 10% reach of contacts Assume by Year 5 – 300 000 TB cases, 2.8 contacts per case, and +- 90% reached by Year 5
ACTIVITIES			
Year 1: Pilot processes to determine model for implementation	NDoH/ Partners	Completed pilot of two interventions in two districts in high-burden provinces	Ring-fencing funds for this activity is required. Issues to be measured include: Algorithm for screening; use of outreach workers or separate teams; yield of TB cases; cost of interventions; effect on case finding in the districts
Define two sets of processes for household contact tracing	NDoH/ Partners	Defined interventions for pilot	
For each set of processes, set target and define indicators	NdoH/ Partners	Defined targets and indicators	
Implement and compare the processes in two high-burden provinces	NdoH/ Partners	Report with comparison on indicators of metrics and implementation	Aim for completion end of Year 1 Report on ease of implementation Redefine metrics and processes
Year 2: Implementation of contact tracing	NdoH/ Partners	Total contacts screened, #TB cases identified, #children <5 years started on PT, #contacts tested for HIV, #TB treatment started	Increase intervention to additional districts in a staggered fashion until national coverage is reached
Define intervention with national SOPs and guidelines	NdoH/ Partners	National SOPs and guidelines	Consider special groups e.g. children, TB deaths etc.; ensure integration with other community services; consider preventive therapy for contacts
Staggered implementation across districts	NdoH	National implementation plan	Aim to cover all districts by Year 5
OUTPUT 2: Continued screening in informal settlements	NdoH/ Partners	Residents screened per year	Total population 3.3 million, 90% reach by Year 5
Implement monitoring and evaluation	NdoH	National SOPs and guidelines for monitoring and evaluation (M&E)	Consider indicators, and ensure system alignment for ease of quarterly reporting

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
ACTIVITIES			
Implement community screening	NDoH/ Partners	# residents screened, # TB cases identified, # TB cases started on treatment	Ensure improved TB education around infection control in informal settlements
Perform formal assessment to understand the yield of TB and maximise efficiency	NDoH/ Partners	Evaluation completed	Aim to complete by Year 1, consider use of TB culture, identify areas of efficiency
OUTPUT 3:Continued screening in correctional facilities	NdoH/DCS		
ACTIVITIES			
Continue activities at correctional facilities	DCS/NDoH	% of inmates screened at different time points: entry, exit and six-monthly (in line with DCS indicators)	
Improve contact tracing in cells when TB cases are identified	DCS/NDoH	# inmates screened as contacts for TB index cases; # TB cases started on treatment	
Improve communication with district system for tracing back to homes	DCS/NDoH	District DCS co-ordination: reporting to district DOH system (electronic TB register, ETR)	
Consider Evaluation to determine: ▪ Frequency of testing ▪ Value of CXR screening ▪ Need for culture as well as Xpert testing	DCS/ Partners	Evaluations completed	
OUTPUT 4: Implement screening for HCWs	NDoH/ Partners	HCWs screened per year	
ACTIVITIES			
Finalize policy for TB and HIV screening in HCWs	NDoH	Finalised policy	
Evaluate processes to encourage screening and tests needed to identify TB, evaluate the use of screening and treatment for LTBI	NDoH/ Partners	Evaluation completed	Aim to complete evaluation in Year 1.
Implement programme for HCW TB screening, including all cadres of HCWs	NDoH/ Partners	# HCWs screened for TB, # HCWs tested for HIV, # HCWs on PT, # TB cases treated	Include TB education for HCWs, screening and consider preventive therapy.

2.4 TREAT: Scale up appropriate short-course treatments for DR-TB

Goal: Decrease morbidity and mortality associated with DR-TB

Outcomes:

1) Decreased rate of loss to the program to less than 5%, failure to less than 3% and death to less than 10% for MDR and rifampicin-resistant (RIF-R)-TB
2) Increased rate of successful treatment, including cure and treatment completion to 70% for MDR-TB and RIF-R-TB

Justification

We anticipate improved DR-TB treatment outcomes. The required length of therapy and the toxicity of certain agents may impede completion of the longer DR-TB treatment regimen. The high proportion of adverse events contributes to the rate of patients being lost to the program. While the shorter regimen still contains an injectable agent with all the associated complications, the duration of administration has been shortened to four months with an option for thrice weekly administration in the last month, provided smear conversion has occurred. It is hoped that these differences will decrease the proportion of patients lost to the program. A second and also important justification for the introduction of the shorter course is the reduction in cost. Programmatic use of this shorter regimen is feasible in South Africa and it has a lowered cost (<US$1000 in drug costs/patient).

Intervention 3: Scale up appropriate short-course treatments for MDR-TB

OUTPUT 1: Steering Committee established for introduction of the 9-month regimen (see Appendix B)

ACTIVITIES:

- Appoint committee members and secretariat
- Schedule and organize quarterly meetings
- Teleconferences every two weeks (bi-monthly)
- Ad hoc meetings as needed

OUTPUT 2: Revised regulatory documents for MDR-TB management

ACTIVITIES:

- Revise MDR-TB policy documents in South Africa
- Revise treatment guidelines
- Link the new MDR guidelines to the Essential Medicines List (EML) process
- Revise the diagnostic algorithms for second line testing

OUTPUT 3: Upgraded laboratory diagnostic services (for second-line line probe assay (LPA))

ACTIVITIES:

- Ensure proficiency in laboratories selected for testing
- Develop laboratory costing and finalized tariff
- Load test method and standard comments on laboratory information system (LIS)
- Load consumables on Oracle
- Procure reagents for testing
- Train initiation sites and labs receiving on-test requisition
- Review implementation every 6 months

Intervention 3: Scale up appropriate short-course treatments for MDR-TB (Continued)

OUTPUT 4: Improved supply chain management established

ACTIVITIES:

- Meet with key stakeholders from AIDS Medicines and Diagnostics Services (AMDS) (including EML), NTP as required
- Review initial anticipated demand shifts and impact on current contract commitment
- Analyse provincial stock situation
- Determine the mechanism for clofazimine registration and supply
- Distribute stock to provincial depots

OUTPUT 5: Trained and mentored staff available to deliver new regimen

ACTIVITIES:

- Convert new guidelines into training materials for all cadres of staff
- Conduct training per province and then re-enforce at a site level
- Conduct regular clinical audits including chart reviews to ensure adherence to guidelines

OUTPUT 6: Electronic Drug Resistance register (EDR) adapted to accommodate new regimens

ACTIVITIES:

- Re-define how outcomes are measured, based on the treatment guidelines
- Change categorization and expand drugs to be entered
- Update data capture and clinical training to ensure adequate capture of outcome

OUTPUT 7: Short-course treatment of DR-TB implemented

ACTIVITIES:

- Implement real-time monitoring of appropriate patient selection for short-course via EDR
- Monitor outcomes: death and loss to follow up
- Assess culture conversion at four months

OUTPUT 8: Implementation of bedaquiline short course

ACTIVITIES:

- Develop operational research protocol for the modified bedaquiline short course
- Selection of initial sites for bedaquiline short course
- Implement operational research protocol for the modified bedaquiline short course

Table 7: Intervention 3: Scale Up Appropriate Short-Course Treatments for MDR-TB
Implementation, Monitoring and Evaluation of Outputs and Activities

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 1: Steering Committee established for introduction of the 9-month regimen (see Appendix B)			
ACTIVITIES			
Appoint committee members and secretariat	NDoH	Formal confirmation of acceptance of membership to Director DRTB by email	Potential members need to be approached and then confirmation of acceptance of committee membership to Director DRTB by email. Dedicated staff will be needed to ensure the administration of the committee.
Schedule and organize quarterly meetings	NDoH	# quarterly meetings convened	
Teleconferences every two weeks (bi-monthly)	NDoH	# bi-monthly teleconferences convened	
OUTPUT 2: Revised regulatory documents for MDR-TB management			
ACTIVITIES			
Revise MDR-TB policy documents in South Africa	NDoH, Partners	Completed MDR-TB policy documents	
Revise treatment guidelines	NDoH, Partners	Revised guidelines reviewed and accepted	
Link the new MDR guidelines to the EML process	NDoH / Clinton Health Access Initiative (CHAI)	Completed link	EML meeting minutes
Revise diagnostic algorithms for second-line testing	NDoH, NHLS	Second-line diagnostic algorithm complete	
OUTPUT 3: Upgraded laboratory diagnostic services (for second line LPA)			
ACTIVITIES			
Ensure proficiency in laboratories selected for testing	NDoH/ NHLS	# laboratories selected	Selected laboratory proficiency reviews

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
Develop laboratory costing and finalized tariff	National Institute for Communicable Diseases (NICD), CHAI	Laboratory costing AND laboratory tariff list	
Load test method and standard comments on LIS	NHLS, NICD	Test loaded on LIS (Yes/No) AND standard comments loaded on LIS (Yes/No)	
Load consumables on Oracle	NHLS NICD	% of required consumables loaded on Oracle	
Procure reagents for testing	NHLS NICD	% of required consumables procured	
Train initiation sites and labs receiving on-test requisition	NHLS NICD	% of initiation sites trained	Training records and attendance registers
Review implementation every 6 months	NHLS NICD	Diagnostic algorithm adherence review	
OUTPUT 4: Improved supply chain management established			
ACTIVITIES			
Meet with key stakeholders from AMD (including EML), NTP as required	NDoH, key stake-holders	Number of meetings with implementation stakeholders convened	Minutes of meetings taken
Review initial anticipated demand shifts and impact on current contract commitment	NDoH, key stake-holders	Anticipated demand shift review	
Analyse provincial stock situation	NDoH, PDOH	% provinces reporting current stock volumes	
Determine the mechanism for clofazimine registration and supply	NDoH, PDOH	Decision on clofazimine registration	
Distribute stock to provincial depots	NDoH, PDOH	Required volume in stock at provincial depot	Provincial depot stock report

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 5: Trained and mentored staff available to deliver new regimen			
ACTIVITIES			
Convert new guidelines into training materials for all cadres of staff	NDoH and key stake-holders	% training materials for all cadres of staff developed	
Conduct training per province and then re-enforce at a site level	NDoH and key stake-holders	% provincial trainings conducted AND % of site level trainings conducted	Training records (provincial and site records)
Conduct regular clinical audits including chart reviews to ensure adherence to guidelines	NDoH and key stake-holders	# clinical audits conducted AND number of follow-ups/interventions required based on clinical audit findings (if appropriate)	Quarterly reports from the clinical auditor to be submitted to the National Steering Committee
OUTPUT 6: EDR adapted to accommodate new regimens			
ACTIVITIES			
Re-define how outcomes are measured, based on the treatment guidelines	NDoH, RIMES, Wamtech	EDR outcomes aligned with new treatment guidelines criteria	
Change categorization and expand drugs to be entered	NDoH, RIMES, Wamtech	EDR drug names and categories/groups aligned with new treatment guidelines criteria	
Update data capture and clinical training to ensure adequate capture of outcome	NDoH, RIMES, Wamtech	Data capturers provided with updated EDR training	
OUTPUT 7: Short course treatment of DR-TB implemented			
ACTIVITIES			
Implement real-time monitoring of appropriate patient selection for short-course via EDR	NDoH	% patients selected for initiation on short course regimen	Patient records, EDR
Monitor outcomes: death and loss to follow-up	NDoH	Recorded outcomes death or loss to follow up	Patient records, EDR
Assess culture conversion at four months	NDoH	Number of patients who have culture conversion at four months	Patient records, EDR, LIS

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 8: Implementation of bedaquiline short course			
ACTIVITIES			
Develop operational research protocol for the modified bedaquiline short course	NDoH and partners	Protocol developed	
Selection of initial sites for bedaquiline short course	NDoH	% sites selected	
Implement operational research protocol for the modified bedaquiline short course	NDoH and partners	Implement operational research protocol;	

2.5 TREAT: Reduce initial loss to follow-up (ILTF) for DS-TB and DR-TB cases

Goal: Reduce TB incidence and mortality
Outcome: Reduced ILTF rate (% bacteriologically confirmed DS-TB and DR-TB cases not commencing treatment within 1 month of a result being available reduced by 90% in 2021 relative to 2015 rates)

Justification
ILTF contributes to ongoing TB transmission as well as individual morbidity and mortality. Published studies suggest that ILTF is a significant global and national problem. A systematic review of 23 studies undertaken in the pre-Xpert era reported ILTF rates ranging between 4% and 38%, with weighted values from studies in Africa of 18% and in Asia of 13%.(1) The pooled estimate of ILTF from fifteen South African studies using smear/culture or decentralised Xpert was 19.4% (95% CI 14.4 – 24.3)(2). Among DR-TB cases, a large nationally representative study reported ILTF rates of 37% (95% CI 35-39%) (3).

Several factors have been found to contribute to ILTF, including, diagnostic delay (4)(5); inefficient diagnostic pathways with multiple visits, results not being available when patients return and poor referral mechanisms (4)(6); the inability to contact patients due to poor recording of addresses (4)(7)(8); delayed contact with patients (9); early mortality (4); and poor patient health (high bacillary load, HIV co-infection, low CD4, psychological distress) (7)(11)

Early screening, improved patient registration, efficient management of results and patient recall can all help to reduce ILTF and contribute to reaching the 2035 End TB Strategy Goals.

Intervention 4: Reduce ILTF for DS-TB and DR-TB cases

OUTPUT 1: Reduction in ILTF rates established as management priority
ACTIVITIES:

- Undertake district baseline assessments and set targets
- Implement electronic system for routine monitoring/reporting on ILTF at facilities
- Implement quality improvement approach to reduce ILTF

OUTPUT 2: Reduced duration and number of visits from symptom onset to treatment initiation
ACTIVITIES:

- Undertake community awareness campaigns on early health seeking for TB
- Implement routine TB counselling of presumptive TB cases
- Implement increased access to TrakCare Lab system
- Pilot automated short message service (SMS) sent to patient to return to facility

OUTPUT 3: Improved identification and recall of cases not returning for treatment
ACTIVITIES:

- Establish use of unique ID (national ID/Health Patient Registration Number (HPRN))
- Implement improved patient registration at facilities
- Implement interactive web-based system for action on positive DS-TB and DR-TB results

Table 8: Intervention 4: Reduce ILTF for DS-TB and DR-TB Cases
Implementation, Monitoring and Evaluation of Outputs and Activities

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 1: Reduction in ILTF rates established as management priority	NDoH, PDoH	% districts with ILTF as key performance indicator for district management	Targets: Y1: 9 sub districts; Y2, expanded to 9 districts Y3, additional 43 sub districts, Y4 full scale up.
ACTIVITIES			
Undertake district baseline assessments and set targets	PDoH Support partners	% districts with target based on baseline assessment / annual progress	ILTF based on laboratory-reported cases. Identify resources and partners to support provinces with baseline assessment. Review progress and revise targets in District Implementation Plans (DIP)
Implement electronic system for routine monitoring/reporting on ILTF at facilities	NDoH	% districts with all facilities reporting	Web-based interactive system for tracking that also generates summary reports. Address internet access at facilities/alternatives.
Implement quality improvement approach to reduce ILTF	Districts	% under-performing districts with quality improvement (QI) to reduce ILTF in place	Undertake quarterly data review; provide feedback to facilities; analyse root causes for gaps; plan interventions; allocate responsibility; monitor improvement. Identify "crisis districts" and provide additional support for interventions (establish standard to define crisis districts e.g., >ILTF 25% Year 1)
OUTPUT 2: **Reduced duration and number of visits from symptom onset to treatment initiation**	Districts	% Xpert/ smear-positive cases commencing treatment within five days of first positive TB screen	Target: 90% Generate automated report from Tier.net
ACTIVITIES			
Undertake community awareness campaigns on early health seeking for TB	Districts Facilities	% facilities with stakeholders providing TB awareness	Identify ward-based outreach team (WBOT)/NGO/community-based organization stakeholders; Provide training; Include TB awareness in routine activities; Develop targeted interventions; Provide additional resources (mobile billboards, loudhailers, etc.)
Implement routine TB counselling of presumptive TB cases	NDoH, PDOH Partners	% facilities meeting "TB awareness standards"	Develop training curriculum and provide training to HCW. Develop educational materials (posters, leaflets, z-card for individuals to take home).

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
Implement increased access to TrakCare Lab system	NDoH NHLS	% facilities with access to TrakCare Lab system	Address user costs: e.g., facility access to cell phone for this purpose; free call access to toll-free number established
Pilot automated SMS sent to patient to return to facility	NHLS PDOH	% patients returning to facilities within 48 hours of result available	Link to improved contact details (Output 3)
OUTPUT 3: Improved identification and recall of cases not returning for treatment	Facilities	% recalled patients returning within 1 month	Routine report from web-based system Target: 90%
ACTIVITIES			
Establish use of unique identification (ID) (national ID/HPRN)	DOH - HIER Unit	% districts implementing unique ID	Identifying district/facility champions. Conduct awareness campaigns / dialogues on use of unique ID. Evaluate impact. Plan QI initiatives: assess number of lab forms with unique ID recorded; identify and address root causes; plan and monitor improvements. Undertake knowledge, attitudes and practices (KAP) surveys in communities
Implement improved patient registration at facilities	Facility managers	% patient records fully completed	Standard use of names as per ID; regular update of addresses; alternative contact details. Review as part of monthly facility audits during support visits.
Implement interactive web-based system for action on positive DS-TB and DR-TB results	NHLS PDoH, Districts, Facilities	% facilities with functional system in use	Develop system; allocate responsibility for identifying and acting on TB/DR-TB cases that do not return for treatment. Identify and allocate responsibility to community tracers to follow up patients; assess community health worker requirements / availability and budget implications

2.6 PREVENT: Scale up preventive therapy for PLWHIV and household contacts

Goal: To reduce TB incidence and deaths among PLWHIV and child contacts through sustainable implementation of affordable, quality-assured 3HP

Outcome: Increased number of PLWHIV and child contacts <5 years starting treatment with affordable, quality-assured 3HP

Justification

In its End TB Strategy, the WHO has included scaling up TB preventive therapy for persons at high risk of developing TB. Two of the 10 indicators to monitor implementation of the End TB strategy are coverage of contact investigations and TB preventive therapy for PLWHIV and child contacts. The target is ≥90% for both. Scaling up TB preventive therapy is therefore essential to meet the End TB targets established by the World Health Assembly.[20]

The uptake of 6-month isoniazid preventive therapy (IPT) for LTBI in high-burden countries for PLWHIV and child contacts <5 years of age remains poor. South Africa has the world's largest IPT programme with approximately 500 000 PLWHIV started on IPT in 2015. However, implementation of continuous isoniazid preventive therapy - defined as use of the preventive therapy regimen for at least 36 months per WHO IPT guidelines in 2010[21]—among PLWHIV in South Africa, has been very poor. A shorter course TB preventive therapy using isoniazid (INH) and rifapentine for 3 months (3HP) is now available. 3HP is associated with less toxicity, better adherence, and similar efficacy to IPT, and this regimen may be logistically easier for programmes to scale up because of the shorter duration and need for only weekly visits. Introduction of a shortened total dosing period, weekly clinic visits, and fixed-dose combination tablets will reduce pill burden, which is especially important for PLWHIV already on ART. Furthermore, introduction of paediatric formulations will improve acceptability of and adherence to preventive treatment in children. Decentralization and integration of 3HP in HIV, child services and other healthcare services will improve access to service delivery and reduce associated time and costs for those eligible for preventive treatment and their caretakers.

Intervention 5: Scale up preventive therapy for PLWHIV and household contacts

OUTPUT 1: Affordable supply of rifapentine secured

ACTIVITIES:

- Conduct forecasting and quantification of 3HP
- Negotiate a volume-based reduction in the price of rifapentine
- Obtain importation waiver to pilot 3HP before registration
- Assist Sanofi to submit rifapentine dossier to Medicines Control Council (MCC) for approval
- Identify domestic funds or alternate funding, such as UNITAID or Global Fund, to procure 3HP
- Develop tools for supply chain management and quantification and forecasting of 3HP to minimize stock outs and losses

OUTPUT 2: Policy for 3HP for PLWHIV and household contacts adopted

ACTIVITIES:

- Revise South African guidelines to include 3HP
- Include rifapentine in the essential medicines list
- Develop educational materials
- Train civil society groups to advocate for 3HP

OUTPUT 3: Expanded demand for 3HP for PLWHIV and household contacts

ACTIVITIES:

- Scale up contact investigations after review of barriers, revision of procedures and registers where needed, and training of relevant staff
- Strengthen existing HIV case-finding programmes and promote innovative strategies for HIV testing such as self-testing, provider-initiated and opt-out testing and counselling at primary health centres as well as use of mobile-technology-based HIV testing and counselling approaches
- Strengthen community education and mobilization programmes to increase uptake of HIV testing, improve acceptance of contact investigations and to create awareness of the benefits of 3HP for PLWHIV and household contacts
- Strengthen linkage into care for PLWHIV that are newly diagnosed or not in care and household contacts, through training of community and HCWs, use of mHealth solutions and introduction of care facilitators to increase number of people accessing 3HP
- Review and revise algorithms for TB screening of PLWHIV and household contacts

Intervention 5: Scale up preventive therapy for PLWHIV and household contacts (Continued)

OUTPUT 4: Delivery of 3HP to PLWHIV and household contacts strengthened

ACTIVITIES:

- Develop or adapt implementation procedures, job aides, educational materials and monitoring and recording tools for TB preventive therapy to include 3HP
- Provide training on new guidelines, as well as recording and reporting forms and educational materials
- Strengthen or introduce quality improvement programmes using the Plan, Study, Do, Act approach to continuously improve delivery of 3HP to PLWHIV and TB contacts
- Strengthen existing adherence support systems and promote use of innovative technologies such as electronic adherence monitoring devices (WisePill/MERM) or mHealth solutions
- TB Think Tanks to coordinate with HIV and MCH Think Tank activities in scaling up 3HP

OUTPUT 5: Evidence for innovative models of delivery for 3HP disseminated

ACTIVITIES:

- Strengthen routine M&E for contact investigations, HIV testing, TB preventive therapy, including treatment outcomes, and pharmacovigilance
- Evaluate innovative strategies to maximize the epidemiological impact of 3HP
- Model the cost effectiveness and epidemiological impact of scaling up 3HP
- Disseminate lessons learnt, best practice models of delivery, results of operational, implementation, cost effectiveness and modelling studies

Table 9: Intervention 5: Scale Up Preventive Therapy for PLWHIV and Household Contacts
Implementation, Monitoring and Evaluation of Outputs and Activities

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 1: Affordable supply of rifapentine secured			
ACTIVITIES			
Conduct forecasting and quantification of 3HP	Aurum CHAI	Forecasting and quantification performed	To be done within the first six months of project launch
Negotiate a volume-based reduction in the price of rifapentine	NDoH Aurum CHAI Global Drug Facility	Price of rifapentine	NDoH should join UNITAID consortium negotiating reduced price for 3HP with Sanofi. In the first year price of 3HP should be reduced from $72 to $36 per patient course. Target price should be met in two years.
Obtain importation waiver to pilot 3HP before registration	NDoH CHAI	Importation waiver obtained	Will need to start using 3HP in pilot phase through an import waiver until rifapentine is registered.
MCC approval for rifapentine	CHAI	MCC approves Sanofi rifapentine	Rifapentine dossier submitted by Sanofi in December 2016. MCC granted approval for fast track review. CHAI to provide assistance to Sanofi to ensure a rapid approval by end 2017
Identify domestic funds or alternate funding, such as UNITAID or Global Fund, to procure 3HP	NDoH Aurum	NDoH budget includes 3HP	If UNITAID proposal successful, could fund 6667 adult patient courses of 3HP during the pilot phase. Following that funding through repurposing Global Fund money, the Conditional Grant, USAID or other multinational donors should also be explored.
OUTPUT 2: Policy for 3HP for PLWHIV and household contacts adopted			
ACTIVITIES			
Revise South African guidelines to include 3HP	NDoH Partners	TB preventive therapy guidelines revised	Partners and TB Think Tank to assist NTP in revising preventive therapy guidelines
Include rifapentine in the EML	NDoH CHAI	Rifapentine included in EML	
Develop educational materials	NDoH Partners	Educational materials developed	Partners to support NTP to develop educational materials for 3HP

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
HIV	NDoH Partners	Number of civil society training sessions held	
OUTPUT 3: Expanded demand for 3HP for PLWHIV and household contacts			
ACTIVITIES			
Scale up contact investigations after review of barriers, revision of procedures and registers where needed; and training of relevant staff	NDoH Partners	Number of contact investigations carried out	This activity will be undertaken by the TB Think Tank intervention group on household contact tracing.
Strengthen existing HIV case-finding programmes and promote innovative HIV testing strategies such as self-testing, provider-initiated, opt-out testing and counselling and of mobile-technology-based HIV approaches	NDoH PEPFAR partners	Number of newly diagnosed HIV-infected persons	Requires collaboration with the HIV Think Tank. PEPFAR implementation partners have a key role to play in supporting the NDoH meet its 90-90-90 target for HIV testing, including use of innovative strategies. Linkage to care of PLWHIV that are newly diagnosed or not yet in care is essential.
Strengthen community education and mobilization programmes	NDoH Partners	Number of Advocacy, Communication and Social Mobilization activities	Advocacy, Communication and Social Mobilization activities should be strengthened to include a TB prevention message and the benefits of 3HP. This activity will be undertaken by the TB Think Tank intervention group on household contact tracing.
Strengthen linkage into care for PLWHIV that are newly diagnosed or not in care and household contacts	NDoH Partners	Number of household contacts accessing care Number of newly diagnosed HIV-infected persons accessing care	Develop and provide training on tools for strengthening linkage to care, including use of innovative approaches such as care facilitators. Need to integrate into the ward-based outreach teams activities.
Review and revise algorithms for TB screening of PLWHIV and household contacts.	NDoH Partners	TB screening tools reviewed	TB Screening tools need to be reviewed. Requires coordination between the following intervention groups: facility-based screening, household contact tracing, TB prevention, and HIV and maternal and child health (MCH) services

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 4: Delivery of 3HP to PLWHIV and household contacts strengthened			
ACTIVITIES			
Develop or adapt implementation materials and tools for TB preventive therapy to include 3HP	NDoH Partners	Operational manual to implement 3HP developed	Practical guideline should include all procedures, job aides, educational materials and recording and reporting tools.
Provide training on new guideline, as well as recording and reporting forms and educational materials	NDoH Partners	Number of HCWs trained on new guidelines and operational manual	3HP to be integrated into provincial and district implementation plans. Employ a train the trainer approach so that provinces and implementation partners can provide training on an ongoing basis.
Strengthen or introduce QI programmes to continuously improve delivery of 3HP to PLWHIV and TB contacts	NDoH Partners	Number of facilities implementing QI programme	3HP needs to be integrated into the activities of the QI intervention group. QI tools to improve the delivery of 3HP need to be specifically developed.
Strengthen existing adherence support systems and promote use of innovative technologies	NDoH Partners	Number of people starting 3HP who complete treatment	Fixed-dose combination and paediatric formulations of 3HP should be rolled out when available to support adherence. WBOT and community-based organisations will be trained to support people on 3HP. Use of electronic medicine devices will be evaluated during the pilot phase (WisePill/MERM).
TB Think Tank to coordinate with HIV and MCH Think Tank activities in scaling up of 3HP	NDoH Think Tank Chairs	Number of joint meetings	TB prevention needs a multisectoral response. NDoH and TB Think Tank Chair will ensure representation from other Think Tanks and include scaling up 3HP into the agendas.

	Who will implement/ monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 5: Evidence for innovative models of delivery for 3HP disseminated			
ACTIVITIES			
Strengthen routine M&E for contact investigations, HIV testing, TB preventive therapy, including treatment outcomes, and pharmacovigilance	NDoH Partners	Recording tools revised to include 3HP: # starting and completing treatment by risk group	M&E needs strengthening to better monitor the impact of interventions on key indicators and identify ongoing challenges. Needs to collaborate with data utilization implementation group.
Evaluate innovative strategies to maximize the epidemiological impact of 3HP	TB Think Tank Medical Research Council	Number of implementation research projects evaluating novel models of delivery	Needs to link with the National TB Research Plan and HIV/TB Implementation Research Committee.
Model the cost effectiveness and epidemiological impact of scaling up 3HP	TB Think Tank NDoH		TB Think Tank Working Group 1 will undertake modelling work to evaluate cost effectiveness and impact of scaling up 3HP.
Disseminate lessons learnt, best practice models of delivery, results of operational, implementation, cost effectiveness and modelling studies	Researchers TB Think Tank	Results disseminated	Results to be disseminated through conferences, publications and quarterly TB/HIV meeting.

2.7 CROSS-CUTTING: Optimize systems for data utilization

Goal: Establish an integrated, real-time TB information system to facilitate improved patient management and health service delivery in keeping with the 90-90-90 strategic targets for TB

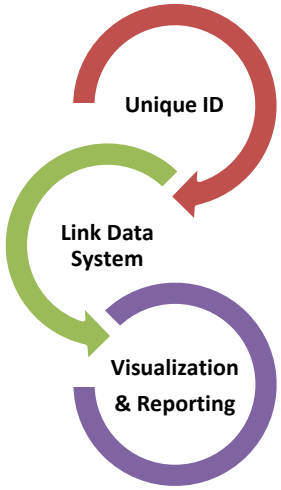
Outcomes:

1) Availability and use of an integrated TB information system (**Figure 5**) which utilizes unique patient identifiers, at all levels of care – for clinical-patient management and to provide regular, accurate, real-time, easily accessible information for clinicians as well as facility/district/provincial and national programme managers (incorporating relevant indicators – e.g., 90-90-90 targets, and aligned to the existing reporting systems, e.g., DIP).

2) HCWs (nurses and clinicians) as well as managers at all levels of the health system who are empowered and accountable in the use of data to direct daily activities in improving health services

and who are broadly capable of identifying programmatic gaps or geographic hotspots that need intervention and assessing impact at their respective levels (**Figure 6**).

Figure 5: Integrated information system



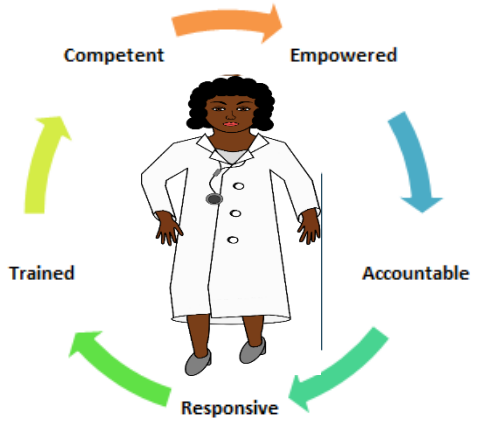


Figure 6: Empowered HCWs and managers

Justification

The principle that one cannot manage what one cannot measure holds true for the TB program and its ability in dealing with the epidemic. There are two main underlying problems:

1) **The lack of data integration across systems**

Currently the TB program data is collected in three *unlinked* electronic data systems: ETR/TIER.net and EDR (which record cases initiated on treatment for DS-TB and DR-TB, respectively) and laboratory data through the Corporate Data Warehouse (CDW) (microbiologically-confirmed TB cases). The linking of these systems is essential for benchmarking and monitoring progress on meeting the 90-90-90 targets. The technical linking is a relatively easy task. To make it accurate, easily applicable and sustainable, the universal usage of a unique patient identifier is a fundamental requirement.

2) **The management and use of the data at all tiers of the system**

Notwithstanding the issues around integration of data, there are still abundant existing data that could be used to better manage individual patients and the TB program at facility, sub-district, district, provincial and national levels. The reasons for this are multifaceted:

- Data capture occurs at the lowest tier of service delivery (usually treatment facility), and the responsibility for data "management" is often given to clerks with limited understanding and insight into the data. This greatly impacts the quality of the source data used for linking and more importantly in the process, may result in the loss of its clinical value for action, which is critical to service delivery.
- Data are usually pushed upward in the data chain but there is generally no feedback loop and no local senior review of data. Consequently, local relevance of the information is lost, important changes are not appreciated, and responses are not made in a timely manner.
- The data systems, even those available at the clinical interface (e.g., TIER.net) are not used to draw up local reports that could assist with facility management (staff allocations, case holding, procurement, etc.). These reports are available but limited by the knowledge of the end users in being able to extract the required information. Local user needs may not be catered for by the system set-up (e.g., clinic relevant reports, patient management).
- The analysis of data to define local problems and refine local strategies in combating issues is greatly lacking. Establishing this capacity creates ownership and with it accountability, which are essential to improve service delivery.

In summary, there is a lack of clear management responsibilities for the data and knowledge on how to use the available data to affect the most appropriate public health responses, as well as the lack of analytical skills available, all of which limit the potential impact of the data to improve services and achieve the End TB targets. Furthermore, establishing this capacity instils ownership, and with it, accountability, which are both important drivers for change.

Intervention 6: Optimize systems for data utilization

OUTPUT 1: Unique identifier fully implemented

ACTIVITIES:

- Standardise existing data recording systems to record the HPRN & SAID/Passport/Refugee No
- Develop public education strategy
- Implement use of unique identifier, aligned with Health Patient Registration System

OUTPUT 2: All relevant NTP patient registration and laboratory data systems used for TB (CDW/ETR/EDR/Tier, etc.) linked using the unique identifier

ACTIVITIES:

- Establish framework for linkage of data systems compliant with legal prescripts
- Audit existing systems to identify best practices and opportunities for synergy and strengthening
- Allocate development of components to data repository level to facilitate data entry, exchanges and utilisation
- Develop and implement software/tools/capacity to link data from multiple sources

OUTPUT 3: Comprehensive, real-time data availability, reporting system and dashboard at all levels (including data visualization, 90-90-90 and other relevant indicator tracking.)

ACTIVITIES:

- Stakeholder engagement to define indicators (aligned to NHIDS/DIP) and end-user requirements for reporting system
- Develop systems specifications in accordance with reporting system, taking into account provincial variations
- Develop, test and implement patient information interface (facility-level), reports and dashboard/s (all levels)
- Build, test and implement systems management reporting and develop SOPs for use to enable assessment of utilisation and exception reports aimed at tracking progress with the 90-90-90 targets and other indicators
- Iteratively improve ease of use of system based on user feedback

OUTPUT 4: Competent HCWs and managers (at all levels of the health system) capable of interpreting and using data effectively

ACTIVITIES:

- Perform computer and data management skills audit and train staff at all levels
- Train end-users/data capturers on data quality management including use of the unique identifier and appoint an information manager per province
- Develop and implement data quality monitoring plan
- Perform baseline data analysis skills audit and provide appropriate training on using data to drive quality improvement
- Establish indicator on manager performance reviews at all levels for standardised report generation against targets
- Develop and implement data utilization monitoring plan
- Host biannual data analysis workshops
- Develop and implement an assessment tool of data use as continuous quality improvement approach (e.g., quicker time to treatment, reduce ILTFU, etc.)

Table 10: Intervention 6: Optimize Systems for Data Utilization
Implementation, Monitoring and Evaluation of Outputs and Activities

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 1: Unique identifier fully implemented			
ACTIVITIES			
Standardise existing data recording systems to record the HPRN & SAID/Passport/ Refugee No	Data Systems Manager/s	System modification for recording the unique identifier.	Systems engineer available to modify software
Public education strategy on the use of identification numbers	N/PDoH (TB and Communications)	Strategy document developed and published	Funds available to produce material (pamphlets), advertisements, etc.
Implement use of unique identifier, aligned with Health Patient Registration System	District DoH	% patients with HPRN /SAID recorded in each system;	First two activities in this table achieved Staff trained: Y1: 20%; Y2: 45%; Y3: 70%; Y4: 85%; Y5: >95%
OUTPUT 2: All relevant NTP patient registration and laboratory data systems used for TB (CDW/ETR/EDR/ Tier, etc.) linked using the unique identifier			
ACTIVITIES			
Establish framework for linkage of data systems compliant with Protection of Personal Information Act and other legal prescripts	N/PDoH (TB/Health Info)	Framework developed	Skilled staff available
Audit existing systems to identify best practices and opportunities for synergy and strengthening	Consultant/ NDoH (Health Info)	Audit report available	Predefined specifications available including requirements for reporting system
Allocate development of components to data repository level to facilitate data entry, exchanges and utilisation (hardware, software, connectivity)	NDoH IT/ Procurement (diff levels)	Proportion of sites ready (hardware, software, connectivity, HR)	Funds available for equipment and connectivity available at clinic level
Develop and implement software/tools/capacity to link data from multiple sources	Consultant / NDoH (Health Info)	Proportion of provinces with patient-level linking of data systems (CDW/ETR-TIER.net/ EDR);	Common Unique ID applied across all systems Y1: EDR – CDW linked in all provinces Y2: ETR/TIER.net – CDW linked 3 provinces Y3: ETR/TIER.net – CDW linked 7 provinces Y4: ETR/TIER.net – CDW linked all provinces Y5: All system linkages maintained

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 3: Comprehensive, real-time data availability, reporting system and dashboard at facility, sub-district, district, provincial and national levels (including data visualization, 90-90-90 and other relevant indicator tracking including site-to-site comparisons, time trends, etc.)			
ACTIVITIES			
Stakeholder engagement to define indicators (aligned to National indicators/DIP) and end-user requirements for reporting system	NDoH / PDoH (TB) and consultant system developer (CSD)	End-user requirements specifications and indicator definitions report available for system	Broad participation achievable
Develop systems specifications in accordance with reporting system, taking into account provincial variations in existing health information management systems	NDoH / PDoH (TB & Health Info) and CSD	Systems specifications document produced	Relevant skills available
Develop, test and implement patient information interface (facility-level), reports and dashboard/s (all levels)	CSD	Proportion of reporting tools produced against expected;	Skills available
Build, test and implement systems management reporting and develop SOPs for use to enable assessment of utilisation and exception reports aimed at tracking progress with the 90-90-90 targets and other indicators	CSD	Achievement level in establishing usable and effective system: 1. Generating reports from system; 2. SOPs developed; 3. Actionable exception reports generated; 4. Useable and actionable system based on user feedback	Close interaction between systems developer and program staff
Iteratively improve ease of use of system based on user feedback	CSD & NDoH / PDoH	Proportion of Improvement Feedback Sessions held per year	Funding for meetings available. Additional technical costs available for improvements.
OUTPUT 4: Competent HCWs and managers (at all levels of the health system) capable of interpreting and using data effectively to improve health service delivery			
ACTIVITIES			
Perform computer and data management skills audit and train staff at all levels	Consultancy/NDoH (HR)	Proportion of staff evaluated and trained	Consultants appointed, and audit tool available and training material developed
Train end-users / data capturers on data quality management including use of the unique identifier and appoint an information manager per province	PDoH (Health Info/TB & Prov Info Manager)	Proportion of required users trained	Information Manager appointed and trained end users made available for training
Develop and implement data quality monitoring plan	Prov Info Manager	Plan developed and responsibilities allocated with time lines;	Performed at each level of the health system

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
Perform baseline data analysis skills audit and provide appropriate training on using data to drive QI	PDoH (Health Info/TB & Prov Info Manager)	Proportion of required users trained	Information manager with suitable additional consultants available
Establish indicator on manager performance reviews at all levels for standardised report generation against targets to ensure accountability and linked with response plan if target not met	N/PDoH (TB and Heath Info)	At least pme indicator requiring report generation with response plan implemented for all manager performance reviews;	Applied at all levels
Develop and implement data utilization monitoring plan	N/PDoH (TB)	Plan developed and responsibilities allocated with time lines;	Systems able to generate monitoring reports
Host biannual data analysis workshops aimed at producing annual reports	N/PDoH (TB)	Annual Report produced;	Workshop held with appropriately skilled people available. Funds to publish report.
Develop and implement an assessment tool of data use as continuous QI approach (e.g., quicker time to treatment, reduce ILTFU, etc.)	N/PDoH (TB)	Assessment tool developed and regularly used	Supported by established data systems that can produce regularised and standardised reports. Skilled staff available to assess.

2.8 CROSS-CUTTING: A Quality Improvement Initiative to close gaps in the TB Care Cascade (BIG Plan- Bridging the Implementation Gap)

Goal: Nationally scaled-up package of interventions developed by and spread through a well-designed and targeted national TB Quality Improvement programme to close gaps in the care cascade

Outcome: Reduction in the care cascade gaps (case-finding, treatment initiation and retention in care).

Justification

The national TB care cascade for South Africa demonstrates significant leakages at each step of the cascade from testing, diagnosing, notifying and treating patients successfully, as described in **Appendix A**. Currently it is estimated that 53% of TB patients are successfully treated, with major leakages occurring once patients have engaged the health system (i.e., been tested or diagnosed but not carried through to the next step). Importantly, we estimate that the majority of presumptive TB cases engage the public health service at some point during the course of their illness but are often missed at screening, testing or treatment leading to these suboptimal outcomes. Even an 85% success at each stage of the cascade will result in less than a 55% treatment success for all TB cases; therefore, to reach >80% treatment success, we must aim to reach 95% (or more) success at each stage.

Intervention 7: A Quality Improvement Initiative to close gaps in the TB Care Cascade

OUTPUT 1: The Bridge the Implementation Gap (BIG) plan for TB control that defines a pathway for change to scale-up best practices nationally

ACTIVITIES: 0-4 months (Set-up)

- Establish NDoH project team. Develop leadership and governance structures to develop BIG plan design, oversight and capacity.
- Build NDoH leadership capability for BIG plan
- Build the guiding coalition
- Develop package of clinical and implementation interventions, tools and tracking indicators based on NTP priorities
- Identify pilot districts/sub-districts (one in each of the nine provinces) and sensitize and prepare for intervention
- Pilot sites prepared to initiate intervention
- District Health Management Teams (DHMTs) build capability to undertake QI intervention

ACTIVITIES: 4-16 months (Launch and pre-scale up piloting)

- Launch the intervention
- Pilot sub-districts facilities learning network
- Develop a learning system to build implementation “change package” and tools for scaling up
- Establish a reliable, timely, accurate reporting system to track pilot districts
- Implement interactive web-based system for action on positive DS-TB and DR-TB results
- Assemble knowledge, tools and experience

Intervention 7: A Quality Improvement Initiative to close gaps in the TB Care Cascade

ACTIVITIES: 16-48 months (Full scale up)

- Launch national scale-up
- National scale-up to all districts within nine provinces
- Quality control to sustain progress
- Responsive national, provincial, district and facility processes to ensure improvement and sustainability

OUTPUT 2: Increase leadership accountability and ownership for the TB program at different levels by establishing a management action framework for TB

ACTIVITIES:

- Establish framework that could increase accountability to pilot in the same nine districts as above
- Determine information needs required to give effect to the framework
- Staff are capacitated on QI techniques and tools through the DIPS process
- Include key TB indicators in the performance agreements of facility managers
- Evaluate impact of framework implemented in nine districts

OUTPUT 3: Decrease the complexity (cost and delays to patients) of current patient pathways to accessing and remaining in care including psychosocial support

ACTIVITIES:

- Map and understand the current patient pathways at three facilities in each of the nine pilot districts
- Intervene at the most important bottlenecks
- Document the successes and challenges in the districts currently piloting the new interventions on ward-based outreach teams, Ideal Clinics, Adherence and Retention care strategy and translate into implementation guide
- Harvest best practices in preparation for scale-up as part of the BIG plan
- Develop a clinical audit tool for monitoring the quality of treatment and care provided to patients
- Conduct KAP surveys to assess impact of community awareness/ education interventions on health-seeking behaviour
- Develop and conduct patient cost survey protocol
- Develop and implement plan to reduce patient costs related to TB treatment based on results of survey
- Conduct patient satisfaction surveys related to patient pathways

OUTPUT 4: Improve data quality

ACTIVITIES:

- Develop a checklist for assessing completeness and accuracy of data at all levels
- Facilitate daily capture of data at facility level
- Conduct facility weekly and monthly data verification
- Conduct training of facility staff on indicators, data management and identification of bottlenecks
- Develop facility cascade dashboards to monitor progress against targets

Table 11: Intervention 7: *A Quality Improvement Initiative to close gaps in the TB Care Cascade*

Implementation, Monitoring and Evaluation of Outputs and Activities

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 1: The BIG plan for TB control that defines a pathway for change to scale up best practices nationally			
ACTIVITIES – 0-4 months (SETUP)			
Establish NDoH project team. Develop leadership and governance structures to develop BIG plan design, oversight and capacity.	NTP Leadership team, supported by core BIG Project Team	Ministerial/DG commissioned BIG Team NDoH/provincial leaders and advisors appointed within a month	Leadership team should be established and supported by QI and implementation experts. High-level NDoH leadership advocates for and announces BIG plan.
Build NDoH leadership capability for BIG plan	NTP leadership and BIG Project Team, NDoH Quality unit	Leadership coaching (one day) within weeks of team assembly	Leadership team understand psychology of change, systems thinking, use of data, importance of learning for implementation and scale up.
Build the guiding coalition	External advisory team	Advisory team meets quarterly	Coalition meets to understand plan and provide inputs.
Develop package of clinical and implementation interventions, tools and tracking indicators based on NTP priorities above for delivery and deployment	NTP, BIG Project Team, tech advisors (QI, clinical, data, supply chain, etc.)	Expert clinical content and implementation meeting (two days) to agree on clinical integrated package of interventions	Package of content and implementation interventions, protocols, tools along the cascade based on the priorities already identified, supported by a core set (<10) of tracking indicators.
Identify pilot districts/sub-districts (one in each of the nine provinces) and sensitize and prepare for intervention	NTP, BIG Project Team,	Each provincial pilot District Health Management Team (DHMT) visited and sensitized within two months	Provincial TB/HIV teams and DHMTs sensitized to BIG.
Pilot sites prepared to initiate intervention	DHMT supported by NGOs	Each pilot sub-district prepared to launch	DHMTs conduct rapid assessment of current cascade performance resources, clinical knowledge.
DHMTs build capability to undertake QI intervention	Key DHMT staff	Three-day meeting ahead of launch	DHMT supervisors equipped to undertake supportive clinical and health system supervision.

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
ACTIVITIES 4 – 16 MONTHS (Launch & piloting)			
Launch the Intervention	Minister, NTP, BIG Project Team, advisory team, provincial and DHMTs	National convening meeting	Teams from district, province, national plus guiding coalition, supported by QI and implementation experts
Pilot sub-districts facilities learning network	DHMT	Learning sessions run by DHMT, supported by NGO	DHMT supported by QI NGOs convenes learning sessions with facility teams
Develop a learning system to build implementation "change package" and tools for scaling up	BIG Project Team, supported by DHMTs, NGOs	Learning system run by BIG Project Team	Regularly communicate best practices and acknowledge great ideas; acknowledging staff ideas and effort is absolutely critical
Establish a reliable, timely, accurate reporting system to track pilot districts	District Management Teams	DHMT and HAST meetings, link to NdoH data teams (DHIS, e-platforms)	Develop, test and implement reporting system for progress reporting at district, provincial and national levels
Assemble knowledge, tools and experience to prepare for scale up	NTP, BIG team, DHMT leads, NGOs	National convening of relevant parties over two days	Build a practical implementation guide, for use during national scale up
Build capability of NdoH and DHMTs to undertake scale up	BIG team, DHMTs, National Quality depts	QI Training sessions	NdoH equipped to undertake QI
ACTIVITIES 16-48 MONTHS (Full Scale up)			
Launch of national scale up	Minister/DG, NTP team, BIG Team, guiding coalition, provinces, etc.	One-day event to celebrate progress, build will for scale up, initiate national scale up	Public launch of National TB/HIV scale-up plan
National scale up to all districts within nine provinces	DHMTs lead, National Quality Unit support, ongoing NGO support	Integration of QI in DHMT work	Supportive supervision and cross-district learning using QI approaches become routine way of undertaking DHMT work, leading to progress on seven agreed indicators and 80% treatment success by 2020
Quality control to sustain progress	NdoH and BIG Project Team and DIPS	Routine reporting at all levels (internal reporting), plus external audits (inspection-based systems)	Agreed quality control indicators (inputs, processes and outcomes)
Responsive national, provincial, district and facility processes to ensure improvement and sustainability	NdoH and BIG Project Team and DIPS	Data review and response systems	Accountable responses to gaps identified through quality control reporting

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
OUTPUT 2: Increase leadership accountability and ownership for the TB program at different levels by establishing a management action framework for TB			
ACTIVITIES			
Establish framework that could increase accountability to pilot in the same nine districts	NdoH and BIG Project Team and DIPS	Establish concept within three months	Supported by implementation and HR experts by empowering staff with the relevant information
Determine information needs required for framework	NdoH and BIG Project Team and DIPS		
Staff are capacitated on QI techniques and tools through the DIPs process	DIPS process	All pilot districts are capacitated within Year 1	
Include key TB indicators in the performance agreements of facility managers		Performance agreements	
Evaluation of impact of the framework implemented in nine districts	BIG Project Team and DIPS	% improvement in the seven indicators; # of times failure to act was escalated	Systems will be designed to have built-in protocols and algorithms for escalated of action
OUTPUT 3: Decrease the complexity (cost and delays to patients) of current patient pathways to accessing and remaining in care including psychosocial support			
ACTIVITIES			
Map and understand the current patient pathways at 3 facilities in 9 pilot districts	Partners & NDOH	27 patient pathways mapped	
Intervene at the most important bottlenecks	Facility, DIP with Partners	% reduction in complexity of patient pathways	
Harvest best practices, successes and challenges	BIG Project Team/ NDoH	Best Practices written	
Develop a clinical audit tool for monitoring quality of treatment and care provided to patients	TB Think Tank	Clinical audit tool finalised	
Conduct KAP surveys	Partners	KAP survey completed	To assess impact of community awareness/education interventions on health-seeking behaviour
Develop patient cost survey protocol (in line with WHO) and conduct the survey	WHO / NDoH	Cost survey completed	
Develop and implement plan to reduce patient costs related to TB treatment based	NDoH	% reductions	Assisted by South African National Aids Council and Social development
Conduct patient satisfaction surveys	WHO	Patent satisfaction surveys	Related to patient pathways

	Who will implement/monitor?	Indicator used to monitor	Operational details for consideration
Output 4 : Improve Data Quality			
ACTIVITIES			
Develop a checklist for assessing completeness and accuracy of data at all levels	NDoH in consultation with districts		
Facilitate daily capture of data at facility level	Facility manager	Completeness of data	
Conduct weekly and monthly data verification	Provincial HAST managers		At facility level
Conduct training on indicators, data management and identification of bottlenecks	Implementation partners		
Develop facility cascade dashboards to monitor progress against targets	System developers/ NDoH/ DIPs		Requires health information exchanges to be present

2.9 Integration of Strategic Interventions

Figure 7: Integration of FIND→TREAT→PREVENT Interventions

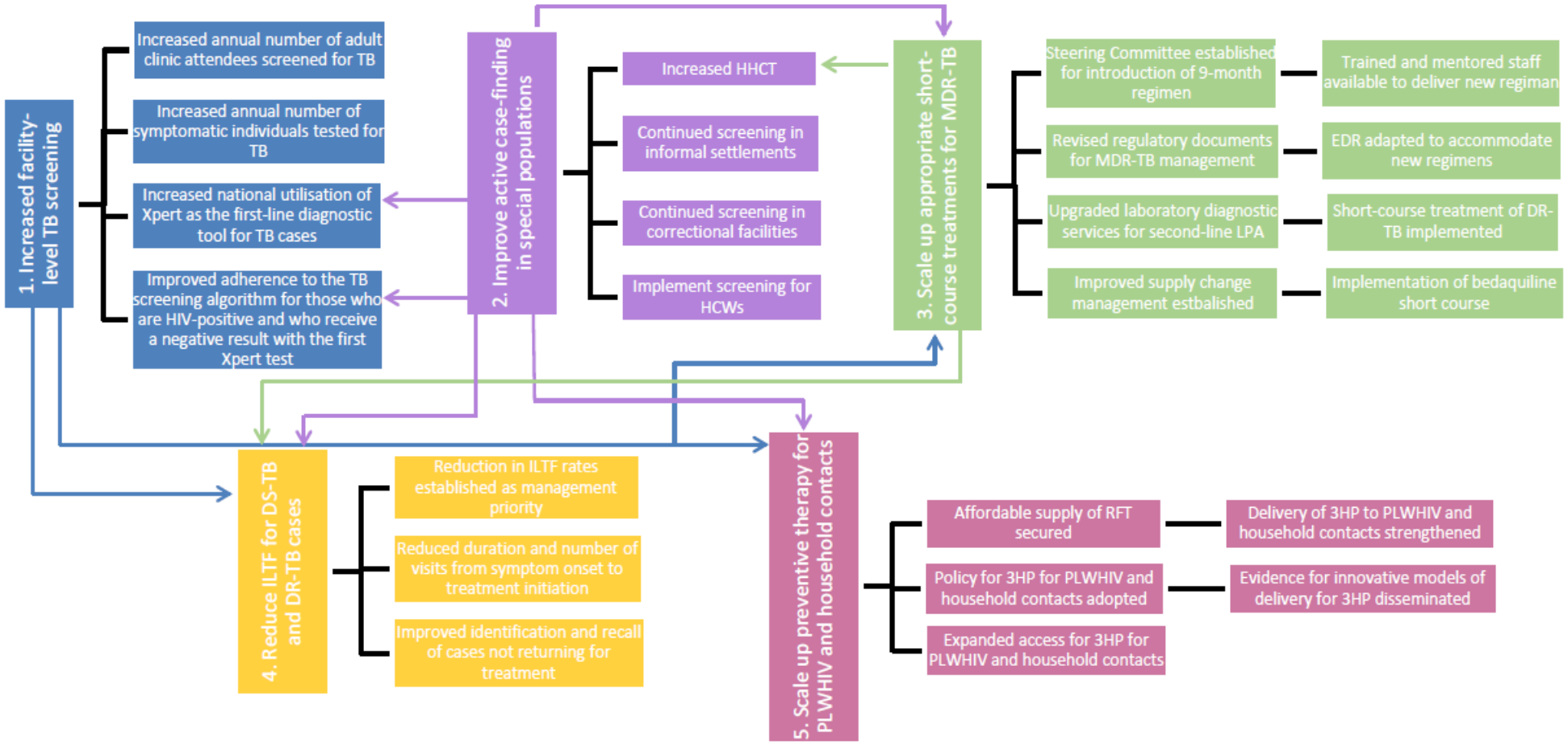
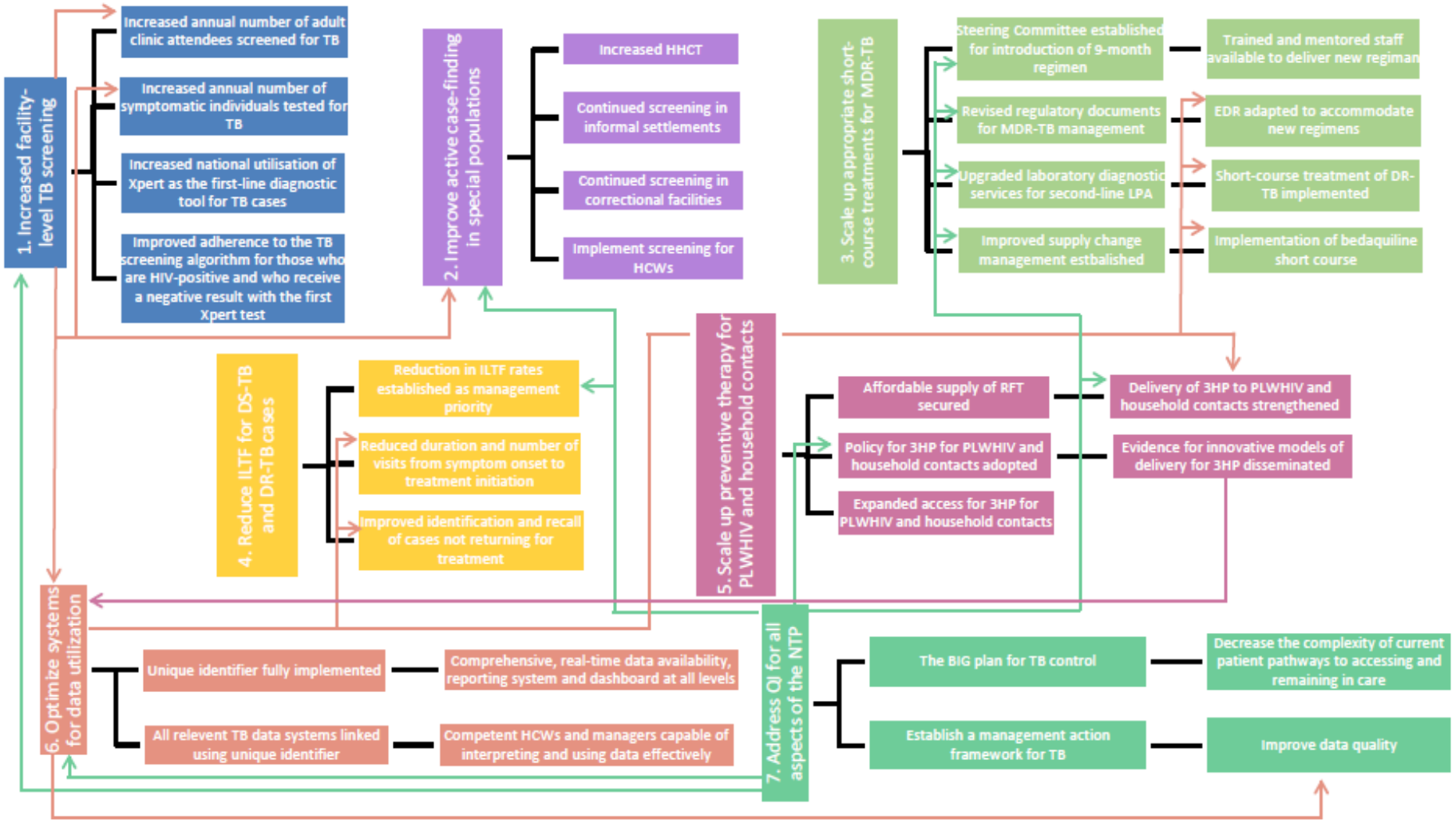


Figure8: Integration of Cross-cutting Issues with FIND→TREAT→PREVENT Interventions

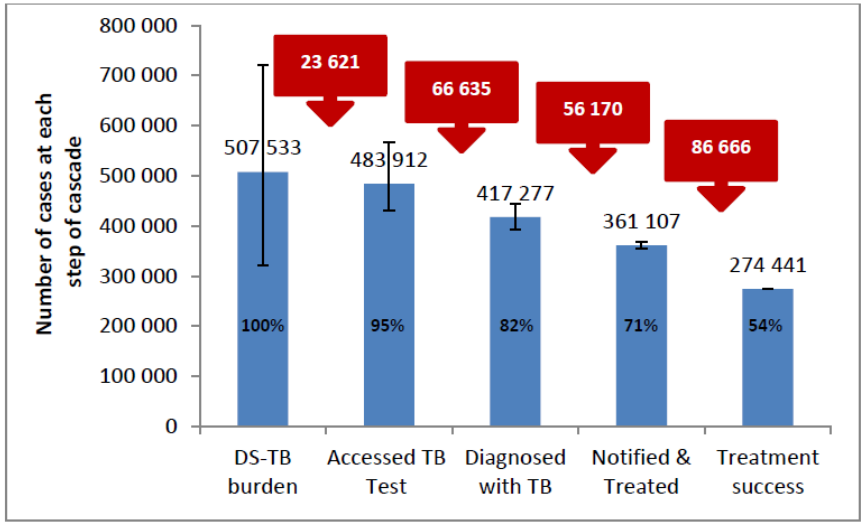


Appendix A: TB Care Cascade Analysis

The TB cascade analysis was undertaken to develop a better understanding of where patients drop out along the "cascade of TB care" in South Africa. Starting with the estimated total TB burden for South Africa, drop-off rates were assessed at the following steps along the cascade of care for DS and DR-TB cases: access to TB tests, diagnosis, notification and treatment initiation and treatment success. The total TB burden was derived from WHO[20] estimates of TB incidence. Multiple data sources were reviewed to explore drop-off rates in the TB cascade. ENREF 7[22-27] Data from 2013 were used in these analyses as it was the most recent, complete, cleaned and validated data available. The Care Cascade for DS-TB cases is illustrated in **Figure 10** and shows significant gaps at each stage, with 54% of the estimated burden successfully completing treatment.

The first gap in the cascade relates to test access. Only 5% of estimated cases did not access testing. The small magnitude of this gap may reflect the broad network of free primary health care facilities with access to TB diagnostic services. The National Income Dynamics Study confirms high levels of health care access: in the three years surveyed only 12.8% of respondents had never accessed health services and 7% with a TB symptom in the last month had not previously accessed health services (ref) However, there was a wide range of possible values for the DS-TB burden (due to the large confidence interval in WHO incidence estimates) and this figure could be an under-estimate.

Figure 10: Care Cascade for DS-TB Cases



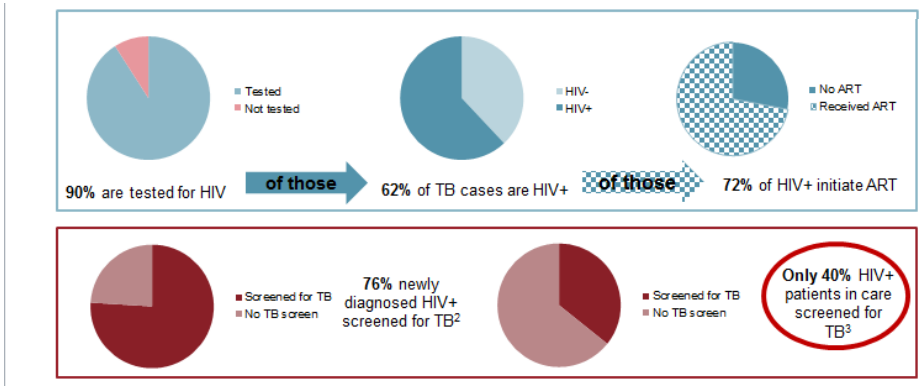
The absolute numbers at each step, range of possible values, losses in relation to the DS-TB burden (as a percentage) and in absolute terms (red boxes) are shown. Source: P. Naidoo et al; JID, 2017, in press

The second gap, estimated at 13%, reflects cases missed at diagnosis due to false negative tests. The third gap, estimated at 11% is attributed to ILTF, patients with a bacteriological diagnosis of TB that do not initiate treatment. The fourth gap relates to successful treatment completion and shows a 17% loss, based on routine data.

For HIV-infected individuals, the care pathway is even more challenging, as shown in **Figure 11**. Those who first access care as TB

patients do relatively well, receiving HIV testing (and treatment, if needed): 90% of these TB patients have an HIV test. Amongst the 62% who were HIV-positive, 72% were initiated on ART. However, those who first access care as HIV patients do less well. A study by Chehab et al examined TB-HIV integration across all nine provinces of South Africa and showed that only 76% of newly diagnosed HIV-positive patients were screened for TB, and only 40% of those on HIV care were screened for TB.[23]

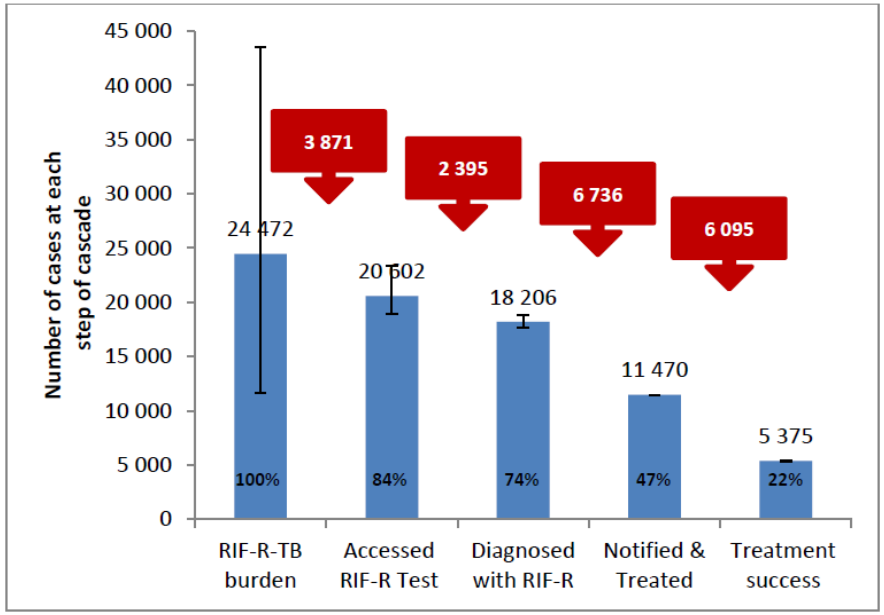
Figure 11: TB/HIV Co-infected Patients Experience More Challenges in the Cascade of Care



Source: P. Naidoo et al; presented at the NDoH TB Think Tank Meeting, 13 July 2016

For RIF-R TB, the cascade was even more dismal, with only 22% of cases successfully completing treatment as illustrated in **Figure 12**. Approximately 16% of cases did not access TB or drug susceptibility tests and 10% were lost during the diagnostic process due to false negative tests. About 28% did not access treatment and 25% of the RIF-R TB burden failed to successfully complete treatment.

Figure 12: Care Cascade for RIF-R TB Cases



The absolute numbers at each step, range of possible values, losses in relation to the RIF-R TB burden (as a percentage) and in absolute terms (red boxes) are shown. Source: P. Naidoo et al; JID, 2017, in press

The root causes of the gaps in the cascade were explored in a review of 55 qualitative and quantitative studies (P. Naidoo et al; JID, 2017, in press). **Table 12** highlights the health system-related gaps. In terms of test access, the gaps reflect the failure to screen patients who are

already using the health facilities. Other factors include the poor sensitivity of the screening algorithm, a failure to test symptomatic patients, and incorrect use of tests and algorithms.

Table 12: Root Causes of Gaps in TB Cascade

Test Access	**Initial loss to follow-up**	**Treatment success**
Failure to screen patients attending health facilities	Weak administration at facility (retrieving results, recalling patients, referrals)	Low patient knowledge levels
Insensitive screening algorithm	Poor mechanisms for patient registration	Poor monitoring of daily adherence
Failure to test symptomatic patients	No facility incentive to register patients	Inadequate HIV care
Incorrect test / algorithm	Diagnostic delay	Poor pro-active use of data for patient management
Cross-cutting issues		
Lack of integrated data (lab, pharmacy, facilities) and limited use of data to manage continuity of care		
Workflow inefficiency (queues, delays, multiple interactions)		
Poor facility management, quality of care		

Source: P. Naidoo et al; presented at the NDoH TB Think Tank Meeting, 13 July 2016

As a result, 40% of patients in 2013 did not get an Xpert test, despite the country having 100% Xpert coverage. The most recent figures show that about 30% do not get an Xpert test. Importantly, a large proportion of HIV-infected patients who have a negative TB test do not go on to get additional follow-up culture tests.

An important issue around the ILTF was the weak administration at facilities in terms of having results available and recalling patients. Also, the mechanism for registration is paper-based, so although patients might be initiated on treatment, the register is located elsewhere. There is also very little incentive, and possibly even a disincentive, to register TB patients. Patients who are unlikely to have a successful treatment outcome might not be added to the register. And lastly, diagnostic delay – either due to late results, smear-negative results, or Xpert-negative culture-positive results – is also associated with loss to follow up.

Factors associated with poor treatment success include low patient knowledge levels and very poor systems for monitoring daily adherence. South Africa has largely moved away from directly observed treatment, short course (DOTS) throughout the country, and community-based care does not always allow for monitoring medication on a daily basis. Also, although many facilities have integrated care, TB and HIV services are generally delivered separately and this leads to poorer outcomes. Lastly, there is very poor proactive use of data for patient management, with cohort reports often completed 6 months after a patient has left the clinic.

Several cross-cutting issues were identified, including the lack of integrated data, which makes the ILTF, for example, difficult to identify and track. Not all facilities are TB registration units, which

makes it very difficult to track patients from a diagnostic centre to a treatment centre. Workflow inefficiencies such as long queues, delays in diagnosis and treatment, and multiple patient/HCW interactions (e.g., as a result of lack of same-day diagnosis and treatment) all contribute to the gaps in the cascade, in addition to poor facility management and perceptions of low-quality of care.

Appendix B: Shorter standardized and modified bedaquiline course of treatment for MDR-TB

Attempts to reduce the length of treatment of MDR-TB have been made to address the long duration of RIF-R-TB or MDR-TB treatment, the toxicity of certain drugs, and the cost of this treatment. This research has been ongoing for several years.

Recently, a standardized treatment regimen lasting 9 to 12 months studied in a number of countries has shown high rates of relapse-free cure in selected MDR-TB patients with an acceptable safety profile. In May 2016, the WHO released guidelines for shorter course treatment for patients with RIF-R-/MDR-TB. The regimen contains kanamycin, moxifloxacin, prothionamide, clofazimine, high-dose INH, PZA and ethambutol, given together in an initial phase of 4 months (with the possibility to extend to 6 months if smear-positive), and followed by 5 months of treatment with 4 of the medicines (moxifloxacin, clofazimine, PZA and ethambutol). This shorter regimen can be used for those patients who have not previously been treated with second-line drugs and in whom resistance to fluoroquinolones and second-line injectable agents has been excluded or is considered highly unlikely. Ideally, all DR-TB patients are to be tested for resistance to fluoroquinolones and second-line injectable agents before starting any DR-TB treatment. This is particularly important for the shorter MDR-TB regimen. The shorter regimen cannot be used when there is intolerance to 1 or more of the drugs in the shorter MDR-TB regimen, extrapulmonary disease or increased risk of toxicity (e.g., drug-drug interactions, cardio-toxicity). The safety in pregnancy has not been established. It should

not be used in. The shorter MDR-TB regimen can be used in PLWHIV. National Antiretroviral Guidelines for treatment of all HIV-infected patients with TB, including DR-TB, within two weeks should apply.

To reproduce the high cure rates achieved by the studies included in the reviews for this guidance, all efforts need to be made to avoid the additional resistance, through careful selection of patients to be enrolled, and effective patient support for full treatment adherence.

The evidence for the effectiveness and safety of the shorter MDR-TB regimen derives from studies where treatment was administered under fairly standardized conditions, and with close monitoring. Thus, the this recommendation is premised on the use of a regimen similar in composition and duration as in the observational studies. Any replacement of medicines or any changes to the duration are only to be considered within the parameters applied in these studies (e.g., gatifloxacin replaced by moxifloxacin; prothionamide replaced by ethionamide; intensive phase prolonged to 6 months if no sputum smear conversion).

In addition to the standardized shorter regimen described above, there is an increasing body of evidence that the addition of bedaquiline can result in a reduction of mortality. Early data presented to the Guidelines Development Group (GDG) meeting to revise WHO policy guidance on the use of bedaquiline in May 2016 incorporated the data of 195 patients who received bedaquiline in the Bedaquiline Clinical Access Programme (BCAP). However, 70 patients did not have outcomes recorded as they had not completed treatment yet. Data collection and analysis of the outcomes will be completed in December 2017. Since the BCAP, bedaquiline has been incorporated in the national programme for XDR, pre-XDR and patients with treatment-limiting toxicities.

Over 3000 patients have received the drug, putting South Africa in the forefront for the adoption of the new drug. Once the standardized shortened course has been adopted by the programme, a second modified regimen will be introduced. In a consensus-building exercise, the South African National Clinical Access Committee steering committee will design a short course that incorporates bedaquiline. To ensure safe rollout of this regimen, an operational research protocol will be developed and implemented.

Appendix C: Estimated costs of the South African National TB Plan 2017-2021

Considerable costs will be associated with achieving the End TB Strategy milestones and targets. An economic model was developed to project costs of the National TB Plan (NTP) 2017-2021. While the NTP looks at five different interventions along the TB control cascade, as well as cross-cutting interventions, the economic model which estimates costs of the NTP only considers the interventions along the cascade, which are:

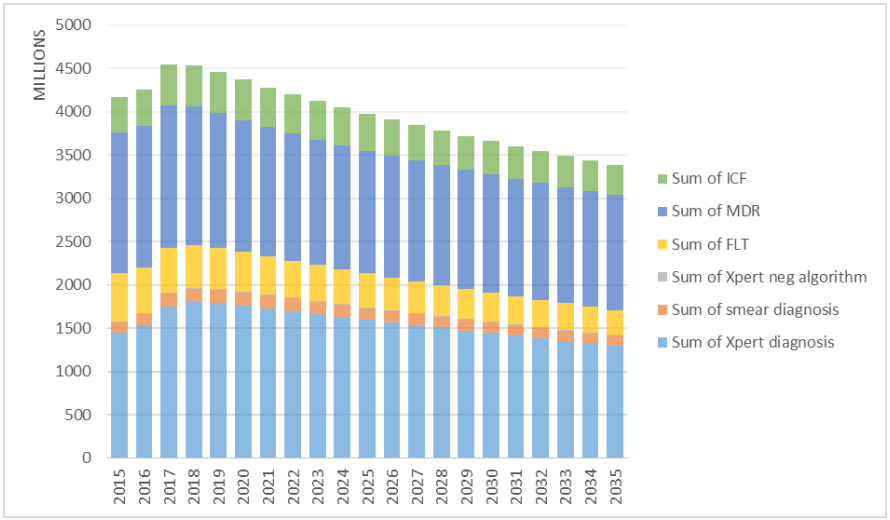
1) Targeted facility-based screening (ICF)
2) Improve household contact tracing for special populations (HHCT)
3) Scale up appropriate short course treatment for MDR-TB
4) Reduce initial loss to follow-up (ILTF) for DS-TB and DR-TB resistant cases
5) Scale up 3HP for PLWHIV and household contacts

Detailed assumptions had to be made for each intervention. These assumptions were informed by literature searches and expert communications. In the model, all new interventions were assumed to be rolled out starting in the year 2017.

Base case

Figure 13 represents the present level of TB expenditure in South Africa projected over the period 2015-2035, in the *base case scenario where no new interventions are added* to the current TB control strategy. The expenditure is approximately ZAR 4.3 billion in 2016 and is expected to decline following the trend in the TB epidemic.

Figure 13: Base Case, 2016 ZAR (Millions)

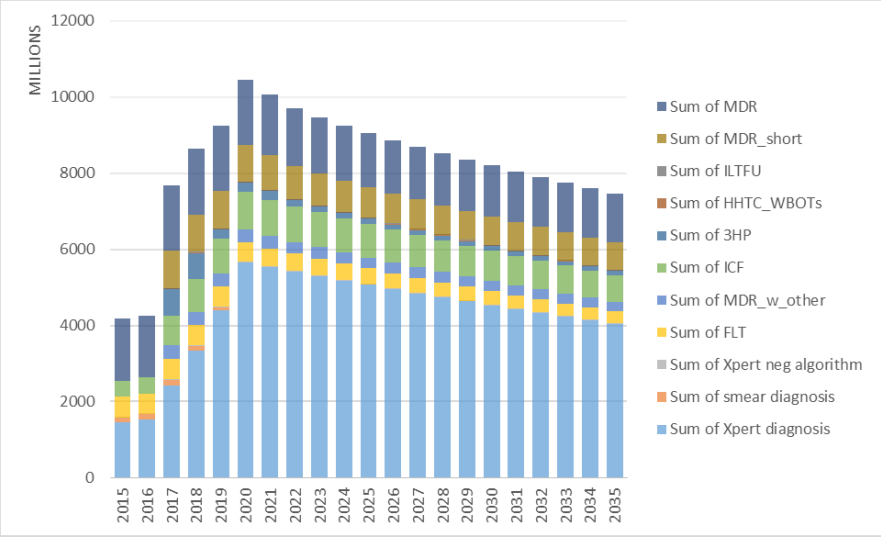


FLT=first-line treatment

Combination scenario

In **Figure 14**, all of the interventions included in the NTP are presented in combination to assess the cumulative resource requirements.

Figure 14: All NTP Interventions, 2016 ZAR (Millions)



ICF intervention: full WHO symptoms screener reaching 90% of PHC attendees. household contact tracing intervention: WBOTs

Appendix D: Workshop Participants

19 – 20 April 2017(alphabetical order)

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Ntombi Mhlongo-Sigwebela
Rizwana Mia
Valerie Mizrahi
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Sizulu Moyo
Cecilia Moyo
Victor Mtshali
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Lindiwe Mvusi
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