Report of the Situational/Gap Analysis of the Drug Resistant TB Programme in Kenya

Report developed for Janssen and Janssen Pharmaceutical
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Abbreviations

ADR	Adverse Drug Reaction
aDSM	active TB drug-safety monitoring and management
AIDS	Acquired Immunodeficiency Syndrome
ART	Anti Retroviral Treatment
CDC	Centre for Disease Control and Prevention
CHVs	Community Health Volunteers
CHWs	Community Health Workers
cPMDT	Community Programmatic Management of Drug Resistant TB
CSOs	Civil Society Organisations
CTLC	County TB and Leprosy Coordinator
CXR	Chest X-Ray
DR TB	Drug Resistant Tuberculosis
DRS	Drug Resistant Survey
ECG	Electrocardiography
HIV	Human Immune Deficiency Virus
IPT	Isoniazid Preventive Therapy
KEMRI	Kenya Medical Research Institute
KNBS	Kenya National Bureau of Statistics
LIMS	Laboratory Information Management System
LPA	Line Probe Assay
MDG	Millennium Development Goal
MDR	Multidrug-resistant TB/
MOH	Ministry of Health
NTLD-P	National Tuberculosis, Leprosy and Lung Disease Program
PEPFAR	President's Emergency Plan For AIDS Relief
PHC	Primary Health Care
PMDT	Programmatic Management of Drug-Resistant TB
PPM	Public-Private mix
RR-TB	Rifampicin-Resistant TB
SDG	Sustainable Development Goal
TB ARC	Tuberculosis Accelerated Response and Care
TB	Tuberculosis
TIBU	Electronic Case-based Surveillance
UHC	Universal Health Coverage
USAID	US Agency for International Development
WB	World Bank
WHO	World Health Organization
XDR	TB Extensively Drug Resistant Tuberculosis

Executive Summary

Background

Janssen pharmaceutical commissioned this rapid situational/gap analysis of DR-TB in Kenya with the aim of identifying gaps that will inform intervention planning. The scope of the rapid situational/gap analysis report covers

- Epidemiological DR-TB data of Kenya focusing on case finding and outcomes.
- Design of health system
- Models of DR-TB care implemented in countries
- Mapping of DR-TB treatment facilities
- What are the applicable policies that drives implementation of DR-TB
- Monitoring and Evaluation mechanism

Method

This assessment was carried out in 5 counties namely Nairobi, Meru, Mombasa, Kisumu and Nakuru, covering 15 facilities. This was carried out using a mixed method approach. A desk review of policy, strategies and relevant documents was carried out with the aim of identifying relevant information that will help to inform the focus of the discussion and interview on the field, secondary analysis of programmatic data; including routine data, using the national, county and facility level data was done. site visit and stakeholder interviews involving service providers, service users and partners were conducted. Furthermore, the key recommendations of the recently concluded report of Green Light Committee (GLC) mission, TB and Drug Resistant TB surveys, Inventory study and Epi-analysis were used for triangulation.

Findings

Tuberculosis poses a serious challenge to the government of Kenya. But over the years the government has achieved many milestones in TB management including improved social protection system. Emphasis was also on the use of local evidence generated through research and numerous surveys and studies to inform policy and intervention planning. The DR-TB model of care is a hybrid of community and facility based model. The DR-TB programme is mainly funded by external funding; this exposes the programme to a threat posed by dwindling funding.

Kenya has an elaborate laboratory network and the country has rapidly adopted many World Health Organization recommendations like the Short Term Regimen for MDR-TB, introduction of Bedaquiline and rapid molecular diagnostics. There are national, county and sub-county clinical review committees that oversees clinical management.

The findings of this review are well elaborated in the chapter on Findings in this document, However, the following findings are key and highlighted below:

- Overwhelming numbers of staff managing the DR-TB patients have not been comprehensively trained on DR-TB management, pharmacovigilance; active Drug Safety Monitoring (aDSM) and Infection Prevention and Control
- Sputum transportation is delayed and quality are sometimes compromised due to sub-optimum transportation condition (temperature) resulting in high rejection rate at the reference laboratory
- LPA and Culture results retrieval are also delayed and a weak auto alert system compromises prompt linkages between laboratory and the facilities
- The laboratory software platform (Labware) not linked to the TB surveillance system (TIBU) for data triangulation
- The clinical management of patients is commendable in terms of choosing the right regimen and requesting the right clinical test in line with the national protocol. However, there seems to be an issue in the programme Adverse Drug Reaction monitoring as well as ECG and X-ray testing
- The country has adopted GeneXpert as the first line of diagnosis for presumptive TB cases, However, a lot of patients are presently diagnosed with smear microscopy without undergoing a resistance testing. GeneXpert functionality compromised by sub-optimum network availability for sending results in some areas, non-functional GeneXpert Modules and failed calibration leading to delay
- Childhood DR-TB diagnosis challenges still occur as a result of problem with diagnosis ranging from inability to collect samples to access to X-ray in some public facilities
- Hearing loss prevention and management is inadequate; no hearing aid provision for patients that lost their hearing as a result of Second Line injectable and audiometry testing implementation challenges exists
- Overall, contact tracing effort is weak and dependent on the funding and availability of community health workers
- There is availability of infection prevention and control focal person and committee with risk assessment done. While Personal Protective Equipment (PPE) were available, there were observed inappropriate use of surgical mask and N-95 mask in many facilities
- There is a need for isolation center where patients that are seriously ill and need hospitalisation will be admitted
- Overall, patients were satisfied with the treatment they received

1. Introduction

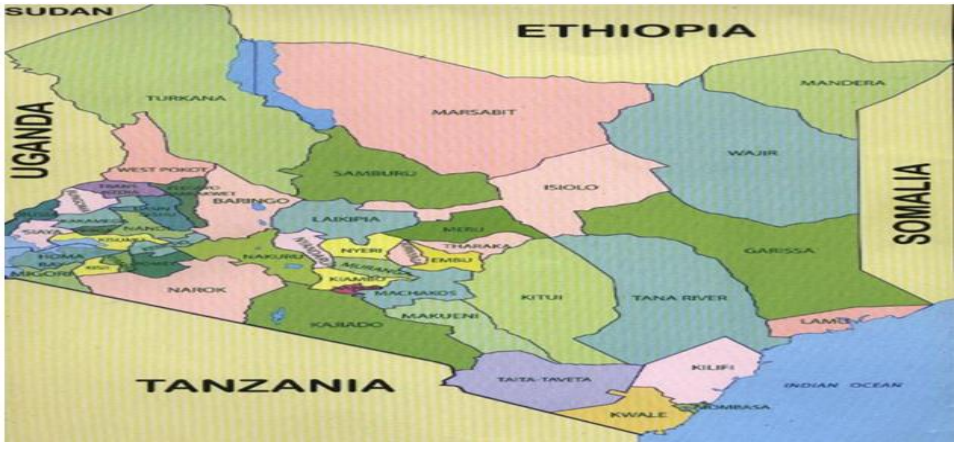
1.1. Country Demography

Kenya has made significant political, structural and economic reforms that have largely driven sustained economic growth, social development and political gains over the past decade (World Bank, 2018)[1]. Kenya political reform stemmed from the 2010 constitutional change that devolved county government. Kenya has 47 autonomously governed counties.

Table 1.1: Health and Socioeconomic statistics[2]

Total population (2016)	**48,000**
Gross national income per capita (PPP international $, 2013)	**2**
Life expectancy at birth m/f (years, 2016)	**64/69**
Probability of dying under five (per 1 000 live births, 0)	not available
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2016)	**256/184**
Total expenditure on health per capita (Intl $, 2014)	**169**
Total expenditure on health as % of GDP (2014)	**5.7**

Figure 1.1: Map of Kenya showing the counties



[1] World Bank. 2018: Kenya overview accessed 05/06/2018 10:54 http://www.worldbank.org/en/country/kenya/overview

[2] Global Health Observatory

1.2. Health care system

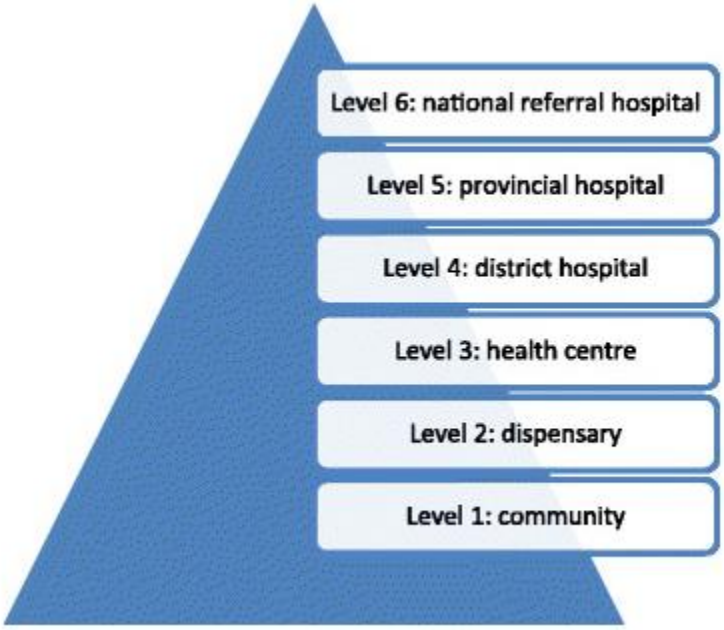
The Kenyan healthcare system operates as three subsystems, being the Public Sector, Commercial Private Sector, and Faith Based Organisations (FBOs). The Public Sector is the largest in terms of the number of healthcare facilities, followed by the Commercial Private Sector and the FBOs. Health financing is mixed and receives funds from taxation, the National Health Insurance Fund (NHIF), private health insurances, employer schemes, Community Based Health Financing (CBHF), user fees (out of pocket expenses), development partners and Non-Governmental Organisations (NGOs).

The government spending on healthcare is approximately 6% of GDP. Approximately 25% of the Kenyans are covered by a public, private or community-based health insurance scheme. Nevertheless, the amount of Out Of Pocket (OOP) spending remains high and poses a barrier to accessing healthcare[3]. According to World Health Organization (WHO) Global TB Report 18% of health funding is from domestic source, 41% international, 41% is still unfunded

In line with the devolution of functions into the 47 counties, in 2013, the public health services (primary and secondary level) moved from the national government and Ministry of Health (MOH) to the county governments. The National MOH function is guided by the Kenya Health Sector Strategic Plan (KHSSP) and now limited to providing support and technical guidance to the counties, managing partnership and regulating the health sector. The mandate of county governments is coordination, planning, and budgeting of control interventions at county level; assuring an uninterrupted supply of anti-TB, drugs and laboratory commodities; ensuring adherence to standards for TB diagnosis, care and treatment; acquisition and maintenance of health and non-health equipment; recording and reporting for TB surveillance; supportive supervision and on-the-job training to health facilities; TB infection prevention and control activities; and ACSM activities in the county. Division of Leprosy Tuberculosis and Lung Disease in the Ministry of Health is responsible for the TB programme in the country.

[3] Embassy of the Kingdom of the Netherlands in Nairobi, September, 2016: Kenyan Healthcare Sector: Market Study Report

Figure 1.2: Levels of health system in Kenya



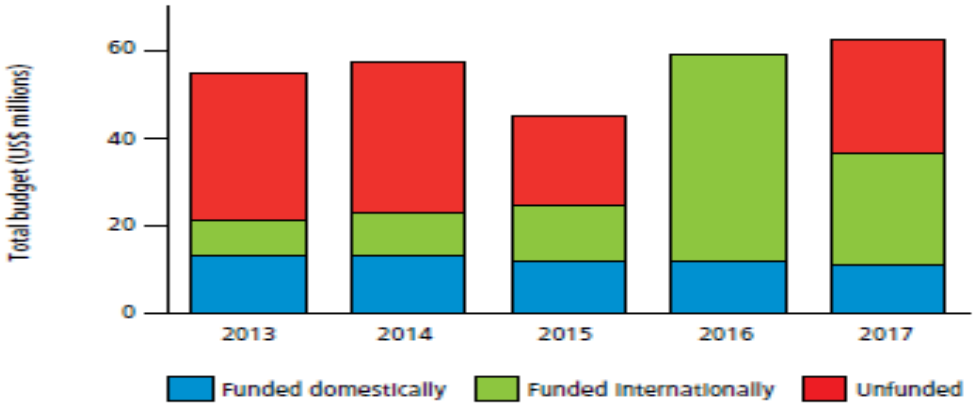
1.3. Private Public Mix

According to NTLD-P, Annual Report 2015, at the end of 2015, TB services were available in 2,280 public, NGO, and private health care facilities majority of which were treatment centers, there is a good partnership with the private sector (not for profit) with the faith based institutions supported in the provision of TB commodities, capacity building, technical assistance and quality assurance. Private for profit organisation also benefits by accessing high quality medicines whose prices are heavily negotiated by the TB program through Kenya Association for Prevention of TB and Lung Disease (KAPTLD). By 2015, 19% of all TB cases notified were managed in 743 private health facilities[4].

While the private sector was the source of 42% of initial care visits, only 20% of TB notifications came from the private sector in 2015. The PPA highlights a key gap in the country's private sector engagement. The informal sector, including pharmacies, is the initial point of care for 15% of presumptive TB patients[5].

[4] NTLD-P, Annual Report 2015
[5] NTLD-P, 2017, Using Patient-Pathway Analysis to inform a differentiated program response to TB: the case of Kenya

Figure 1.3: Kenya Health funding trends[6]



1.4. TB burden in Kenya

The country is among the 14 countries globally that are in all the three lists of high burden countries for TB, TB/HIV and MDR-TB[7]. The estimated incident for TB in the country is 348/100,000 pop, translating to about 169,000 TB cases occurring annually, the mortality rate (excludes HIV+TB) is 60/100,000 population.

TB notification for 2016 cohort indicated that 77,376 cases of TB were notified; this is significantly lower than the WHO estimated incident cases for Kenya for the same period. Therefore, there exists a high number of missing cases in the country. The 2016 TB prevalence survey indicated that the TB burden in Kenya is higher than previously estimated. The prevalence to case notification ratio is 3.5:1 translating to 40% missed cases annually[8]. The burden is higher in males, the HIV un-infected and those living in urban settings. Among the notified cases only 26% were tested with rapid diagnostics tools. Below is an overview of the case notification.

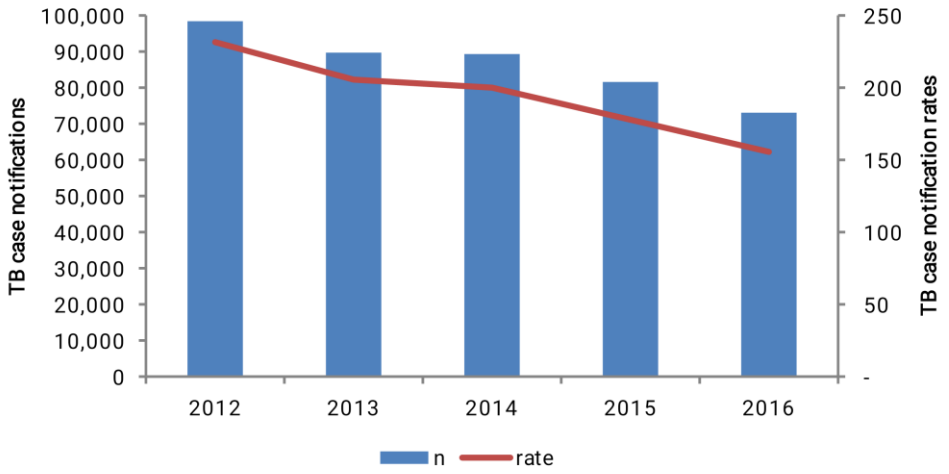
Table 1.2: TB case notifications, 2016

Total cases notified	77 376
Total new and relapse	76 335
— % tested with rapid diagnostics at time of diagnosis	26%
— % with known HIV status	96%
— % pulmonary	83%
— % bacteriologically confirmed among pulmonary	70%

[6] WHO Global TB Report 2017
[7] WHO Global TB Report 2017
[8] Kenya TB Prevalence survey 2016

The TB notification rate seem to be on a downward trend until 2016 when the case notification began to rise, however, the level of underreporting and under diagnosis has not been ascertained. This downward trend is inconsistent with the number of missing cases that exists.

Figure 1.4: National TB notifications and rates in Kenya 2012-2016



The Kenya TB programme recognized the problem of the missing cases and has put interventions in place and set new targets for the TB programme to improve performance.

Figure 1.5: Revised National targets for TB programme

TB/HIV Revised targets; Kenya,2017

Theme: Finding all the Missing TB Cases

Indicators	Targets
Case notification	**Increase case detection by 10% adults** **Children: 10% of cases notified**
Treatment Success Rate	• DS - 90% • DR TB – 80% • Cure rate – 90%
Xpert utilization rate	• 80% • No. of tests, denominator , and %
IPT uptake among < 5's	• Children : 1:1 • 80% of all PLWHIV
RR TB surveillance	• 50% New cases • 100% among all previously treated
HIV testing & ART uptake	100%
Health Care workers screening	50%
Time to treatment initiation	Sample collection to treatment initiation - target 2 days

1.5. Epidemiology of DR-TB in Kenya

Kenya is classified as a high burden MDR/RR-TB country and since the establishment of programmatic management of DR TB in the country in 2009, the proportion of cases notified and initiated on treatment has increased over the years. In 2013 Kenya changed from hospital based model of DR-TB management to ambulatory and community DR-TB care model. Kenya has a higher rate of MDR TB amongst the refugee population. In this population more than 70% of the TB patients notified have a history of previous TB treatment.

Table 1.3: Overview of DR-TB case finding

Drug-resistant TB care, 2016

	New cases	Previously treated cases	Total number[c]
Estimated MDR/RR-TB cases among notified pulmonary TB cases			1 300 (910–1 600)
Estimated % of TB cases with MDR/RR-TB	1.3% (0.68–1.9)	9.4% (8.7–10)	
% notified tested for rifampicin resistance	26%	42%	20 884
MDR/RR-TB cases tested for resistance to second-line drugs			204
Laboratory-confirmed cases			MDR/RR-TB: 326, XDR-TB: 9
Patients started on treatment[d]			MDR/RR-TB: 326, XDR-TB: 7

Treatment Success Rate for 2014 MDR/RR-TB cohort is 72% and the only XDR case that were managed over this period was also successfully treated.

1.5.1. National DR-TB Prevalence Survey

The Kenya fourth National DR-TB Prevalence Survey (DRS) was conducted between 2014 and 2015. The findings of this survey shows that the prevalence of multi-drug resistance tuberculosis in Kenya, from the findings of this survey, has been found to be lower than the WHO estimates for new and previously treated TB patients.

The MDR TB survey findings showed a prevalence of 0.67 (95% CI 0.2-1.1) among new cases and a prevalence of 2.0 (95% CI 0.2-3.9) for previously treated patients compared to the WHO Global Report, 2014, where an estimated 3.5% (95% CI: 2.2–4.7%) of new cases and 20.5% (95% CI: 13.6–27.5%) of previously treated cases had MDR-TB. This low level of MDR TB amongst both new and previously treated TB patients is not surprising. This is because Kenya has shown a steady but slow rise in MDR TB cases detected over the years as opposed to WHO estimates which have consistently been more

than three times the reported cases. The WHO estimates may have been based on inaccurate assumptions. Only 21% of the survey participants were infected with HIV[9].

Table 1.4: Overall result DR Survey

MDR-TB	
New = 0.7% (0.2-1.1)	Retreatment = 2.1% (2.1 - 3.9)
Rifampicin resistance	
New= 1.3% (0.8-2.0)	Retreatment = 5.2% (2.5-9.3)
Isoniazid resistance	
New =5.5% (4.5 – 6.7)	Retreatment = 6.7% (3.6-11.2)

1.7. Scope of the Rapid Assessment

Janssen pharmaceutical commissioned this rapid situational/gap analysis of DR-TB in both Kenya with the aim of identifying gaps that will inform intervention planning. The scope of the report of this rapid situational/gap analysis covers

- Epidemiological DR-TB data of Kenya focusing on case finding and outcomes.
- Design of health system
- Models of DR-TB care implemented in Kenya
- Mapping of DR-TB treatment facilities
- What are the applicable policies that drives implementation of DR-TB
- Monitoring and Evaluation mechanism

[9] Kenya National DRS 2014-2015

2. Methodology

This assessment was done using a mixed method approach. A desk review of policy, strategies and relevant documents was carried out with the aim of identifying relevant information that will help to inform the focus of the discussion and interview on the field, secondary analysis of programmatic data; including routine data, using the national, county and facility level data was done. Site visit and stakeholder interviews involving service providers, service users and partners were conducted. Furthermore, the key recommendations of the recently concluded 2017 report of Regional Green Light Committee (rGLC) were used for triangulation.

2.1. Sampling

Purposive Sampling of counties and facilities to be visited was carried out jointly by the NTLD-P and Optidel with the following guiding principles:

- Covering different counties with highest burden of DR-TB
- DR-TB facilities
- Community TB
- Laboratories
- Public Private Mix (treatment facilities and laboratory)

Table 2.1: Counties and facilities covered by the assessment

Counties	Facilities
Nairobi	National TB Reference Laboratory (NTRL)
	Kenya Medical Supply Agency(KEMSA)
	Shauri Moyo Clinic
	Bahati MDR TB Clinic
Meru	Consolata Mission Hospital
	Muthaara Subcounty Hospital
Mombasa	Mlaleo Health Centre
	Kongowea Health Centre
	Port Reitz Health Centre
Kisumu	Pandipieri-Faith Based Dispensary
	Jamamogi Oginga Odinga Teaching & Referral Hospital (JOOTRH)
Nakuru	Langalanga Sub-county Hospital
	Al Gadhir Center-Private
	Nakuru County Referral Hospital
	Bondeni Dispensary

2.2. Information management

The field visit helped to gather information to inform triangulation of data with the desk review report and other available sources. The field interviews and discussions were in line with the guideline for the Programmatic Management of Drug Resistant TB. Open ended interview and discussions were held with programme managers at national and county levels. Partners were given a template to help with the identification of funding gap.

The laboratory report of recently concluded GLC mission and programme review reports at national and sub-national levels were assessed to inform the desk review.

Collated data; mainly qualitative were analysed and validated by national team and partners.

Table 2.2: Data Collection process and guide

Source	Method	Respondent	Question guide
National	Document review, presentation data review and interview of DR-TB team and partners	Policy makers: National TB Programme staff	- Policy guiding PMDT - Pharmacovigilance-aDSM, ADR - Planning and Budgeting - Capacity and support structure - Roles and contributions of Partners supporting DR-TB - Social Protection - Short Regimen implementation - National Laboratory network GeneXpert roll out, specimen transportation - Referral network - TB Commodities including Drug - Key challenges
County and sub-county level	Document review, presentation data review and interview with TB control officers, DR-TB treatment sites and partners	County and sub-county level level staff	- Strategy for implementation of national policies - Gaps in implementation - Short term regimen implementation - Pharmacovigilance - aDSM, ADR - Partners support - Monitoring and Evaluation - Community DR-TB - Laboratory network and functionality GeneXpert roll out, specimen

			transportation - Referral network - TB Commodities including Drug - Key challenges
Service delivery level	Facility staff interview and discussion, document review, observation	Service providers	- Services provided - Patient flow/process mapping - Access to the facility - Referral system - laboratory and GeneXpert - Community DR-TB - Partners support - Human Resource Capacity - Information on capacity building - Monitoring and Evaluation - Key challenges
Patient Interview	Interview and discussion with patients	Patients (On admission and in the community)	- Client story on TB- Start of Symptoms till date - Social protection - Contact tracing - Access to services and Referrals - Patient perceived gaps
DR-TB data	Extraction of national Data for analysis, verification and validation	DR-TB Data	- Relevant data

2.3. Reporting

Validation and analysis was done with presentation of findings at the national level. Further analysis and synthesis of information took place in line with the scope of the assessment and key findings collated. The report was structured to address the key questions to be answered as stated in the scope of the assignment.

2.4. Limitations of the Review

- The inclusion of only few facilities through purposive sampling, did not allow for fully representative sampling
- The team acknowledge the possibility of recall bias in responses to the interview questions, especially when follow up questions were made. However, for interviews with service providers there were documentary evidence available to verify the information that were provided.

Nonetheless, the constraints and challenges highlighted were mitigated by triangulating information at all levels of care visited, detailed desk review of national level documents and programmatic data. This report was also validated with other reviews and assessment that were recently conducted in the country, hence, this situational/gap analysis is reflective of the current status of the DR-TB in Kenya.

3. Findings

The findings below are based on the synthesis of the field work interviews and observation, focused group discussion and the desk review of the following documents; most of which are used to inform the TB interventions in the country

a. National Strategic Plan on Tuberculosis, Leprosy and Lung Diseases 2015 – 2018,
b. GLC Report ,2017
c. Mid-Term Review of the National Tuberculosis Leprosy, Lung Disease Program of the Ministry of Health, Kenya, 2017
d. Epidemiological review in Kenya February 20-24, 2017
e. An Assessment of the Economic Burden Incurred by Tuberculosis Patients and Their Households in Kenya, 2017
f. Inventory Study: Under-Reporting of Sputum Smear-Positive Tuberculosis, Kenya 2015
g. NTLD-P, 2017, Using Patient-Pathway Analysis to inform a differentiated program response to TB: the case of Kenya
h. Adherence Study
i. Report on Data Assessment for Tuberculosis Key, Vulnerable and Underserved Population in Kenya
j. Report on Contribution of Community Health Volunteers in Referral of Tuberculosis Patients in Kenya

3.1. Political level

Tuberculosis poses a serious challenge to the government of Kenya and the management of this disease is the function of the National Tuberculosis Leprosy and Lung Disease Program (NTLD-P). The emergence of DR-TB also compounded the already existing problem. But over the years the government of Republic of Kenya has achieved many milestones in TB management.

The ministry of health ensured that the development of the new strategy was informed by local evidence by ensuring the implementation of numerous surveys and studies to inform intervention planning; of note are the DR-TB survey, TB prevalence survey, patient catastrophic cost survey, sustainability study, Inventory study and TB Epi analysis.

The DR-TB budgetary commitment is borne largely by partners, mainly the Global Fund and the USAID, these funding have limited geographical coverage and Government commitment needs to be made available to address the funding gap in line with the Universal Health Coverage vision.

3.2. Policy and system level overview

The country has moved rapidly in adopting many new and novel tools like the Short Term Regimen for MDR-TB, introduction of new drugs and GeneXpert in response to the WHO guidance. However, there has been obvious challenges that stands as barriers to implementation; most of these barriers are related to funding, implementation challenges; diagnostic coverage, specimen transportation, specimen retrieval and capacity building.

As indicated in the TB sustainability study, dwindling funding is a threat to any donor driven programme, the same goes for the DR-TB programme, the pace and the intervention coverage will be determined by the funding limitations. The challenge for the DR-TB programme is to bring to scale the interventions that are being implemented currently in a sustainable manner. A proper funding gap analysis will have to be carried outto inform future funding and investment case.

3.3. Service delivery

The following achievements had been a milestone in the management of DR-TB in Kenya since 1980. The achievement points to the fact that Kenya is an early adopter of new tools, evidence based approach, as well as, leading-edge technology

Table 3.1: Summary of major achievements

1980: The Government of Kenya launched the National TB Leprosy and Lung Disease program

1980-1998: Establishment and consolidation of the National Leprosy and Tuberculosis Control Programme (NLTP)

1984-1987

- In 1984 the first case of AIDS was diagnosed in Kenya
- In 1987 the Government of Kenya set up the national AIDS control programme (NASCOP) to address the HIV epidemic

1993-1998

- 1993: WHO launched the DOTS strategy for controlling TB
- 1993: Pilot programme using an eight-month regimen (2SRHZE/6TH) for smear-positive TB patients and a 12-month regimen (2STH/10TH) for smear-negative and extra-pulmonary TB patients.
- 1997: Nationwide expansion of TB short-course chemotherapy for new smear-positive pulmonary TB patients
- 1998: TB short-course chemotherapy introduced for new smear-negative and extra-pulmonary

cases

- 1994: Survey of HIV infection in smear-positive TB patients was carried out; in a sample of 1364 TB patients from 17 districts, the median prevalence of HIV was 36% (26−45%; interquartile range), but in some districts in Western Kenya, up to 80% of TB patients were HIV-positive

2003-2008

- 2003: National MDRTB TB surveillance
- 2008: Introduction of MDR TB treatment for first 40 patients in the public sector

2005-2006: Expansion Public Private Mix (PPMDOTS) initiative developed jointly by the Kenya Association for Prevention of Lung Diseases (KAPTLD) and the NLTP to five large and 20 rural districts in 2006.

2013: Operationalization of the devolved systems

2014-2015: 4th National Drug Resistance Survey

2015-2016: National Prevalence Survey

2017: Introduction of Short Term Regimen and new molecules for DR-TB

3.4. Model of PMDT

The DR-TB model of care is a hybrid of community and facility model; there are three existing variants of decentralised model that are implemented for DR-TB care in the country

a. Ambulatory community model; patient received drug from the community
b. Ambulatory facility; patient receive drugs at facilities
c. Facility base 'isolation'; DR-TB patients that require hospital care are hospitalised

The clinical care and programmatic management of the three models are linked to catchment health facilities.

Table 3.2: Model of Care by DR-TB Patients between 2013 - 2017.

Model of Care	Number	Percent
Missing	7	0.34%
Community Based	1341	65.41%
Facility Based	682	33.27%
Inpatient	20	0.98%
Grand Total	**2050**	**100.00%**

3.5. Funding Sources

The principal source of funding for DR-TB programme is Global Fund, and followed by the USAID through the TB ARC; a USAID funded NGO

There is also a clinical mentorship support provided by the Médecins Sans Frontières (MSF) for quality clinical management at the facility level especially in Nairobi County. There seems to be limited partners' engagement, dwindling funding[10], limited coverage and implementation challenges for DR-TB. However, there is a good coordination of partners with clear role definition expressed at all levels of government.

Table 3.3: Global Fund contribution to DR-TB programme in Kenya

Global Fund
Key Principal Recipients (PR): AMREF and the Ministry of Finance
Areas of Support • Diagnosis – GeneXpert, Culture, DST and LPA • Procurement of all second line medicines • Short Term Regimen for DR-TB • New molecules - Delamanid and Bedaquiline being introduced • Nutrition supplements • Monthly social support and National hospital social insurance fund (NHIF) for MDR-TB patients • Sputum transportation from peripheral sites • Green Light Committee technical assistance missions • Pharmacovigilance – trainings

3.6. Partnership

At the national level, there are two main partners supporting the DR-TB programme through funding from the GF and USAID. Partnership coordination is well organised with clear role definition

Partner coordination and role definition trickle down to the county levels: An example is the Mombasa county partner support overview below.

[10] NTLD-P, 2017, Sustainability Framework for TB Control in Kenya

Table 3.4: List of Stakeholders in DR-TB programme in Mombasa county

Partner	Support offered	Gaps identified
Centre for Health solutions(CHS)	• TB Supervision • TB County and sub county sensitizations • Quarterly TB Performance review meetings • Provision and maintenance of the county TB Tibu patient register	• Facility TB sensitizations • Monthly Data review meetings • School TB health awareness creation
Global fund	• Periodic TB trainings and sensitizations • Provision of laboratory diagnostic smear microscopy reagents-pert cartriges, N95 ETC • Social support for Dr-TB Patients(NHIF) • Monthly DR-TB Patient stipents-6000/- for transport to health facility and food support	• Big gap exists in Health care workers capacity building in TB • Community health volunteer support
Aphia pwani	• TB/HIV quarterly Technical working group meetings • DR-TB quarterly clinical review meetings • Gene xpert specimen networking	Monthly Sub county and Facility DR-TB clinical review meetings
KAPTLD	Private public partnership	Specimen transportation to x-pert sites from small private units

3.7. TB Laboratory Network

Kenya has an elaborate network of microscopy and GeneXpert laboratories distributed countrywide to perform smear microscopy and GeneXpert tests respectively. In 2015, there were 2,172 public microscopy centres and 651 laboratories engaged in TB Diagnosis in the private sector and 126 Gene Xpert testing sites in the public sector and 5 in the private sector. The National Tuberculosis Reference Laboratory (NTRL) supports the co-ordination of EQA for all sites. More than 85% of the laboratories were

participating in the national EQA[11]. By 2015, Kenya had 3 public laboratories conducting culture and DST and 5 laboratories conducting Line Probe Assay (NTRL, Aga Khan, CDC Kemri Kisian, EDARP and Nairobi Hospital).

The findings below emanate from the interview of the staff of the National Tuberculosis Reference Laboratory (NTRL); the apex TB laboratory in the country.

The following challenges were identified:

- Sputum transportation
    - Delay in reaching laboratory
    - Optimum transportation condition not maintained (temperature).
    - Packaging and filling of laboratory forms not appropriately done
    - High contamination rate
    - Increasing rejection rate (currently at 6%)
    - Different models of specimen transportation
- Linkage with programme is weak auto-alert not being done. Communication of results is through e-mail and sometimes not received by the health facilities due to various challenges; no dedicated e-mail for retrieval of results, sometimes clinician's private e-mails are used and it poses a problem after disengagement of clinician's service with that facility
- MGIT has no back-up UPS in case of power outage, the transition to a power generating set causes loss of specimen under processing
- There is a need for relevant DR-TB training in order to appreciate the programmatic challenges facing the DR-TB programme and also capacity building on active Drug Safety Monitoring (aDSM)
- There is an increasing Quality concern with discordant result between GeneXpert and LPA results
- Need for revision of laboratory SOPs and Guidelines to reflect the current developments in new tools and regimen
- Laboratory Information System not consistent with changing algorithm
- The laboratory software platform (Labware) not linked to the TB surveillance system (TIBU) for data triangulation

3.8. Specimen transport

The approach to specimen transport is not consistently done; the follow up blood tests are supposed to be transported by Lancet Laboratory through a USAID (TB ARC) funded project. This arrangement is limited only to TB ARC geographical coverage sites.

[11] NTLD-P, Annual Report, 2015

Facilities that are not in this coverage area are left to seek an alternative mode of specimen transport.

Healthcare workers have tried to find a way around transporting these specimens with some challenges:

- Staff sometimes batches and transport samples under suboptimal condition and sometimes protocol for transporting hazardous substance are not followed
- Sometimes the DR-TB staff tries to use the HIV viral load sample transport system but not always successful, because this arrangement is not covered by the NGO that transports viral load as part of their responsibilities

There are significant delays and quality issues that arises from the challenges of specimen transportation.

3.9. Diagnosis

The timing of diagnosis is done appropriately as indicated in the clinical protocol. However, the use of the results for follow up management of the patient is compromised because of challenges of result transportation and retrieval.
The country has adopted GeneXpert as the first line of diagnosis for presumptive TB cases, but currently, there is no 100% coverage. A lot of patients are presently diagnosed with smear microscopy without undergoing a resistance testing.
The following challenges were identified

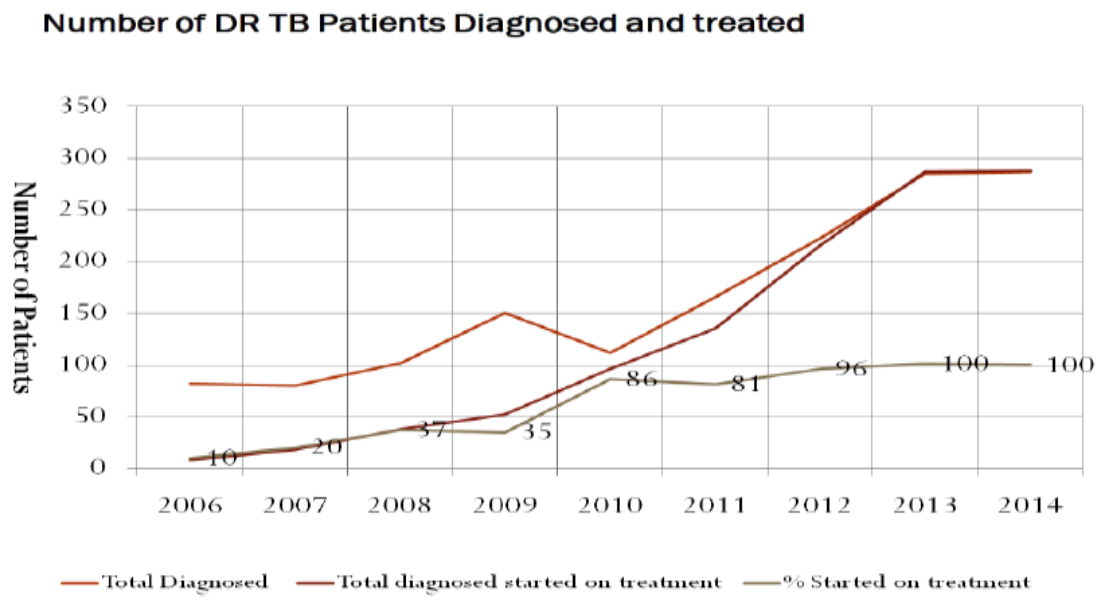
- GeneXpert functionality compromised by:
    - Poor network availability for sending results in some areas
    - A high volume facility visited has no printer, hence, results are handwritten and error prone (it was indicated that positive result had been mis-captured as negative result in the past)
    - Non-functional GeneXpert Modules; even though some facilities have four modules GeneXpert machines, it is common for some of the modules not to be working or failed calibration leading to delay and compromised quality of results.
- A disconnect between the national utilization rate of GeneXpert and the facility reality was observed specifically in Bahati clinic.
    - It was observed that Bahati clinic with about 40 clinics as a GeneXpert catchment area have a huge specimen backlog that has to be dealt with. In order to deal with these specimen backlog, the facilities classified some samples to be a high risk and are prioritised for prompt testing. The catchment clinic swere told to batch samples for a month before sending to the clinic for GeneXpert tests. Even though this was not a consistent finding in the other

counties visited, it was indicated to be the current situation in some facilities within Nairobi county

- The clinic also has one of the four modules of the GeneXpert not working

- Line Probe Assay results are delayed and sometimes this compromised clinical care, some facilities presented patients that have waited for more than 3 months for LPA result. Furthermore, the non-availability of the LPA 2 results might lead to poor clinical management of patients because there is no quick evidence of resistance to second line medicines
- Culture and DST results experience a very long delay of up to 8 months and sometimes was never retrieved in the course of the management of the patient. This challenges occurs more in two of the assessed counties outside of Nairobi i.e. Meru and Nakuru Counties
- Childhood DR-TB diagnosis challenges still occur as a result of problem with diagnosis ranging from inability to collect samples to access to X-ray in some public facilities. X-ray has to be paid for by the clients before a refund can be requested.

Figure 3.1: DR-TB cases diagnosed and put on treatment



3.10. Treatment monitoring capacity

The clinical management of patients is commendable in terms of choosing the right regimen and requesting the right clinical test in line with the national protocol. However, there seems to be an issue in the programme Adverse Drug Reaction monitoring as well as ECG and X-ray testing.

a) Audiometry, ECG and X-ray testing
    - Services not universally available
    - Where available, mostly, not in full functional condition
        - Some audiometry testing centers are very close to high noise zone and compromises the quality of the test, these facilities have no sound-proof room for audiometry testing and TB ARC comparative testing of quality of audiometry testing between two centers using same patient recorded a highly discordant result for the patient
    - It is a universal practice for Patient/ staff to sometimes pay for X-ray, ECG wherever services are not available in public sector. Refund mechanism for tests is "Use your money, pay later even though I don't know when" as indicated by a staff at sub county level.
        - The field staff seems not to fully understand the refund procedures that sometimes served as a barrier to accessing these tests and compromises quality of DR-TB care
        - Some end up not doing the test because of the inability to pay
    - Access
        - Audiometry tests are done by the ENT specialist only in a centralised location and requires long booking in some instances
        - ECG and X-Ray are sometimes only available in private facilities in some counties
    - Capacity of staff on understanding and interpreting the audiometry result is very limited e.g. understanding between sensorineural and conductive hearing impairments. This affected case management in one of the facilities visited where a conductive hearing loss was interpreted to be an indication for switching therapy
        - The inconsistency in the reporting format for the audiometry test is also a big challenge for healthcare workers. The format of reporting varies depending on where the test was done
        - Sometimes there is no follow up test result because of access issues

b) Baseline and follow up laboratory tests
    - Sometimes staff demonstrates low capacity on interpreting results

- Led to cases of wrong clinical management decision

c) Pharmacovigilance and ADR monitoring
   - This is a major challenge across the board
   - There seems to be a lot of patients that have experienced ototoxic effect from the injectable, even though audiometry testing is part of the baseline tests, the implementation is with many challenges in terms of accessibility and timeliness. There is also no provision of hearing aid for patients with hearing loss in the programme plan. A staff captured this by saying "It is cured but deaf intervention"
   - Lack of training on pharmacovigilance was expressed across the facilities
   - Reporting inconsistency and not in line with WHO standard especially for aDSM for the introduction of new drugs
   - Hearing loss; no hearing aid provision for patients that lost their hearing as a result of Second Line injectable

3.11. DRTB Clinical Review Committees

The national guideline clearly spells out the role of the clinical review committees in maintaining the quality of care and oversight of the clinical management of DRTB patients. The best practise is in MSF supported Nairobi County.

The constitution and implementation is not consistent all across the counties. Oversight is lacking in some sites with resultant amplification of resistance over months of wrong choices of regimen e.g. Patients with baseline Hearing loss placed on kanamycin etc.

- Apart from the Nairobi county where MSF is providing clinical mentorship support there is an inconsistent implementation in line with the clinical committee meeting checklist tool developed by the national, the efficiency decreases at sub county level
- Reason for non-functionality given as lack of capacity of technical committee members to clearly identify their roles in the management of DR-TB
- Partners support seems to be key a contributing factor in successful conveyance

3.12. Contact tracing

Overall, contact tracing effort is weak and dependent on the funding and availability of community health workers. The community health workers are usually linked to health facilities, but, a few of the facilities visited do not have community health workers linked to them and the facility staff use their own resources to carry out contact tracing and

patient tracking. This is done at the instance of absence from the facility during the time of community visit.

3.13. Infection Prevention and control

The facilities assessed have infection prevention and control focal person and committee in place, all of them indicated that risk assessment were done. Windows are opened and most facilities have a waiting area that are with free flow of hair. There are some instances where there are infrastructural challenges as a barrier in optimising the infection prevention and control practises in facilities, rearrangement of sitting position could have helped. Two facilities that would benefit from further support on IPC are Consolata Hospital patient waiting area; Registration hall and TB room of Bondeni dispensary, Nakuru.

Personal Protective Equipment (PPE) availability was evident in almost all facilities except in Langalanga sub-county hospital where N-95 mask was in shortage. In the same facility, there is also no biosafety cabinet. Also observed in some facilities is the inappropriate use of N-95 by DR-TB patient instead of the surgical face mask; IPC capacity development will be required to strengthen the implementation of IPC.

Healthcare worker screening is not consistently done in line with the national protocol that recommended twice a year. In some instances, even when done it is not documented and it is at the private request of healthcare worker that feels that there has been a risky exposure.

Household IPC seems to be weak and this needs strengthening in order not to perpetuate community transmission as a result of the decentralised management of DR-TB.

3.14. Isolation facilities/Palliative care

In line with the previous recommendation of the GLC mission, the country is urged to expedite the renovation of the isolation unit at Kenyatta National hospital (KNH) and establishment of the centres of excellence which are much needed to start in-patient care for seriously ill DR-TB patients. This gap analysis also corroborated a need for well-equipped isolation centers in the counties.

The facilities visited indicated a need to have a place where patients that are seriously ill and need hospitalisation will be admitted. We visited a proposed building that had been identified by the management of Jaramogi Oginga Odinga Teaching & Referral Hospital; this facility had been upgraded by the CDC and will benefit from an assessment by the national team as one of the possible isolation wards.

The GLC mission report indicated that the "NTLD-P is working with counties to increase the capacity for decentralized admission of ill DR-TB patients; 3 counties have confirmed their commitment. The NTLD-P is requesting external support for this process. There are currently 34 inpatient beds at 3 sites (Homa Bay, MTRH, and KNH)".

The KNH Isolation center experiences similar challenges that are common to all assessed facilities, this includes ADR management, use of staff money to pay for patients tests, delay in culture result. The following peculiar challenges also occurs at KNH:

- Stigma associated with working in the isolation ward; this was made worse by the death of a nurse that was infected with DR-TB just two months before visiting the hospital, although this nurse was not a staff of the isolation ward
- Isolation center exists with a lack of facility to refer patients that require palliative care
- Inability of the county facilities to follow up on patients that are discharged from isolation ward. The staff indicated that "once they get out of the door after discharge they go bad again"
- Isolation with only bed and no entertainment e.g. Television in isolation rooms (see annexure)
- A need to develop the capacity of the consultants on DR-TB as well, some consultants have no knowledge of DR-TB management and this affects the management of patients
- The isolation staff also require trainings that is specific for management of isolation center of this type
- The staff in this center are often exempted from the county focussed trainings because they are counted as national and not part of Nairobi county
- ADR reporting is done without any feedback

It is also of note that the only doctor that manages the hospital is trained by Janssen in South Africa and advocated for this level of training for other colleagues as well. This center also could be used as one of the centers of excellence for the management of DR-TB in Kenya.

3.15. Social support

In Kenya, the Ministry of East Africa Community (EAC), Labour, and social protection coordinates a safety net programme that disburses KES 2000.00 per month to eligible individuals like the elderly, people with disabilities. In addition, the National Tuberculosis Leprosy and Lung Disease Program (NTLD-P) operates a Global Fund

supported TB specific cash transfer programme that disburses KES 6000 to all DR-TB patients enrolled on treatment[12].

These programme is implemented across the board and in some cases with nutritional support for eligible patients with low or borderline Body Mass Index (BMI). There are access challenges that were observed at the facility level; some of the eligible patients could not access the social support services because of the loss or lack of their identity documents.

Patients also indicated that this social support service is very useful and helps them to meet some of their nutritional and transport needs. It was also observed by the healthcare workers that this helps to strengthen adherence to treatment

3.16. DR-TB Capacity Building

"I am learning on the job" a response of a staff managing two Pre-XDR cases

Following the findings of these gap analysis the following trainings are crucial for the success of the DR-TB care in the country:

- Overwhelming numbers of staff managing the DR-TB patients have not been comprehensively trained on DR-TB management; some indicate that the only training they received is the sensitisation training on STR
- Training audit to ascertain the training need of all categories of staff at the county, sub-county levels is needed
    - Physician, paediatricians, pharmacists, medical officers, clinical officers, nurses e.t.c.
    - This training should also cascade down to the level of community health workers
- There is no identifiable center of excellence for the DR-TB management that can serve as capacity building hubs; this was part of the plan that was not carried out in the last Strategic Plan
- IPC training is also a need for all levels of staff; this can be presented as part of a comprehensive DR-TB training package
- DR-TB clinical and programme management training is needed to also address issues of reporting and using data to inform decision making

3.17. Drug supply system and supply chain management

The Kenya Medical Supply Authority (KEMSA) is responsible for the drug supply chain management in Kenya. The body is responsible for the distribution of medicines to

[12] The First Kenya Tuberculosis Patient cost survey 2017

facilities in the country. However, the TB programme medicine distribution is run in parallel and does not do directly to the facilities but to the sub-county stores.

There has been no stock out of medication and any TB commodity in the last one year. There is also no issue of drug expiration. There seems to be a process underway to streamline the TB and KEMSA distribution line for better efficiency and coordination like all other medicines.

3.18. Patients issues

In the course of the assessments patients on treatment were presented in all health facilities visited and key challenges observed were discussed with the facility team and both quality of clinical and programmatic management were assessed.

Overall there is a good effort to adhere to the clinical protocol and national guidelines, however, deviation occurred in some cases where test results retrieval was a challenge. Patients were managed with results of specimen that were taken over 4 months ago in some cases.

Patients that were interviewed were satisfied with the treatment they are receiving but some are confused about why they are not receiving a STR of 9 months regimen rather that the long conventional regimen. It also emerged that more need to be done in patient pre-treatment counselling in order for the patients to be informed of the possible side effects of medication.

It was also observed that a lot of patient education and DOT supporter counselling will be important to improve patient adherence to medication; a particular DOT supporter was noticed to have been discouraging patient from continuing with medication in one of the sites.

Concern was also raised about the coverage of the social support coverage; a case of a mother gets a social support and use it to feed her child came up in one of the clinical audit meeting. An SOP might be necessary to define eligibility for additional social support in special cases; there will be a need to agree on criteria for inclusion and requesting modalities.

4. SWOT Analysis of DR-TB Programme

Strength	Weakness
• Early adopter of international standard • Conduct of relevant survey and studies to inform policy • National Strategic Plan is available • Policies and guidelines available and up to date • Committed national, county and facility staff • Adoption of GeneXpert as first line of diagnostics • Establishment of TB and DR-TB surveillance system • Introduction of new molecules and STR • Establishment of clinic audit committee for quality check • Strong and efficient social support system • Effective drug supply and supply chain management • Good clinical management	• Funding is donor driven • Diagnostic: specimen movement challenges • Delay in test result retrieval • Access to ECG and X-Ray – out of pocket payment for services • Patient pretreatment education • DR-TB Capacity building • Inadequate isolation center for DR-TB patients that needs hospitalization • Sub-optimal Infection Prevention and Control • Contact tracing not consistently done in all facilities • Clinical committee effective in some counties and not in others • Pharmacovigilance and Adverse Drug Reaction reporting and feedback
Opportunity	**Threat**
• Strong partner support (GF and USAID) • Strong local research and context settings for adoption of international standards • Strong IT infrastructure in country • Strong private health institutions	• Dwindling donor funding

4.1. Conclusion

The DR-TB programme has a lot of strengths as well as weaknesses. There are also a lot of opportunities that can be taken to move the programme forward. However, the major threat to the programme is the dwindling donor funding. An attention to these will help in strengthening the DR-TB programme.

5. Priority Gaps

The gap analysis of the Kenya DR-TB programme brought out many issues that will need urgent attention, however, the following are considered to be the priority gaps that can be seriously considered for support:

1. Strengthening specimen transportation and result retrieval across the board
2. Relook into the placement model of GeneXpert to address rejection in some centers, as well as, strengthen maintenance of the tool to improve functionality
3. Build the Capacity of all categories of staff on DR-TB management, IPC and pharmacovigilance to improve quality of DR-TB care
4. Establishment of more isolation centers for hospitalization of DR-TB patients that are eligible for admission
5. Decentralize audiometry testing and consider task shifting of test services, ensure quality and standardize report template- South Africa model can be benchmarked
6. Establish centers of excellence for DR-TB in line with the National Strategic Plan; these will also serve as training hub for the programme
7. Improve access to ECG and X-ray testing to improve the quality of DR-TB care
8. Strengthen the contact tracing approach nationally for improved efficiency
9. Provide mentorship support to the clinical review committees at county and sub-county level in order to improve the quality of DR-TB care

6. Annex

	Partners working on Global Fund Grant
MOH	Division, NTLDP, NASCOP, Antimicrobial resistance task force, Min. of Culture and social protection
Development partners	CDC, USAID, GF, TB ARC, WHO,World Bank,
Implementing partners	MSF, CHS-TEGEMEZA, MSH, KEMSA,KAPTLD, AMREF, CHAK , IOM, APHIA-plus, private labs
	Senate and Health committees, Parliamentary Health Committee, CoG, County teams, CDH, CECs, County Tb coordinators
Learning institutions	UoN, Moi, Aga Khan, KMTC
Associations	KMA,KPA, COC,KHF (Kenya Health Federation), Kenya Hospice Association,
Regulatory bodies	PPB, KMPDB, KNRHC,
CSO	Stop TB Partnership, KELIN
Patients reps.	
Others	NHIF, HSS, Prisons, communication bodies, congregate settings, FEKE,