

REPUBLIC OF KENYA



MINISTRY OF HEALTH

Guidelines for Public -Private Partnership for TB Prevention and Care in Kenya



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FOREWORD



Tuberculosis (TB) is a disease of major public health concern in Kenya. It is the fourth leading cause of death, presenting an enormous economic burden to the nation and negatively impacting the lives of its citizens. In the last two decades, Kenya has made significant investments aimed at achieving a satisfactory level of TB control. The End TB Strategy which is the vehicle expected to lead to the achievement of the health related targets of the Sustainable Development Goals emphasizes building strong linkages with all health care providers. The non state or private health care sector is an important player in the delivery of health services in Kenya and ranges from unlicensed informal providers to large health institutions that offer state of the art health care services. This sector offers numerous opportunities for advancing public health gains in TB prevention and care due to its vibrant, always growing and competitive nature that can be utilized to enhance access and quality of TB prevention and care services.

The TB Patient Pathway Analysis conducted in Kenya in 2016 showed that 27% of TB patients initiated on care sought services in the formal private sector and 15% went to the informal

health providers. The study recommends greater engagement of the formal and informal private sector as a critical strategy to finding the missed TB cases. In addition, a large proportion of private health care providers, including those highly qualified, adopt diagnostic and treatment approaches for TB that are at variance with recommended international and national standards. This has the potential to lead to errors in TB case management which in turn could lead to the generation of Drug Resistant TB (DRTB).

The Kenya Tuberculosis Prevalance Survey 2016 reported a much higher prevalence of TB than previously estimated. It recommends engaging the private sector as one of the key strategies to provide a robust response that will ensure that no TB cases go undetected and untreated. These guidelines are therefore developed to foster better, stronger and sustainable partnerships between the public and the private health sector and reflect the GoK's commitment to ensuring that quality TB services are made available to all Kenyans irrespective of the sector they seek care. It is my hope that this guidance will provide the much needed framework and impetus to engage all private sector players and end TB by 2030.

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PREFACE

Kenya's TB disease burden is alarmingly high. From about 1990 there was an exponential growth in the absolute numbers of TB cases notified to the National Tuberculosis Leprosy and Lung Disease Program (NTLD-P) until 2007 when a "peak" was reached. The TB case notification rate (CNR) increased from about 50 per 100,000 population in 1990 to peak at 320 per 100,000 in 2007 and has been gradually declining since then. However, according to Kenya National prevalence Survey 2016 the actual epidemic of TB is much larger at 558 per 100,000. Of the many drivers of the large TB disease burden in Kenya, the continuing HIV epidemic has been the most important. The HIV epidemic evolved rapidly following the identification of the first case of HIV disease in 1984 and by the mid nineties estimates of HIV infection prevalence rate in the adult population between the age of 15 and 49 years were hitting 14% or so after which it has declined by more than 40% to reach 6.7% to 6.0 % (Kenya HIV estimates 2016). This number implies that a large proportion of the Kenyan population still remain vulnerable getting infected with TB. There is however, a ray of hope. The adoption of the 'test and treat' will further accelerate the access to life saving ART and hence TB prevention.

The HIV epidemic is however, not the only driver of the TB epidemic. According to the Kenya National TB Prevalence Survey 2016, 83% of all prevalent cases are HIV negative. To further reduce the burden of TB, measures aimed at tackling the other drivers of TB such as poverty and its consequences (malnutrition, poor access to health services, overcrowded living and sometimes poor working conditions), tobacco smoking , diabetes mellitus, excess alcohol consumption and substance abuse would also need to be intensified. This requires us to building partnerships across all sectors.

Kenya has built a strong national TB control programme with nationwide decentralization of TB services and integration into community health services . This crusade against TB may

however, be threatened if the private sector is not engaged. It is with this in mind that pillar 3 of WHO's End TB strategy supports the engagement of all care providers with use standardized evidence based and internationally accepted approaches to TB prevention, care and control. These guidelines have been developed to promote, scale up and enhance the quality of the public –private mix approach for TB prevention, care and support in Kenya. It is hoped that staff at all levels of the NTLD-P, technical and funding partners and the wide array of non-state health care providers will find these guidelines not only appropriate but will use them to enhance the scope and quality of PPM in Kenya.

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LIST OF ABBREVIATIONS

ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immunodeficiency Syndrome
ART	Anti Retroviral Therapy
CB-DOTS	Community Based Direct Observed Thearapy
CBO	Community Based Organization
CDC	Centres for Disease Control and Prevention (United Sates of America)
CDR	Case Detection Rate
CHAK	Christian Heath Association of Kenya
CPT	Cotrimoxazole Preventive Therapy
CRL	Central Reference (TB) Laboratory
CTLCS	County TB and Leprosy Coordinators
DOT	Directly Observed Therapy
DOTS	Directly Observed Therapy Short Course
DR TB	Drug Resistant Tuberculosis
DST	Drug Susceptibility Testing
E	Ethambutol
EPTB	Extra-pulmonary Tuberculosis
EQA	External Quality Assurance
FBOs	Faith Based Organizations
FDC	Fixed Dose (Drug) Combination
GDF	Global Drug Facility
GFATM	Global Fund to Fight AIDS, TB and Malaria
GoK	Government of Kenya
H	Isoniazid

HBC	Home Based Care
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HR	Human Resource
IC	Infection (TB) Control
ICF	Intensified TB Case Finding
IPT	Isoniazid Preventive Therapy
ISTC	International Standards for Tuberculosis Care
IUATLD	International Union Against TB and Lung Diseases (UNION)
KAPTLD	Kenya Association for the Prevention of Tuberculosis and Lung Diseases
KCOA	Kenya clinical officers association
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KEPH	Kenya Essential Package of Health
KMA	Kenya medical association
KPA	Kenya pediatric association
KPHA	Kenya public health association
LIPA	Line Probe Assay
M.tb	Mycobacterium tuberculosis
MDGs	Millennium Development Goals
MDRTB	Multi – Drug Resistant TB
MGIT	Mycobacterium Growth Inhibitor Tube
MOMS	Ministry of Medical Services
NASCOP	National Aids and Sexually Transmitted Diseases Control Program

NGO	Non Governmental Organization
NHSSP	National Health Sector Strategic Plan
NTLLP	National Tuberculosis Leprosy and Lung Diseases Program
NTLP	National Tuberculosis and Leprosy Programme
PAs	Professional Associations
PDAs	Personal Data Assistants
PEPFAR	Presidential Emergency Plan for AIDS Relief
PLWHA	Patient Living With HIV/AIDs
PPM	Public Private Mix for TB Care and Control
PSK	Pharmaceutical Society of Kenya
PTB	Pulmonary Tuberculosis
R	Rifampicin
S	Streptomycin
SCTLCs	Sub- county TB and Leprosy coordinators
SCTLCs	Sub county TB and Leprosy Coordinators
TB	Tuberculosis
WHO	World Health Organization
XDRTB	Extensive Drug Resistant Tuberculosis
Z	Pyrazinamide

EXECUTIVE SUMMARY

In 2016, Kenya was placed by the World Health Organization (WHO) in the lists of countries with a high absolute or per capita burden of TB, TB/HIV and Drug Resistant Tuberculosis. This is despite of the vigorous pursuance of recommended strategies for the care and prevention of TB in the last 2 decades with great progress has being made especially to reduce the burden of HIV associated TB, through succesfull implementation of the TB/HIV collaborative activities. Unfortunately, the emergence of drug resistant TB (DRTB) in the last decade has complicated the public health response considering its lengthy,expesnsive,toxic and often less successful treatment.

While in the last decade Kenya appeared to be on track to achieve recommended TB care and prevention targets, with a high estimated TB treatment coverage (formerly case detection rate (CDR) and treatment success rate (TSR), the results of the recently the just completed national TB disease prevalence survey and drug resistance survey suggests that the proportion of incident TB and MDR-TB cases that remain undiagnosed and untreated is unacceptably high at 55% and 67% respectively. It implies that Kenya may be very off track to achieve the target to end TB as a public health threat by 2030 and calls for a paradigm shift in the way responses to the TB epidemic are planned and implemented in the country in line with the End TB Strategy.

Though Kenya has been implementing public-private partnership initiatives over the past 15 years, several gaps have emerged in the approach. First, the engagement has been limited to the hospitals and clinicians in urban areas leaving out the informal private health sector and private chemists. According to the patient pathway analysis the informal private providers are an important part of the TB patient pathway provide initial point of care of about 15% of all persons with presumptive TB. Second, the involvement of the formal private in TB care and prevention has not been desirably optimized according to the patient pathway analysis. Many

private sector players still lack access to TB diagnosis and treatment; 40% of initial care visits for TB occur in the private sector, yet in 2015 the sector accounted for only 20% of TB notifications.

These guidelines have therefore been developed to accelerate the scale up of PPM across the whole country, in addition to supporting DRTB prevention, diagnosis and treatment within the private health sector. Moreover, these guidelines support and emphasize the engagement of non-formal private health care providers, private laboratories and private chemists in TB prevention, diagnosis and treatment. They will enable the private health providers to offer essential public health related activities such as screening, diagnosis, treatment, referral, case recording, reporting and contact investigation. In addition, they will support the private health providers integrate TB prevention, diagnosis and treatment in other existing health services like maternal and child health, HIV, non-communicable diseases in line with the End TB Strategy.

The development of these guidelines involved a lot of consultative meetings as well as evidence review from local findings. The guidelines are therefore expected to be a living document and will be updated as more experience and new knowledge is gained.

This document is intended to be used by private health care providers, TB and HIV care and control officers of National and County Government, health partner organizations, the Civil Society and TB communities to provide guidance towards planning, implementation, scale-up and monitoring of PPM action plans interventions.

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CHAPTER 1: INTRODUCTION

1.1 Background

Kenya has a total population of 45 million constituting 49.6% men and 50.4% women. Majority of the population is rural (67.7%) while 32.3% live in urban settlements. An estimated 61% of the population comprise of young people below the age of 24 year. Nairobi, the capital city, is the main urban area with a population of over 3 million people. Kenya is a lower-middle income country with a per capita gross national income (GNI) of \$1,340. Health accounts for 8% of the total expenditures. The country has an estimated 45.6% of population below poverty line¹. The second pillar of the End TB Strategy provides for engagement of all care providers- public, voluntary, private or coropoarte private care providers. This will among other things ensure all patients are notified, high quality TB care provided by both formal and informal providers, workplace TB programs are implemented, quality assurance of tests performed in private laboratories and quality TB medicines are dispensed by all providers.

The private health sector in Kenya contributes over 50%² of all health care provided in the country. Tuberculosis patient care pathway analysis revealed that a significant proportion of TB patients, ranging from 25% in the previous North Eastern Province to about 51% in Nairobi first visit a private health provider when they become ill. The non-state health care sector comprises of both the not for-profit and for-profit health care providers. The not for-profit health care providers include health care facilities owned by Non-Governmental Organizations (NGOs) and Faith Based Organizations (FBOs). The for-profit or self-financing include a wide range of formal and informal providers. In a well-functioning PPM effort, all these health care

¹ Kenya National Bureau of Statistics 2009/2015 projection; World Bank 2015

² National Health Sector Strategic Plan (NHSSP II)

providers should be networked through the Public–Private Mix approach to contribute to the national response to TB.

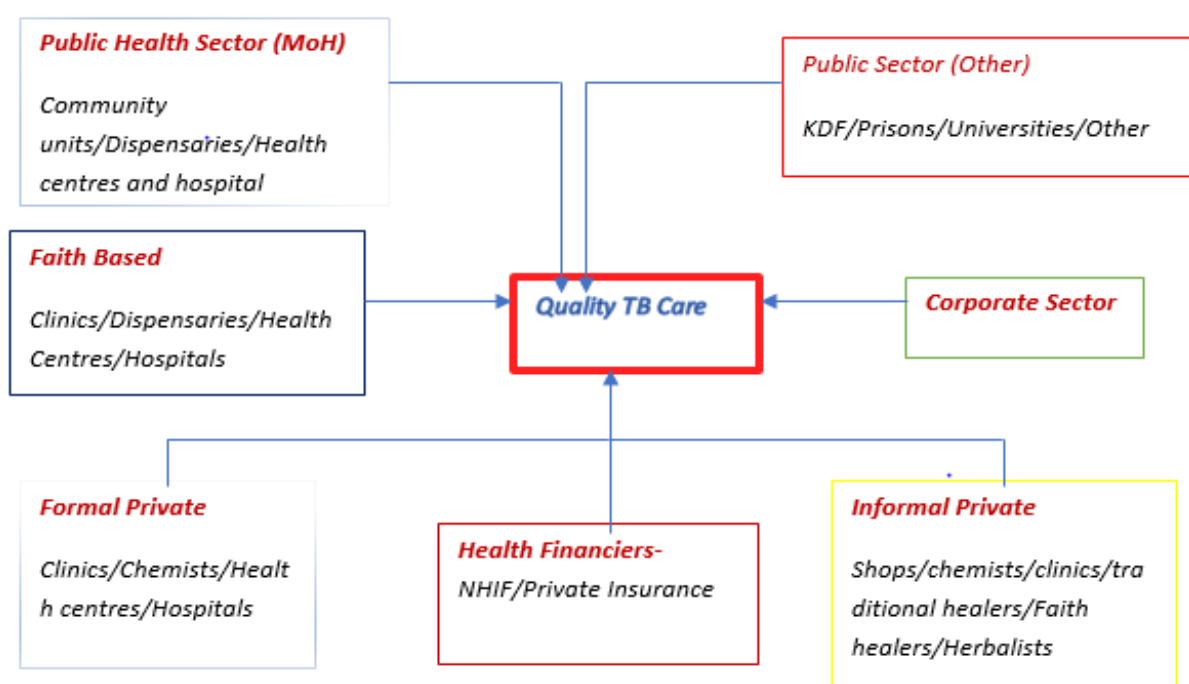


Figure 1: The array of health care service providers in Kenya: working together for quality TB care

1.2 Tuberculosis and HIV/AIDs in Kenya

Tuberculosis is the 4th leading cause of mortality in Kenya³. Kenya is classified as a TB, TB/HIV and MDR-TB high burden country⁴. According to the Kenya Prevalance Survey, an estimated 169,000 people fell ill with TB in Kenya in 2016, only 77,376 of them were diagnosed and put on treatment. In addition, an estimated 1300 fell ill with DR-TB with only 428 of them diagnosed and put on treatment. This represents 54% and 67% of the people with TB and MDR-TB who remain undiagnosed and untreated every year.

³ Kenya Health Policy (2014-2030)

⁴ WHO Global TB Report 2016

Between 2012 and 2016 TB case notification declined on average by 6% annually - from 98,400 to 73,066 with the biggest decrease (10.4%) in 2016 (fig 2).

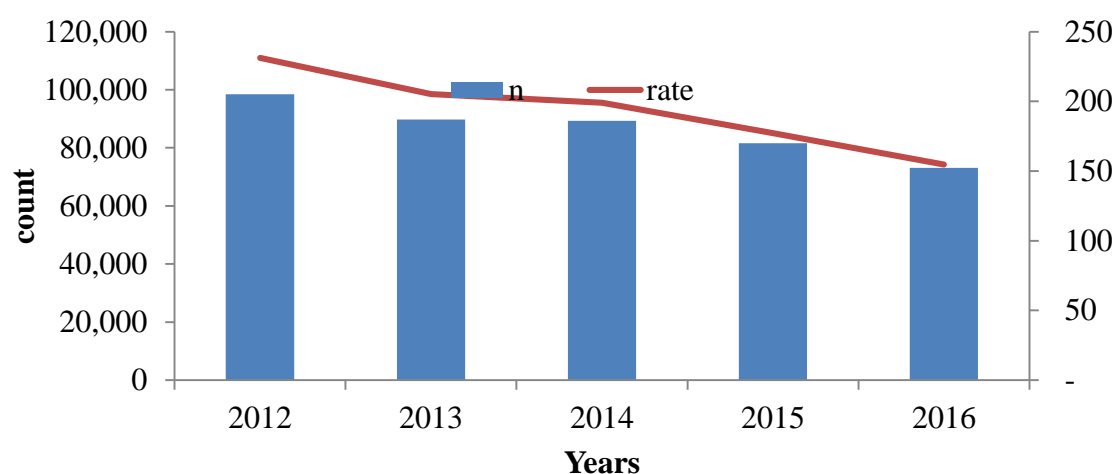


Figure 2: National TB notifications and rates in Kenya 2012-2016

This is attributable to the transition to a devolved government system, changes in diagnostic algorithm and reporting system. Notably, an estimated 21% of patients are diagnosed⁵ but not notified while the decline in 2016 could also be explained by industrial action by health care workers including the doctors' strike in the last quarter of 2016.

In 2016, the highest number of TB cases were in the age group 25-34 years. TB notification was higher in men of all age groups (routine TB surveillance-TIBU). Men aged 45-54 years and women 35-44 years had higher number of cases (443 and 221 per 100,000 pop) respectively⁶. This corroborates with the prevalence survey that indicated 70% of cases are in those below 44 years with age group 25-34 years having the highest burden (716 per 100,000 population) and Men of all ages being more affected (809/100,000) compared to women (359/100,000). Young men (25-34 years) have the highest disease burden (972/100,000). While women suffer a relatively lower disease burden, older women (≥ 65 years) have higher

⁵ Under-Reporting of Sputum Smear-Positive Tuberculosis, Kenya – 2015

⁶ Epidemiological review in Kenya February 20-24, 2017

burden 450/100,000). About half of TB cases were in 11 counties with Nairobi accounting for 15.5% (11,317) of all cases⁵.

The country has also rapidly achieved high rates of HIV testing for TB patients. By 2014, 95% of notified TB cases were tested for HIV, of whom 39% were found to be HIV positive. Of the patients found to be living with HIV, 92% were provided with cotrimoxazole preventive therapy and 63 % with anti- retroviral treatment, a remarkable feat indeed. Since the anti-retroviral treatment program was initiated in 2003, an increasing number and proportion of people living with HIV (PLHIV) have been placed on this quality of life enhancing and life prolonging treatment⁷. Anti retro –viral treatment is known to exert significant TB preventive effects and thus the roll of ART in Kenya is likely to have contributed to the observed decline in TB case notification this is further strengthened by Isoniazid Preventive Therapy for Latent TB⁸.

The implementation of PPM initiative in Kenya has been involving the private self-financing sector for many years. There have also been several initiatives to engage the informal private health sector in both the urban and rural settings. The NTLP begun to engage faith based health (FBO) service providers many decades ago and thus these providers, for purposes of TB care and prevention, are considered part of the network of the public-sector TB service providers. The table below provides a summary of the contribution of formal for profit or self-financing health care providers to TB case notification and the TB treatment success rate in patients treated by these providers.

7 Kenya HIV County Profile 2016

8 Guidelines on use of Antiretroviral drugs for treating and preventing HIV infections 2016

Table 1: Case notification and treatment success rates of patients treated by private providers

Year	Cases Notified	Proportion of cases notified by PPs	Treatment Success Rate	Year
2012	18,901	23%	86%	2012
2013	17, 320	21%	86%	2013
2014	16, 788	21%	86%	2014
2015	15, 199	19%	86%	2015
2016	13, 434	16%	-	2016

1.3 Tuberculosis Prevention and Care strategies in Kenya

The goal of the National Strategic Plan (NSP) for TB, Leprosy and Lung Health (2015-2018) is to accelerate the reduction of tuberculosis through provision of people-centered, universally accessible, acceptable and affordable quality services in Kenya. The five strategic objectives as defined in the NSP include: sustaining gains made in TB prevention and care, intensifying efforts to find the “missing” TB cases, reduce transmission of TB, prevent active disease and morbidity, and enhancing the quality of TB care services. The impact measures include reducing the TB incidence by 5% by 2018, compared to baseline 2014 figures.

The NSP for TB prevention and care is currently due for revision in 2018 to align with the END TB strategy, mid-term review of TB NSP 2015-2018, Kenya TB prevalence survey, Drug Resistance survey (DRS) and PPM action plan.

2.1 Rationale for PPM

Kenya being a resource-limited country with a high TB, TB/HIV, DRTB burden, patients with symptoms suggestive of TB seek care from a wide array of health-care providers. These health care providers are not often linked to NTLD-P and may serve a large proportion of presumptive TB cases. The size, types and roles of these care providers vary greatly within the country. In some settings there is a large private commercial sector and numerous NGOs while in others there are public sector providers (such as general and specialized hospitals) that operate outside the scope of NTLD-P. Evidence suggests that failure to involve all care providers in case finding for TB presumptive cases hampers case detection, delays diagnosis, leads to inappropriate and incomplete treatment, contributes to increasing drug resistance and places an unnecessary financial burden on patients.

According to the Kenya TB patient pathway analysis, about 40% presumptive TB patients seek care in the private sector (Figure 2) with 15% in the informal private sector. Engaging all relevant health care providers in TB prevention and care through PPM approaches is an essential component of the second pillar of WHO's End TB Strategy. PPM for TB care and control represents a comprehensive approach for systematic involvement of all relevant health care providers in TB control to promote the use of the International Standards for TB Care (ISTC) and achieve national and global TB control targets. PPM encompasses diverse collaborative strategies such as public-private (between NTP and the private sector), public-public (between NTP and other public sector care providers such as general hospitals, prison or military health services and social security organizations), and private-private (between an NGO or a private hospital and neighborhood private providers) collaboration. PPM also implies engaging relevant care providers in prevention and management of MDR-TB and in the implementation of TB/HIV collaborative activities.

Kenya TB Patient Pathway

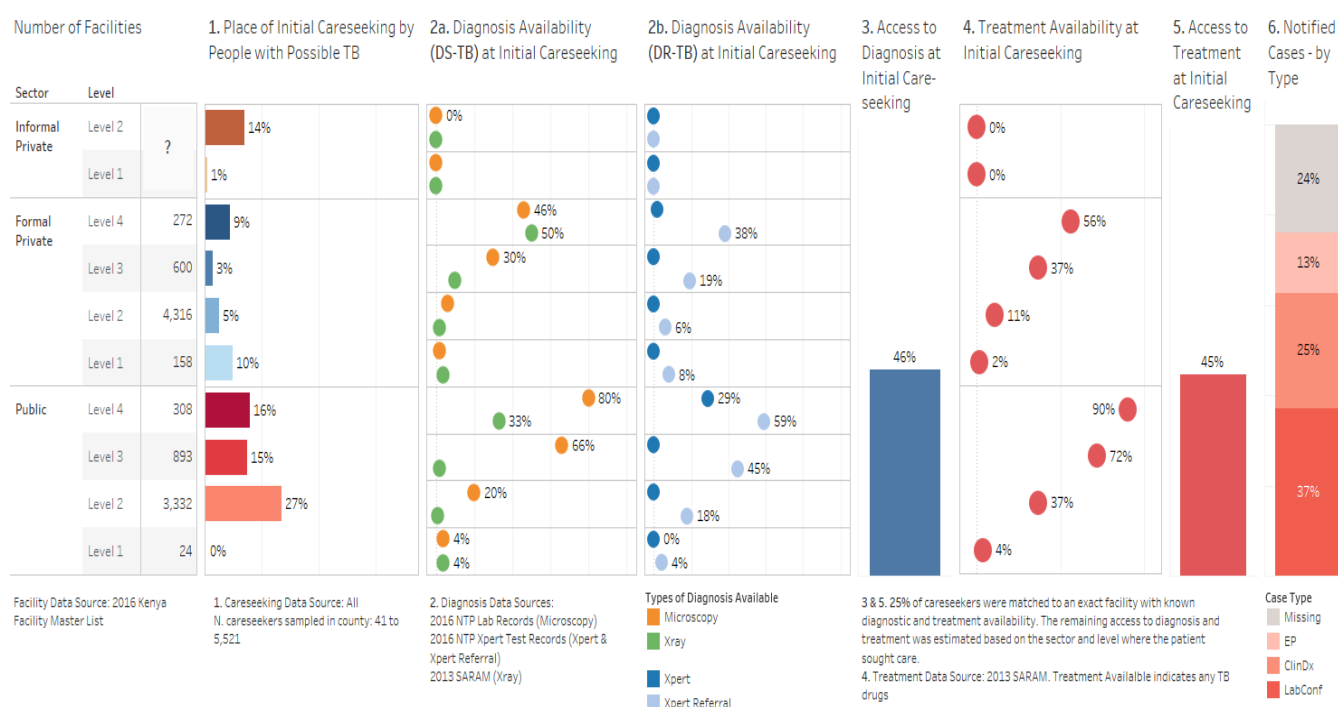


Figure 3: Patient Pathway—Kenya National Profile

Engagement of all providers including private providers will assist in reducing delays in TB diagnosis to get TB patients on treatment sooner and thus cut out TB transmission which should eventually impact on TB incidence.

2.2. PPM in Kenya

The implementation of PPM for TB prevention, care and control in Kenya was initiated in 1997 as a joint effort of the NTLD-P and KAPTLTD which is a professional association of chest physicians. The NTLDP provided the initial funding and TB medicines for the project while the chest physicians mobilized their peers and others to promote standardized TB case management with recording and reporting. KAPTLTD later negotiated for subsidized drug prices from one pharmaceutical company that remarkably lowered the cost of TB medicines. This has ensured that more than 300 facilities supported by KAPTLTD provide TB services in line with the International Standards of Tuberculosis Care (ISTC). The hospitals offer the full

range of TB services with TB medicines provided at a cost to the patients in some of these hospitals. Currently, an increasing number of the private facilities receive free medicines from the NTLD-P. In general private for profit or self financing hospitals will charge a fee for virtually all services offered.

The PPM initiative train and support health care providers to diagnose, treat, record and report TB cases according to the ISTC and national guidelines. The M&E tools used are in line with the NTLD-P requirements. The data accruing is routinely collected by Sub County TB and Leprosy Coordinators (SCTLCS) and relayed to the County and national levels.

There are efforts to engage corporate organizations in workplace TB prevention and care interventions which include creating awareness, screening services, diagnosis and treatment. In addition, informal health care providers are engaged in creating awareness, identification and referral of presumptive TB cases among their clients.

Concerted efforts in engaging all care providers led by NTLD, KAPTLCD and partners have consistently contributed to national TB case-finding efforts. This has resulted in a sustained increase in cases notified from the private sector.

2.3. The PPM vision

PPM contributes to the NTLD-P vision which is to reduce the burden of lung diseases and render Kenya free of tuberculosis and leprosy.

2.4. The PPM goal

The PPM goal is to strengthen and expand the engagement of all health care providers in the fight against TB, in order to strengthen efforts in finding missed cases, sustain treatment outcomes among diagnosed cases, and improve access to TB and DR-TB care services. The goal will be to contribute to the national End TB targets.

2.5 PPM strategic objectives

- I. Ensure effective leadership and stewardship of PPM through resource mobilization, active oversight/management, and coordination of PPM activities.
- II. Strengthen collaboration with professional associations and private sector partners.
- III. Scale-up implementation of current service delivery PPM models and introduce innovative PPM models for TB care.
- IV. Enhance the quality of PPM implementation by standardising monitoring, recording and reporting of PPM activities.
- V. Strengthen capacity building for public-private mix activities.
- VI. Strengthen the regulatory, legislative framework and promote UHC/social protection mechanisms for PPM activities.

2.6 PPM implementation Challenges

Some of the challenges in implementing PPM are include:

1. Despite the long period of PPM implementation in the country, coverage of private health care providers in the provision of TB control services remains low and uneven across counties, ranging from 0% to 65%.
2. There were also significant knowledge gaps among private providers in all areas of TB Prevention and care
3. The supply of anti-TB medicines to large private health care facilities has suffered constraints including disruptions, change to a less user friendly packaging and change in prices.
4. Private laboratories participating in PPM activities were not participating in microscopy EQA schemes, raising fears of quality of diagnosis.

3.1 Health Sector Policy and Strategy

The National Health Sector Strategic Plan (NHSSP) provides the operational road map for the implementation of health policy framework. The overall goal of the current Health Sector Policy in force is to promote and improve the health of all Kenyans through the deliberate restructuring of the health sector to make health services more effective, accessible and affordable to all.

The second National Health Sector Strategic Plan (NHSSP II) recognizes the different health care needs of individuals as they go through life's six distinct cycles of pregnancy, delivery and the new born; early childhood; late childhood; adolescence; all life cycle cohorts/adulthood; and the elderly. The NHSSPII describes an essential package of care, the Kenya Essential Package of Health (KEPH) and highlights the provision of TB (DOTS) and HIV care services as among the key health interventions to be delivered especially to the youth and adolescence (13-24 year olds) and the adult segments of the population (25-59 year olds).

3.2 Health Facility Ownership, Distribution and participation in provision of TB services

Of the total (8875) health care facilities that are registered in Kenya currently, 4500 (51%) are public (MOH, Local authority, armed forces, parastatals, state corporations) while the remaining 49 % are owned by Faith Based Organizations (FBOs), NGOs, private companies and private self financing institutions, individuals or groups of individuals⁹. The regulation of

⁹ Kenya Master health facility list www.kmhfl.health.go.ke

health care providers and services is the responsibility of the GoK through the ministry of health.

Except for a proportion of dispensaries, the entire network of public, FBO and NGO based health care facilities form part of the network of DOTS providers set up by the NTLD-P. The exact proportion of private – self financing health care facilities that is currently participating in the provision of TB services is however not known.

3.3 The array of private health care providers in Kenya.

3.3.1 Faith based Health Services

The Faith Based Health Service is the second largest provider of health services in Kenya. The most well known network of faith based health providers include those operated by the Christian Heath Association of Kenya (CHAK) and the Kenya Episcopal Conference of Catholic Bishop (KCCB). Collectively this network of providers is responsible for about 40% of health care provided in the country. In some parts of Kenya FBO health care is the only available health services The FBO network of health care facilities has been part of the network of TB service providers engaged by the TB control programme for a long time. Each FBO health care facility provides TB care services appropriate to its health infrastructure capacity. Thus most FBO hospitals will provide the full range or some of the TB services which include laboratory diagnosis, TB culture, chest x-ray, TB treatment for TB and DRTB, recording and reporting of TB cases, HIV counselling and testing, provision of CPT and ART to HIV infected TB patients and default retrieval. Other than for a minimal fee charged for consultations before the diagnosis of TB is made, TB services are free in most FBO health care facilities. The NTP provides laboratory reagents, anti-TB drugs, and also trains and supervises health care workers. However, just as in the mainstream public health care sector, patients who need a chest x-ray are charged a fee.

3.3.2 Private for profit (or self financing) health care facilities

Kenya has a large number of private for profit or self financing health care facilities. The very large ones operate as tertiary care centres offering services that are similar to what is offered at the national referral hospitals. Many of the large hospitals are equipped with modern state of the art equipment and have in their staff compliment some of the most qualified health care personnel. These hospitals largely serve urban elites and those with health insurance procured for them by private or public corporate institutions. There are also a large number of medium sized and small facilities which may have physical infrastructure comparable to what may be present in an average county hospital.

Some private facilities receive drugs from the government and are expected to pass these drugs to their patients for free or at a minimal cost.

3.3.3 Corporate/ Workplace Health Services

Recognizing the impact of TB and HIV on company productivity and profitability, businesses are increasingly participating in interventions aimed at improving the health of their workforce or even the community, as part of their corporate social responsibility. Business-led initiatives have demonstrated their potential to play a useful role in the care and control of TB. A number of corporate organizations provide health care services at the workplace or other site for their workers and their dependants. The health infrastructure available at these sites is in general compatible to what is available (or should be available) in a health centre/Level 3 or dispensary/level 2, though some companies manage hospitals/level 4 facilities.

The NTLD-P in collaboration with partners will initiate workplace TB care programmes which include training and support of peer educators, active screening of workers for TB, workplace treatment support for patients on TB medications and other activities. In cases, where there is an already existing workplace health program, TB services should be integrated into it. It is also anticipated that some corporate organizations will contribute finances and or support TB

care and control including care for DRTB in some other way, as part of their corporate social responsibility programmes.

There are a number of corporate organizations providing health services to their employees and dependants. There have been few initiatives engaging corporates such as flower farms in Naiyasha, Kenya airways, Central bank of Kenya, Barclays bank, Kenya Ports Authority linking them to the NTLD-P providers offering TB services. However, there are no corporate sector intervention currently being systematically implemented. Priority should be placed on initiation and implementation of work-place interventions in the corporates/factories/industries that employ large numbers of poor and vulnerable groups. Illustrative activities in such interventions could range from awareness creation, health education, TB screening programmes targeting factor workers, training of peer educators to treatment support programmes among others.

3.3.4 Individual private for profit health care providers

This group is made up of formal private health practitioners such as medical doctors, clinical officers, nurses and medical laboratory technologists. Most of the individual private health providers are concentrated in urban areas. In general persons, seeking care from individual private providers pay fees for consultation, laboratory tests and medicines either through out of pocket or health insurance.

Since many presumptive TB suspects first approach a neighborhood private practitioners, their engagement represents an opportunity to reduce diagnostic delay and disease transmission. There is also the potential to share service delivery thus moderate the workload on frontline health workers in the public health sector. Low income patients also use services of private practitioners. Therefore engaging them could help reduce costs of care for the poor.

The County and sub-County TB Coordinators are required to map and identify all the private providers in their counties and appropriately engage them. Qualified and trained private health

care practitioners can undertake almost all the tasks from identifying suspects to making a diagnosis, notifying the patient and providing supervised treatment but may need to be supported for some tasks such as defaulter retrieval. Some private practitioners may choose to simply refer their cases or may be willing to supervise patients referred to them for that purpose by the public sector.

In addition, any gaps that exists in tracking referrals from the private to private, private to public and public to private sectors should be identified and reporting systems to address these accordingly strengthened.

3.3.5 Retail pharmacies and chemists

Pharmacists are included in the array of providers, as people tend to seek medicines from them for their ailments. The TB patients pathway analysis conducted in 2016 indicated that 50% of patients with TB symptoms seek initial care in the private sector including private pharmacies. The retail pharmacies and chemists therefore, have an important role in early TB case identification by referral of presumptive cases to a TB diagnostic centre. The current engagement strategy targeting the pharmacists have been mainly addressing the Pharmaceutical society of Kenya, with minimal direct interventions targeting pharmacists for service delivery.

The County and sub-County TB coordinators should map and identify private pharmacies in their areas and appropriately engage them to refer all people with presumptive TB to health facilities for further evaluation. Practical mechanisms for fast tracked service should be put in place for the referred patients at the destination health facility.

The objective of the proposed pharmacist engagement model is to promote identification of presumed TB cases by the pharmacist and their prompt referral to the network of NTLD-P engaged health facilities /providers to facilitate early and complete diagnosis and management of TB.

3.3.6 Non governmental organizations (NGOs)

These are not-for-profit organizations that are independent from state or government organizations. They offer a wide range of health care services including TB services. NGOs are well suited to participate in TB prevention and care activities as they are credible, have access to communities and vulnerable populations, and show greater flexibility of work. Collaboration with NGOs is important because in some settings, they are the only major non-NTLD-P providers of TB care and prevention, and serve a large number of presumptive TB and TB cases. Their involvement will ensure that presumptive TB cases or patients, especially among marginal communities and in remote areas, have access to standardized TB services in line with international standards. The strengths of NGOs in reaching communities through advocacy, communication and social mobilization, can be capitalized on to expand awareness and access to high-quality TB care and control. NTLD-P will increase participation of NGOs in TB prevention and care through capacity building, equipments and supply of TB commodities.

3.3.7 Informal Care Providers

Informal private practitioners are individuals working independently, providing health services in an unevenly regulated context (e.g. traditional healers or indigenous practitioners) or practitioners not fully qualified to provide services that they provide (e.g. non-qualified providers, village doctors, drug sellers, etc.). For the purpose of these guidelines informal care providers comprise:

1. Traditional healers/indigenous practitioners, Herbalists and faith healers
2. Grocers and Shopkeepers
3. Drug shops/sellers
4. Village doctors

These providers can be engaged to identify presumptive TB case and refer to a health facility for diagnosis and treatment. They can also be engaged in provision of DOT for TB patients living in the neighbourhood but are not entrusted with medical tasks. They may also contribute significantly to enhancing community awareness about TB. Mapping and sensitization is required before they are engaged.

Mapping of informal providers, developing data collection tools and IEC tools for engaging the ISPs, conduct sensitization events targeting ISPs, and provide non-financial and financial incentives to optimize their engagement in referring presumptive TB cases.

5.6 Private laboratories

There are 285 private laboratories currently providing TB diagnostic services mainly through smear microscopy and few Xperts in the country. Nearly 65% of the private laboratories (185/285) participate in the external quality assurance. It is currently unclear how many TB cases were diagnosed through these private laboratories. Proposed activities under the model will be to strengthen the collaboration with the private laboratories. Linkages between public and private laboratories offering TB bacteriology services will be vigorously pursued to ensure that the TB laboratory service is quality controlled and quality assured. Mechanisms will be established to link diagnosed cases from the private laboratories to the NTLD-P network of providers for appropriate case management.

CHAPTER 4: IMPLEMENTING PPM FOR TB PREVENTION AND CARE AT THE DIFFERENT LEVELS:

THE ESSENTIAL STEPS

4.1 NLTP and Other county Staff Sensitization and preparedness

It is critical to ensure that MOH (NTLD-P) and county staff (CHMT & SCHMT) are fully sensitized about PPM and have internalized the goal, the mission and objectives of PPM. The local capacity for effective implementation of PPM should be identified and roles of various players outlined. TB prevention and care teams should include PPM activities during the development of annual work plans. The resources that will be needed to support PPM and to document PPM activities, outputs and outcomes must be made available as PPM implementation begins. A national PPM Technical working group (TWG) will monitor the PPM activities.

As highlighted in figure 4 below, NTLD-P will work with intermediary agencies like the Kenya Association for the Prevention of Tuberculosis and Lung Diseases, Kenya Medical Association, Kenya Paediatric Association, Kenya Clinical Officers Association, Kenya Nurses Association etc to facilitate establishment of linkages with the diverse private health sector actors.

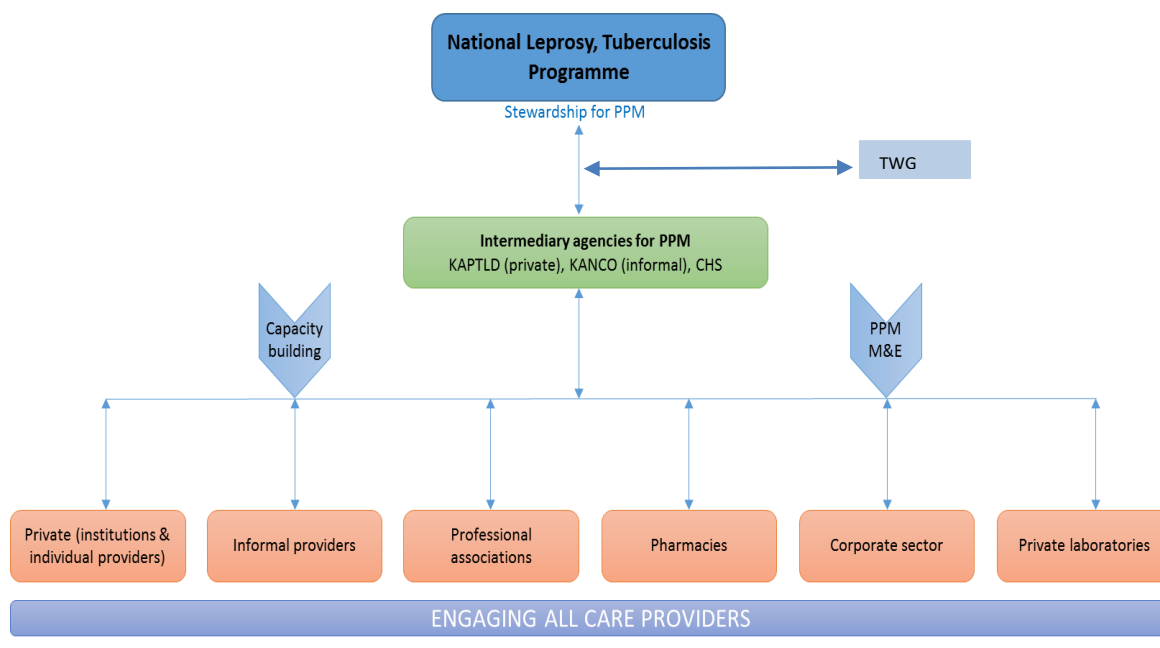


Figure 4: NTLD-P Linkages with the diverse private health sector actors.

4.2 Provider mapping and selection

The NTLD-P, County and sub-County TB Coordinators shall map all health care providers in and prioritize them for engagement based on their capacity and willingness. An agreement of the terms of engagement will be done through a Memorandum of Understanding (MOU) between the NTLD-P/ County Health Departments and the health provider. The MOU will define which task each party will perform.

4.3 Tasks in PPM Implementation

Table 2 below provides the list of the various institutional and individual providers against their clinical and public health tasks in TB prevention and care in the country.

The NTLD-P, county health departments including public health facilities are responsible for providing both clinical and public health tasks, quality assurance of laboratories, programme monitoring and evaluation, drugs and supply management, TB advocacy and overall stewardship for PPM. The role of professional associations (KMA, KPA, NAK, KPHA, KCOA, PSK etc) and regulatory authorities will be to train providers, M&E and enforcement

of policies. Private institutions, corporate and individual private providers have the capacity to undertake all clinical and few public health tasks such as notifying TB cases, providing treatment support and tracing loss to follow-up.

Table 2: Health Care Provider Task Mix in TB/DRTB Care in Kenya

		Government including military and prison health services				Faith based Organizations/NGO			Private providers including corporate				Informal Sector	Professional/Regulatory Bodies
	Task	NTP / DOTS agency	Hospitals	Health centers	Dispensary	Hospitals	Health centers	Dispensary	Hospitals	Clinics	Retail pharmacy	Standalone laboratories	TH/Herbalist/Faith healers	
CLINICAL TASKS	Identify presumptive TB cases	X	X	X	X	X	X	X	X	X	X	X	X	
	Collect Specimens	X	X	X	X	X	X	X	X	X	X	X		
	Refer and record presumptive TB cases	X	X	X	X	X	X	X	X	X	X	X	X	
	Carry out Smear microscopy	X	X	X	X	X	X		X			X		
	Gene-Xpert (where available)	X	X	X		X	X		X			X		
	Culture and DST	X	X			X			X					
	HIV testing and Counselling	X	X	X	X	X	X	X	X	X		X		
	Diagnose TB	X	X			X			X					
	Prescribe TB Treatment	X	X	X	X	X	X	X	X	X				
	Prescribe DRTB treatment	X	X			X			X					
	Patient education/awareness	X	X	X	X	X	X	X	X	X	X			
PUBLIC HEALTH TASKS	Notify cases	X	X	X	X	X	X	X	X	X	X			
	Provide treatment supporters (DOT)	X	X	X	X	X	X	X	X	X	X			
	Trace loss to follow-up	X	X	X	X	X	X	X	X	X	X			
	Contact tracing / investigations	X	X	X										
	Training of providers	X	X			X								X
	Supervision	X				X								
	Quality Assurance of Laboratories	X												
	Programme Monitoring and Evaluation	X												X
	Drug and other commodities supply management	X												X
	TB Advocacy	X												
	Enforcement of policies	X												X
	Provide Stewardship (regulation & financing)	X												X

4.3.1 Definition of Tasks

a. Identification of TB symptomatics and other persons who need TB screening:

A presumptive TB case is anyone who presents with TB signs or symptoms (cough of any duration, fever, drenching night sweats and loss of weight loss, chest pains, hemoptysis, etc). All engaged providers should carry out this very basic task.

b. Refer Presumptive :

Where TB bacteriology services are not available on site, all presumptive TB cases should be referred to the nearest health facility for investigations and management. All informal providers and private chemists should refer presumptive TB cases. All providers referring TB suspects should fill out an appropriate presumptive cases referral form. DRTB suspects include all re-treatment cases (failed initial treatment, return after default, recurrent/relapse TB) or TB patients known to have had contact with a known case of DRTB before the onset of the current episode of TB. Where diagnostic facilities for DRTB are not available on site, all DRTB suspects should be referred to a DRTB diagnostic facility. The local SCTLCS should advise engaged providers where to send patients suspected to have DRTB for diagnosis. For all such patients a DRTB referral form provided by the SCTLCS should be filled.

c. Collect specimens

Provider should use the SOPs for sputum collection by instructing patient on how to produce a good quality sputum specimen, sputum packaging procedures, designate places for sputum collection and using the appropriate sputum collection containers. All specimens submitted to the laboratory must be in properly sealed containers and must be accompanied with an appropriately filled laboratory request form.

d. Record and report cases

All TB cases should be recorded in the appropriate register and notified to the NTLD-P through the SCTLIC.

e. Carry out TB bacteriology

All presumptive TB cases should have sputum smear microscopy or a WHO endorsed TB bacteriologic test prior to treatment initiation. Health facilities with the capacity to carry out TB bacteriologic test should carry out this task in accordance with the National TB diagnostic algorithm. The minimum requirements for a facility to carry out a TB bacteriologic service should be an appropriate TB laboratory infrastructure that includes:

- Trained personnel
- Available space and appropriate bio safety measures
- Working equipment which are regularly maintained
- Available reagents
- A quality control and quality assurance system

f. Carry out HIV testing and counselling

All providers should provide information about HIV and offer an HIV test to presumptive and TB cases.

g. Prescribe TB treatment

All patients with a TB diagnosis should receive anti-TB drugs based on the national treatment guidelines (see TB treatment guidelines). Requirements for a health facility to qualify as a TB treatment centre will include;

- Trained Human Resources
- Presence of an infection transmission prevention plan

- Availability of medicines to treat and to manage adverse effects
- Access to laboratory services to monitor progress and drug side effects
- Availability of recording and reporting tools

h. Education to Patients

For both drug susceptible and drug resistant TB, patients should be counselled about TB treatment at the initiation of treatment. The patient should be informed about:

- The diagnosis
- The treatment (drug names, colour, doses, duration)
- Need for adherence
- Side effects to be expected and what to do when these occur
- Simple measures to prevent transmission of TB
- Follow up procedures including clinical reviews and laboratory monitoring
- Contact investigation procedures
- Nutrition and TB

i. Provide Treatment supporters (DOT)

All TB patients should identify treatment supporters who will ensure that the patient takes medication as prescribed and where necessary accompanies the patient to the facility. The treatment supporter may be a family member, a workmate, or a health care worker. Patients should not be coerced to have a specific type of treatment support but should be allowed to choose their own supporters.

j. Trace TB treatment interrupters (defaulters)

The provider in partnership with the local NTLD-P staff and the PPM DOTS agency should put in place mechanisms to trace patients who do not turn up for treatment and follow up on the designated clinic days.

k. Training of Providers

The health providers will ensure that continuous and task appropriate training is provided to all health care workers engaged in the management of TB and DR TB in collaboration with the NTLD-P to ensure that TB management practices conform to national and international standards.

l. Supervision

The NTLD-P and partners involved in PPM will ensure facilitative supervision is carried out on a regular basis to all TB diagnostic and treatment centres to ensure that a high quality TB service for both drug susceptible and drug resistant TB is achieved and maintained. Health Institutions participating in a PPM TB prevention and care initiative should allow and support these supervisory visits.

m. Quality Assurance of laboratories

Linkages between public and private laboratories offering TB bacteriology services will be enhanced to ensure that the TB laboratory service in both sectors is quality controlled and quality assured. The National TB reference laboratory will carry out its public health obligation of TB drug resistance surveillance and coordination of quality assurance and quality control in all TB bacteriology laboratories. However, private sector laboratories offering TB bacteriology and which have the capacity and willingness to coordinate quality assurance will be encouraged and supported to do so.

n. Monitoring and evaluation and Operational Research

The NTLD-P will ensure that standardized recording and reporting tools are made available to the TB treatment centres, training of the health providers and regular supervision in the private sector. The PPM indicators will be set for use. Operational research should be an integral part of the PPM plan and should be undertaken to provide the evidence base for policy and practice recommendations. This may be conducted to address specific questions, such as cost effectiveness of different approaches, impact of PPM on diagnostic delays, equity in access, and identification of factors of success and sustainability. This will normally require collaboration with a research institution or equivalent.

o. Drug and other commodities supply management

All TB/DRTB treatment centres should maintain a continuous and adequate supply of TB commodities. TB medicine should be sourced from the NTLD-P or a source approved and or known to the NTLD-P. For second line drugs the source should only be the NTLD-P. To avoid creation of DR TB, NTLD-P will work with the pharmacy and poisons board (PPB) and other partners to ensure rational use of antimicrobials that have effect on *Mycobacterium tuberculosis* and to limit outlets of such products to facilities that have the necessary infrastructure to (trained personnel, drug ledgers etc) promote their rational use. These include the fluoroquinolones.

p. Enforcement of policies

All professional associations should offer continuous professional development for their members to include adequate knowledge of TB and DRTB and adherence to the national guidelines. All professional and regulatory bodies should enforce the regulation of health

care practice and the sale of medicines and laboratory commodities. Emphasis should be laid on the regulation and registration of medicines to ensure prescription only medicines are not sold over the counter, counterfeits are eliminated and the irrational use of antimicrobials is curtailed to guard against the development of drug resistance.

q. Coordination of PPM

At the national level a PPM and Lung Health Technical Working Group (TWG) has been formed and charged with the task of formulating national PPM policies and strategies, guidelines and to coordinate the efforts of partners. The TWG is also responsible for the development of national PPM action plan, implementation, monitoring and evaluation.

The County Health departments should establish PPM technical working groups bringing together all the relevant stakeholders.

The global experience suggests that Professional Associations (PAs) have a significant role to play in the development and implementation of PPM initiatives. Thus the engagement of PAs should be an essential part of PPM development that will act as the conduit to the large number of private providers.

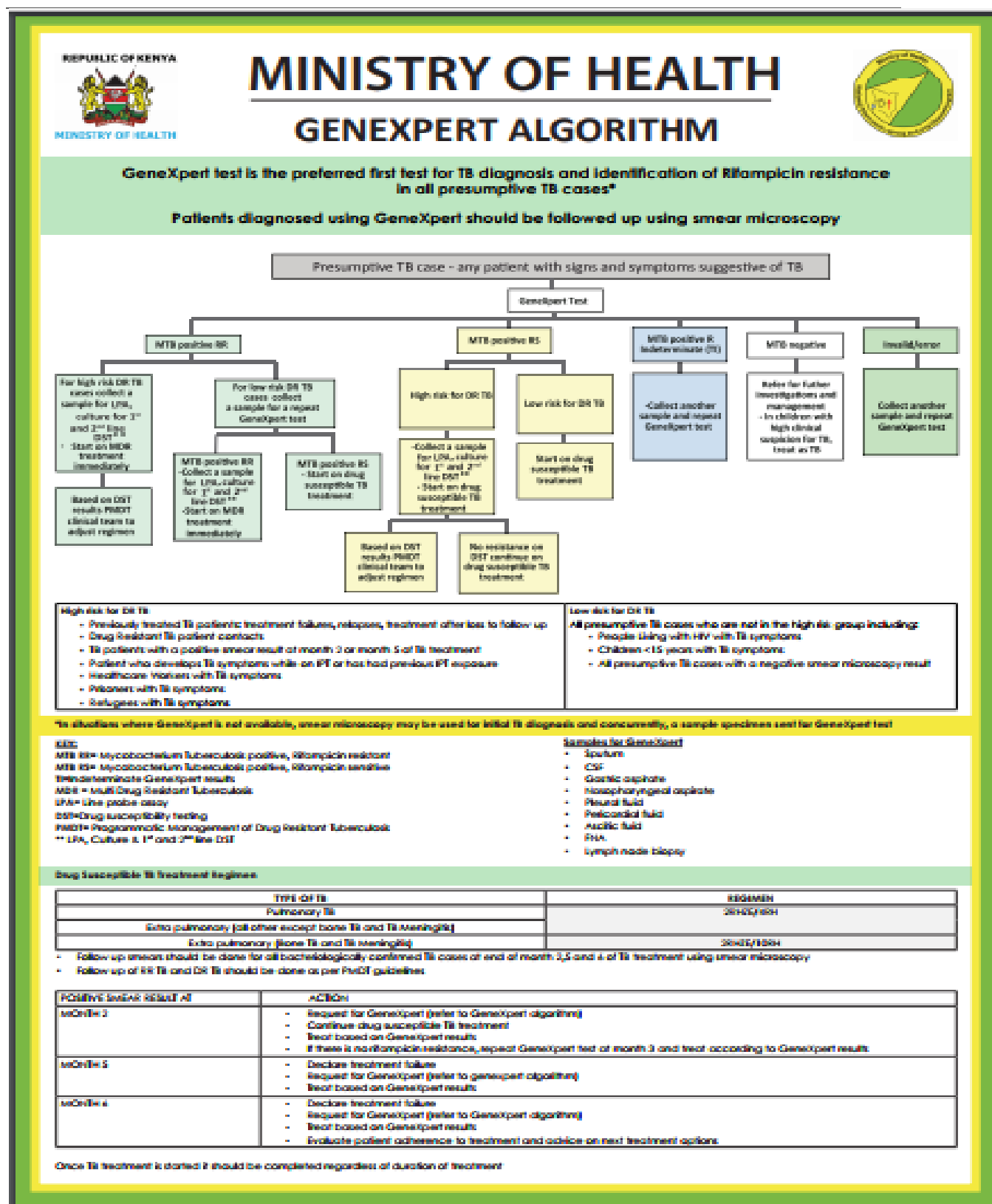
4.4 Provider Training

A training strategy should be based on the task mix, need-based training material for different providers, adapted to local context and working condition of provider, adopt training material and modules from NTLD-P, device follow-up structure linked to program supervision activities and revise training program based on evaluation. Participation and contribution should be recognized through certification and accreditation as appropriate.

OTHER REFERENCES

1. **Ministry of Health.** *Mid-term review of NTLP report*, 2014
2. **National TB, Leprosy and Lung Diseases Programme.** *Guidelines for management of tuberculosis in Kenya, version 2013*
3. **KAPTLD.** *PPM TB ARC report, Q2 2016*
4. **Ayisi et al;** *Care seeking and attitudes towards TB treatment*; BMC Public Health 2011, 11:515
5. **Mutinda et al;** *Health seeking behavior, practices for TB*; Journal of biology, agriculture and health care; Vol 4, No 14, 2014
6. **National Council of Law, Kenya.** *Public Health Act*, Chapter 242, Revised edition 2012
7. **World Health Organization.** *Guide to develop a national action plan for public-private mix (PPM) in tuberculosis*

ANNEX 1: GENEXPERT ALGORITHMS



High risk for DR TB

- Previously treated TB patients: treatment failures, relapses, treatment after loss to follow up
- Drug Resistant TB patient contacts
- TB patients with a positive smear result at month 3 or month 5 of TB treatment
- Patient who develops TB symptoms while on PT or has had previous PT exposure
- Healthcare workers with TB symptoms
- Prisoners with TB symptoms
- Refugees with TB symptoms

Low risk for DR TB

All presumptive TB cases who are not in the high risk group including:

- People living with HIV with TB symptoms
- Children <15 years with TB symptoms
- All presumptive TB cases with a negative smear microscopy result

*In situations where GeneXpert is not available, smear microscopy may be used for initial TB diagnosis and concurrently, a sample specimen sent for GeneXpert test

Abb:

MTB RR= Mycobacterium Tuberculosis positive, Rifampicin resistant

MTB RS= Mycobacterium Tuberculosis positive, Rifampicin sensitive

RI=Indeterminate GeneXpert results

MDR= Multi Drug Resistant Tuberculosis

UPL= Urea probe assay

DST=Drug susceptibility testing

PMDT= Programmatic Management of Drug Resistant Tuberculosis

** UPL, Culture & 1st and 2nd line DST

Samples for GeneXpert

- Sputum
- CSF
- Gastric aspirate
- Nasopharyngeal aspirate
- Plural fluid
- Pericardial fluid
- Ascitic fluid
- RNA
- Lymph node biopsy

Drug Susceptible TB Treatment Regimen

ANNEX 2: NATIONAL TUBERCULOSIS REFERENCE LABORATORY TESTING ALGORITHM

