MID-TERM REVIEW

OF THE

NATIONAL TUBERCULOSIS, LEPROSY& LUNG HEALTH UNIT

OF THE

MINISTRYOF HEALTH, KENYA

28 FEBRUARY – 12 MARCH 2014

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Finally, the review team extends its thanks to the Cabinet Secretary, Principal Secretary, Director of Medical Services and the Head of the Division of Communicable Disease Prevention and Control, for their ongoing leadership and active participation in the debriefing.

This report was written primarily by the international expert team, in collaboration with national counterparts and in discussion with the Ministry of Health. Dr. Christy Hanson led the review.

ABBREVIATIONS & ACRONYMS

ACSM	Advocacy, Communication, and Social Mobilization
AFB	Acid-fast bacilli
AFRO	African Regional Office (of the World Health Organization)
AIDS	Acquired immunodeficiency syndrome
AMREF	African Medical and Research Foundation
ART	Anti-retroviral therapy
BSC	Bio-safety cabinet
BSR	Blinded slide rechecking
C+	Culture positive
C-	Culture negative
CBO	Community-based organization
CCT	Conditional cash transfer
CDC	United States Centers for Disease Control
CDR	Case detection rate
CHS	Centre for Health Solutions
CNR	Case notification rate
CPT	Cotrimoxazole Preventive Therapy
CR	Cure rate
DALY	Disability-adjusted life year
DCDPC	Division of Communicable Disease Prevention and Control
DOT	Directly observed treatment
DOTS	Directly observed treatment, short-course
DRS	Drug resistance surveillance
DR-TB	Drug resistant tuberculosis
DSSM	Direct sputum smear microscopy
DST	Drug susceptibility testing
DTLC	District TB Lab Coordinator
DMLT	District Medical Laboratory Technologist
EQA	External quality assessment
ETR	Electronic TB registry
FIND	Foundation for Innovative New Diagnostics
FDC	Fixed dose combination
FM	Fluorescence Microscopy
GDF	Global Drug Facility
GF	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GLC	Green Light Committee
H	Isoniazid
HC	Health center
HCP	Health care provider
HIMS	Health Information Management System
HISP	Health Insurance Subsidy Programme
HIV	Human immunodeficiency virus
HSSF	Health sector services fund
IC	Infection control
ICC	Inter-agency coordinating committee
ICF	Intensified case finding
IEC	Information, education, and communication
INH	Isoniazid
IPT	Isoniazid preventive therapy
ISTC	International Standards on TB Care
KAPTLD	Kenyan Association for the Prevention of Tuberculosis and Lung Diseases

KEMSA	Kenya Medical Supplies Agency
KNCV	Royal Dutch Tuberculosis Foundation
KPA	Kenya Pediatric Association
LMIS	Laboratory Management Information System
M&E	Monitoring and evaluation
MC	Microscopy center
MDG	Millennium development goal
MDR-TB	Multidrug resistant tuberculosis
MOP	Manual of procedures
MSF	Medecins Sans Frontieres
MTB	Mycobacterium tuberculosis
MTR	Mid-term review
NACC	National AIDS Control Council
NASCOP	National AIDS and Sexually Transmitted Infections Control Programme
NCC	National Coordinating Committee
NGO	Nongovernment organization
NHA	National Health Accounts
NSR	No smear result
NTLD	National Leprosy, Tuberculosis and Lung Disease control Program
NTRL	National TB Reference Laboratory
NPS/NTPS	National TB Prevalence Survey
OOP	Out-of-pocket
PBG	Performance-based grant
PLHIV	People living with HIV
PMDT	Programmatic Management of Drug-resistant Tuberculosis
PP	Private practitioners
PPM	Public-Private Mix DOTS
QA	Quality assurance
QAS	Quality assurance system
QC	Quality control
QMRL	Queensland Mycobacterium Reference Laboratory
R	Rifampicin
RCC	Regional Coordinating Committee
S+	Smear positive
S-	Smear negative
SOP	Standard Operating Procedures
SRL	Supranational Reference Laboratory
TA	Technical assistance
TAT	Turn-around time
TB	Tuberculosis
TB/HIV	TB disease and HIV infection
TIBU	Treatment Information from Basic Unit
TSR	Treatment success rate
USAID	United States Agency for International Development
WHO	World Health Organization
ZN	Ziehl-Neelsen

BACKGROUND

Kenya is one of the twenty-two high tuberculosis (TB) burden countries that together account for more than eighty percent of the world's TB cases. The World Health Organization (WHO) estimated that there were 120,000 new cases of TB in Kenya in 2012. The estimated 9,500 (5400- 15,000) deaths due to TB make it the fourth leading cause of mortality in the country. Since 2006, a gradual decline in case notifications has persisted, suggesting that incidence may be declining following years of high treatment success, currently over 88% for new smear-positive cases. Case detection has been enhanced through community engagement, inclusion of the private sector, intensified case finding, pro-poor enablers such as nutritional support, TB/HIV collaborative activities, and an increased focus on identifying TB in children. Slightly over 8% of 89,320 notified cases in 2013 were among children.

HIV/AIDS continues to be an important driver of the TB epidemic in Kenya, with approximately 38% of patients with TB also living with HIV (TB/HIV). TB-related deaths among people living with HIV have declined from a high of 12% in 2004 to 5% in 2012, as access to antiretroviral therapy (ART) and cotrimoxazole preventive therapy (CPT) have increased. Over 656,000 TB patients have initiated ART; representing 74% of HIV infected TB patients in 2012. Nearly all (98%) HIV infected TB patients initiated CPT in 2012.

Programmatic management of drug-resistant TB (PMDT) was initiated in 2007. In 2013, 248 cases of multi-drug resistant TB (MDR-TB) were identified and started on treatment. Thirty percent of reported MDR-TB cases are among refugees residing in Kenya. The Kenyan Government made an important humanitarian and public health decision to manage these cases with the resources and infrastructure of the Ministry of Health. WHO currently estimates that there are 2750 cases of MDR-TB in the country. A drug-resistance survey is being planned to substantiate or modify these estimates.

The number of new leprosy cases detected in the country has also been in decline over the past decade, with 139 cases notified in 2013. The health system currently manages grade 1 or 2 disabilities in 48% of the cases notified. Kenya is considered to be in the post-elimination stage for leprosy.

Kenya adopted a new Constitution in 2010, which guarantees fundamental social and economic rights to its people. Access to quality health care, including reproductive health; emergency treatment; social protection and equal access to resources and opportunities are some of the basic human rights provided for in the Constitution. These rights are seen as fundamental to the country's success in achieving middle-income status as envisioned in the economic development agenda, entitled "Kenya Vision 2030".

With the introduction of the new Constitution, the devolution of government functions and resources to 47 newly created counties is swiftly changing the mode of operations for the health sector, including the management of TB, leprosy and lung health. The health sector, previously characterized by central-level planning and supply-side financing, is shifting to devolved planning and demand-side financing modalities including national health insurance, conditional and performance- based grants, and equity-enhancing allocations of national resources. The devolution presents opportunities for local prioritization and adaptation of TB and leprosy control, and support for targeted and patient-centered care. In 2013/14, all funds for TB control were devolved to the counties, including funds for commodity procurement. A new health sector strategy and health policy are being finalized, to be followed by realization of the newly identified priorities and targets. While the activities of the National Tuberculosis, Leprosy and Lung Health Unit (NTLD) have been considered priority areas; they are not consistently well represented in the new plans and indicators.

The NTLD must not only engage actively in the devolution process but has the opportunity to be a pathfinder as it capitalizes on the emerging structures to reach marginalized populations and support county-level capacity for planning, budgeting and quality service implementation.

EXECUTIVE SUMMARY

With a vision to reduce the burden of lung disease in Kenya and render Kenya free of TB and leprosy, the NTLD has been implementing activities within the framework of a five-year (2011-2015) national strategy. By 2015, the NTLD aims to increase the case detection rate of bacteriologically confirmed TB to 80% and to successfully treat 90% of notified TB cases. It also aims to achieve zero disability due to leprosy. At the mid-point in the implementation of this plan, a Mid-Term Review (MTR) was conducted to assess the progress of the NTLD in implementing its plan and to identify implementation gaps.

The MTR was conducted within the context of a rapidly devolving health system that gives increasing responsibility to 47 newly formed counties. All government funding for TB and leprosy, including commodities and support for implementation, was devolved to the counties in 2013. In accordance with the Constitution, all devolved funds were bundled and no line item for health, or TB, was specified. Counties were not advised on how to plan for or cost activities in support of TB and leprosy control. No TB or leprosy commodities have been procured by the counties and a supply stock-out for retreatment cases is looming within months. The central unit maintains responsibility for normative functions and technical leadership, while all implementation arrangements have become the responsibility of the counties. The emergence of a new health sector strategy is imminent and will reflect the new government structures. Recommendations were considered in light of these changes in the health system. This report details the major findings and recommendations of the MTR, which involved international consultants, donors and technical partners supporting a multi-sectoral group of Kenyan experts, partners and agencies.

MAIN FINDINGS AND RECOMMENDATIONS

KEY ACHIEVEMENTS

Kenya is globally recognized as a **pathfinder for TB and leprosy control**. Within the African region, Kenya was the first country to achieve WHO targets for case detection and treatment success of new smear-positive pulmonary TB cases. **Treatment success continues to be a hallmark of the programme**, with rates among new smear-positive cases averaging over 88% among HIV-negative patients, 82% among PLHIV, and approximately 82% among those being treated for MDR-TB. The country has been **a leader in rolling out TB/HIV collaborative activities**, with over 93% of patients with TB being tested for HIV in 2013, 98% of patients with TB disease and HIV infection (TB/HIV) receive cotrimoxazole preventive therapy (CPT) and 74% being started on anti-retroviral therapy (ART). The review found that in 75% of facilities visited, TB and HIV services were offered in the same room for patients with TB/HIV. The uptake of TB screening among PLHIV has improved, with 83% screened for TB at their last visit, among the sites visited.

Kenya was one of the first countries in the region to embrace the systematic involvement of private providers in TB control, through its Public-Private Mix (PPM) model. Over **10% of notified cases now come from the private sector**. Kenya was also the first country in the region to

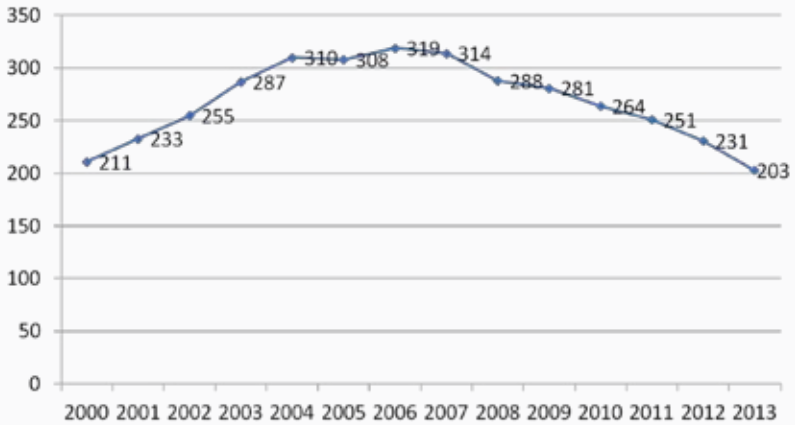
Introduce a case-based electronic recording system for monitoring programme activities. Known as TIBU, this system is now used nationwide.

Community engagement in TB control has been facilitated by the rollout of a national strategy, with an **increasing number of civil society organizations and local partners** becoming involved. Information, Education and Communication materials for TB have been developed and disseminated nationally.

Activities to increase case detection and to **improve the care of children with TB have been initiated**. Guidelines, on-the-job tools and capacity building activities have been developed. All pediatric formulations of recommended medicines were available in many of the facilities visited. Currently, 11.4% of cases identified are children.

These inaugural and sustained successes have led to what appears to be a steady **decline, since 2006, in the case notification rate (CNR), which may resemble a decline in the incidence of TB** (figure 1).

Figure 1. Declining CNR suggests decline in incidence



The review acknowledged the presence of three pillars that seem to support the success of the NTLD. These include:

1) **Sustained government commitment**: The **Government of Kenya's financial contributions to TB have increased** gradually over the past decade and now account for approximately 28% of all spending on TB control in the country. The country has maintained government funding for commodities and a strong staffing structure that extended from and linked the central level to the primary health care system, key indicators of government commitment. Stock-outs of anti-TB medicines at facility level were reported only rarely during the MTR site visits. The review team commended the Government of Kenya on its humanitarian and important public health decision to treat MDR-TB among refugees residing in Kenya.

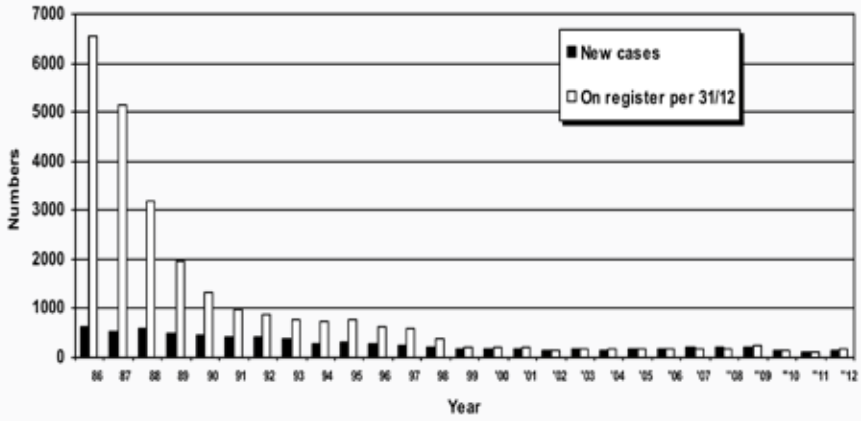
2) **Evidence-based innovation**: As evidenced by its early adoption of innovations in TB control, such as PPM, community-based care and TB/HIV collaborative activities, the NTLD has historically operated with a willingness to identify challenges in the programme and to try new approaches. It has systematically piloted new approaches, learned from the early experiences, and scaled-up what works. The recent **nationwide rollout of TIBU**, the electronic case-based recording system, is a tremendous achievement by the NTLD. It will enable real-time evaluation of programme performance, including the identifications of any emerging challenges to be addressed, at any level of the health system.

The **adoption and rollout of new diagnostic technologies** is to be commended. The country currently has 70 Xpert MDR/RIF machines, 5 culture laboratories, and 150 LED microscopes, operating within the network of 1860 diagnostic facilities (1:25,000 population). Scale-up of Xpert represents a tremendous opportunity to more rapidly and accurately diagnose and treat TB in people living with HIV and among children, as well as to identify drug resistance.

3) **Strong partnerships:** Under solid stewardship by the Government, the NTLD benefits from long-standing partnerships with its donors and technical partners, especially USAID, Global Fund, WHO, CDC, KNCV, World Bank, GDF, and FIND. In addition, it has been able to mobilize and ensure collaboration with Community-based Organizations (CBOs), non-governmental organizations (NGOs), Stop TB Partnership, and the private sector. Its s**ustained engagement with partners through the Inter-Agency Coordinated Committee** (ICC) and its five component working groups, is to be applauded.

Leprosy control is fully integrated in the primary healthcare network. Kenya's successful efforts in leprosy control have placed the country in a **post-elimination phase.**

Figure 2. Declining notification of leprosy



MAIN CHALLENGES

To NTLD is well positioned to emerge as a flagship programme within the new health sector strategy, and to contribute to the sector-wide target of a 62% reduction in deaths due to communicable diseases by 2018. To do so, the review team identified challenges that will need to be overcome related to 1) preventing transmission and disease; 2) finding all TB and leprosy patients; 3) ensuring that all TB and leprosy patients are cured; and 4) securing an enabling environment for quality TB control.

Preventing transmission and disease

The NTLD has excelled in establishing a solid foundation for the control of TB and leprosy disease through the primary health care network. While enhancing the quality of these operations, it can also move into the next era for TB control with an enhanced focus on preventing transmission and disease. Specifically, the team observed limited use of Isoniazid Preventive Therapy (IPT) among PLHIV, and among the childhood contacts of people diagnosed with TB. Infection control (IC) practices were found to be inconsistent, and generally sub-optimal in many health facilities serving patients with TB. Cases of TB disease were noted among health workers in many of the sites visited.

Finding all TB and leprosy cases

a. Diagnostics network: Four broad challenges to ensuring timely diagnosis of TB were identified. The first relates to the introduction of new diagnostic technologies. The review team noted the absence of an up-to-date strategic plan that articulates the levels at which the various new technologies should be positioned and for what purposes. In some cases, the new technologies may be able to replace more antiquated and error-prone methods. For example, the use of Xpert as the first tool for diagnosing TB among PLHIV is not yet routine. The further decentralization, concurrently, of culture capacity and Xpert machines may not be efficient. High-quality culture is difficult to implement, while Xpert can accomplish much of the culture would be used for at county level and is simpler to implement. The second relates to the limited access to, high patient cost of, and inferior quality of x-rays for TB diagnosis. Finally, while the coverage of external quality assurance was reported as 85%, the review team found inadequate quality testing practices and a lack of timely feedback of results to inform good practice. Mentorship and technical assistance to laboratory technicians was found to be irregular. The final challenge will be to remove the financial and geographic barriers to high-quality diagnostic services, especially for children and at-risk populations.

b. TB/HIV collaborative activities: In the context of a quickly evolving diagnostic and care landscape, the TB and HIV programs are operating with antiquated guidelines for implementation of the five I's [1] . HIV testing among patients with TBs was routinely conducted and monitored, and teams found that recording of TB screening among people living with HIV was done but not consistently reported through standardized data capture systems. This presents challenges to the monitoring of programme performance related to the screening policy. Limited access to diagnostics beyond smear microscopy is a major barrier to clinicians screening for TB among PLHIV.

c. Intensified Case Finding (ICF) activities among contacts of TB and MDR-TB patients remains limited. Barriers to ICF were noted, including the costs of transport, food and x- rays.

d. Childhood TB: There remains limited access to diagnostics for childhood TB, especially quality chest x-ray, TST and Xpert. Fee-based testing presents a financial barrier for many families. The team found poor integration between maternal and child health (MCH) clinics, pediatric clinics, emergency rooms and TB service providers. Staff at all levels of the health system showed a low index of suspicion for pediatric TB and were not aware of new treatment guidance and dosing.

e. PMDT: Drug resistance testing is limited mostly to retreatment patients, missing many patients with resistance.

f. Leprosy: The review noted a low index of suspicion for leprosy among health care workers, even in geographic areas where new cases of leprosy have been reported.

1 Intensified case finding, Isoniazid preventive therapy, Infection Control, Initiate early antiretroviral

Ensuring that all patients are cured

a. **Monitoring and evaluation**: Monitoring, supervision, quality control and evaluation of program activities were sub-optimal at all levels of the system. This deficit was most severein the diagnostic network, as noted above. The gaps appeared to be largely associated with a lack of clarity at county-level about the availability of funding for supervision, following devolution. The TIBU may support more routine monitoring, but the system is not yet utilized optimally and there are still challenges in data quality. Capacity to utilize the TIBU- generated local data for decision-making was lacking.

b. **Care for patients with MDR-TB**: While the treatment outcomes for PMDT have improved every year since 2008, social and nutritional support for patients remains inconsistent. At the county level, there are limited isolation facilities, no functional PMDT clinical teams, and pharmacovigilance was found insufficient. The high burden of MDR-TB among refugees presents a public health challenge, particularly given the political sensitivities inherent in working with this population.

c. **Community-based car**e: Systematic linkages between providers of community-based care and health facilities were not consistently found, leaving some care providers without the needed mentorship and support required to deliver quality care.

d. **Social determinants of TB**: The World Bank estimates that Kenya's poverty rate was, in 2013, between 34 and 42 percent. While this is down from 47 percent in 2005, the social determinants of TB cannot be overlooked. In the Kenyan Demographic and Health Survey, financial barriers to care were a primary cause of delayed care seeking. The review team identified financial barriers stemming from transportation costs and fee-based diagnostic tests, as well as lack of nutritional and financial support during the intensive phase of treatment. The NTLD estimates that 17% of patients with TB are severely malnourished and a further 21% are moderately malnourished. In addition to affecting treatment adherence, due to nausea with the drugs, malnourishment has been found to negatively affect treatment outcomes.

e. **Public-private mix**: While evidence has suggested that nearly half of care seeking for TB and other lung health issues is done through the private sector, only 10.5% of TB cases were notified by the private sector in 2012. Further scale-up is needed of collaborative public-private mix interventions may be required to ensure the nationwide application of International Standards of TB Care, particularly through the private providers.

Sustaining government commitment and stewardship in a devolved system

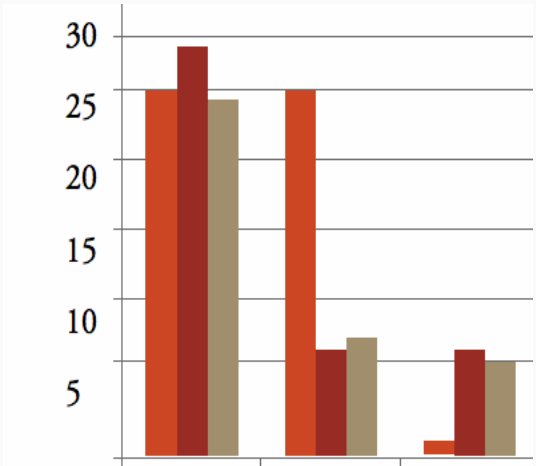
The review acknowledged the potential for devolution to further patient-centered care by enabling county and sub-county level adaptations to service delivery that align with specific population needs. However, the team also recognized risks that will need to be mitigated to ensure that the successes of a cohesive national progamme are sustained through the prioritization of TB, and consideration of leprosy, by all 47 counties. Key challenges will include:

a. **Ensuring a stable and quality assured drug supply nationally**: Limited capacity for commodity management was found at all levels of the system. At the time of the review, a 3-month stock of several TB medicines needed for retreatment cases was all that was remaining at the Kenya Medical Supplies Agency (KEMSA). Funding for TB commodity needs was devolved to the counties in 2013. No county had, at the time of the review, tendered for TB medicines or ordered through KEMSA. A normal procurement cycle can take 6-9 months. At the time of the review, quantification was being carried out by NTLD with support from TB commodity security sub-committee, of which KEMSA is also a member. KEMSA remains responsible for procurement, storage and distribution to counties. The crisis will be temporarily mitigated through an emergency procurement, a donation from the Global Drug Facility and potentially supported by supplemental funding from the Government of Kenya. However, a long-term solution will be needed to avoid future disruptions, stock-outs, or the introduction of sub-standard TB medicines

b. **Closing the financing gap for TB control:** Over the next 5 years, the MTR estimated that the NTLD will face a financing gap of nearly $200 million, which represents half of its required funding. Data from the National Health Accounts (NHA) suggested that while TB accounts for over 6% of deaths and nearly 5% of DALYs in the country, it receives only 1% of total health expenditures for priority areas. This can be compared to malaria's contribution to nearly 6% of deaths and 7% of DALYs, but in receipt of 25% of total health expenditures for priority areas.

c. **Ensuring sustained priority for TB prevention and control at central and county levels**: TB is not fully considered within the health sector strategy (e.g. the only indicator for TB is treatment success rate), and is not an integral part of the essential health package that is forming the basis for emerging/expanding demand-side, performance-based and social support financing schemes. For example, the direct facility cash transfer program called the Health Sector Services Fund (HSSF) or the health insurance for poor families called the Health Insurance Subsidy Programme (HISP) does not include TB prevention and control services. At county level, health plans were not available for review as they were still being developed, but the inclusion of TB and leprosy activities is not guaranteed.

Figure 3. Total health expenditure for priority areas, 2010



	HIV/AIDS	Malaria	TB
THE	25	25	1
Deaths	29.3	5.8	6.3
DALY	24.2	7.2	4.8

d. **Re-profiling the functions and staff of central unit to support new roles**: The functions of the central unit have expanded to include: a) high-level policy formulation to include TB in emerging health system strategies, plans, and demand-side financing modalities including national health insurance and social protection programs; b) coordination of a comprehensive programme through guidance / support to 47 counties; and c) continued technical leadership. This will overstretch the current central unit team, even while further devolution of staff is ongoing. Additional skills, particularly related to economics and statistics, may be required at the unit or division level.

e. **Building the capacity of counties and renewing a comprehensive national program**: Planning and budgeting tools to support county-level planning for TB and leprosy control activities, including drug quantification estimates, have not yet been developed. Counties were not aware of the funding availability for / or had not programmed funding for TB or leprosy control activities, including supervision. As such, activities had, in many cases, ceased.

f. **Shifting epidemiology of TB**: With the potential to detect drug resistance, improved capacity to diagnose TB among children and PLHIV, the ongoing refugee crisis, and the aging of the epidemic, the epidemiological mix of patients under care will change in future years. Building the capacity of county-level planners to recognize these trends locally and to support relevant activities will be needed to ensure care for these populations.

Priority recommendations

Responding to the challenges identified above, the MTR recommends specific actions to support: 1) preventing transmission and disease; 2) finding all people with TB and leprosy; 3) ensuring that all patients with TB and leprosy are cured; and 4) securing an enabling environment for quality TB control. The agent to whom the recommendation is made is noted after each recommendation.

Preventing transmission and disease

1. **Develop a "Prevention" sub-component of the 5-year national strategy to accelerate activities aimed at the prevention of TB transmission and disease, and leprosy transmission and disability (NTLD and partners).** The MTR recommends that the plan prioritize activities for high-risk groups such as PLHIV, children, health workers, marginalized or impoverished, and those with drug-resistant disease. In some cases, operational research to better understand the barriers to scale-up, or to measure the impact of the interventions prior to full scale-up, may be warranted. Consider the following aspects of prevention:

    a. IPT for PLHIV and for children in contact with people diagnosed with TB
    b. Intensified case finding among contacts of patients with MDR-TB, childhood contacts of any TB or leprosy case, and in counties with highest poverty rates
    c. Infection control in laboratories and health facilities
    d. Reductions in diagnostic delay to reduce transmission and improve outcomes
    e. Prevent nosocomial transmission
    f. Early initiation of ART and CPT

Finding all TB and leprosy cases

2. **Ensure technical assistance and quality assurance (NTLD, NTRL, county health offices)** through a cascade from central to community levels. Given that many of the county and sub-county staff are new, NTLD and NTRL staff are encouraged to refresh the capacity of TB and leprosy focal points in the counties for planning and conducting supportive technical assistance. This can be accomplished through routinely scheduled technical assistance visits, development and dissemination of on-the job tools, and through continuous medical education. Ensure county ownership and designated funding of technical assistance within county health plans; including monitoring of sub-counties, health facilities, laboratories and community-based treatment partners to ensure implementation of technical standards, including updated SOPs for new diagnostic technologies, and treatment protocols for pediatric and drug-resistant TB. Revise the tools available to guide county- level staff in their supervision of more decentralized levels, based on the new county structure.

Preventing transmission and disease

3. Develop a comprehensive strategy for improving access to timely diagnosis of TB (NTRL and NTLD).

a. Revise the diagnostic algorithms to take into account the availability of new technologies, such as Xpert. The MTR suggests expanding the use of Xpert as the initial diagnostic tool of choice for people living with HIV, children, and among those with presumed drug resistance.

b. Update the national policies and develop a diagnostics network plan that considers how to optimize diagnostic efficiency that limits costs, distance to access diagnostic testing and delays in the receipt of results to patients, and increases the feasibility of ensuring the quality of diagnosis by the NTRL and NTLD. The plan should include timely referral systems for Xpert and culture. Indicators of success will include reduced delay of receipt of diagnostic results, especially for drug-resistance. The updated policy will define the levels of the health system at which specific tools should be positioned and for what purposes. Mapping of the geographic barriers to access to diagnosis should be considered as expansion plans are made. Further scale-up of the number of Xpert machines should be based on the revised policy (ies), quantification / documentation of workload, and ability to guarantee quality. Identify and ensure the capacity of laboratory sites to support drug resistance screening for all retreatment cases and high-risk new cases, such as PLHIV and children.

c. Pilot mobile digital X-ray units in high volume sites with a vision for wider roll out.

4. Make x-rays and Xpert testing free for children The financial barriers to diagnosis may delay notification of childhood TB cases. Consideration should be given to removing the financial cost of diagnostic tests to all presumptive TB patients, particularly for the poor and among those living with HIV.

5. Enhance the quality of existing TB Culture & DST labs (NTRL) and optimize their access and utilization. Reassess the need of multiple culture labs, given the thrust on innovative molecular technologies for rapid DST.

6. Update the national TB/HIV guidelines and ensure implementation of the 5 I's through the devolved county structure (NASCOP, NACC and NTLD). Specific activities include:

d. Mapping of all TB/HIV activities required to fully implement the 5 I's to responsible technical and implementation units. This may form the basis for designation of funding lines during the upcoming application, via a common concept note, to the Global Fund.

e. Develop a staffing plan, in accordance with the responsibility mapping. The MTR encourages consideration of existing capacities and the need to conduct further training on TB/HIV given the changes in county and sub-county staff, in particular.

7. Rapidly accelerate the engagement of all care providers (KAPTLD, KPA, NTLD, county health officers, CSOs and stakeholders).

f. The MTR concluded that while Kenya has been a model internationally for its early engagement of the private sector, the contribution from the private sector and NGO facilities to case finding should be at least twice the current levels. To enhance collaboration, counties may be encouraged to: map all service providers and encourage engagement, include private providers in capacity building activities, supportive supervision visits, and as recipients of job aides and national guidelines.

g. To improve linkages with MCH services, the MTR encourages the NTLD to develop a plan to engage the Kenya Pediatric Association (KPA) and MoH MCH program in awareness raising, capacity building and technical norms dissemination among their members / providers.

h. The MTR encourages enhanced engagement with civil society organizations and other community-based case structures, including their formal linkages to health facilities through the signing of Memoranda of Understanding.

Ensuring that all patients are cured

8. **Enhance supportive supervision at all levels** particularly from central-to-county level during the 3-years of transition to the county structure (NTLD). The nature of supportive supervision from central to county level must be expanded to build capacity for planning, advocacy, budgeting, quality assurance of labs and facilities, and data monitoring.

    a. Creation of on-the-job tools: the MTR noted a lack of on-the-job guides or tools to serve as reminders to key policy and implementation principles. As the infrastructure to support electronic data management rolls out, potential for web- based refresher training may be optimized to address the ongoing training needs that result from high staff turnover

    b. Update and disseminate, as part of supervisory visits, IEC and on-the-job tools for leprosy, specifically to raise the index of suspicion for leprosy in targeted sub- counties.

9. **Strengthen the systems that support PMDT** Establish PMDT teams at each level to monitor case finding and patient management. Establish admissions facilities in each county for MDR-TB patients, and promote the availability of nutritional and other social support for those being managed on an outpatient basis. Ensure adequate inclusion of PMDT in the TIBU system. Set up an interagency /inter-ministerial team to address the cross border MDR-TB problem.

Sustaining government commitment and stewardship in a devolved system

10. **Sustain central government funding and nationally pooled procurement of anti-TB medicines (MoH, KEMSA, NTLD and county health offices),** assuring the quality, timely ordering and best pricing of the national supply. In the immediate term, allocate emergency funding for the procurement of anti-TB medicines sufficient to re-establish at least a twelve-month buffer stock at central level. KEMSA to build capacity at county level for quantification of needs and management of commodity supplies. Special attention to pharmaco vigilance for PMDT to be included. Counties to invest in improvements to the infrastructure and capacity of counties/sub-counties to store and distribute within their catchment areas.

11. **Ensure sufficient capacity for all TB activities, at appropriate levels. Prioritize the capacity building at county level for all aspects of TB and leprosy control. Re-profile staffing requirements of the central unit (NTLD, Division of Communicable Disease Prevention and Control (DCDPC), NHA, WHO).** Recognizing that counties are receiving support and guidance from all domains of the central MoH, the MTR encourages the DCDPC to consider efficiencies that may be derived in providing TB and leprosy-specific guidance within the context of coordinated support to counties; i.e. collaborating with other communicable disease programs. Some of the specific needs include:

    a. Urgently meet with county health teams to more elaborately define and document the roles and responsibilities of the various levels, including the need(s) for technical assistance. Articulate the human resource requirements and skill sets needed at all levels.

    b. Develop tools and build capacity to support robust county-level planning and budgeting for TB and leprosy. The MTR was envisaging a simplified version of the WHO planning tool for TB control that could offer counties a way of recalling all priority activities and for determining budget needs. The tool would include a module for determining commodity requirements. The MTR encourages the central unit to prioritize technical assistance to each of the counties for the development of the TB and leprosy components of county health plans. An iterative process of national planning by the NTLD, combined with the aggregation of activities from county plans, must be completed annually to identify and rectify any gaps in priority activities.

    c. Promote the establishment of inter-agency coordinating committees to assist with planning, budgeting, implementing and monitoring activities. The ICCs would all partners such as the private sector, MCH programme, CSOs and communities, at county and sub-county levels.

    d. Central unit to monitor, annually, the sufficiency of county health plans with respect to TB and leprosy control. NTLD to monitor expenditures on TB, through the NHA sub-account and via expenditure tracking from Treasury to facilities

e. Re-profile the staff of the central unit to ensure in-house capacity for a) high-level policy formulation to include TB in emerging health system strategies, plans, and demand-side financing modalities including national health insurance and social protection programmes; b) coordination of a comprehensive programme through guidance / technical assistance to 47 counties; and c) continued technical leadership. Additional skills, particularly related to economics and statistics, may be required at the unit or division level.

12. Strengthen the use of data for decision making (MoH, NTLD, research institutes and partners). The MTR was enthusiastic about TIBU and encourages the NTLD to continue to refine it to meet more programmatic needs. Among the specific recommendations are:

a. Conduct quarterly, systematic data quality assessments to improve the completeness, accuracy and consistency of surveillance data.

b. Build capacity on data management at all levels and enhance supervision/mentorship on the job. Ensure availability and usage of all standardized revised recording and reporting tools at all levels

c. Expand TIBU to better link with the Laboratory Management Information System (LMIS), and to cover additional areas such as PMDT and prevention and intensified case finding activities. DCDPC to consider if other disease monitoring and the HMIS can be linked to TIBU. MTR specifically advises to explore integrating TB and HIV surveillance to complement the integrated control activities. MoH encouraged to prioritize the improvement of the quality of the vital registration system to better capture TB deaths.

d. Finalize a core set of analytical outputs from TIBU, i.e. a "dashboard" that can be generated at any level to facilitate the use of real-time data for decision making even where analytical capacity is weak.

e. Promote the inclusion of TB and leprosy targets and M&E strategies within county health strategies and work plans.

f. Develop and implement a prioritized operational research agenda within the next 5- year plan and continue building operational research capacity (learning while doing/mentorship) throughout the health system. The MTR recommends that 10% of the total budget for TB control operations (not including drugs) be maintained for monitoring and evaluation, and operational research to inform the programme and health sector. The dormant Research Forum should be revived to enhance collaboration with research institutions to accelerate the completion and dissemination of operational research and enhance building of local capacity

13. Actively participate in national policy and planning process in the move towards universal health coverage, ensuring that TB and leprosy control are appropriately positioned (MoH, NTLD, with partners). TToward this end, specific recommendations include:

a. Articulate the investment case for TB control in Kenya, with targeted policy briefers to inform county and national level policy-development. It may be necessary to change perceptions that TB and leprosy are sufficiently funded or can operate sustainably on supply-side financing.

b. Define the reimbursement package that would be required to fully reimburse service delivery providers for the care of a TB or MDR-TB case. Ensure that these are made available to the NHIF, for the purposes of consideration under the HISP and other future insurance schemes.

c. Ensure the inclusion of TB, and leprosy where appropriate, in broad sector strategies and initiatives. Actively collaborate across the MoH, including with NHA, NACC, NASCOP, and Policy & Planning; with other sectors such as labor, education, and social protection; and with external partners working on devolution, such as the World Bank. Some of the immediate needs include:

i. Health sector strategy: targets for TB should include both notification and treatment outcome indicators
ii. Health policy: TB should be included within the essential health package
iii. Social protection: TB patients should be eligible for nutritional, transportation and cash support
iv. Monitor the impact (positive and negative) of devolution and emerging financing modalities on TB case notifications and treatment outcomes, with a view to learning lessons for scale-up of what works

MID-TERM REVIEW METHODOLOGY

The aim of the mid-term review was to perform an assessment of the National TB, Leprosy and Lung Diseases Unit. The review aimed to assist the Government of Kenya to **identify and prioritize high-impact interventions** that will further strengthen TB control and further progress toward leprosy elimination, particularly in the **context of changing government structures**, the **evolving epidemiology of TB** in the country, and new **opportunities for funding** through Government of Kenya and external sources.

The objectives of the mid-term review were:

1) To review the progress of the National TB Program during the period 2011-2014

a. To assess the progress made by National TB Program and identify the key challenges for the full implementation of the current strategic plan 2011-2015 as per the objectives and set targets
b. To review the findings of an in-depth epidemiological assessment, as they relate to understanding progress and remaining challenges

2) To identify implementation challenges, and emerging needs and opportunities

a. To assess the alignment of the National TB Program with the new constitution and devolved system of government (County government), health policy, Kenya Health Sector Strategic Plan III (KHSS II), Kenya Medium Term Plan (MTP) II and vision 2030, including poverty reduction
b. To identify under-served and at-risk populations for TB, MDR-TB, TB/HIV and pediatric TB
c. To identify best practices that warrant scale-up

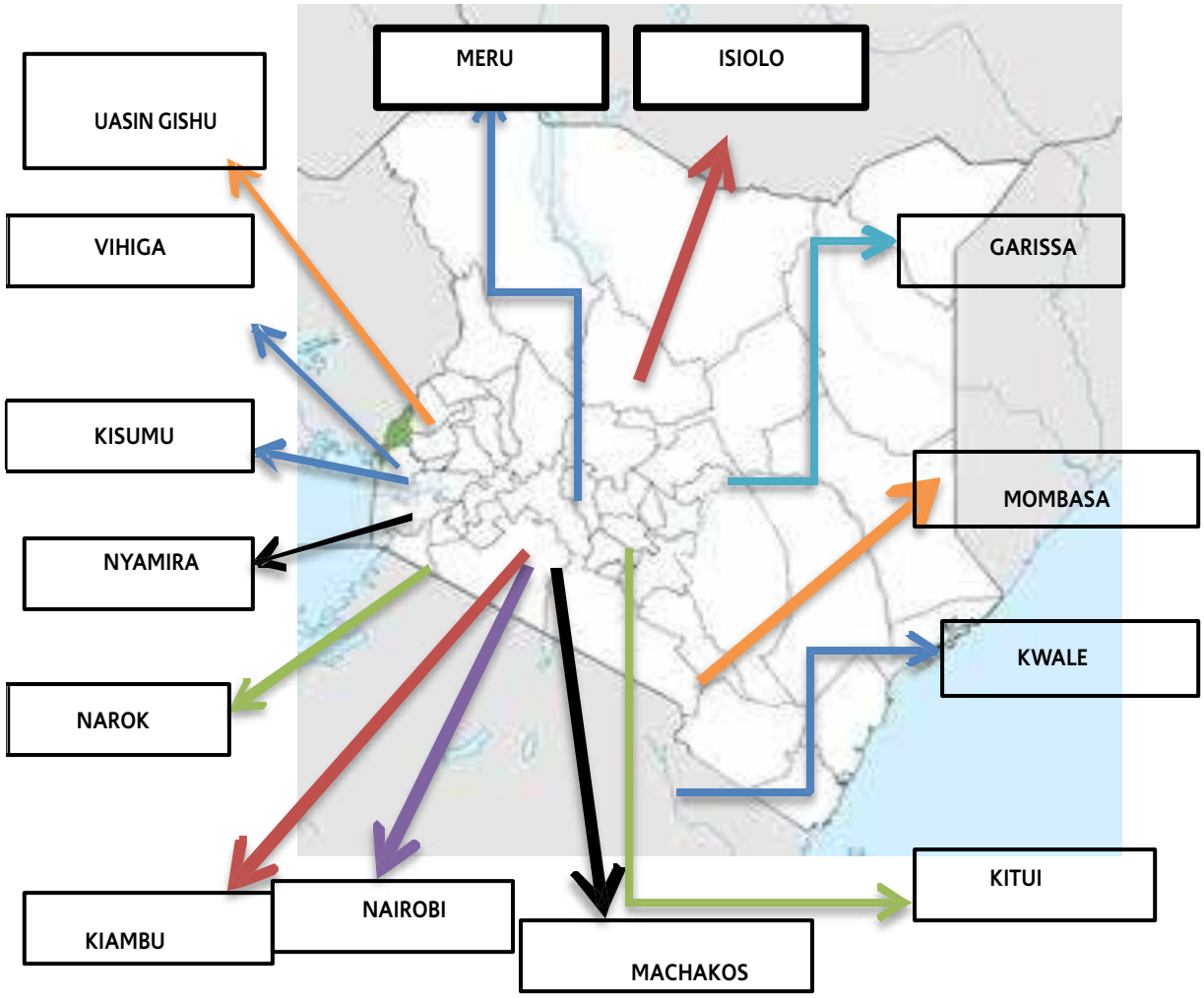
3) To prioritize high-impact interventions and plan for the future of TB control

a. To identify and prioritize actions needed to enhance the implementation of the current plan and accelerate progress in future
b. To identify and prioritize programming and financing gaps

c. To engage stakeholders and funding partners in updating the strategy of the National TB Program

The review team was comprised of 18 external experts from 14 countries, and over 40 Ministry of Health staff (annex 3). The team represented 15 county health offices, 13 partner organizations, and 8 community service organizations. The review team visited county offices, service delivery and diagnostic facilities in 14 counties (figure 4).

Figure 4. Counties visited



Thematic teams

1. DOTS expansion and enhancement
2. Enhanced diagnostics
3. ACSM, community TB care
4. TB/HIV
5. Childhood TB
6. PMDT
7. PPM and lung health
8. Leprosy control
9. M&E, HMIS, operational research
10. Policy and financing
11. Commodity supply and management (concurrent GDF and GLC reviews)

Among the facilities visited were: 15 county or referral hospitals, 23 sub-county hospitals, 9 private or mission hospitals, 33 health centers, 16 dispensaries, 4 prisons, Dadaab refugee camp, the Central Reference Laboratory, KEMSA and the KEMRI/CDC laboratory in Kisumu. The team also interviewed representatives from key policy-making and financing organizations and offices, such as Treasury, National Health Insurance Fund, MoH office of policy and planning, MoH National Health Accounts, World Bank, WHO, Futures Group, and Centre for Health Solutions. A full list of review team members and persons met is included in Annex 3.

The review was informed by an epidemiological and impact assessment conducted by CDC and staff from WHO/Kenya (annex 1). The teams met for an orientation on 28 February, including briefings by the Health Planning and Policy unit of the Ministry of Health, the National AIDS Control (NASCOP) program, and spent one week in the field. Nine teams were mobilized, with each individual having dual responsibilities for: a) reviewing the overall performance of TB and leprosy control in specific geographic areas, and b) for conducting an in-depth review of a thematic area.

Concurrent missions of the Global Drug Facility and Green Light Committee brought additional expertise and insights to the MTR.

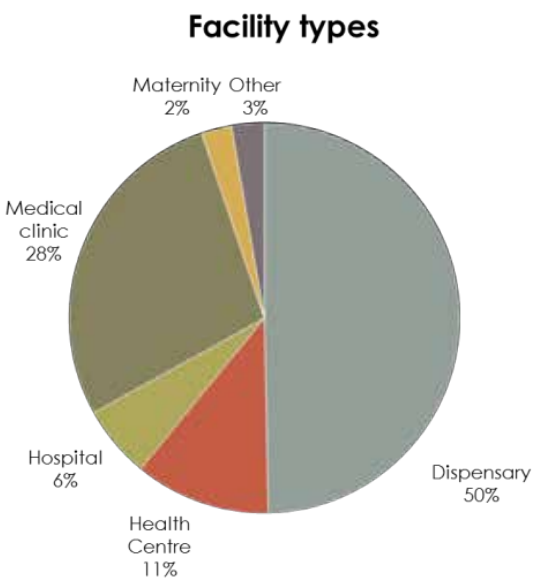
Standardized questionnaires were developed based on the defined objectives of the review and with inputs from each of the thematic teams (annex 4). The questionnaires were used to ensure that a consistent baseline of quantitative and qualitative data were collected from each region and site visited. The completed questionnaires were shared with the relevant thematic teams. At the end of the field visits, each team prepared and presented a summary of the findings from their geographic area (annex 2). With the backdrop of perspectives and findings from various regions, the teams compiled theme-specific findings and recommendations. Final recommendations were discussed in plenary and agreed by all members of the MTR before being presented to stakeholders and senior Ministry of Health officials.

DETAILED FINDINGS; DOTS EXPANSION & ENHANCEMENT

INTRODUCTION

The political commitment to address tuberculosis is evidenced by a well-organized response management structure, the NTLD, within the Ministry of Health (MOH) with relevant policy, strategies and guidelines developed in line with international recommendations. The provision of anti-tuberculosis drugs and laboratory diagnostics are also mainly financed through public funding. Response management structures and functions at the county and sub-county levels are evolving within the context of the government's recent devolution policy. TB, leprosy and lung health service delivery is fully integrated into the primary health care network and utilizing all levels of the health care system (figure 5).

Figure 5. Types of health facilities



Source: Master Facility List, 2012

Overall the country made considerable progress in expanding access to quality TB diagnosis and treatment services over the last 5 years. Currently, TB microscopy services are provided in about one-third (33%) of health facilities in the country, with 91% of hospitals, 74% of health centers, 20% of dispensaries and 15% of clinics having capacity to provide the service. This translates to 1 TB microscopy centre per 25,000 population compared to 1/60,000 in 2008. Access to initial diagnosis of TB has been enhanced through rollout of Xpert MTB/Rif, which allows for rapid identification of rifampicin resistant cases for early initiation of DR-TB treatment.

Access to mycobacterial culture and drug susceptibility testing (DST) on the other hand, has remained limited as currently 1 culture facility serves approximately 20-25 million population compared to 5 million recommended by WHO. Consequently, a high turn-around time of up to 3 – 6 months has been experienced which could potentially delay treatment initiation for drug resistant cases. Similarly, access to other key supportive diagnostic methods including Chest X-ray was also found to be limited in most health facilities mainly as a result of prohibitive costs to TB patients as well as inadequate quality and interpretation of radiographs for TB diagnosis especially in children

Achievements

TB treatment services: Remarkable progress has been recorded in decentralization of TB treatment with well-defined referral pathways. Currently 1 TB treatment or follow-up centre serves less than 15,000 population. The programme has maintained high treatment success rates of above 85% during the last 5 years. Timely treatment initiation was observed especially for diagnosed sputum smear positive patients.

In collaboration with partners such as the African Medical Research Foundation (AMREF), the programme has initiated projects to reach under-served population, mainly urban slum dwellers (Kibera), prisons, refugees; mobile and hard-to-reach reach populations with TB diagnostic, treatment and care services. The national TB management guidelines are largely adhered to in the field with application of appropriate guidelines and related tools including algorithms, SOPs, job aids in most treatment units.

Patient support is incorporated in the treatment with family members, community volunteers and Community Health Workers (CHW) providing adherence support, and retrieval of loss to follow up cases. Innovations to minimize loss to follow-up through use of mobile technology platforms (e.g. SMS reminders in some sites) were being implemented.

Health promotion materials were found in various health facilities, but not all. The impact of these materials on patient education and adherence has yet to be assessed.

Active Case Finding Approaches: The Kenyan NTP has implemented a number of active TB case finding initiatives on a limited scale in parts of the country including intensified case finding as a component of a community health strategy involving monthly household visits by community health workers to screen for TB and other conditions; and a community-based cough monitor program implemented in Western Kenya, which included active case finding.

TB, poverty, and social protection initiatives: The AMPATH Safety net, an income/ livelihood and food security initiative of the Kenyan Government in collaboration with USAID was found to be an innovation for possible scale up towards poverty alleviation among TB patients as a medium to long- term measure.

Key Challenges

1. **Programme coordination function and supportive supervision at county and sub-county levels in the devolved system not clearly defined;** There are investigations for people with presumptive TB and the programme has increased the absolute numbers of sputum smears done towards investigation of persons with presumptive TB. However, this has not resulted in a corresponding increase in the number of notified TB cases. High-risk populations including PLHIV specifically targeted for intensified TB case finding using Xpert MTB/Rif. TB screening in PLHIV and in people counseled and tested for HIV (HCT, pre-ART, ART, ANC) is being implemented but without systematic recording and reporting in most cases. Systematic TB screening at the point of triaging is not a standard practice in general OPDs or hospital wards and while that have been mobile team activities to remote areas, the quality/standardization of documentation and follow up on TB screening practices in the field needs strengthening.

2. **Sub-optimal active TB case finding approaches at both health facility and community levels**. Although systemic contact investigation is a policy of the national TB programme, the implementation of contact investigation is not systematic and in most cases not properly documented. Some community-based TB care platforms exists, which can be utilized for implementation of systematic contact investigation, but so far the linkages are inadequate. A national committee of CSOs along with two community-based care models were established under ENGAGE-TB. These emerging community-based platforms may be effective conduits for promoting and implementing contact investigations.

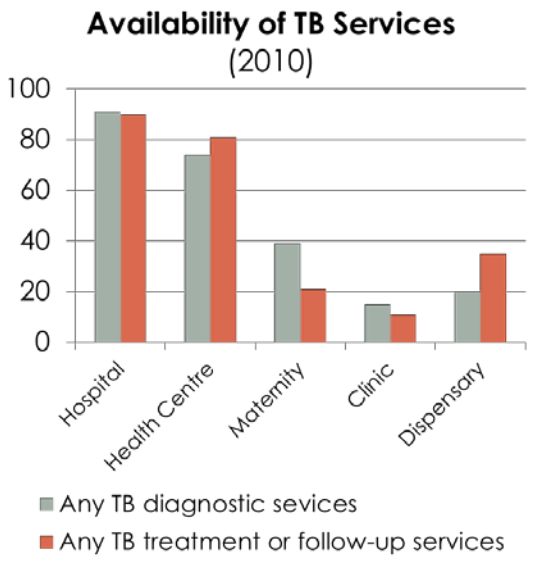
3. **Diagnostic delays experienced especially among smear negative patients**. A diagnostic delay survey is currently being undertaken in Kenya by the NLTD-Unit, as there are limited data available on diagnostic delays. Results of a brief literature search showed that average patient delays ranged from 42 -129 days. One such study reported that 58% of all patients presented to the health facility more than 3 weeks after the onset of symptoms. In addition to contributing to TB transmission in the community, these long delays in seeking care for TB symptoms impact the pool of prevalent TB cases in the community. There is limited coverage of culture and DST with high turn-around time for results and limited access to quality-assured X-ray services and new diagnostics to support TB diagnosis.

4. **Socio-economic barriers to treatment adherence and inadequate DOT noted,** while some models for the provision of nutritional support have been launched, their effectiveness has not been fully evaluated nor is there a defined programme strategy to provide nutritional supplementation as a component of anti-TB therapy.

5. **TB care and human rights;** the Kenyan constitution provides for health as a basic human right, however, the TB diagnosis, treatment and care National Public Health act is under revision.

6. **Engagement of all levels of the health system**; Despite efforts to build capacity for TB prevention, detection and care at all levels of the health system, it is estimated that fewer than 40% of dispensaries are able to provide TB treatment (figure 6).

Figure 6. Availability of TB services within PHC



Source: 2010 Service Provision Assessment Survey

Recommendations

1. Strengthen coordination and supportive supervision at county and sub-county levels to address HCWs knowledge gaps and improve quality in case management;

2. Strengthen and scale up intensified TB case finding. Systematic TB screening and contact investigation at health facility and community levels with improved linkages; and documentation of presumptive TB cases.

3. Strengthen implementation and monitoring of systematic TB screening in general OPDs, dispensaries and hospital wards; expand scope of contact investigation.

4. Allocation of resources should be commensurate with service delivery demand / where patients are identified and treated (i.e. more at dispensary level).

5. Address barriers to accessing quality X-ray services for TB diagnosis; including cost and technology enhancement;

6. Improve access to critical enablers including nutritional support and social protection for TB patients. Evaluate the impact and if significant, incorporate therapeutic nutritional support into anti-TB treatment.

7. Increase access to culture and DST.

8. Streamline Xpert scale up for broader TB screening. Need to coordinate roll-out among all implementers

9. Scale up ENGAGE-TB initiative nationally to incorporate TB screening, diagnosis and treatment support services in the work of health and non-health NGOs;

9. Expand the scope of the use of mobile technology in patient care

10. Consider use of technology platforms e.g. SMS printers for results transmission to minimize TAT for results of laboratory investigations especially culture and DST.

11. Develop a national policy on CSO engagement in TB prevention, treatment and care, as well as the operational guidance for the engagement of CSOs in TB care (ENGAGE-TB) for health promotion, empowerment and community-based initiatives. Extend involvement and participation of affected populations in TB control programme planning and implementation, resource availability (financial and technical) to support and scale up community level interventions, and ENGAGE- TB approach in Kenya enabling integration of TB screening, diagnosis and treatment services into the work of both health and non-health NGOs/CBOs.

DETAILED FINDINGS: ENHANCED DIAGNOSTICS

Introduction

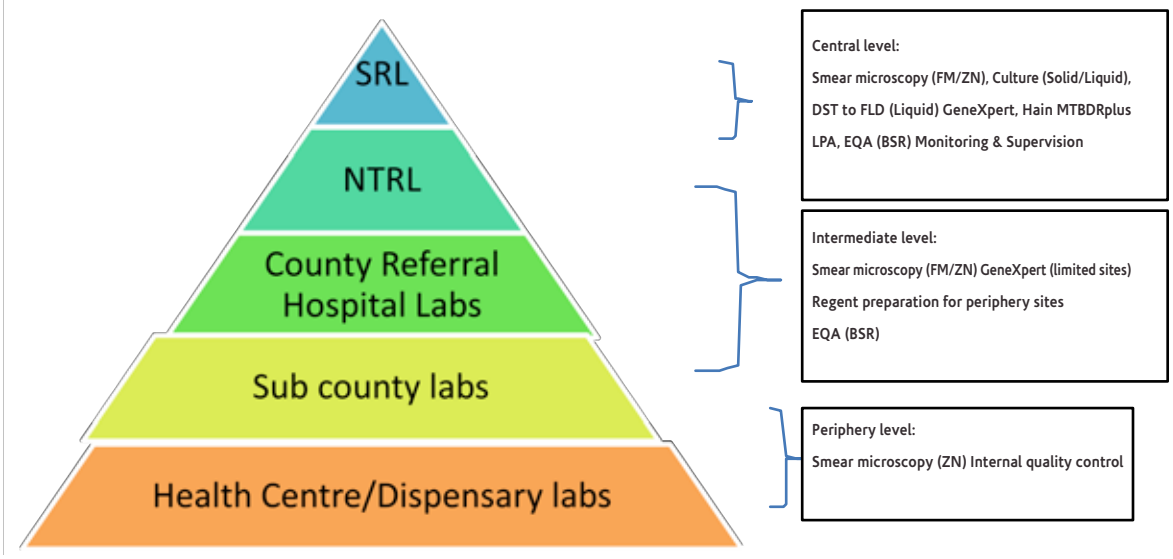
NLTD provides basic TB diagnostic services through decentralized network of sputum microscopy laboratories embedded within the general health services at various levels. There are 1860 TB diagnostics sites against 2992 TB treatment centers. Of these labs, 70% are under public, 20% under voluntary sector and 10% under the private sector. TB diagnostic services are offered at most hospitals (91%) and health centers (78%). At lower level of health services, about 20% of dispensaries and 15% of clinics offer TB diagnostic services. About 88% of TB sputum microscopy facilities are currently under EQA system monitored by NLTD through district functionaries (District Medical Laboratory technicians). All laboratory technicians who perform microscopy are employed after recognition through a medical lab accreditation body. Culture and Drug susceptibility testing (DST) services are presently available in 2 public labs. Availability of culture & DST labs is much lower at 0.2 per 5 million populations National TB reference laboratory at Nairobi, oversees the provision of culture & DST services in the country. About 10% of health facilities in the country have access to chest X-ray and radiological interpretation.

Devolution of health system is being rapidly pursued, as per new country constitution. This, in principle, devolves functions at provincial level of existing health system to county level.

1.0 Laboratory Network Structure

Kenya has a well-structured laboratory network (Figure 7).

Figure 7. TB Laboratories in Kenya



Supranational Reference laboratory: The QMRL, Brisbane, Australia, is the SRL for Kenya that provides support to NTRL in terms of technical assistance (TA) and training (culture, DST, LPA).

Central/Level III: NTRL in Nairobi does solid culture (LJ), liquid culture (MGIT), DST 1st line (Liquid), microscopy (Zn & FM), LPA (R/H), and identification of M. tuberculosis complex (MPT64). Being the NTRL, it is also involved in providing EQA (BSR) and monitoring and supervision of other the provincial laboratories. It should be noted that the majority of the cases presented at NTRL are re-treatment/ follow-up cases. There has been a recent change in organizational structure in relations to the laboratory.
Intermediate/Level II: The 12 provincial laboratories are involved with the diagnosis of new cases using either ZN or FM. Specimens from all the follow-up cases are sent to NTRL for further analysis, including culture.

Peripheral/Level I: There are 1818 microscopy centers performing either Zn or Fluorescence (130 sites) microscopy. Upon clinicians' request, some of these sites refer samples culture laboratories culture and DST.

Apart from NTRL, there are 7 other TB culture laboratories (5 private and 2 public) within the country providing TB culture and or DST services. There are provisions for three upcoming laboratories to perform culture/DST and a proposal for the construction of 6 other culture laboratories (Annex). It should be noted that currently, there are no formal links for data sharing between these laboratories and NTRL. The consultants were informed that these laboratories provide information on laboratory diagnosed TB cases to the NTP directly. Apart from NTRL and KEMRI CDC- Kisian, it was not clear what EQA programs are available for other culture laboratories.

2.0 Inspection of the NTRL

The current laboratory is a refurbishment of the pre-existing Central Reference Laboratory. It is the national TB laboratory for Kenya and is dedicated to providing TB services only. The laboratory has adopted WHO accredited technologies and is currently performing Zn/LED microscopy, solid/liquid culture and 1st line DST using BACTEC MGIT 960. NTRL participates in the EQA programs for culture through Antwerp, SRL. Line Probe Assay (Hain Lifescience MTBDRplus) is performed on all smear positive cases directly from the specimen or from culture if required.

GeneXpert (Xpert MTB/RIF assay - Cepheid) is also routinely performed It should be noted that all the samples are cultured using liquid and solid (LJ) culture. Currently, there are 16 staff members (including 14 scientist and 2 support staff) who are well qualified (9 with degree, 4 with diploma, and 1 with certificate). The laboratory is well catered for with sufficient number of staff members,

equipment and stock levels to perform as a Reference Laboratory. The consultants also had the opportunity to visit the construction site of the future NTRL that is substantially funded by US CDC. The consultants were impressed with the design of the building and it was felt that those involved in the design, construction, and funding of the new laboratory were deserving of congratulation for the work achieved thus far.

Though the laboratory is well catered for, there are no continuous service contracts in place for equipments such as BACTEC MGIT 960, microscopes, Bio-Safety Cabinets, GeneXpert, and LPA equipments. The phenomenon of lack of service contract was noticed at all levels. There is no regular back up of MGIT 960 data As a reference laboratory, NTRL should be performing both 1st and 2nd line DST, however, currently, NTRL is only offering 1st line DST (S, R, H, E). The EQA for DST Culture for round 16, 17, and 18 were not available. Unfortunately, NTRL did not participate in round 19. Round 20 has been recently submitted however, of the 20 isolates received, results for only 15 of the cultures were submitted. Looking at the workload statistics for the year 2013 stated that the contamination rate of liquid culture is 16.6% and for solid culture is 23.6% (Annex 2). Though the safety manual indicates staff check is performed on regular basis, no records could be found to back this up. It also noted that there is a high turn over of the staff at NTRL, approximately 60% of the staff members including the Laboratory Head is new. Therefore, a lot of time is spent in continuous training of the new staff.

3. Inspection of CDC/KEMRI reference lab

The lab functions as referral facility for erstwhile Nyanza province. About 1550 Xpert MTB/RIF tests were performed annually for MDR-TB suspects from the region, along with Liquid culture & DST. The laboratory is well equipped with TB containment facility, GX-IV modules, LPA facility and works in close coordination with NLTD. About one half of samples referred for Xpert MTB/RIF test were Negative for MTB Complex, in 2012 and 2013.

4. Sample referral system and result turn-around time

In 2010, a courier-based sputum TB specimen referral system was initiated for routine surveillance of TB/MDR control in the country. Using a courier system, sputum specimens from each district are delivered to NTRL for Culture and DST. It should be noted that for Nyanza province (mainly Kisumu and Siaya counties) CDC/KEMRI labs work as reference laboratory. Laboratories are not supplied with proper containers for transportations of samples. It was noted that the samples are generally packaged in old medication containers obtained from the pharmacy that are not fit for the purpose. One major challenge for the surveillance system is transportation delays where laboratories do not send samples in a timely manner i.e. within a day or two after collection, which affects the sample quality and hinders the culture results.

Extended laboratory culture/DST result turnaround times was also noted as a challenge in some areas where the results were not received on time. However, upon investigation of 10 samples from a district hospital and dispensary, indicated adequate transportation time (i.e. samples arriving in the laboratory the same or the following day after samples were sent) and adequate time for releasing the results from the laboratory (NTRL). The bottleneck appeared to be in the mechanism where the result is only sent to the DTLC/PTLCs who then distributes the results to the respective sites. The mechanism for result distribution should be strengthened where the results should be sent to the requesting laboratories, DTLC/PTLC and if possible to the requesting doctors electronically.

5. Rapid TB Diagnostics

5.1 Roll out of LED Microscopy

About 130 LED- FM microscopes, under NLTD, were introduced in 2012-13. The plan is to roll out LED microscopy to other 1364 laboratories in near future. A national level roll out plan is available that guides site selection and implementation. Briefly, the labs were selected based on the number of smear microscopy performed. During the first phase of implementation, all the labs that had more than 5 smears per day were chosen to LED implementation. Second phase will cater for laboratories that have 1-5 smears per day and third phase will cater for laboratories that have less than 1 smear per day. Effective coordination for implementation of the LED microscopy has been noted to be a challenge. Training including refresher training on regular basis, SOPs, availability of reagents and service contracts for the microscopes are some of the issues that needs to be addressed as soon as possible.

5.2 Roll out of GeneXpert

The Xpert MTB/RIF test is introduced at 70 health facilities by Feb 2014, by MOH and partners. Kenya is expected to have a total of 440 machines by end of 2016. A national level Xpert MTB/RIF rollout plan guides site selection, and implementation. Briefly, the country developed a standard GeneXpert site assessment tool in collaboration with key partners including WHO, CDC and USAID. Sites were selected based on TB work load (5-20 specimens per day), HIV workload (at least 500 patients on care and on ART), facility serves mobile community and congregate settings, equity, infrastructure, logistic, and treatment capacity for all identified DR TB as per guidelines. Effective coordination has been noted as a challenge GeneXpert implementation. It should be noted that placing of

GeneXpert in areas with low volume TB workload areas (i.e. 5 TB sample per day) might result in under utilization of the machines. Where possible, samples should be transported to the nearest centre to adequately utilize the machine. Adequate distribution of cartridge does seem to be an issue resulting in a number of cartridges being expired prior to distribution. This could be resolved by having a record of the usage of the cartridge per site and distributing cartridge either using pull or push strategy. The existing criteria of patients subjected for GeneXpert includes: sputum smear positive relapses, return after defaulting, failure re-treatment, MDR TB Follow up, New case PTB, Sputum smear negative relapse, failure 1st line, extra pulmonary, MDR TB contacts, however, there is no provisions for performing GeneXpert on HIV positive cases and pediatric cases. Currently, not of the 70 machines implemented have a plan for service contracts past their 2 years warranty period.

6.0 Quality Control/External Quality audit

External Quality Assessment (EQA) for ZN smear microscopy was introduced in 2009 and by 2012 about 88% of the operational microscopy laboratories were enrolled in the EQA scheme. On-site evaluation (OSE), and blinded rechecking of a systematic sample (uniform, 12 smears/ lab) of routine sputum smears forms tools for EQA. OSE and random rechecking are performed, quarterly, by DMLT. Slide samples are brought to district level labs where controllers will help in rechecking and notifying the results. ZN and FM staining reagents are prepared at the district level, and supplied to peripheral labs. Internal quality control slides (one positive and one negative, prepared locally at each lab) are used daily at some labs, and weekly at some other labs to assess quality of stains. Panel testing is not used as a routine EQA tool, except for training and orientation purposes. NTRL helps conduct national level EQA trainings for the lab staff from districts and performs EQA for twelve Provincial labs. A major challenges here is, with devolution of services, NTLD need to review EQA guidelines for sputum microscopy such that all 47 counties are adequately supervised, at least one OSE visit per year, from the higher level (national level). The review teams noted that the results of EQA were fed back to the laboratories in a timely manner, if at all. This limits the utility of EQA as a performance-enhancing measure.

7.0 Biosafety/Infection Control

Majority of the sites visited did not have clear guidelines or infrastructure in place for appropriate Biosafety or infection control measures. Adequate ventilation, regular training/knowledge of infection control and or clear and spacious work environment were some of the challenges observed. Some of the test performed did not have any written SOPs indicating the risks involved. This not only compromises the assay performed but all puts the staff at risk. There have been reported cases of laboratory staff being infected of TB.

Infection control was similarly lacking in health centers visited. Among 65 facilities, only 18.5% had masks available for staff and 15% had them for patients.

8.1 X-Ray

It should be noted that X-ray is not readily available on site and its accessibility is a major challenge due to logistical issues (transportation and transportation and X-ray cost).

Key Achievements

1. Decentralized TB laboratory network (1 microscopy lab for about 25,000 populations). Over 1800 labs providing TB diagnostic services, improving access up to dispensary and clinic level. This enabled to achieve and maintain WHO targets for case notifications, in last few years.
2. Adequate technical expertise and quality assured operational capacity for external quality assessment (EQA) of sputum microscopy. DMLT as EQA focal person for sputum microscopy. Stains are prepared and quality assured at district level.
3. At national level, NTRL is operational with adequate technical staff to provide support to Program in C&DST, and help rollout of innovative new diagnostics. New laboratory buildings for NTRL are expected to strengthen the infrastructure, biosafety, and infection control.
4. Availability of Xpert MTB/RIF in the country with ambitious plans to exponentially increase number of instruments in the country
5. Good sample referral system using courier services
6. Good collaboration between research facilities and NTLP e.g. with Kisumu CDC/KEMRI lab

Key Challenges

1. Inadequate quality assurance measures for existing C&DST labs in the country and formal network of C&DST labs with NTRL. Need of guideline/policy document for culture & DST labs under NTRL/NLTD (as part of Lab strategic plan), and stringent quality assurance measures.
2. Effective service/maintenance contracts for equipment, at NTRL and other laboratories.
3. Extended delays in laboratory results from NTRL reaching the referring health facilities (turnaround times for treatment initiation).
4. Poor coordination in Xpert MTB/RIF implementation e.g. in including cartridge distribution
5. Weak logistics support for microscopy especially on distribution of laboratory reagents.
6. Lack of clarity on reporting structure in new devolved system especially on EQA
7. Inadequately trained supervisors at the county level
8. Infection control measures in peripheral labs, along with adequate human resources in the labs.

Recommendations

National level

1. Develop a comprehensive strategy for improving access to timely diagnosis of TB (NTRL and NTLD).

a. Revise the diagnostic algorithms to take into account the availability of new technologies, such as Xpert. The MTR suggests expanding the use of Xpert as the initial diagnostic tool of choice for people living with HIV, children, and among those with presumed drug resistance.

b. Update the national policies and develop a diagnostics network plan that considers how to optimize diagnostic efficiency that limits costs, distance to access diagnostic testing and delays in the receipt of results to patients,, and increases the feasibility of ensuring the quality of diagnosis by the NTRL and NTLD. The plan should include timely referral systems for Xpert and culture. Indicators of success will include reduced delay of receipt of diagnostic results, especially for drug-resistance. The updated policy will define the levels of the health system at which specific tools should be positioned and for what purposes. Mapping of the geographic barriers to access to diagnosis should be considered as expansion plans are made. Further scale-up of the number of Xpert machines should be based on the revised policy(ies), quantification / documentation of workload, and ability to guarantee quality. Identify and ensure the capacity of laboratory sites to support drug resistance screening for all retreatment cases and high-risk new cases, such as PLHIV and children.

2. Enhance the quality of existing TB culture & DST labs and optimize their access and utilization. Reassess the need of multiple culture labs, given the thrust on introduction of innovative molecular technologies for rapid Rifampicin resistance analysis; and underperformance or no EQA measures in existing culture labs. Develop a policy document addressing quality standards for C&DST labs. Network C&DST labs under NTRL (as part of Lab strategic plan), ensuring stringent quality assurance measures.

3. Ensure all laboratories performing culture/DST should participate in an accredited QAP. Results of the QAP to be submitted to NTRL/NTP on regular basis.

4. NTP with the assistance of NTRL to organize training of all laboratories on regular basis either through staff rotation programs (to laboratories that are performing well
as evaluated through performance in EQA program e.g. KEMRI CDC- Kisian) or through on-site training by a trained personal from laboratories that are satisfactory performing in their EQA requirements (e.g. Brisbane/Uganda SRL and or KEMRI CDC- Kisian).

5. Ensure systematic rollout of GeneXpert Xpert MTB/RIF test. Update GeneXpert implementation plan, keeping in view the experiences gains so far, and strategic planning for next few years.

6. Ensure clear cartridge distribution strategy is in place.

7. Strengthen sputum transport system for C&DST referral to NTRL, and Xpert test with aim to improve turnaround times for lab results.

8. Extend Xpert MTB/RIF test to high workload HTC facilities with an effort to increase early TB diagnosis as well as increased ART coverage. In high HIV prevalent regions make Xpert MTB/RIF as an initial diagnostic test, with effective decentralization of GX machines. Ensure that the criteria for Xpert include HIV positive and pediatric patients.

9. Strengthen EQA for sputum microscopy. Orient all lab staff on blinded rechecking feed-back (FP an FN), and develop a summary table with most frequent errors, reasons and suggestive corrective measures. Display the table in all labs. Include FM microscopy blinded rechecking program into the EQA guidelines. Distribute Revised AFB Laboratory Registers with columns for (a) contacts (b) HIV status (c) XP test

10. NTP to ensure that staff retention policy is in place for NTRL to allow for less disruption in daily workflow and to ensure that expertise not diminished from the laboratory.

11. Pilot trials with the mobile digital X-ray units in high burden sites with a vision for wider roll out.

12. NTLD and NTRL to develop an operational plan to reinforce infection control capacity and activities in health facilities and laboratories

NTRL

1. In order to reduce TAT for Culture and DST, develop effective coordination mechanisms between NTRL and program as well as lab services at county level.

2. Strengthen the quality assurance measures, at all levels. Ensure regular participation in the DST proficiency testing program through an SRL as well as microscopy EQA through NICD

3. Service/maintenance contract(s) should be renewed for all laboratory equipment at NTRL with timely servicing of all the equipment.

4. A three week advanced level refresher training should be offered to at least two staff members performing cultures at an SRL or in an a laboratory that are competent in TB liquid/solid culture and DST. Remaining staff should receive training / refresher training to ensure all staff members are competent in culture/DST.
5. Ensure satisfactory results in culture EQA is obtained prior to engaging in training of other culture laboratories.

6. Strengthen NTP/NTRL EQA supervision of county labs for (a) comprehensive on- site visits with adequate frequency (b) timely feed- back on blinded rechecking. Progress towards an accredited EQA AFB smear laboratory network under NLTD.

7. Develop capacity: DST for PZA and second line drugs.

8. Ensure a mechanism for result distribution is in place where results are sent electronically to the requesting laboratory and the requesting doctors together with PMLT's in timely manner.

9. Ensure that the recommendations made by external consultant during prior visits are addressed.

County level

1. Ensure adequate human resources for high workload laboratories, and retain staff at peripheral labs. Train/orient newly appointed county lab coordinators, and peripheral lab staff on EQA and infection control measures. For disinfection of the used sputum cups, and sputum slides, a commercial grade phenolic solution is suggested, instead of reagent grade.

2. Ensure that adequate stocks for stains are maintained. Document IQC measures for batch-preparation of stains.

3. Ensure adequate funds for sputum microscopy EQA supervisory visits, and prompt feedback on deficiencies, for initiating corrective measures.

4. Strengthen the infection control measures, trainings, and adequate ventilation in TB labs. This would mean improvement of infrastructure in some TB laboratories to accommodate shortage of space.

DETAILED FINDINGS: ACSM & COMMUNITY TB CARE

Advocacy, Communications and Social Mobilization

Achievements

1. There were TB Information, Education and Communication (IEC) materials in various health facilities visited
2. TB medicines and microscopy are free in all public facilities.

Challenges

1. Minimal budgets and slow roll out of ACSM activities at all levels
2. Limited advocacy capacity at the county levels
3. Limited funding allocations by counties to enable community engagement or local advocacy
4. TB is still seen as a vertical program at sub county level, limiting community engagement

Recommendations

1. Increase investment in community systems/advocacy
2. Develop MOUs between NTLD and its partners at all levels
3. Advocate for inclusion of TB in the existing and future social protection plans
4. Sensitize TB patients on their rights and responsibilities

Community-based care

Achievements

1. Existence of CSOs and local partners (supported by AMREF, APHIA plus, Walter Reed)
2. Existence of strong linkages between the community and health facilities, especially through community health strategies that contribute to community-based TB care (treatment supporters, default tracing, case finding, health education/treatment adherence counseling, livelihood programs for patients cough monitors)
3. Involvement of expert patients in advocacy and treatment support

Challenges

1. Community TB activities are not adequately harmonized and integrated into the NLTD monitoring and reporting system, resulting to under-representation of the community contribution to case finding.
2. No coordination structure among CSOs, CBOs and CUs engaged in community-based TB care in some areas
3. Poverty and food insecurity are barriers to treatment adherence. Food through most nutritional support programmes is restricted to women, children <5yrs, or HIV infected individuals. There are minimal social protection schemes currently benefitting TB patients.
4. There is marginalization of some groups (poor, disabled, nomads, gender-based exclusion).

Recommendations

1. Add community-based care indicators into the TIBU system to mirror the reporting of CSO involvement captured in the NTLD-Unit monitoring system
2. Introduce a register for presumptive TB to allow capturing of screening and referral results, and to enable treatment

follow-up.

3. Increase the investments in community systems strengthening to ensure community health workers engaged in TB work are within an established community unit structure and a sustainable incentive system is available.
4. Develop MOUs between NTLP and its partners at all levels
5. Secure and provide nutritional support to all malnourished TB patients and those from low socio-economic groups
6. Advocate for inclusion of TB in the existing and future social protection plans
7. Integrate TB into other health and development related programs such as nutrition and MNCH programmes
8. Improve coordination and engagement of all stakeholders in the planning, implementation, monitoring , and evaluation of activities
9. Map TB partner activities at all levels to align community partners within the NTLD plan
10. Intensify involvement of former TB patients as TB ambassadors

Key population and hard to reach population (focus: prisons)

Achievements

1. Integration of TB/HIV services under one roof
2. Standardized tool for screening of inmates at entry to prison
3. National guidelines and TB treatment standards followed in prison settings
4. 100% HIV testing among TB patients and screening of TB among HIV in prisons
5. Supportive supervision by DTLC/DMLT
6. TB program ownership by prison officers (OJT by IMC)

Challenges

1. Congestion and poor ventilation within the prisoners' confinement cells
2. No infection control plans in place
3. High turnover of experienced staff in TB management
4. Regular patients transfer to other prisons without their medical documentation

Recommendations

1. Need for capacity building on development and implementation of infection control plan
2. Strengthen inmate referral system by transferring TB patients with their medical records and making follow-up
3. Advocacy and sensitization of prison managers to overcome structural barriers to TB control.
4. Improve access for marginalized groups and populations (needed in hard to reach areas)

Gender and Human Rights

Achievements

1. All health facilities visited had service charter displayed
2. TB screening, microscopy and medicine are free in all public facilities

Challenges

1. More male TB patients than females. It is not known if this reflects the true epidemiology of the disease, or gender-based barriers to care.
2. TB likely under-reported among low socioeconomic groups
3. Teams observed that patient confidentiality was not always respected. In particular, the names of patients, including those with MDR-TB, were openly used by health staff without the need to identify individual patients. Patient confidentiality should be reinforced.

Recommendations

1. Need to sensitize the community on TB facts so that they can come for early TB screening

DETAILED FINDINGS: TB/HIV

Introduction

Kenya has been a leader in the implementation of WHO recommended collaborative TB/HIV activities. They have widespread integration of TB and HIV services under the same roof and often in the same room. In 2012, 94% of patients with TB had a documented HIV test result. Of patients with TB/HIV, 98% are receiving CPT and 74% are on ART.

The findings and recommendations regarding TB/HIV are based on quantitative, qualitative, and observational data collected by Field Teams participating in the 2014 mid-term National TB and Leprosy Program Review. We asked Field Teams to visit HIV clinics during their site visits and use a standardized data collection tool to interview HIV clinic staff and abstract data from patient charts. The tool included items to assess the integration of TB and HIV services, implementation of the 3I's (Intensified Case Finding, IPT, and Infection Prevention and Control), and barriers to the diagnosis and treatment of TB among people living with HIV (PLHIV).

Quantitative data:
We asked staff to randomly select and review the charts of 25 PLHIV registered at each HIV clinic. The rationale for abstracting data was to provide us with a sample of data on the extent to which the ICF/IPT algorithm was being implemented for PLHIV. Of the PLHIV screened, what proportion screened positive and then received a diagnostic evaluation (e.g., smear, x-ray, Xpert). Then, of the PLHIV screening positive and evaluated, what proportion was diagnosed with TB disease. For the PLHIV screening negative, we asked the Teams to determine the proportion documented to have been initiated on TB preventive therapy (IPT).

Qualitative data:
We asked each Field Team to meet with HIV clinic staff and ask them closed and open ended questions about TB/HIV clinical practice (e.g., how do you screen for TB among PLHIV). The questionnaire concluded with the following two questions: "What are the biggest challenges you face when trying to screen or diagnose TB among people living with HIV?" and "As a healthcare worker, what would you ask from the National TB and HIV Programs so that you could do your job better?"

The other source of qualitative information that formed the basis for this report were the TB/HIV section of each team's Field Report. Inductive content analysis was used to identify themes from the Field Reports and open-ended questions.

Observational data:

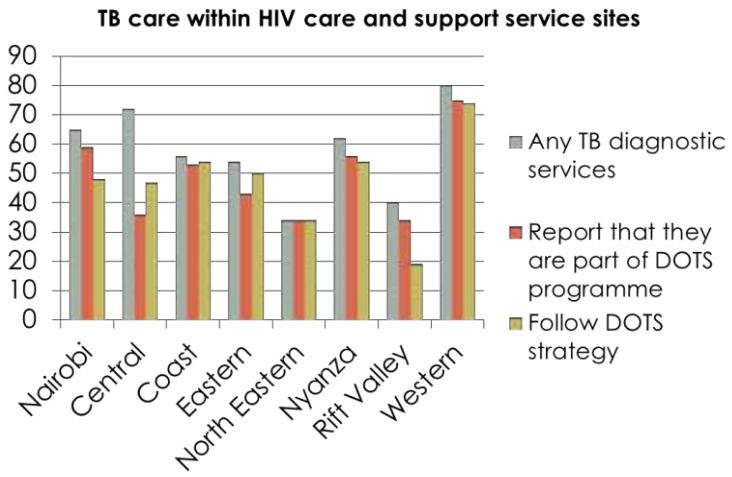
We asked each Field Team to observe clinic practices and verify the presence of any TB screening tools and IPC plans. The observational assessment included an evaluation of the waiting area at each facilities HIV clinic and qualitative assessment of whether it was crowded at the time of their visit and the extent to which it was ventilated.

These results are based on HIV Clinic Data Collection forms submitted by the nine Field Teams and represent 44 HIV Clinics. Other HIV Clinic Forms may have been completed and submitted to the MOH but were not available in time to be included in this analysis.

Achievements

Kenya remains a leader among nations with respect to the implementation of WHO recommended collaborative TB/HIV activities. More than 90% of patients with TB are reported to have been tested for HIV and based on our data an estimated 83% of PLHIV were screened for TB at their last clinical encounter. The observed level of TB/HIV integration (both services provided in the same room) affords an opportunity for the Kenyan program to scale-up TB preventive therapy, implement improved infection control practices, and refine other elements of Kenya's 5I's (the 3I's plus "Integration" of TB/HIV services and "Immediate" initiation of ART).

Figure 8. Percentage of health facilities with TB/HIV care



Source: 2010 Service Provision Assessment Survey

Based on the data from 44 HIV clinics, 82% of PLHIV were screened for TB at their last clinic visit. Of the 838 PLHIV screened, 7% screened positive, and 93% screened negative. Of PLHIV with a positive screen, 81% were evaluated and of those evaluated 62% were diagnosed with TB. Among the PLHIV screening negative, 2% were started on TB preventive therapy (IPT).

Qualitative and observational data

Forty of 44 sites (91%) were observed to be using the MOH ICF/IPT tool for TB screening among PLHIV. Of note was that some of the sites were using the older version of the tool and some sites had to make photocopies of the forms
as they experienced stock-outs of the cards. Staff at 79% of facilities reported that TB and HIV services were "integrated" such that both services were provided in the same room. Based on observational assessment, the waiting areas at 77% of HIV clinics were well ventilated.

Key Challenges

The following themes were reported by staff to be the biggest challenges to screening for and diagnosing TB among PLHIV:

1. Thirty percent of staff at HIV clinics reported that at least one staff person had been diagnosed with TB in the previous year. There is little space in clinics for patient flow and reduced risk of nosocomial transmission among staff.

2. The costs and travel associated with getting an x-ray (patient level barriers) prevents patients from getting the recommended diagnostic evaluation and is a staff barrier to making a diagnosis. There are then delayed or missed diagnoses because of insufficient diagnostic capacity, with limited x-ray and GeneXpert capabilities. There is an inability to get sputum samples from patients especially children.

3. There are staff shortages and insufficient training on TB/HIV clinical guidelines and practices on the provision of IPT.

Recommendations

Based on our review of available epidemiological reports, collection of data, and observation of clinical practices we would recommend that the National Tuberculosis, Lung Disease, and Leprosy Unit and the National AIDS & STI Control Programme work together to implement the following 5 Key Recommendations:

1. Revise, disseminate, & implement TB/HIV guidelines consistent with WHO's 3I's and Policy for Collaborative TB/HIV Activities; Provide staff training, CMEs, and supportive supervision on the 5I's. Ongoing training is critical because of high staff turnover and the inherent need for refresher training. Develop the 5I's implementation plans at all levels (National, County, Sub-county, and facility level) and implement a system for monitoring TB among healthcare work

2. Develop staffing plan to support expanded access to diagnostics and implementation of 5I's; many sites are already reporting staff shortages so additional staffing will be needed to support implementation of the 5I's. In addition, consider some task shifting to other programs to support implementation of the 5I's.

3. Reduce barriers to ICF among PLHIV; Revise the algorithm to make GeneXpert the initial test for PLHIV. Provide patients with TB and TB/HIV enablers for travel (e.g., reimbursement for travel to and from the clinic and for diagnostic evaluation, DOT, or follow-up), and provide x-rays at no cost to PLHIV. Pediatric drug formulations are needed and nutritional support to help patients tolerate anti-TB and ART drugs.

4. Scale-up IPT for PLHIV after ruling out TB; provide guidelines for IPT as part of the TB screening and diagnostic algorithm. Procure INH for clinicians to provide IPT for PLHIV.

5. Conduct operations research on 5I's implementation; evaluate performance of the ICF/IPT screening tool to assess why only 7% screened positive. Measure timing of ART initiation among people with TB diagnosed with HIV because there is no data on timing of ART initiation among people with TB/HIV. Implement and evaluate

innovative approaches to improving access to TB diagnostics such as the use of GeneXpert as an initial test for PLHIV, and incentives/ enablers for diagnostic evaluation.

DETAILED FINDINGS: CHILDHOOD TB

Introduction

The infant mortality rate in Kenya has dropped from 68/1000 live births in 2000 to 43.6/1000 in 2012, indicating the success of the Kenyan health system. However the under 5 mortality rate is not yet on track to achieve the MDG 4 of reducing child mortality by 2015 and in Kenya an additional 113,000 lives of children <5 years need to be saved in order to do so. In Kenya, 10,634 TB cases were reported in <15 year olds in 2012 which comprises 10.7% of all TB. Almost 28% of all child TB cases were in <1-year-old children. Of the reported TB cases 93% were tested for HIV and 30% were found to be positive. In Kenya, given the low diagnostic capacity for TB in peripheral health facilities particularly for children <5 year age, the important question remains that what proportion of <5 year old children with TB are not reaching diagnosis and treatment and are thereby contributing to child mortality?

Achievements

The Kenya National TB and Leprosy Unit of the Ministry of Health, has recognized childhood TB as a key intervention area and has included it in its Strategic Plan (2011-2015). A Child TB focal person has been appointed in the National TB program full time as of September 2013. The Kenya Pediatric TB working group was formed in 2011 with expert representation from the National TB program, KEMRI, NASCOP, University of Nairobi, Moi Teaching and Referral Hospital, CDC Kenya and ICAP. New 2013 stand-alone national child TB guidelines, clear job aids- including diagnostic and preventive algorithms, treatment charts, training curricula and tools have been developed with working group consensus. Child anti-TB formulations (dispersible fixed dose combinations, isoniazid 100mg and ethambutol) are available in Kenya through KEMSA. The treatment guidelines are in-line with current WHO recommendations.

Key Challenges

1. Diagnostics: All field visits revealed sub optimal diagnostic capacity for childhood TB. There was low index of suspicion for child TB among HCWs, particularly in the MCH clinics and absence of displayed child TB diagnostic and treatment algorithms in most clinics. Often in lower level facilities either Kenya Child TB guidelines were not found or when present, were outdated. Very few children were referred to TB clinics for TB diagnostics. The diagnostic testing for children relied on clinical history, chest X-ray if available and sputum only if the child was able to expectorate (with no instructions given on how to expectorate). Teams also expressed concern that in <5 year olds in whom gastric aspirates would help with bacteriologic confirmation, none were attempted (due mainly to lack of skilled staff). At sub- county level a similar approach was followed and in many facilities children were referred to County hospitals for CXR where distance and cost became a barrier to TB diagnosis. When CXR was available at sub-county health facilities the images were often of poor quality and their interpretation was not reliable, adding yet another barrier to accurate diagnosis. In facilities where expert testing was available it was not used to test pediatric samples.

2. Linkage of services: There was poor linkage between the MCH clinic, pediatric OPD, pediatric casualty, inpatient wards and the TB clinic.

3. TB surveillance: Most county and sub-county hospitals had recorded fewer than 5 children with TB in the quarter under review, although one facility in Nairobi recorded 109 children. This indicates very low child TB case detection overall. Pediatric cases comprise <9% of the TB caseload per facility. Nationally, the TB case notification for children dropped significantly in 2013 compared to 2012. The review team noted that the overall <15 year old TB case notification for counties seems higher in the national TB database compared to the trend observed in TB registers reviewed. This should be assessed more formally.

4. Child TB outcomes were not routinely recorded in facility TB registers. In County hospitals children were diagnosed and referred to lower facilities for treatment, hence treatment outcomes were not known. The true number of child TB suspects referred from lower facilities for diagnostics was not known as there was no mechanism to track them, contributing to TB under-diagnosis. Reporting on Child TB outcomes is inaccurate and incomplete in the TIBU system.

5. Among notified TB data from Meru, we found a high proportion of adolescents (16-18 year olds) with 80% sputum smear positivity rate. This is extremely concerning as adolescents are a high-risk group that need closer evaluation for early diagnosis, TB prevention and social support measures.

6. PMDT: We did not find any child DR-TB cases and poor contact tracing of child contacts of MDR TB adults.

7. TB/HIV: HIV testing of children with TB was not complete, and among those tested was as high as 50% in some facilities.
8. Treatment: There was inconsistent availability of pediatric dispersible FDCs at peripheral health facilities and incorrect quantification of drug supply for children. In many facilities visited, large supplies of pediatric formulations were nearing expiry. INH for IPT was either stocked out or near expiration. Quantification, distribution and management of the pediatric drug supply was a noted weakness. Parents were the treatment supporters for children with TB, which is less than optimum.

9. Prevention: Contact investigation and management was not routinely practiced at most facilities visited by field teams. Staff often were not convinced about the benefits of contact management and had the misconception that IPT may produce resistant strains or were worried about its accidental use in case of TB disease. IPT uptake was very low everywhere and IPT registers were not available anywhere. Some health staff creatively registered the patients on ITP in the TB unit register due to lack of a formal register.

Recommendations

1. Ensure access to quality TB diagnostics to all children at no cost. Ensure CXR facilities (either through mobile digital CXR services or installation of quality CXR services accessible to lower level centers with a capacity for reliable interpretation via web linkage). Current child TB diagnostic algorithms and tools to made available at all facilities dealing with children at all key areas of child-care. Expert testing should be the first diagnostic test for children with proper expectorated/induced sputum samples or gastric aspirate samples from <5 year olds.

2. Child TB capacity building (knowledge and skill development) on diagnosis, management and prevention, to be included in routine TB trainings. Child TB should be included as a module in undergraduate medical school curricula as well as in nurses training curricula.

3. Develop linkages between MCH clinics, pediatric clinics, casualty, pediatric inpatient wards and the TB clinic. Identify a child TB CO/MO at each health facility to ensure integration, monitor and facilitate patient and information flow between departments (One way to do this will be to maintain a child TB suspect register)

4. Monitor and improve child TB data management and outcomes reporting.

5. Ensure that child TB drug procurement and ordering is in line with program needs to avoid over and under stocking.

6. Mandate HIV testing in all children with TB and ICF as well as IPT (once disease ruled out) in children with HIV. Ensure quick turnaround and follow-up of HIV PCR in <18 month olds.

7. Mandate contact management of all children of MDR TB contacts and urgent diagnosis and treatment of child contacts with TB disease.

8. Scale up contact tracing in children in order to increase child TB case detection and IPT uptake, as well as provide IPT registers.

9. Operational research: Mentorship program by NTLD to enable CTLC and county child TB contact MO/CO plan, fund and implement operational research projects.

DETAILED FINDINGS: PROGRAMMATIC MANAGEMENT OF DRUG RESISTANT TB

Introduction

The MDR-TB component of the NLTD is well established and adequately managed. Revised MDR-TB treatment guidelines were published in August 2012. In 2013, 287 cases of MDR-TB were reported. Treatment success rates were above 67 % for MDR-TB in 2011.

A national MDR-TB Focal Person provides guidance to the counties. A national MDR-TB committee supports her. Decentralization of MDR-TB care is extensive, with 226 MDR-TB treatment sites for 287 newly registered MDR-TB patients in 2013. Refugees from Somali make up 30 % of MDR-TB population. At the level of county, the County TB coordinator is responsible for linkage of MDR-TB patients to care, treatment initiation and follow up. The NLTD uses hospitalization for the very sick, and only until they are clinically stable. Ambulatory and community-based treatment are the commonest models of care. DOT is provided at selected health facilities, networked to community health workers who treat patients in the community.

The number of MDR-TB cases detected in Kenya has risen steadily since 2010, when only 112 cases were detected. WHO estimated that there were 1800 new cases of MDR-TB in Kenya in 2012. A drug-resistance survey is planned to substantiate a more precise estimate. With Xpert rollout, it is expected that the number of MDR-TB cases detected will increase.

Table 1. Prediction of MDR-TB case notifications 2013-2016

	2013	2014	2015	2016
Estimated number of MDR-TB cases among TB patients notified (considering notification pattern with use of Xpert)	**287**	**380**	**480**	**380**

Achievements

Case findings strategies are in accordance with WHO recommendations. The treatment regimens are also in line with WHO recommendations using WHO-pre qualified, quality assured second line drugs. MDR-TB treatment models include hospitalization for the very sick patients at 4 sites, ambulatory care and community care. Drugs to manage side effects are available free of charge to the patients at the treatment sites. Drug adverse events are reported to National Ministry of Health. DST for first-line (Rifampicin, Isoniazid, Ethambutol and Streptomycin) are done at NTRL and second- line (Kanamycin, Capreomycin and Ofloxacin) are done outside the country. There is an External Quality Assurance programme for the laboratory provided by a Supra-National Laboratory. One hundred and seventy six health care facilities have infection control plans.

There are four admission sites: Kenyatta National Hospital (15 beds), MTRH (8 beds), Homabay (11 beds) and Dadaab (80 beds).

Kenyatta is a national hospital, which has a 15-bed isolation ward for MDR-TB patients. There is a Medical Doctor who treats patients, but who also has other duties within the hospital. There are nursing personnel assisting with the management of MDR-TB. These people are trained on MDR-TB management. Audiology is not accessible to MDR-TB patients. Patients are admitted here until they are stable. Admission duration varies from 2 to 3 weeks, depending on the patient's condition. The bed utilization rate was around 50 % on average during the visit. There is a XDR-TB patient in care here. The patient has culture-converted and still doing well.

The admission rooms are adequately ventilated; patients spend their time in their rooms. Enhanced ventilation systems are used. Staff members have N95 respirators.

Patients did not receive any enabler(s) during the year 2013. However, as from April 2014, MDR-TB patients will receive 6000

KES (almost US $ 100)/month for their transportation to health care facilities and possibly nutritional support.

The MSF site ("Green house") was also visited. This facility had 46 MDR-TB patients on treatment. Smear negative patients are seen first and the smear positive are seen after 09h00. This is excellent in order to separate the patients with different levels of risk. MDR-TB patients have their own entrance area, to minimize the risk of transmission. This facility makes use of a private laboratory and laboratory results are acquired quicker than in other sites. The Xpert machine is well utilized with all Xpert positive, Rif resistant started on treatment and specimen collected for DST to Rif, INH, Ofx and injectables. One sample is sent to the local laboratory, the other one goes to the reference Antwerp Laboratory. Patients receive counseling before and during treatment. A clinical psychologist gives attention to those that need it. A mental assessment is conducted upon admission. Of the 8 recommendations made following an external review in October 2012 (table below), 5 were resolved, 2 are currently being addressed, while only one remains. The remaining challenge, increasing the bed capacity of DR-TB is repeated here as a recommendation.

*T*able 2. Summary of recommendations from October 2012 mission

No.	Recommendation	Outcome
Case finding strategies		
1	Further expansion of PMDT in terms of suspects screened and enrolment is needed. The aim is to test all retreatment cases, all non- converters of Cat 1, contacts of MDR- TB cases and HIV positive individuals.	Cases finding strategies for DR-TB now include all retreatment cases, all non- converters of Cat 1 at end of month 2 of treatment , contacts of MDR-TB cases and HIV positive individuals. In addition, health care workers and refugees are included.
Laboratory		
2	Xpert decentralized needs to be addressed	Xpert roll-out done as per the following criteria: • High workload facilities meaning > 58 microscopies/day and/or >500 HIV patients • Equity: every county to get at least one Xpert machine • Mobile populations and hard-to- reach are also prioritized
3	A DRS and analysis of DST results is needed to know the rate of DR-TB among the different suspect categories and to make realistic projections for PMDT expansion in the coming years, and to judge the appropriateness of the present standard MDR- TB regimen.	DRS planned for April 2014. Preparation under way. Analysis of DST results is planned.
4	The laboratory network in the periphery	Renovation of laboratories done

Challenges

1. Delays in diagnosis: All facilities complained about delayed MDR-TB laboratory results. For the patients visited at Machakos Hospital, the delay between the date drug resistance was presumed to the time of treatment initiation was 6 months. Patients start treatment after receiving baseline tests results. Treatment initiation will only take place after the results of baseline investigations are sent back from the laboratory. This practice worsens the results delay from the laboratory. In addition, patients have to pay for these tests. Baseline tests are only started once the drug package is received. Delay in drug delivery of 1 month after diagnosis was also observed

2. TB microscopy and culture are supposed to be done on a monthly basis. However, compliance with this directive was not observed. Follow up laboratory tests were done for only 40 % of patients.

3. Patients previously exposed to SLD still receive the standardized MDR-TB regimen. DST to an injectable and fluoroquinolone not done routinely for all confirmed MDR-TB cases. The MTR acknowledged that this is in the pipeline.

4. Ototoxicity appears to be an important problem among MDR-TB patients receiving kanamycin.

5. Monitoring and evaluation of MDR-TB needs some improvement. No DR-TB support visits/clinical audit tools were found. There is a need to review the TB supervisory visit tool to cover DR-TB adequately or design a DR-TB specific tool. There is a need to develop an electronic medical record for DR-TB patients.

6. Hearing tests, while done at the MSF site, were not accessible at other sites visited.

7. Masks to protect health workers are not consistently available. Of the facilities visited during the review, around 70% of health workers and patients did not have access to masks:

Table 3. Availability of masks for infection control

Availability of Mask	Staff			Patients
Yes	12	18.5%	10	15.4%
No	46	70.8%	45	69.2%
Unknown	7	10.8%	10	15.4%
Total	65	100.0%	65	100.0%

Recommendations

Decentralization of MDR-TB care was done quickly, and this has affected the quality of care. Strengthening clinical MDR-TB care is an imperative. Monthly MDR-TB clinics and programmatic review is necessary. Supportive supervision to the counties is necessary. Early release of TB culture and DST results is another imperative.

Organizational

1. Update check list for supervisory/support visits to adequately cover DR-TB or design a specific DR-TB tool
2. Fund and organize monthly DR-TB clinics at county hospitals
3. Fund DR-TB training for programme officers and for clinicians. This needs to include advanced pediatric DR-TB management.
4. Finalize, print and disseminate MDR-TB workplace policy

Laboratory

1. Strengthen communication between the TB programme and the reference laboratory;
2. Establish an effective system to communicate laboratory results in a timely manner;
    a. Laboratory results to show date sample was collected, date results became available in the laboratory and date it was sent to facilities. Facilities to indicate when they received laboratory results. Delays in result transmission should be actively monitored and delayed results; i.e. more than 5 days to be actively followed up.
3. There is a need for more physical space for the national TB reference laboratory; which will hopefully be addressed with the completion of the new laboratory structure
4. Need to strengthen routine 2nd line DST for confirmed MDR samples
    a. It is recommended that the NTLD refine the diagnostic algorithm to enable screening for Rif-resistance among all high-risk groups.

Treatment and care of patients

5. Ensure provision of audiometry to MDR-TB patients and those receiving streptomycin.
6. Add / allocate additional beds for MDR-TB patients. It is advisable that each county has a few beds for admission, with appropriate infection control measures in place.
7. Strengthen/establish PMDT teams in each county. Involve clinicians in these teams.
8. Treatment initiation not to be delayed by baseline DST tests. Ensure standard 2nd line treatment initiation as soon as samples have been collected for baseline DST tests, with timely revision of the treatment regimen if needed based on DST.
9. Scale-up availability of social support to patients; monitor impact on adherence.
10. Build capacity for managing pediatric MDR-TB

Drug management

15. Strengthen side-effects management, recording and reporting
16. Accelerate update of new molecules such as bedaquiline and delaminid, once available

Infection Control

17. Ensure all facilities develop and implement TB IC plans

Recording & Reporting

18. Expand TIBU to fully incorporate case management of MDR-TB patients.
19. Adhere to the TB programme stationary for MDR-TB patients; update MDR-TB records with regard to laboratory results at facilities.

DETAILED FINDINGS: PUBLIC PRIVATE MIX & LUNG HEALTH

Introduction

The Kenyan NLTD is a front-runner in the implementation of the 4th component of the STOP TB strategy: Engaging All Care Providers. The non-state sector is a major player in provision of health services in the country. "Collectively, this sector provides nearly 50% of all health care provided to Kenyans (Ministry of Health Kenya in National Leprosy and Tuberculosis Treatment Guidelines, 2013: 135). In Mombasa County, for example, it is estimated that the sector represents about 60% of the entire health sector.

As in many other countries, there is a wide spectrum of health providers ranging from the formal to the informal. In Kenya, according to the National Leprosy and Tuberculosis Treatment Guidelines, those in the informal sector include: Traditional healers, Herbalists and faith healers; Grocers and Shopkeepers; Home-based care groups providing care to persons living with HIV and other volunteers; and Community units – Lay community health care workers (CHWs) and Community Health Extension Workers.

Effective implementation of PPM is expected to contribute to universal access to TB care in the country; early and improved case-finding leading to minimum diagnostic delays, improved treatment outcomes and reduced (direct and indirect) costs for the poor. To what extent is the NLTD striving towards these goals? In putting together this report, relevant sections of the NLTD annual reports from 2007 to 2012 were reviewed to provide a backdrop for the findings (and recommendations) of the nine (9) field groups who conducted the mid-term review.

The 2010, 2011 and 2012 reports provided specific sections on PPM and suggest a significant and (slightly) increasing contribution to case finding in the national effort. Total number of TB cases notified by the private sector rose from 7,160 (in 2010), 9,039 (in 2011) to 11,000 in 2012.

Notified cases in 2012 constituted about 11% of total cases notified by the NLTD. Although the percentages increases have been small, the trajectory is unarguably upwards. Other performance indicators, according to the 2012 report include: HIV testing among TB patients: 86%; ART uptake: 72%; CPT uptake: 94%; TB treatment success rate: 80.5%; Loss to follow up: 7.1%; Transferred out: 6.6%; Died: 5.5%. Taking account of the background information from the annual reports and the findings of the field groups above, the following achievements/challenges are collated and the corresponding recommendations proposed:

Achievements

1. Programs: In sites visited, there was adherence to international standards for TB care and national guidelines. The increasing contribution of the 'private' sector to national case- detection/notification was noted. Documented linkages and referrals between public and private providers were found in several areas. For example, in Mombasa and Kwale counties, there are established referral networks with the public sector for presumptive TB cases and those who cannot afford treatment in private sector, and collaboration with the public sector for GeneXpert examination. There is good collaboration with national TB programme through monthly support supervision, treatment standardization & case notification. 31% of the private sector are engaged in TB care and control and there are established referral networks with the public sector for presumptive TB cases and those who cannot afford treatment in private sector.

2. Treatment: There is free TB treatment in most private facilities using recommended FDCs and inclusion in NTP-led supportive supervision with good treatment outcomes, which are similar to national program average. There are HIV tests offered for patients with TB.

3. Health Facilities: There is one community health worker attached to the facility (in counties Kisumu and Nyamira). Effective community TB units are linked to health facilities (in counties Meru and Isiolo) and former TB patients play an active role in community TB control, best practiced in Isiolo. There are provisions of affordable and accessible care through engagement of smaller clinics in the community through supply of free anti-TB drugs. In Nairobi and Narok some HCWs trained in PAL, and there is frequent KAPTLD supervision of private sector facilities. The faith-based hospitals seems not all fully linked in the PPM program and some of those visited in Machakos were not aware of KAPTLD.

Key Challenges:

1. Private-Public Facility Integration: There are still a significant number of private facilities/actors not engaged in TB service provision. This is especially true of the providers in the 'informal' sector. TB screening, diagnosis and treatment in private facilities under CTLC supervision (Meru) happen without a formal agreement with the GoK. Some private facilities do not adhere to standard treatment guidelines, especially in larger 'high end' facilities. In counties Machakos and Kitui there only faith-based facilities encountered as private.

2. Staff Training and Accountability: There is limited inclusion of private providers in county level trainings and an absence of job aids and tools especially in 'low-end' facilities. Private and FBO providers were not found to be well linked to CBTBC providers and many were not notifying TB cases to the NLTD. There is a high staff turnover and the community TB activities reporting system is not harmonized; integration into the health system is unclear (e.g. in Meru and Isiolo counties). There is a low index of suspicion of pediatric TB among other staff in private hospitals. Typically only the DOTS provider is familiar with the national guidelines.

3. Financial Concerns: The Fees at PPM facilities might be a barrier for patients at faith-based hospitals (105 Ksh for sputum test, 550 Ksh for CXR) as reported in counties Machakos and Kitui where there a charge for sputum test where laboratory commodities are freely provided to the private laboratories. In counties Vihiga and Uasin Gishu there is inadequate funding for PPM. In Nairobi and Narok the cost of TB drugs and absence of child FDCs are a barrier to access.

Recommendations

1. County & ZTLCs to map/re-map all non-state facilities with potential for TB service provision and engage them appropriately. Special consideration should be given to providers in the 'informal' sector.
2. County and ZTLCs to ensure that private sector facilities are not discriminated against in trainings and provision of essential job aids/tools. Guidelines and tools on management of childhood TB should be given special attention!
3. Identify & empower respected professional colleagues as focal persons/champions at the various facilities to spear- head TB services while promoting ISTC and the patients' charter. The NLTD may consider translating the patients' charter into appropriate local languages for ease of comprehension by the patients.

4. Enhance CBTBC linkage for private providers. The linkages to the community need to be strengthened through greater collaboration with community health extension workers.
5. Strengthen OJT and CME to help address the observed high staff turnover in many private sector facilities
6. Improve quality of supportive supervision e.g. by ensuring that (private) facilities have current guidelines and tools as well as following up on implementation of recommendations.
7. Consider decentralizing ART services to suitable private sites to improve access
8. Memorandum of Understanding (MoU) needs to be signed by private practitioners/facilities caring for TB patients, as stipulated by current national guidelines.
9. The NLTD should revisit the current policy of user-fees (for anti-TB drugs) in some private facilities with a view to abolishing them and making anti-TB medicines free of charge for ALL TB patients.
10. Operational research: We recommend that appropriate studies be carried out (at national level) to explore trends in diagnostic delay, costs/cost-effectiveness of TB services under the PPM approach as well as to review the quality of care. An inventory study to be carried out among the private sector may quantify the extent to which diagnosed cases are reported to the NTLD.

DETAILED FINDINGS: LEPROSY CONTROL

Introduction

WHO has declared the elimination of leprosy in Kenya, defined as fewer than 1 case per 10,000 population. Nonetheless, active transmission of the disease is still know to be occurring in a few counties and late-stage morbidity and disabilities are still being identified. Notifications of new cases have declined from 630 in 1986 to 145 in 2012. Among those newly registered, 27% had grade 1 disabilities while a further 21% had grade 2 disabilities.

Achievements

1. As reported in counties Mombasa and Kwale, the number of registered leprosy cases continues to significantly decline, and trends of leprosy prevalence including new cases continue to decrease "post –elimination".
2. The guidelines for management of leprosy and reporting tools are available; leprosy control activities such as diagnosis with laboratory confirmation of suspect cases, tracing and treatment of cases with MDT suspected contact, school screenings, and awareness campaign exercises continue to be implemented, funds allowing. INFO, an Italian Leprosy organization provides limited funds for some activities in few sub-counties.

3. In counties known to have leprosy cases, District TB/Leprosy coordinators were well trained and capable of diagnosing and managing uncomplicated leprosy cases. Additionally, guidelines for leprosy management and training curriculums are available. There are tools for capturing leprosy data, patient appointment cards, patient treatment cards and leprosy facility registers available. Leprosy data are also captured on the e tool.

4. MDT drugs are available in good quantity in all facilities with registered leprosy cases, and in good quality with an expiration date in May 2016. The administration of these drugs is in line with the guidelines. There is no evidence of imported leprosy cases from neighboring countries, as all the cases seen were all from Kenya, and none had travelled out of the country.

Key Challenges:

1. There is limited resource allocation to leprosy-control activities; low political commitment to leprosy control at all levels of government; limited human resource capacity to suspect, diagnose and manage leprosy at all levels of health services; and low awareness of leprosy among the general population. County plans and budgets for leprosy are very limited and, if available, restricted to World Leprosy Day. Additionally, the Leprosy partnership with INFO is a one-year project that is ending soon.

2. Active case finding exercises continue to yield remarkable numbers of new leprosy cases of the Multi Bacillary (MB) type, which is highly infectious. These cases include children, which is evidence of active transmission in the communities. The last single exercise yielded 15 new cases, out of which all were MBs. Thus, the MB proportion was 100% and the 6 children among the new cases put the child case proportion at 40%. 5 of these children had disability grade 2, a 33% proportion, indicating that some cases were detected late. This 100% MB in a single active leprosy case search is an indication of continuing leprosy transmission; and delay before diagnosis.

3. The level of awareness of the public and the suspicion index of leprosy was very poor among general health workers and persons interviewed in the health facilities visited. The ability to diagnose is limited only to the DTLCs. In the facilities visited, no posters or other IEC material on leprosy was seen.

4. Training or retraining of health workers on leprosy is not routinely done, and the opportunity to combine this with the globally funded TB trainings is not being effectively utilized. The reporting and recoding materials are obsolete, not readily available, and not properly used. Very few of the patients had the leprosy patient cards completed with charting of their lesions. VMT/ST is not done routinely as prescribed in the manual, and is not recorded. No ancillary drugs, such as Prednisolone and loose Clofazime, for treating reaction were seen.

Recommendations:

1. Funding: Review emerging sector plans to ensure that leprosy-specific plans and targets are reflected in the national, county, and sub-county annual work-plans and budget allocations. Prioritized funding will be needed to implement the "post-elimination leprosy activities". MOH and NLTD to continue dialogue with international Leprosy Donor communities, such as ILEP, AML, GLRA, NLR, etc., to solicit for support of the leprosy component in the national TB/Leprosy Control Programme, particularly in the endemic counties.
2. Training: Develop Human Resource Capacity plan for orientation of health workers on suspecting, diagnosing, and managing leprosy cases at all levels of health services. Update all the reporting and recording tools on leprosy. Train GHW on their utilization and capacity building among facility health workers for increasing their suspicion index for leprosy. This training should be facilitated through the county and the Central Office of the National TB/Leprosy Programme. In addition, reorientation and retraining of health staff on early signs and symptoms of leprosy should be continuous.
3. Leprosy surveillance: Efforts must be made to maintain a high level of suspicion on leprosy among health workers in other counties also, especially at the skin disease clinics. Intensify leprosy cases finding activities such as contact tracing of diagnosed leprosy patients, school contact tracing, and market educational campaigns on detection.
4. Public Awareness: IEC materials, such as leprosy posters and handbills, should be developed, printed and circulated by the county and the Central Office of the National TB/Leprosy Programme. These materials should be placed in appropriate places in the health facilities. Particularly in the county Kwale, radio messages can also increase public awareness, and other public campaign activities should be implemented on a regular basis.

DETAILED FINDINGS: MONITORING & EVALUATION, & OPERATIONAL RESEARCH

Introduction

The National Leprosy, Tuberculosis and Lung Disease Unit (NLTD-Unit) has made great achievements in surveillance, monitoring and evaluation (M&E) and operational research (OR) by developing an electronic patient based surveillance system named TIBU which is functional country wide. Kenya is the first African country to have a patient based electronic system at national level. Now that the system is operational further improvements need to be made to ensure good quality data. Data management capacity needs to be improved at all levels. TIBU could be expanded to cover additional areas, for example integrated TB-HIV surveillance, incorporation of presumptive TB cases, contact tracing and many others. The data from TIBU should be used real time to guide program activities at all levels and to monitor M&E indicators. It should be ensured that all the recording and reporting tools at all levels are up to date, including the paper based system at the facility level. The central level should guide the counties to develop county specific M&E plans based on the national strategic plan, setting county specific targets. The NLTD-Unit/MOH should use the TB surveillance system TIBU to keep Kenya a flagship model for evidence based TB control by utilizing the full functionality of the system. To enhance evidence based TB control OR capacity should continue to be built. There should be more focus on learning while doing and translation of study results to TB control implications. Staff should be encouraged to contribute to the regional and global evidence base by presenting their findings at national and international conferences and publish manuscripts in peer-reviewed journals. To ensure research is focused and addresses the key challenges the TB program faces a collaborative OR agenda outlining key priority research questions should be developed with all key stakeholder to move TB control forwards in Kenya.

Achievements

In the national strategic plan 2011-2015 the NLTD-Unit /MOH set out to improve, expand and use the strategic information system to enhance linkages between all the program areas to strengthen program performance. Five specific sub-objectives were defined:

1. To put in place a national case based electronic surveillance system at all levels;
2. To Improve the quality and use of strategic information, including feedback at all levels;
3. To build capacity for and enhance research to improve program performance;
4. To carry out population based survey to establish the burden of TB, Leprosy and Lung Disease;
5. To measure impact of selected programmatic interventions.

Sub-objective 1: To put in place a national case based electronic surveillance system at all levels

Achievements

Information about TB notification in Kenya has traditionally been reported from facilities to the national level through a paper-based recording and reporting system, where data were aggregated from the district level upwards. In order to improve the routine TB surveillance in Kenya, the NLTD-Unit started in 2009 with technical support of several partners (TBCARE, KNCV, WHO, CDC and others) to transform their routine TB surveillance system into an electronic patient based reporting and recording system called the Treatment Information Basic Unit (TIBU). The system was piloted in 2010 and was implemented and rolled out nationwide by the end of 2012. TIBU is a multicomponent modular system that incorporates TB surveillance and programmatic management. In the TIBU system, sub-County Tuberculosis and Leprosy Coordinators (sCTLCs) transcribe case- based data from TB treatment facilities into tablet computers from which the data is wirelessly uploaded to a national database on the cloud. The case-based data are used from the national database for monitoring and evaluation of tuberculosis trends and activities throughout Kenya. The TIBU system is prepared for multi disease surveillance and other TB surveillance related components are under development of which a supervision module is piloted.

Kenya has made a big step forward into electronic recording and reporting and with the new TIBU system will even be enabled to include integrated disease surveillance like TB/HIV and additional support modules. The TIBU system serves as a flagship model for many other disease surveillance systems within and outside the country.

Challenges

1. Data quality and data management capacity

During the field visits to the 14 counties information was collected via the health facility tool to verify specific data in TIBU. Based on the data available in the TB treatment register at the facilities the notification data for quarter 4 of 2013 was collected. The collected data was crosschecked with the available notifications in TIBU for the same period by 2 international consultants. The percentage of underreporting of 1201 notifications cross-checked was nearly 4% (Table 4). This percentage reflects a total difference of 43 cases among 1201 cases recorded in the TB treatment register but not included in TIBU. In addition, a comparison was made using the absolute differences between the 2 data sources, i.e. if TIBU had 5 cases and the treatment register 6 the difference is 1 while if TIBU had 5 cases but the treatment register 4 the difference is also 1. Although the balance would be zero, the absolute difference would be 2. The summed absolute difference was 181 cases, 15% out of the 1201 cases reviewed.

Table 4 Level of underreporting in TIBU as obtained during the Mid Term Review (3-9 March 2014) for Q4 2013:

Underreporting	1201		-43	-3,58%
Difference In Reports	1201		181	15,07%

The field teams also collected specific information on the treatment outcome, which was the treatment success (cured/completed) for the Q4 2012 cohort to conduct consistency checks between the digital data in TIBU and the data from the paper TB treatment register. Data could be checked for 45 health facility data collection forms. The results of the data comparison indicated that: in TIBU 99 more cases successfully treated were registered than found in the paper based TB treatment register and in 33 cases less treatment success was registered in TIBU compared with the paper based TB treatment register. Overall in the cohort Q4 2012 of 45 health facilities in 10 counties 66 cases of treatment success were reported in TIBU, which could not be confirmed by the TB, treatment registers in the health facilities.

Using the TIBU digital database for 2012-2013 based on observation from the field visits the quality of the data was assessed for selected indicators. Not all indicators seem to be accurately reflected in the system. For example the variables related to the calculation of the BMI should be improved.
18% of the persons recorded in TIBU over 2012-2013 have a height of ≥ 2 meters, which seems incorrect. 30,589 of the 190,047 records have a height of 99m, which could be a height in cm or indicate a missing value. 113 people had a weight above 150 kg, which seems rather unlikely.

Reported BMI in TIBU was missing for 6911 cases and reported values ranged from 0- 800 with an interquartile range from 15.8-21. Although values below 10 and above 50 are physically unlikely, 22% of recorded BMI was in this category and these probably represent errors in recording and reporting. Reported BMI was in 12955 (7%) cases not matching the BMI calculated using height and weight. This illustrates the need that all variables in TIBU should be checked for completeness, consistency and accuracy systematically and routinely both at county and national level in order to optimize data quality of routine TB surveillance data. It was observed that at the county and national level the capacity on data management expertise needs to be improved and expanded.
The implementation of the renewed routine TB surveillance system TIBU demands new ways of supervision and data quality auditing to assure the highest possible data quality in the new system.

TIBU evaluation

A recent evaluation of the TIBU system conducted by CDC and NLTD-Unit in October 2013 concluded that TIBU had important strengths but data quality was mixed and there is need for improvement. Box 1 lists the summarized findings and key recommendations of the TIBU system review. All of them are still valid.

Box 1: Summarized Findings and key recommendations of TIBU evaluation by CDC October 2013

Findings

TIBU's main strengths are its usefulness, simplicity, acceptability, representativeness, and timeliness. Data quality was mixed. The majority of data items for cases were completed, though dates for HIV tests, and dates for treatment outcome, and treatment regimens had high proportions of missing values. A number of cases from the 2012 data in TIBU were not able to pass basic validation checks. Concordance between source documents and TIBU was limited. Flexibility, sensitivity, and predictive value positive could not be accurately assessed in this evaluation. Stability, though currently adequate, could be improved.

Recommendations

TIBU could be immediately strengthened with the following recommendations:

a) Update source documents, TB treatment guidelines, and TIBU to conform to revised WHO case definitions for presumptive, bacteriologically confirmed, and clinically diagnosed tuberculosis;
b) Establish scientific steering committee at the national level to receive, review, and track proposals for conducting research with case-based data from TIBU;
c) Offer additional training to local staff on exporting and analyzing TIBU data from both tablet and PC platforms in order for them to improve TB case management at facilities and to better understand the characteristics of TB in their reporting zones;
d) For a retreatment or transfer case, TIBU should allow DTLCs to correctly register the case in order to limit DTLCs from using workarounds that ultimately lead to duplicate case counts and poor data quality;
e) To improve data quality, develop, and distribute SOPs at the national and county levels for reviewing and improving data quality, such as examining completeness, concordance, and validation;
f) Identify reporting zones with poor data quality and conduct additional on-the-job training to emphasize to staff the importance of accurate record keeping in source documents;
g) Work with software development team to investigate issues of TIBU tablet computers blacking out or hanging during data entry, and to continue improving TIBU stability; and
h) Pilot TIBU updates before deploying them nationwide.

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Recommendations

1. Conduct routine and systematic data quality assessments (DQAs) to improve data completeness, consistency and accuracy;

2. Enhance/built data management capacity and expertise at all levels by increasing the number of staff tasks with data management activities and enhance capacity via on the job training;

3. Enhance supervision and mentorship on the job at county and facility level to improve quality of recording and reporting. Review the existing supervision system and enhance using of the supervision checklist and provide immediate feedback. Consider developing a performance based scoring system to score and rank the facilities;

4. Install a TIBU data committee to guide and approve the usage of data from TIBU outside of routine surveillance. Such a committee should assure that data from TIBU are made anonymously without any personal identifiers and are used according to the rules and regulation on the use of medical data and avoids duplication of investigations. Persons/institutions that wish to use data from TIBU should request clearance from the committee before data is accessible. The committee could consist of the national NLTD- Unit M&E head/data manager but also county representatives and other relevant stakeholders/ partners. In the Netherlands the so-called "registratie commissie" (registration commission) reviews request for use of data from the Dutch TB surveillance system Osiris; It should be explored whether the Research Task Force could take up this task when it is activated again (see further under sub-objective 3).

5. Continue developing and optimizing TIBU to optimize the current system. Box 1 outlines different suggestions for improvements of TIBU based on the review field visits;

6. Expand the TIBU system with additional functionalities to cover additional areas of the surveillance system (i.e. contact screening and patient referral) but also explore the option of an integrated TB-HIV and Lung Disease surveillance. Box 2 has a list of suggestions for expanding the system in the shorter or longer term;

7. Make use of real time TIBU data to guide program activities at all levels to maximize the use of the current electronic surveillance system. For example it could be verified whether all those that did not smear convert at month 3 where requested to submit sputum to test for MDR.

Box 2: Specific suggestions to improve TIBU

a) TIBU does not count for treatment duration with exactly 24 weeks but 6 months which gives problem as the system reports when you want to indicate cured/completed as outcome that the treatment period is not yet completed;
b) For patients from whom CD4 count is not done at baseline it is not possible to add a result for CD4 count for follow up (6month later). Therefore these entries are lost in TIBU;
c) The column for culture/Gene Expert result column does not have a date to indicate when the sample was send, because of that time taken to receive results cannot be measured;
d) The WHO guidelines for timing of follow up smears have changed to 2, 4, 6 months while TIBU still reflects 2, 5, 6 months. This gives difficulties in entry as the earlier date entered is not accepted;
e) Ensure that all variables in TIBU are validated (i.e. the BMI is not always consistent with the variables that register height and weight);
f) Ensure that all laboratory and other screening results, which are registered in TIBU, are exactly matched with the case the results belong to. Usage of unique client identification codes and for example barcode systems are not yet in use.

Box 3: Explore possibilities to incorporate in TIBU

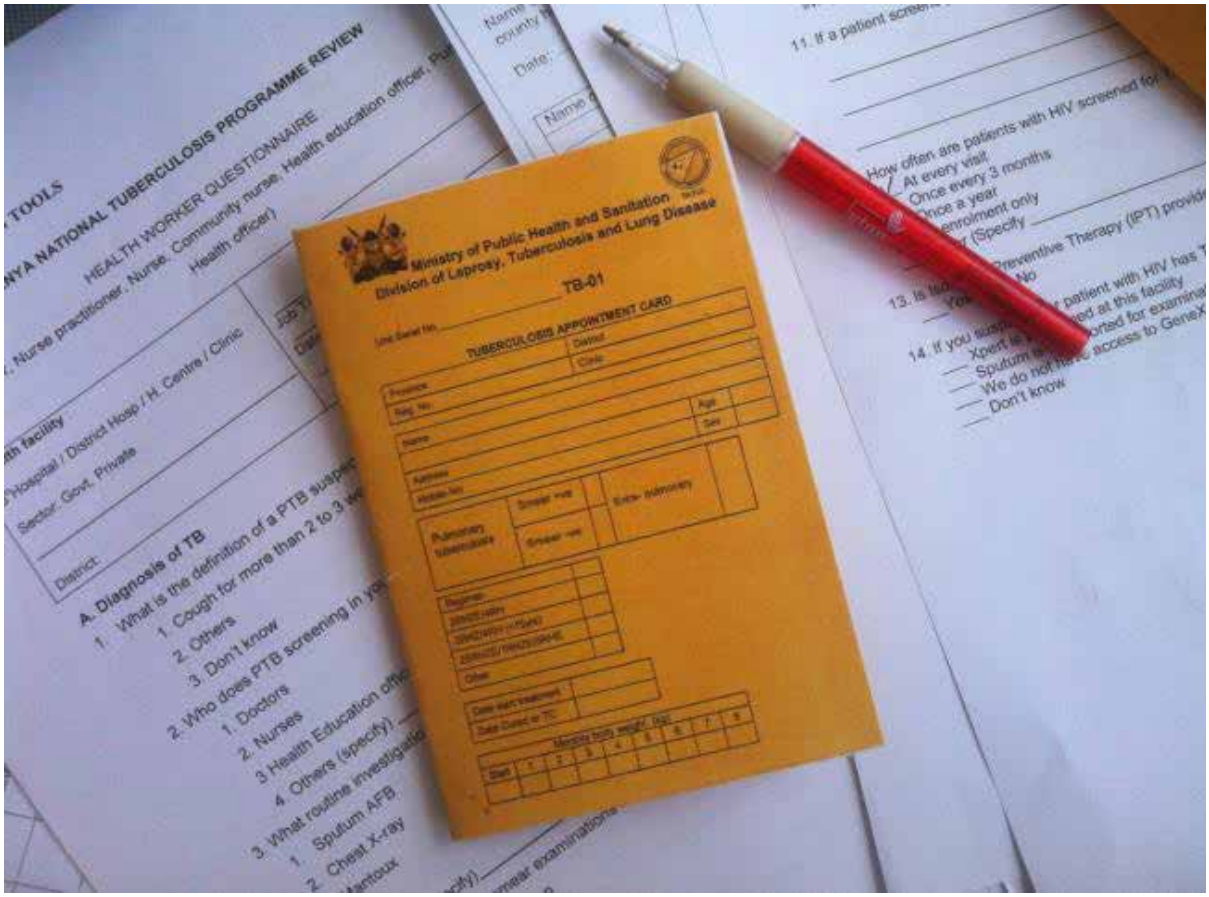
a) Include suspect register for both TB and MDR;
b) Take diagnosed cases (or even suspect) as a start of the surveillance system and not only those starting on treatment
c) Capture referral and transfers in/out;
d) Capture community involvement;
e) Include risk groups in the national surveillance;
f) Integration TB and HIV surveillance ;
g) Include lung health surveillance;
h) Enhance leprosy surveillance using TIBU
i) Link with LIMS and commodity management;
j) Explore adding variables on TIBU on to DHS;
k) Phase-wise implementation of TIBU at facility level
l) Accommodate community based TB control activities even if it is at aggregate level;

Sub-objective 2: To improve the quality and use of strategic information, including feedback at all levels

Achievements & challenges

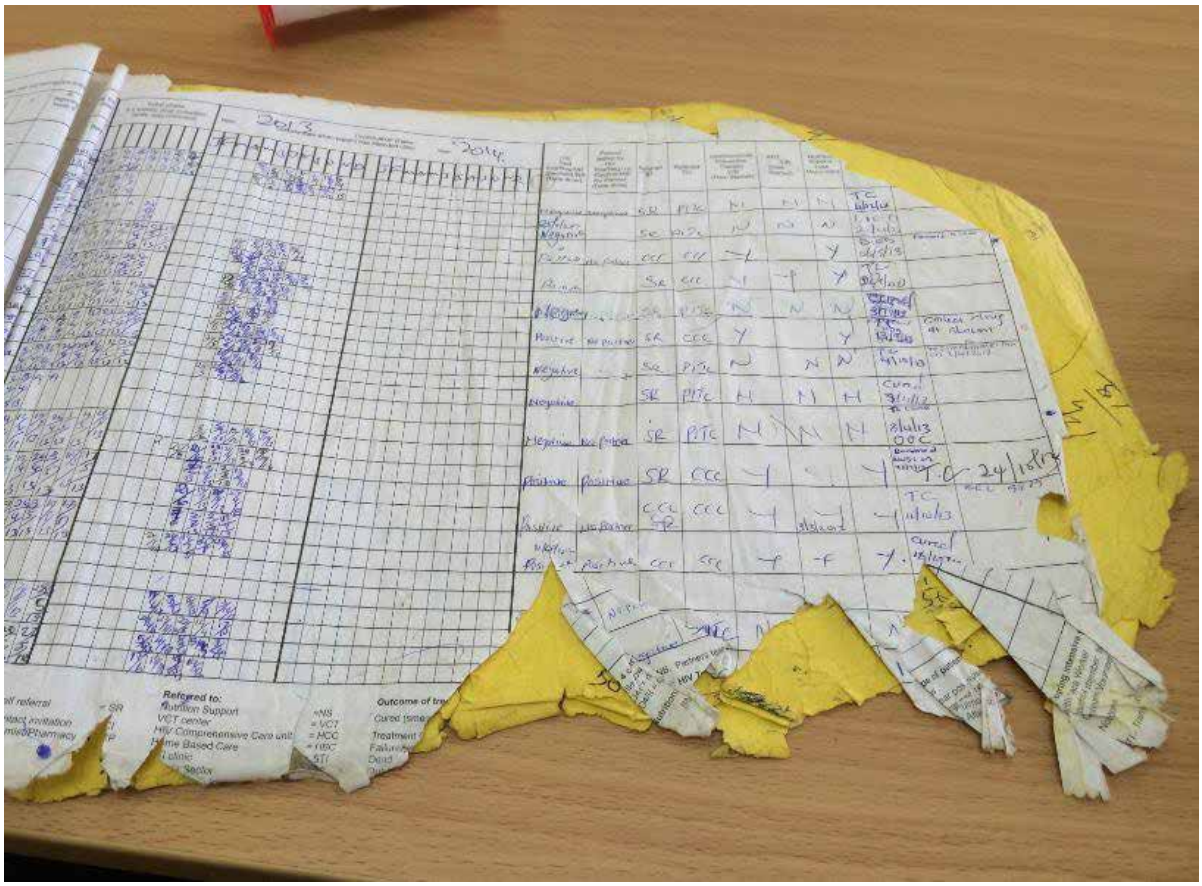
During the field visits to the different counties the review teams observed that the health facility staff in general is very motivated to keep the recording and recording tools up-to-date as most registers were well filled. Also several staff showed creative ways to record details that could not be covered with the existing tools. For example in Mutomo sub-county in Kitui county the sCTLC registered the children put on IPT in the TB treatment register of the respective facilities as she did not have an IPT register. However, in some health care facilities visited not all R&R tools were kept in good order. In some facilities, specifically those in Machakos Sub County, the TB patient treatment cards (TB5) were not in use for the last 2 years because of stock outs and all information was only registered in the TB treatment register. In a private hospital in the sub country they reproduced the TB patient treatment card in smaller format (see picture 1) and used them instead. In one district hospital visited the TB treatment register was not kept well and some parts of the register were not

Picture 2 Reproduced patient TB treatment card due to stock out as observed in Machakos County



readable anymore leading to loss of data as not all the patients registers on the damaged part had completed treatment (see picture 2), however this was an exception.

Picture 2 Register in poor state observed in Machakos County



Several facilities actively discussed TB data during their staff meeting either quarterly or monthly after they prepared their reports. In several facilities trend/numbers for TB indicators were displayed on the wall in the facility (see picture 3). Most "analysis" was restricted to trends in the standard set of TB indicators. When verified during the visits to the facilities in the counties it was noted that not in all instances all those diagnosed in the laboratory where also registered in the treatment register.

This could be due to different reasons: i) some people are requested for a sputum test in the laboratory but they are from a neighboring facility and return their for diagnosis; ii) for those smear negative in the lab it is not sure whether eventually they were diagnosed with TB and therefore these could not be compared; iii) some persons might not return for their sputum results and hence do not receive a final diagnosis. In none of the facilities visited a TB suspect register was used. The current surveillance systems starts when persons are registered in the treatment register as from there, they are entered into TIBU and formally counted for notification in the former paper based system.

If diagnosis or even presumptive TB would be used as the start of the surveillance system it would be much easier to trace whether all those investigated for TB eventually got a diagnosis of TB and if so whether all have started TB treatment. Other additions to the surveillance system that would need to be considered are listing of all contacts investigated for and identified as having presumptive TB. All those referred for treatment closer to their home before started on treatment should also be listed as currently these cannot be traced. At the same time it should be ensured that all those on treatment are notified. In one facility it was observed that the Daily Drug administration register, meant to register all drug issued on daily basis was used to register all those on treatment outside of the sub county before transfer to a facility closer to their home, even if treatment was ongoing for over 4 months.

Recommendations

1) Ensure availability and usage of all standardized revised R&R tools at all levels
2) Introduce M&E tools to capture all presumed and diagnosed TB cases (i.e. suspect, contact tracing)
3) Guide counties to develop their M&E plan as part of defining their health strategy
4) Improve the quality of the vital registration system to better capture TB deaths
5) Use real time TIBU data to guide program activities at all levels (national, county and HF), i.e. treatment outcome, all diagnosed cases starting treatment etc.

Sub-objective 3: To build capacity for and enhance research to improve program performance

Picture 3 Some indicators displayed on the wall in a health care facility

Achievements

In recent years operational research (OR) capacity is being built in cooperation with AMREF/MOI University and CDC Kisumu. AMREF provides OR training with support from Global Fund Round 9 to strengthen community systems and operations research for TB control. The project began in January 2011 and will end in December 2015 and is being implemented in two phases, phase I ended in June 2013. AMREF hired Moi University School of Medicine to conduct OR training to 200 TB field officers by the end of the project period. To date 160 persons have been trained, with 110 trained in Phase I. Among them are DTLCs, DMLTs, Clinical Officers and staff from AMREF-GFTB and NTLD-Unit. The OR training takes 5 days and each class has between 25-30

participants. The training aims to improve on knowledge and skills of participants to write OR proposals and conduct OR projects. Some of the TB field officers trained in OR in Phase I presented their projected at the Lung Health Conference held in Nairobi in October 2013. During Phase I of the project, there was no provision for follow up of those trained but this was rectified in Phase II after approval of additional funding by Global Fund to support those trained to develop research projects. A Technical Working Group consisting of Moi University, Egerton University, NTLD – Unit, AMREF and WHO has been formed to develop the Terms of Reference for OR follow up and support and also identify priority areas for TB research in Kenya.

In addition to the AMREF program KEMRI/CDC in Kisumu has trained about 35 staff, 20 from MOH and 15 from KEMRI in the use of existing data to enhance program performance. Over a 6-

12 months period, students (individual or in groups) conduct an OR project being mentored by CDC staff and taught the technical background during multiple sessions (formulating a research question, data cleaning and analysis and result interpretation, writing an abstract and presentation).
Kenya has a history of evidence-based programming and results of studies conducted in the recent years have been used to guide policy. A systematic review and analysis of drug resistance patterns during 2011 GLC mission led to a change in the drug regimen. Results of the IPT pilot roll out sites were analysis to verify the feasibility of the approach in children (Masini et al 2013).
Increasingly program staff is disseminating their OR results. During the last UNION conference in Paris in November 2013, the program presented several abstract. It should be noted that most staff involved in OR are from the central level. Involvement of staff at county level in OR is limited with only in few of the visited counties staff reporting involvement in OR for example in Isiolo and Meru where the SCTLC initiated OR projects and 6 staff were trained on OR.

Challenges

Given the increase in OR capacity building there is a limited number of projects conducted and so far none of the staff trained in OR in the AMREF/MOI program have conducted an OR project although more attention will be given to follow up of those trained in the next phase of the program. During the site visits it was felt that at facility level and even at county level there is low awareness on the use of data besides the reporting of the standard TB indicators. However, OR ideas exist at different level especially at county level but at this level there is still limited capacity to carry out OR. Although many ideas exist there does not seem a targeted approach to what study are needed to enhance TB control. Since the development of the strategic plan 2011-2015 the list of OR priorities has not been updated.

The research task force established in 2009 and consisting of representatives of research organizations and technical partners became dormant after a few meetings. During the inception meeting on 23rd April 2009 the research task force was mandated to provide overall coordination of TB research activities and more specifically:

1. Coordinate all TB and TB/HIV research activities to ensure conformity with identified national research priorities
2. Maintain an inventory of planned, ongoing and completed TB research projects
3. Mobilize resources for TB and TB/HIV research
4. Planning for TB/HIV research
5. Quality control

Recommendations

1) Develop a systematic way of research priority setting of TB, Leprosy and Lung disease at all levels

2) Continue building OR capacity using a learning while doing approach and mentorship and encourage those being trained to use their skills to conduct OR. Evaluate the current OR trainings conduced and decide whether a revised approach is needed;

3) Implement priority research at all levels (national, (sub)-county and health facility level);

4) Encourage staff conducting TB OR to publish their results and translate findings into key policy messages; consider organizing a manuscript-writing workshop with assistance of technical partners to enhance skills on manuscript writing and facilitate the process to contribute to the global evidence base.

5) Update the national OR agenda and adjust it to county level to align the focus with the country health development plan and implement the outlined priority research. A list of OR topics identified during the review is outlined in box 4. Based on the review the following topics would be a priority:

    a. The yield of the ICF tool both among PLHIV screened at each visit as well as among prisoners seems relative low. The study by Masini et al (2013) suggested that "although symptom screening may work well in children with higher CD4 cell counts, its utility may be limited in those with severe immunosuppression." Based on these findings an investigation into the quality of implementation of the current TB-HIV screening algorithm to identify presumptive TB and those eligible for IPT is needed to verify if there is any need for adjustment in the strategy or enhancement of the existing tools.

    b. Based on incidental report of discordance between culture results of CRL and GeneXpert results obtained at county level machines it would be good to verify the concordance between all samples for which both culture and Gene Expert is available.

    c. A key finding from this review is that TB in children is likely underdiagnosed and a study would be needed to assess the level of under diagnosis and whether all children suspected of having TB indeed have access to diagnostic services. Such an initial study could be followed by an implementation study using mobile X-ray to enhance diagnosis in children.

6) Enhance the link between the program and research institution in and outside the country to foster OR collaboration

7) Revive research task force and hold regular meetings to steer TB research activities within the NLTD-Unit and ensure priority research to enhance TB control is being conducted. Explore whether the research task force can take up TIBU data regulation as well (seen under sub-objective 1).

Box 4: List of OR ideas resulting from the MTR:

- Assess causes of high default rate among TB patients and the impact of patient education and incentives (Meru)
- Xpert use for improved TB case detection among adults and children (Meru and Isiolo)
- Low proportion of TB in children out of total reported in Kenya
- Low IPT uptake in PLHIV and child contacts
- Indirect costs of TB management in hard to reach areas; Is TB treatment really free?
- Determine true status and timing for Out of Control clients
- Outcomes for ICF for PLWHA
- Prospective study of incidence of TB among PLWHA
- Investigate the perceived high PTB+ rates in some areas
- Investigate at national/county level the concordance between Xpert results and culture results;
- Assess the level of implementation of IC measures/policy at national/county level;
- Assess the coverage of testing of MDR suspects at national/county level to identify groups not covered optimally currently;
- Conduct implementation study to align IPT with ART follow up to demonstrate whether it increases uptake of ART;
- Evaluate the impact of information on TB given to the patient by HCW and develop methods to improve this;
- Conduct implementation studies to test new approaches of sharing knowledge (to be developed);
- Compare the trends in CD4 count between TB-HIV co-infected patients with those HIV+ without active TB;
- Investigate distribution of primary versus acquired MDR resistance;
- What is the reason of the high number of deaths observed among HIV negative TB patients is some specific sites (OR question for health facility in Kitui/Machakos county)
- Why does the area have high caseload of MDR-TB?
- Which patients not sputum convert after 2 months?
- Assessing the time taken to initiate ARVs for co-infected TB-HIV patients.
- What is the reason of the high number of death observed in HIV negative TB patients?
- Investigate at county level whether all those in laboratory registers are in the treatment register to track initial defaulters/ link with referral system
- Introduce suspect register t know which of those smear negative were eventually diagnosed with TB and how long the delay in diagnosis is. For example in Mbitini clinic in Kitui it was observed that for one SM- patient the delay was 27 days, while for another this was 2 months;
- Conduct an implementation study on use of suspect register to identify under reporting
- Evaluate the impact of nutritional support on case finding and treatment adherence
- Assess the geographical, social and economic barriers to care for the poor
- Determine the full costs of TB care, to quantify the reimbursement needed for TB in insurance schemes
- Evaluate the impact of NHIF on TB case detection and treatment success among civil servants
- Conduct inventory study to investigate whether all TB cases diagnosed in the private sector are also notified to NTLD
- Investigate the observation that case notifications by county poverty rate indicate case finding is lagging in the poorest counties. It is not known if this is a reflection of the actual epidemiology or barriers to care.
- Evaluate the financial barriers for TB patients as part of the prevalence survey, or conduct participatory poverty assessments (PPAs) to prioritize social health protection measures that would best support TB patients.
- Evaluate the impact of current nutritional support programs on TB case finding and treatment outcomes.
- Pilot test the inclusion of TB in a demand-side financing model as part of the rollout of HISP, which includes a transport subsidy.

Sub-objective 4: To carry out population based survey to establish the burden of TB, Leprosy and Lung Disease

In 2008 the NLTD-Unit started drafting the protocol for the prevalence survey. Ethical clearance for the protocol was obtained from KEMRI in 2011 and funding was secured under the Global Fund round 9 that was granted in 2010. A draft data management plan and draft SOPs have been developed but still need to be finalized. Although progress has been made, preparations have been halted because of delay in procurement of mobile chest X-ray machines. Currently WHO is requested to handle the procurement and the final updated specification document has been completed in February 2014. Procurement is expected to take at least 6 months and the current expectation is that the survey could start towards the end of 2014.
Beside the planned national TB prevalence survey a DRS survey has been in preparation since 2010. Funding is secured and the survey is scheduled to start in April 2014 and results should be available in the first quarter of 2015.

Recommendations

Continue preparations and start data collection for the national TB prevalence survey as soon as possible for the country to base its planning on accurate data of the actual TB burden and gain other valuable insight in terms of health seeking behavior and which proportion of prevalent cases are already captured by the NLTD-Unit. The developed protocol should be reviewed to verify if any adaptations are needed given the guidance provided by the WHO global task force on impact measurements based on experience from surveys around the globe that are recently completed or currently ongoing.

Conduct the planned DRS soonest and before the start of the TB prevalence survey to get an accurate figure on the MDR-TB burden in the country.

Sub-objective 5: To measure impact of selected programmatic interventions
The NLTD-Unit conducted several studies in the last years. Not all planned studies outlined in the NSP 2011-2105 were completed (table 5)

Table 5 summarizes the status of the five sub-objectives as outline the National Strategic Plan 2011- 2015. Besides these the new strategic plan should consider what the impact of devolution on TB control is and how roles and responsibilities will have shifted in the new system and how it can optimally function in the devolved system.

Table 5 Overview of planned OR projects as per NSP 2011-2015 with their current status

Study	Status
a. Carry out delay in diagnosis survey	field data collection ongoing
b. Carry out a ACSM KAP survey	completed - report written, results to be disseminated
c. Carry out a survey to determine the reasons why TB patients default	This has not been done countrywide. Done in some counties like Nairobi by officers for masters program
d. Carry out evaluation of TB Gender and Poverty initiatives being implemented in 2 districts (Mutomo and Kitui)	Status unclear
e. Carry out an evaluation of the impact of pediatric diagnostic criteria on treatment outcomes	Not done due to funding unavailability
f. Carry out a survey on barriers to access of TB care	Not done due to funding unavailability - should be considered in the next plan
g. Conduct baseline needs assessment for special groups (Immigrant, prisoners and uniformed forces)	Not done due to funding availability - should be considered in the next plan
h. Carry out a survey on current practices on pediatric TB treatment	Protocol at the ethical review committee for approval
i. Carry out regular post marketing surveillance	Not yet systematic
j. Conduct survey to determine the contribution of CB DOTS to TB care	Not yet done
k. Pilot introduction of Rifabutin containing regimen in HIV patients on PI	Not done.

Table 6 Achievement of the five sub objectives as outlined in the National Strategic Plan 2011-2015

Sub objectives	Achieved
1) To put in place a national case based electronic surveillance system at all levels	YES
2) To improve the quality and use of strategic information, including feedback at all levels	ONGOING
3) To build capacity for and enhance research to improve program performance	ONGOING
4) To carry out population based survey to establish the burden of TB, Leprosy and Lung Disease	PLANNED
5) To measure impact of selected programmatic interventions	ONGOING

DETAILED FINDINGS: POLICY

Introduction

Kenya Vision 2030, the development blueprint for the country, was finalized in 2007. It aims to achieve "a globally competitive and prosperous Kenya with a high quality of life by 2030." The health sector forms a key component of the social pillar of Vision 2030.

In-line with the new Constitution adopted in 2010, the devolution of government functions and resources to 47 newly created counties is swiftly changing the mode of operations for the health sector, including the management of TB, leprosy and lung health. The health sector, previously characterized by central-level planning and supply-side financing, is shifting to devolved planning and demand-side financing modalities including national health insurance, conditional and performance-based grants, and equity-enhancing allocations of national resources.

Within the health sector, the Kenya Health Policy Framework (KHPF)[2] has been the basis for the health development agenda in Kenya since 1994. The framework emphasizes "quality health care that is acceptable, affordable and accessible to all." The implementation of this framework was divided into two five-year strategic plans: the National Health Sector Strategic Plan (NHSSP I, 1999-2004), the National Health Sector Strategic Plan II (NHSSP II, 2005-2010). A new National Health Sector Strategic Plan III (NHSSP III, 2012-2017) if being finalized. NHSSP III has the following policy objectives that relate to the control of TB, leprosy and improvement of lung health; all of which are
aligned with the realization of the Health Sector Vision[3]:

1) **Eliminate communicable conditions**: This is to be achieved through reducing the burden of communicable diseases, till they are not of major public health concern.
2) **Halt, and reverse the rising burden of non-communicable conditions**. This is to be achieved by ensuring clear strategies for implementation to address all the identified non-communicable conditions in the country.
3) **Provide essential health care.** These shall be medical services that are affordable, equitable, accessible and responsive to client needs.
4) **Minimize exposure to health risk factors**. This aims at strengthening the health promoting interventions, which address risk factors to health, plus facilitating use of products and services that lead to healthy behavior in the population.
5) **Strengthen collaboration with other sectors**. This aims to adopt a 'Health in all Policies' approach, which ensures the Health Sector interacts with and influences design implementation and monitoring processes in all health related sector actions.

2 KHPF 2012-2030
3 Draft National Health Sector Strategic Plan III

Figure 9. Sequence of major policy evolutions

2007 Vision 2030 drafted

2007 Health Sector Services Fund (HSSF): direct cash transfer to remote facilities for essential health (n=3000)

2010 New Constitution enacted

2013 Abolition of user fees

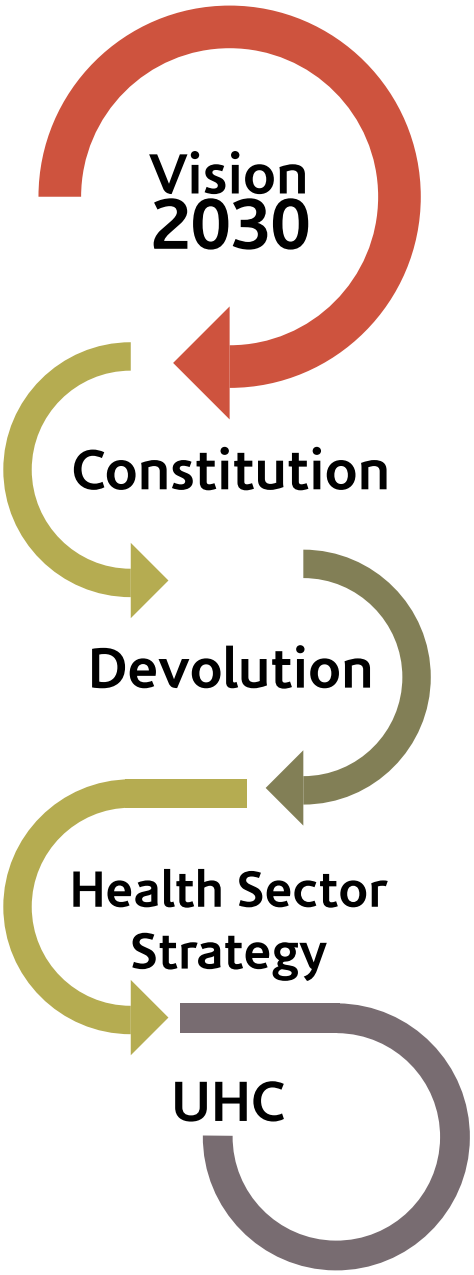
2014 Health funding devolved

2014 New health sector policies and plan 2012 - 2030

2014 Launch of HISP (500 households per county)

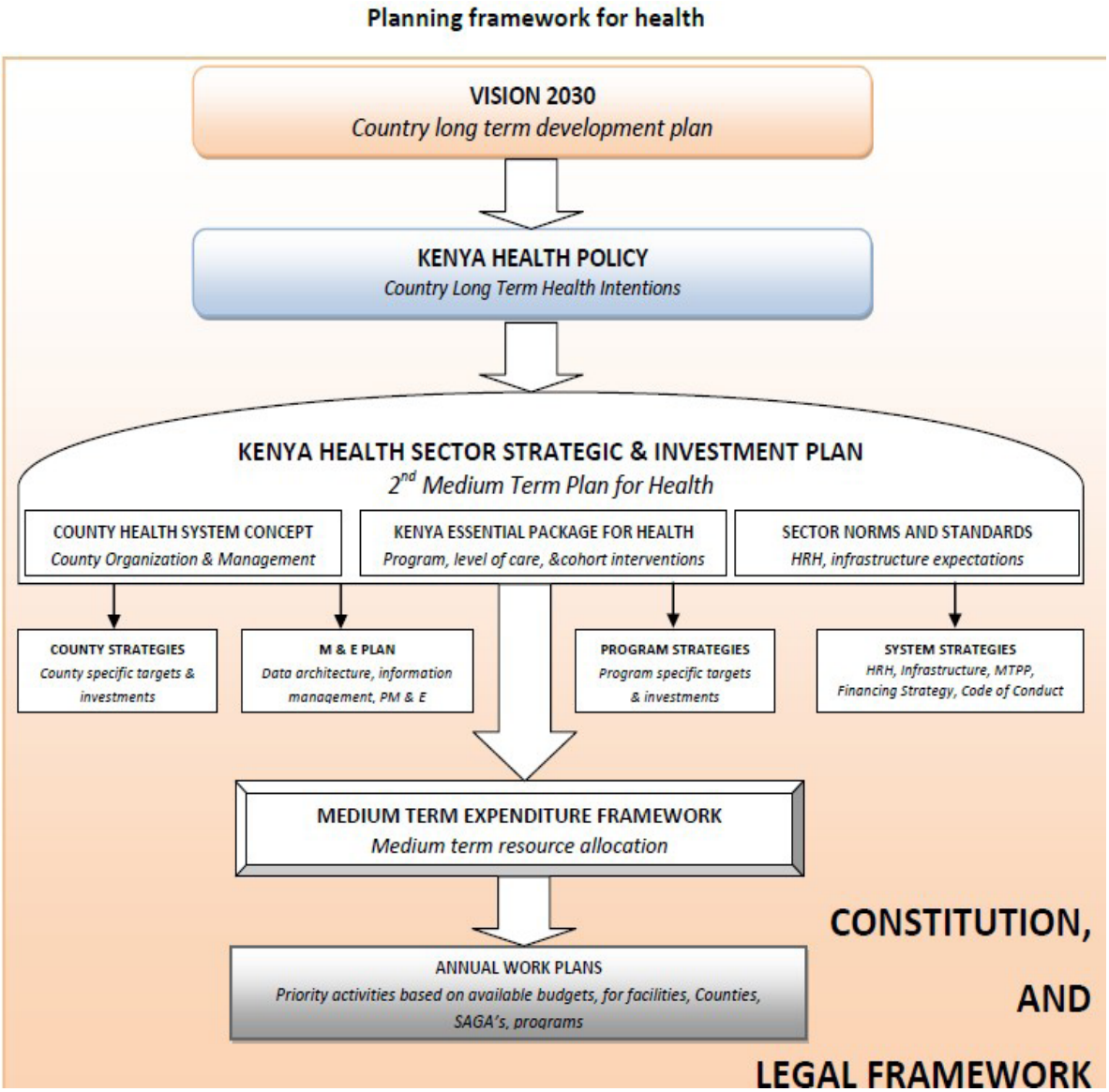
2014 Scale-up of results based financing (through HSSF)

UHC Social Protection, Access and Coverage



Introduction

Figure 10. Planning framework for health



Achievements

Sustained political commitment to TB has been fundamental to the success of the NLTD. Among the performance indicators of the new HSSP is TB treatment success, with a goal of reaching 90%. In addition to the government's commitments, the NLTD has nurtured strong partnerships at national and decentralized levels, with donors, international and national NGOs, CSOs, and technical partners through its inter-agency coordinating committees (ICCs).

Kenya will remain a legacy in sub-Saharan Africa for being the first country to reach the WHO targets for TB case detection and treatment success. The NLTD has successfully managed a high quality programme through a cascade of TB and leprosy coordinators at decentralized levels; i.e. provincial and district level prior to devolution. The network of trained and skilled health workers has consistently enabled the rapid uptake of new policies and technologies, while also providing the platform for supportive supervision to address operational challenges on a systematic basis. The full integration of TB and leprosy service provision into the primary care system enabled mentorship and decentralized touch points for coordination with community based organizations and care providers.

Kenya maintains a policy of evidence-based strategy development and programme implementation. Having the first real-time electronic data management system is evidence of the desire for data. New approaches, such as the engagement of all care providers and collaborative TB/HIV activities, have

scaled up rapidly and successfully in Kenya due both to the cascade system, and the use of evidence of their effectiveness to achieve buy-in at all levels.

Leprosy has also been controlled successfully through the cascade system, and within the primary health care network. Kenya is now in the post-elimination phase of control

Challenges

The devolution presents opportunities for local prioritization and adaptation of TB and leprosy control, and support for targeted and patient-centered care. In 2013/14, all funds for TB control were devolved to the counties, including funds for commodity procurement. In accordance with the Constitution, all devolved funds were bundled and no line item for health, or TB, was specified. Counties were not advised on how to plan for or cost activities in support of TB and leprosy control. No TB or leprosy commodities have been procured by the counties and a supply stock-out is looming within months. A new health sector strategy and health policy are being finalized, to be followed by realization of the newly identified priorities and targets. While the activities of the NLTD have been considered priority areas, they are not consistently well represented in the new plans and indicators.

Translating the cascade model of technical excellence and assistance into the new structure is ongoing and will require additional human resources and new skill sets, given the expanded number of administrative units and new requirements for planning capacity at county level.

TB remains a disease of the poor in Kenya. Over half of patients are malnourished, to some degree, at the onset of treatment with 17% being severely malnourished and a further 22% being moderately malnourished. Poor nutritional status is known to negatively impact treatment adherence and outcomes[1]. A review of case notifications by county poverty rate demonstrated that case finding is lagging in the poorest counties. It is not known if this is a reflection of the actual epidemiology or barriers to care, but it is cause for concern and should be further investigated. The majority of nutrition support programs that can benefit TB patients target women and children, leaving male TB patients without equitable access.

With its solid foundation, the Kenyan NLTD is ready to move to the next level in TB control. With an already declining rate of notifications suggesting that incidence may be coming down, it is time to build on the program's solid foundation with a stronger focus on the prevention of transmission and disease. The Health Sector Policy calls for a 62% decline in deaths due to communicable diseases by 2018. To contribute its part to this goal, the NLTD will need to a) implement the quality enhancements recommended in this document; b) re-align the program's operations to the new
county structure, ensuring unified commitment from central and county levels; and c) quickly introduce / expand prevention efforts, including reducing diagnosis delay to diminish transmission.

1 http://digitalcommons.calpoly.edu/cgi/viewcontent.cgi?article=1009&context=fsn_fac

Recommendations

The NTLD must not only engage actively in the devolution process but has the opportunity to be a pathfinder as it capitalizes on the emerging structures to reach marginalized populations and support county-level capacity for planning, budgeting and quality service implementation.
To this end, the MTR recommends:

1. **Ensure that a comprehensive national program is maintained within the devolved context.** The devolution of responsibility for TB and leprosy control operations to the county and sub-county levels must urgently be met with revised working modalities between all levels. The MTR identified the following needs, listed sequentially below. All activities may be achieved in collaboration with other communicable disease control programs, particularly if this facilitates greater county engagement.
    a) Articulate and document the devolution of responsibilities for all TB activities; i.e. considering all dimensions of programme implementation, the NTLD is encouraged to work with counties and sub-counties to detail which activities will be completed at each level.
    b) Ensure the county and sub-county structure can support all designated activities; e.g. identify a TB focal point for each level, inventory and address any capacity building needs; and develop on-the-job tools and disseminate existing guidance to promote national standards. The NTLD may need to assign its staff to visit and provide technical assistance to a select group of counties such that all counties have a point person within the central unit.
    c) Support and monitor the inclusion of TB and leprosy within county health plans.
        i. Develop a template(s) for planning and budgeting of TB control activities, including commodity requirements, for use at county level.
        ii. NTLD to provide commodity estimates, based on past utilization, to each county, as well as details of budget availability through the Global Fund or other partners
        iii. Assess, annually, all county health plans with a view to providing technical assistance if challenges to TB or leprosy control have been identified.
        iv. Complete stakeholder mapping at all levels and support planning meetings to engage stakeholders in county planning
        v. NTLD to strategically fill county-level budget gaps with off-budget support, perhaps considering performance-based support that incentivizes county contributions. County plans and budget shortfalls to be aggregated for resource mobilization efforts, with county involvement in planning for future donor funding proposals.

2. **Actively engage in policy discussions** at national level. Ensure that TB and leprosy are appropriately considered in all domains as the country moves toward universal health coverage. This includes:

    a) Ensure TB is included within the Essential Health Package that forms the basis for national insurance, health sector services fund (HSSF) and other funding schemes.

    b) Develop the investment case for TB control, with appropriate messaging of its pro-poor targeting (and social protection targeting), cost-effectiveness, health and/or productivity impacts for specific audiences. The MTR suggests that WHO and the Health Policy group be engaged to support the development of evidence-based, one-page advocacy papers.

    c) Define the benefit package needed for full reimbursement of TB diagnosis and care, including drug-sensitive and drug-resistant TB, for inclusion of TB through the health insurance packages: National Hospital Insurance Fund (NHIF) and Health Insurance Subsidy Programme (HISP). Considerable costing and economic analysis may be required to enable this shift to demand-side financing.

    d) Ensure TB control indicators (notifications and treatment success) are among the performance measures for all national and county health care policies and strategies, such as the emerging national health policy, health strategy, and health financing policy.

    e) Monitor the impact of devolution, HISP, HSSF, social protections such as food support, and other new initiatives on TB case notifications and treatment outcomes at national and devolved levels. Utilize evidence to learn lessons and inform future policy and planning efforts.

2. **NTLD to actively seek to expand its partner base**; to facilitate the mainstreaming of programme priorities into the devolution and Universal Health Care (UHC) processes.
    a) Systematic collaboration with other government actors should include National Health Accounts (NHA), Treasury, MoH Policy & Planning division, Social Protection, Ministry of Labor (workplace-based DOTS and labor policy to protect TB and leprosy patients), Ministry of Education (potential information raising and TB screening in schools) and NACC (TB/HIV).

    b) The review also noted the importance of engaging non-governmental partners and donors who are key partners in the health sector such as the World Bank and DANIDA, to ensure that TB and leprosy are well integrated in emerging pro-poor, insurance and social protection strategies.

    c) Seek to harmonize efforts with other disease programs within the communicable diseases division;
    e.g.

        i. Integrate other communicable diseases within TIBU, or a TIBU-like system
        ii. Single planning / financing tool (e.g. WHO TB financing tool, simplified)
        iii. Shared capacity building activities
        iv. Shared advocacy to counties for appropriate priority-setting and planning for communicable diseases
        v. Hire an economist and statistician (at least 2 years) at division level to support analytical work required to monitor impacts of new technical approaches and devolved implementation

    d) The review team encourages the NTLD to engage medical parliamentarians; i.e. Parliamentary Committee on Health, for continued support to communicable disease control.

3. **Re-profile skill sets required at central unit to support counties.** The changed role of the central unit will require the unit to maintain specialized technical expertise for areas such as programmatic management of drug resistant TB, while expanding its direct technical assistance to all 47 counties and engaging in concurrent national policy and high-level planning discussions. During the transitional phase of the next 2-3 years, the intensity of the policy engagement, capacity building and technical assistance to counties should not be underestimated. The MTR encourages the Ministry of Health to support a revised staffing mix for the central unit that will enable it to successfully manage this increased workload, at least in the medium term.

4. **Global Fund success to be protected**. The MTR acknowledged the successful turn-around of the NTLD's performance under its Global Fund grants. The current success must be sustained with any future devolution of this funding only based on evidence of adequate accounting capacity at county-level to not place their national grant at risk.

5. **Address the social determinants of TB through policy change and new social protection schemes.**

    1. Evaluate the financial barriers for TB patients as part of the prevalence survey, or conduct participatory poverty assessments (PPAs) to prioritize social health protection measures that would best support TB patients.

    2. Identify and explicitly remove the financial barriers contributing to diagnostic delay and at the point of care; e.g. promote free diagnostic services for children.

    3. Evaluate the impact of current nutritional support programs on TB case finding and treatment outcomes. Explore the expansion of programs to include male TB patients.

    4. Pilot test the inclusion of TB in a demand-side financing model as part of the roll-out of HISP, which includes a transport subsidy.

DETAILED FINDINGS: FINANCING

Introduction

Kenya is progressing toward Universal Health Coverage, with increasing reliance on demand-side and performance-based financing that promises to bring resources to where patients – especially the poorest patients – are seeking care. Since 2007, the Health Sector Services Fund (HSSF) has provided cash to remote health facilities for the provision of the essential health package. Currently, over 3000 facilities benefit from the HSSF, which is co-financed by the World Bank and the Danish International Development Agency (DANIDA). Additional Financing (AF), a scheme that provides conditional grants to counties to increase access to primary health care, with priority focus on maternal health, has been piloted and will be scaled up with World Bank support.

Similarly, Kenya is piloting a comprehensive in- and out-patient healthcare service package for the very poor, called the Household Insurance Subsidy Programme (HISP). The insurance scheme is managed by the National Health Insurance Fund, which primarily serves civil servants, and will enable several thousand households across the country to access 'free-to-patient' health care services. The benefit package provides a subsidy for all services within the Essential Health Package. The pilot phase includes 500 households in each county.

As shown below, the United States government is the largest donor to the health sector, supporting both public and non-public actors with a disbarment of over 0.5 Billion US$ in calendar year 2010, which is a sharp increase since 2005. Donor contributions to TB control accounted for a slightly larger proportion of the budget for TB (42%) than for the overall health sector (34.5%), while the proportion of funding that comes from the Government of Kenya for TB control and overall health care spending is nearly equal at approximately 28% (figure 13).

Figure 12. Total donor contributions to health 2002-2012

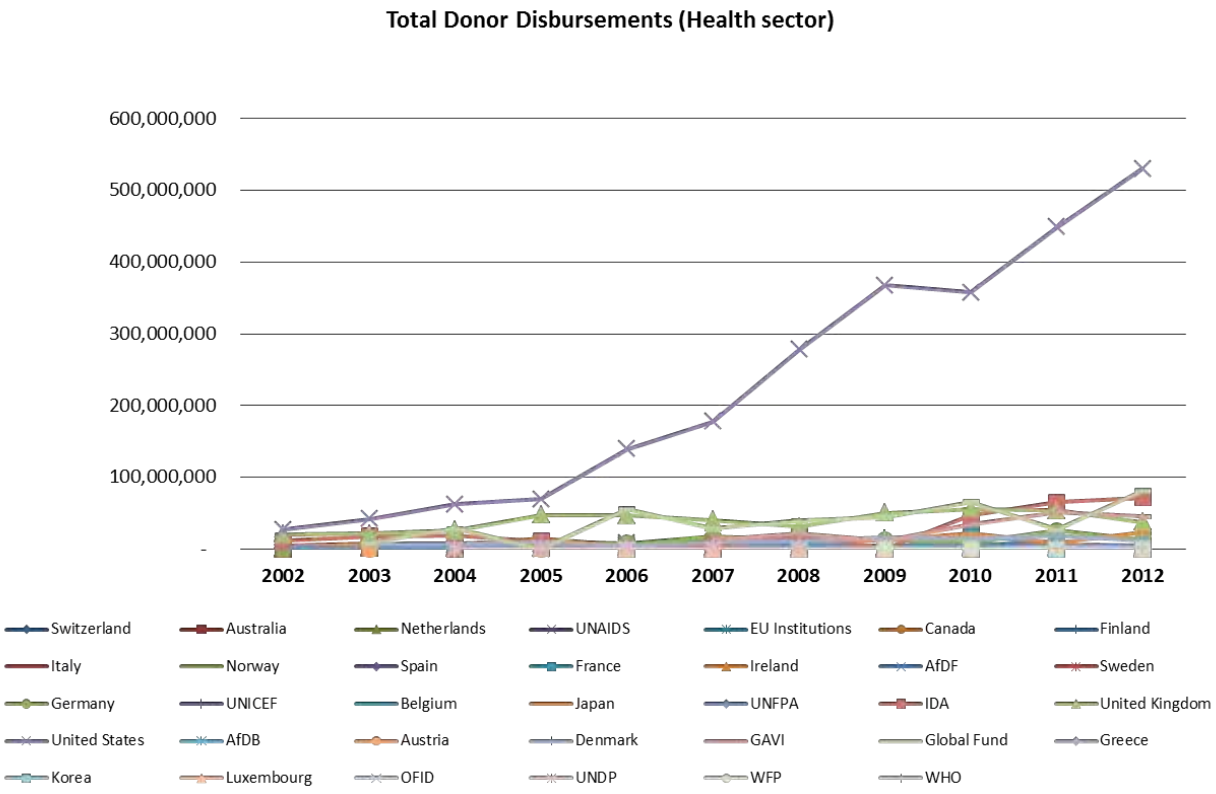


Figure 13. Percentage of budgetary contributions to TB and overall health sector

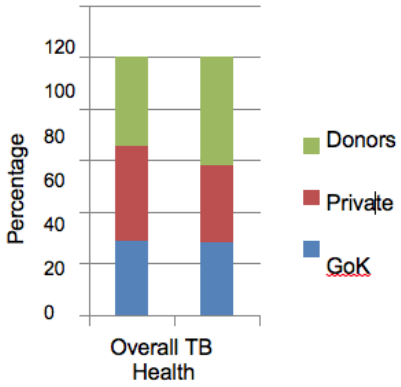
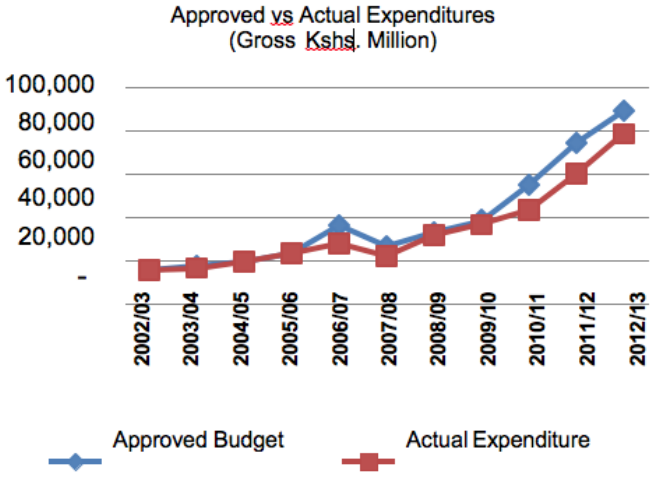


Figure 13. Percentage of budgetary contributions to TB and overall health sector



Achievements

Public funding to the health sector has risen more than four times in the last nine years. The MoH approved budget increased from Kshs. 15 Billion in 2002/03 FY to Kshs. 89 Billion in 2012/13 FY while the actual expenditures over the last decade have grown in nominal values from Kshs 15 billion to Kshs 79 billion, representing an overall growth rate of 412% in the same period. The country is able to expend nearly all funding approved for use by the Ministry of Health (figure 14).

Government financing to the NLTD has steadily increased over the past five years. According to the 2009/10 National Health Accounts, total health expenditures for TB services (THETB) was Ksh 1.4 billion ($17.8 million), representing

1.1 percent of GDP and 1.1 percent of all health spending on priority areas, with the main financing source for TB activities in 2009/10 being donor funding, at 42 percent of THETB, followed by the private (including households) and public sector resources at 30 percent and 28 percent, respectively. The breakdown of financing sources is listed in table 5.

Table 6. Breakdown of Financing of TB activities by source in 2009/10

Financing Source	Amount (Kshs)
Central Government Revenue	353,273,512
Regional and Municipal Government Revenue (Local authorities)	7,977,141
Parastatal Employer Funds	19,864,539
(Private) Employer Funds	54,818,130
Household Funds	351,925,430
Other Private Funds	2,571,916
Rest of the World Funds (Donors)	561,493,596
Grand Total	1,351,924,263

Most resources for TB were used to finance Prevention and Public Health activities which accounted for the largest proportion of total health Expenditures on TB, at 38.9 percent, followed by outpatient care, at 27.1 percent; Inpatient Curative care accounted for 17.9 percent of Total Health Expenditures on TB (figure 15). As noted in the earlier section on DOTS Expansion, the majority of public funding is absorbed by hospitals, rather than the more decentralized health centers and dispensaries (figure 16).

Figure 15. TB expenditures by function, 2009/2010

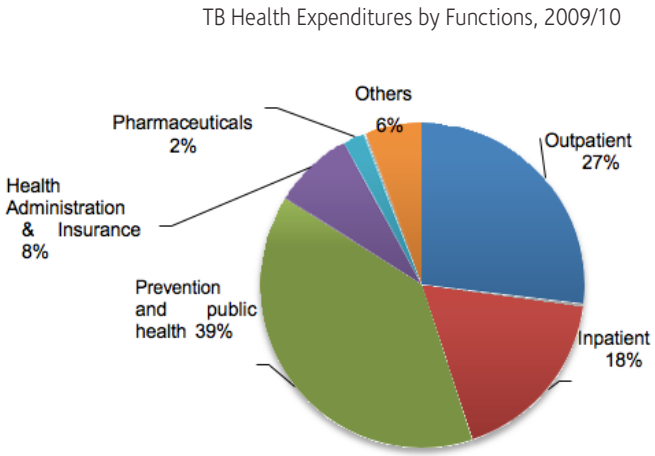
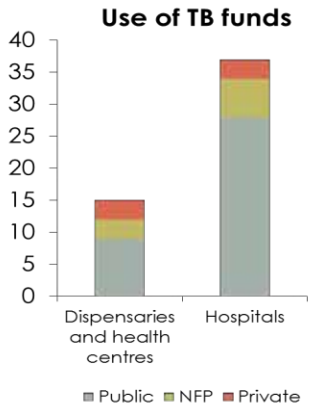


Figure 16. TB expenditures, by facility type



Source: NHA, 2009/2010

The number of health workers has increased in the sector overall and especially at the primary level facilities. Since TB and leprosy control activities are implemented through the primary care system, health workers enable quality service delivery.

Table 7. Number of health workers 2007-2011

Health Personnel	2007	2008	2010	2011	No. per 100,000 pop.
Doctors	6,271	6,623	7,129	7,549	19
Dentists	931	974	974	930	3
Pharmacists	2,775	2,860	3,097	3,205	8
Pharmaceutical Technologist	1,680	1,815	2,233	2,409	6
Nursing officers	12,198	14,073	29,678	34,071	86
Enrolled Nurses	31,917	31,917	34,282	34,576	87
Clinical Officers	5,797	5,035	8,598	9,793	25

Source: Economic Survey 2012

Challenges

While total health expenditures have increased by Kshs 40 billion in the last ten years, development partners account for most of the increase. As shown in the table below, the total health expenditures accounting to the National Health Accounts increased significantly between 2001/2 and 2009/10.

The share of the development partners in total health expenditure has more than doubled while the share of private out-of-pocket spending has decreased. The total amount spent on healthcare, including private payments and development partner contributions, was around Kshs 3,203 (US$42) per person in 2009/10; an increase of 20 percent over 2001/2. According to the National Health Accounts (NHA), private expenditures on health have remained at about Kshs 45 billion in 2009/10; out of which 80.5 per cent was out-of-pocket expenditures.[4]

Table 8. Trends in Health Expenditure (Kshs) 2001/02; 2005/05; and 2009/10

Indicators		2001/02	2005/06	2009/10
Total population - million		31.2	35.6	38.6
Total real GDP Kshs billion		1,118.8	1,519.4	2,273.0
Total Government expenditure (Kshs billion)		211.5	401.5	761.8
Total Health Expenditure (Kshs billion)		57.1	70.8	122.9
THE per capita Kshs		1,831	1,987	3,203
THE per capita (US$)		23	27	42
THE as a % of nominal GDP		5.1%	4.8%	5.4%
Government health expenditure as a % of Government total expenditure		8.0%	5.2%	4.6%
Financing sources as a % of Total Health Expenditure	Public	29.6	29.3	28.8
	Private	54.0	39.3	36.7
	Household	51.1	35.9	30.0
	Donor	16.4	31.0	34.5
	Other	0.1	0.4	0.0
Source: MOMS & MOPHS: National Health Accounts, 2009/10				

The high out of pocket expenditure and dependency on donors especially on priority interventions has prompted the government to embark on the process of developing a health financing strategy. In the short term, NHIF will be restructured to play a bigger role in financing health.

Given inflation and the rapidly increasing gross domestic product, the proportion of public health expenditure has remained at about 8 per cent over the years. Kenya has not met the agreed 15 per cent as per the Abuja targets set by African countries to meet the Millennium Development Goals.

4 Ministries of Health, National health Accounts 2009/10

TB control through the public sector has traditionally been funded via supply-side financing structures, with a central budget allocated to provinces and districts based on a common strategic plan. As the country moves toward universal health care with a heavier reliance on demand-side financing, such as through national health insurance, the sustainable financing of TB control will require new approaches to planning for and supporting TB control activities. Many of the demand- side financing approaches being tested, such as HISP, can benefit local health workers and facilities. If TB is excluded, its control will be challenged by an understandable preference to identify and care for other types of patients.

There remains a large financing gap for the NTLD. The MTR estimated that over the next five years, approximately US$400 million will be required with nearly 50% remaining as unmet need. The funding gap for leprosy has not been carefully calculated.

Recommendations

Many of the recommendations in the Policy section above have financing implications. Additional recommendations include:

1. Regardless of funding modality, TB care must remain free for TB patients. In addition, the MTR recommends that diagnostic screening be made free for children and the poor.

2. MoH to identify ways to close the financing gap(s) for TB and leprosy, particularly considering how to utilize health insurance, social protection and conditional grants to subsidize the costs of care for poor TB patients.

3. Monitor TB expenditures and activities to ensure there are no gaps in programming as funding shifts to demand-side and performance-based modalities. To best inform the evolving health policies and financing modalities, and ensure that funding for TB continues to increase, the NTLD will need to:

    a) Track the NHA TB sub-account, through county budgets

    b) Conduct periodic TB expenditure tracking from treasury to facilities, including all sources of funding

DETAILED FINDINGS: COMMODITY SUPPLY & MANAGEMENT

Introduction

Since 2008, the Government of Kenya (GOK) has been allocating funds for procurement of TB medicines to complement donors' support in this area. Procurement of TB medicines under GOK and some donors' support is done through Kenya Medical Supplies Agency (KEMSA). A centralized procurement mechanism is currently being implemented using open international competitive bidding for all medicines, except for TB medicines supplied through the Global Drug Facility (GDF) where direct procurement method is used. Quantification of TB medicines is done annually by the NTP in collaboration with TB commodity security sub-committee followed by biannual reviews. The whole process from quantification, advertising for tender, submitting bids, bids evaluation, contract negotiation and signing to the time when TB medicines arrive in the country takes around 6-9 months.

Once procured, TB medicines are stored and distributed from the central KEMSA store. Distribution of TB commodities is done quarterly up to sub-county level where they are further distributed to health facilities. In principle, a pull system is supposed to be followed upon receiving consolidated TB stock status reports from sub-counties. Currently there are 210 sub-counties countrywide that each have 12-15 facilities under its catchment area.

To ensure that adequate quantities of TB medicines are maintained, NTP has set minimum- maximum stocks to be kept at each level; a Sub count level maximum stock level is 6 months and
minimum stock level is 3 months. Meanwhile health facilities are required to maintain a maximum of 3 months of stocks and a minimum of 1 month of stock.

Achievements

1. **High government and donor's commitment to support TB medicines procurement**: The GOK continues to fund for TB medicines procurement and the budget has increased annually from 1.2 M USD allocated in 2009 to 2,588,217.02 USD dedicated in 2013/2014. This indicates an increase of over 100% in a span of 5 years. Apart from GOK funding, Kenya has also been receiving financial support from several donors in closing the financial gap for procurement of TB medicine. These include Global Fund, UNITAID, World Bank and USAID. In addition, the country receives pediatric grant support from the Global Drug Facility (GDF) since 2008 and is now receiving 2nd Term 2nd year pediatric grant. Adult GDF grant support was received from 2002 and ended in 2010.

2. **There is an uninterrupted supply of most of first- and second-line TB medicines at the central level**. Great efforts have been made to ensure a stable supply of most of the TB medicines in the past 12 months. For example, availability of category I patients' kits currently used by almost 90% of all TB cases, medicines for re-treatment cases and second line TB medicines was assured even during this transition period when the country is experiencing a shortage of funds for TB medicines procurement.

3. **There is an Existence of TB logistic management system (LMIS)**: Integrated commodity recording and reporting tools are in place which include electronic and paper based monthly reporting forms for use at sub-county and health facility level respectively, facility dispensing register and stock cards or register.

4. **A Functional TB commodity security sub-committee is in place**: The committee provides an oversight role in the implementation of TB commodity management activities including monthly stock status monitoring, forecasting, and procurement planning.

5. **A Pharmacovigilance system exists**, ADR reporting tools are in place, and some HWs from TB treatment sites have been trained.

Key Challenges

1. Medicine Procurement and Stock Supply; Some TB medicines have a stock status of less than 3 months, resulting in potential stock-outs in the near future. This was reported to be due to the absence of funding at central level for procurement of TB medicines in 2013/2014, and limited awareness at County level that funding for commodities had been devolved. All TB funds were devolved to counties with limited guidance on how to use the money. Devolution occurred when the country had already submitted Procurement and Supply Management (PSM) Plan to Global Fund indicating only a 40% gap. There is limited availability of INH 100mg and INH 300mg in visited sites and a stock out at the central level. Stock of pediatric drugs are not well balanced, with some counties reporting stock outs while others were overstocked and with expiring supplies.

2. Reporting and Data Tools and Management; There are low reporting rates, use of outdated reporting tools, and inaccurate stock related reports; Although LMIS tools were revised, the updated tools were not available in all facilities, some facilities were still
using old tools (which do not capture all medicines) and some did not have the tools in place. 210 consolidated reports are expected at KEMSA every month based on the current existing number of sub counties. However, less than 50% of expected reports are being submitted and some of them are not accurate.

3. There are challenges related to pharmacovigilance system, including frequent occurrence of adverse drug reactions (ADRs) - especially those related to second line TB medicines - and limited capacity to monitor ADRs - particularly at the peripheral level. Under- reporting of ADRs results in the inability to quantify the magnitude of the problem, hence making it difficult to estimate the right quantity of ancillary medicines needed. In addition, follow up on the quality of products becomes a challenge.

4. There is inadequate data to support accurate quantification of INH, ancillary medicines, and second line medicines. Data on the actual number of cases enrolled under each regimen mix is currently not well captured. There is no system for tracking the proportion of patients experiencing adverse drug reactions (ADRs), and a limited availability of data on patients receiving IPT was also observed.

5. There is a lack of training on TB commodity management at all levels. Given devolution, the lack of capacity at County levels was most acutely detrimental to programme operations.

6. Distribution and storage; There is an inadequate distribution system, use of push systems, and untimely delivery of commodities. Despite the fact that a pull system is recommended for distribution of TB medicines, a push system is mostly used which was explained to be due to lack of data or inaccurate reports from health facilities. Untimely distribution of TB medicines was also observed. The storage conditions in some TB clinics and sub-county stores visited were inadequate and with insufficient space, complete absence of or inadequate shelving, and poorly controlled temperatures.

Recommendations

1. Develop and implement a high-level policy and plan for ensuring a stable national commodities supply for TB. The plan must enable the efficiency gains of pooled procurement and centralized quality control.

2. MoH needs to continue allocating funding for TB medicines and ensure emergency procurement to avoid treatment interruptions: Although MoH requested for supplementary budget from the Ministry of Finance, it is important to note that, even if the funds are to be made available by the GOK, the lead time will still be long in this critical shortage of medicines. Therefore, there is an urgent need to conduct emergency procurement of some TB medicines especially for re-treatment cases.

3. Build counties' capacity to quantify and consider pooled procurement system for TB commodities to ensure efficiency, economies of scale and quality products are procured.
4. Rationalize the quantification, distribution and stock management for pediatric formulations to ensure a stable and consistent supply across the country.

5. Ensure availability of Isoniazid both 100mg and 300mg tablets and scale up IPT.

6. Strengthen the existing TB Logistics Management Information System (LMIS) to facilitate better information flow and allow data driven decision-making. Print and distribute updated recording and reporting tools throughout the country and ensure their correct use. Conduct regular data quality audit; investigate and address factors causing under reporting; integrate stock related data validation into quarterly review meetings; build capacity of counties and promote stock related data aggregation, analysis and use at county level for timely decision making.

7. There is a need to build the capacity of counties to support TB commodity management issues. First by trainings newly appointed county pharmacists and TB and Leprosy Coordinators (CTLCs) and effectively engaging pharmacy staff at all levels in TB commodity management. Then, consider re-designing TB commodity distribution and reporting system and engage counties in data consolidation and reporting as a means towards improving counties oversight role to the sub counties.

8. Strengthen existing supportive supervision system and ensure TB commodities are well covered by standardizing TB commodity supervision packages for use by new governance structures-counties. This should include performance-monitoring indicators related to TB medicines' supply chain management and the NTLP should regularly collaborate with partners to support counties' to implement regular supportive supervision.

9. Improve storage infrastructure and capacity of counties/sub-counties to store and distribute within their catchment areas.

10. Consider tracking information on proportion of patients experiencing particular ADRs in the current electronic TIBU system and information on MDR TB patients enrolled under each regimen to guide future quantification process.

11. NTLP needs to strengthen collaboration with Pharmacy and Poison Board (PPB) to improve the pharmacovigilance System for TB. In addition, NTLP should consider scaling up pharmacovigilance trainings and explore possibilities of implementing other PPB initiatives such as active surveillance for selected TB medicines.

ANNEX 1 . TB EPIDEMIOLOGICAL & IMPACT ANALYSIS

ANNEX 2 . GEOGRAPHICAL TEAM

REPORTS FROM FIELD VISITS

ANNEX 3. MID - TERM REVIEW PARTICIPANTS & PERSONS MET

Team 1	Team 2	Team 3	Team 4	Team 5	Team 6	Team 7	Team 8	MoH HQ
1. Program management including commodity management	Programmatic Management of DRTB	4. TB/HIV and Childhood TB	6. DOTS expansion and enhancement(including community TB care, ACSM, intensive case finding and poverty)	Laboratory Management	Operation Research, TB Surveillance, HMIS and general M&E	5. Public Private Mix and Lung Health.	Leprosy Control.	Overall programme management and Financing
Uasin Gishu Vihiga	Garissa Refugee camp	Kisumu Nyamira	Meru Isiolo	Kiambu NTRL/Culture labs	Kitui Machakos	Nairobi Narok	Kwale Tana River	Nairobi
Salama Mwatawala Samson Kefas	Dr Norbert Ndjeka	Dr Eric Pevzner Dr Farhana Amanullah	Dr Sanni Babatunde Mr. Kenneth Musis	Sushil Pandey Dr Ajay Kumar Thurimala	Nico Kalisvaat Evelyn Klinkenberg	Dr Robert Makombe	Dr Joseph Chukwu	Christy Hanson
Prof Obimbo Maurice Maina Margaret Mungai	Tome Julius Dr Charles Njuguna Ronald Ngiela	Dr Amukoye Maureen Syowai Peter Njuguna	Dr Kevin Cain Samuel Kinyanjui	Prof Mutilu Dr. Abraham Katana Jesse Wambu	Frida Njogu Dr Jane Ongango	Hillary Kipruto Brenda Mungai Damaris Miriti	Joel Kangangi Duke Mobegi Beatrice Kirubi	
Jackson Kioko David Mugambi Jane Onteri	Kamene Maureen Rose Wambu Gloria Kaari Jeremiah Okari	Mary Osano Aiban Ronoh Margaret Njeri Kigen Moses	Misoi Samuel Faith Ngari Ann Makenga Mutisya John	Susan Gacheri Margaret Ndisha James Gachengo	Enos Masini Newton Omale Obadiah Njuguna	Immaculate Kathure Wesley Tomno Richard Muthoka	Sekento James Nduta Waweru	Jackson Kioko Bernard Langat Silas Kamuren
Evelyn Kibuchi Dr Mugo	Lucy Ngati	Jacinta Muthengi	Bwana Dickens	Julian Ongonge	Grace Gitonga	Sammy Ariithi	Chakaya Jeremiah	
John Kembe Heather Njuguna	Joseph Sitienei Francis Muu	Micah Anyona Mamo Umuro	Josephine Wahogo Christine Awour	Dorcas Kiptui Irene Mukui	Ruth Kitetu Mr Kisoo	Elikana Onguti		
Dr Agere Ego Pamela Juma	Joseph Njinju Elizabeth (Bureti)	Omondi John Beatrice Kariuki	Franklin Mwenda Mary Wambura	Elizabeth Mueni Joseph Biwott	Sammy Rop Bernard Sande	Eunice Kiilu Samuel Ogweno	Amukanga Jack Obiero	

LIST OF PERSONS MET DURING THE MIDTERM REVIEW TEAM 5

NO.	Name	Station	Designation	Sex	Telephone	Email
1	Michael N Thuita	Thika Level 5 Hospital	County Coordinator .	M	0722704700	thuita.ndegwa@gmail.com
2	Christopher M Kimaru	Head-laboratory		M	0722885837	kimaruchristopher@yahoo.com
3	James M Mwangi	Sub county Tb and Leprosy	Coordinator	M	0724892832	mwangijames@yahoo.com
4	Rosalind Murugami	Chief Nursing Officer		F	0720006969	rosamurugami@yahoo.com
5	Dr Stephen N Waiguru	County Health Director		M	0721276644	snjuguna200@gmail.com
6	Lucy Gatakaa Miriti	Nurse		F	0723546793	lucygmn@yahoo.com
7	George Kimotho Muchori	Clinical Officer		M	0721814724	
8	Kennedy Mbogo Wanjiku	Medical Lab Technologist		M	0720504819	mbogo.kennedy@yahoo.com
9	Judith Wanjohi	Pharmacist		F	0717898150	nyawesly@yahoo.com
10	Emma Kagunya	Pharmacist		F	7237710107	kiggemma@yahoo.com
11	Elizabeth Macheche	Nursing Officer		F	0721412071	machechew@yahoo.com
12	David Nduati	Lab Manager		M	0722662894	nduati250@yahoo.com
14	Dr L Kimuhu	County Pharmacist		F	0720800531	liiynjeri@live.co.uk
15	Joseph Nganaga			M	0720267178	
16	Caroline Njeri	St Mulumba Hospital	HTC Nurse	F	0721440667	

NO.	Name	Ruiru District Hospital	Designation	Sex	Telephone	Email
1	Dr Ngugu Jesse	District Medical officer		M	0721267702	ngugi200@yahoo.com
2	Nancy W. Ndungu	Nursing officer		F	0720895793	nancyndungu@yahoo.com
3	Michael N Thuita	CTLC		M	0722704710	thuita.ndegwa@yahoo.com
4	Paul Gakuha Ndungu	Health Adminstrative officer		M	0722641242	pgakuha@yahoo.com
5	Dr Tabitha Kimani	Senior pharmacist		F	0720006086	tabikim@yahoo.com
6	Mercy Muchina	SCPHN		F	0722314781	mercymuchina@yahoo.com
7	Purity Kanini Muchiri	Nursing officer		F	0722330491	purimuchiri@gmail.com
8	Rachel Wachu Mwangi	Nursing officer		F	0721423776	rachel.wachu@yahoo.com
9	Shem Gichohi Kibe	Medical Lab Technologist		M	0713564228	shemtibe88@gmail.com
10	Samwel Gishimu Mureithi	Senior Public health Officer		M	0721774439	muresagvotiive@yahoo.com
11	Polycarp Kariuki Chandi	Ruiru District Hospital	STLC	M	0722770513	polycarpchandi@yahoo.com

NO.	Name	UTHIRU /WANGIGE	Designation	Sex	Telephone	Email
1	Hellen Mburia	Wangige Hospital	Nursing Officer	F	0722535736	kwammburia@gmail.com
2	Dorcas Mwangi	Clinical Officer		F	0724246890	dorcymwangi@yahoo.com
3	Susan itugi	Nursing Officer		F	0716222160	sussy@yahoo.com
4	Charles Koigi	Public Health officer		M	0721453483	Koigi.charles @yahoo.com
5	Zacharia Njoroge Njogu	Patient		M	0714451283	
6	Alison K. Mburia	HPO		M	0722736642	allyssonkagami@gmail.com
7	Dr Nasri Mohamed	Medical Officer		F		
6	Esther W Nganga	CHW		F	0720735660	
7	Rachel W Njau	Nursing Officer		F	0722971129	njaurachel963@yahoo.com
8	Amos Mwangi	Tigoni Hospital	Medical Lab Technology	M		
9	Loice Kitungi UTHIRU DISPENSARY	Public Health officer		M	0722377796	loisemutua@yahoo.com
10	Magdalene W Kamau	SCTLC		F	0724166124	magdawkamau@gmail.com
11	Eunice Wambui Njoroge	Nursing Officer		F	0072132875	
12	Mary Nungari	CHW/HTC		F	0725672062	marykwalero@gmail.com
13	Michael Thuita	CTLC		M		Thuita.ndegwa@yahoo.com

NO.	Name	KARURIRHDC	Designation		Sex	Telephone	Email
1	Richard Munene	Clinical Officer i/c Karuri	RHDC	M	0723724558		richardndiritu@gmail.com
2	Rahab Waweru		Nurse	F	0726448308		waweruraheb@yahoo.com
3	Damaris Ndegwa		STLC	F	0726304397		damarisndegwa44@gmail.com
4	Niceta Njagi		Nurse	F	0722704710		nicetawangari@yahoo.com
5	Lucy W Tamoo		Lab. Technologist	F	0722364993		tamoolucy@gmail.com
6	Moses W Muiruri		Lab. Technologist	M	0726201901		moseswanyoike@gmail.com
7	Michael N Thuita		County CTLC	M	0722704710		thuita.ndegwa@gmail.com
8	Meshack Mbuyi	SACODEP	CHW	M	0725023112		mbuyimeshack@gmail.com
9	Peter G Wanyiri		CHW	M	0716198353		peterwanyiri@gmail.com
10	Julia Amayo		CHW	M	0722764421		juliaamayo@gmail.com
11	ViVian OUKO		CHW	F	0712321221		ovyananca@gmail.com
12	Alice Ngesa		CHW	F	0725998497		ngesa.alice@gmail.com
13	Phillip Omoti SACODEP		CHW	M	7511262271		argiayona@gmail.com
1	Ronald M Atambo	NTR Laboratories	MLT	M	0720581795		ronaldatambo@yahoo.com
2	Aricha Stephen		MLT	M	0725200312		arichasteve@yahoo.com
3	Judy Migwi		MLT	F	0720978989		judyjoob2006@yahoo.com
4	Mary Wanjiru Mbugua		MLT	F	0721687045		marywanjiru57@gmail.com
5	Jeniffer Wanjiku		MLT	F	0721687045		jnjeggu@gmail.com
6	Catherine W Githinji		MLT	M	0722298006		camagi65@gmail.com
7	Fredrick Shikami		MLT	M	0724130624		mikashindifre@yahoo.com
8	Zipporah Mwongera		MLT	F	0721270931		zmwongera@yahoo.com
9	Margaret W Wanyeki		MLT	F	0721884194		mwanyeki@yahoo.com
10	Solomon C Bundi		MLT	M	0723356803		leobully@yahoo.com
11	Atanus Mungai		SS	M	0712849128		amungai@nltp.co.ke
12	Elizabeth Wangui		MLT	F	0720728900		egikanju@nltp.co.ke
13	Nancy Cherop	NTR Laboratories	Data Clerk	F	0727089364		cheroptele09@yahoo.com

ANNEX 4 . QUESTIONNAIRES USED FOR FIELD VISITS

ANNEX 5 . PRESENTATION SLIDES FROM DEBREIFING SESSIONS

KNH Grounds,Nascop Building,Upper Hill,Nairobi
P.O. Box 20871 - 00202 Nairobi
info@nltp.co.ke
http://www.nltp.co.ke

The National Tuberculosis, Leprosy and Lung Disease Unit:
ISO 9001:2008