POST-2015 CONSENSUS

Post-2015 Development Agenda

Kenya Perspectives

Tuberculosis

SPEAKERS

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Anna Vassall is Senior Lecturer in Health Economics at the London School of Hygiene and Tropical Medicine. She is a health economist with around twenty year of experience in economic analysis. Her first degree is in economics. She then worked in the NHS supporting funding/contracting. She then took an MSc in Health Planning and Financing at the LSHTM, thereafter working for DFID as a health economist in the UK and Pakistan. This was followed by a period at Royal Tropical Institute (KIT) Amsterdam working on health planning and financing, aid effectiveness and the cost-effectiveness of tuberculosis and reproductive health in a wide range of low and middle income countries. Thereafter she directed and provided economic support to European Community and World Bank funded health sector reform and development projects in Yemen, East Timor, Syria and Sudan. Her PhD is in the economic evaluation of tuberculosis control. She has worked as an academic since 2010 (at LSHTM) specializing in research into the economics of HIV and TB, with a particular focus on health services and systems. Her current research interest is the costs and economic evaluation of HIV, TB and Sexual Reproductive Health. She has a keen interest in 'real world' evaluation methods and incorporating a broader health systems perspective in economic analysis. She has also published on health services financing, in particular the role of development assistance finance

Table of Contents

Summary: White Paper Report by Anna Vassall

Tuberculosis (TB) is a serious public health issue in Kenya. About 120,000 people a year develop TB (48,000 of them being HIV-positive) and 18,600 people die from it. It is the fourth largest cause of death, being responsible for about 6% of all deaths. Nearly two people an hour die from TB, despite effective treatments being available.

All this is despite considerable progress having been made. Kenya was the first African country to achieve World Health Organization (WHO) targets for detecting and treating cases. Numbers of cases reported has reduced, while mortality has hardly changed, although fewer deaths are from those also living with HIV (down from 15,000 in 2004 to 9,500 in 2013).

The current situation can be dramatically improved. The target proposed is a 90% reduction in TB deaths and an 80% reduction in new cases by 2030, while ensuring that no family is burdened with catastrophic expenses. In Kenya, that could be achieved by spending about 6.7 billion shillings ($71 million) a year to increase detection rates, strengthen primary health care provision and treat more patients.

This sounds a lot, but it would give each TB patient on average about another 31 years of life. Also, treating one patient should prevent at least one more case developing, so overall this annual investment would produce about 330,000 additional years of life for Kenyans.

Even valuing a year of life at just 95,000 shillings ($1,000), the low end of the range, means that each shilling spent gives benefits worth at least 5 shillings, as well as saving lives. If a year of life is valued at $5,000 (475,000 shillings) then the benefits are at least 26 shillings for each one invested.

People are first latently infected with TB. 5% going on to develop active TB within eighteen months and the same percentage at risk of developing TB later in life. The risk of developing active TB is significantly increased following HIV infection – and therefore TB is strongly associated with HIV.

Most cases are drug-sensitive and respond well to standard treatment with a combination of drugs, but failure to complete a proper course of treatment encourages the development of multi-drug resistant TB (MDR-TB), which is difficult and costly to treat and has poorer outcomes. Around 2.6% of all cases of TB in Kenya are multi-drug resistant.

But diagnosis is quite complex, since many symptoms are similar to those for other common diseases, and treatment takes several months. In the meantime, loss of earnings for the sufferer may drive families into poverty, multiplying the burden of the disease.

Diagnosis using a microscope to screen sputum samples is cheap and the most common method used. However, it may miss substantial numbers of sufferers and there are new tests (Xpert) that may can improve detection rates and find cases of drug-resistant infection. However, these tests are more expensive. Detection rate in Kenya is about 75%, which is good but must be improved further to meet the targets. Treatment of most cases takes six months and, in Kenya, the adherence rate is good, which contributes to the 86% cure rate.

HIV infection is a key driver of TB development and so a main focus of control efforts. About 1.6 million Kenyans are living with HIV, which increases the risk of developing and dying from TB. Over 93% of TB sufferers are tested for HIV and 83% given anti-retroviral treatment. HIV sufferers with latent TB can be given preventative therapy to avoid the disease developing, but by April 2014 only 6,000 out of half a million eligible people were receiving this treatment.

There are other aspects to an effective programme. Poverty can prevent people seeking treatment, since the overall cost of an episode of TB care, including lost earnings, is over 33,000 shillings on average. Poor nutrition can reduce chances of a cure. Both issues need to be addressed. Community healthcare provision also needs to be strengthened to improve counselling and increase adherence to treatment.

Overall, although TB control is not expensive in comparison to other healthcare investments and despite the clear economic justification for increased efforts, the National Leprosy, Tuberculosis and Lung Disease Programme estimates that only 40% of control needs are currently funded.

Tuberculosis remains a serious public health issue in Kenya, despite good progress in recent years. According to the World Health Organisation (WHO) around 120,000 persons developed TB in 2013, (of these around 48,000 were living with HIV) [1]. Around 19,000 people die from TB in Kenya every year. Tuberculosis accounts for just over 6% of the total deaths in Kenya annually, and TB is Kenya's fourth largest cause of death. Hence, every hour, almost two people die of TB in Kenya, despite effective treatment being available.

Kenya has made considerable progress towards controlling TB. Commendably, within Africa, Kenya was the first country to achieve World Health Organization (WHO) targets for case detection and treatment success for TB; reflecting a long-standing historical commitment to tackling this deadly disease. Incidence and case notification have been declining since 2005. Case notification has reduced from a high of 116723 in 2007 to 89170 in 2013. Mortality has remained more static, aside from some reductions in those persons also living with HIV, where deaths have reduced from 15000 in 2004 to around 9,500 in 2013.

The economic case for sustaining this strong commitment and investment in TB control in Kenya is compelling. Put simply, TB treatment is low cost and effective, and this combination results in substantial economic return. Moreover, the delivery of high quality TB services can also prevent the spread of the disease to others and slow the emergence of multidrug- resistant TB (MDR-TB), a dangerous and costly form of TB. Investment in TB is also important from a poverty reduction perspective, where the costs of accessing treatment, nutritional decline and loss of earnings may force those with TB into poverty.

This short report presents the economic case for maintaining investment in TB control post 2015 in Kenya. The report first provides an overview of the targets for TB, the disease and the main TB control interventions. It then outlines the costs and benefits of investment the different TB control interventions in Kenya; arguing that TB control should be a priority investment in Kenya's post 2015 development agenda.

Our starting point for this presentation is the global post 2015 strategy, supported by the World Health Assembly. This declaration aims to end the global TB epidemic, with targets to reduce TB deaths by 90% and new TB cases by 80% by 2030, while ensuring no family is burdened with catastrophic expenses due to the disease.

TB control: what can be done?

In simple terms the disease of TB has two stages. The first is *latent TB* infection, when a person first becomes infected with TB. Of those infected, approximately 5% develop *active TB* disease (become TB cases) within 18 months, followed by a further 5% risk of developing active TB disease over a lifetime. Left untreated, active TB can be fatal. Active TB can be broadly divided into two types: TB which is drug- sensitive – responding well to a standard combination first line treatment; and, multi-drug resistant TB (MDR-TB) which is resistant to

two or more drugs in the first line standard TB regimen. The treatment of MDR-TB has poor outcomes, is complex and can be costly [2-4]. While MDR-TB can be spread and circulated among populations, its origins lie in the misuse, poor delivery and adherence of TB treatment [5]. In Kenya around 2.6% of all TB cases have MDR-TB.

The National Leprosy, Tuberculosis and Lung Disease Programme (NLTD) in Kenya is long standing; and has developed three national plans during its existence; the last of which outlines the strategy for TB control for 2015-2018. This strategy highlights a range of investments that may substantial progress Kenya towards the post-2015 targets [6].

A key driver of TB in Kenya is HIV and hence is a primary focus for further TB control improvement [7]. According to the UNAIDS Global Report 2013, Kenya is ranked 4th in the world in terms of HIV prevalence, with an estimated 1,600,000 people living with HIV in the country. Unfortunately, the risk of developing active TB increases substantially following HIV infection [8]. HIV also substantially increases the risk of mortality from TB. However, the presentation of TB in those living with HIV is atypical, meaning that TB in those living with HIV can be difficult to diagnose [7]. Kenya has been a leader in rolling out TB/HIV collaborative activities to address these multiple challenges. In 2013, over 93% of patients with TB disease were tested for HIV and around 83% started on anti-retroviral therapy (ART) for HIV. However much more needs to be done if the post-2015 targets are to be reached.

For those with latent TB, who are co-infected with HIV, the WHO therefore recommends the use of preventative therapy to reduce the risk of developing active TB. The optimal treatment regimen for latent TB is still being evaluated, but currently the WHO recommends a 6-9 months treatment of one TB drug (isoniazid) [9]. Alternative or complementary strategies for some population groups are 36 months to lifelong treatment for persons living with HIV [10], or shorter course combined therapies (for example a 3 month combination of two TB drugs isoniazid and rifapentine [11]). Preventative therapy is a relatively low-cost intervention, which can be delivered alongside HIV treatment. Yet, by the end of April 2014, despite over half a million persons living with HIV being eligible for preventative therapy for TB in Kenya, just under 6,000 persons received preventative therapy for HIV, according to the national TB health information system[6].

Identifying those who develop active TB is complex. The symptoms of (active) pulmonary TB include cough, fever, night sweats and weight loss, many of which are similar to symptoms of common diseases. However, ensuring early detection of active TB cases is fundamental to reducing transmission. As with most TB programmes, Kenya relies primarily on 'passive case finding' to identify cases of active TB. This strategy is based on the expectation that those with TB symptoms will present at health services for their symptoms, and that health facilities and staff are sufficiently equipped and skilled to recognise and act on them. Kenya

has a good rate of case detection at around 75% of all cases, but nevertheless this needs to be further improved if deaths from TB are to continue to be reduced. As with other settings, delays in seeking care for TB can be as long as 2-3 months in Kenya. A recent study found that being knowledgeable about TB, distance to clinic and where help is sought first have a significant effect on patient delay [12]. Addressing some of these barriers (particularly financial and geographical barriers) may therefore help improve TB case detection. In addition, further improvements may be required to ensure that all those persons living with HIV, and other risk groups, such as those with diabetes, are regularly screened for TB, as they receive HIV care. Finally, Kenya may need to further expand its co-operation with the private sector, to ensure that those who seek care there first are diagnosed correctly [13].

The most common method of diagnosis of TB is smear microscopy. This is recommended by the WHO and is widely used In Kenya, as a low cost method of TB diagnosis. Those who have positive smear test, are described as having 'smear positive' TB, and are the most infectious of TB patients. However, microscopy is far from a perfect test, and may miss substantial numbers of those with active TB [14, 15]. This is a particular issue for those also infected with HIV. While X-ray and other methods can help, they are often not regularly performed to a high quality [16]. Since 2011, the WHO therefore recommends the Xpert MTB/RIF assay for widespread use in the diagnosis of TB. Xpert MTB/RIF increases chances that a case of TB can be diagnosed [17], however the cost per test is considerably higher than that of smear microscopy [18]. However, despite its high cost, Xpert has been found to be potentially cost-effective across a number of sub-Saharan settings [19], and there are few other options for those with HIV.

The treatment of drug susceptible TB involves delivering a standard regimen of TB treatment usually for six months, divided into two phases; an intensive phase for two months and a four month continuation phase. During both phases treatment must be adhered to maximise treatment success and prevent drug resistance developing. In the last twenty years the WHO has recommended the Directly Observed Treatment Strategy (DOTS). Kenya has a very high coverage of DOTS. With this good treatment monitoring, and high adherence, TB treatment is very successful, with over an 86% cure rate in Kenya [1]. Nevertheless there are still some improvements to be made, particularly around reducing treatment default. A recent study found that while of those with poor treatment outcomes, 64% defaulted, 32% died, and 4% failed treatment. HIV was also associated with poor treatment outcomes. The authors conclude that increased efforts to ensure patient retention during treatment, especially in persons living with HIV, are needed to reduce poor treatment outcomes in Kenya [20].

A recent study examining treatment adherence in Kenya found that many factors influenced default from treatment including poor information, low income and HIV status. Enhanced patient pre-treatment counselling and education about TB were therefore recommended by the study authors [21]. Moreover, In Kenya, defaulter tracing should occur, but in practice may not be carried out regularly. The NLTP also

has a policy that encourages utilisation of community health workers to supervise TB treatment [34], however in practice, although pilots have been promising, this approach has proved to be unsustainable at scale [22]. More work therefore has to be done to ensure systematic linkages between providers of community based care and health facilities; and additional support for community care providers to deliver quality TB care.

MDR-TB provides additional challenges; and will be an important area for investment going forward if deaths rates are to be further reduced. Microscopy cannot identify new drug- resistant TB, but Xpert MTB/RIF can identify cases of rifampcin-resistant TB, a strong indication that a patient has MDR-TB. Culture based tests also are used to diagnose MDR-TB. However, cultures required substantial laboratory infrastructure and even very short gaps in between the patient going to be tested for TB and receiving the test result can lead to high levels of default during the diagnostic process [23]. Unfortunately, the treatment of MDR-TB is also far more complex than first-line treatment and still requires some hospitalisation. It can take 24 months or longer. Ensuring good access to drugs in essential, including regimens that can treat more extensively resistant forms of TB. Moreover the, the laboratory needs to support both the diagnosis and appropriate treatment of MDR-TB can be complex and costly. These multiple challenges, and the expense of treatment, mean that treatment coverage of MDR-TB is low, with less than 10% of those with MDR-TB initiated on treatment [24]. Once started on treatment, MDR-TB treatment success is around 70% relatively high compared with many other low and middle income countries.

Finally, the social determinants of TB cannot be overlooked in Kenya. Poverty is key to care seeking behaviour and treatment default. Moreover, poor nutrition can substantially worsen treatment outcomes. The World Bank estimates that Kenya's poverty rate in 2013 was between 34% and 42% [6]. TB and its treatment can still cause poor households substantial economic loss, primarily from loss of earnings while feeling unwell, thus further exacerbating this cycle of poverty. A recent study found at that the average cost of a complete episode of TB care to be around in Kenya to be over US$350 (over 33,000 shillings) [25]. Hence improved social and nutritional support to those with TB and their families may also be a key intervention to further improve TB control in Kenya.

In summary, the short report above highlights the fact that strengthening TB control to achieve the post-2015 targets requires continued sustained investment in TB services, particularly those living with HIV in Kenya – if deaths from TB are to be further reduced. Particular attention needs to be given to diagnosing TB in those living with HIV and expanding the treatment of MDR-TB cases. Strengthening diagnosis capability also requires continued support to laboratories and all the systems that support them, including systems to transport samples and quality control services. For treatment, ensuring a high quality of adherence support remains essential, and the treatment of MDR-TB may require some additional infrastructure investment. Social and nutritional support may also prove important in improving both diagnostic and treatment success.

Programmatic, management and information support to all these services need to have the capacity to enable and support these investments; and ensure that funding flows and is spent in an efficient manner.

Costs and Benefits of reaching TB control targets in Kenya

Despite the fact that considerable effort needs to be made, TB control has high economic returns for every Shilling invested. There are limited number of studies that examine the cost-effectiveness of TB prevention, diagnosis and treatment from Kenya; and these are mostly focussed on diagnostics and conducted around a decade ago [26]. We therefore estimate the cost of TB services using the WHO TB Planning and Budgeting Tool and information from more recent studies on current treatment practices. Using this approach, we estimate that it costs around US$190 (around 18,000 shillings) to treat a case of drug susceptible TB in Kenya. We add 50% to reflect the potential cost of additional health systems strengthening and programme support. We estimate the costs of MDR-TB treatment in Kenya to be around US$4500, based on reported expenditures from the WHO, and an assumption of six months initial hospitalisation. We also add a cost of US$30 to screen and provide IPT to those living with HIV. We also add a 50% mark-up to both these costs to reflect additional programme support.

To reach the global TB target by 2030 of reducing deaths from TB from the current 18,600 to under 2000 deaths per year will require a substantial effort, with high levels of detection and diagnosis in particular to ensure that those with HIV access treatment in a timely manner. We therefore estimate the annual total cost of the TB control programme required to reach the targets to be around US$71 million (6.745 billion shillings). This is US$ 49 million (4.628 billion shillings) above TB programme funding in 2013 that was around US$23 million (2.185 billion shillings). This leaves a considerable funding gap, but is broadly in line with the NTLDs estimate of the funding gap of US$200 million over the next five years [6].

This investment will give anyone in Kenya who would otherwise have died from TB around 31 additional years of life on average, based on the fact that the average age to contract TB in Kenya is around 30 years, and the life expectancy in Kenya is currently around 61 years. Finally, treating TB does not just benefit the patient, but also prevents transmission, conservatively reaching and treating one person with TB, will prevent at least one more case of TB. In total, if scaled up to levels to achieve the TB targets the TB programme in Kenya will produce around 330,000 additional years of life for the annual investment described above.

We value the life years saved using the Copenhagen Consensus recommended methods from of using an economic value of US$1000 (95,000 Shilling) and US$5000 (475,000 Shillings). Applying this value to life years saved describe above, we find (see table below) that the economic return per Shilling spent ranges from around 5.3 to over 33.6, making TB control a sound economic investment post -2015.

		Benefits (Shillings millions)				Benefit for Every Shilling Spent			
		3%		5%		3%		5%	
Target	Costs (Shillings millions)	YLL L	YLL H	DALY L	DALY H	DALY L	DALY H	DALY L	DALY H
Reduce TB deaths by 90%	4,628	31,171	155,853	24,447	122,234	**$6.7**	**$33.6**	**$5.3**	**$26.4**

We conclude that the economic case for TB control in Kenya is strong. TB control continues to be chronically under-funded in Kenya, yet the costs of addressing TB are not substantial compared to other development and health investments. Moreover, the NTLD has proven itself capable of running a successful TB programme. The economic case for strengthening the health systems and services to support TB control presented here is therefore one of the most convincing in the area of public health today – and TB control should be a core part of the post-2015 development effort in Kenya. Nevertheless, financing this effort will take considerable political will - given that the NTLD estimates that only 40% of current TB control needs are currently being funded [1].