

# TB AND HIV

## CONCEPT NOTE

Investing for impact against tuberculosis and HIV

SUMMARY INFORMATION			
Applicant Information			
Country	MALAWI		
Funding Request Start Date	1 <sup>ST</sup> JULY 2015	Funding Request End Date	31 <sup>ST</sup> DEC 2017
Principal Recipient(s)	1. MINISTRY OF HEALTH. 2. ACTIONAID		
If the programs are to be managed as separate grants:			
Funding Request Start Date for HIV	N/A	Funding Request End Date for HIV	N/A
Principal Recipient(s) for HIV	N/A		
Funding Request Start Date for TB	N/A	Funding Request End Date for TB	N/A
Principal Recipient(s) for TB	N/A		

## SECTION 1: COUNTRY CONTEXT

Malawi, like most countries in Southern Africa, has a high burden of both TB and HIV resulting in an overstretched health system. As a response to the dual TB/HIV epidemic, integration was introduced in 2008 with the development of a TB and HIV implementation framework and associated guidelines to assist effective implementation of integrated TB/HIV services.<sup>1</sup> TB and HIV services are available all over the country, in most cases within the same health facility. In 2013, 92% of the notified TB cases knew their HIV status. Of those with known HIV test result, 56% of them were co-infected with HIV. Likewise, 98% of people living with HIV (PLHIV) attending ART clinics get screened for TB. This joint TB/HIV concept note aims at addressing prioritized gaps based on current evidence and updated National Strategic Plans (NSPs) of the two diseases.

### 1.1 Country Disease, Health Systems and Community Systems Context

#### 1.1.a Current and evolving trends of TB and HIV

##### HIV Prevalence

Malawi continues to experience a serious generalized HIV epidemic affecting all sectors of society. The first HIV infection was diagnosed from stored blood samples collected in 1982<sup>2</sup> and the first AIDS case was documented in 1985. HIV prevalence among adults (15–49) increased sharply in the 1990s, reaching a peak at 16.4% in 1999 and has declined steadily since then, reaching 12.0% in 2004 and 10.6% in 2010.<sup>3</sup> Latest epidemiological models indicate a prevalence of 10.3% among adults (15–49 years) in 2013.<sup>4</sup>

HIV prevalence varies considerably by gender, age, socio-economic characteristics, and geographic location. Based on 2010 MDHS data, HIV prevalence in the 15–49 age group is higher among women (13%) than men (9%). The largest disparity is in the 15–19 year age group (3.7% in women and 0.4% in men). There is feminization of the epidemic in Malawi where 58% of PLHIV are female. *HIV prevalence is highest amongst females* 15 to 19 years (female 4.2% and male 1.3%); 20 to 24 years (female 6.4% and male 2.8%); 25 to 29 years (female 13.5% male 6.9%); 30 to 34 (female 20.7% and male 10.8%); 35 to 39 years (female 23.8%, male 18.1%); 40 to 44 years (female 20.4%, male 20.9%) and 45 to 49 years (female 16.1%, male 14.9%). However, the decline in prevalence has been offset by the rapid population growth in Malawi, resulting in a fairly stable number of PLHIV, moving from 1.1 million in 1999 to 1.0 million in 2013.<sup>5</sup> The stable HIV population size is a result of a concurrent decline of new infections and AIDS deaths due to the rapid ART scale-up: by June 2014 half of the HIV population was on ART.<sup>6</sup>

##### Geographic Variation

Figure 1 shows the geographical distribution of HIV prevalence, which broadly follows the distribution of population density. This leads to a considerable concentration of PLHIV in the south and in a few urban centres in the north and central regions. In 2013, over 50% of the 1 million PLHIV were living in six of Malawi's 28 districts, which account together for 42% of the country's population (all six are in the south). Urban/rural differences in HIV prevalence are much more pronounced in the northern and central regions, while rural HIV prevalence is similar to urban prevalence in the southern region.

<sup>1</sup> Ministry of Health, TB/HIV framework, 2012

<sup>2</sup> Glynn JR, Ponnighaus J, Crampin AC, et al. The development of the HIV epidemic in Karonga District, Malawi. *Aids* 2001;15(15):2025–9.

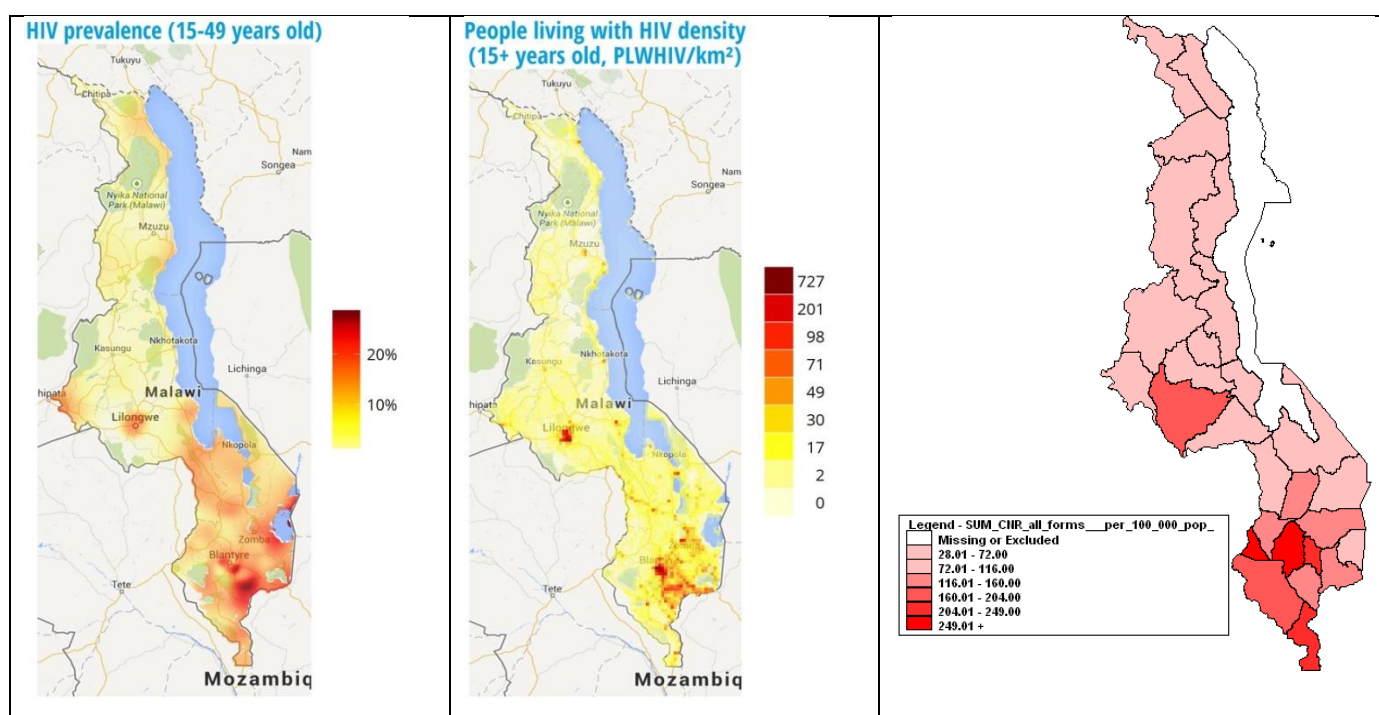
<sup>3</sup> National Statistical Office (NSO) and ICF Macro. 2011. *Malawi Demographic and Health Survey 2010*. Zomba, Malawi, and Calverton, Maryland, USA: NSO and ICF Macro.

<sup>4</sup> Malawi Prevention Response and Modes of Transmission Analysis: Distribution of new HIV infections in Malawi for 2013: *Recommendations for prevention strategies*.

<sup>5</sup> UNAIDS. The GAP Report. Geneva, 2014.

<sup>6</sup> Integrated Quarterly HIV Program Report April–June 2014 (MoH).

Figure 1: Geographical distribution of HIV based on geospatial modelling of 2010 MDHS data (UNAIDS) and of TB notification rates (2013 TB Program data)



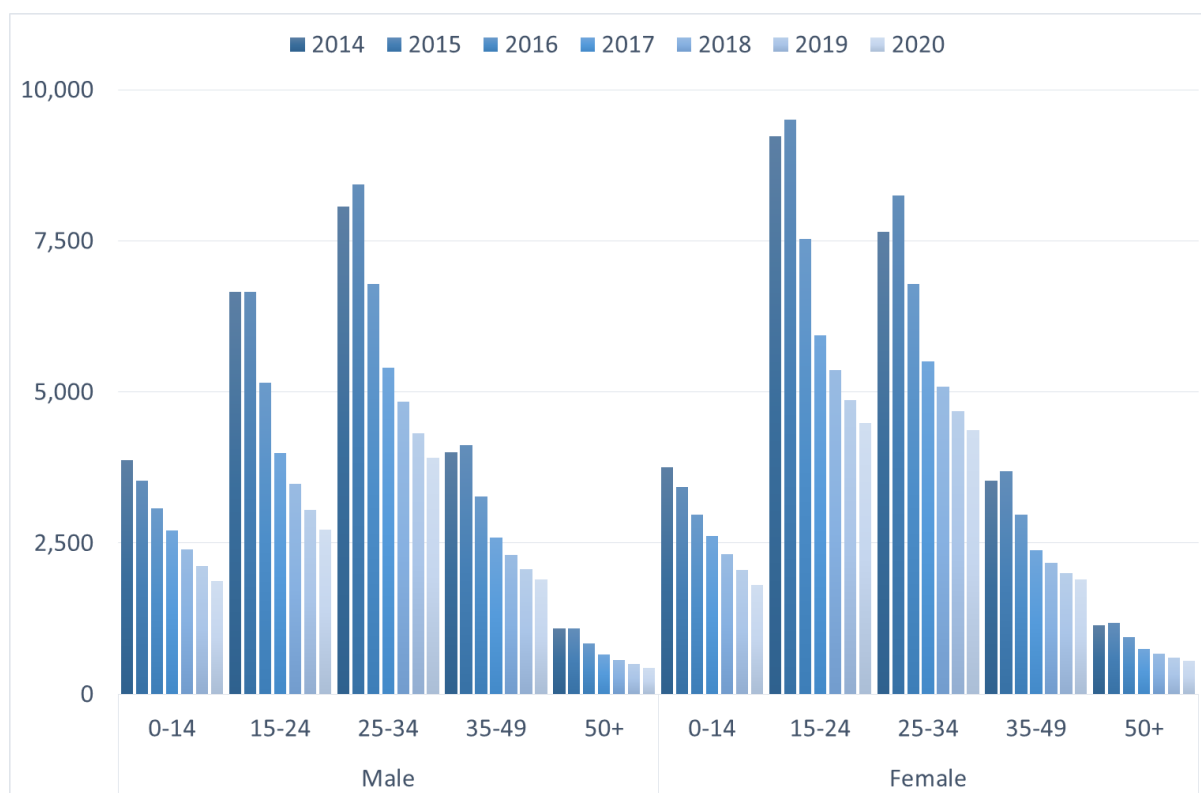
## HIV Incidence

In the absence of direct incidence measurements at the national level, incidence is estimated from epidemiological models (Spectrum) based on prevalence trends measured in ANC or population surveys. The most recent such estimates suggest a national average HIV incidence of 0.41 per 100 person-years among adults (15–49).<sup>7</sup> This implies a decline of 45% from 0.74 at the start of the current HIV prevention strategy in 2009. However, the most significant decline in new HIV infections started in the late 1990s, before the scale up of prevention interventions. Incidence peaked at 2.2 per 100 adults in 1999 and was estimated at 1.4 per year at the beginning of the ART program in 2004. This early decline follows the natural course of the epidemic and was probably also driven by a reduction of risky sexual behaviour as the population became aware of HIV as the cause for the massive death wave with over 90,000 deaths in 2004.

Figure 2 shows the projected decline in the number of new HIV infections by age and gender between 2014 and 2020, assuming continued ART scale-up reaching the 90-90-90 treatment goals by 2020. In 2014, 52% of all new infections were estimated to be among females and 36% of these were adolescent/young women (15-24 years). The absolute number of new infections among adults between 25-34 years is thought to be similar for men and women. This is the peak age group for new infections among males. The most significant absolute decline in new HIV infections is projected to occur in the most affected age groups in 2014/2015.

<sup>7</sup> Joint United Nations Program on HIV/AIDS (UNAIDS) Malawi, May 2014 HIV estimates.

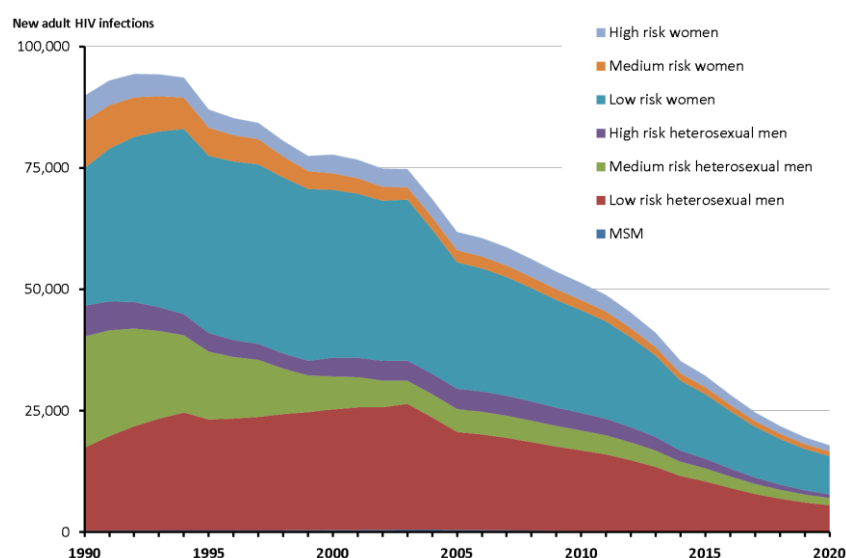
Figure 2: Projected number of new HIV infections by age and gender 2014 - 2020 (Spectrum / AIM)



### Factors Influencing HIV Transmission

The distribution of HIV incidence by risk group is shown in Figure 3 (estimates from the 2014 Goals model). The model assumes continued ART scale-up to cover 81% of all PLHIV by 2020, leading to a dramatic and sustained reduction in new HIV infections among adults.

Figure 3: Goals Model estimates for the number of new HIV infections among adults (15-49 years) by sex and risk category (1990-2020).



Key drivers of the HIV epidemic are:

- A high number of lifetime (successive) sexual partners: the average partnership duration in urban Malawi was estimated at 2.5 years in the low risk group (with 1.5 years between partnerships) and 1.3 months in the high risk group (with 11

days between partnerships).<sup>8</sup> Concurrent partnerships probably have little additional impact on HIV transmission at the population level.<sup>9,10</sup>

- The 2013 Modes of Transmission (MOT) Study estimated that 67% of new HIV infections occur among low risk heterosexual relationships (married and co-habiting partners with one sexual partner per year); 12% occur in the casual heterosexual (more than one partner per year) risk groups; and 8% among their partners. These three groups account for around 88% of new infections.
- A model for sub-Saharan Africa estimated that female sex workers (FSW) and their clients may account for 10-20% of HIV transmissions.<sup>11</sup> This is slightly higher than the 2013 MOT study for Malawi that estimated 6.6% of infections result from FSWs, their clients and partners of clients. Female sex workers in Malawi bear a disproportionately large burden of HIV infection (70%) (Chizimba et al 2011). It is estimated that there are 19,295 sex workers in Malawi. The majority of them, estimated at 7, 023, are found in major cities. Most of the sex workers are aged between 16 and 29 years, which implies that a lot of young girls are driven into sex trade at a tender age.
- Low/inconsistent condom use: only 24% of males and 28% of females report using condoms the last time they had sex with a non-regular, non-cohabiting partner (MDHS 2010). Availability, misconceptions and lack of women's negotiating power have contributed to low and/or inconsistent condom use.
- 25% to 30% of new HIV infections among adults are thought to be from sex with a partner with early infection and the cumulative risk of transmission in the first three months of infection may be up to 26%.<sup>12</sup> However, up to 75% of sexual transmission in the population is thought to be from people in the long latent period of infection.<sup>13</sup>
- Widespread poverty and the economic gradient between older males and younger females drive transactional sexual relationships. However, the most common form of intergenerational sex, with the widest age gap and lowest condom use in the region occurs within marriages and steady partnerships.<sup>14</sup> Due to the higher cumulative risk of HIV infection in older adults, these age-disparate relationships are responsible for the increased incidence and prevalence among younger women. These age and economic disparities are more pronounced in urban areas and in the southern region (historically a trade region) and probably explain the clustering of HIV in these areas.
- Young women and girls may be more vulnerable to HIV infection due to lower socioeconomic status, high prevalence of sexual and gender-based violence (GBV) (41% of women and girls in the 2010 MDHS reported physical and/or sexual violence); and specific socio-cultural practices, such as initiation ceremonies, widow inheritance, and offering of 'dry sex' to please the partner. A 2012 GBV survey by the National Statistical Office revealed that 61% of females reported having experienced sexual violence compared to 39% of males. Harmful masculinity attitudes and behaviours play a big part in making young men vulnerable to HIV infection, since they encourage them to also engage in intergenerational sex as well as multiple concurrent partnerships.
- Low male circumcision prevalence is likely to have contributed to female-to-male transmission: only 22% of men (15-49) in the 2010 MDHS said they were circumcised, and there was widespread regional and ethnic variation. Self-reporting may over-estimate circumcision prevalence by up to 50% and the actual proportion of Malawian men fully circumcised may be only 11%.
- There is conflicting evidence about the magnitude of the effect of curable STIs fuelling HIV transmission. However, the high prevalence of ulcerative and other STIs and the relatively low rates of appropriate STI treatment are likely to make a considerable contribution to HIV transmission in Malawi. A recent modelling study from South Africa suggested that scale-up of syndromic STI treatment in South Africa may reduce STI associated HIV transmissions from around 40% to 15%.<sup>15</sup>

<sup>8</sup> Powers KA, Ghani AC, Miller WC, et al. The role of acute and early HIV infection in the spread of HIV and implications for transmission prevention strategies in Lilongwe, Malawi: a modelling study. *The Lancet* 2011; 378(9787):256-268.

<sup>9</sup> Tanser F, Barnighausen T, Hund L, Garnett GP, McGrath N, Newell ML. Effect of concurrent sexual partnerships on rate of new HIV infections in a high-prevalence, rural South African population: a cohort study. *Lancet* 2011; 378(9787):247-55.

<sup>10</sup> Sawers L. Measuring and modelling concurrency. *J Int AIDS Soc* 2013; 16:17431.

<sup>11</sup> Pruss-Ustun A, Wolf J, Driscoll T, Degenhardt L, Neira M, Calleja JM. HIV due to female sex work: regional and global estimates. *PLoS One* 2013;8(5): e63476.

<sup>12</sup> Powers KA, Ghani AC, Miller WC, et al. The role of acute and early HIV infection in the spread of HIV and implications for transmission prevention strategies in Lilongwe, Malawi: a modelling study. *The Lancet* 2011; 378(9787):256-268.

<sup>13</sup> Hollingsworth TD, Anderson RM, Fraser C. HIV-1 transmission, by stage of infection. *J Infect Dis* 2008; 198(5):687-93.

<sup>14</sup> Wyrod R, Fritz K, Woelk G, et al. Beyond sugar daddies: intergenerational sex and AIDS in urban Zimbabwe. *AIDS Behav* 2011;15(6):1275-82.

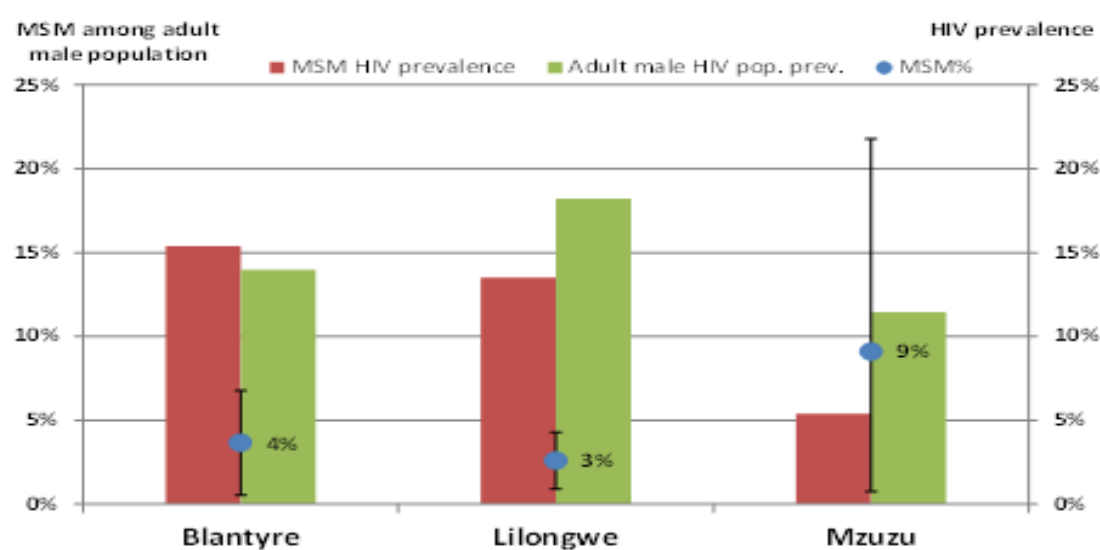
<sup>15</sup> Johnson LF, Dorrington RE, Bradshaw D, Coetzee DJ. The role of sexually transmitted infections in the evolution of the South African HIV epidemic. *Trop Med Int Health* 2012;17(2):161-8.

Current data for men who have sex with men (MSM) in Malawi suggest they are not a major driver of the overall HIV epidemic, though they are considered a key population because of structural barriers they face in accessing information and services due to marginalization and criminalization, and high rates of risky behaviours and misconceptions among recently surveyed MSM that facilitate transmission of HIV and other STIs.<sup>16</sup>

Figure 4 shows MSM population size and HIV prevalence estimates for MSM in three of MSM study sites - Blantyre, Lilongwe and Mzuzu, combined with general adult male HIV prevalence estimates for these cities. Estimating the MSM population size is fraught with difficulties and may be subject to bias due to the criminalization and marginalization of this group in Malawi. The survey used indirect methods (unique object multiplier and 'wisdom of the crowd') to estimate total MSM population sizes. These absolute estimates are surrounded by wide confidence intervals that are shown as prevalence ranges in the figure (using the total adult male population in the three cities as the denominator). HIV prevalence among MSM was very similar to that of men in the general population in the other 4 MSM study sites as well. This finding is also consistent with the Goals model estimates. While some studies have shown significantly higher HIV prevalence in MSM in specific locations, these are generally comparing national averages of the general male population rather than for the general male population for that same location. 3% to 4% of men in urban Lilongwe and Blantyre can be estimated to be MSM (excluding the very low precision estimate from Mzuzu), which is consistent with results from larger surveys in Europe and the US.<sup>17</sup> Nationally, the study estimated MSM to make up 1.84% of the Malawian male population 20-39 years of age (95%CI: 0.65% - 6.2%), consistent with other estimates from African countries.

While HIV prevalence among MSM may be similar to that among men in the general population in the same geographic locations, HIV prevalence in large prisons is considerably higher than among the population where the prisons are located. A 2012 Malawi prison survey revealed HIV prevalence exceeding 40% in two central prisons among both male and female inmates.<sup>18</sup> A 2002 study documented 28% of STI cases among male inmates in two rural Malawi prisons were acquired within the prisons, indicating same-sex sexual activity.<sup>19</sup> 10% of male inmates reported engaging in same-sex relations in exchange for food or sleeping space. The majority of male prisoners engaging in homosexual activity in Malawi prisons are likely "contextual MSM," engaging in same sex sexual behaviour while incarcerated, but returning to heterosexual relations upon release.

*Figure 4: Estimated prevalence of MSM among adult males in Blantyre, Lilongwe and Mzuzu and comparison of HIV prevalence among MSM and the general adult male populations in these three cities (2013).*



<sup>16</sup>AL Wirtz, G Trapence, V Gama, D Kamba, R Chalera, L Klein, R Kumwenda, T Chikoko, M Mangochi, S Baral. *Final report to UN Joint Team on HIV&AIDS in Malawi through UNDP: HIV Prevalence and Sociobehavioural Characteristics among Men Who Have Sex with Across Seven Sites in Malawi*. Johns Hopkins University and the Centre for Development of People. 01 December 2014

<sup>17</sup> Sell RL, Wells JA, Wypij D. The prevalence of homosexual behaviour and attraction in the United States, the United Kingdom and France: results of national population-based samples. *Arch Sex Behav* 1995;24(3):235-48.

<sup>18</sup>Mwapasa, V. et al (2012). Prevalence and Risk Factors for HIV, Sexually-Transmitted Infections and Tuberculosis in Malawian Prisons. *Malawi Prison Services*.

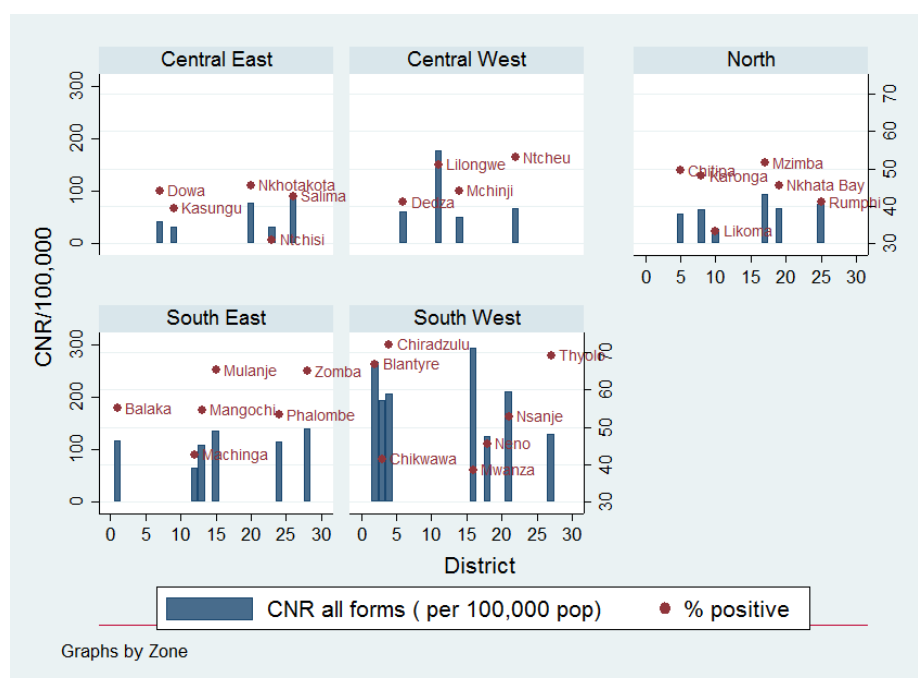
<sup>19</sup> Zachariah, R. et al (2002). Sexually transmitted infections among prison inmates in a rural district of Malawi. *Transactions of the Royal Society of Tropical Medicine and Hygiene* (2002) 96, 617-619.

## Tuberculosis

Tuberculosis remains a major public health problem in Malawi and is among the priority conditions included in the Essential Health Package (EHP) of the Malawi Health Sector Strategic Plan.<sup>20</sup> The HIV epidemic has triggered an enormous increase in TB notifications from around 5,000 in 1985 to a maximum of over 28,000 in 2003. Since the start of ART scale-up in 2004, annual TB case notifications have declined consistently; reaching 19,359 in 2013 (see Figure 6). HIV remains the most important risk factor for developing active TB disease in Malawi.

Routine HIV ascertainment in TB clinics was fully established in 2007 and testing rates have been maintained at around 90% since then. The proportion of TB patients testing positive for HIV has declined from 65% in 2007 to 56% in 2013, which is probably due to the increasing ART coverage and the reduced TB incidence among PLHIV at the population level. The observed reduction in TB incidence could also be attributed to improved coverage of HIV testing among TB patients, reducing the selection bias for HIV testing. The proportion of HIV-positive TB patients already on ART when starting TB treatment has increased from 40% in 2010 to 65% in 2013 and 88% were reported to start ART during the registration period. This is likely related to the introduction of routine TB symptom screening in ART clinics: 98% of PLHIV attending ART clinics are currently screened using standard TB screening criteria at every clinic visit and about 1% of patients screened reported at least one TB symptom and were investigated for active TB.

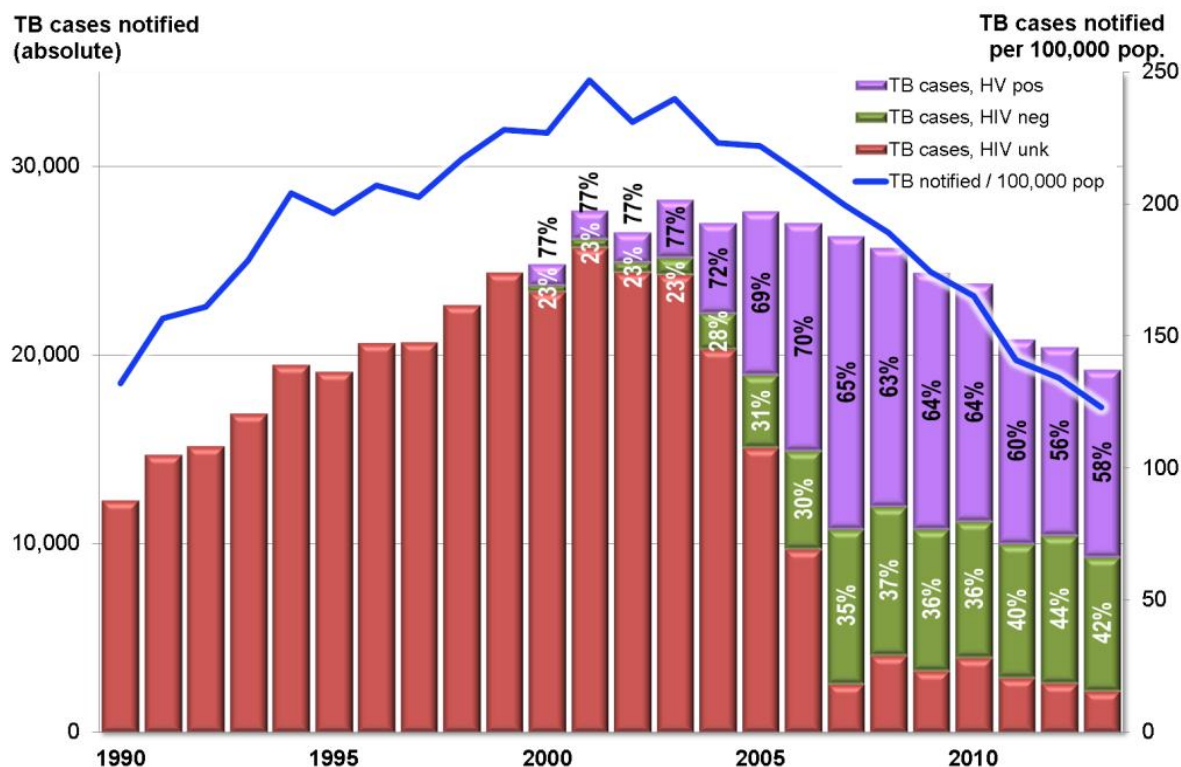
Figure 5: Case notification rate vs. HIV positivity rate among registered TB patients by districts, 2013



Note: In the figure above, case notification rate is on the left scale while HIV positivity rate is on the right scale.

<sup>20</sup> Malawi Health Sector Strategic Plan 2011-2016

Figure 6: TB cases notified 1990-2013 by HIV status



#### TB Burden

According to the WHO Global TB Report 2014, TB incidence and case notifications in Malawi have both declined over the past decades (Error! Reference source not found.). However, TB incidence estimates are likely to be adjusted upwards in the light of the TB prevalence survey ( Figure 7: *Summary case notification rate by districts, 2013*

Figure 8).

Provisional results from the national TB prevalence survey 2013/2014 indicate a TB prevalence of 286/100,000 in the general population (all ages).<sup>21</sup> The prevalence rate however is higher at 451/100,000 among adults<sup>22</sup>. During the same period, the case notification rate of pulmonary TB cases among adults was 133/100,000. This represents 24% of the prevalent pulmonary TB cases and 35% of smear-positive TB cases detected among adults. According to the same survey, up to 39% of bacteriologically confirmed cases would have been missed if X-ray screening was not applied, implying that symptom screening alone in high risk groups could potentially miss a significant proportion of TB cases. It is against this background that NTP has decided to move to active case finding with chest x-ray as an additional screening tool to enhance diagnosis of the less sensitive symptomatic and sputum microscopy approach.

Among all TB cases notified in 2013, 35.3% were new smear-0positive pulmonary TB cases, 31% were new smear-negative pulmonary TB cases and 22.2% were extra-pulmonary TB cases. This entails that more than 50% of TB cases (smear-negative plus extra-pulmonary cases) are diagnosed without bacterial confirmation; signifying the importance of deploying other or newer technologies/diagnostics, including chest X-ray and fine needle aspiration (FNA), that assist TB diagnosis..

#### Geographic and Socio-Demographic Variation

Provisional prevalence survey results indicate that the urban adult population has the highest TB prevalence (1,006/100,000). The rural adult population's prevalence is 372/100,000. This finding is consistent with the case notification rates in the districts

<sup>21</sup> Banda. R.P. Malawi Nationwide Tuberculosis Prevalence Survey Provisional Results. November 1, 2014. Presentation World Lung Health Conference, Barcelona, Spain.

<sup>22</sup> Data Analysis Mission, Malawi TB Prevalence Survey 1-5 December, 2014

with a high proportion of urban population (Blantyre, case notification of 266/100,000) & Lilongwe, 177/100,000) which are higher than the districts with rural populations.

The geographical distribution of TB case notifications is very similar to the distribution of HIV in Malawi (See Figure 7). High TB and HIV burden overlap is shown in urban centres of Lilongwe and Blantyre and in districts like Chiradzulu and Nsanje in the south.

Figure 7: Summary case notification rate by districts, 2013

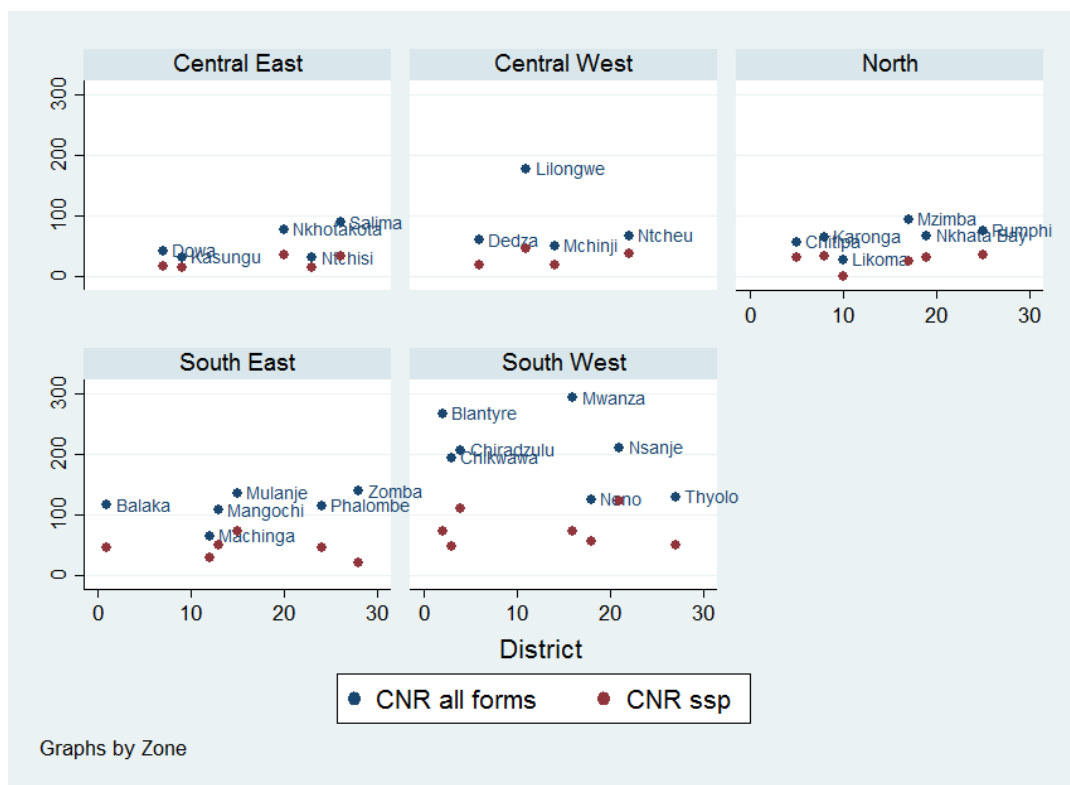
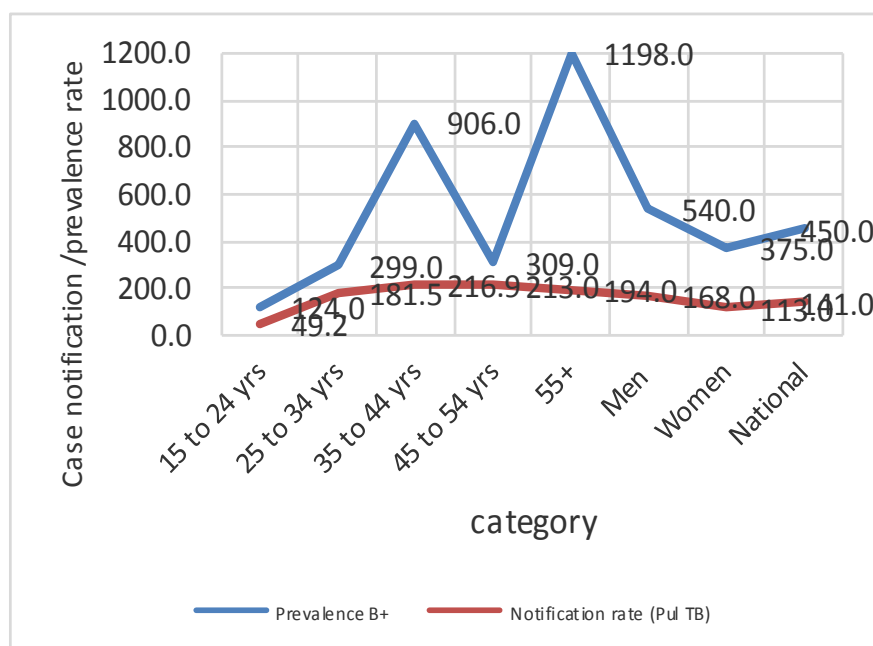


Figure 8: Age and sex distribution of prevalent TB cases, National TB prevalence survey 2013/14



Mwanza, Blantyre, Nsanje and Chiradzulu have the highest TB notification rates, and this heterogeneity of TB disease was also confirmed through prevalence survey (*Figure 7*). Of 72 clusters, 34 clusters had no TB cases while five had prevalence rates of greater than 1000/100,000. Based on TB notification data, a total of 12 out of 28 districts have a high burden of TB and these will be prioritized.

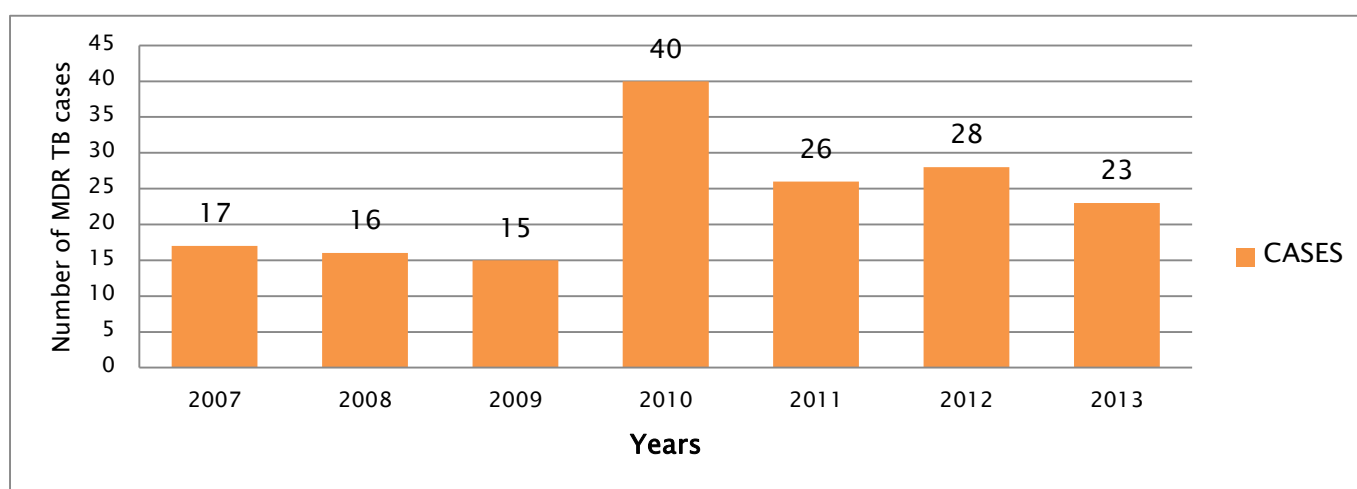
There was also variation in TB disease burden by sex and age in both notification data and prevalence data. Both sets of data show that the rate of TB is higher in the middle age group (35-44 prevalence at 906/100000) as well as older age group (55 and above with prevalence at 1198/100,000). On the other hand, these age groups also account for most of the cases missed as revealed by analysis of the TB prevalence survey. Men (540/100,000) have a higher disease burden than women (375/100,000), based on prevalence and notification data. A similar percentage of TB cases is missed among men and women. There is no plausible explanation for differences in these groups. While mobility, work environment, access, health seeking behaviour and biological factors can be possible explanations for the observed differences, further exploration through operations research is necessary.

The death rate among new smear-positive cases in 2012 was at 8% and the overall estimated mortality rate among all forms of TB cases has declined from 18/100,000 in 2005 to 9.3/100,000 in 2012.

### Drug-Resistant TB

Drug-Resistant TB (DR-TB) is an emerging problem in Malawi. Until the end of 2013, 165 MDR-TB cases were confirmed and enrolled for treatment. Whereas WHO estimates an annual MDR-TB case load at 161, only 28 (17%) of MDR-TB cases in 2013 were notified (NTP program data and 2014 WHO Global TB Report). This signifies a huge gap in the diagnosis and notification of MDR-TB cases, and this concept note seeks to address this gap. The 2010 Drug Resistance Survey (DRS) indicated an MDR-TB prevalence of 0.4% among new smear-positive and 4.8% among retreatment smear-positive cases. Although no cases of Extensively Drug Resistant TB (XDR-TB) have been reported to date, the DRS reported a high level of resistance to some second line drugs.<sup>23</sup>

*Figure 9: Trend in MDR-TB case finding 2007-2013*



#### 1.1.b Key populations with low access; contributing factors to this inequity

The definitions of “key”, “vulnerable”, “at risk” and “affected” populations/groups vary among different disease programs and entities. MSM and FSW are key populations for the HIV epidemic and response in Malawi. There is little information available on the internationally identified HIV key populations of transgenders (TGs) and injecting drug users (IDUs) in Malawi; they are thought to be very few in number currently and thus are not specifically targeted in Malawi’s key population programming at this time. However, it is anticipated that TGs will be reached through MSM-focused programming. Program adjustments will be made as needed if these populations are identified through service provision, research or other activities. Other populations sometimes identified as key, such as prisoners and clients of sex workers, are defined as vulnerable populations in Malawi for purposes of HIV policy and programming consistency. Other HIV-vulnerable populations/groups in Malawi include, but are not

<sup>23</sup> Abouyannis M, Dacombe R, Dambe I, Mpunga J, Faragher B, Gausi F, et al. Drug resistance of Mycobacterium tuberculosis in Malawi: a cross-sectional survey. Bulletin of the World Health Organization. 2014;92(11):798-806. Epub 2014/11/08.

necessarily limited to, adolescent girls, OVC, women, discordant couples, fisher folk, uniformed forces, estate workers, vendors and long distance truckers. Vulnerable populations are targeted through general population programming in the Concept Note.

For tuberculosis, key populations are those who are more vulnerable and/or at higher risk for TB. These include: PLHIV; Health care workers<sup>24,25,26</sup>; Urban populations; Age groups >55 years; Household contacts of PTB<sup>27</sup>; Prisoners<sup>28,29</sup>; Children <5<sup>30,31,32,33</sup> and Diabetic patients.<sup>34,35</sup> Table 1 summarises the characteristics and size of the main vulnerable/at risk groups for TB in Malawi.

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<sup>24</sup>Harries AD, Nyirenda TE, Banerjee A, et al. Tuberculosis in Health Care Workers in Malawi. *Transactions RSTMH* 1999; 93(1):32-35.

<sup>25</sup>Baassano I, Nunn P, Williams B, Pivetta E, Bugiani M, Scano F. Tuberculosis among Health Care Workers. *Emerg Infect Dis.* Mar 2011; 17(3): 488–494.

<sup>26</sup>Menzies D, Joshi R, Pai M Risk of tuberculosis infection and disease associated with work in health care settings. *Int J Tuberc Lung Dis.* 2007;11:593–605.

<sup>27</sup>Glynn JR, Crampin AC, Yates MD, et al. The importance of recent infection with *Mycobacterium tuberculosis* in an area with high HIV prevalence: a long-term molecular epidemiological study in northern Malawi. *J Infect Dis* 2005; 192: 480–87.

<sup>28</sup>Kanyerere HS, Banda RP, Gausi F, et al. Surveillance of Tuberculosis in Malawian Prisons. *Public Health Action* 2012; 2(1):10-14.

<sup>29</sup>Government of Malawi. Ministry of Health. Malawi Policy on Tuberculosis Control in Prisons. June 2007.

<sup>30</sup>Roadmap for childhood tuberculosis: towards zero deaths. WHO, 2013.

<sup>31</sup>Kanyerere H, Mpunga J, Makombe R, Dambe I, Mbendera K<sup>1</sup>. Tuberculosis Control in the Paediatric Population in a Central Hospital in Malawi. Abstract. IUATLD Conference, 2013.

<sup>32</sup>Gupta KB, Gupta R et al Tuberculosis and Nutrition. *Lung India.* 2009. Jan-Mar; 26(1)9-16.

<sup>33</sup>Republic of Malawi. Human Resources for Health. December, 2010.

<sup>34</sup>Stop TB Department. Tuberculosis and Diabetes. A collaborative framework for care and control of Tuberculosis and Diabetes. [www.who.int/tb](http://www.who.int/tb).

<sup>35</sup>Pao V, Lee GA, Grunfeld C: HIV therapy, metabolic syndrome, and cardiovascular risk. *CurrAtheroscler Rep* 2008.

Table 1: Vulnerable populations for TB in Malawi

Risk populations	Estimated size (not mutually exclusive)
<b>PLHIV</b>	1 million (adults and children) <sup>36</sup>
<b>Health workers</b> <sup>37,38,39, 40</sup>	19,800 (includes medical and clinical officers, medical assistants, nurses, pharm and lab techs, environmental health officers, Health Surveillance Assistance, HTC counsellors) <sup>41</sup>
<b>Urban residents</b>	294,000 (14% of total population 15.6 million. 14% are considered urban poor 14%) <sup>42, 43</sup>
<b>Older adults (&gt;55)</b> <sup>44</sup>	975,000 <sup>45</sup>
<b>PTB household contacts</b> <sup>46</sup>	12,802 pulmonary TB cases 2013 <sup>47</sup> and HH size 4.6 <sup>48</sup> = ±58,889 total household contacts. Of HH members, 8889 <sup>49</sup> are expected to be under five children. Thus 8000 children are expected to be eligible for IPT. 17,000 (12,802 pulmonary TB cases 2013 <sup>50</sup> and HH size 4.6 <sup>51</sup> = ±58,889 total number of persons exposed. Of those ±10% are PLHIV= 46,543. Of HH members, 12,346 <sup>52</sup> are children under 5. Thus the number for IPT is 4,654+12,346=17,000 persons requiring IPT
<b>Prisoners</b> <sup>53,54,</sup>	±38,000
<b>Children &lt;5</b> <sup>55,56,57</sup>	±3 million children<5; 47% stunted; TB contacts under 5
<b>People living with diabetes mellitus</b> <sup>58,59</sup>	5.6% adult population 25-65 with altered fasting blood glucose = ±270,000 at higher risk for TB. <sup>60</sup>
<b>Miners</b> <sup>61,62</sup>	±3000

Although “structural barriers” to HIV programming exist in Malawi in the legal and policy environment for key populations<sup>63</sup>, there are no legal barriers for TB programming.

<sup>36</sup> The Gap Report. UNAIDS Geneva 2014 p21.

<sup>37</sup> Harries AD, Nyirenda TE, Banerjee A, et al. Tuberculosis in Health Care Workers in Malawi. Transactions RSTMH 1999; 93(1):32-35.

<sup>38</sup> Baussano I, Nunn P, Williams B, Pivetta E, Bugiani M, Scano F. Tuberculosis among Health Care Workers. Emerg Infect Dis. Mar 2011; 17(3): 488–494.

<sup>39</sup> Menzies D, Joshi R, Pai M Risk of tuberculosis infection and disease associated with work in health care settings. Int J Tuberc Lung Dis. 2007;11:593–605.

<sup>40</sup> H. S. Kanyerere, F. M. Salaniponi. Tuberculosis in HCW in a Central Hospital In Lilongwe. NT J TUBERC.

<sup>41</sup> GoM, Ministry of Health. Provisional results: Services provision assessment 2013.

<sup>42</sup> GoM. National Statistic Office. Zomba 2009.

<sup>43</sup> GoM National Welfare Survey. Zomba. 2009.

<sup>44</sup> Banda. R.P. Malawi Nationwide Tuberculosis Prevalence Survey. Provisional Results. November 1, 2014. Presentation World Lung Health Conference, Barcelona, Spain.

<sup>45</sup> GoM. National Statistic Office, Zomba. 2009 Population projections.

<sup>46</sup> Glynn JR, Crampin AC, Yates MD, et al. The importance of recent infection with Mycobacterium tuberculosis in an area with high HIV prevalence: a long-term molecular epidemiological study in northern Malawi. J Infect Dis 2005; 192: 480–87.

<sup>47</sup> WHO Country Profile Malawi 2014.

[https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO\\_HQ\\_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=MW&LAN=EN&outtype=pdf](https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=MW&LAN=EN&outtype=pdf). Accessed 29 January 2015.

<sup>48</sup> GoM. Demographic Health Survey. 2010.

<sup>49</sup> Republic of Malawi. 2008 Population and Housing Census Preliminary Report .

<sup>50</sup> WHO Country Profile Malawi 2014.

[https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO\\_HQ\\_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=MW&LAN=EN&outtype=pdf](https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=MW&LAN=EN&outtype=pdf). Accessed 29 January 2015.

<sup>51</sup> GoM. Demographic Health Survey. 2010.

<sup>52</sup> Republic of Malawi. 2008 Population and Housing Census Preliminary Report .

<sup>53</sup> Kanyerere HS, Banda RP, Gausi F, et al. Surveillance of Tuberculosis in Malawian Prisons. Public Health Action 2012; 2(1):10-14.

<sup>54</sup> Government of Malawi. Ministry of Health. Malawi Policy on Tuberculosis Control in Prisons. June 2007.

<sup>55</sup> Roadmap for childhood tuberculosis: towards zero deaths. WHO, 2013.

<sup>56</sup> Kanyerere H, Mpunga J, Makombe R, Dambe I, Mbendera K<sup>1</sup>. Tuberculosis Control in the Paediatric Population in a Central Hospital in Malawi. Abstract. IUATLD Conference, 2013.

<sup>57</sup> Gupta KB, Gupta R et al. Tuberculosis and Nutrition. Lung India. 2009. Jan-Mar; 26(1)9-16.

<sup>58</sup> Stop TB Department. Tuberculosis and Diabetes. A collaborative framework for care and control of Tuberculosis and Diabetes. www.who.int/tb.

<sup>59</sup> Pao V, Lee GA, Grunfeld C: HIV therapy, metabolic syndrome, and cardiovascular risk. Curr Atheroscler Rep 2008.

<sup>60</sup> GoM. Malawi National STEPS Survey for Chronic and Non-communicable Diseases and their risk factors. 2009. Final Report.

<sup>61</sup> Report of the Mid-Term Review Malawi, 2014.

<sup>62</sup> SADC. Declaration on Tuberculosis in the Mining Sector 2012.

<sup>63</sup> Global Commission on HIV and the Law. Global Commission on HIV and the Law: risks, rights & health. New York: UNDP; 2012 [cited 2013 Jan 30]. Available from <http://www.hivlawcommission.org/index.php/report>

The Malawi Penal Code criminalizes same-sex relationships and earnings from prostitution and brothel keeping (FPAM, 2011), leading to arbitrary arrests and detention of people thought to engage in MSM or sex work. Police transgressions against these key populations are commonly alleged and treated with impunity. This impedes access to HIV-related information and services. A recent report documented 76 cases of human rights violations of sexual minorities, mostly MSM, including police beatings and humiliation, arbitrary arrest, and denial of health services that took place in 2013 in four districts across the country.<sup>64</sup>

The 2009 regional study on MSM in Malawi, Namibia, and Botswana and the Comprehensive HIV Prevention Intervention (CHPI) study for MSM in Malawi identified fear of accessing or denial of health services due to stigma and discrimination as a significant barrier for MSM (11% of 200 and 22% of 338 Malawian MSM, respectively).<sup>65</sup> In both studies, MSM experienced fear of arrest, social stigma, discriminatory attitudes by healthcare workers, lack of confidentiality and the dual stigma of being MSM and HIV-positive. Negative provider attitudes and behaviours towards FSW and MSM can deter health-seeking behaviours (especially for STIs) and discourage key populations who do access services from reporting fully on their sexual activities, which may result in them being provided with incomplete or inappropriate services. Some MSM in the CHPI study reported being reluctant to report fully on their sexual activities or STI symptoms and healthcare providers reiterated concerns about lack of confidentiality among some clinical staff, having witnessed instances when an MSM was treated as a spectacle when seeking treatment for rectal STIs. MSM participating in the Global Fund Country Dialogue consultations reported that they were often shunned by their families and communities, and were excluded from community activities once their sexual orientation was known. Approximately 10% of 1053 MSM in Blantyre, Lilongwe and Mzuzu reported having been raped and subjected to physical violence.<sup>66</sup>

The 2011 Family Planning Association of Malawi (FPAM) FSW study noted that 934 out of 950 sex workers (98.3%) reported experiencing abuse, and of those, two-thirds had experienced physical abuse and over a quarter had been raped. These abuses were rarely reported to authorities for fear of reprisal from the perpetrators. The study also reported that self-stigma and social discrimination (e.g., from community members and local church leaders) were commonly experienced. Similarly, 59% of 682 recently surveyed sex workers reported they felt ashamed to be sex workers. Information is mixed regarding the degree of stigma and discrimination FSW experience in accessing health services. 306 out of 682 FSW surveyed said they were ashamed to admit they were sex workers to social or healthcare workers in their community (2013 BBSS). Some FSW reported anecdotally during all three regional Global Fund Country Dialogue consultations that they felt discouraged from seeking health services due to the poor attitudes and treatment from health workers, particularly from nurses. On the other hand, 86.3% of 684 FSW thought sex workers were treated fairly in hospitals (2013 BBSS).

These structural barriers have thus far hindered the development and delivery of a standardized comprehensive package of services for FSW and MSM outside of limited projects though recognition and efforts are growing for building and expanding a more focused, strategic approach for addressing HIV related needs of key (and vulnerable) populations.

### **1.1.c Human rights and gender barriers to access health services**

An effective response to the epidemic requires that the rights to equality before the law and freedom from discrimination are respected, protected and fulfilled—in particular, in gender relations among women, men, girls and boys. Malawi has enacted legal frameworks that can support strengthening of gender-transformative programming in the HIV response such as the Prevention of Domestic Violence Act of 2006, Child (Care, Protection and Justice) Act of 2010, Deceased Estates (Wills, Inheritance and Protection) Act of 2011; and, Gender Equality Act of 2013. Legal gaps still exist such as weak enforcement of existing laws or lack of critical HIV related laws (HIV and AIDS law, human trafficking law and Marriage and Family Relations law).

Punitive laws and an inaccessible justice system have been identified as key human rights barriers in Malawi. Unprofessional health worker conduct is a commonly mentioned barrier to accessing services. This may include judgmental attitudes towards adolescents seeking contraceptives, condoms and HIV testing, especially for girls.<sup>67</sup>

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<sup>64</sup> Human Rights Violations on the Basis of Real or Perceived Sexual Orientation and Gender Identity in Malawi 2014 Report. Centre for Human Rights and Rehabilitation and Centre for Development of People; September 2014; p. 6-9.

<sup>65</sup> Wirtz AL, Trapence G, Jumbe V, Kamba D, Umar E, Ketende S, Berry M, Stromdahl S, Beyrer C, and Baral S. Implementation of a comprehensive HIV Prevention Intervention for men who have sex with men in Malawi: assessment of feasibility and impact. November 2013. Baltimore: USAID | Project Search: Research to Prevention.

<sup>66</sup> Wirtz A, Trapence G, Gama V, Kamba D, Chalera R, Baral S. Preliminary report to UN Joint Team on HIV & AIDS in Malawi through UNDP: HIV Prevalence and Sociobehavioural Characteristics among Men Who Have Sex with Men in Blantyre, Lilongwe, and Mzuzu, Malawi. Blantyre: Johns Hopkins University and the Centre for Development of People, 2014.

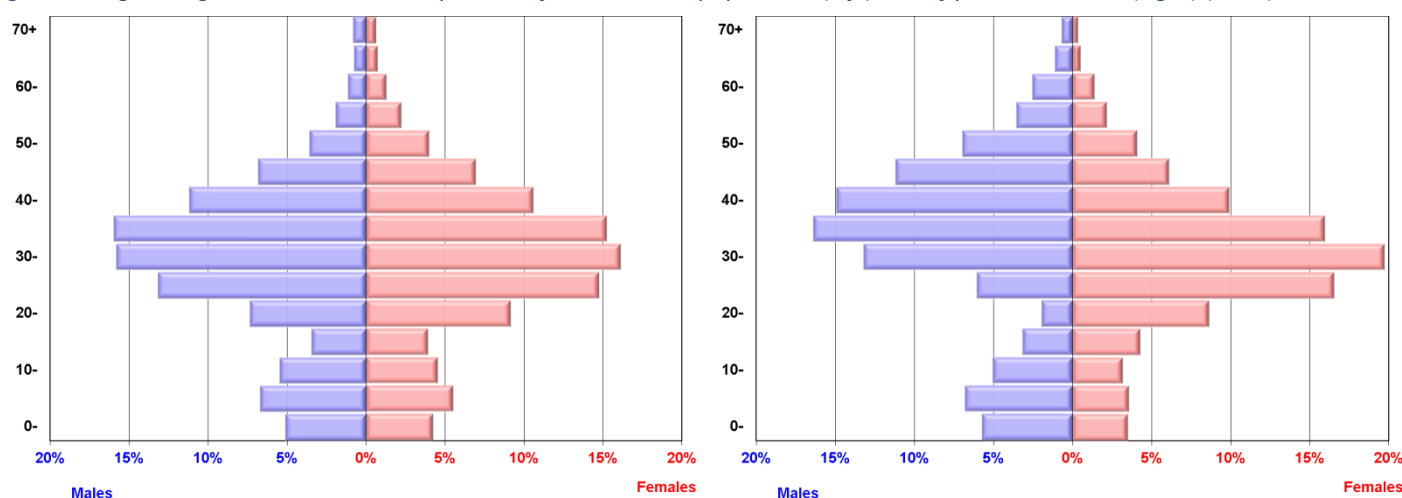
<sup>67</sup> Gender Assessment of the National HIV Response, 2014.

HIV-associated stigma and discrimination have been cited as barriers for accessing HIV prevention, treatment and care services.<sup>68</sup> Furthermore, tuberculosis-affected people are perceived negatively in the community, and women were found to be more affected by the socio-cultural consequences of tuberculosis.<sup>69</sup>

Prevailing masculinity norms may discourage male involvement in their own health, such as seeking HIV/AIDS information or obtaining HTC. Gender-based violence (GBV) is commonly reported in Malawi.<sup>70</sup> This is mainly because the ratified international and regional instruments have not been effectively implemented and cultural traditions have long condoned most forms of domestic violence as private issues without need for external interference. As a result, most violence against women, particularly domestic violence such as wife beating, incest, and child defilement, goes unreported. Disclosure of HIV infection among spouses may be hindered by fear of GBV and some husbands may prevent women from accessing HIV services.<sup>71</sup> Low education levels make women particularly susceptible to messaging by some religious groups in Malawi that discourage ART use.<sup>72</sup>

However, the impact of gender barriers on ART access in Malawi appears to be modest: Figure 10 shows that overall ART coverage is largely gender-balanced.<sup>73</sup>

*Figure 10: Age and gender distribution as percent of the total HIV population (left) and of patients on ART (right) (2013).*



The relative over-representation of younger females and older males on ART compared with the total HIV population is mainly explained by two factors:

- Younger average age at infection in women, resulting in more women with advanced HIV disease among young adults (15-34).
- Routine HIV screening and universal ART eligibility among pregnant women attending ANC (Option B+), leading to earlier diagnosis and treatment initiation. There is no comparable route for routine provider initiated HIV testing and treatment initiation for men. In 2013, estimated ART coverage among adults (15+) was 42% among men and 62% among women.

For TB, all Malawians are entitled to access free health services. However, distribution of health services is skewed towards urban and peri-urban settings, hence, infringing on rights of certain sectors of society. As women have limited ability to control household resources, women are likely to face barriers of accessing health services including TB services. Past research undertaken in Malawi has demonstrated that the economic impact for patients affected by TB, according the definition of the post 15 Global TB strategy (expenditure of >40% of income), just to access diagnosis for TB is considered “catastrophic”,

<sup>68</sup> NAC (2014). HIV National Strategic Plan: 2015 -2020 pp.46-49.

<sup>69</sup> Simwaka BN, Bello G, Banda H, Chimzizi R, Squire BS, Theobald SJ. The Malawi National Tuberculosis Program: an equity analysis. *Int J Equity Health* 2007;6:24.

<sup>70</sup> GBV survey 2012.

<sup>71</sup> COWLHA 2012.

<sup>72</sup> Gender Assessment of the Malawi National HIV Response, 2014.

<sup>73</sup> HIV population estimates from the 2014 Spectrum model. Age and gender disaggregation among ART patient based on a representative sample of 29,091 patients from sites with electronic medical record system (mid 2013).

especially for the poor. The costs are estimated to be upwards of 244% of their total monthly income. This rises to 574% when essential expenditures on food are excluded<sup>74,75</sup>.

#### **1.1.d Health and community systems**

##### **Health Systems Context**

The Department of HIV and AIDS and the National TB Control Program (NTP) of the MoH are responsible for coordination, policy development and implementation for HIV and TB prevention and control. Key functions of the departments include:

##### **Procurement and Supply Management**

For the past decade, disease control programs have established parallel procurement, storage and distribution systems recognizing the existing constraints of the Central Medical Stores system with the exemption of the TB Program. The MOH/HTSS Pharmaceuticals together with HIV, Malaria and TB programs co-ordinate key PSM functions such as the quantification, procurement planning and monitoring for EMHS, HIV, Malaria and TB program commodities. Other PSM functions such as Procurement, central level warehousing and national distribution are currently being outsourced to third party procurement agents. In 2012, GOM and development partners developed and a joint strategy for integrating the parallel supply chains into one supply chain managed by CMST. Reforms at CMST are ongoing to create the necessary capacity and expertise to procure, store and distribute essential medicines however the benchmarks for the required capacity in all areas including financial management have not been fully met. As such the Ministry of Health as had to maintain outsourced service providers for procurement and warehousing & distribution services. A CMST Reform Monitoring Committee was constituted to monitor the implementation of the CMST reforms and implementation of the integration strategy.<sup>76</sup> The committee is composed of representatives from the CCM, MOH, USAID, Health Donor group, CHAM and CMST.

The HIV and Malaria PSM system has been designed to meet the need for 100% uninterrupted availability of ARVs, anti-malarial medicines and test kits at all service delivery points and discussions are underway to have a harmonized system for TB Programs. Central Medical Stores Trust (CMST) has established a dedicated well-managed central warehouse for all HIV and malaria commodities that manages receipt, inventory, and dispatches directly to all 700 sites on a 2 monthly schedule.

MoH has a dedicated logistics team including program officers, technical assistants and logistics fellows within the HIV Department that carries out forecasting, procurement planning, inventory allocation and supervision for all sites. Several innovative features have been added to this system (toll-free supply hotline managing thousands of calls with sites each quarter, central coordination and authorization of all commodity transactions and reallocations, data warehouse for site level service and logistics data, etc.). Site level HIV inventory data are verified each quarter at all 700 ART sites through the integrated HIV Program supervision exercise. In 2014, the Malaria Program integrated into this warehousing and distribution system, adding further efficiencies. Central warehousing and distribution have recently been contracted out to a commercial company (Bolloré Africa Logistics) collaborating with CMST to delivering the most efficient and cost-effective supply chain management across the entire health sector. TB Program commodities are currently managed by the CMST through central and regional warehouses and district level distribution is coordinated by the District TB Officers. Integration of supply chain management systems and strategies to improve the distribution of supplies is outlined in the draft National Medicines Policy.

There is a general need for infrastructure upgrades at over 70% of all health facilities in Malawi. This includes expansion and improvement of storage capacity. The highest priority investments are included in the allocated funding amount. Significant investments have been made to integrate program commodities into the national LMIS.<sup>77</sup> Recent initiatives include SMS and web-based LMIS reporting so distribution of commodities can be the most efficient possible.

##### **Health Information Systems (HIS)**

Over the last decade, Malawi has established and maintained an integrated M&E system for the HIV Programs that is built on quarterly supportive site supervision visits to all 700 health facilities. This system combines regular data verification and review of clinical notes from primary patient records with continuous quality improvement and targeted clinical mentoring. Site visits are coordinated by the HIV Department and carried out by district and zonal program staff, supported by implementing partners.

<sup>74</sup> Kemp J., et al. Can Malawi's poor afford free tuberculosis services? Patient and household costs associated with a tuberculosis diagnosis in Lilongwe. Bulletin of the World Health Organization. 2007;85 (8).

<sup>75</sup> Simwaka BN, Bello G, Banda H, Chimzizi R, Squire BS, Theobald SJ. The Malawi National Tuberculosis Program: an equity analysis. International journal for equity in health. 2007;6:24. Epub 2008/01/01.

<sup>76</sup> Joint Strategy for Supply Chain Integration in Malawi, December 2012.

<sup>77</sup> Malawi: Kamunyor, Joy, and Emma Stewart. 2013. Malawi: Business Case for an Electronic Logistics Management Information System. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4 and Task Order 7.

Malawi's standardized M&E tools and the Integrated HIV Program Report, which has been published without fail since 2005, have become an international benchmark for HIV Programs. External data quality audits have confirmed the highest ratings for completeness, accuracy and timeliness of data.<sup>78</sup>

The HIV Program has developed a national point-of-care electronic medical record (EMR) system. Development, deployment and maintenance of this system are carried out by an indigenous organization (Baobab Health Partnership) with PEPFAR funding support. About 30% of the national ART patient cohort is currently managed at EMR facilities. Malawi was the first country in Africa to fully integrate HIV status ascertainment and PMTCT into ANC and maternity registers and reporting forms. The TB and HIV Programs are currently working on a full integration of their strategic information and supervision systems. The integration will follow a stepwise approach guided by the joint integration plan that will be developed by TB/HIV technical working group. The HIV Program is currently exporting data to the District Health Information System, which serves as the central repository for MoH service data and a full integration of these systems is planned. One limitation of the current HIS for both HIV and TB is that issues of gender, vulnerable and key populations are not adequately addressed.

### **Financial Management**

Resources for the national HIV and TB Programs have primarily been managed by National AIDS Commission (NAC) and MoH. The HIV Program has largely been funded by donors, with the government providing modest direct financial contributions, whilst bearing the burden of health service providers and infrastructure for service delivery. On the other hand, the MoH and donors have complemented the contribution towards financial resources for the TB response.

The overall financial management structure continues to improve with time, with renewed focus on improving efficiency, effectiveness and value for money. This has been evident through continuous efforts to strengthen the capacity of the control and management of public and donor resources. Whilst the existing financial management systems have been able to facilitate the rapid program scaling up and achievement of desired results in many aspects through management of significant volumes of financial and other resources, there are still areas that require improvements. These include: increased numbers of skilled financial management personnel, strengthened internal controls, record keeping and reporting.

### **Health and Community Workforce**

Malawi has implemented a 6-year Human Resource Emergency Plan and a 6-year Emergency Pre-service Training Plan to address a serious human resources for health (HRH) gap. A 52% salary top-up for 11 priority cadres was introduced in 2005 to improve retention and payment of both monetary and non-monetary incentive packages were approved to attract health workers to rural and underserved areas. Based on a Service Provision Assessment conducted in 2013, staff numbers have increased considerably in the last five years: as of 2013, there were: 397 medical officers (+109%); 1,463 clinical officers (+109%); 1,161 medical assistants (+64%); 5,616 nurses/midwives (+30%); 9,163 health surveillance assistants (+9%). In spite of these gains, the HRH capacity in Malawi remains very low and geographical distribution of HRH can lead to inequity. The national HIV and TB Programs have been adapted to these severe staffing constraints through a) rigorous simplification and standardization of guidelines and protocols; b) task-shifting, including nurse-based ART initiations (since 2005), TB treatment initiation by (non-medical) TB officers, HTC by HSAs/trained lay providers; c) quarterly program supervision of all service delivery points Service Delivery Points (SDP).

### **Service Delivery**

Scale-up of HIV and AIDS services under the ambitious 90-90-90 targets outlined in the NSP will increase demands placed on the delivery of services. Integrated care is the premise for most biomedical interventions, which is hampered by weak delivery capacity due to limited infrastructure and human resources. To ensure effective service delivery, a key area of focus will be scaling up of general service and lab infrastructure, lab equipment and the commensurate increase in human resources to meet the expected demand combined. Although the country achieved a global population coverage of TB microscopy per 100,000 population, there has been variation in distribution of microscopic centres among districts and most of the centres are concentrated in urban centres where only 15% of the population resides. New technologies for diagnosis of TB are being introduced and expanded. The challenge is related to sustainability and maintenance of these technologies.

Malawi recently adopted the WHO laboratory quality checklist and over 40 laboratories are enrolled in the Strengthening Laboratory Management towards Accreditation (SLMTA) Program. These efforts will improve the diagnostic capacity for TB as well and address challenges in inadequate and poorly maintained equipment along with challenges in sample transportation between facilities and quality control laboratories.

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<sup>78</sup> John Snow Inc. Data Quality Audit for HIV/AIDS in Malawi (MLW-102-G01-H, MLW-506-G03-H, MLW-708-G07-H). Arlington, VA, 2011.

## Community Systems Context

Umbrella organizations like Malawi Network of AIDS Service Organizations (MANASO), Malawi Network of People Living with HIV (MANET+), and Malawi Interfaith AIDS Association (MIAA) have large community constituencies including non-governmental, faith and community-based organizations and networks that are coordinating activities at district and community levels. The Faith Community covers different networks such as Malawi Council of Churches, Anglican Council of Malawi, Episcopal Conference of Malawi, Evangelical Association of Malawi, the Quadria Muslim Association of Malawi and Muslim Association of Malawi among others, which are also umbrellas for churches and church organizations. At the Community level there are District and City Interfaith AIDS Committees overseeing the implementation of the HIV activities. There are also 1434 Support Groups affiliated to Community-Based Organizations.

The Non-Governmental Organizations include both the local and international NGOs, each with a specific HIV mandate and area of coverage. For issues regarding key populations there are organizations such as the Centre for the Development of the People (CEDEP) and Centre for Human Rights and Rehabilitation and Theatre for a Change among others that have programs targeting these populations. At present CEDEP is the only Local NGO providing services to MSM. However there are a number of local organizations providing services to FSW. The National HIV Response is in the process of setting up a sub-committee for the key populations within the Prevention Technical Working Group.

Some NGOs such as Southern Africa Trust (SAT) Malawi, Coalition of Women living with HIV and AIDS (COWLHA) have been implementing gender-transformative programs in HIV at national and community levels.

Over the years, the CSOs have developed the capacity to provide and support delivery of health services at the community level. In addition, the CSOs have also been involved in facilitating linkages and referral systems between the communities and the health facilities. The Ministry of Health has provided trainings for the CSOs to provide services according to national guidelines and also check compliance in service provision.

Other key activities implemented by the CSO include: advocacy; capacity building; resource mobilization; community mobilization for action; monitoring and supervision; learning and evaluation; care and support.<sup>79</sup>

Most of these organizations have not focused on TB control activities in the past and their potential to increase case detection and management has remained untapped. However, there are community initiatives for TB that mainly involve establishment of community sputum collection points which are linked to diagnostic sites. Members of the community manage these sputum collection points under the supervision of health surveillance assistants. Currently interventions are being implemented largely through unpaid volunteers. However, there is a high dropout rate due to irregular supervision and incentive mechanisms. Families are highly engaged in treatment and care of TB cases as family DOT supporters. Health surveillance assistants are also responsible for tracking lost and follow-up cases, and oversee treatment follow-up at family level. They also ensure that patients have sputum follow-up during treatment by collecting and transporting samples to the nearest health facility.

Currently a Community Service Delivery Strategy is being developed to guide service delivery at the community.

## 1.2. National Strategic Plans for HIV and TB

### 1.2.a Key goals, objectives and priority areas for HIV and TB

#### National Strategic Plan for HIV and AIDS (2015-2020)

The overall goal is to reduce HIV morbidity and mortality and to reduce transmission through interventions with clear evidence of impact. By the end of 2020, 90% of all PLHIV will be diagnosed; 90% of these will be initiated on ART and retained in care; and 90% on ART will attain viral suppression. Reaching these 90-90-90 goals in 2020 will result in 756,000 (73%) of the projected 1,036,000 PLHIV being virally suppressed, leading to a dramatic reduction in sexual and vertical transmission at the population level. The NSP has three main objectives as stated below:

#### **NSP Objective 1: 90% of PLHIV know their HIV status**

The main priority for the HTC program is to identify as many PLHIV as early as possible and to facilitate ART initiation as soon as possible. The target is to attain 90% coverage of Provider Initiated Testing and Counselling (PITC) in high yield health service

<sup>79</sup> The Independent Review of Malawi National Response to HIV/AIDS for Financial Year 2012/2013.

delivery points, such as ANC, maternity, out- and in-patient clinics, TB and STI clinics, Nutrition Rehabilitation Units (NRU), combined with targeted community testing interventions.

An additional objective is to link HIV-negatives to appropriate prevention services, such as condoms, social behaviour change communication (SBCC), voluntary medical male circumcision (VMMC), and to make appointments for re-testing based on risk assessment.

Another goal is to maintain 90% of PITC among TB patients. Additional strategies include expansion of routine PITC and linkage to ART for TB suspects and for family/household contacts of TB cases.

### **NSP Objective 2: 90% of known HIV-positives are initiated on ART**

Full decentralization of ART to primary health facilities has been completed in 2012. Simplified and standardized protocols have allowed task-shifting of ART initiation and follow-up to all mid-level health workers, including clinical and medical officers, nurses and midwives.

Expanded ART eligibility criteria have been implemented since April 2014 (CD4 500, universal eligibility for children under five, all positive pregnant women, discordant couples, HIV-positive TB patients). About 80% of PLHIV are eligible for ART under the 2014 guidelines, and inclusion of universal eligibility for discordant couples would increase this to 90%. From 2016, the national ART program will introduce universal ART eligibility for all PLHIV in order to eliminate diagnostic bottlenecks and further simplify protocols that currently serve to delay ART initiation in 10-20% of people tested positive. National guidelines are revised by TWGs under the MoH leadership after extensive stakeholder consultation including CSOs, PLHIV, health regulatory bodies and development partners.

Early ART reduces TB risk by 51%, AIDS-defining clinical events by 51%, and primarily clinical events by 27%.<sup>80</sup> Early ART (within 2 weeks of starting TB treatment) is essential for the management of HIV-associated TB.

### **NSP Objective 3: 90% of people on ART will be virally suppressed**

Maintain and improve current levels of retention and adherence through public education, group- and individual support for patients.

Continue scale-up of viral load monitoring to ensure timely switch to second line ART for patients failing first line therapy.

Continuous quality improvement for HIV services through supervision and targeted clinical mentoring.

Table 2 shows the programmatic and cost implications of introducing universal ART eligibility (UT) in 2016 vs. maintaining the 2014 Malawi ART eligibility criteria (WHO stage 3 / 4, CD4 500, universal eligibility for pregnant / breastfeeding women and children U5). The incremental cost for this policy change amounts to about USD 5.8 million between 2015 and 2017. The comparison of these scenarios reveals the following:

- The UT policy puts no additional demand on health worker force or infrastructure. This is due to the fact that pre-ART and stable ART patients follow the same follow-up schedule (3 monthly) and the amount of time and clinical expertise required does not differ. From 2016, all patients in otherwise enrolled and followed up in pre-ART clinics will enter into ART follow-up.
- Maintaining a pre-ART program, including clinical and CD4 monitoring, CPT and IPT, requires significant resources (USD 12.4 million for 2016 and 2017). Most of these resources are required for running and maintenance of decentralized CD4 count services.
- With over 700 ART/PMTCT sites, ensuring regular CD4 monitoring (and ART initiation between 350 and 500) for all patients in pre-ART would require further significant investments in CD4 machines (about 160 are currently available) and/or expansion of a rapid sample transportation system. These additional investments have not been considered in Table 2 and they would further reduce the cost difference.

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<sup>80</sup> Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2012; 365(6):493-505.

Table 2: Comparison of patient numbers and program cost of maintaining the 2014 Malawi ART eligibility criteria and introduction of universal eligibility from 2016

Policy	Program	2015		2016		2017		Total (2015-17)
		Patients	Cost (USD)	Patients	Cost (USD)	Patients	Cost (USD)	Cost (USD)
CD4 500 (2014 Guidelines)	ART	541,603	83,916,227	591,036	93,406,822	637,880	102,826,331	
	pre-ART	27,462	2,908,871	47,025	5,080,727	66,927	7,375,581	
	<b>Total</b>	569,065	86,825,099	638,061	98,487,550	704,807	110,201,912	295,514,561
Universal eligibility (2016 Guidelines)	ART	541,603	83,916,227	638,061	100,838,615	704,807	113,614,902	
	pre-ART	27,462	2,908,871	0		0		
	<b>Total</b>	569,065	86,825,099	638,061	100,838,615	704,807	113,614,902	301,278,616
							<b>Difference</b>	<b>5,764,055</b>

### National Strategic Plan for TB (2015-2020)

The goal of the NTP is to reduce TB-related morbidity and mortality by 75% by the end of 2025 compared to the 2014 baseline, with two strategic objectives: 1) Reduction of TB-related mortality by 50% by the end of 2020 from the 2014 baseline; and 2) Reduction of TB burden/prevalence by 50% by the end of 2020 from the 2014 baseline (Malawi Ministry of Health, September 2014, p. 33).

Four main pillars of the revised TB NSP are: 1) Integrated case finding and patient centred TB diagnosis, treatment, care and support; 2) TB/HIV collaboration and integration; 3) Prevention and impact mitigation 4) Program Management (Malawi Ministry of Health, September 2014)

#### **NSP Objective 1: Improved integrated, patient-centred diagnosis, treatment and care:**

##### **Targets:**

- Improving case notification rate to 168/100,000, by end of 2016 fiscal year from 121/100,000. By the end of fiscal year 2020 in NSP, the CNR will reach 252/100,000.<sup>81</sup>
- Attaining 90% treatment success rate from 84% (among new smear-positive TB cases).

Intermediate results include:

- Decentralization of TB diagnosis from a density of 1 site per 62,257 population to 1 site per 38,000 population.
- Scaling up the number of TB treatment centres from 247 to 458.
- Increased community involvement in TB suspect identification, diagnosis and treatment.
- Improving TB case finding among vulnerable groups and high risk population.
- Initiating 100% of patients diagnosed with multidrug-resistant TB (MDR-TB) on appropriate treatment.

Performing culture and first-line drug susceptibility testing (DST) to 85% of all retreatment patients.

#### **NSP Objective 2: Improved TB/HIV integration and collaboration:**

Intermediate results include:

- 90% of co-infected TB/HIV patients receive ART within their TB treatment period.
- 95% of notified TB patients have documented HIV result.
- 60% of eligible private providers engaged in TB/HIV services.

#### **NSP Objective 3: Prevention and impact mitigation**

Some Intermediate results include:

<sup>81</sup> NB. Target is likely to be overestimated as NTP used prevalence data for projection of expected cases and targets.

- 80% of districts have partnerships engaging TB patients, ex-TB patients and civil societies in TB prevention and control activities.
- 80% of eligible TB patients are registered and receiving a complementary service in the community.
- Provide IPT for 75 % eligible children below five who are household contacts of the infectious pulmonary TB cases.

#### **NSP Objective 4: Program management**

Intermediate results include:

- Improved stewardship and program oversight.
- Improved coordination and partnership.
- Improved leadership and management.
- Strengthened monitoring, evaluation and operations research.

#### **HIV/TB Collaborative Activities**

The aim of integrating health services is to reduce waiting times and out of pocket expenses for patients and to facilitate timely access to all required interventions by reducing the need for referrals.<sup>82</sup> Service integration has emerged as an essential component in the response to the TB/HIV epidemic.<sup>83</sup>

The TB and HIV programs historically operated as parallel programs until 2010 when concerted efforts to implement collaborative activities were put in place. TB and HIV have now moved a step further by undertaking joint planning (through this concept note) which has resulted in consensus on developing TB/HIV curricula and training materials, TB/HIV TWG meetings, TB/HIV review meetings to monitor collaborative activities as well as TB/HIV monitoring and evaluation framework through quarterly supervision visits. Good progress has been made in the HIV testing of TB patients, with over 90% of TB patients screened for HIV in 2013.<sup>84</sup> Routine PITC will be extended to all TB suspects recorded in the 'cough register' to increase HIV diagnosis and timely ART in this high risk population. All nurses and clinicians providing ART will be trained and certified in TB diagnosis and treatment initiation to facilitate timely TB treatment, including for HIV patients with a presumptive diagnosis of TB.

The integration of TB management and ART in a "one stop service" has been challenging due to several staffing and logistical constraints. The TB program relies primarily on community health workers for TB management. They lack the basic clinical skills to be trained and certified in the provision of ART. Continuous triaging and physical separation of patients with active TB/TB suspects is required to reduce the risk of nosocomial transmission of TB. These challenges are thought to contribute to delayed diagnosis, treatment and increased loss to follow-up.

There is an increasingly close collaboration between the TB and HIV Programs in Malawi:

- A TB-HIV technical working group (TWG) meets regularly to review policies, implementation and progress towards objectives.
- Joint supervision has been successfully piloted.
- Routine TB symptom screening has been fully established in HIV clinics.
- One-stop-shop clinics for TB treatment and ART have been successfully implemented at two central hospitals.
- Integrated screening and management of TB and HIV in prisons is being piloted.
- A national TB-HIV framework and joint work plan have been developed.
- There is provision of IPT to HIV infected clients who has TB contacts not yet on ART.
- There is provision of CPT to HIV and TB co-infected clients within TB settings.

<sup>82</sup> WHO: *Integrated Health Services - What and Why?*. [http://www.who.int/healthsystems/technicalbrief\\_final.pdf](http://www.who.int/healthsystems/technicalbrief_final.pdf).

<sup>83</sup> Kodner D: All together now: a conceptual exploration of integrated care. *Healthc Q* 2009, 13:6-15. [PubMed Abstract](#).

<sup>84</sup> WHO Country Profile 2014 Malawi.

## Cross-cutting Priority Program Areas Identified in the NSP for TB and HIV:

- Human resources for Health: Malawi continues to have the lowest ratio of health workers by population in the southern African region, with 0.3 doctors and 3.5 nurses per 10,000 people (10% and 30% of the regional average, respectively).<sup>85</sup> With most HCW working above their capacity, several aspects of clinical guidelines are only partially implemented and the index of TB suspicion in OPD and MNCH attendees is low. Knowledge of TB Infection Control (TB-IC) in both TB and HIV services may not be translated into practice (p 51 TB NSP). Remedial approaches included in both NSPs cover joint HIV and TB in-service trainings; quality improvement interventions; joint monitoring, supportive supervision and clinical mentoring. Pre-service curricula will be upgraded to reflect these advances.
- Laboratory systems strengthening: The Lab NSP includes high-capacity PCR machines at all central hospitals; quality assured LED microscopy and molecular-based diagnosis (GeneXpert) for improved and expedited TB diagnosis, and other point-of-care technologies as they become available (HIV NSP section 10.4 p56). Early Infant Diagnosis (EID) and Viral Load (VL) monitoring will be further scaled up through use of dried blood spot samples (DBS) and an integrated sample transportation system covering all districts. Close collaboration between the HIV and TB programs will ensure maximal efficiencies for reliable sample transportation and timely delivery of results.
- Monitoring and evaluation: Both the TB and the HIV NSPs recognize the importance of M&E. Reporting tools will be gender-sensitive and capture information on KAPs and other vulnerable groups for both TB and HIV.
- Awareness and community mobilization: The NTP NSP notes stigma associated with TB and HIV, requiring interventions at community and facility level. The engagement of CSOs in this activity will ensure that a package of awareness activities is delivered to all communities.
- Supply chain management: The NSPs recognize the need to streamline supply chain systems for more efficiency and effective delivery of supplies and to mitigate stock-outs (p 68). Implementation of the Laboratory Information Management System (LIMS) at all laboratories in central hospital and other molecular (PCR) testing facilities will improve results turnaround time, forecasting and reliable supply chain management of laboratory reagents, supplies and consumables with the aim of eliminating recurrent stock-outs and testing interruption for the TB and HIV programs (p57 section 10.4 HIV NSP).

### 1.2.b Implementation, outcomes and impact to date, including TB/HIV activities

#### HIV Program

Aside from a clearly mapped-out scale-up plan for biomedical services, the 2011–2016 NSP focused on program integration and appropriate referrals such as partner HTC, and the integration of behaviour change messages and referrals within counselling services. It also included programs for reducing multiple and concurrent sexual partners and other prevention interventions (HTC, PMTCT, STI management, blood and injection safety, VMMC, timely initiation of ART, condom programming, community mobilization, life skills education and HIV communication). The following interventions were implemented:

#### Biomedical Prevention

##### Voluntary Medical Male Circumcision

Given the low MC prevalence and the 60% reduced female-to-male transmission risk for circumcised men, MoH has endorsed an ambitious VMMC scale-up plan (2015–2020), targeting 10–34 year old males. The Malawi MC model predicts an almost linear effect of MC prevalence on HIV incidence, so any increase will prevent HIV infections, but 80% MC coverage is required for a significant long-term prevention effect.<sup>86</sup> As of September 2014, a total of 150,000 circumcisions have been conducted in Malawi, the majority through United States Government (USG)/Malawi implementing partners who recorded 67,385 MCs in six high impact districts between October 2012 and September 2013. Between October 2013 and September 2014, USG implementing partners achieved 68,334 MCs provided through static and outreach service delivery sites at an average cost of \$134.48<sup>87</sup>.

<sup>85</sup> Malawi Service Provision Assessment Survey 2013–2014. Preliminary staffing analysis (Personal communication, Dr Jahn, Department for HIV and AIDS, MoH).

<sup>86</sup> Achieving the HIV Prevention Impact of Voluntary Medical Male Circumcision: Lessons and Challenges for Managing Programs, Sema K. Sgaier, Jason B. Reed, Anne Thomas, Emmanuel Njeuhmeli, 6 May 2014, PlosOne.

<sup>87</sup> All cost data included in this section is sourced from the 2014 PEPFAR Expenditure Analysis (EA), self-reported by implementing partners. Historically, PEPFAR's model in Malawi has been to wrap around the Global Fund grant implementation and support the successful scale-up of programs. Therefore, PEPFAR-related expenditures do not typically include costs covered by Global Fund such as commodities, or those covered by MOH such as facilities and salaries. The exception to this is the VMMC, CSW and MSM Prevention programs, the costs of which are all covered by PEPFAR partners.. PEPFAR EA data includes contain all investment, recurrent, program management, and strategic information spending for that program area.

Performance deficits are mainly explained by severe human resource constraints and challenges with demand creation targeting all audiences including women.

#### HIV Testing and Counselling

In order to scale up HIV testing and counselling, Malawi has task-shifted HTC to health extension workers and lay staff with additional HTC training. These cadres have delivered the bulk of HTC services for the last 10 years. In 2013 and 2014, over 5,000 existing providers underwent an HTC 'skills intensive training' to improve the quality of HTC testing at facility level. There are currently 724 static and 188 outreach HTC sites. The HTC program is currently testing about 430,000 clients per quarter, at an average unit cost of \$2.73. With a commodity cost of about \$1.1, this brings the HTC cost to approximately \$3.83 per person tested. Nine percent of all clients tested are positive, and 37% are accessing HTC for the first time. As ART coverage increases, the cost of HTC will also increase; this is because many more tests will need to be conducted to find the remaining HIV-infected individuals. Malawi is already experiencing the diminishing returns in HTC, as the proportion of first-time testers receiving a positive result is well below national prevalence.

Malawi already implemented a policy of mandatory confirmation of HIV infection before ART initiation in 2011, recognizing the heightened importance of accurate HIV test results for patients started on ART irrespective of clinical or immunological staging (such as under Option B+). WHO has subsequently issued a general recommendation supporting this decision (November 2014). Firm establishment of this policy in the Malawi program will greatly facilitate the move to universal ART eligibility for all PLHIV, which is planned for 2016.

825 static and 534 outreach sites provided HTC and more ART/PMTCT sites were integrated over the period of review.<sup>88</sup> Various HTC delivery modes have been implemented to facilitate access for all sectors of society. Provider Initiated Testing and Counselling (PITC) has been successfully established in TB, STI, ANC and maternity clinics, but routine PITC among outpatients or on medical wards is only implemented at some facilities. According to the MoH program report, a total of 2.7 million tests were conducted between January 2012 and March 2014. Out of these 31% were on males and 69% were on females, 48% of whom were pregnant. Out of all the people tested and counselled, 58% were 25 years old and above, 42% were aged 15-24 years, and 7% were children younger than 15. The majority of the HTC was done through PITC (56%) or through referrals and access to HTC sites (43%). 49% of clients accessed HTC with their partner and 33% accessed HTC for the first time in their lives.

In order to address the concept of gender and its relationship to cultural norms in the context of HTC, power imbalances, intimate partner violence and communication, the 2013 Malawi Comprehensive HIV Testing and Counselling Training included these issues in the couples testing module. The guidelines are currently under revision in 2015, and are further expanding to address PITC for those experience gender-based violence, and linkages to follow-up care. .

#### Condom Promotion and Distribution

A total of 31 million (30 million male and 1 million female) condoms were distributed in the public sector in the financial year 2012/2013. This represents 79% of the annual target. Out of these, 70% were distributed free through MoH and CBOs. The NSP 2011-16 aimed to ensure a continuous supply of male and female condoms and contraceptives through existing programs (Family Planning, HTC, MCH, and STI management). As part of Bridge II project activities, trained community based condom distributors in 8 districts distributed 3,887,709 USG-procured free male condoms between October 2012 and September 2013. For October 2013-September 2014, USG-supported socially marketed male and female condoms continued to register increased sales with record high sales of male condoms at 14,200,890 in high-risk settings. An additional 55,948 female condoms were sold in salons and through sex worker "queens". This was complemented by free condom distribution to vulnerable populations. A community based distribution program utilized trained volunteers to further distribute 11,837,517 free male condoms in eight districts.

#### Prevention of Mother-to-Child Transmission

Option B+ for PMTCT has resulted in a rapid increase in coverage for PMTCT with resultant reduction of transmission rates from mother to child to less than 9% by 2013.<sup>89</sup> The success of Option B+ is due to the very high ANC attendance rates in Malawi<sup>90</sup> combined with high HTC coverage using routine provider-initiated testing. The extensive decentralization of ART services to all facilities with ANC or maternity services has anecdotally contributed to greater acceptability of ART and reduced stigma overall. In 2013, retention of Option B+ women is comparable to the national average of ART retention at 12 and 24 months. Site level investigation has revealed that retention statistics are negatively affected by women who are documented as having initiated ART, but who do not return for their first refill visit after a month; an uptake challenge and not a retention challenge.

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<sup>88</sup> MoH Program Report 2013.

<sup>89</sup> WHO. *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach* June 2013. Geneva.

<sup>90</sup> National Statistical Office (NSO) and ICF Macro. 2011. *Malawi Demographic and Health Survey 2010*. Zomba. Malawi, and Calverton, Maryland, USA: NSO and ICF Macro.

Malawi established exposed infant follow up program from birth to 24 months of age in which infants are tested using DNA-PCR at 6 weeks and offered routine rapid testing at 12 and 24 months to facilitate early infant diagnosis. Malawi has introduced unique identifiers for exposed infants to allow for tracking & monitoring of exposed infants. In December 2013 90% of all known exposed infants received nevirapine (NVP) syrup prophylaxis and 63% were enrolled into exposed infant follow up before 2 months of age. Malawi has made significant progress in implementing option B+ for PMTCT since programming was launched in 2011. By the end of December 2013, there were 689 static ART/PMTCT sites providing HTC and initiating ART within ANC & maternity settings, including government, mission, and the private sector sites. A total of 11,815 HIV-positive pregnant women were on ART out of an estimated 15,750 in quarter 4 2013, equivalent to 75% ART coverage. 73% were retained on ART 12 months after initiation of ART.

The Malawi PMTCT program promotes male involvement according to WHO standards. CSOs including Malawi Interfaith Organization, *Mai Mwana* and community level CBOs are playing an important role in the mobilisation of pregnant women and their spouses to participate in PMTCT programs. Men to Men clubs (using Stepping Stones approaches) address men's behaviours, attitudes and gender stereotypes that discourage sero-status disclosure, intimate partner violence and women's vulnerability to HIV.

### STI Management

The total number of STI treated between July 2013 and June 2014 was 192,820. Considering the 80% completeness of reporting, this number represents an estimated 65% STI treatment coverage. Of the total number of STI cases treated, 40% were males and 60% were females, 13% of whom were pregnant. Two-thirds were 25 years and above, 23% were 20-24 years and 9% were under 20 years old. Nearly ninety percent of clients were symptomatic and the remainder were asymptomatic partners presenting with a referral slip from their infected partner. Of the symptomatic clients, 90% were index cases and 10% were partners.<sup>91</sup>

### **Non-Biomedical Prevention**

#### Social Behaviour Change Communication (SBCC)

BCC programs have primarily aimed at reducing risky sexual behaviour by increasing risk awareness and knowledge. There has been a notable shift from the development and distribution of traditional IEC materials to a more comprehensive response including complementary interventions (community mobilisation, one-on-one and interactive communications) and referrals to health services (HTC, PMTCT Option B+, condoms, VMMC). Between July 2012 and June 2013, 573 outreach audio-visual shows were conducted and 2,984 interactive sessions in schools, communities and workplaces were held. The shift to more interactive SBCC interventions has been accompanied in a decline in production of IEC materials from a total of 3,017,066 in 2009/2010 to 1,044,284 in 2012/2013. Interventions on the ground were complemented by national level interventions via radio, TV and print. The use of radio and TV plays a crucial component in SBCC efforts given the wide coverage of these media, and their being easily accessed by the intended beneficiaries. During July 2012-June 2013, the public sector supported a total of 342 hours of radio airtime and 92 hours of TV playtime for delivery of various messages on HIV and AIDS.

#### Targeted interventions for OVC, Girls and Young Women (10-24)

Small-scale interventions to empower girls have been successfully implemented (Go Girls Initiative, GLOW project, etc.). The YOUTH ALERT mass media program continues to have wide reach among adolescents with complementary activities specifically targeting girls. During implementation of youth alert between 2002 and 2009, the abstinence rate among youth (15-24) was increased to 3.8%.<sup>92</sup> Currently, there are 800 youth clubs where young people gather to listen to and discuss a youth-owned radio program. Dedicated youth friendly health services (YFHS) with family planning (FP) and outreach service delivery are critical to efforts to reach out to girls and young women. In the period July 2012 to June 2013, a total of 2,979,120 visits by young people to YFHS to access services were registered. HIV testing and counselling, being an entry point to HIV care and support services is also provided in YFHS sites. In 2012/13 financial year, 49,890 (25,982 male; 17,710 female) youths were tested for HIV and received results in YFHS facilities. A total of 4,488,260 (4,088,880 male: 399,380 female) condoms were distributed to youths through YFHS facilities. Normative change interventions targeting leaders, parents to prevent early child marriage, cultural practices which promote early sex initiation, cleansing, and GBV have demonstrated impact within targeted geographic areas of the country (i.e. 11 high prevalence southern districts). In 2013, a total of 1,156 frontline service providers were sensitized on gender, gender based violence (GBV), rights and responsibilities of PLHIV. Furthermore, 914 community mobilization and school level sessions on gender equality, human rights, prevention of harmful cultural practices, stigma and discrimination were conducted.

<sup>91</sup> Integrated HIV Program Reports 2013 Q3 – 2014 Q2.

<sup>92</sup> PSI Malawi Re-launching Youth Alert Mix Program July 2014. Nyasa Times. 26 July, 2014. <http://www.nyasatimes.com/2014/07/26/psi-malawi-re-launches-youth-alert-mix-programme/>. Accessed 27 January, 2015

Other interventions for young people, adolescent girls and young women shall include:

- Addressing barriers to services and misinformation, e.g. training for TB/HIV health and community service providers to provide youth friendly and confidential integrated sexual reproductive and health services and information covering TB/HIV prevention, treatment and care.
- Training teachers and community workers to provide gender-transformative, rights-based and age-appropriate HIV and sexual reproductive health education for girls and boys targeting in and out-of-school settings. Content will include culture and prevention and elimination of GBV.
- Linking survivors of GBV to access to medical resources including PEP and legal services.
- Strengthening capacity and involvement of organizations for young people, associations for young people LWHIV, community leaders to implement gender-sensitive and rights-based sexuality education, peer education and referrals in TB/HIV programs.

#### Comprehensive Key Population Interventions

The current response to key populations has been based on mapping and identification of hot spots. Interventions are focused on risk reduction, condom and lubricant promotion and access, demand generation for HIV services, community based HTC events, and tracked referrals. Cumulatively to date, NGOs have reported reaching about 1,400 MSM (at a unit cost of \$245.16) and 7,700 FSW (at a unit cost of \$41.58) with one or more interventions. However, these activities have not been standardized or well-coordinated to date. Strengthening the enabling environment to remove structural barriers to accessing services is also a key focus.

#### Interventions Focusing on Gender, Human Rights and Culture

Improving the quality of life for people living with HIV (PLHIV) is a top priority for the national response. Key strategic approaches adopted in Malawi include:

- Reduction of stigma and discrimination in all settings
- Reduction of gender-based violence in all settings
- Promotion of gender sensitivity in all program interventions
- Promotion of a legal and policy environment that protects human rights and dignity of PLHIV and of key and vulnerable affected populations
- Facilitation of effective participation of vulnerable people in decision-making, designing, implementing, monitoring, and evaluating HIV and AIDS programs
- Advocacy for the enforcement of legal and social rights of PLHIV, OVC, and other affected people including key populations.
- Lobbying and advocacy for the enforcement of the Gender Equality Act 2013 which was enacted on April 1 2014 and provides legislation aimed at promoting gender equality and equal integration of men and women in all functions of society, prohibiting and providing redress for sex discrimination, harmful practices, sexual harassment and providing for public awareness and promotion of gender equality.

The USG-funded BRIDGE II project reached 582,883 people in the southern region between 2009-2014 through community based discussion groups, using the project's participatory tools, with over a quarter million reached in the last two years of the project. The project's "Open Day" activities (community organized events addressing HIV prevention related topics) reached 1.7 million people over the six years of the project, with 362,589 and 347,522 people reached in 2012/2013 and 2013/2014, respectively. Just under 109,000 community members were referred to HTC, PMTCT, FP and other health services. Under Tasankha (the BRIDGE II mass media program), over 11,000 radio spots (almost 6000 in the last two years) aired on VMMC, PMTCT, multiple concurrent partnerships, discordancy, and living positively, as well as 2,678 radio programs aired on national and community radio stations (with almost 2 thousand over 2012 – 2014).

## Treatment, Care and Support

### ART Program

Malawi has passed an important milestone in June 2014: over half a million patients are now alive on ART. This is equivalent to 50% of the total HIV-positive population and it means that close to 1 out of 20 Malawian adults is now living on ART. This achievement seemed purely aspirational only a few years ago.

Malawi spearheaded the implementation of an integrated ART/PMTCT program following the development of the Option B+ policy in 2011. This led to a decentralization of ART/PMTCT services to all remote and rural MNCH sites which became de facto full ART sites for initiation and continuation of ART in pregnant women and all other patients. About 80% (498,004 out of 621,645, Jan –Dec 2013) of pregnant women attending ANC access HIV testing with 8% testing positive and are enrolled into care (option B+). The rapid scale up of Option B+ was facilitated by the high ANC attendance rates in Malawi (>95%).

Malawi's innovative approach dramatically accelerated PMTCT scale up and coverage increased from around 30% in 2010 to 75% in 2013. With rapid increase of ART coverage among HIV positive women in the reproductive age range, an increasing proportion of women in need of PMTCT are already on ART when getting pregnant: the latest quarterly program reports indicate that half of all HIV positive pregnant women diagnosed were in this group with the best protection against MTCT.

The national program also established a standard pre-ART program for children and adults and a standard program for EID and follow-up to age 24 months for HIV exposed children. These initiatives have increased early initiation of ART resulting in reduced morbidity and mortality amongst HIV infected children and adults.

In 2014, Malawi raised the CD4 threshold for ART eligibility from 350 to 500. This resulted in a 20% increase in quarterly ART initiations (from around 25,000 to 30,000), primarily from patients monitored in the pre-ART program. This acceleration of ART scale-up has been successfully absorbed by the program and the growing patient numbers are managed by a large number of peripheral ART sites. Preliminary findings from the MATCH 2.0 study from 2014/2015 confirmed the extremely low cost per ART patient per year:

*"Between 2010 and 2014, Malawi increased the number of patients on ART from 251,000 to 505,123 and has adopted ambitious new treatment policies (CD4<500, Option B+, etc.). Since 2010, the 6 sampled facilities experienced an average of 163% growth in HIV patient volumes. However, average cost PPPY at the 6 facilities remained comparable, increasing from an average cost of \$134 PPPY in 2010 to \$149 PPPY in 2014. (Overall cost by facility ranged from \$124 to \$176 PPPY.) Since 2010, ARV costs increased by 62%, as a result of the switch from d4T to TDF-based regimens; however, this was largely offset by reductions in service delivery costs, and specifically personnel and fixed costs, which were spread across increased patient volumes. Malawi's shift to 3-month ART prescriptions for stable patients – as well as increased task shifting – also led to decreased personnel costs over the 2010 study. Lab costs remained low due to limited access to viral load and other tests across the country. Initial results from sampled facilities suggest that, to date, ART scale up may lead to even lower service delivery costs than previously observed, as fixed costs are spread over larger patient numbers, and trends such as task shifting and multi-month scripts reduce HRH costs. In Malawi, these costs reductions were offset by increased ARV costs, but in countries that had previously switched to TDF-based regimens, total ART costs on a per-patient basis may be going down. This trend may enable increased availability of viral load testing which would drive up costs, but improve overall quality of care. This study will be repeated in Zambia in 2015 to provide an additional data point."*

Figure 11: Patients alive on ART at the end of each quarter in Malawi, stratified by size of facility (number of patients alive on ART)

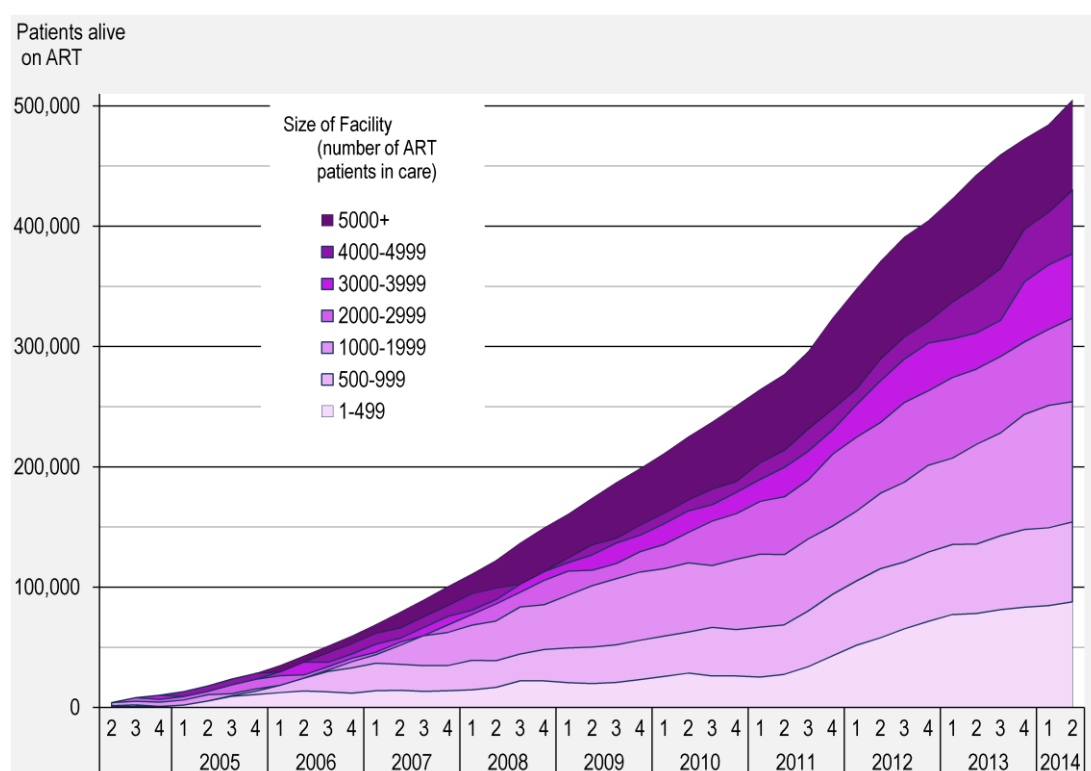


Figure 11 shows the increase of patients alive on ART by the end of each quarter. The number of patients alive on ART increased by 18,328 in Q2 of 2014. Figure 11 also illustrates the on-going decentralization of Malawi's ART program. From Q3 2011, the greatest increase in ART patient numbers was seen at sites with fewer than 500 patients alive on ART. By the end of June 2014, **54%** of the national ART patient cohort was in care at sites with fewer than 2,000 patients. This decentralization has allowed re-balancing the work load, making a further scale-up manageable for the national program.

Early mortality on ART has declined from 11% in 2005 to 3% in 2013. The latest quarterly program report confirmed the 12-month ART retention target of 80% for both adults & children has been reached. A further improvement of ART outcomes is expected from the adoption of the key 2013 WHO recommendations for ART eligibility (universal treatment for prisoners and children under five; raising the CD4 count threshold to 500).

**Early Infant Treatment:** EID & T was piloted in 2005 and standard HIV Exposed Infant (HEI) follow-up was rolled out following the implementation of the 2011 PMTCT/ART guidelines. By June 2014, a cumulative 118,642 HEI had been enrolled in follow-up. Quarterly enrolment of (known) HEI is almost 100% with 70% enrolling under the age of two months. About 80% of 628 sites with HEI collect DBS samples for DNA-PCR testing and samples are transported to one of seven labs that are performing the testing. Based on recent DNA-PCR results, the average transmission rate in HEI under six months has declined to 3.2%. This is attributed to the successful scale-up of Option B+, reaching about 80% coverage of all HIV-infected women in the population by mid-2014. However, early ART initiation among infected infants has remained unsatisfactory due to delayed transmission of DNA-PCR test results and high loss to follow-up among HEI.

**VL monitoring and timely switch to 2nd line:** The National Treatment Program has started rolling out routine VL monitoring for patients on ART to facilitate early detection of treatment failure and timely switching to second line ART. Eight laboratories in the national program provided VL testing. VL coverage in 2014 was estimated at only 17% of ART patients due for VL monitoring. This is due to delayed establishment of VL sample collection at peripheral sites and health worker challenges. The impact of VL monitoring on the rate of 2nd line initiation has been moderate to date with a quarterly increase of about 400 patients on 2nd line ART over the last year.

#### TB/HIV Management

In 2013, 89% of all TB patients had their HIV status ascertained and 94% of HIV positives were receiving ART. Out of these, 59% were already on ART when starting TB treatment and 41% started ART during or after TB treatment. Intensified case finding (ICF) in HIV clinics identified a total of 8,216 patients with symptoms consistent with TB who were referred for TB investigations.<sup>93</sup>

#### Care and Support

Before ART scale-up, the Community Home-Based Care (CHBC) program played an important role in providing palliative care and social services by. Successful ART scale-up has reduced the number of patients requiring palliative care dramatically and CHBC programs have refocused their activities to support treatment retention and adherence. During the 2012/2013 financial year, CHBC programs delivered 178,000 (89%) of the targeted 200,000 household visits. A cumulative total of 1,236 community volunteers and health personnel were trained in CHBC/palliative care, representing 72% achievement of the annual target. With the continued increase of PLHIV living healthy lives with ART, CHBC activities will continue to be adapted over the coming years.

### **TB Program**

Implementation of the NSP 2012–2016 enabled Malawi to strengthen the provision of quality DOTS services, to initiate programmatic management of drug-resistant TB (PMDT) and to build on community-based interventions introduced in the early part of this decade. TB treatment is available in all public health facilities. Christian Health Association of Malawi (CHAM), a private not-for-profit, contributes to 37% of health services including TB services. A handful of private facilities provide similar services. (Further disaggregation will be done to review the contribution of private for-profit facilities). The number of TB microscopy sites is 257 (1 centre covering approximately 62,256 population), a coverage that meets the general recommendation of 1 microscopy laboratory per 100,000 population, although distribution is inequitable.<sup>94</sup> With resources from this application, the Government of Malawi intends to further expand TB microscopic service to improve the population coverage to 1 per 35,500 population. Decentralization of TB registration has reached 247 sites but this represents only about 1/3 of ART sites. Collaboration with partners enabled specimen transportation from facilities without on-site TB microscopy services. One hundred and seventeen (117) LED microscopes are used in all 28 district laboratories and in other facilities with large TB burden. A total of 42 GeneXpert platforms are operating in 25 districts.<sup>95</sup>

The current algorithm identifies the following eligible groups: presumptive MDR-TB cases, PLHIV with sputum-smear-negative result, retreatment cases and hospitalized patients. Different partners have played their role in scaling up the procurement, distribution and use of GeneXpert platforms. TB REACH<sup>19</sup> and TB CARE II<sup>11</sup> contributed the largest number of existing GeneXpert platforms. The effect of GeneXpert on improved TB case finding is yet to be evaluated since the program has been implemented for three years. Based on experience in pilot project areas, the estimated contribution of GeneXpert is between 8-12 % of all notified cases in the implementation sites.<sup>96</sup>

<sup>93</sup> Global tuberculosis report 2014. WHO|TB data. [www.who.int/tb/data/](http://www.who.int/tb/data/).

<sup>94</sup> Malawi NTP Mid-Term Review Report 2014, p 32.

<sup>95</sup> Malawi NTP Mid-Term Review Report 2014, p 32.

<sup>96</sup> Personal Communications with Project managers ( TB CARE II and TB REACH).annual report ( TB CARE II and TB REACH).

The mid-term review of the TB NSP 2012–2016 concluded that despite considerable funding challenges, key TB program performance indicators had been maintained within internationally accepted levels.<sup>97</sup> Malawi successfully treated 82% of new and relapse cases registered in 2012. However, the treatment success rate for retreatment cases excluding relapses was only 57% for the same year. Nearly 92% of all TB patients in 2012 were tested for HIV and 56% were HIV-positive; 90% of these were receiving cotrimoxazole preventive therapy (CPT) and 88% received ART.<sup>98</sup> The first nationwide drug resistance survey (DRS) performed in 2009/2010 indicated a prevalence of MDR-TB of 0.4% (CI 0.1%-0.8%) among new TB patients and 4.8% (CI 3.1-6.1%) among retreatment cases.<sup>99</sup> With the support of partners, TB infection control (TB-IC) has been introduced into all district hospital and CHAM facilities but not all high volume clinics to date. Implementation is dependent on oversight from the IP committees and is variable.

## **TB/HIV**

### HIV Testing in TB Patients

Routine HIV status ascertainment among TB patients was fully established in 2007 and has been maintained at around 90% since then (see [Figure 6](#)). Until 2010, about 66% of TB patients tested were HIV-infected. The measured co-infection rate has started to decline slowly, reaching 56% in 2013, which is very similar to the 59% HIV prevalence among TB cases estimated by WHO. This is consistent with near-complete, non-selective HIV ascertainment among TB patients.

### ART Coverage among Co-Infected Patients

In line with the high rates of HIV ascertainment, ART coverage among HIV-positive TB patients has been consistently above 90% (by the end of TB treatment) for several years.<sup>100</sup> Program data from 2013/2014 indicate that 92% of HIV positive TB patients were on ART by the end of TB treatment and about 2/3 of these were already on ART when starting TB treatment.

### Intensified Case Finding (ICF)

ICF in pre-ART and ART clinics has been implemented consistently since 2011. ICF coverage among ART patients has stabilized at >95% and the point prevalence of positive screening outcomes is around 1% of all patients in care. The continuously increasing proportion of ART patients among TB treatment initiations is probably related to the scale-up of active TB case finding in ART clinics.

### Isoniazid Preventive Therapy (IPT)

IPT is another essential intervention for TB prevention. Given daily for six months, it reduces the overall risk of TB in PLHIV by 33%. In addition, if given to children aged five years and below, it protects them from developing active TB. To this effect, all children five years and below who are household or close contacts of TB index cases and who have active TB ruled out, should be offered IPT for not less than six months irrespective of their HIV/ART status. All other age groups (above five years) who are in contact with a TB index case and who have active TB ruled out and who are also HIV positive, should be offered IPT for a period of not less than six months irrespective of their ART status. In summary, in Malawi the criteria for starting IPT include: 1. A child under five years of age irrespective of their HIV status, who is a contact of a known TB index case and where active TB has been ruled out, and 2. a PLHIV who is a contact of a known TB index case, where active TB has been ruled out. IPT should be given with pyridoxine to prevent neuropathy.

All pre-ART patients with a negative screening outcome for TB symptoms are eligible for IPT. The first (large scale) distribution of isoniazid and pyridoxine for the HIV programs reached the sites during July 2012.

A total of 35,082 (79 %) of 44,479 patients retained in pre-ART were on IPT by the end of June 2014. Isoniazid was in stock at 606 facilities during the July 2014 supervision visit. IPT coverage may increase further over the next quarters.

## **Impact: Mortality**

An estimated 834,000 Malawians have died of AIDS since the start of the epidemic in the 1980s. Figure 12 shows the number of annual AIDS deaths among men, women and children between 1990 and 2020. The AIDS death wave is thought to have peaked at 93,000 in 2004 and started to decline rapidly with introduction of free ART later that year. Malawi's rapid and successful ART scale-up between 2004 and 2014 is estimated to have:

<sup>97</sup> Malawi NTP Mid-Term Review Report 2014, pp. 9-10.

<sup>98</sup> WHO Country Profile 2014 Malawi.

<sup>99</sup> Malawi DRS survey Report 2011.

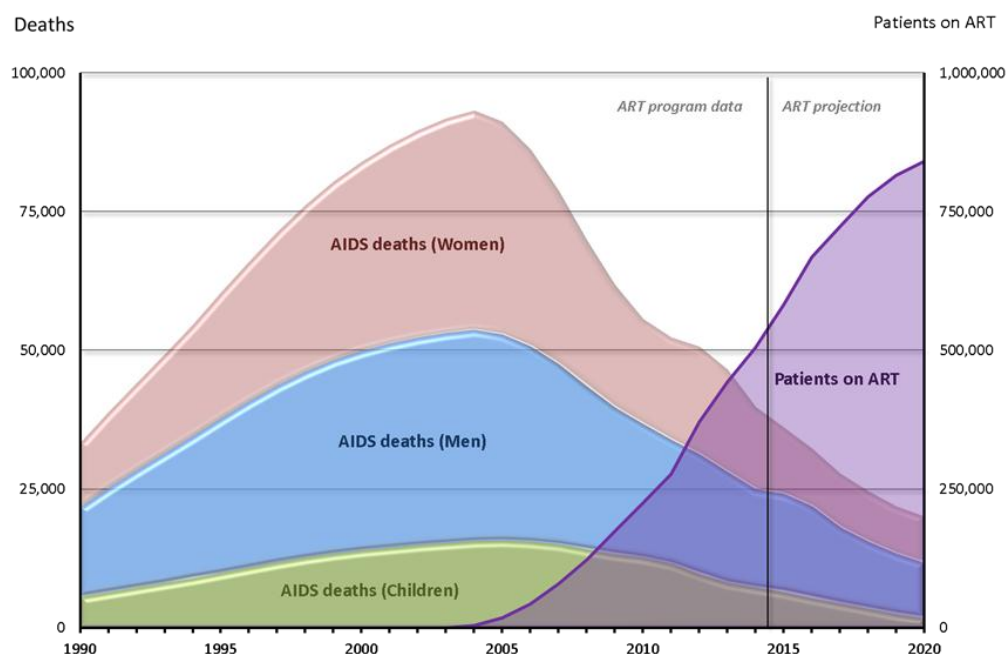
<sup>100</sup> MoH Malawi: Integrated HIV Program Report April-June 2014.

- Averted 275,000 AIDS deaths
- Gained 1.4 million life-years, primarily among young adults in their peak productive life period.

In spite of the ART scale-up, HIV remains the leading cause of death among adults (15-49 years): in 2013, 38,000 (66%) of 56,500 deaths in this age group were attributed to HIV. The relative burden of HIV among children (0-14 years) was lower with 10,000 (10%) of 104,000 deaths attributed to HIV.

The mortality rate among new smear-positive TB cases is thought to have declined from 18 (per 100,000) in 2005 to 9 (per 100,000) in 2012. WHO estimated 3,400 TB deaths among HIV positives (all ages) in Malawi for 2013. This would imply that only 7% of the total 48,000 deaths among HIV-positives were due to TB, which is much lower than the 30-50% attributed to TB in autopsy studies among HIV positives in the region<sup>101</sup>. However, the TB prevalence survey shows that TB prevalence and incidence may be twice as high as previously estimated and this would be consistent with a much higher TB mortality in PLHIV.

*Figure 12: Estimated AIDS deaths (2014 Spectrum model) and ART scale-up (MoH program data up to mid-2014)*



### Impact: HIV Incidence

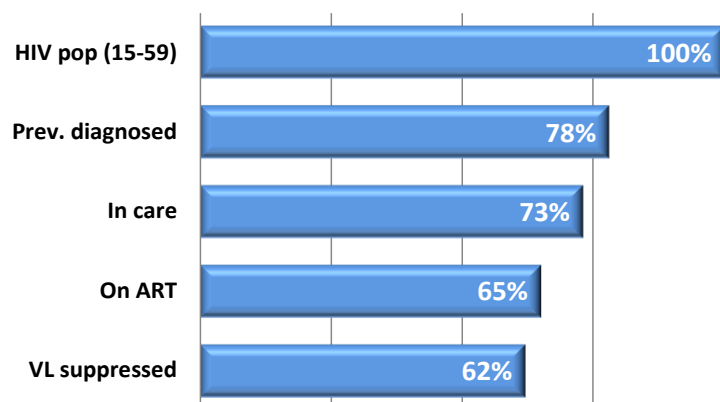
By mid-2014 – 10 years after the start of ART roll-out – half of the 1 million HIV positive Malawians were on ART and incidence had declined to 0.4. This massive decline in the new infection rate has outpaced the population growth, which is threatening to offset any reduction in new infection rates, and it has led to a sustained reduction of the absolute number of people newly infected each year from 120,000 in 1999 to 33,000 in 2014. Significant gains have also been made for paediatric infections through implementation of Option B+ in 2011: in just 3 years, the number of children infected by their mothers (including during the breastfeeding period) has declined by 66% (from 30,000 in 2010 to 10,000 in 2014).

These model estimates have recently been corroborated by a high quality, population-based survey in a large household sample in Chiradzulu district (2013).<sup>102</sup> This survey directly measured HIV incidence and prevalence, and ART coverage and viral suppression rates among the HIV-positive population. HIV prevalence among adults (15-59) was 17% and incidence was 0.4 (0.6 in women and 0.2 in men). This low incidence in spite of high HIV prevalence was consistent with excellent coverage along the treatment cascade in the population. To date, these are the best treatment outcomes at the population level documented anywhere in the world. Out of all HIV-positive adults: 78% had been previously diagnosed, 73% were in care, 65% were on ART and 62% were virally suppressed.

<sup>101</sup> Cox JA, Lukande RL, Lucas S, Nelson AM, Van Marck E, Colebunders R. Autopsy causes of death in HIV-positive individuals in sub-Saharan Africa and correlation with clinical diagnoses. *AIDS Rev* 2010;12(4):183-94.

<sup>102</sup> Maman D, Etard J-F, Zolower D, et al. Chiradzulu HIV Impact in Population Survey. In: Epicentre, ed. Paris: Medecins Sans Frontieres, 2014.

Figure 13: Treatment cascade for the HIV-infected adults (15-59) in Chiradzulu district (2013). Proportions are for all HIV infected adults (not nested).



Long term viral suppression rates were excellent with 90% of patients achieving viral loads of <1,000 after seven or more years on ART. Although this cross-sectional survey was unable to prove the causal link between high ART coverage and the low rate of new infections, this is very likely considering the ground-breaking results from the HPTN052 trial which was conducted in Malawi and eight other countries in 2010/11, showing that early ART reduces HIV transmission between sexual partners by 96%.<sup>103</sup> Low circumcision rates in Chiradzulu give further weight to the successful ART program as the main driver of low HIV transmission rates (only 1.7% of men were medically circumcised and another 27% reported full traditional circumcision).

### 1.2.c Challenges, lessons learned, plans how to address the constraints described

Although the progress made and the successes achieved in Malawi are notable, there were a number of limitations experienced. These included:

#### VMMC

##### Limitations

The uptake of VMMC has remained low. Demand creation activities have been inadequate resulting in many men being reluctant to undergo surgery and concerns of abstaining from sexual activity for six weeks. Severe HRH constraints and low numbers of health workers trained in VMMC have limited scale-up and decentralization of VMMC services. Weak in-country logistics coordination has led to shortages of VMMC commodities at some sites.

##### Lessons Learnt

Prioritising males between 10 and 34 will increase uptake and impact. The VMMC program will become more sustainable long term through introduction of early infant male circumcision (EIMC) in combination with parental education. In addition, the introduction of innovative ways for service delivery, such as using VMMC medical devices like Prepex, and revamped demand creation activities will scale up VMMC, continue to provide national support and address misconceptions. It is also necessary to encourage female champions to promote VMMC.

<sup>103</sup> Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2012;365(6):493-505.

## HTC

### Limitations

Figure 14: National HTC program outputs 2008-2014

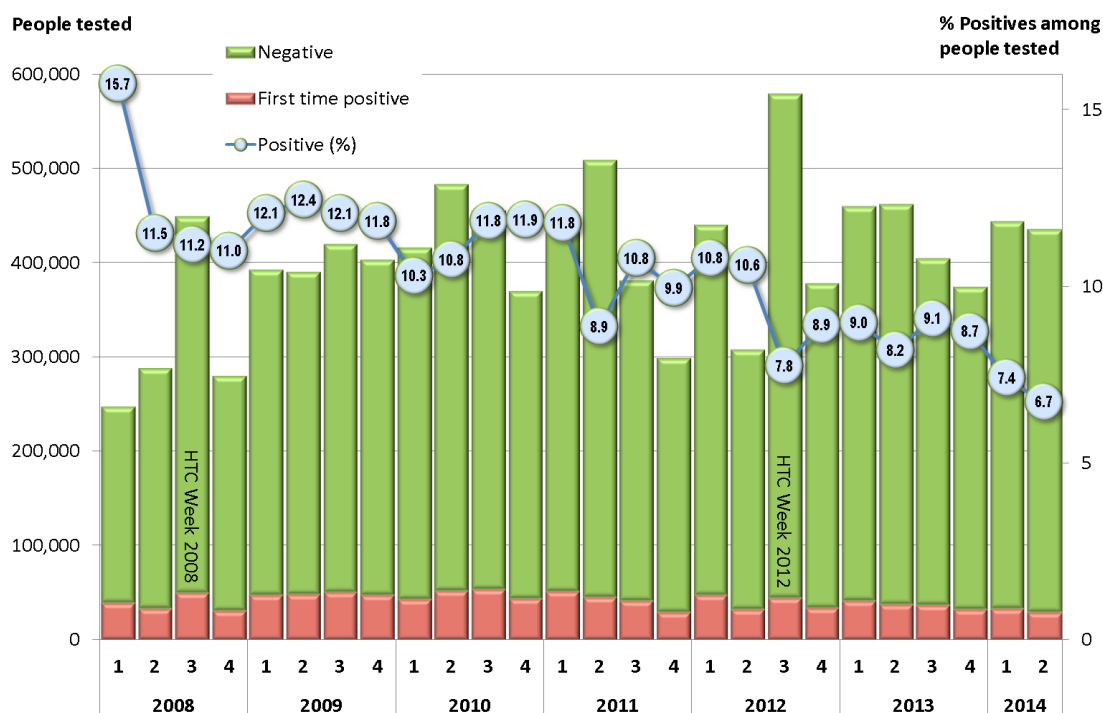


Figure 14 shows that HTC outputs have flat lined around 400,000 tests per quarter since 2009 and the program has only achieved about 60% of the ambitious scale-up target of 2.8 million tests to be performed between July 2013 and June 2014. National HIV testing week campaigns in 2008 and 2012 resulted in a short-term increase of people tested and a small increase in the number of HIV positives identified. However, both of these increases were followed by a drop below average outputs in the following quarter, significantly reducing the net effect of the campaigns. The main reasons for the recent underperformance have been:

- Reliance on HSAs trained as HT Counsellors. These cadres are low-paid, inconsistently supervised and frequently engage in other activities that are incentivised by allowance payments, leading to HTC service disruptions at health facilities.
- Underreporting of tests performed at many peripheral testing units and in outreach and community settings.
- Concerns about 'protocol drift' and poor proficiency of some HTC staff have been addressed by a national re-training and re-certification campaign for all active HTC providers in 2013. This led to further service disruptions as staff was taken out of their stations to attend trainings and about 10% failed their practical examination and had to suspend testing.
- Poor stock management of test kits has led to supply ruptures in 2010-2012. However, centrally coordinated active supply management, daily inventory reporting at all testing locations and focused supervision have led to significant improvements and almost universal availability of test kits at all sites.

Figure 14 also illustrates how the number and proportion of new HIV diagnoses among all clients tested has gradually declined between 2010 and 2014. Over the last 2 years, the proportion of positive tests has been significantly lower than the HIV prevalence among adults (around 10%; over 90% of clients tested are adults). This is primarily explained by two factors:

- Over 50% of PLHIV are already on ART and the number and prevalence of PLHIV not knowing their status continues to decline significantly. The 'law of diminishing returns' implies that an ever-increasing number of clients will need to be tested in order to identify sufficient numbers of positives to attain the targeted ART scale-up to 90-90-90. This will be coupled with a scale-up of PITC among patient groups with elevated risk in order to increase efficiency and diagnostic yield.
- False negative test results are thought to be a particular problem in congested ANC clinics and during campaigns, where testing protocols and incubation times may not be adhered to. Proficiency testing and external quality assurance testing

have not been implemented consistently and remedial action has not always been taken when problems were identified.

There is some indication that HTC access may be lower in MSM compared with the general population: Around 60% of MSM in Blantyre, Mzuzu, and Nkhata Bay, but only around 30% in Lilongwe and in other rural sites, reported ever being tested for HIV. Across the seven sampled locations, 50-98% of MSM who tested positive in the survey said they did not know they were infected.

### ***Lessons Learnt***

These challenges will be addressed in the 2015-2020 NSP by a) improved active data collection at all health facilities and enhanced passive reporting from stand-alone HTC sites; b) daily inventory reporting at the testing room level; c) quarterly, centrally coordinated distribution of HIV test kits to all testing sites; and d) introduction of dedicated “HIV Diagnostic Assistants” seconded to all health facilities.

The highest yield of HIV-positives is realized from the health facilities. Programmatic costs for community testing (HTC campaigns) are significantly higher when compared with facility-based testing and, with only a fraction of the yield, need to be more targeted for a higher yield. Impact mitigation interventions targeting OVCs provide an important opportunity to identify unknown positives among OVC.

### **Condom Promotion**

#### ***Limitations***

The condom program has been affected by challenges related to uptake and supply. These included supply ruptures at different locations, especially in rural areas and hotspots that are frequented by key populations. Condom use in long-term discordant couples has not been sufficiently promoted although over 40% of new infections are estimated to occur within this group. Gender inequalities disempower women and girls from being able to negotiate safer sex and condom use. Women prefer male condoms, indicating that female condoms are uncomfortable or they lacked confidence in using them. However, female condoms are commonly requested by FSW. Procurement is based on past consumption data and not forecasting of condom needs or demand. There are challenges in condom programming coordination and strategic leadership.

#### ***Lessons Learnt***

Comprehensive condom programming using a ‘total market approach’ covering education and distribution in all HIV and AIDS programs is needed. Condom promotion through campaigns will increase uptake, including that of female condoms. There is also a need to use condom champions to promote condoms among targeted key and vulnerable populations. Condom programming committees have been revived to improve condom forecasting and programming nationwide. Implementing partners of donors such as USG have been very successful in promoting and distributing both free and socially marketed condoms. GoM intends to coordinate closely with such programs to replicate results where possible. A national condom steering committee is in place and will be invigorated to coordinate these activities. The committee will utilize the geographical burden of HIV in the districts for distribution of condoms with high HIV-burden districts receiving more condoms per male.

### **Social Behaviour Change Communication Intervention**

#### ***Limitations***

Implementation of evidence based SBCC is still inadequate. There is low coverage in many of the hot spots, and there is insufficient focus on structural barriers to behaviour change, particularly related to GBV. Low rates of male engagement in routine ANC presents a barrier for couples testing and facilitated disclosure.

#### ***Lessons Learnt***

SBCC programs should be evaluated and tailored for impact and cost-effectiveness. SBCC interventions should be targeted towards primary prevention and retention in care, focusing on key, vulnerable and high risk populations. SBCC packages should address gender and cultural norms that determine service utilization. Demand generation needs to be complemented by condom access and strong linkages to services.

### **Comprehensive Interventions for Key and Vulnerable Populations**

#### ***MSM and FSW***

#### ***Limitations***

Key population size estimates have been geographically limited and their reliability uncertain, making it difficult to assess service coverage and to track referrals. The most recent estimates are from the 2014 BBSS (analysis underway) and the just released 7-site MSM study. HIV services are not tailored specifically to MSM or FSW. MSM and FSW often report they feel deterred from

accessing health services or attempt to conceal their sexual activity, which may lead to receiving inappropriate or incomplete services, especially for STI management.

There is limited coverage of sex work interventions in Malawi with most organizations operating in selected areas. This is largely due to the fact that most implementers have limited capacity in sex work programming characterized by limited number of personnel, expertise and skills needed for designing, planning, implementing and monitoring sex work interventions. There is also very weak coordination and networking among organizations implementing sex work programs in Malawi. This is heightened by lack of visible leadership on sex work from public institutions.

### ***Lessons Learnt***

The CHPI study demonstrated the feasibility of providing a comprehensive package of HIV prevention services to MSM, of high client retention, and moderate improvements in behaviour. Standardized comprehensive service packages need to be developed (peer-based education, risk reduction and condoms/lubricant, routine HTC, and STI screening). “Safe spaces” with trusted providers need to be established and service packages need to be targeted to areas where key populations can be found in high numbers. Available data do not support the assumption that MSM are a significant driver of the HIV epidemic in Malawi, based on the relatively small population size and similar HIV prevalence in MSM compared with the general adult male population in the surveyed locations.

### ***Adolescent Girls, OVC, Youth***

### ***Limitations***

Implementation of primary prevention for youth and Youth-Friendly Health Services (YFHS) has remained unsatisfactory and prevention and impact mitigation for GBV has been identified as a major gap in the response. There are few integrated models targeting girls or youth similar to the design of Go Girls! <sup>104</sup> For YFHS, there are capacity problems - lack of trained staff, inadequate staff at health centres (which makes it difficult to prioritize needs of youth), and inadequate SRH supplies and materials (e.g., condoms and information packs). Adolescents have cited lack of privacy and judgemental health worker attitudes as the main deterrents for seeking SRH services and STI treatment. Although life skills education has been integrated within the primary and secondary school curricula, teaching of life skills has faced various challenges. While almost every district also has NGOs and CBOs promoting life skills education amongst out-of-school youth and for in-school youth clubs, participation of girls in such life skills clubs is often poor. Associations for young people living with HIV (YPLHIV) have been established in all districts to encourage meaningful involvement but they are not yet functional due to capacity and resource constraints.

### ***Lessons Learnt***

Targeted interventions addressing broader SRH issues are needed (e.g. delayed sexual debut, fertility, marriage, sexual violence, intergenerational sex, transactional sex) through comprehensive programs which include behavioural prevention, condoms, service packages, referrals to YFHS, education, and economic strengthening. It is necessary to modify some approaches in the YFHS package to provide more youth access to the services. OVC adolescents are a critical population currently not reached with comprehensive prevention services despite their increased vulnerability. Strategies for prevention, impact mitigation/social protection need increased focus on male and community norms/practices around GBV with robust linkages to services.

### ***Prisoners***

### ***Limitations***

The 2012 HIV, STI and TB prevalence prison study documented that health care services provided in prisons, including those for HIV, STI and TB, are often of substandard quality and often do not adhere to national guidelines. Frequent stock outs of reagents and/or drugs were reported. Poor hygiene, water supply, sanitation, indoor air pollution and nutritional quality of food were also noted. These factors facilitate disease transmission and hinder effective care and recovery. Distribution of condoms is still not permitted in prisons. Referral services for inmates upon release from prison need to be strengthened and expanded to meet their prevention and care needs.

### ***Lessons Learnt***

Provision of prisoner-targeted information may help prevent and better manage HIV, STI and TB in prison and after release. Provision of frequent routine HTC, STI and TB screening and treatment in prison can facilitate identification of positive cases for prompt referral into appropriate care. The adoption of “test and treat” in prisons should improve health of HIV+ prisoners and reduce transmission of HIV among inmates.

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<sup>104</sup> Johns Hopkins Bloomberg School of Public Health/Centre for Communication Programs (2011). Malawi Resource and Program Mapping. Johns Hopkins Bloomberg School of Public Health/Centre for Communication Programs. Baltimore, Maryland. Developed under the terms of USAID Contract No. GHH-1-00-07-00032-00, Project SEARCH, Task Order 01. Pg1.

## Gender

### Limitations

The 2014 Gender Assessment of the National HIV Response identified several limitations: lack of consistency in compiling sex disaggregated data, including for the transgender group; inadequate programming of gender-based violence and gender-transformative programs for hotspots which address HIV related gender and cultural norms, vulnerability of women and girls to HIV; vulnerability for boys and men to HIV, masculinity and access to HIV and SRH services for men; and inadequate capacity of teachers, health and other service providers to offer gender-transformative services.

### Lessons Learnt

It is necessary to scale up gender-transformative HIV interventions to promote gender equality and to reduce women's and girls' vulnerability to violence and HIV. HIV program staff and service providers should be trained in gender-transformative HIV approaches and advocacy, and provided with tools to plan, implement, monitor and report on key populations and vulnerable groups.

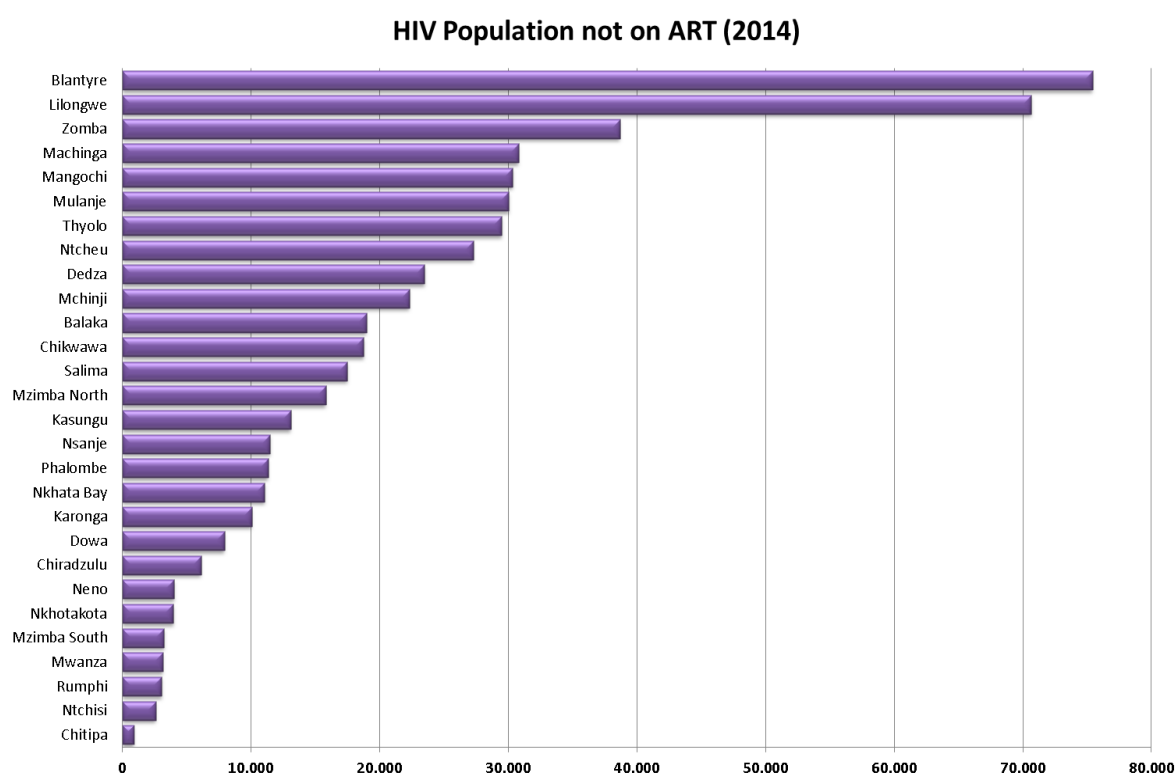
## ART/ PMTCT

### Limitations

Similar to all other countries in the region, ART coverage among children (29%) has remained lower than for adults (54%) (Program results from June 2014 using all PLHIV in the denominator).

Triangulation of district HIV population estimates with ART program data (June 2014) reveals considerable differences in ART coverage and shows that the largest number of HIV-positives not yet on ART is concentrated in a relatively small subset of Malawi's 28 districts: 50% of the estimated 540,000 PLHIV not on ART by June 2014 were in six districts (Blantyre, Lilongwe, Zomba, Machinga, Mangochi and Mulanje).

Figure 15: Distribution of the estimated HIV population not on ART by district (June 2014)



Uptake and retention among pregnant women enrolled under Option B+ has been suboptimal with around 80% of HIV pregnant women identified at ANC (not yet on ART) actually initiating ART and about 7% of those who started lost to follow-up at 24 months after ART initiation.<sup>105</sup> The majority of women classified as lost to follow-up are likely to have stopped/interrupted ART, but others will have transferred to another facility without notifying the previous site and the actual proportion retained on ART

<sup>105</sup> Malawi Integrated HIV Program Report October, 2013.

may be higher than reported. Most of the women lost to follow-up failed to return after their first visit and many of these may have never actually started ART due to inadequate counselling and preparation in the initial phase of implementation.

Major challenges for ART include:

- Low paediatric & infant ART coverage
- Adherence and retention in care
- Sample transportation for EID & routine VL testing

### ***Lessons Learnt***

The program is closely examining the different modes of delivery to further improve uptake and retention on Option B+, such as improved, standardized patient education, a well-coordinated long-term public education campaign, scale-up of peer-support groups and expert clients with linkages to health facilities (see 2014 m2m report). An integrated sample transportation system that would cater for all lab needs at the facility including EID, VL and sputum.

Early identification of HIV-positive people and enrolment in care would support the 90-90-90 goal. Retention in care ensures optimal monitoring on ART and the attainment of viral suppression.

## **STI**

### ***Limitations***

The reported STI program coverage has remained unsatisfactory due to a combination of factors such as poor documentation and reporting in the public sector and even more in the private sector where many STI clients prefer to go due to issues of confidentiality. PITC coverage among this high risk patient group has remained unsatisfactory due to lack of integrated STI/HTC services. Referrals to HTC services and weak back-referrals have led to missed opportunities for testing and access to HIV services.

### ***Lessons Learnt***

Training and regular supportive supervision visits should improve the consistency and quality of STI services and reporting in both public & private sectors. The substantial proportion of STI clients aware of their HIV-positive status, coupled with HIV-negative repeat STI clients, indicate insufficient implementation of positive living strategies and risk. Integration of STI/HTC services will lead to increased HTC for STI clients who have a higher prevalence than the general population and hence will contribute significantly towards the 90-90-90 NSP targets.

## **TB Program**

### ***Limitations***

The mid-term review identified inadequate financing as the main challenge to implementation of TB activities, resulting in the NTP being highly dependent on external funding. It is therefore imperative that the NTP ensures that the gains so far made are not lost and that the current NSP and successor NSPs are adequately funded.<sup>106</sup> Infrastructural deficiencies at many peripheral facilities preclude TB diagnosis and implementation of TB infection control (IC) measures.<sup>107</sup> Insufficient human resources for health and absence of a coordinated human resource development approach hindered implementation of the NSP. The NTP will increase engagement with the appropriate departments in the MoH to strengthen human resources for TB. The recently released provisional results of the prevalence survey indicate that Malawi has low performance in TB case detection as only 35% of all expected smear-positive TB cases are notified. The predominant modality of case detection is passive except for PLHIV. This has resulted in missed opportunities for early case detection in health care settings. Although the NSP 2012-2016 mention vulnerable populations and activities are on-going, there were no specific strategies for each of the vulnerable and at-risk populations.

Most hospitals are not structured suitably for TB IC for TB and MDR-TB case management. Health facilities do not systematically implement TB IC policies/ strategies. There is no mechanism to monitor the TB IC implementation in health care setting.

Absence of linkages between Maternal, Newborn and Child Health (MNCH) services and TB/HIV services prevents the provision of integrated paediatric TB/HIV care. GeneXpert platforms are installed in 40 sites, and utilization has not been optimal for varying reasons. These include lack of awareness, reluctance by clinicians and poor TB screening among PLHIV and other risk groups as well as low index of suspicion for MDR-TB among providers. The current reporting system does not capture GeneXpert contribution at the national level.

Limited DST facilities with weak sample transportation has hindered optimal MDR-TB case finding. PMDT is entirely community based and linkage between hospitals and community based MDR- TB care providers is poor. Nearly 25-30% of MDR-TB patients

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<sup>106</sup> Republic of Malawi, Ministry of Health. National Tuberculosis Control Program. Strategic Plan for the Year 2015 to 2020.

<sup>107</sup> Malawi NTP Mid-Term Review Report 2014, p 34.

die before treatment is initiated, mainly attributed to delays by the patient, as well as the health system. This includes late presentation of patients to health facilities and a lengthy diagnostic pathway. Access to clinical follow-up and ancillary laboratory services is limited, and so are bacteriological follow-up tests on these cases. These deficiencies have informed this request for support to improve clinical monitoring and facilitate appropriate follow-up of DR TB patients.

The involvement of communities in TB control activities is hindered by the lack of enablers to enhance treatment adherence.<sup>108</sup> The NSP has strategies to enable the provision of quality and comprehensive services based on needs to vulnerable and at risk populations, and to ensure equity and a rights-based approach to the provision of services.<sup>109</sup> The NSP also articulates the importance of determining the scope and responsibility of community level workers including volunteers. The community level workers will work towards improving public awareness towards TB, identification of presumptive TB cases, referral to diagnostic facilities, treatment follow up and defaulter (lost to follow-up patients) tracing.

The TB data system is still mostly paper-based, except at zonal and central levels, and the TB surveillance system is parallel to the national health management information system (HMIS) system.<sup>110</sup> TB data are collated at district level and are not available as case based data at central level, preventing full analysis of program performance. The latter does not capture most core TB control variables. The development, piloting and implementation of an electronic TB register is described in the NSP as a critical step in resolving these deficiencies. Integration of quarterly supportive supervision with existing HIV supervision system will strengthen the quality of service delivery and data issues in an efficient way.

### **Lessons Learnt**

The NSP describes activities to address these deficiencies and to overcome geographical barriers by increasing the number of facilities providing TB diagnostic services.

Approximately 95% of TB cases are detected in facilities through passive case finding, but there is minimal active TB triaging/screening in facilities.<sup>111</sup> The prevalence survey has also revealed that 65% of prevalent cases had been in a health care setting at least once, which indicates a high rate of missed opportunities. Systematic TB screening in all health care setting will be a key strategy. Although 98% of PLHIV are reported as screened for TB in ART settings, less than 1% have symptoms and are investigated for TB but the proportion diagnosed with TB is unknown.<sup>112</sup> To address these deficits, the NTP revised the chronic cough register (CCR) in 2014 to incorporate GeneXpert tests and to enable TB screening and testing in all parts of facilities (Child Wellness clinics, Antenatal Care Clinics, HIV care settings and general out-patient departments). Increased availability and improved use of these registers will be emphasized to raise the case detection rate.

TB disease burden in Malawi tends to be heterogeneous. There is a tendency to cluster by geographically defined areas and specific population groups. Although undertaking and availing prevalence data at subnational (zone, district) level is not feasible, existing data (notification and laboratory data) will be used for stratification and focus interventions. NTP will work to intensify efforts for TB detection in areas where the risk and burden of TB is high.

Introduction of new technology requires a series of orientations for health workers to facilitate efficient use. GeneXpert helps to improve early detection and diagnosis of TB. The turnaround time is short and can be used as a point of care for patients who have an increased risk of TB, outreach/mobile/active TB case finding efforts and groups who are likely to have adverse treatment outcomes if diagnosis is delayed. Power availability and interruption, health workers awareness, sample transportation, size of eligible population and improved quality of TB screening are important factors that should be considered while scaling up GeneXpert.

Community based MDR-TB management has helped NTP to enrol 165 MDR-TB patients. Initiation of MDR-TB treatment requires prior evaluation of patient for other conditions or comorbidities that may affect choice of treatment modality. Quality of MDR-TB management has to be strengthened through improved linkage between clinical service team and community level. Although health workers have been trained, close clinical mentoring is required to maintain quality services. Follow up of patients (clinical and laboratory) needs to be ensured through provision adequate support for patients and strengthening the capacity district and referral hospitals. Strengthened recording and reporting will support better clinical and programmatic management.

To cater for the constrained funding for programmatic activities highlighted in Section 1.1, the NTP increased joint trainings and supervisory visits with the HIV Department. Challenges encountered highlighted the need for schedules and tools to be realigned to accommodate both programs. Coordinated trainings and supervisory visits have been prioritized in the NSP.

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<sup>108</sup> Malawi NTP Mid-Term Review Report 2014, p 39

<sup>109</sup> Malawi NTP Mid-Term Review Report 2014, p 14

<sup>110</sup> Malawi NTP Mid-Term Review Report 2014, pp. 46-47

<sup>111</sup> TB CARE II Malawi Quarterly Report, Q3 2014

<sup>112</sup> Malawi Integrated HIV Program Report October, 2013, p 9

Lack of integration of TB IC into general infection prevention (IP) and lack of management and oversight of both of these results in limited progress in TB IC implementation and on-going transmission of TB, especially in health care facilities and other at-risk environments such as those found in correctional facilities.

#### **1.2.d Linkages with National Health Strategy. How will implementation impact disease outcomes?**

The Health Sector Strategic Plan (HSSP) (2011 – 2016) indicates HIV and TB as priority conditions that are included in the Essential Health Package (EHP) for Malawi. Consequently, implementation of the national health strategic plan also predominantly addresses programmatic needs of HIV and TB response. Evidently, significant investments in human resources for health (HRH) that have led to doubling and tripling in numbers of some health cadres from the 2004 levels have resulted in increased coverage of various interventions in the HIV and TB response. Task shifting arrangements, as enshrined in the national health strategic plans have improved access to interventions such as HTC for HIV and case detection for TB.

There is also concurrence in focusing on strengthening various components of the health system as presented in the HSSP and National Strategic Plans for HIV and TB response. The content in all strategies highlights the need to strengthen human resources, laboratory capacity, procurement and distribution of essential services, and continue decentralization of service delivery for HIV, TB and general health services.

Specifically, the linkages are also demonstrated by the fact that the policy and resource implications of achieving HIV and TB objectives, as enshrined in respective NSPs, are predominantly addressed in the HSSP. For example, the cross-cutting components of the health system including HRH, health financing and procurement and supply chain systems will be required to achieve the goals and the three objectives of the NSP for HIV and AIDS response (“90-90-90”) and the goals and the two objectives of the TB NSP (reducing TB prevalence and TB mortality by 50%) requires an aggressive response to scaling up TB and HIV case detection and treatment, as well as the implications on cross-cutting components of the health system such as human resources for health; health financing and procurement and supply chain systems.

Correspondingly, the HSSP mentions investment in HRH needs in terms of increasing numbers and improving skills of health workers to effectively deliver the EHP which includes HIV and TB interventions. Improving access to medicines and medical supplies including commodity security for HIV and TB also represents a key outcome of the HSSP. Health infrastructure development to support delivery of TB and HIV services such as construction of TB microscopy laboratories, rehabilitation and expansion of laboratories, expansion of some health facilities to cater for ART/PMTCT and TB service provision have been implemented. With regard to health financing linkages, the national health strategy pursues increasing financial resources for the health sector and improving efficiency in delivery of health services including HIV and AIDS. More recently, a health financing strategy is being proposed to achieve additional resource generation and technical and allocative efficiency.

Some content divergence between the HSSP and HIV NSP has been noted and will be addressed in the successor to the current HSSP. While the HSSP prescribes task shifting as a way of increasing personnel coverage in the health system, it is silent on providing specific cadres for HIV testing services as indicated by the HIV NSP in the context of an overburdened cadre of Health Surveillance Assistants (HSAs). Achieving the second and third objectives of the HIV NSP and the component of TB case detection has implications on the need for specialized equipment and laboratory investigations such as viral load monitoring and GeneXpert testing. The HSSP highlights issues of improving the skills of laboratory personnel and procurement of essential equipment and reagents to meet the service needs in these programmatic components. Furthermore the HSSP highlights the need to strengthen community participation and utilize community outreach clinics among the strategies to improve access to essential health services. This provides a specific linkage to TB and HIV service delivery considering that community health service delivery models would be required to promote adherence to ART, case detection for TB and patient tracking systems.

#### **1.2.e Country processes for reviewing and revising the NSPs (timeline for a new plan, how key populations will be meaningfully engaged)**

Three main reviews processes for the 2015-2020 NSP for HIV and TB will take place concurrently. These include:

**Joint Reviews of Progress on Implementation** of the Operational Plan: this will take place quarterly with the executive committee of the Malawi HIV and AIDS Partnership Forum (MPF). The complete MPF meets bi-annually to review progress. The independent assessment/review of the operational plan by and independent team acts as an accountability process. Additionally, NAC and pooled donors have quarterly meetings to review progress towards agreed upon milestones.

**Mid-term Review:** The midterm evaluation of the TB and HIV programs will focus on achievements, challenges, emerging issues and recommendations for the remaining half of both NSPs, and will take place in 2017.

**End-of-term Review** - The final NSP evaluation will be conducted in 2019 to provide the evidence base for the next HIV and TB NSPs. Independent evaluators will carry out the midterm and end-term evaluations.

Mid- and end-term reviews for both programs shall engage key and vulnerable populations as key informants in the review process.

### 1.3 Joint Planning and Alignment of TB and HIV Strategies, Policies and Interventions

#### 1.3.a Plans for further alignment of the TB and HIV strategies, policies and interventions

##### Steps for the Improvement of Coverage and Quality of Services

**Integration of TB and HIV Services:** Joint policy and strategic planning will be conducted through existing structures for coordination at the national level, including program oversight for HIV-TB program planning and monitoring of implementation progress of key areas including tracking of performance coverage and quality of services. There will be on-going review of technical assistance and capacity building needs to improve competencies at national and sub-national levels. Gender-sensitive M&E and evaluation systems for TB and HIV will be integrated, including effective supervision and performance appraisal. At the community level, capacities for existing structures will be enhanced for further integration of HIV and TB services.

- All high volumes sites will develop a work plan towards “one-stop services” for TB/HIV management.
- Where staffing and infrastructure permit, services will be reconfigured to integrate HIV service into TB clinics, specifically PITC and ART initiation after conducting through assessment. The HIV program scale-up provides an opportunity for integrating TB treatment. Where integration is not feasible linkage systems will be developed.
- Building on the success of the Integrated HIV Quarterly Monitoring and Supervision process, there is an opportunity for the TB program to leverage this while ensuring that the funding source for the activity is institutionalized within the respective national plans.
- Different existing models of integration of care will be evaluated and lessons will be incorporated in the redesigned model for scale-up.
- The integration process will be led by integration plan that clearly outlines
  - Scope and deliverables
  - Long term and short term targets
  - Prerequisites for one stop service and targets in specified period
  - Timelines for expected deliverables

**IPT scale-up strategy – summary of considerations:** Malawi started implementation of IPT among pre-ART patients in 2011 using a simplified protocol of giving IPT for the whole duration of pre-ART and stopping it at the time when ART is started. The 2011 and 2014 Malawi Clinical HIV guidelines specify:

*Give IPT to the following: HIV infected children and adults who are not on ART, regardless of WHO clinical stage or CD4 count; Children under 5 years (HIV negative or unknown HIV status) who live with a patient with pulmonary TB (sputum smear negative or positive) who has not yet completed 2 months of TB treatment. Start IPT at enrolment for pre-ART follow-up and continue for as long as the patient is in pre-ART follow-up. Stop IPT when ART is started. Do not give IPT to a patient who has any signs suggestive of active TB: such patients need full investigation for TB and combination TB treatment if confirmed to avoid TB drug resistance. IPT is well tolerated and can be taken with CPT and in pregnancy. Give 1 tablet of pyridoxine 25 or 50mg 24-hourly to children and adults who are taking IPT. Stop IPT when the patient starts ART, regardless of how long IPT has been taken.*

IPT coverage among the 40,000 pre-ART patients remained low for the first 2 years of implementation, but has reached 80% by mid-2014. These national guidelines are an adaptation of WHO recommendations, based on extensive deliberations by the PMTCT/ART TWG in 2010 and 2013. The key considerations for this national policy were:

- Prioritization of pre-ART patients who are likely to have the greatest benefit from IPT (TB incidence is reduced once ART is started).
- Simplicity of prescribing similar to lifelong CPT allowing for national implementation in all 700 sites with pre-ART services.
- Indications for poor sensitivity of intensified case finding / ability to rule out active TB in overburdened ART clinics.
- Reduced pill burden for patients starting ART to maximize benefits of the simple one-pill-a-day first line ART regimen for optimal ART adherence.
- Minimize the risk of side effects among patients on ART (IPT side effects may be wrongly attributed to ARVs, threatening good ART adherence).
- Prioritizing ART and CPT storage and distribution requirements (full implementation of IPT and pyridoxine in the ART clinics would require significant expansion of central and site level storage capacity).

The rationale for these policies has been reviewed again in 2014 for the new NSP and the TWG recommended expanding IPT for all prisoners living with HIV (including those on ART) while maintaining the recommendation to hold back on a full implementation of IPT for the general ART patient cohort that will have grown to over 600,000 in the implementation period. A special IPT taskforce has been formed to review and advise the PMTCT/ART TWG in May/June 2015 on an updated IPT policy for the 2016 edition of the National Clinical HIV Guidelines.

Outside of HIV clinic settings, IPT will continue to be scaled up among TB household contacts, including all children under 5 (regardless of HIV status) and older children and adult living with HIV (regardless of ART status). In this group, IPT will be provided for six months. Implementation will be strengthened through orientation and mentorship of care providers both in the HIV and TB service outlets all over the country. Maximum effort will be made to strengthen the quality of TB screening, contact tracing and increased IPT adherence and completion rate among prison inmates during incarceration and linkage with the public health services upon release. The lessons learned in this interim IPT co management will be documented and local evidence will be used to inform future IPT policy reviews.

#### **Opportunities for Joint Implementation of Cross-Cutting Activities**

**Human Resources for Health:** It is necessary to assess workload to guide health workforce projections for integrated TB-HIV services. Capacity building approaches include the joint revision of clinical guidelines, programmatic monitoring/supervision and clinical mentoring programs. Pre-service and in-service training modules will be updated to reflect integrated TB-HIV service delivery, gender and human rights. Joint Capacity Building Approaches will ensure that HCW healthcare workers are trained to identify, diagnose and treat clients with TB and HIV. As a stop-gap measure, current TB focal clinicians and nurses at TB registration/initiation sites will be trained in ART/PMTCT services.

Technical assistance currently seconded to the national programs will continue to support programmatic integration improvements and efficiencies, including the development of operational guidelines and standard operating procedures for integrated TB HIV service delivery and M&E.

**Infrastructure:** Many health facilities have outdated designs, hampering integration. Where physical space allows for joint location or one-stop shops, these will be expanded. During routine supervision visits, the implementation of infection control activities will be conducted to ensure the risk of TB transmission is reduced given the infrastructure limitations.

**Diagnostic Services:** National laboratory systems strengthening activities will be scaled up. A national sample transportation system has been developed for EID, CD4 and viral load and is expected to attain national coverage in 2015. This network will include TB samples where diagnostic capacity is limited. Opportunities for integration and strengthening using the HIV platform will be explored for systems for diagnostic and drug commodity forecasting, lab quality control systems for diagnosis, and relaying HIV and TB results to sites and patients. National laboratory systems strengthening activities will be scaled up. A national sample transportation system has been developed for EID, CD4 and viral load and is expected to attain national coverage in 2015. This network will include timely TB specimen transportation. Systems for diagnostic and drug commodity forecasting, laboratory quality control systems for diagnosis, and relaying HIV and TB results to sites and patients will be integrated and strengthened, building on and improving current platforms.

**Procurement and Supply Chain Management (PSM):** There are opportunities for commodities procurement for the two programs to complement each other commodity procurement of for mutual benefit. For example, procurement of Hifalutin by

the TB program for TB patients who are also on second line ART, isoniazid preventive therapy and pyridoxine for pre-ART, eligible children and household contacts as per current policy. There is also an opportunity to integrate further commodity and drug distribution to lower levels.

**Health and Community Systems Strengthening:** Community health workers responsibilities are similar for TB and HIV, and will be enhanced to ensure awareness, reduce stigma and gender inequality, case finding, tracking clients lost to follow-up, adherence and retention and linkages to services that address impact mitigation. Capacities of existing community structures will be developed to better implement and promote TB/HIV activities to create awareness, reduce stigma and promote treatment adherence, among others.

### **Expected Efficiencies that will Result from this Joint Implementation**

Joint training, monitoring and clinical mentorship will serve to optimize use of limited HR human and financial resources. Strengthened referral systems between health services and the communities will enhance timely diagnosis, and improve patient outcomes, reducing suffering and death. Timely joint data collection will allow for improved quality of data and informed planning and implementation.

Quality of health care provided is a current focus area for Ministry of Health (headquarters). The MoH is currently identifying QA experts in Malawi with the view to focus on service delivery and have a tool to consistently measure quality of care provided by individual, private and public facilities. In the future MoH will harmonise documents on QA, develop a structure to implement these reforms and develop guidelines. This concerted effort to improve quality and standardise quality of care addresses all diseases including TB and HIV.

### **1.3.b Barriers that need to be addressed in this alignment process**

**Human Resources Capacity:** Lack of capacity to diagnose HIV and TB and insufficient knowledge and skills among health workers towards provision of integrated TB/ HIV care are the main barriers to provision of integrated TB/HIV services in lower level health facilities offering TB treatment. In addition to being understaffed, they lack vital cadres of health workers like medical officers and comprehensively trained nurses. This level of under-staffing and absence of critical cadres of health workers may work against the proposed strategy of using the existing human resource for provision of integrated TB/HIV care as suggested by WHO. There is a lack of knowledge and skills among health care providers towards provision of integrated, gender sensitive and rights based TB/HIV. Such knowledge gaps are likely to lead to delays in diagnosis of TB and institution initiation of care.

**Contextual Barriers:** A major barrier to integration of activities and programs is the legacy of decades of running the programs vertically and separately which continues to influence the structural location of TB/HIV programs and communication between managers. The legacy of national HIV and TB programs' vertical institutional arrangements has limited collaboration historically and requires an orientation of programmatic staff and buy-in. The discrepancy in the rate of decentralization for TB and HIV has also impacted on collaboration at facility level and similar reorientation would be required.

**Funding Barriers:** The financing fund flows have been uneven due to the vertical management of TB and HIV programs. The HIV program receives funding from multiple external donors, and these funds are earmarked with less flexibility of using the funds outside HIV activities (other than some Global Fund resources). In contrast, the TB program has limited funding sources mostly from Global Fund, USG and government.

**Physical Barriers:** The historical mechanism of providing TB/HIV services as vertical services located in different places at facility level is an obstacle for the provision of integrated TB/HIV services. Even at health facility level where TB/HIV services are under one roof, patients are usually assessed by one health worker in one consulting room and then referred to another consultation room. This results in the loss of patients in the referral process and creation of long queues.

**Program Implementation Barriers:** Low TB case detection rates inherently limit early detection and treatment, and need to be addressed. The case management of HIV has been expedited through the availability of point of care diagnostics with rapid test kits reducing waiting times. However, TB diagnostics rely on lab-based tests with an inherently longer turnaround time. Introduction of GeneXpert at ART clinics is expected to address this significantly.

**Structural Barriers:** Workforce projections at national level and deployment practices have not factored in programmatic scale-up and workload for HIV and TB clinics. Synergies have been missed and community health worker responsibilities have not traditionally reflected TB-HIV integration. This will be addressed through training, standard operating procedures (SOPs) and community linkages through CSOs.

**Stigma and Discrimination:** There are still high levels of stigma and discrimination related to TB and HIV which results in non-disclosure and delays in seeking medical attention either at the facility or community level. Key challenges that perpetuate stigma

and discrimination in Malawian society include: absence of stigma and discrimination guidelines in the country; inadequate redress mechanisms for those who have been stigmatized and discriminated against; lack of HIV and AIDS legislation; inadequate knowledge of PLHIV rights by the general public; and lack of knowledge of their rights by PLHIV themselves: as a result, they accept stigma and it goes unchallenged.<sup>113</sup> Stigma associated with TB results in social isolation and affects both sexes.<sup>114</sup> TB patients are perceived negatively in the community, and women were found to be more affected by this.<sup>115</sup> Most chose to keep their diagnosis secret from people outside their close family due to fear of rejection and isolation. Other cultural beliefs and gender norms also influence health-seeking behaviour. This has hampered the provision of TB and HIV at community level. Community awareness campaigns will be vital in addressing this.

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<sup>113</sup> Safari Mbwewe, Executive Director, MANET+, interview by Lloyd Simwaka, Lilongwe, 10 September 2014

<sup>114</sup> *Gender in Tuberculosis in Gender and Health*. WHO, 2002.

<sup>115</sup> Simwaka B, Bello G, Banda H, Chimzizi R, Squire B, Theobald S. The Malawi National Tuberculosis Program: an equity analysis *International Journal for Equity in Health* 2007, 6:24.

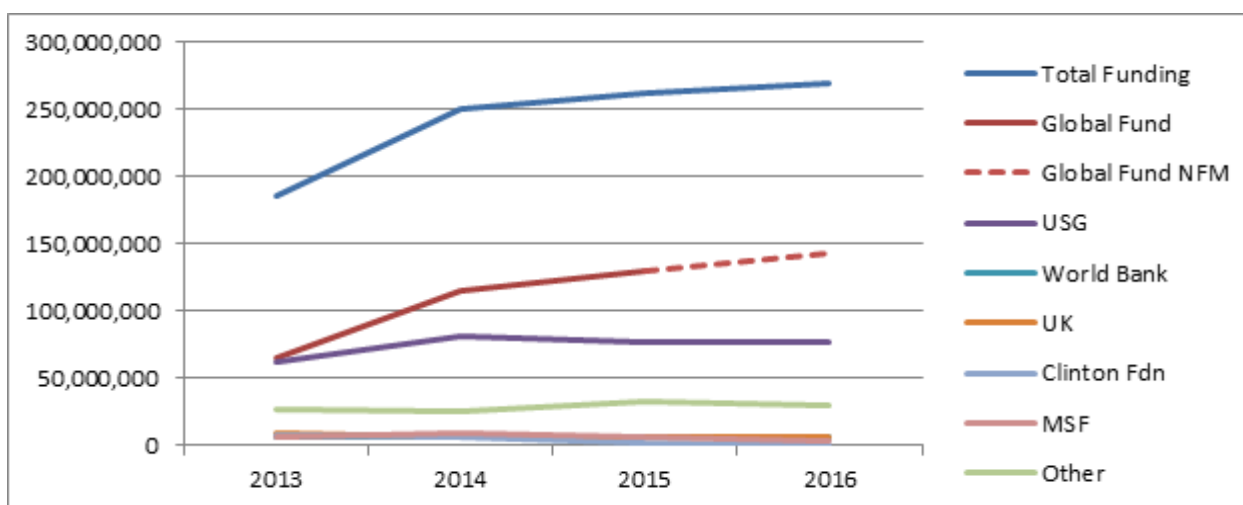
## Funding Landscape, Additionality and Sustainability

### 1.1. Overall Funding Landscape for Upcoming Implementation Period

#### 1.1.a The availability of funds for each program area and the source of such funding for HIV

With Government and donor commitments, Malawi's HIV program has made tremendous achievements. The majority of funding in recent years has come from the Global Fund and the US Government, and this trend is projected to continue through 2017. Figure 16 below demonstrates the increasing need for additional resources to sustain the gains of the national HIV program and support achievement of the NSP 90-90-90 targets. It will be critical for the Government of Malawi to explore new and sustainable financing mechanisms during this period to ensure a sufficient HIV response moving forward.

Figure 16: External Resources by Donor for HIV, Projection Post-2014 (in USD)<sup>116117</sup>



Government contributions to the HIV program are expected to increase through 2017, from USD 10,557,083 in 2012-13 to USD 12,314,254<sup>118</sup> in 2016-17, marking a 16.64% increase. Given the limited resources, Malawi has adopted a strategic investment approach whereby evidence-based, high impact interventions are prioritized. The recently revised National Strategic Plan (NSP) utilized an investment framework that aims to maximize the benefit of HIV interventions, support a rational resource allocation based on country epidemiology and context, encourage prioritization and implementation of the most (cost)-effective programmatic activities, and increase efficiency in HIV prevention, treatment, care, and support programming. Table 3 outlines the total cost of the NSP over the fiscal year 2015-17 period (2 fiscal years), the subsequent donor contributions, and overall funding gap. The 2015-2020 NSP was primarily informed by two analyses: 1) a 'GOALS' modelling analysis, comparing the net impact and cost of multiple concurrent interventions and 2) an analysis of the financial sustainability of HIV interventions. The GOALS analysis showed diminishing returns from all other prevention interventions in a national context of universal ART as population level viral load is reduced and incidence declined. The financial sustainability analysis highlighted the need for a realistic funding assumption which prioritizes allocative efficiency.

Table 3: Funding Landscape for HIV NSP, 2015-17 (in USD)

Resource Need/Availability	Amount
Total NSP Budget	498,828,650
Total Resources Available	258,445,335 (46.01%)
Financial Gap	269,311,273 (53.99%)

<sup>116</sup> Global Fund NFM amounts include only the within allocation request.

<sup>117</sup> Malawi Resource Mapping Round 3 Master Database

<sup>118</sup> Extracted from CPF calculation

The Government of Malawi in consultation with partners conducted a thorough resource mapping (RM) exercise to understand the programmatic areas that were adequately funded and those that had significant funding gaps. Table 4 below summarizes the annual funding gap for each programmatic area based on the estimated cost in the NSP and this resource mapping work. Please note that this financial gap analysis has not taken into account the potential Global Fund NFM money, which has been requested to fill critical funding gaps.

With the recent revision of the HIV National Strategic Plan, one of the most notable drawbacks in the projected financial gap analyses is the limitations of RM data. The data collected in Round 3 of resource mapping by the Ministry of Health asked partners to state funding according to activities and objectives of the Malawi's HIV NSP 2011-2016. Due to the change in structure and associated objectives and activities, the financial gap analysis that is presented was conducted only on the intervention level. The same limitations also exist for the TB program given their recent revision of their NSP and subsequent realization of the RM data limitations. However, while the information from the financial gap analysis may be high-level, it can inform and guide the government/partners to reallocate excess resources committed to certain program areas that are projected to be over-funded going forward.

Table 4: HIV Financial Gap Analysis by Programmatic Area (in USD) <sup>119</sup> Programmatic Area	2015-16 (Fiscal Year)			2016-17 (Fiscal Year)		
	NSP	RM**	Gap <sup>120</sup>	NSP	RM	Gap
Condoms	7,169,664	6,464,778	(704,886)	9,154,518	6,480,123	(2,674,395)
Behavior Change Communication/Community Mobilization	1,700,408	5,436,672	3,736,264	1,798,104	5,224,754	3,426,650
HIV Testing and Counselling	13,986,750	5,228,420	(8,758,330)	14,446,157	4,463,678	(9,982,479)
Medical Male Circumcision	13,469,925	10,369,961	(3,099,965)	24,514,629	10,014,255	(14,500,375)
STI Case Management (e.g. Syphilis)	4,934,016	873,203	(4,060,813)	5,554,873	868,130	(4,686,742)
PMTCT	8,011,092	8,816,249	805,157	8,584,177	7,799,989	(784,188)
Blood Safety	2,614,762	1,767,800	(846,962)	3,068,853	1,767,836	(1,301,018)
Post Exposure Prophylaxis	95,055	2,266	(92,789)	43,662	2,333	(41,328)
ART	105,210,194	20,709,837	(84,500,357)	115,502,954	19,839,134	(95,663,820)
Opportunistic Infections	12,846,563	5,035,136	(7,811,426)	13,586,219	4,849,981	(8,736,239)
HIV-Tuberculosis ***	4,361,552	4,108,916	(252,636)	910,337	4,109,025	3,198,688
Nutrition Support with ART	5,178	263,424	258,246	3,017	257,203	254,186
Community/Home-based Care	1,246,564	1,399,247	152,683	1,418,844	1,359,576	(59,268)
Other Treatment	5,712,536	6,633,796	921,260	5,940,837	6,491,907	551,069
Viral Load Testing	6,989,867	2,998,760	(3,991,107)	7,632,582	2,120,184	(5,512,397)
CD4 Testing	1,565,436	1,960,813	395,377	-	998,966	998,966
Early Infant Diagnosis	902,971	1,958,382	1,055,412	905,937	1,877,264	971,327
Cross Cutting Labs	7,177,955	5,399,395	(1,778,560)	6,830,022	5,104,767	(1,725,254)
HIV Impact Mitigation	3,196,333	5,077,958	1,881,626	3,530,543	5,077,544	1,547,000
Cross-Cutting HIV Activities	25,443,083	38,320,494	12,877,411	32,850,086	36,913,180	4,063,094
CSO Activities****	8,132,918		(8,132,918)	7,779,478		(7,779,478)
Total	234,772,820	132,825,507	(101,947,312)	264,055,830	125,619,828	(138,436,003)

\*\*RM Donors include: USG, World Bank, UKAid, CHAI, MSF, Dream Foundation, UNAIDS, SIDA, OXFAM, Abbott, World Vision amongst others. Please note that GF NFM is not included here

\*\*\*HIV-Tuberculosis NSP need is not reflective of total need in the intervention as some activities have been captured in the TB NSP

\*\*\*\*RM Donors do not separately report for this category

The prioritized interventions within the NSP have demonstrable impact towards new infections and mortality reduction. Therefore, given more resources, a plausible approach would be to fund the gaps above. For the period covered by this concept note, a number of programmatic areas are already adequately covered by domestic resources, external donors, or a combination of the two. Specifically, BCC/Community Mobilization, nutrition support, other treatment (psychosocial support), CD4 and EID testing, HIV impact mitigation, and cross-cutting HIV activities all have adequate funding through 2017. While these areas may

<sup>119</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

<sup>120</sup> All numbers in red reflects a gap, all numbers in black refers to adequately resourced. Please note that there is no 100% alignment between the donor funds and the resource requirements. Due to recent revision of the NSP, we anticipate donor alignment in upcoming financial years

portray adequate funding from an intervention standpoint on activities, it does not reflect the financial gap for commodities. Global Fund has historically been the donor providing funding for drug commodities and related labs and diagnostics, hence, in some areas that seem to have adequate funding, such as EID testing, funding for commodities has also been requested. It should be noted that Malawi will phase out CD4 testing beginning in 2016-17 as it adopts a revised “Test and Treat” policy.

The HIV program in Malawi is heavily dependent on external donors. A 2012 study calculated that *Malawi would require almost 8% of GDP to maintain its entire HIV positive population on ART, which makes Malawi the most dependent country in the world for outside funding for its treatment program.*<sup>121</sup> Although donor commitments could potentially change, Malawi’s HIV donors have tentatively committed to the main activities listed in Table 5. These commitments have helped Malawi to prioritize its funding request from the Global Fund to fill key gaps in its response, further detailed in Section 2.1.b.

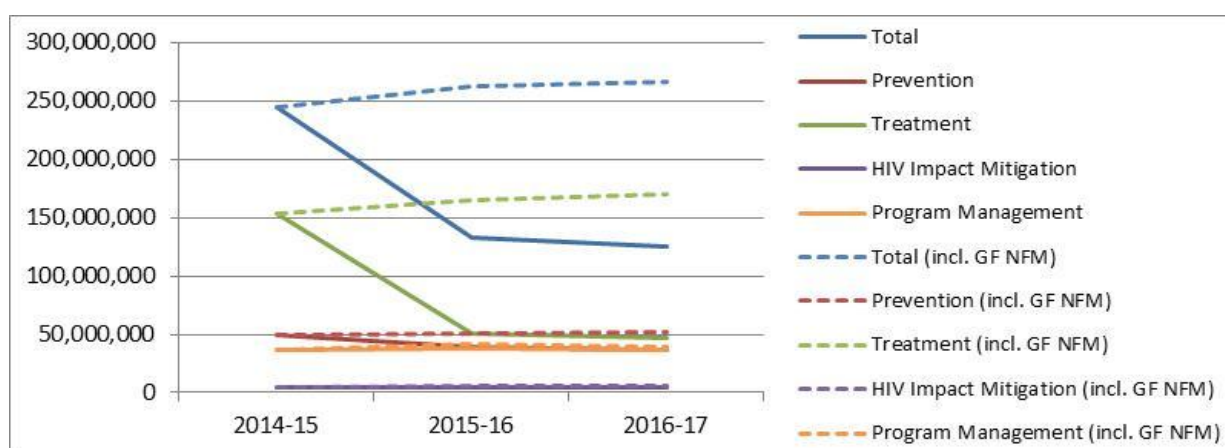
*Table 5: Main Donor Commitments by HIV Activity (in USD)<sup>122</sup>*

Main Funding Source	Fiscal year 2014 – 2017 Total**	Main Activities Funded
GoM	39,601,257	ART, VMMC, Cross-cutting HIV platform
GF (dispersed)	73,285,288	HIV Commodities, Cross Cutting HIV activities
GF (excluding NFM; including forecasts up to June 2015)	112,861,013	HIV Commodities, cross-cutting HIV platform, HTC, OIs, Labs
USG	236,342,654	BCC, Condoms, VMMC, ART, Cross-cutting HIV platform
World Bank	18,360,000	VMMC, Cross-cutting HIV platform
MSF	20,710,126	VL, ART, HTC, Cross-cutting HIV platform
UKAid/DfID	19,746,880	EID, HTC, PMTCT
CHAI	9,749,523	ART, CD4 testing

**\*\*Please note that this excludes GF NFM because it is not yet confirmed (Concept Note under development)**

Figure 17 shows the current budgeted resources for the four pillars of the HIV NSP. These amounts represent donor figures that have been incorporated into their budgets and may not reflect the full amount of resources that will be available for future years. According to Resource Mapping, stakeholders in the HIV sector reported only USD 132.8 million of resources currently budgeted for 2015-16, not including Global Fund NFM grants. The total resources available for HIV in 2014-2015 (USD 244.97 million) are largely driven by the costs related to treatment and care (USD 154.06 million or approximately 63% of total resources) – represented by the solid green line. The lack of other donors filling the treatment and care funding gap with the expiration of the current Global Fund grants has been one of the key factors in Malawi’s prioritization of its Global Fund envelope. The dotted lines represent the resources available after factoring in Malawi’s NFM within allocation request, which will be used to fill key gaps, so that the country can provide a balanced national response.

*Figure 17: Resources Available for HIV NSP Pillars (in USD)*



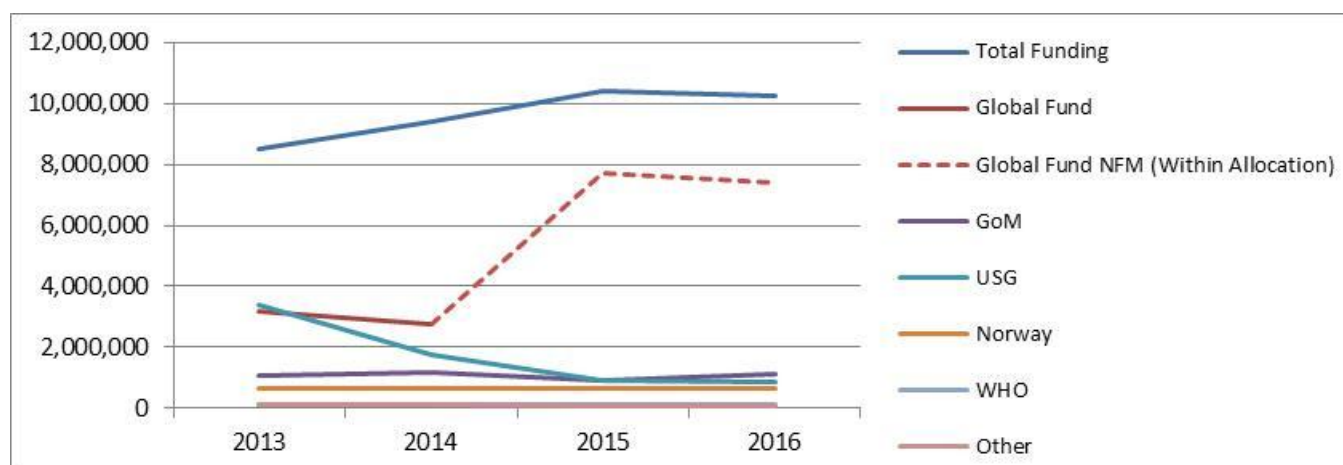
<sup>121</sup> Williams, B.G. and E. Gouws. Affordability, cost and cost-effectiveness of universal anti-retroviral therapy for HIV. ARXIV 2012 [cited 2014 13/08/2014]; Available from: <http://arxiv.org/abs/1206.6774v2><http://arxiv.org/abs/1206.6774v2>

<sup>122</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

## Tuberculosis

Malawi's TB program has over the years primarily been funded by the Government of Malawi, USG, the Global Fund, and Norway, among other donors. As shown in Figure 18, a portion of current commitments from USG (TB Care) will be ending in 2015, but the GoM is already in the process of obtaining additional funding from Challenge TB, which would likely offset the decrease in funding due to the ending of TB Care II grants. The bulk of TB resources have been from previous Global Fund grants, and it is critical for the TB program to secure Global Fund NFM financing in order to meet programmatic funding needs for an effective TB response.

Figure 18: External Resources by Donor for TB, Projection Post-2014 (in USD)



The Government of Malawi has been a consistent donor to the national TB program with contributions to the TB program expected to increase nearly 30% from USD 780,745 in 2013 to USD 1,107,290<sup>123</sup> in 2016. In the past, this support has primarily gone to 2<sup>nd</sup> line TB treatment and cross-cutting platform costs, while the Global Fund has covered 1<sup>st</sup> line treatment and a significant portion of diagnostic services.

The Government recently revised and costed its NSP for TB to cover the period of 2015-20. Table 6 below outlines the total cost to cover the two year period of this funding request, the resources available, and the subsequent financial gap.

Table 6: Funding Landscape for TB NSP, Fiscal Years 2015-17 (in USD)<sup>124</sup>

Resource Need/Availability	Amount
Total NSP Budget for year 1 & Year 2	38,978,666
Total Resources Available for year 1 & Year 2	5,504,313 (14.1%)
Financial Gap	33,474,352 (85.9%)

The year 3 NSP budget (July 17 to June 2018) is \$18,625,000 and the total 3 year NSP budget is \$57,603,000. Of this a total of \$39,578,00 (68%) is requested in this CN for the two and half years.

The Government in consultation with partners conducted a thorough resource mapping exercise to understand the programmatic areas that were adequately funded and those that had significant funding gaps. Table 7 summarizes the funding gap for each programmatic area based on the estimated cost in the TB NSP and the projected funding from various donors. Categorization in Table 8 is based on resource mapping areas.

<sup>123</sup> (taken from Financial Gap Analysis, CPF Table).

<sup>124</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

Table 7: TB Financial Gap Analysis by Programmatic Area (in USD) <sup>125</sup>

Programmatic Area	2015-16 (Fiscal Year)			2016-17 (Fiscal Year)		
	NSP	RM**	Gap <sup>126</sup>	NSP	RM	Gap
BCC / Awareness	223,794	117,114	(106,680)	153,346	133,832	(19,514)
Microscopy	3,008,515	371,152	(2,637,363)	3,191,306	374,544	(2,816,762)
Chest X-ray	3,465,115	-	(3,465,115)	2,644,196	-	(2,644,196)
TB Culture	461,568	1,457	(460,111)	1,078,157	2,047	(1,076,110)
GeneXpert MTB / RIF	1,907,945	1,018,553	(889,392)	1,820,174	1,018,553	(801,621)
DOTS - 1L treatment	1,810,139	70,680	(1,739,459)	2,616,535	70,715	(2,545,820)
2L treatment of MDRTB	2,614,792	514,026	(2,100,765)	3,302,257	582,845	(2,719,412)
TB Nutrition (excludes HIV / TB)	-	30,935	30,935	-	35,485	35,485
Cross-cutting TB activities	5,440,444	551,017	(4,889,427)	5,240,385	611,358	(4,629,027)
<b>Total</b>	<b>18,932,311</b>	<b>2,674,934</b>	<b>(16,257,377)</b>	<b>20,046,355</b>	<b>2,829,379</b>	<b>(17,216,976)</b>

\*\*RM donors include: USG, WHO, Norway, MSF, WFP, Anglican Diocese, SIDA, UNICEF amongst others

There are many funding shortfalls for the TB program. Although donor commitments could potentially change, Malawi's TB donors have tentatively committed to the main activities listed in Table 8. These commitments have helped Malawi to prioritize its funding request from the Global Fund to fill key gaps in its response.

Table 8: Main External Donor Commitments by TB Key Programmatic Activity (in USD)<sup>127</sup>

Main Funding Source	Fiscal Year 2015-2017 **	Main Activities Funded
GoM	2,042,450	Prevention (BCC), 2nd Line and TB Cross cutting platform costs
USG	1,756,732	1 <sup>st</sup> Line, Diagnostics (Microscopy, GeneXpert)
WHO	271,000	Diagnostics (GeneXpert)

- \*\*Please note that this excludes GF NFM because it is not yet confirmed (Concept Note under development)

Figure 19 shows the available and anticipated resources for key TB programmatic areas. These amounts are based on results from the resource mapping exercise conducted by the Government of Malawi in consultation with partners. Donors have included such estimates in their budgets but it does not represent the actual amount of resources that will be dedicated to TB programs during the coming years.

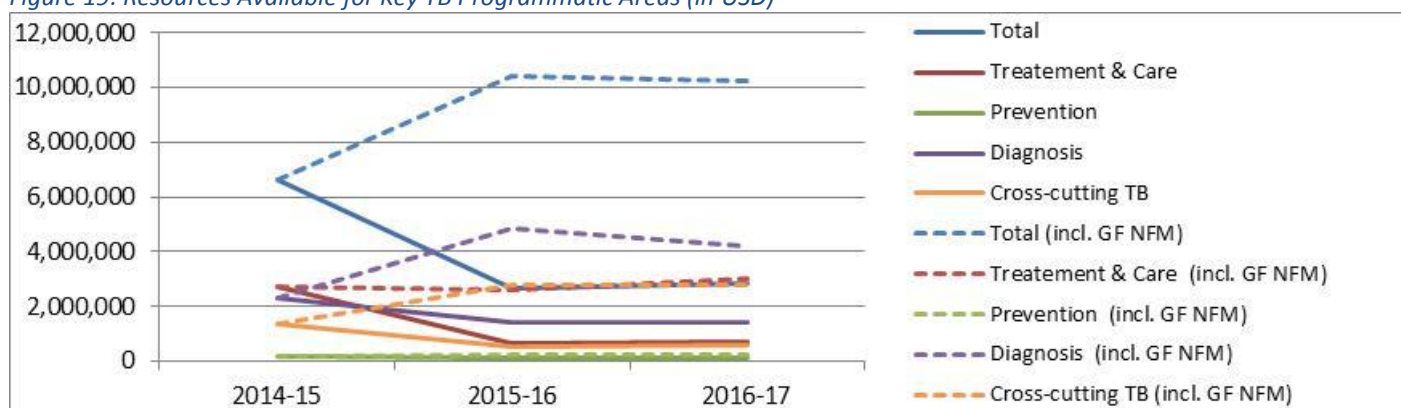
The total resources available in 2014-2015 (USD 6,603,029) are largely driven by the costs related to treatment activities (USD 2,735,040). A subsequent 59.5% decline in the available resources by 2015-16 is primarily due to the decrease in contribution from USG and the ending of current Global Fund grants that were supporting the bulk of treatment costs. The dotted lines represent the amount of resources available after including the NFM within allocation request. The additional financial support from Global Fund is essential for filling in key funding gaps.

<sup>125</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

<sup>126</sup> All numbers in red reflects a gap, all numbers in black refers to adequately resourced

<sup>127</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

Figure 19: Resources Available for Key TB Programmatic Areas (in USD)



## HSS

In 2014-15 a total of USD \$198.06 million was budgeted towards HSS activities (defined in Table XX). The majority of which is allocated to Health Worker Salaries and Benefits (27%). Bilateral partners contributed 36% of what was budgeted towards HSS funding in the previous year and the Government of Malawi contributed 32%. In this HSS application there is a significant focus on Supply Chain Management, Human Resources for Health and Service Delivery (lab equipment). There has been significant investment in these areas by both partners and by Government during the 2014-15 FY. Particularly, PSM made up 20% of the HSS investment, the majority of which was funded by multilateral partners like the Global Fund. Similarly significant investment was made in HRH, 19% of funding for HSS was diverted for Health Worker Training both in-service and pre-service largely by bilateral donors especially USAID. Lab equipment made up 6% of the total HSS investment for the same financial year mostly funded by CDC. There has been significant investment by multiple actors into HSS activities in Malawi, and, as a result, the government feels HSS funding should be looked at from a whole of system perspective rather than the amount invested solely by GOM or by Global Fund.

Table 9: HIV Financial Gap Analysis and Subsequent Funding Requests by Programmatic Area (in USD)<sup>128</sup>

Cost Category	Private Companies	NGOs & Foundations	Multilateral Partners	Gov't of Malawi	CHAM	Bilateral Partners
Capital Medical/Lab Equipment	24,144	3,219,460	2,063,659	1,396,337	215,077	5,554,352
Health Worker Salaries/Benefits	1,121,117	1,657,268	314,151	44,931,365	1,342,708	4,504,755
Health Worker Training - In-service	40,791	1,167,695	2,900,795	1,309,947	52,834	18,670,043
Health Worker Training - Pre-service	1,272	210,266	1,184,000	3,991,254	1,186,264	7,324,917
Infrastructure	558,150	2,435,636	2,388,355	8,849,155	881,278	16,173,664
Referrals		747,329		2,259,195	6,893	16,929
Research and M&E	256,430	1,616,455	3,640,442	83,216	6,856	12,597,803
Service Level Agreements				659,504		556,073
Supply Chain Management	1,504,497	1,128,146	30,364,078	840,778	144,747	5,963,345
<b>Total</b>	<b>3,506,401</b>	<b>12,182,256</b>	<b>42,855,480</b>	<b>64,320,751</b>	<b>3,836,655</b>	<b>71,361,879</b>

### 1.1.b How the proposed Global Fund investment has leveraged other donor resources

#### HIV

Malawi conducted a comprehensive prioritization and gap analysis of the National Strategic Plan and resource mapping exercise to maximize resources available from all donors supporting the National Response. In some cases, where other donors have provided the full funding required in a programmatic area, the CCM has targeted other key priorities that remain underfunded.

<sup>128</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

Where donors have provided partial funding for a high impact program, the CCM has prioritized this within its funding request. Key strategies adopted in this concept note are to leverage opportunities from other donor investments and to select priority areas where they can achieve greatest impact given the disease burden. A brief rationale for areas for which the CCM is requesting funding for from Global Fund to supplement current donor funding is outlined below.

1. HIV Commodities: Please note that the HIV commodities referred to here includes commodities for ART, Blood safety, Condoms, Opportunistic Infections, STI Case Management and Syphilis Screening, Viral Load Testing, HIV Testing and Counselling, Early Infant Diagnosis, Cross Cutting Labs, and PMTCT. This is the largest funding gap and represents over 83% of Malawi's request for funding within its NFM allocation. Related PSM costs account for 17% of the NFM allocation. Historically, the Global Fund has funded the procurement of HIV commodities whilst other donors have provided funding for the supporting activities and quality improvement interventions for all program areas. The Government of Malawi has committed an additional USD 8.5 million towards the procurement of a portion of the ART commodity buffer.
2. Healthcare worker trainings: Donors, largely the U.S. Government, have committed 50% of funding for training healthcare workers on ART, PMTCT and TB; thus, the CCM has requested the remaining 50% to complete these vital series of trainings.
3. STI case management: Donor commitments are also unable to fully meet the need in STI case management. Malawi has therefore requested funds amounting to USD 1.75 million within allocation to prioritize new healthcare worker training and quarterly supervision visits in this programmatic area. An additional USD 2.45 million has been included in the above allocation request for activities specified in Section 3.
4. HIV Testing and Counseling: Within HIV Testing and Counseling, stakeholders identified priority activities that must be included, which include testing commodities, mobile testing of key populations, HTC mentoring, commodities for panel testing, and ongoing quality control. After accounting for the U.S. Government funding for 75% of the HTC mentoring, each of the previously mentioned activities have been included in the within allocation request to meet this critical funding gap. After accounting for other donor contributions and the within allocation request of USD 579,660, Malawi is also submitting an above allocation request of USD 2.35 million in HIV Testing and Counseling for activities specified in Section 3.
5. VMMC: USG/PEPFAR and the GoM/World Bank will be making sizable contributions to male circumcision. As detailed in Section 3, USG/PEPFAR is targeting eight high-prevalence districts and the World Bank will support VMMC in the remainder of districts in priority zones. The above allocation amount will cover additional VMMC human resource capacity, procurement of VMMC commodities, demand creation, operational research activities, and strengthening of quality assurance, supply chain and M&E systems for VMMC.
6. Blood safety: Included in the above allocation request from Global Fund is USD 1.38 million for blood safety activities. This amount will supplement the Government of Malawi's contributions, the U.S. Government's contribution of 24% of the total Malawi Blood Transfusion Service's budget as well as other donor contributions to provide a fully funded blood safety program.

Table 10: HIV Financial Gap Analysis and Subsequent Funding Requests by Programmatic Area (in USD)<sup>129</sup>

Programmatic Area	NFM Total			Included in Commodity Funding Request	Remaining Gap	Mitigation of funding gap
	NSP	Current Funding	Gap			
Condoms	16,324,182	12,944,901	(3,379,281)	1,087,500	(2,291,781)	Supported by other partners
Behaviour Change Communication/Community Mobilisation	3,498,512	10,661,426	7,162,914	-	7,162,914	
HIV Testing and Counselling	28,432,908	9,692,098	(18,740,809)	15,806,597	(2,934,212)	NFM within allocation and above allocation
Medical Male Circumcision	37,984,555	20,384,216	(17,600,339)	-	(17,600,339)	NFM above allocation
STI Case Management and Syphilis Screening	10,488,889	1,741,334	(8,747,555)	4,549,606	(4,197,949)	NFM within allocation and above allocation
PMTCT	16,595,268	16,616,238	20,969	369,272	390,242	

<sup>129</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

Blood Safety	5,683,615	3,535,635	(2,147,979)	766,837	(1,381,142)	NFM above allocation
Post Exposure Prophylaxis	138,717	4,600	(134,117)	-	(134,117)	Funding to be covered by partners
ART	220,713,148	40,548,970	(180,164,178)	201,463,152	21,298,974	
Opportunistic Infections	26,432,782	9,885,117	(16,547,665)	18,664,785	2,117,120	
HIV-Tuberculosis	5,271,888	8,217,941	2,946,053	497,785	3,443,838	
Nutrition Support with ART	8,195	520,627	512,433	-	512,433	
Community/Home-based Care	2,665,408	2,758,823	93,415	-	93,415	
Other Treatment	11,653,374	13,125,703	1,472,329	-	1,472,329	
Viral Load Testing	14,622,449	5,118,944	(9,503,505)	12,202,391	2,698,886	
CD4 Testing	1,565,436	2,959,778	1,394,343	-	1,394,343	
Early Infant Diagnosis	1,808,908	3,835,646	2,026,739	1,561,979	3,588,717	
Cross Cutting Labs	14,007,977	10,504,162	(3,503,814)	4,911,845	1,408,030	
HIV Impact Mitigation	6,726,876	10,155,502	3,428,626	-	3,428,626	
Cross-Cutting HIV Activities	58,293,169	75,233,674	16,940,505	-	16,940,505	
CSO Activities	15,912,396	-	(15,912,396)	-	(15,912,396)	NFM CSS within allocation and above allocation
<b>Total</b>	<b>498,828,650</b>	<b>258,445,335</b>	<b>(240,383,315)</b>	<b>261,881,749</b>	<b>21,498,434</b>	

## Tuberculosis

With a much smaller donor landscape, the TB program has to strategically prioritize interventions in order to maximize impact. The TB program undertook multiple prioritization workshops to fully analyse the results of previous resource mapping exercises and leverage other donor resources.

Over the years, the TB program has been funded primarily by the Government of Malawi, USG, the Global Fund, and Norway, among other donors. GoM's funding is mostly allocated to prevention activities (BCC), 2nd line and TB cross-cutting platform costs; Global Fund USG funds mainly contribute to 1st line and diagnostics (microscopy, GeneXpert); WHO supports case detection and diagnostics.

Though partners (excluding Global Fund) are able to provide financial support that covers a portion of funding needs from 2015 to 2017 (Table 7), funding gaps still exist in almost all programmatic areas. Based on analysis of the financial gaps, the TB program identified high priority items that were then placed either within allocation or above allocation in the Global Fund Concept Note. For example, in the NSP intervention area of "Integrated, patient centred diagnosis treatment and care," certain activities are prioritized as they face a 100% funding gap, such as active case finding among high-risk groups, expansion of TB registration sites, strengthening of the TB laboratory network, and awareness creation. Likewise, in "Prevention - through reduced transmission in health services and among known cases," activities with a major funding gap were also placed within allocation, such as provision and distribution of isoniazid (INH for IPT) and pyridoxine for household contacts.

### 1.1.c For program areas that have significant funding gaps, planned actions to address these gaps

#### HIV

Delivering a technically sound and efficient response in Malawi is difficult with funding gaps in key programmatic areas. Beginning in 2015, these significant funding gaps, especially related to treatment and care, are cause for much concern, careful planning, and prioritization. As previously noted, information from this financial gap analysis can inform and guide the government/partners to reallocate excess resources committed to certain program areas that are projected to be over-funded. A summary of the HIV financial gap analysis by programmatic area is below.

Table 11: Funding Gaps by HIV NSP Pillar (in USD)<sup>130</sup>

NSP Program Area	Funding Gap by NSP Pillar								
	2014-15			2015-16			2016-17		
	Need	Available	Gap	Need	Available	Gap	Need	Available	Gap
Treatment	125,167,267	154,064,732	-	147,012,205	50,467,706	96,544,499	153,475,868	47,008,006	106,467,862
Prevention	38,452,383	49,265,141	-	56,219,983	38,959,349	17,260,635	71,462,358	36,621,098	34,841,260
HIV Impact Mitigation	2,085,023	5,050,052	-	4,733,554	5,077,958	-	4,854,248	5,077,544	-
Program Management	34,044,005	36,585,399	-	26,807,077	38,320,494	-	34,263,357	36,913,180	-
Total	199,748,677	244,965,324	-	234,772,820	132,825,507	113,805,134	264,055,830	125,619,828	141,309,121

The funding gap depicted in

Table 11: shows that there is an increasing financial gap trend towards over the next few years. In the area of Treatment, which has a gap of USD 96.55 million in 2015-16 and USD 106.47 million in 2016-17, ART is the main driver of this gap, which explains why the bulk of the HIV NFM request is for commodities.

It should be noted that according to Malawi's Round 3 Resource Mapping exercise, the total resources available in 2014-2015 for HIV amount to USD 244.97 million. Of this, USD 110.24 million (or 45%) is for ART drugs, and the remaining USD 134.73 million (55%) is for supporting activities to link patients to treatment and care, as further detailed below. The Global Fund currently provides USD 86.11 million (or 78%) of Malawi's current ART in 2013-14. The current NFM request is in line with this with the bulk of the requested funding (USD 207.64 million of USD 266.73 million, or 75%) going to ART. Furthermore, it should be noted that of this request, USD 176.34 million (or 85%) is needed to maintain the current 570,000 patients on ART for the two year period. Of the remaining USD 31.29 million (or 26%) of the ART funding request, USD 24.92 million is requested to help Malawi in its scale-up to the 90-90-90 targets and USD 6.37 million is requested for the ART commodity buffer. Additionally, the Government of Malawi understands the importance of taking ownership of the HIV program and has committed an additional \$8.5 million towards the procurement of the ART commodity buffer, the remainder of which is included in the above allocation request.

As previously mentioned, the bulk of Malawi's funding request will be used to maintain current ART eligibility. In comparing patient numbers and the associated program cost between maintaining the 2014 Malawi ART eligibility criteria and introduction of universal eligibility from 2016, the incremental cost of changing the eligibility guidelines amounts to approximately \$5.8 million between 2015 and 2017. Sustaining the current patients and maintaining 2014 criteria of CD4 500 costs approximately \$295.5 million while scaling up to universal eligibility costs approximately \$301.3 million – a difference of \$5.8 million to enroll over an estimated 65,000 patients on ART by 2017.

Although Malawi will be heavily donor dependent for the foreseeable future, the Government is exploring possible alternatives to sustainably contribute to the HIV response. A series of taxes and levies on things such as income, alcohol, phone airtime, tobacco, and airlines are being considered that have the potential to contribute more funds to finance the health sector and HIV programs. An analysis of these potential income sources can be found on page 70 of the HIV NSP.

## Tuberculosis

The TB NSP faces considerable funding challenges to deliver a sound response. The costed TB NSP shows a growing need to scale-up diagnostics services and subsequent case management. The NSP seeks to further decentralise TB diagnosis and treatment to peripheral facilities and community levels in the public and private sectors, to consolidate programmatic management of drug-resistant TB, and roll out further implementation of TB/HIV collaborative activities and interventions as part of both TB and HIV/AIDS Control strategies. Table 12 shows the financial gaps by thematic area over the years. The government will need to carefully plan the timing of delivering the goals set forward in the NSP due to these considerable funding gaps, or look for opportunities, including increasing domestic funding for TB, to cover the gaps.

<sup>130</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

Table 12: Funding Gaps by TB Programmatic Area (in USD)<sup>131</sup>

NTP Program Area	Funding Gap by NSP Pillar					
	2015-16			2016-17		
	Need	Available	Gap <sup>132</sup>	Need	Available	Gap
Treatment/Care	4,424,931	615,641	(3,809,290)	5,918,792	689,045	(5,229,747)
Prevention	223,794	117,114	(106,680)	153,346	133,832	(19,514)
Diagnosis	8,843,143	1,391,162	(7,451,980)	8,733,832	1,395,144	(7,338,689)
Cross-cutting TB	5,440,444	551,017	(4,889,427)	5,240,385	611,358	(4,629,027)
<b>Total</b>	<b>18,932,311</b>	<b>2,674,934</b>	<b>(16,257,377)</b>	<b>20,046,355</b>	<b>2,829,379</b>	<b>(17,216,976)</b>

The largest gaps in the TB response relate to diagnostics, treatment/care activities, and cross-cutting TB activities. The Ministry of Health will continue to actively advocate for and engage with the Ministry of Finance to secure non-earmarked funds for the TB response.

## 2.2. Counterpart Financing Requirements

2.2 Counterpart Financing Requirements		
Complete the Financial Gap Analysis and Counterpart Financing Table (Table 1). The counterpart financing requirements are set forth in the Global Fund Eligibility and Counterpart Financing Policy.		
<b>2.1a. For TB and HIV, indicate below whether the counterpart financing requirements have been met. If not, provide a justification that includes actions planned during implementation to reach compliance.</b>		
Counterpart Financing Requirements	Compliant?	If not, provide a brief justification and planned actions
i. Availability of reliable data to assess compliance	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
ii. Minimum threshold government contribution to disease program (low income-5%, lower lower-middle income-20%, upper lower-middle income-40%, upper middle income-60%)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
iii. Increasing government contribution to disease program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

<sup>131</sup> Data taken from HIV-TB JCN Financial Analysis, version GF Final.

<sup>132</sup> All numbers in red reflects a gap, all numbers in black refers to adequately resourced

**2.2b. Compared to previous years, what additional government investments are committed to the national programs (TB and HIV) in the next implementation period that count towards accessing the willingness-to-pay allocation from the Global Fund? Clearly specify the interventions or activities that are expected to be financed by the additional government resources and indicate how realization of these commitments will be tracked and reported.**

Despite heavy reliance on external donors, the Government of Malawi remains committed to contributing increased funding to the HIV and TB programs. Total budgetary allocations to health and HIV were USD 163.7 million in 2013-14 as a revised estimate. Budgetary allocations to health and HIV have reduced in the 2014-15 budget to USD 133.8 million due to reduced donor inflows and high levels of arrears and domestic debt. This is considered an exceptional situation making it difficult to increase allocations to health and HIV in this financial year. Malawi expects 2015-16 to be a more normal year and has budgeted USD 187.9 million for health and HIV, increasing to USD 190.84 million in 2016-17.

As part of the prioritization retreats that took place in developing the New Funding Model, key gaps in the response for both TB and HIV were presented to the Ministry of Health for consideration of the Government's additional commitments as part of its willingness-to-pay allocation. The Ministry of Finance has committed an additional USD 21.5 million for the period covered by this Concept Note. Table 13 outlines the areas and activities pertinent to the HIV and TB programs that are expected to be covered by these willingness-to-pay funds through December 2017. Of the USD 21.5 million, USD 11.35 million will be allocated to HSS portions that have implications on HIV and TB, and the remaining USD 10.15 million will be allocated to malaria commodities, which faced an extensive funding gap to meet projected need. Additionally, it should be noted that the Government of Malawi recognizes the importance of beginning to take ownership of the HIV program and has also committed USD 8.5 million to the ART commodity buffer,

*Table 13: Activities Funded by Willingness-to-Pay*

Area	Request (USD)	Description of activities
Supply Chain	5,750,000	Support expansion of medicines storage infrastructure for priority districts
Human Resources for Health (HRH)	2,500,000	Training of Clinical and Pre-clinical tutors/instructors, medical assistants, clinical officers, pharmacy assistants, lab assistants/technicians, in-service mentors; increasing number of clinical facilities supporting pre-service instruction (model wards); strengthening HR Management through improved allocation, distribution, forecasting of staff via iHRIS
Laboratory Strengthening	3,100,000	Pharmacovigilance and market surveillance; service maintenance contracts for lab equipment; sample transportation; external quality assurance

The Ministry of Health has a number of financial mechanisms in place for tracking expenditure towards health and health related activities. Tracking tools and surveys include National Health Accounts, National Spending AIDS Assessment, Resource mapping and Public expenditure tracking systems (PETS) and service provision surveys. The frequency of these assessments and tracking exercise varies but are complementary to each other.

**2.2c. Provide an assessment of the completeness and reliability of financial data reported, including any assumptions and caveats associated with the figures.**

Malawi's fiscal year starts in July and ends in June the following year. For this exercise, "2015" represents "July 2015-June 2016".

Financial Gap Analysis:

- The gap table is 100% complete for the funders included in the table. There is however a potential that "smaller" funding agencies have not been included. This does not significantly affect the available resources.

Counterpart Financing (CPF) Table

- The CPF table shows that Malawi has 6-8% (HIV) and 6-12% (TB) counterpart financing for HIV and TB. In addition to the quantified resources exhibited in the table, Malawi resources, such as HR, Platform costs, infrastructure costs towards HIV and TB programs, have not been catered for in this table.

NSP Costing of Interventions

- We adopted an activity-based costing exercise, detailed to every activity in the program implementation. Actual program expenditure data was used from different implementing partners on the ground. Inflation has been catered for in the upcoming years. All other assumptions are included in the detailed costing workbook attached.

#### Available Resources

- Malawi conducts a regular and consistent resource mapping exercise supported by partners. This exercise is detailed enough to give commitments from various partners. Completeness and reliability of the data is very high. However, we note a caveat with any commitments made for this, as in certain instances there is under- or over-disbursement. The under-disbursements override the over-disbursements. Analysis for 2012-13 round 3 of resource mapping shows that the actual disbursement fall short of commitments by about 13%. However, we also note that the disbursement rate for GoM funds to the National AIDS Commission is between 90-95%.

### 2.1. Programmatic Gap Analysis

#### 2.1.a HIV

##### i) Treatment Care & Support – ART

ART remains the mainstay of the national response to HIV in Malawi as not only does it reduce morbidity and mortality and improve the quality of life for PLHIV, it also has the greatest impact on prevention of transmission of HIV. This is attributed to the reduced viral load burden in the population. However currently programmatic gaps exist, with ART coverage for adults and children at 49%. Coverage for children is lower than adults (40% vs. 80% for adults). Some of the challenges contributing to this include but are not limited to inadequate human resources, low treatment literacy levels, suboptimal retention in ART in some facilities with some geographical areas having lower ART coverage (NSP). The current transitional (interim) funding covers commodities (ARVS, HTC test kits, lab reagents (for viral load and EIDs and OI drugs) for the period July 2014 to June 2015.

This concept note is sourcing funding in the new funding model to build on top of the existing support and adapts best practices by also addressing human resource challenges through training and clinical mentoring focusing on pre-service as well as in-service training to ensure health workers who graduate are available to immediately provide ART/PMTCT services. Clinical mentoring will also be crucial to ensure health workers are equipped with skills to handle paediatric cases and routine viral load monitoring for ART failure. Treatment literacy will be addressed through an expanded SBCC program through the print & electronic media, IEC using community structures, while retention and adherence will be ensured through community linkages and expert clients and/or support groups. The concept note also seeks to source funding to improve the quality of care by further scaling up routine viral load screening to all the 28 districts in Malawi to monitor adherence, detect ART failure and ensure timely switch to second line. A programmatic gap exists for procurement of laboratory reagents and consumables to support viral load scale up. The focus will be on ensuring effective forecasting and quantification for procurement of reagents/consumables to support VL scale-up.

##### ii) PMTCT

Malawi has been very successful with the implementation of option B+ for PMTCT with the resultant reduction in mother to child transmission of HIV by 66% (program data). However, there are still an estimated 6,250 new infections occurring amongst those aged 0-11 years. Most of the remaining MTCT events are thought to occur among women newly infected later on in pregnancy or breastfeeding period. The concept note will thus source additional funding for procurement of testing reagents to identify all HIV infected pregnant or breastfeeding women in the population through routine testing during and after pregnancy as well as during EPI vaccination at 9 months (NSP section).

The HIV ascertainment rate amongst pregnant women is 67% (2013 program data). This is compounded by early loss to ART follow-up among HIV positive pregnant women due to a not-so-well-coordinated education information campaign on option B+. Peer-support services such as the Mother2Mother program, use of expert clients and couples counselling as well as male involvement interventions to facilitate disclosure will be essential to ensure retention in care.

Low infant ART coverage (18%) is attributed to programmatic challenges such as suboptimal identification of exposed infants in maternity, DNA-PCR testing at six weeks and extended turnaround time for DNA-PCR results (NSP). DNA-PCR testing is performed in central labs, requiring well-coordinated logistics for sample transportation and communication of results. Low uptake of testing for exposed infants at 12 and 24 months due to limited access to HTC has also led to low infant ART coverage, the national program intends to introduce a HTC dedicated cadre to ensure exposed infants have access to routine testing as well as mothers in ANC, maternity, postnatal and during under 5 clinics. The current cadre (HSA) has other responsibilities other than HTC and this has led to missed opportunities.

Defaulter rate among young women and adolescent girls is higher than the other age groups (Lighthouse). This will be addressed through targeted education information campaigns for young women and adolescents with adolescent health corners where they can access HTC, ART and adherence counselling services.

Complementing investments through the NFM to scale up paediatric ART coverage will be the joint PEPFAR/Children's Investment Fund Foundation (CIFF) "Accelerating Children's HIV/AIDS Treatment (ACT) Initiative". This effort aims to achieve a target of 42,220 additional children (0-14 years) and 2,439 additional adolescents (15-19 years) on treatment during the two-

year initiative in Malawi. This will include direct support to service delivery activities and systems strengthening interventions to support the scale-up.

### **Family Planning**

Malawi has one of the highest fertility rates in the world, posing a challenge for Prongs 1 and 2 of the PMTCT program. MDHS 2010 estimates a modern contraceptive prevalence rate (CPR) of 42% among married and unmarried, sexually active women, with an unmet family planning need of 26% among married women. The modern CPR for married and unmarried, sexually active women 15-19 and 20-24 is 27% and 38% respectively. The unmet need among 15-19 and 20-24-year-old married women is 25% and 27% respectively. This indicates that most adolescent and young women do not access contraceptives and over a quarter of those married wish to delay or limit having children. Programmatic challenges include low literacy rates, child marriage, gender inequalities leaving women disempowered to practice family planning, human resource constraints and weak supply chain systems for family planning commodities.

The national program has introduced Provider Initiated Family Planning (PIFP) services in the ART/PMTCT program to offer one-stop shop services for ART and family planning. However, the family planning services are limited to Depo-Provera and condoms (dual FP). It is necessary to expand the services to include other options with due consideration for drug interactions, especially with clients on ART to avoid compromising the efficacy of ART drugs. Expansion of FP options will need to take into consideration capacity needs (training & mentoring) as well as the availability of FP commodities.

### **iii) Prevention Programs for General Populations**

#### **HTC**

HIV Testing and Counselling (HTC) is a priority area as this is an entry point to prevention, treatment, care and support interventions. Current programmatic gaps have been noted with 82% of pregnant women received an HIV test result while only 40% of HIV-exposed infants received an HIV test result. This is mainly attributed to the following challenges: human resources for HTC and quality of testing. HSAs provide HTC services while also performing other duties in the community, including working as drug store clerks in some health facilities; this has affected access to HTC especially in ANC/maternity/EID/STI and other points of care.

HTC will be significantly scaled up through Provider Initiated Testing and Counselling (PITC) where health care workers actively encourage patients to be tested for HIV with the aim to find the positives and achieve the ambitious 90-90-90 targets by 2020. This strategy has demonstrated the highest yield for positives. This will be prioritized during provision of services for family planning, TB, sexually transmitted infections and acute medical care, as well as antenatal and maternity care services, among others.

The Ministry has recommended a dedicated HTC cadre to support counselling and testing; this cadre will go a long way in enabling the program to achieve national targets for care and treatment. Also critical to HTC is the need to provide quality results. USG/PEPFAR will support district partners in all 28 districts to address quality of testing and second the dedicated HTC cadre ("HIV Diagnostic Assistants") in all health facilities whilst awaiting government creation of the post. It is envisaged that the success of this approach will accelerate government approval of the creation of the dedicated HTC cadre position. In addition, as we scale up HTC services in line with ART scale up, there is need to improve infrastructure by providing appropriate rooms for counselling.

Quality assurance and proficiency testing have been selective and inconsistent, leading to suboptimal quality of testing in some facilities. It is necessary to address this gap to mitigate the consequences of giving out false test results to clients. Funds are being sought in this application to support procurement of test kits and quality control reagents to guarantee uninterrupted availability of commodities (NSP, section 5.5).

#### **Blood Safety**

The Malawi Blood Transfusion Service (MBTS) is striving to provide blood products for the entire country using voluntary non-remunerated donors and quality assured screening for transfusion transmissible infections (TTIs). However, for the last years, MBTS has not been able to meet the entire national demand meeting about 65% of national need while several hospitals continue to supplement or rely entirely on blood units collected from replacement donors. MBTS has been availing consistent data throughout, but blood safety reports from some health facilities have been incomplete and inconsistent.

The ART/PMTCT quarterly supervision teams are now tasked with active collection of blood donor and cross-matching data from the registers in all hospitals and health facilities that provide the service. A total of 20,242 blood units were collected in Malawi in Q1 2014 and out of these 18,850 were screened (93%) for at least HIV, syphilis and Hep B. The current major gap has been ensuring that reagents are available for testing for all transmissible infections (HIV, syphilis, Hep B, Hep C and Malaria (Q1 2014

program report). Funds will be sourced through the concept note for commodities and supplies, while other activities will be funded through domestic MoH and partner resources, including USG/PEPFAR.

## STI

Sexually Transmitted Infections (STI) are a risk factor for HIV transmission and hence an important area for HIV prevention through early and effective management of STI. Currently the coverage and quality of STI services is not to the required standards. Gaps exist in the management of STI using syndromic management where only about 60% are treated according to guidelines. Inadequate numbers of trained providers and lack of regular supervision to those providing the service has contributed to non-adherence to standard guidelines. The lack of integration of STI with HTC in some health facilities has led to clients who are referred for testing at the standalone HTC site not accessing the service after receiving their STI treatment as most are lost along the way, leading to sub-optimal HTC coverage for clients accessing STI services. STI program reporting and documentation is also a big challenge as it is often incomplete leading to inadequate data for forecasting and quantification for STI drugs. Therefore it is necessary to revamp the STI program by training its providers and regularly supervising them to ensure standards are adhered to and data captured to aid quantification and program implementation. (NSP, section 3.1). Funds will be sourced through the Concept Note to procure commodities and offer training to increase coverage from the current 41% (NSP results framework) to 65% in 2017.

## Condoms

Condom programming is an integral component in the HIV prevention agenda as an effective and inexpensive HIV prevention intervention. Efforts have been made through the 2011 – 2016 NSP to ensure continuous supply of male and female condoms. However, despite these efforts, low and inconsistent use of condoms continues to exist due to reasons explained on page 47 under section 8.4 of the NSP. According to the last DHS (2010) 23.5% of males and 27.5% of females with more than two partners in the last 12 months used a condom at their last sexual encounter. Most of the challenges centre around quantification of condoms and unequal distribution of condoms with some facilities experiencing stock outs while others are oversupplied. A condom programming committee has been established to streamline quantification and distribution of condoms nationwide.

The NSP section 8.4 provides some measures that would increase use of male and female condoms whose efficacy is 87%, estimated through the Malawi Investment Case results of 2013. PEPFAR is currently focusing on condom promotion and distribution in six high-burden districts in Malawi.

## VMMC

While VMMC has the potential to reduce female-to-male HIV transmission by up to 60%<sup>133,134, 135</sup>, in Malawi VMMC uptake has been initially slow but has picked up with over 150,000 circumcisions conducted by September 2014. The national response has been to provide VMMC services initially in eight high-prevalence districts with support from USG/PEPFAR and expand to more districts with support from World Bank and other partners to ensure maximum impact. The main challenges have been demand creation, involvement of females and community leaders, inadequate qualified providers to conduct the circumcision and issues with supplies of commodities/consumables for male circumcision.

The VMMC program coverage targets have been reduced from 80% to 60% taking into account pace of scale-up. The GoM estimates a target of 1,300,568 circumcisions in 14 priority districts from 2015-2019, with 226,027 circumcisions estimated to be done in 2015/2016. The program will source further funding and technical support from USG/PEPFAR, World Bank and implementing partners to increase coverage for male circumcision in the 14 highest prevalence districts and over time to all districts in the country. However, additional VMMC commodities and training, demand creation, couples counselling for men and their female partners, mobilizing female champions and community leaders to promote VMMC and operational research are needed.

## Vulnerable Populations

HIV-vulnerable populations (aside from the key populations of MSM and FSW) will be served through targeted general population prevention programming. These include, but are not limited to, prisoners, clients of sex workers, adolescent girls, OVC, women, discordant couples, fisher folk, uniformed forces, estate workers, vendors, and long distance truckers. Illustrative programmatic gap analysis information follows for some of these groups.

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<sup>133</sup> Auvert B, Taljaard D, Lagarde E, et al. [Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: The ANRS 1265 trial.](#) *PLoS Medicine* 2005;2(11):e298.

<sup>134</sup> Gray, RH, Kigozi G, Serwadda D, et al. [Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial.](#) *The Lancet* 2007;369:657-666.

<sup>135</sup> Bailey RC, Moses S, Parker CB, et al. [Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial.](#) *The Lancet* 2007;369:643-656.

While HTC, STI and TB management, and ART treatment are available or accessible to inmates through referral in Malawi prisons, quality services, drugs, other commodities, and targeted information are not consistently available. USG/PEPFAR and MSF will supplement GoM resources to ensure prisoners' access to standardized screening for HIV, STI and TB and relevant educational materials, including addressing "contextual MSM" issues in prisons.

Young women and adolescent girls have increased vulnerability to unintended pregnancy, HIV and STI. There are barriers to accessing FP, HIV and STI services for young women and girls, and youth in general.

GIZ has also committed resources of between €2 million - €3 million per year for four years (2013 – 2016), targeting 1.8 million adolescents aged 10-19 years in 10 districts. The program focuses on SRH and HIV prevention services, life skills and sexuality education, and prevention of unintended pregnancy. USG/Family Planning (FP) funds and KfW are also implementing a PSI/SIFPO Malawi program in KfW districts to strengthen access to and increase uptake of youth-friendly health services (YFHS) by ensuring quality YFHS provision that includes targeted demand generation for youth SRH and expanded availability and choice of FP services. Services are provided at both social franchise and outreach sites by trained YFHS providers. HIV services (HTC, STI screening and treatment, and GBV) and HIV referrals) will also be provided through the existing FP/SRH platform utilizing dedicated outreach mobile teams and social franchise networks.

GoM, through the MOGCSW with support from KfW and EU, is implementing the Social Cash Transfer Program (SCTP) in nine districts targeting the chronically ill, orphans, labour-constrained, girl children and ultra-poor households. GoM, through the Ministry of Education, Science and Technology (MOEST), will continue to provide life skills education through the school curriculum and youth clubs for out-of-school youth. LSE empowers young people to make informed choices and decisions about their health, including developing healthy lifestyles and gaining wider knowledge on sexual and reproductive health issues.

Women are included as a priority vulnerable group for HIV prevention efforts, due to their increased susceptibility to HIV infection, including biophysical and socio-economic considerations, gender roles, male/female power imbalances, and risk of GBV. As part of the efforts to address gender dimensions of HIV and AIDS, the Government of Malawi in partnership with various CSOs implemented a Women, Girls, HIV and AIDS (WGHA) Program throughout the country as one major response that has so far signalled Malawi's commitment towards reducing HIV infection rates of women, as well as reducing the impact of the HIV epidemic on women. The efforts and gains made through the program have provided an opportunity to motivate formulation of improved programs of a similar nature. Despite the gains made so far, women and girls still lack adequate SBCC information and services tailored to their specific HIV prevention needs, although HIV prevalence rates among women are higher than those for men.

Violence Against Women and Girls (VAWG) is one of the most widespread abuses of human rights affecting women in Malawi with 61% of females reporting having experienced sexual assault (NSO, 2012). Furthermore, intimate partner violence against women was common at the point of discovery of one's partner's HIV-positive status (COWLHA, 2012).

Although PMTCT has high priority in the national HIV response and the fact that Malawi has implemented the Option B+ protocol, key gaps remain of male involvement despite interventions by some districts councils and CSOs that sought to promote male participation and facilitate the transformation of attitudes relating to masculinity and male dominance in HIV programs, including male partner involvement in PMTCT.

#### **iv) Prevention Programs for MSM and transgenders (TGs)**

In Malawi, there is limited data on MSM population sizes, population in need, and intervention coverage and gaps, especially for older MSM. A seven-site MSM HIV prevalence, socio-behavioural and population size estimation study released at the end of 2014 estimates MSM make up about 1.84% of the overall male population aged 20-39 years in Malawi, or about 38,734 individuals. This is consistent with other estimates from African countries.<sup>136</sup> There is little information currently on transgendered people (TG) in Malawi and their numbers are thought to be very low.

The CHPI study demonstrated the feasibility of providing a comprehensive package of community level services to key populations (MSM specifically) in Malawi including peer outreach and targeted risk reduction education, condoms and lubricant distribution, routine HTC and STI screening and management, and facilitated referrals to "key population-friendly" clinical services. To date, there has been only one local NGO, the Centre of Development of People (CEDEP), providing targeted services to MSM, serving approximately 1400 (4% population coverage). Services are concentrated in the three largest cities, and the lakeshore districts of Nkhata Bay and Mangochi. Besides service barriers related to stigma and discrimination and criminalization of same-sex sexual relations, there is a lack of capacity in terms of the number of organizations available and capable of providing

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<sup>136</sup> AL Wirtz, G Trapence, V Gama, D Kamba, R Chalera, L Klein, R Kumwenda, T Chikoko, M Mangochi, S Baral. *Final report to UN Joint Team on HIV&AIDS in Malawi through UNDP: HIV Prevalence and Sociobehavioural Characteristics among Men Who Have Sex with Across Seven Sites in Malawi*. Johns Hopkins University and the Centre for Development of People. 01 December 2014.

a package of MSM-targeted prevention services. Available funding is largely from USG/PEPFAR (for services, lubricant and capacity building) for geographically targeted areas of the country where MSM can be found in higher number. Concept Note resources will allow expansion to other geographic hotspots. Prevention programming for “contextual MSM” in prisons will be addressed under prevention programs for the general population, with resources coming from GoM, USG/PEPFAR, MSF, NORAD and others.

#### **v) Prevention Programs for Sex Workers and their Clients**

There have been several studies addressing FSW in Malawi (i.e., 2011 FPAM FSW study, 2006 and 2013 BBSS), though comprehensive data on FSW is limited and there is a lack of information on male sex workers. FSW population size estimates in Malawi to date are widely considered conservative. Based on FSW population size estimation studies in sub-Saharan Africa, the population in need is estimated at 1.5% of females 15-49 (approximately 55,000).<sup>137, 138</sup> There are a number of funders and implementers of services targeting FSW, and to a lesser extent their clients; current FSW coverage is estimated at 7,700 (14%) based on service provider data.

The current national response is fragmented and intervention responses are not sufficiently comprehensive to include key services (i.e., targeted peer risk reduction education, male and female condoms and lubricant, routine HTC, STI screening and treatment, family planning, and facilitated referral to FSW-friendly clinical services in a standardized or coordinated manner). Referrals are difficult to track. There are service barriers related to stigma and discrimination and criminalization of sex work. The Sex-worker Alliance, established in 2012, shows great promise for HIV-related coordination and advocacy efforts, but organizational and technical capacity of the national and existing district chapters is limited and district chapters have been established in about 1/3 of the 28 districts.

Funding is from GoM, USG/PEPFAR, UN, MSF, NORAD and others. Starting in 2015, DFID is providing support for assessing the capacity of local organizations in providing key population services, including for FSW. Concept Note resources will allow expansion to other geographic hotspots. Targeted prevention programming for clients of sex workers is covered through prevention programs for the general population. As noted above, Malawi plans on applying for Global Fund Special Initiatives Funds to address weaknesses in FSW and other key and vulnerable population strategic information to enhance planning and programming.

#### **2.1.b Tuberculosis**

##### **i) Case Detection and Diagnosis**

###### **Health Service Delivery (Diagnostics)**

Malawi meets the WHO standards regarding population coverage of TB diagnostic centres; however, these microscopy services are unevenly distributed. The main modality of detection relies on passive case detection and most patients make repeated visits before a diagnosis is made.<sup>139</sup> A total of 40 functional GeneXpert platforms are currently in the country augmenting the point of care smear microscopy. GeneXpert contributes 8-12 % of the total notified TB cases in 2013. However, these platforms are underutilized due to differing algorithms among implementers, limited knowledge among health workers and weak transportation systems. All the GeneXpert are purchased and procured by partners. The partners are building the capacity of health workers in public health facilities. The Functional X-ray services are limited to district and high volume centres, where many units are in a state of disrepair. The provisional results of the prevalence survey indicate that X-ray is superior to symptomatic screening in terms of ability to detect cases. It is envisaged that scaling up X-ray will increase detection of TB cases in high-risk groups; nearly USD 2.0 million is available for two years from USG and WHO for general program support and diagnostic capacity building

##### **ii) Vulnerable and High-Risk Groups**

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<sup>137</sup> Odek WO, Githuka GN, Avery L, Njoroge PK, Kasonde L, et al. (2014) Estimating the Size of the Female Sex Worker Population in Kenya to Inform HIV Prevention Programming. PLoS ONE 9(3): e89180. doi:10.1371/journal.pone.0089180

<sup>138</sup> J Vandepitte, R Lyerla, G Dallabetta, F Crabbe, M Alary, A Buv. Estimates of the number of female sex workers in different regions of the world

<sup>139</sup> Kemp et al. Can Malawi's poor afford free tuberculosis services? Patient and household costs associated with a tuberculosis diagnosis in Lilongwe. Bulletin of the World Health Organization 2007; 85:580-585.

Children account for 10-12 % of notified TB cases with children under five having a greater risk of TB. Malawi has high rates of malnutrition (stunting 47%)<sup>140</sup> and HIV (100,000 children with HIV,<sup>141</sup> further increase the risk of TB among children<sup>142</sup>). Health care workers are also at increased risk of TB compared to the general population <sup>143,144,145</sup>. There is no local experience of addressing TB among health care workers so far; however, internationally recognised standard interventions will be implemented. The risk of TB is high among urban residents (1006/100000) and those aged >55 (1198/100000) compared to prevalence in adult population (451/100,000). Based on the STEPS survey on NCDs the burden of Diabetes Mellitus (DM) is high among adult Malawians at 5.6%. As the comorbidity of TB/DM is an established fact, NTP will work towards improving integration of TB screening in NCD clinics.

Targeted interventions for these groups are expected to yield high impact. Although the prison population is low in number, conditions in these facilities foster transmission of TB and HIV in higher rates. Various interventions are being piloted to ensure active case finding, providing early diagnosis prevention and treatment.

The key strategy for key populations is to implement active case finding strategy using digital mobile X-ray and GeneXpert platforms for screening and diagnosis. The resources gap and available resources are shown in the above diagnostics section.

### 2.1.c Health Systems Strengthening

The Government of Malawi is committed to strengthening the health systems as evidenced by the HSSP outcomes for improved equity and efficiency. Successful implementation of the national HIV response relies upon strong and functional health systems to achieve more equitable and sustained improvements across health services and health outcomes. This concept note proposes an investment in strengthening the systems for procurement and supply chain management, human resources for health, and laboratory service with the majority of investments in HSS initiatives derived from government of Malawi funding.

Supply chain management for public health commodities is one of the critical components of Malawi's healthcare system; GoM offers free healthcare services to patients at all public healthcare facilities, which underscores the need for a robust and effective supply chain system. Over three quarters of public health facilities in Malawi lack adequate storage space to store HIV and other health commodities in appropriate and secured conditions; this is currently a major threat to program implementation, considering the risk to product quality and security.

Currently, there are multiple public supply chains operating in Malawi. These include Central Medical Stores Trust (CMST) as well as several disease-specific parallel systems, due in part to weakness in existing national systems combined with increased volume of donor-supported commodity procurements. In Malawi, all ARVS, RTKs, and other HIV related commodities are procured by the Global Fund, while other donors provide technical assistance for managing HIV commodities at the national and sub-national levels, including service delivery points.

A well-performing health workforce for the HIV program requires sufficient numbers and skills mix for service delivery and program management. Malawi has a chronic shortage of skilled health care personnel. Shortage of health workers is exacerbated by a failure to retain those who are in the system due to a number of factors including a low remuneration package and shortage of accommodation especially in hard-to-reach/serve areas. Continued ART scale-up will require at least a moderate increase of HR allocation to ART services while clinical protocols will need to remain simple and streamlined. Increasing pre-service training outputs, in-service training through clinical mentoring, task shifting through training and placement of lay counsellors, expert patients and other volunteers to increase the health workforce will improve linkage, retention and adherence to treatment.

With the scale-up of pre-ART and ART, PMTCT including Option B+, HIV counselling and testing (HCT), TB/HIV and malaria services, the demand for laboratory services have increased in scope and complexity, particularly at the referral and district health facilities. Moreover, strengthening network linkages between laboratory services and care and treatment at the community and urban health facilities calls for expansion of point-of-care (POC) testing and a coordinated sample transportation system for more efficient implementation of the EHP and other health services. Therefore it is necessary to maintain capacity and enhance laboratory infrastructure in order to provide high quality HIV-specific as well as broader health services at the community, district and central health facilities levels.

<sup>140</sup> Government of Malawi. Demographic Health Survey. 2010.

<sup>141</sup> Government of Malawi. Ministry of Health. Integrated HIV Program Report. January – March 2014 HIV Quarterly report.

<sup>142</sup> Roadmap for childhood tuberculosis: towards zero deaths. WHO, 2013.

<sup>143</sup> Harries AD, Hargreaves NJ, Gausi F, Kwanjana JH, Salaniponi FM (2002) Preventing tuberculosis among health workers in Malawi. *Bull World Health Organ* 80: 526–531.

<sup>144</sup> Harries AD, Nyirenda TE, Banerjee A, Boeree MJ, Salaniponi FM (1999) Tuberculosis in health care workers in Malawi. *Trans R Soc Trop Med Hyg* 93: 32–35.

<sup>145</sup> Kanyerere HS, Salaniponi FM (2003) Tuberculosis in health care workers in a central hospital in Malawi. *Int J Tuberc Lung Dis* 7: 489–492.

Health infrastructure in Malawi is in dire need of attention. Not only are there not enough facilities, but the standing facilities cannot cope with the volume of clients and often do not have water or electricity, impeding quality health care provision. Despite Malawi's small size and relatively good road system, drug stock outs and inconsistent commodities have affected the quality of health services in the country.

#### **i) Procurement and Supply Chain Management**

A strong procurement and supply chain management system is critical to the success of the ART/PMTCT and TB programs. To ensure commodity availability throughout the health system, the MoH and implementing partners continue to provide support to address key procurement and supply chain management gaps in procurement, storage, distribution and stock monitoring at all levels. The PSM strengthening interventions will focus on outsourcing critical PSM functions such as procurement; warehousing and distribution functions; capacity building at all levels, strengthening storage infrastructure, strengthening the physical inventory during integrated supportive supervision and LMIS support. These interventions will build on existing efforts by the Ministry of Health and partners to improve PSM as illustrated by supply chain Integration efforts. Leveraging on public private partnerships is key to the success of the supply chain.

A good example of such a functional partnership is the one between the Central Medical Store Trust (CMST) and Bollore Africa Logistics (BAL). Partners have continued to provide technical support to ensure that PSM capacity is institutionalized within Ministry of Health for forecasting, quantification, pipeline monitoring and distribution planning of HIV and TB commodities. The Ministry of Health, Department of HIV/AIDS receives support from PEPFAR for a fellowship program in areas of M&E, Supply Chain, ART care and treatment. MoH counterparts and fellows are mentored by technical assistants within the Ministry of Health. The fellowship program will enable the MoH build sustainable technical expertise in this critical area leading to a stronger, more resilient PSM system.

#### **ii) Human Resource Management**

The continued shortage of trained health workers remains a significant barrier to improving the health status of Malawians. However, human resources for health continue to be a major challenge as the MoH currently has a 52% vacancy rate. In addition, there is disparity in the distribution of the health work force at various levels, with greater concentrations registered in the health facilities located in the cities, district headquarters and semi urban areas. (MoH, 2012). Furthermore human resource development approaches to recruitment, training and retention strategies, attrition remains high among health workers. Investment in improving the capacity of health care training institutions provides a long-term investment in the skills of healthcare workers.

#### **iii) Service Delivery**

With the scale-up of pre-ART and ART, PMTCT including Option B+, HIV counselling and testing (HCT), malaria services and high TB/HIV co-infection rates, the demand for laboratory services has increased in scope and complexity. Weaknesses in lab systems are compounded by limited laboratory equipment and personnel to operate it, an absence of continued regular quality assurance of lab services, and growing numbers of the population in remote areas. Some of these weaknesses are being addressed through PEPFAR investments in laboratory expansion and sample transportation, but those investments are not sufficient to provide coverage to lab services across the country. The investments in this request will ensure quality of laboratory services and meet the increase in demand likely to arise to meet the 90-90-90 targets and to improve TB diagnosis rates. As of now, over half of TB cases currently remain undiagnosed according to the 2014 TB prevalence survey. Ensuring the quality of pharmaceuticals that reach Malawi and establishing a system to detect adverse reactions will address some gaps in current quality assurance practices when testing pharmaceuticals. Key interventions under service delivery include: pharmacovigilance and post market surveillance; service contracts; sample transportation; and external quality assurance.

The standard tool in Malawi for Health Information Systems is DHIS2, a web-based tool and currently operational at all district health offices. However, this tool only captures a limited number of variables from disease control programs including TB and HIV. In order to inform program planning, the disease control programs continue to maintain a parallel system that collects more variables to facilitate program planning and management. The existence of parallel data collection systems puts a strain on the already scarce HRH (HSSP, p34). There are plans within the NTP to migrate from paper-based recording and reporting system to an electronic case based reporting and recording system. There are plans within the national public health monitoring and evaluation body to integrate the parallel systems into the DHIS2. There is support from development partners to build capacity of the public health sector to effectively generate, manage, disseminate and utilize health information at all levels of the sector for program management and development. This activity will complement current investments by PEPFAR in the clinically

oriented Baobab Health Information System, which provides electronic medical records for approximately 50% of ART patients and includes a TB module.

#### **2.1.d Community Systems Strengthening**

CSO and CBOs will be the entry point for supporting communities to participate in the AIDS response and to play a role strengthening health systems overall. CSO and CBO umbrella organisations, namely MANASO, MIIA and MANET+ have large constituencies which when harnessed will be central to the effective delivery of HIV/TB prevention, testing, ARV and TB treatment and AIDS care in ways that also protect human rights.

In this application, it is envisaged that CSO and CBO are particularly qualified to play two key additional roles:

- Advocating for services that are often inaccessible to marginalized populations such as women, and girls, sex workers, men who have sex with men (MSM) and people with disabilities.
- Demand accountability from Principal Recipients, government and all the key stakeholders providers in the NSP

Malawi needs to scale up the provision of community-based care and support services in support of the Pre-ART and ART programs, increased TB Case notification and detection, early diagnosis of the disease and ensuring increased emphasis in catchment areas of high-burden facilities, where the absolute number of patients requiring community support is highest. Considering the focus of the 90-90-90 principle as well as increased TB case detection, it is evident that the capacity of the community structures needs to be strengthened and the role of the communities should be enhanced so that the opportunities and local available resources in the community are taken on board in policy and decision-making at national and community levels.

Key and vulnerable populations will be specifically targeted with interventions to improve their access to health services and ensure that their human rights are respected and protected.

##### **i) Advocacy and Social Accountability**

There are laws and policies in the country that have punitive effects on key populations. There have also been reported cases of stigma and discrimination against key and vulnerable populations for HIV and TB. However, the number of organizations and forums for decision makers, health facilities, service providers accountable in the design and delivery of services including protection of the rights of the key affected and vulnerable populations are limited. Capacity of NGOs/CBOs working in communities will be strengthened to be able to advocate for concerns of affected/targeted populations.

##### **ii) Community-Based Monitoring**

There is limited knowledge among different organizations about community-based monitoring to assess adequacy of services, monitor progress of implementation of activities and also document and report on cases of human rights abuses and stigma and discrimination. This limits engagement with decision makers at all levels.

##### **iii) Community Engagement**

The extent of the HIV/AIDS pandemic in Malawi exerts pressure on the health sector, including its workforce which is estimated to have a 52% vacancy rate. In addition, there is inequality in terms of the distribution of health workers with high numbers in health facilities that are in cities, district headquarters and semi-urban areas. This requires community engagement to mitigate the problem. The HIV response has engaged communities to improve ART uptake, retention and adherence through patient education as well as peer support groups. As Malawi transitions to a point where the majority of ART patients have been initiated early, and may never have experienced the debilitating effects of HIV-related illnesses, extra attention needs to be paid to promoting and maintaining adherence and retention in care. Despite the simplicity of the ART regimen, the importance of ensuring the single daily tablet is taken on schedule remains critical to the success of the overall ART program. However, over the years there has been limited community engagement in matters regarding TB and TB/HIV to improve design, delivery and monitoring of service delivery.

##### **iv) Capacity Building of Community Sector Groups**

Most stakeholders in the community systems have capacity gaps in the technical and financial expertise to comprehensively design, implement, document and monitor gender transformative and rights based TB/HIV programs. In addition, they require

organizational development support to strengthen management, administration, and governance. New research findings in the National Response also require constant capacity building.

## 2.2. Applicant Funding Request

### 2.2.a Strategic Overview

This funding request addresses the rationale and prioritization laid out in Malawi's revised NSP 2015-2020 for HIV and TB. Interventions have been prioritized based on local and regional evidence for impact on incidence and mortality, considering Malawi's constrained human and financial resources. A further aggressive ART scale-up is imperative: HIV remains the leading cause of death among adults (15-49) in spite of the successful ART program, reaching 50% of all PLHIV by 2014 with TB ranking highest on the list of HIV related deaths. Although TB/HIV co-infection has declined over the last 10 years, the TB burden is twice as much as previously estimated according to the latest TB prevalence survey (451/100,000 amongst adults). Malawi's health services continue to have a very poor capacity to diagnose and manage HIV-related diseases. There is overwhelming evidence, including from Malawi, that early ART reduces TB risk by 51%, AIDS-defining clinical events by 51%, and primary clinical events by 27%.<sup>146</sup>

Malawi was the first country in Southern Africa to implement universal life-long ART for all HIV infected pregnant and breastfeeding women. This resulted in a 66% reduction of vertical transmission within three years. Based on Malawi's proven ability to sustain a rapid ART scale-up in spite of severe health system constraints, the new NSP aims to meet the *90-90-90 Treatment Targets* laid out by UNAIDS in 2014, preparing to control the HIV epidemic by 2030. By the end of 2020, Malawi aims to have:

- Diagnosed 90% of all PLHIV
- Started and retained 90% of those diagnosed on ART
- Achieved viral suppression for 90% of patients on ART

Reaching these 90-90-90 goals in 2020 will result in 760,000 (73%) of the projected 1,042,000 PLHIV being virally suppressed, leading to a dramatic reduction in sexual and vertical transmission at the population level.

The vision of the TB program is to increase the TB notification rate from 121/100,000 to 235/100,000 by the end of NFM through intensified and active case finding. This will include systematic TB screening in all health facilities and in each service delivery outlet. In addition, community TB activities will be strengthened (enhanced TB case finding) through awareness creation and health education using community service organizations. Active TB case finding strategy will be employed to improve case finding among high-risk groups (key affected population) and high-burden areas. This will involve establishment of routine regular outreach TB screening schedules using mobile vans with mobile X-ray machines and GeneXpert diagnostic platforms. In addition, the quality of TB screening in HIV services will be improved through the provision of supervisory tools that will ensure that health workers apply the screening tools regularly and consistently.

This funding proposal covers key program areas required to meet these objectives through:

- Targeted support for districts and sub-populations with the largest numbers of PLHIV not yet on ART (see Figure 15 on page 34).
- Geographical prioritization to focus on high-yield areas will be done through stratification by urban and rural categories for TB/HIV. Urban districts have higher TB prevalence (1,006 /100,000) compared to rural (369/100,000). Population residing in underserved areas of the four cities (Lilongwe, Blantyre, Zomba and Mzuzu) will be targeted for active TB case finding. Twelve districts with high notification rate will also be prioritized. In the prioritization, diagnostic service coverage was also considered.
- For urban population mobile outreach team using mobile vans with: (X-ray, GeneXpert) will be used for TB screening and diagnosis in addition to symptomatic TB screening. Expansion of CSCP and community strengthening service will focus on high-burden districts.

<sup>146</sup> Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2012;365(6):493-505.

Table 14 Package of key interventions per prioritized geographic entities, Malawi.

Intervention	Urban poor	High burden districts (12)	16 districts (not prioritized)
Maintaining and expansion of DOTs service	<ul style="list-style-type: none"> <li>Establish additional microscopic facilities</li> <li>Establish new TB registration sites</li> </ul>	<ul style="list-style-type: none"> <li>Establish additional microscopic facilities</li> <li>Establish new TB registration sites</li> </ul>	<ul style="list-style-type: none"> <li>Strengthen existing TB registration sites.</li> </ul>
Active case finding using mobile clinics (X-ray, Gene pert)	<ul style="list-style-type: none"> <li>Conduct outreach screening.</li> <li>Conduct Community Mobilization</li> </ul>	<ul style="list-style-type: none"> <li>Target congregate settings such as prisons</li> </ul>	NA
Systematic TB screening (OPD, MNCH, and Diabetic clinics)	<ul style="list-style-type: none"> <li>Conduct systematic TB screening in health facility service outlets</li> <li>Conduct regular supervision</li> </ul>	<ul style="list-style-type: none"> <li>Conduct Systematic TB screening</li> <li>Conduct regular supervision</li> </ul>	<ul style="list-style-type: none"> <li>Conduct systematic TB screening in health facility service outlets</li> </ul>
Strengthen TB case finding through expansion of CSCP	<ul style="list-style-type: none"> <li>Increase number of functional sputum collection points in urban settings</li> </ul>	<ul style="list-style-type: none"> <li>Expand community sputum collection points</li> </ul>	<ul style="list-style-type: none"> <li>Strengthen existing community sputum collection points</li> </ul>
Community TB care CSO strengthening presumptive TB identification and referral	<ul style="list-style-type: none"> <li>Conduct house to house visits</li> <li>Conduct regular review meetings</li> <li>Strengthen and expand contact investigation through HSAs and CSOs</li> <li>Conduct health education /promotion activities including school health programs</li> </ul>	<ul style="list-style-type: none"> <li>Conduct regular review meeting</li> <li>Conduct health education /promotion activities including school health programs</li> <li>Liaise with HSAs and CSOs to strengthen and expand contact investigation</li> </ul>	<ul style="list-style-type: none"> <li>Conduct health education and promotion activities for the general population</li> <li>Strengthen and expand contact investigation through HSAs and CSOs</li> </ul>

- Uninterrupted supply of well-tolerated ARVs and other basic HIV commodities at all 700 service delivery points.
- Scale-up of targeted PITC and testing among key populations, dramatically increasing the proportion of PLHIV who know their status.
- Improve ART uptake, retention and adherence through focused public and patient education and national scale-up of peer-support groups.
- In all districts basic DOTs will continue to be the main TB management strategy. An aggressive approach will be used to address case detection and treatment of MDR-TB cases.
- Early detection and treatment of co-infected clients with use of GeneXpert.
- Continue scale-up of scheduled viral load monitoring to support timely switch to 2<sup>nd</sup> line ART and devise innovative approaches to increase retention in care.
- Supporting communities through CSOs to participate in the HIV/TB response and to play a role in community systems, strengthening advocacy for removal of legal barriers and developing capacity to address needs of males, females, key populations and vulnerable groups in TB/HIV interventions.

The funding proposal also includes key supplementing strategies for primary prevention and improved access to health services for the general population with targeted interventions for key and vulnerable populations. This will support a sustained reduction in new HIV infections.

### **Health Systems Strengthening**

The majority of HSS activities identified by the CCM and the Concept Note writing team will be paid for by the Government of Malawi as part of its Willingness to Pay contribution. This includes USD 5.75 million to support expansion of medicines storage infrastructure for priority districts (PSM), USD 2.5 million for Human Resources for Health, and USD 3.1 million for service delivery largely focusing on strengthening lab services.

The requested HSS portion within the Global Fund Allocation is a modest (USD 2.87 million) the majority of which is allocated to training (USD 2.84 million) and a smaller amount to ensuring appropriate contributions to the revision of the Public Health Act (USD 21,581).

Additional requests above the allocation total to USD 4.373 million include USD 1.9 million for a logistics management information system and procurement mentoring, USD 1.95 million for pre-service training of HCW and support for HCW retention and USD 0.5 million to expand lab maintenance service contracts.

### **2.2.b Allocation by Module**

The writing team has followed a very stringent prioritization process in the allocation of funding for the different modules with high impact interventions such as ART/PMTCT and prevention interventions among key populations being within allocation. The above allocation's main priorities include HIV commodities for the extended six-month period (July -December 2017), the six-month buffer that could not be accommodated within the allocation much as it needed to be, and community services for key populations (MSM/FSW) such as mobile HTC/condom provision.

#### **i) Prevention Programs for the General Population**

##### **HTC**

USD 12.09 million of the allocated funding will be invested in HTC scale-up with a main focus on PITC in order to identify the positives required to reach the 90-90-90 targets by 2020. This includes timely procurement of adequate HIV testing and quality control commodities and DBS bundles for early infant diagnosis. PITC will be targeted at general medical wards, outpatients, communities, EPI program and under-5 clinics. Special emphasis will be placed on paediatric wards, under-5 clinics, EPI programs, nutrition rehabilitation clinics as well as OVC to increase paediatric ART coverage. The allocated funding will cover the period July 2015-June 2017.

An additional above allocation of USD 4.67 million is requested for the general population (USD 5.41 million including key populations), with USD 2.32 million of commodities required to cover the extended grant period (July 2017-December 2017) and USD 2.35 million will allow further scale-up of community based HTC activities, targeted HTC campaigns in geographical hotspots and development of a coordinated HIV self-testing program throughout the grant period.

Table 15 shows the targeted HTC and ART program outputs in the NSP before the background of the epidemiological projections for 2014-2020. As explained in Section 1, the total HIV positive population is projected to remain fairly constant due a parallel decline in new HIV infections and AIDS deaths. Several key assumptions and conclusions from these detailed projections demonstrate the feasibility of reaching the 90-90-90 treatment targets by 2020:

- HTC outputs will identify sufficient numbers of HIV positives to sustain the targeted number of new ART initiations required to reach the 90-90-90 targets by 2020. This is in spite of the decreasing 'diagnostic yield' for HIV testing anticipated in parallel with the declining prevalence among the population not yet on ART.
- Client-initiated, voluntary testing will remain an important entry point into care.
- PITC coverage at ANC will be maintained at high levels while routine repeat testing at maternity and in EPI clinics will be scaled up significantly to identify new infections in pregnancy and during breastfeeding that are becoming the predominant route of remaining MTCT.
- The diagnostic yield and the number of new ART initiations through PMTCT will decline considerably as ART coverage among women of reproductive age is ahead of other population groups due to Option B+.
- PITC scale-up in specific in- and outpatient settings will be maintained at high levels (TB) and scaled up significantly in currently underutilized settings (STI, VMMC, FP, EPI vaccination clinics).
- 85% of all ART initiations will be through client-initiated testing and through PITC in ANC, STI and for in-patients

- A focused improvement of STI services (coverage and quality) combined with high PITC levels is expected to become an important entry point into ART.
- Geographically and population-specific targeted testing campaigns will increase efficiency and serve to reach PLHIV not accessing the other HTC modes.

Other assumptions and conclusions for the ART program scale-up shown in Table 15 are explained in the Treatment section below.

Table 15 shows how the targeted HTC outputs by sub-population/delivery mode will identify sufficient numbers of HIV-positives to sustain the targeted number of new ART initiations that are required to reach the 90-90-90 targets by 2020. The 'diagnostic yield' will decrease in parallel with the declining prevalence among the population not yet on ART, requiring a significant increase in total clients tested and an adjustment of provider- and client-initiated testing modes each year.

*Table 15: Summary of program output and scale-up assumptions to reach the 90-90-90 treatment targets by 2020*

	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	Source / Comment
Total Population							
Total Population	17,217,941	17,760,255	18,322,408	18,904,378	19,505,379	20,125,886	NSO Malawi, 2008 Population Projections
Total Births	678,617	691,443	704,203	717,164	730,302	743,503	
Women attending ANC	631,000	632,000	644,400	656,000	668,000	680,000	
HIV Population							
Total HIV Population	1,055,344	1,052,924	1,050,274	1,046,981	1,043,178	1,038,665	AIM
Adults	917,581	923,460	928,909	933,547	937,411	940,323	AIM
Children	137,763	129,464	121,365	113,434	105,767	98,342	
Total New infections	41,652	36,584	31,875	28,094	24,915	22,494	
Adults	33,991	29,835	25,977	22,997	20,516	18,741	(PLHIV - on ART)/ pop)
Children	7,661	6,749	5,898	5,097	4,399	3,753	
HIV among pop. not on ART	2.7%	2.2%	1.8%	1.4%	1.2%	1.0%	
HTC Outputs							
Relative diagnostic yield	100%	78.87%	65.02%	52.03%	42.50%	35.78%	Diagnostic yield reduces with prevalence among pop. not on ART
Total Tests	1,479,875	2,615,238	2,641,390	3,512,719	4,022,835	4,428,512	
Mobile Testing of KAPs	14,660	26,123	25,971	33,484	37,043	39,566	
Client-initiated HTC	420,674	1,265,210	969,246	1,408,795	1,514,426	1,552,010	
Campaign Mode HTC	250,000	316,965	384,469	480,533	588,196	698,619	
Self-testing	-	-	90,900	156,261	216,082	230,802	
PITC: Inpatient	38,333	63,517	90,177	92,882	95,668	98,538	
PITC: STI	82,412	118,538	162,063	213,641	239,217	266,299	
PITC: VMMC	45,000	46,350	47,741	49,173	50,648	52,167	
PITC: ANC	517,420	600,400	612,180	623,200	634,600	646,000	
PITC: Maternity	12,191	46,806	82,999	176,027	272,455	372,232	
PITC: Family Planning	-	-	8,752	27,045	46,427	66,948	
PITC: Prisons	40,000	42,000	44,100	46,305	48,620	51,051	
PITC: EPI	-	-	32,844	100,349	170,326	242,825	
PITC: TB	22,244	22,984	23,749	24,543	25,367	26,218	
Confirmatory Tests	36,942	66,345	66,200	80,483	83,759	85,235	
Treatment Program Outputs							
Total ART initiations	102,618	144,229	118,215	121,943	110,209	99,111	Based on group-specific proportions for expected positive tests and ART uptake among those newly diagnosed (detailed assumptions in NSP costing)
Adults	86,752	127,497	101,892	104,881	93,816	85,728	
Children	15,866	16,732	16,323	17,062	16,394	13,383	
ART initiations by HTC mode							
Mobile Testing of KAPs	1,026	1,442	1,182	1,219	1,102	991	
Client-initiated HTC	30,772	72,997	46,103	53,614	47,085	40,626	
Campaign Mode HTC	6,000	6,000	6,000	6,000	6,000	6,000	
Self-testing	-	-	3,546	4,878	5,510	4,956	
PITC: Inpatient	6,386	8,346	9,769	8,050	6,774	5,875	
PITC: STI	10,178	11,547	13,015	13,727	12,557	11,769	
PITC: VMMC	1,755	1,426	1,211	998	840	728	
PITC: ANC	34,408	31,491	26,472	21,561	17,937	15,373	

	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	Source / Comment
PITC: Maternity	463	1,403	2,051	3,480	4,400	5,062	
PITC: Family Planning	-	-	216	535	750	910	
PITC: Prisons	7,600	6,294	5,448	4,577	3,926	3,471	
PITC: EPI	-	-	406	992	1,375	1,651	
PITC: TB	4,028	3,283	2,797	2,312	1,953	1,699	
<b>Total ART attrition rate (annual)</b>	<b>8.70%</b>	<b>8.70%</b>	<b>8.70%</b>	<b>8.70%</b>	<b>8.70%</b>	<b>8.70%</b>	
Adults	8.10%	8.10%	8.10%	8.10%	8.10%	8.10%	Program data Including ageing
Children	15.20%	15.20%	15.20%	15.20%	15.20%	15.20%	
<b>Total ART dropouts</b>	<b>50,975</b>	<b>58,451</b>	<b>63,330</b>	<b>68,112</b>	<b>71,567</b>	<b>73,720</b>	
Adults	42,812	49,158	53,109	56,988	59,748	61,695	
Children	8,163	9,293	10,221	11,124	11,819	12,025	
<b>Total People in HIV care</b>	<b>612,381</b>	<b>698,159</b>	<b>722,912</b>	<b>776,743</b>	<b>815,385</b>	<b>840,776</b>	
Patients in pre-ART	30,132	30,132	-	-	-	-	
<b>Total on ART (end year)</b>	<b>587,134</b>	<b>656,343</b>	<b>719,202</b>	<b>769,928</b>	<b>810,799</b>	<b>839,830</b>	AIM / MoH projection
Adults	532,980	596,271	652,303	697,388	733,480	760,805	
Children	54,154	60,072	66,899	72,540	77,320	79,025	
ART coverage (Adults)	<b>58%</b>	<b>65%</b>	<b>70%</b>	<b>75%</b>	<b>78%</b>	<b>81%</b>	
ART coverage (Children)	<b>39%</b>	<b>46%</b>	<b>55%</b>	<b>64%</b>	<b>73%</b>	<b>80%</b>	

## VMMC

Existing resources for the period of the Concept Note from GoM/World Bank (USD 6.13 million) and USG/PEPFAR (USD 18.92 million) are allocated to VMMC scale-up in 14 high HIV prevalence districts targeting 226,027 (2015-2016), 248,358 (2016-2017) 10-34 year-olds, supporting training, VMMC commodities such as Prepex kits, equipment for both static and mobile services including demand creation, operational research and strengthening of VMMC quality assurance, M&E and other activities. The MoH plans to eventually (2017-2020) integrate VMMC services into existing health services and scale-up to all districts including early infant male circumcision.

The requested above allocation funding of USD 17.6 million will be invested into increasing VMMC human resource capacity, commodities procurement, demand creation activities, and operational research, allowing further expansion of VMMC scale-up for an additional 198,000 men circumcised.

## STI

Malawi will invest a total of USD 6.3 million (2.3%) of the allocated funding into critical STI program support. This investment constitutes only a small proportion of the total allocated funding, but it addresses key programmatic gaps and is expected to prevent a significant number of new HIV infections in the general population and among FSW, their clients and among MSM by:

- Ensuring uninterrupted availability of standard STI diagnostic and treatment commodities at all public and private sector sites through supplemental procurement.
- Dramatically increasing access to STI diagnosis and management according to national guidelines through integrated STI/HIV/TB refresher trainings and joint supportive site supervision.
- Targeting STI screening and management among adolescents, FSW and MSM (facilitated through provision of comprehensive HIV prevention service packages to FSW and MSM).

An additional USD 3.89 million above allocation is requested to be used to procure STI/OI commodities (USD 1.44 million) to cover the extended period at the end of the grant (July 2017-December 2017) while USD 2.45 million will be utilized to train peer-educators on STI screening and management to enhance the uptake of STI services among of key populations (MSM, FSW), and to boost promotion of youth friendly health services in health facilities to improve access to STI/HIV services for young women & adolescents.

It is important to note that the HIV prevention needs of vulnerable populations, including prisoners, are addressed through General Population Prevention programming. Prisoner-specific funding through the Concept Note is not being requested. Prisoner-targeted support from USG/PEPFAR (nearly USD 500,000 annually), MSF and other sources will complement GoM activities for addressing prisoners' HIV prevention-related needs i.e. HIV/STI and TB screening, advocacy for condoms in prisons, provision of IPT & CPT and Test and treat as TasP.

## **Blood Safety**

USD 766,837 of the funding allocation will be invested into supplementary procurement of basic commodities for the Malawi Blood Transfusion Services (MBTS) to ensure 100% availability of consumables for collection and diagnostic screening of blood products for Transfusion Transmissible Infections (TTIs) at current output levels.

Total above allocation request is USD 1.70 million. USD 318,521 is for blood safety commodities from July to Dec 2017, and an additional USD 1.38 million is requested above allocation to enable MBTS to increase the pool of voluntary non-remunerated (VNR) donors to meet 100% of the national need for blood products. This will completely eliminate the need for family/replacement donors who currently contribute 30% of units transfused to fill the demand-supply gap. In the context of a generalized HIV epidemic, VNR donors are at a low risk for incident HIV infection, while replacement donors are known to pose a high risk due to higher prevalence of TTIs.

## **Condoms**

Existing resources are allocated for condom procurement, promotion and distribution through USG (USD 7.37 million), DIFD (USD 1.55 million) and the World Bank (USD 546,000). USD 1.1 million is requested within the allocation to be invested into strengthening the PSM system to ensure adequate amounts of condoms are procured and distributed according to need, targeting high HIV burden areas. Providers will be retrained and demonstration models (male and female) made available to ensure proper and consistent use of condoms through public and social marketing strategies. Key populations will be selectively targeted for condom promotion, including provision of lubricants through standardized comprehensive prevention packages (lubricants provided by USG). GoM will coordinate closely with implementing partners successful donor-funded condom promotion and distribution programs to replicate results where possible.

## **Community-Based Support**

USD 1.9 million above allocation funding will be invested in community based HTC activities that orient and mobilize young women and men on risk perception and reduction and health seeking behaviours to promote accessing relevant health services.

## **Prisoners (Vulnerable Population)**

It should be noted that the HIV prevention needs of vulnerable populations, including prisoners, are addressed through General Population Prevention programming. Prisoner-specific funding through the Concept Note is not being requested, though Concept Note funding will support HIV/TB prevention, treatment, care and support needs of Malawi's approximately 12,000 prisoners<sup>147</sup> through several of the modules. This will include six-monthly HIV testing and TB screening, intensified TB case finding, universal IPT for all HIV-positive prisoners without active TB, universal ART (using the test and treat approach for Treatment as Prevention (TasP), and GF-supported commodities. Prisoner-targeted support from USG/PEPFAR (nearly USD 500,000 annually), MSF and other sources will complement GoM activities for addressing prisoners' HIV/TB prevention, treatment, care and support-related needs.

## **Adolescent Girls, Young Women, OVC (Vulnerable Populations)**

It should be noted that HIV prevention needs of adolescent girls, young women and OVC as vulnerable populations are addressed through targeted General Population Prevention, PMTCT and CSS funding/programming in the Concept Note. This includes CSS within and above allocation funding for gender and human rights sensitization, training and advocacy targeting political, community, and faith leaders and constituents, healthcare providers, and others. In addition to GoM efforts through MoH, MoGCSW and MoEST, a number of partners are supporting various programs for this target group during the period of the CN. This includes the PEPFAR/Nike Foundation/Bill and Melinda Gates Foundation's DREAMS Initiative, with 2-year funding expected to begin mid-2015. GIZ has also committed €2 million - €3 million per year for four years (2013 - 2016) to reach 1.8 million adolescents aged 10-19 years in 10 districts with SRH and HIV prevention services, life skills and sexuality education, and prevention of unintended pregnancy. Activities are implemented by BLM, Pakachere and MOEST. USG and KfW also are jointly funding adolescent demand creation for SRH and YFHS. Furthermore, KfW and EU are supporting GoM through the MoGCSW to implement the Social Cash Transfer Program (SCTP) in nine districts.

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<sup>147</sup> Malawi National Prisons Service, 25 July 2014; International Centre for Prison Studies; <http://www.prisonstudies.org/country/malawi>; accessed 18 January 2015.

## **ii) Prevention Programs for MSM & TGs**

USD 278,671 of the allocated funding will be invested in the first two years for providing a standardized comprehensive prevention package for MSM to reduce risky behaviour, create demand for and provide condoms and lubricant (lubricant will be provided by USG), regular HTC and STI management, and use of qualified, MSM-friendly clinical services, while reducing stigma and discrimination in health care and community settings in non-USG/PEPFAR key population priority districts (PEPFAR is providing USD 2.15 million annually for key population activities in five high MSM concentration districts). Training and small stipends for peer educators and clinic navigators/expert clients as well as supported referrals to health facilities for confirmatory HIV testing, STI management, TB screening, and care assessment for HIV+ clients will be covered within allocation. The above allocation amount of USD 344,734 is requested to expand HTC, condom supporting activities and community sensitization and focus groups, specifically targeting MSM, and reach all MSM targeted in the final six months of the Concept Note (July - December 2017). Development of MSM-targeted HIV prevention information and materials will be supported through USG/PEPFAR (as will provision of lubricant) while production of the materials for use by peer educators in Concept Note-supported geographic areas will be covered by within allocation Concept Note resources.

As described elsewhere, public sector community-based HTC campaigns, PITC and STI management reaching MSM will be supported under the General Population Prevention module. Care and treatment for HIV-positive MSM will be provided through the Treatment and Care module. MSM-related clinical and sensitization training for health care workers will be supported through the General Population Prevention and CSS modules. Police and community sensitization, advocacy for human rights, gender and legal reform and legal assistance to facilitate MSM prevention will be covered under the CSS module.

7,000 MSM will be targeted in the first year (including 1037 with Concept Note resources), increasing by 5-10% per year as systems and capacity are developed, given national MSM-focused programming is new in Malawi and there is currently only one local NGO providing services to MSM. To address this bottleneck, CSS module funding is requested for a number of capacity development activities to expand and strengthen the number of local NGOs, community groups and networks able to serve MSM (as well as sex workers). This bottleneck will also be mitigated through health care worker sensitization training in the General Population Prevention module and police and community sensitization activities in the CSS module, as noted above. Furthermore, USG/PEPFAR, UN and DFID funding will be used to assess and build capacity and expand the number of local groups able to serve MSM. MSM will be targeted in areas where they have been identified in the highest concentrations not already reached through other efforts, primarily urban areas, some tourist areas and lakeside communities, including the seven MSM study sites.

## **iii) Prevention Programs for Sex Workers and their Clients**

The within-allocation funding (USD 267,198) will be invested in providing a standardized prevention package for FSW that will include peer-led risk reduction information, routine HTC and STI/TB screening, provision of male and female condoms and lubricant (lubricant will be provided by USG), facilitated referral to qualified, FSW-friendly clinical services, mobile HTC, and stigma and discrimination reduction activities for health care and community settings in non-USG/PEPFAR key population priority districts (PEPFAR is providing USD 2.15 million annually for key population activities in five high FSW concentration districts). Training and small stipends for peer educators and clinic navigators/expert clients will be supported within allocation. The above allocation amount of USD 340,731 will be invested into expansion of community-level HTC and condom promotion/delivery activities, and community sensitization, reaching additional FSW in years 1 and 2, and all FSW targeted in the final six months of the Concept Note. FSW-targeted HIV prevention information and materials will be developed through USG/PEPFAR, while production/duplication for use in Concept Note-targeted areas will be covered through within allocation resources.

As described elsewhere, public sector community based HTC campaigns, PITC and STI management reaching FSW will be supported under the General Population Prevention module, as will services for clients of sex workers. Care and treatment for HIV-positive FSW will be provided through the Treatment and Care module. FSW-related clinical and sensitization training for health care workers will be supported through the General Population Prevention and CSS modules. Police and community sensitization, vocational training capacity building, advocacy for human rights, gender and legal reform, and legal assistance to facilitate FSW prevention will be covered under the CSS module.

8,776 FSW will be targeted in the first year (including 1,000 with Concept Note within allocation resources). FSW reached by Concept Note resources will increase by 500 annually as systems and capacity are developed, given that national FSW-focused programming is relatively new in Malawi. The above allocation request is anticipated to reach an additional 250 and 500 FSW in years 1 and 2, respectively, and 1,000 FSW targeted between July - December 2017. FSW will be targeted in areas where they have been identified in the highest concentrations not already reached through other resources, primarily urban areas, border communities, active trade areas, agricultural estates, tourist areas and lakeside communities.

#### iv) PMTCT

USD 4.4 million of the allocated funding will be invested in reducing the drop-off in each step of the PMTCT cascade. A new focus is on identification of new HIV infections in pregnancy and during breastfeeding as these are responsible for the majority of vertical transmissions in the era of Option B+. PITC will be extended to immunization clinics to find exposed infants missed in the PMTCT cascade. A range of interventions to reduce loss-to-follow-up will be implemented: mother–infant follow-up service delivery model, and addressing HR challenges for HTC to reduce missed opportunities for follow-up testing of exposed infants. Funding will be invested into improving sample transportation through Riders for Health as well as introducing innovative strategies to reduce turnaround times for DNA-PCR results for EID & Treatment.

Above allocation funding of USD 6.0 million will also be invested into community based-activities to strengthen uptake and retention amongst pregnant and breastfeeding women in PMTCT and TB services through the use of expert clients, peer-support groups such as M2M, male involvement and community dialogue interventions. An additional USD 777,502 is requested for PMTCT commodities during the extended 6 month period at the end of the grant (July 2017-December 2017).

#### v) HIV Treatment Care & Support

Within allocation funding of USD 245 million will be required for treatment commodities and PSM related costs (ARVs and EID commodities of USD 209 million, OI drugs of USD 18 million, viral load monitoring and other HIV lab commodities of USD 17 million). In addition, USD 89,043 will also be used to ensure adherence and retention of patients in care through expert clients, defaulter tracing initiatives involving community.

Another USD 62.46 million is requested above allocation to maintain the central buffer stock (6 months) and facility level buffer stock (3 months) for ARVs for a total of 9 months taking into consideration the lead time from procurement, ocean freight to delivery in-country. An additional USD 582,436 is requested for EID, USD 3.01 million for viral load, and USD 1.50 million cross cutting labs procurement. Given the budget constraints, this could not be accommodated in the allocated amount. Additional funding will enable the National Program to ensure commodity security at the end of the NFM period. Please also note that the commodity buffer has also taken into account supporting labs and diagnostics in other interventions, such as HTC.

If PMTCT treatment commodities is also taken into account (currently part of the PMTCT module), USD 222 million (83%) of the within allocation funding will be required for core commodities for the treatment program (ARVs, OI drugs, DBS bundles/reagents for EID and viral load monitoring and other HIV lab commodities). Total procurement, shipping and handling charges for all HIV commodities account for USD 46.2 million in the NFM. Out of these, 40.7 million are offshore charges currently levied through the PPM and 5.5 million are spent in-country, comprising warehousing, distribution and quality assurance testing. PEPFAR funds support program implementation and QI to ensure effective and efficient use of GF-procured commodities. One anticipated risk is the timeline from concept note submission; TRP review up to Grant negotiation and signing. To mitigate any potential stock outs of HIV commodities during the implementation period, the PR intends to submit an application for extension of the Interim Funding grant to cater for procurement of HIV commodities in June 2015.

Table 16: Summary of HIV commodity Funding Request (July 2015 to Dec 2017)

Funding Needed:	2015-2016	2016-2017	Total	Buffer
ARVS	59,217,900	24,312,522	44,720,136	43,858,557
OI/STI	6,695,749		8,611,979	
Diagnostics & Labs	8,714,102	4,525,736	9,306,538	6,618,763
PSM Costs (Cross Cutting)	15,161,264	6,134,829	14,066,896	9,936,779
Total Gap	89,789,015	34,973,087	76,705,548	60,414,098

Public education around Option B+ and ART has been identified as a key weakness in the current response and allocated funds will also be utilized for a concerted public and patient education strategy. Ensuring that the population is well informed in the importance of knowing one's status and accessing ART early is a priority as Malawi aims to reach the 90-90-90 targets. Allocation funding will also be used to ensure adherence and retention of patients in care through expert clients, defaulter tracing initiatives involving community.

As shown in Table 16, ART program attrition is assumed to remain constant at current levels (8.7% annually). This is conservative ('pessimistic') estimate is taking into account the potential for increased defaulter rates among patients starting ART early who have not experienced serious HIV morbidity. Ageing and increased adverse outcomes (undiagnosed treatment failure, toxicity) among the maturing ART cohort are also assumed to drive up attrition. These effects will partly offset the improved program retention that's expected from the following:

- Significantly reduced early mortality due to early treatment initiations.
- Low toxicity rates due to selection of a favorable 1st line regimen.
- Increased timely identification and switching to 2nd line for patients failing 1st line ART through continued scale-up of routine VL monitoring.
- Improved adherence and retention from targeted interventions supporting the 90-90-90 treatment goal (scale-up of peer support groups, national treatment literacy campaign, targeted support for defaulter tracing at sites with elevated attrition rates, etc.)

In the total within allocation commodity budget, commodities and offshore procurement charges account for a total of 83% and 15% respectively, hence the financial management of these offshore PSM related resources will not be a constraint during the implementation period. However, there are opportunities for the Global Fund PPM division to further negotiate procurement charges downwards given the value of commodities included in this application. Increasing volumes of commodities provide opportunities for pooled procurements and hence competitive cost efficient supply chain interventions at all levels. PSM strengthening activities (improving monitoring of commodities to improve logistics decisions and increasing storage capacity at the facility level) will lead to a more appropriate and effective distribution of ARVs. Further investment into HRH to build the capacity of health care training institutions and to improve training of health care workers will lead to better quality of care and adherence to current treatment guidelines.

An additional USD 62.46 million is requested above allocation to maintain the central buffer stock (6 months) and facility level buffer stock (3 months) for ARVs for a total of 9 months taking into consideration the lead time from procurement, ocean freight to delivery in-country. An additional \$580,000 is requested for EID and \$3.01 million for viral load. Given the budget constraints, this could not be accommodated in the allocated amount. Additional funding will enable the National Program to ensure commodity security at the end of the NFM period. Please also note that the commodity buffer has also taken into account supporting labs and diagnostics in other interventions, such as HTC.

In the total within allocation commodity budget, commodities and offshore procurement charges account for a total of 83% and 15% respectively, hence the financial management of these offshore PSM related resources will not be a constraint during the implementation period. However, there are opportunities for the Global Fund PPM division to further negotiate procurement charges downwards given the value of commodities included in this application. Increasing volumes of commodities provide opportunities for pooled procurements and hence competitive cost efficient supply chain interventions at all levels. PSM strengthening activities (improving monitoring of commodities to improve logistics decisions and increasing storage capacity at the facility level) will lead to a more appropriate and effective distribution of ARVs. Further investment into HRH to build the capacity of health care training institutions and to improve training of health care workers will lead to better quality of care and adherence to current treatment guidelines.

## **vi) Tuberculosis Care and Treatment**

### **TB Case Detection and Diagnosis**

A total of USD 5,382,930 is assigned from within the allocation for case detection and diagnosis. This intervention is the centre of TB prevention and control. The government of Malawi covers the human resource and infrastructure related costs, whereas other donors contribute to procurement of diagnostic equipment. They also provide technical support and capacity building. However, the current burden of TB necessitates rapid expansion of diagnostics capacity, which is still a major gap. These funds will be invested into improving the TB case finding through raising awareness, improved diagnostic capacity, as well as implementation of enhanced and active case finding activities in healthcare settings and in different high-burden and hotspot areas respectively.

Health education and promotion activities will be organized by health workers in each health care setting and by CSOs in the community. IEC materials will be produced and distributed in OPDs, ANC and other service outlets. Systematic TB screening will be implemented in all OPDs, inpatients and MNCH clinics irrespective immediate presenting symptoms. More activities related to active case finding have been articulated in the vulnerable/high-risk groups section. To expand TB diagnostics, 7 GeneXpert platforms will be procured and placed at facilities with high volume ART sites, priority TB diagnostic sites and hotspots. Other

partners will also provide support to run the existing GeneXpert platforms. Sample transportation systems will be integrated with existing systems in order to improve efficiencies and optimal utilization of the existing GeneXpert platforms.

Diagnosis of smear-negative TB, Childhood TB and Extra-Pulmonary TB is a regional and national challenge. Due to lack access and institutional capacity for diagnosis of these groups, treatment initiation is delayed and increased and risk of TB-associated death is higher than in smear-positive TB cases. Access to X-ray service will be enhanced through provision of seven additional fixed digital X-ray machines for selected high volume hospitals as well as training of clinicians on chest X-ray interpretation. Service providers' competencies will be enhanced through training and onsite mentoring. In line with WHO recommendations, conventional microscopes in high volume facilities will be replaced with LED microscopes.

In addition, a total of USD 4,903,949 has been assigned in the above allocation. This allocation will be used to further scale up systematic TB screening in order to reach more missed cases. An additional 14 GeneXpert platforms will be procured to support other high volume sites (OPD, MNCH and ART sites). The GeneXpert algorithm will be standardized across partners and public facilities nationwide. Maximal utilization will be ensured through networking of satellite health facilities under defined catchment areas.

IEC materials specifically tailored to the Community Sputum Collection System will be printed and distributed. A sputum transportation tracking system will be developed and piloted. Should the above allocation not be approved, the TB diagnosis will depend on light microscopy, which has less sensitivity and long turnaround time, translating to fewer cases being detected and delayed treatment initiation.

If the above allocation amount is not granted, the expected additional 17,744 new TB cases may not be reached within the two years grant period. Neither will 23,119 TB cases targeted in the last six months of the period July to December 2017. In the event that there is no above allocation funding, the only option will be to depend on the existing diagnostic capacity.

HSS investment into interventions improving laboratory infrastructure through the provision of proper maintenance contracts for laboratory equipment, supporting the PMPB for field visits to health facilities for post market surveillance to ensure medicines and supplies are in good condition post distribution, will support efforts to treat and detect TB cases. Investment into PSM initiatives to improve the storage capacity and the quality of logistics decisions would also strengthen the above investment into TB detection. Further investment into sputum sample transportation will address inequities in access to health services in more remote parts of Malawi or areas where there are few appropriate healthcare workers to carry out case detection.

## **Treatment**

For first-line TB treatment USD 3,302,176 is assigned from within the allocation envelope. This amount is intended to procure first-line anti-TB drugs with further decentralization of TB registration sites. These drugs are quantified using the standard PSM quantification procedures as elaborated in the Malawi Quantification of Health Commodities 2014 Report (pages 55 to 64). However, some of the data from the 2014 report has been updated to reflect the relevant TB cases findings from the 2013-2014 TB prevalence survey (these updates are reflected in the "Concept Note TB FLD Quantification sheet"). (Both references are included in the list of references annex.) Existing sites will be supported through provision of mentoring and refresher training. Close monitoring of all retreatment cases with appropriate referral to DST sites (GeneXpert and culture/DST facilities) will be strengthened. DOT will remain the key strategy of TB treatment in Malawi with more engagement of family or community DOT supporters.

In the above allocation, USD 2,492,241 will be used to procure first-line drugs for additional 17,000 TB cases that will be identified through the above allocation amount under case detection and diagnosis. If the above allocation is not granted, 25% (23,000 TB cases) will have no provision for medications. On the other hand, if case detection and diagnosis is not met for the above allocation target, the need for procurement for drugs may not arise.

## **Prevention**

A total of USD 557,536 is assigned from within the allocation for TB prevention. This funding will be invested into: (1) Improving TB infection control measures in health care settings and (2) Provision of IPT for those eligible as per the national guidelines. At the national level, activities include advocacy for integrating TB infection control policies into Malawi's Infection Prevention Program (IP). At district level, activities will focus on orientation of District Health Management Teams (DHMTs) in the enhanced Management roles of the Infection Prevention Committee (IPC); improved skills of IPC members through training and regular clinical mentorship. Implementation of TB IC in 400 high-volume ART centres will be supported by PEPFAR partners. Activities will include advocacy for streamlining TB infection control and revision of SOPs to ensure that infection control practices are implemented in all facility service points. Part of the funding will also support infrastructure upgrading. At the district level, orientation of DHMTs will be conducted to facilitate the oversight function of infection prevention and control.

Contact tracing will be strengthened to ensure all household contacts are screened and provided with treatment or IPT as appropriate.

USD 202, 044 will further support TB IC in health facilities for infection control practices improvement, provision of IPT and pyridoxine for all household contacts of pulmonary PTB and facility upgrades. The resources will also be used to procure PPEs for health care workers in high risk TB environment as well as procurement and fitting of germicidal UV lamps in isolation, TB wards and general medical wards.

### **Community TB Care**

A total of USD 284,698 has been assigned from within the allocation to support community TB care. This amount will be used to monitor and provide technical support to CSOs as they implement the planned activities with funds allocated under the CSS module. The NTP will support TOT and give oversight to nationwide umbrella CSO organizations such as MANASO, MIIA and MANET+. These organizations will in turn train and oversee work implemented by community-based organizations to deliver a package of services that include increasing community awareness for TB and TB/HIV, decrease stigma and discrimination, and support early diagnosis and treatment adherence. Systems will be put in place for ensuring linkages between CSOs, health facilities and community networks to support patients and their families to mitigate the impact of TB and TB/HIV.

Above-allocation amount of USD 4,036,330 will be used to expand community sputum collection points and motivate community volunteers. Specific activities under this funding will go towards procurement and maintenance of bicycles, umbrellas, raincoats, boots to be provided to community volunteers as non-monetary enablers. The volunteers will be recruited and maintained in high burden sites. In addition to sputum collection and transportation, the volunteers will support awareness creation, conduct house-to-house visits, treatment adherence support, referral of presumptive cases to health facilities and organization of impact mitigation for affected individuals.

### **Vulnerable and At-Risk Populations**

A total of USD 1,306,977 has been assigned from within the allocation. Although there are a few partners working in TB case finding among some high-risk groups (PLHIV and prisoners), their coverage and scope is limited. This funding allocation is requested to support strategies targeting high-risk groups and vulnerable populations through enhancing early case detection and treatment initiation. This group is important to attain the ambitious target of case finding and contain the spread of the disease. It will improve quality of care to reduce morbidity and mortality and decrease transmission to others. Urban poor and communities with known high rates of disease (including older age groups) will be reached through mobile clinics. Two mobile vans will be procured and fitted with digital radiography and GeneXpert platforms to ensure rapid diagnosis and treatment initiation. Staff for these mobile clinics will be allocated from the MoH. In collaboration with the prison health service authorities, TB registration sites will be established in all five major prison facilities. Support will be provided to the NTP and the HIV department who will work in collaboration with other partners (HIV Module) to orient and train correctional facility management staff on TB and TB/HIV. This will ensure that systematic screening upon admission to facility and exit. Annual screening including use of chest X-ray will be done to prison inmates and staff in the five major prison facilities (TB/HIV budget) with the support of the mobile clinic teams.

Contact investigation will be strengthened. Household contacts of infectious TB cases will be screened for TB at home with further referral of presumptive TB cases to health facilities. NTP will advocate for establishment of surveillance among HCW. Contact investigation and improved IPT coverage will be key focus areas in addressing childhood TB. It will be strengthened through engaging community health workers who will screen household contacts of index cases. Health workers will also be trained to improve their competencies to identify and treat children with Tuberculosis. Global road map for childhood TB will be adopted and adapted.

Miners, ex-miners and their communities will be targeted. A guideline for TB screening of miners, ex –miners and their families (regular) will be developed in line with SADC memorandum of understandings and guidelines on TB in mines and cross-border communities. Training will be provided for health workers working the mining sector. A system of referral linkage of mining institutions with healthcare facilities will be established. Migrant miners across borders will be tracked. NTP will work with SADC to harmonize treatment regimens so that migrant TB patients don't have to switch regimens. Patients with diabetes will be screened regularly, starting with four central hospitals.

In addition, a total of USD 2,896,619 has been assigned in the above allocation. This will support expanded active case finding. An additional two mobile vans fitted with digital X-ray and GeneXpert will be procured. Running and maintenance costs of these mobile vans will be paid from this allocation. Mobile clinics will extend outreach to other high-risk groups. Zonal level meetings will be conducted to train HCW on expansion of *Wellness* Centres, introduce TB surveillance and regular screening among health care workers along with other general health conditions to minimize fear of stigma and discrimination. Incentives will be provided to volunteers supporting CSCP. If the above allocation resource is not available, TB screening will be limited to symptomatic approach (lower sensitivity than X-ray screening). However, this will be an inadequate response to the burden of disease as reflected by results from the prevalence survey.

## **Program Management of Tuberculosis (Including M&E)**

A total of USD 1,767,143 is assigned from within the allocation for program management of TB. Funding for program management will support the NTP's roles and responsibilities of ensuring an effective and efficient response to the epidemic. Almost 75% of this allocation will support three key activities: Coordination of public and private sector partners at all levels, including improved linkages with communities (23%); monitoring and evaluation (31%), which includes regular monitoring meetings, establishment of a case base electronic surveillance data system and strengthening supply chain management (19%) ensuring adequate quality-assured medicines, laboratory and other supplies and materials. Other activities include advocacy, and certification of facilities to provide integrated TB/HIV care.

In addition, a total of USD 1,191,305 has been assigned in the above allocation. The resources under this allocation will be used for expansion of M&E activities and implementation of the repeat Drug Resistant TB Survey (DRS) and other research. If the above allocation for program management is not approved, monitoring of drug resistance and other activities will be compromised significantly. However, efforts will be made to find alternative resources.

## **vii) Multidrug-resistant TB (MDR-TB)**

### **Case Detection of MDR-TB**

Budget Allocation - USD 860,029 of the allocation funding will be invested in MDR-TB scale-up strategies to address the most at-risk populations in order to ensure early detection and rapid treatment initiation, limiting transmission.

- Capacity building of HCW: The PMDT training module will continue to be part of overall TB prevention and control training now jointly implemented with HIV, to improve awareness and knowledge of HCW. This will ensure fast tracking of those at risk for MDR-TB to further diagnostic services. In-service training and refresher training will sensitize HCW to improve the utilization of GeneXpert.
- Laboratory strengthening: The capacity of the Central Reference Laboratory (CRL) and both regional reference laboratories will be strengthened to confirm MDR-TB with rapid molecular tests (LPA and MGIT) in a phased approach. Staff in all reference laboratories will be trained and the required supplies for genotypic and phenotypic investigations will be procured. Sufficient supplies of GeneXpert cartridges will also be provided.
- Surveillance of retreatment cases: All retreatment cases will have access to GeneXpert, culture and DST.
- Sample transportation: This element has been budgeted for in the HSS component of this JCN.
- Feedback of laboratory information results: This will build on current SMS platforms already in place (through partner support - TBREACH). Laboratory information will be sent to treating facilities in a timely manner to better manage and monitor progress of treatment.
- Central Reference and regional laboratories upgrade: In addition to further expansion of Quality Management Systems for diagnostics, first-line DST will be strengthened and second-line DST will be introduced.

A total of USD 4,449,200 **above allocation resources** will be used for off-site training of laboratory staff each year. Sentinel surveillance of new smear-positive cases will also be established in selected high-volume sites where  $\pm$  50% of newly diagnosed pulmonary cases are reported. This will require additional genotypic and phenotypic assays. If this amount is approved for case detection, 12,600 cases requiring further investigation will be assessed for MDR-TB. If the above allocation resources are not granted, it would be difficult to identify expected MDR-TB incident cases among new smear-positive TB cases. These cases will therefore remain in the community and continue to transmit drug-resistant TB strains.

Additional resources will be sought to complement MDR-TB case finding effort, including maintaining proficiency of laboratory staff.

### **Treatment of MDR-TB**

Within-allocation funding of USD 1,445,828 will be invested in MDR-TB treatment. The mainstay of MDR-TB control is early detection and prompts treatment resulting in decreased morbidity, mortality and on-going transmission. The allocation will be used to procure quality assured second-line anti-TB drugs for treatment of identified incident cases and includes shipping and in-country handling charges, warehousing, distribution and quality assurance testing.

A total of USD 4,010,984 above-allocation funds will be sought for treating the additional MDR-TB patients that will be identified. We anticipate that 100% of diagnosed MDR-TB patients will initiate treatment. If above-allocation funds are not approved for detection of MDR cases, then the need for procurement of second-line anti-TB drugs to treat additional cases will not arise.

## **MDR-TB Prevention**

A total of USD 259,236 within-allocation funding will be used for MDR-TB prevention activities. The main activities will focus on improving infection control practices in health care settings (early detection, separation, rapid treatment (F.A.S.T.)), in addition to ensuring safe environments for all patients and healthcare workers to prevent transmission.

Resources under this allocation will go towards the following interventions:

- Update and implementation of Infection Control Plans: All health facilities providing care and treatment and follow-up to MDR-TB cases will update and implement TB infection control plans.
- Infrastructure improvements and renovations: Twenty hospitals will be supported to create and maintain one isolation room per facility. The two existing culture laboratories will be renovated and equipped to accommodate LPA technology will be supported in the three MDR referral centres. A third culture and DST laboratory will be built and equipped in the last year of the NFM to accommodate the increased demand for these services. The third anticipated laboratory will benefit from the equipment package to undertake LPA.
- Procurement of personal protective equipment: Surgical and respirator masks for MDR-TB patients and HCWs will be procured. Note: The prevention efforts under this allocation will complement infection control practices strengthening at 400 health care facilities (under PEPFAR support) and MDR-TB service units.

With USD 228,778 above allocation case detection resources NTP expects that more MDR presumptive patients will be identified and these will require support for preventive measures (e.g. surgical masks).

## **viii) TB and HIV Joint Programming**

USD 691,554 of the allocated funding will be invested into strengthening non-HSS TB/HIV collaborative activities, focusing on early diagnosis and treatment initiation for co-infected patients. Activities include integrated TB/HIV certification, refresher trainings and joint program monitoring and supervision. Diagnostic pathways will be significantly streamlined by trainings on presumptive diagnosis and treatment of TB. INH will be procured and distributed. Implementation of INH provision will be monitored. Rifabutin will be procured to be used as treatment for TBHIV infected patients. Cross cutting activities including capacity building of health workers and integrative supervision and review meeting are dealt in the HSS module of this application.

Additional funding will be invested in development and production of TB self-screening tools to improve TB screening of PLHIV. Resources from all funding sources will be more efficiently coordinated and will support a comprehensive response to both the TB and HIV epidemics. This will include prioritization of high-impact interventions within HIV and TB core packages of care (90-90-90 in HIV) and GeneXpert in high-risk populations as well as targeting populations that have less access to services for various reasons, e.g. key populations and populations that are vulnerable. The implementation of these programs will contribute towards reduced barriers, and increased access to diagnosis, treatment and care.<sup>148</sup> Enhanced community engagement will contribute towards the expansion of delivery of a services package and increased penetration into communities. Effective implementation of the former will support increased case finding treatment and adherence. Where relevant, new diagnostics will be employed to improve diagnosis and more rapid treatment initiation.

The above allocation resources of USD 1.5 million will be used to improve screening for TB in ART and PMTCT clinics, and printing of self-administered questionnaires with pictorial illustrations to be introduced in these care settings (ART and PMTCT clinics). Since this is a new innovation, implementation will be closely monitored to ensure that the initiative is contributing to increased TB case identification among PLHIV.

## **ix) Health System Strengthening (HSS)**

### **Procurement and Supply Chain Management**

A total of USD 5.75 million will be provided by the Government of Malawi (Willingness to Pay) to support storage improvements at 200 priority health facilities. During the implementation period funds are being sourced to cover procurement of HIV commodities which will have to be procured, stored and distributed in accordance with National and Global Fund, PSM and

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<sup>148</sup> WHO. Systematic screening for active tuberculosis. Principles and Recommendations. 2013.

Quality Assurance guidelines. The PR has identified strengthening health facility storage infrastructure as a key intervention that will lead to improved quality of logistics data of medicines including HIV/TB commodities.<sup>149</sup>

Other PSM interventions highlighted below have been included in the above allocation request (USD 1.96 million). These include strengthening laboratory and medicines logistics management information systems (LMIS), including medicines management supervision and mentoring functions. Implementation of an electronic stock management system for medicines and supplies will result in better quality logistics data. Investment in commodity monitoring systems will enable a more effective distribution of commodities by improving the logistics decisions. Interventions under PSM aim to support the availability of medicines and medical supplies for patients on ART, and malaria and TB patients while developing a system that can improve access to medical supplies and commodities for all patients in the country.

### **Human Resource Management**

A total of USD 2.5 million will be provided by the Government of Malawi (Willingness to Pay) to be allocated across activities supporting health training institutions to ensure delivery of quality training for healthcare workers undergoing both pre- and in-service training, support for pre-service education scholarships to complement existing support from other partners and to provide an in-service mentorship program for new health care workers. This will include investments in library and IT infrastructure in training facilities.

USD 2.85 million is requested within allocation for cross-cutting activities. This includes:

- Support for district clinical review meetings (including an extra day for TB-HIV coordination) - USD 635,652
- Support for an annual new HCW orientation and semi-annual refresher training (printing manuals, job aids, guidelines) - USD 1,999,126
- National level 5 day training of TB focal people on ART administration - USD 211,065

The above allocation budget request is USD 2.29 million including USD 1.45 million for bursary support to train 100 medical assistants, 50 clinical officers, upgrades to bachelor's degree for 24 clinical officers, 50 pharmacy assistants, and 50 laboratory assistants. USD 0.5 million is proposed to enhance healthcare worker retention by conducting renovations on healthcare worker accommodation in 50 remote hard-to-fill posts in areas of high TB and HIV prevalence. This will be done primarily by ensuring access to water and electricity at these sites. This would improve staff retention by creating an environment where HCW will not feel that they are lacking basic comforts that other well-trained professionals can access. An additional USD 0.3 million is requested to cover the district clinical review meetings for TB/HIV during from July to Dec 2017.

### **Service Delivery**

A total of USD 3.1 million will be provided by the Government of Malawi (Willingness to Pay) to be allocated across activities strengthening service delivery, namely lab services and quality assurance for pharmaceuticals. Lab services will be strengthened by increasing access to services through expansion of sample transportation services, maintaining lab equipment and performing external quality assurance of lab services.

In detail, USD 0.5 million will be allocated to service maintenance contracts for lab equipment such as CD4 machines, viral load machines and EID machines. These monies will maintain both existing and new equipment and increase access to quality laboratory services for a greater population.

A further USD 0.6 million will be allocated to sample transportation and builds on existing funding by PEPFAR. Currently, PEPFAR funds transportation between the health facility and the district hospital. However, not all services including TB cultures, viral load and EID are provided at the district level and so transport to main testing facilities is required. USD 0.8 million will be allocated to external quality assurance for lab services, ensuring that both the tests themselves are valid and that diagnostic staff are competent to utilize lab machinery and to carry out tests. Consequently, both increased transportation of samples coupled with greater availability of lab equipment will lead to increased access and quality of lab services to a larger proportion of the population.

A further USD 1.2 million will be allocated to pharmacovigilance and post-market surveillance activities. This will improve the quality of drugs received in Malawi through testing in designated WHO pre-qualified laboratories, and adverse reactions to pharmaceuticals will be monitored. Specific activities include: development of SOPs for pharmacovigilance; development and printing of tools; integrating electronic reporting system into current system; and quarterly monitoring visits to health facilities.

Considering the significant investment by the Government of Malawi in improving lab services, the above allocation budget request for USD 0.6 million over 2.5 years will be invested into additional service and maintenance contracts for medical

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<sup>149</sup> USAID | DELIVER PROJECT Task Order 4. 2014. A Rapid Assessment of Health Commodity Storage Capacity for Public Health Facilities in Malawi. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4.

equipment especially diagnostic equipment. This will build on existing commitments by the Government of Malawi to fund maintenance and service contracts for equipment. By doubling the amount allocated to maintaining equipment it is anticipated that diagnostic services will be able to reach both an increased number of people and cover a greater geographical area as the Government of Malawi and PEPFAR are expanding sample transportation services.

### **Governance and Policy**

USD 21,581 within the Global Fund allocation has been requested to update the Public Health Act to address issues around infectious diseases. The Public Health Act is currently undergoing a period of review. This amount of money will ensure that there is appropriate consultation with infectious disease experts when reviewing the Public Health Act. By establishing laws around infectious disease control, institutions are able to act with a clearer, established, enforceable mandate.

## **x) Community System Strengthening (CSS)**

### **Advocacy for Social Accountability**

The total budget for this intervention is USD 393,752. A total of USD 242,552 within allocation will support Zonal advocacy sessions with Policy and Lawmakers for the protection of human rights and reviewing laws that have punitive effect on key and vulnerable Populations. There will also be advocacy sessions with Policy and law makers in relation to the HIV/AIDS Bill. Discussions will focus on the gaps existing in the Policies and laws and recommendations on modification of the policies and laws in order to improve access to health services by Key and Vulnerable Populations. Periodic reviews will be done on the progress made in the review of the policies and laws.

USD 151,200 above allocation will be used to produce and disseminate briefs on the Gender ACT and the HIV/AIDS Bill to create awareness on the current provisions in the policies and identify the existing gaps.

### **Social Mobilization, Building Community Linkages, Collaboration and Coordination**

For social mobilization, building community linkages collaboration and coordination a total of \$1,349,708 is budgeted within allocation. These funds will be used to support provision of Community based Outreach and moonlight HTC for Key and Vulnerable Populations, facilitate Community Sputum collection points, training and supporting mother groups in TB, HIV and TB/HIV and supporting interface meetings between Community Workers and Health facilities on ART, HTC, TB, and TB/HIV. Furthermore the funds will also support mapping for Condom and Lubricants Dispenser outlets, training clinic navigators/expert patients or peer educators to conduct healthcare referrals for their peers amongst key and vulnerable populations for HIV and TB and training faith leaders and community leaders on adherence to ART and TB drugs. Expert TB patients will be used to promote treatment adherence, TB contact and default tracing and identify kids that are PTB contact and need to go for follow up.

An above allocation amount of USD 4,788,318 will be used to conduct Zonal trainings on condom access and use specifically on acceptability awareness for faith leaders and community leaders and orientation of Health Care Workers on rights of key and vulnerable populations including issues of rights in Provider Initiated Testing. In addition the funds will support community dialogues on issues of gender and human rights with Community and Faith leaders and Initiators, support mobilization, creation, coordination of community structures and actors to implement TB/HIV interventions, supporting production and airing of Radio and TV Programs and training for male and female care givers in gender sensitive and rights based TB, HIV TB/HIV care. The funds will also support Focus group discussion within the community to promote integration of cured TB and MDR TB Cases within the community for psychosocial support. These clients will be linked to institutions implementing income generating activities to mitigate the impact of the two diseases. Existing Open days will also be used to integrate TB Screening for referral to Health Facilities.

The above allocation will also support Vocational Training and legal aid for Key and vulnerable populations in cases of Human Rights Violations.

There will also be training for the Alliance for Female Sex Workers in Networking and Coordinating and quarterly meetings for the Alliance.

### **Community-Based Monitoring**

Activities under this intervention have a total budget of USD 499,864. There is a USD 117,196 within allocation to support the training of Community Volunteers in Community Score Card including documenting and reporting human rights violations. M and E visits will also complement the documentation and reporting of human rights violations of Key and Vulnerable Populations. The funds will also support tracking of TB/HIV expenditure on gender, key and vulnerable populations, young people in national and donor funded budgets in order to advocate for Government support for HIV/AIDS activities. ART, HSS among others.

USD 382,668 above allocation will be used to among others train CSOs in M and E, Research, Gender and Human Rights in order to mainstream Gender and Human Rights in the TB/HIV activities in addition to building capacity to document and report on Human Rights violations.

### **Institutional Capacity Building**

Activities under this intervention will build the capacity of the CSOs to plan and implement activities and integrate TB and HIV, Gender and Human Rights. In addition, the activities under this intervention will target law enforcers and Health Care workers to orient them on issues of Human Rights and Key Populations in order to deal with allegations of police abuse, and discrimination at the health facilities.

USD 833,519 within allocation is assigned to finance development of gender transformative and rights based guidelines on confronting stigma and discrimination in TB, HIV and TB/HIV, Sensitization of police on importance of reaching out to key populations at risk of HIV infection, the importance of appropriately addressing domestic and sexual violence cases in the context of HIV and the negative consequences of illegal police activity on justice and on the HIV response, training for Health Care Providers and police on GBV prevention, stigma and human rights for key populations, development of tools on mainstreaming TB/HIV for CSOs including integration of activities to reduce duplication and baseline survey including informative survey for key and vulnerable populations. In addition, the funds will also support training for prison personnel regarding the prevention, health care needs and human rights of prisoners living with or at risk of HIV and TB infection including integration of TB/HIV services in prisons and scale up youth friendly HIV/TB interventions with a rights based approach and gender and training CSOs in HIV/TB, rights based and gender transformative approaches.

USD 2,087,903 (above allocation) is dedicated to conducting mapping exercise for CSOs working on HIV to integrate TB, TB/HIV, Gender, Human Rights, Young People, key and vulnerable populations, developing and disseminating TB/ HIV action plans on gender, Human Rights and Key Populations, developing and disseminating gender transformative and rights based guidelines and tools targeting Girls, women and men and boys to combat GBV, early child marriage, intergenerational and transactional sex, masculinity, culture. The funds will also support training for teachers on age-appropriate gender transformative rights based sex and sexuality education in and out of school and operational research on CSS related TB/HIV and enabling factors.

## 2.3. Modular Template

### 2.3.a HIV Program

Malawi's HIV program interventions are focused around the following five modules: Prevention for general population which includes HTC, STI, condoms, VMMC and blood safety; Prevention for MSM and TG; Prevention for FSW and their clients; PMTCT; Treatment, care & support. The budget allocations are described below, including the interventions and the rationale for prioritizing these interventions and the expected outcomes and impacts:

#### i) Prevention Programs for General Population

##### HTC

**Budget Allocation** - USD 12.09 million of the allocated funding will be invested into HTC and the additional funding requested is USD 4.67 million.

**Intervention and Rationale** - scale-up of the HTC program with a main focus on PITC in order to identify the positives required to reach the 90-90-90 targets by 2020. This includes timely procurement of adequate HIV testing and quality control commodities and DBS bundles for early infant diagnosis. PITC will be targeted at general medical wards, outpatient facilities, communities, EPI programs and under-5 clinics. Special emphasis will be placed on paediatric wards, under-5 clinics, EPI programs, nutrition rehabilitation clinics as well as OVC to increase paediatric ART coverage. The additional above allocation funding of USD 2.32 million is requested to procure commodities for continued HTC/Lab services during the extended period beyond the grant from July-December 2017, while USD 2.35 million will be used for further scale-up of community based HTC activities, targeted HTC campaigns in geographical hotspots and development of a coordinated self-testing program..

**Expected Outcomes and Impacts** – reduced new HIV infections.

##### VMMC

**Budget Allocation** - Existing resources from USG/PEPFAR are allocated to VMMC scale-up in eight high-prevalence districts, expanding to 14 priority districts during 2015-2019 with GoM/World Bank resources and over time to all districts in the country with further funding and technical support from USG/PEPFAR, World Bank and implementing partners. Additional funding above allocation will be USD 17.6 million.

**Intervention and Rationale** - The above allocation requested through this concept note will be invested in increasing the human resource capacity for VMMC, procurement of commodities for VMMC, demand creation, operational research and improved VMMC systems for quality assurance, supply chain and M&E.

**Expected Outcomes and Impacts** - reduced new HIV infections.

##### STI

**Budget Allocation** – The amount within allocation is USD 6.3 million (2.3%) of the allocated funding and an additional an additional above allocation of USD 3.89 million.

**Intervention and Rationale** – the STI program addresses key programmatic gaps and is expected to prevent a significant number of new HIV infections in the general population and among FSW, their clients and among MSM by:

- Ensuring uninterrupted availability of standard STI diagnostic and treatment commodities at all public and private sector sites through supplemental procurement.
- Dramatically increasing access to STI diagnosis and management according to national guidelines through integrated STI/HIV/TB refresher trainings and joint supportive site supervision.
- Targeting STI screening (including mobile screening) and management among FSW and MSM.
- The above allocation of USD 1.44 million is requested for the extended 6 month period at the end of the grant (July 2017-December 2017) for procurement of STI/OI commodities, while USD 2.45 million will be used to train peer-

educators on STI screening and management to enhance the uptake of STI services among of key populations, and to boost promotion of youth friendly health services.

**Expected Outcomes and Impacts** - reduced new HIV infections.

### **Blood Safety**

**Budget Allocation** – USD 766,837 within allocation and USD 1.7 million above allocation for Blood Safety

**Intervention and Rationale** – the funding within allocation will be invested into supplementary procurement of basic commodities for the Malawi Blood Transfusion Services (MBTS) to ensure 100% availability of consumables for collection and diagnostic screening of blood products for transfusion transmissible infections (TTI) at current output levels. The above allocation funding of USD 1.38 million would enable to increase the pool of voluntary non-remunerated (VNR) donors to meet 100% of the national need for blood products. This will completely eliminate the need for family / replacement donors who currently contribute 30% of units transfused to fill the demand-supply gap. In the context of a generalized HIV epidemic, VNR donors have low risk for incident HIV infection, replacement donors are known to pose a high risk due to higher prevalence of TTI. The remaining above allocation of USD 318,521 is for blood safety commodities from July to Dec 2017.

**Expected Outcomes and Impacts** – reduced transmission of HIV

### **Condoms**

**Budget Allocation** - USD 1.1 million within allocation

**Intervention and Rationale** - The allocated funding will be invested into expanding the availability of condoms through strengthening procurement and distribution processes according to need, targeting high-HIV burden areas. Providers will be retrained and demonstration models (male and female) made available to ensure proper and consistent use of condoms through public and social marketing strategies. Key populations will be selectively targeted for condom promotion including provision of lubricants (lubricant to be provided by USG/PEPFAR) as a part of comprehensive prevention service packages

**Expected Outcomes and Impacts** – reduce new infections.

### **Community-Based Support**

**Budget Allocation** - USD 1.9 million above allocation

Community based HTC activities focused on orientation and mobilization of young women and men on risk perception and reduction and health seeking behaviours to promote accessing relevant health services.

**Expected Outcomes and Impacts** – reduced transmission of HIV

### **ii) PMTCT**

**Budget Allocation** - USD 4.4 million within the allocation and USD 6.8 million above allocation will be for PMTCT.

**Intervention and Rationale** – the main focus will be in reducing the drop-off in each step of the PMTCT cascade. A new focus is on identification new HIV infections in pregnancy and during breastfeeding as these are responsible for the majority of vertical transmissions in the era of Option B+. PITC will be extended to immunization clinics to find exposed infants missed in the PMTCT cascade. Funding will also be invested into strengthening uptake and retention amongst pregnant women through the use of expert clients, peer-support groups such as M2M, male involvement interventions, and community dialogues promoting PMTCT and TB services access. A range of interventions to reduce loss-to-follow-up will be implemented: mother–infant follow-up service delivery model, defaulter tracing, and addressing HR challenges for HTC to reduce missed opportunities for follow-up testing of exposed infants. Funding will be invested into improving sample transportation through Riders for Health as well as introducing innovative strategies to reduce turnaround times for DNA-PCR results.

Above allocation funding of USD 777,502 is requested for PMTCT commodities to cover the extended 6 month period at the end of the grant (July 2017-December 2017). The remaining above allocation amount of USD 6.0 million will be invested into strengthening uptake and retention amongst pregnant women through the use of expert clients, peer-support groups such as M2M, male involvement interventions, and community dialogues promoting PMTCT and TB services access.

**Expected Outcomes and Impacts** – reduce new infections.

### iii) Prevention programs for key populations

#### Prevention Programs for MSM and TG

**Budget Allocation** – USD 278,671 of the allocated funding will be invested in programs for MSM for the first 2 years of the Concept Note period. This includes HTC testing, community based interventions, and condom commodities for this group. The above allocation amount of USD 344,734 will support additional community-level HTC and condom promotion activities as well as MSM programming for the last six months of the Concept Note period.

**Intervention and Rationale** – The requested funding will be invested in reducing risk behaviours, increasing access to HIV/STI services for MSM, and reducing stigma and discrimination faced by MSM, including in health care settings. The allocated funding will support provision of a standardized comprehensive preventive package for MSM in targeted geographic areas that will include peer-led/ delivered risk reduction education, provision of condoms/lubricants, routine HTC and STI/TB screening, and facilitated referral and tracking to MSM-friendly clinical services and legal services, peer educator and expert patient training and stipends, and community sensitization and focus group discussions involving MSM. The above allocation amount of USD 344,734 is requested for additional HTC commodities and to expand the number of peer educators for HTC, condom supporting activities and community sensitization activities specifically targeting MSM and to provide the same MSM programming as years 1 and 2 for the last six months of the funding period (July - December 2017). This will complement USG/PEPFAR USD 2.15 million annual funding for key population activities.

**Expected Outcomes and Impacts** – The within allocation funding will establish the provision of the standardized MSM prevention package in the priority geographic areas selected, along with health care provider and community sensitization activities in those same communities for a more supportive healthcare and community environment aiming to reach a targeted 1037 and 1350 MSM in years 1 and 2, respectively. The above allocation funding will allow in years 1 and 2 the engagement and training of additional peer educators and expert patients/client navigators, purchase of additional commodities, and expansion of sensitization activities both in type and number to support more concentrated service provision as well as expansion to additional priority geographic areas to better serve identified MSM and reach additional MSM. It will also fund all MSM activities for the extended 6-month grant period in year 3 to serve an expected 793 MSM. The impact of these activities will be reduced new infections among MSM and a more supportive enabling environment.

#### Prevention Programs for Sex Workers and their Clients

**Budget Allocation** - The within-allocation funding is USD 267,198 and above allocation request is USD 340,731 to support HTC testing and community based interventions for FSW, additional FSW targets for years 1 and 2, and FSW programming for the last six months of the funding period. USD 340,731 will be invested into expansion of community level HTC and condom promotion/delivery activities, reaching additional FSW in years 1 and 2, and all FSW targeted in the final six months of the Concept Note.

**Intervention and Rationale** –The within-allocation funding will be invested in provision of a standardized prevention package for sex workers that will include peer-led risk reduction information, male and female condom and lubricant provision (lubricants provided by USG/PEPFAR), routine HTC and STI/TB screening, facilitated referrals to FSW friendly clinical services, including family planning, mobile HTC activities, stigma and discrimination reduction among health care workers and the community, and training and stipends for peer educators and expert patients/client navigators. The above allocation of USD 340,731 is requested for HTC, condom supporting activities, and community sensitizations, specifically targeting FSW, reaching an additional 250 and 500 FSW in years 1 and 2, respectively, and all of the FSW programming in the July – December 2017 period of the Concept Note. This will complement annual funding from USG/PEPFAR of USD 2.15 million for key population activities and annual funding from the UN of USD 300,000-350,000 annual support for sex worker activities.

**Expected Outcomes and Impacts** – The within allocation funding will establish the provision of the standardized FSW prevention package in the priority geographic areas selected, along with health care provider and community sensitization activities in those same communities for a more supportive healthcare and community environment in order to reach a targeted 1000 FSW in the first year. The above allocation funding will allow in years 1 and 2 the engagement and training of additional peer educators and expert patients/client navigators, purchase of additional commodities, and expansion of sensitization activities both in type and number to support more concentrated service provision as well as expansion to additional priority geographic areas to better serve identified FSW and reach additional FSW. The above allocation funding is expected to serve an additional 250 and 500 FSW in years 1 and 2, respectively. It will also fund all FSW activities for the extended 6-month grant period in year 3 to serve an

expected 1000 FSW. The impact of these activities will be reduced new infections among FSW and their clients and a more supportive enabling environment.

#### **iv) Treatment Care & Support**

**Budget Allocation** – the total allocation for treatment, care and support will be USD 245.27 million and USD 72.74 million above allocation.

**Intervention and Rationale** – The allocated funding will be required for core commodities for the treatment program (ARVs, OI drugs, DBS bundles/reagents for EID and viral load monitoring and other HIV lab commodities) and PSM related costs to support off shore procurements, freight, insurance, warehousing, distribution and quality assurance, and expert patient emoluments.

Public education around Option B+ and ART has been identified as a key weakness in the current response and allocated funds will also be utilized for a concerted public and patient education strategy. The need to ensure the population is well informed about the importance of knowing one's status and accessing ART early is a priority as Malawi aims to reach the 90-90-90 targets. Allocation funding will also be used to ensure adherence and retention of patients in care through expert clients, defaulter tracing initiatives involving community.

The above allocation is requested to provide for a 9 month (6 months central & 3 months facility level) buffer stock for ARVs to ensure commodity security at the end of the NFM period.

**Expected Outcomes and Impacts** – reduced mortality in adults and children.

#### **2.3.b TB Program**

For the grant period, a total of USD 39,734,552 is being requested by the PR for TB control activities. Of the total requested amount, USD 15,166,551 will be within allocation and USD 24,411,451 will be in the above allocation. While both the within allocation and above allocation resources are meant to cover the two years of grant implementation, additional resources have been factored into above allocation resources to cover key program activities during the extended implementation period July and December 2017.

Six priority strategic interventions have been identified for funding allocation: 1) Case detection and diagnosis, 2) Treatment 3) Prevention 4) Community TB Care, 5) Vulnerable groups and 6) Program management. The first three priorities will result in increased case detection, rapid diagnosis and early treatment initiation. The three interventions will contribute to a decrease in TB disease burden and transmission of the infection within communities. Active case finding among vulnerable and high-risk populations will supplement the passive case finding that has traditionally been implemented over the years. Target groups for active case finding will include the urban poor, hot spots,<sup>150</sup> household contacts of pulmonary TB cases, persons aged 55 years and above, prison inmates, staff and healthcare workers. Improving and expanding treatment capacity will be prerequisites for expanding case finding. The fourth intervention, community TB care, is intended to build the capacity of community-based organisations (CBOs) network to support awareness creation, demand creation for services and addressing some of the barriers to positive care seeking behaviour. The fifth priority will address access barriers for vulnerable populations and improving availability of services. Finally, improved program management is intended to strengthen NTP management capacity in providing strategic direction, efficient and effective coordination among partners, ensuring adequate supplies of quality medicines and improve information systems including generation of new evidence through operational research and measurement of progress.

#### **i) TB Prevention, Treatment and Care**

##### **Case Detection and Diagnosis**

**Budget Allocation** – within allocation is USD 5,382,929 and above allocation is USD 4,903,949.

**Intervention and Rationale** – Intensified case finding will mainly target attendants of OPD and MNCH and services at all facilities across the country as there has been a missed opportunity to identify presumptive TB among this population.

**Within allocation:** In collaboration with the Health Education Unit (HEU), health promotion materials will be developed, produced and distributed to facilities across the country. Different channels of communication will be utilized to create awareness for action (radio, TV, health workers and print materials). Health facilities will organize health promotion activities utilizing the IEC materials that will be produced.

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<sup>150</sup> 20% of the clusters in the prevalence survey

Intensified case finding will entail systematic TB screening of patients presenting to health facilities irrespective of the immediate reason for seeking care. A tracking system for presumptive TB cases in OPD will be in place and appropriate tools distributed to all facilities. Implementation of intensified case finding strategies in MNCH and SRH settings will ensure that female attendees within the reproductive age group, which is at high risk for HIV and TB, are systematically screened for TB. Presumptive TB cases identified in OPD, SRH and MNCH clinics will be directly referred to the laboratory for further assessment. For implementation of systematic TB screening, SOPs and tools will be developed and implemented.

Active case finding targeting communities and vulnerable groups is dealt in the subsequent sections (vulnerable groups section). Community Sputum Collection Points (CSCPs) will be strengthened and expanded to assist identification of presumptive TB cases, sample collection and transportation to diagnostic facilities. Health worker competencies will be enhanced through training and refresher training and supported by regular monitoring and supervision and a strengthened system of referral. In line with WHO policy recommendation on LED microscopy scale-up, the diagnostic network will continue to be strengthened by replacing conventional microscopes with LED microscopes in high volume laboratories as well as further expansion of the network to ensure adequate coverage of services. Use of current GeneXpert platforms will be strengthened by, among other things, ensuring that guidelines are adhered to facilitate optimal use and expanded to seven more sites with high caseloads of PLHIV.

**Above allocation:** USD 3,320,146 is being requested for use in year 1 and year 2 of the grant towards procurement of an additional 14 GeneXpert platforms for high volume facilities and five units of X-ray machines. The GeneXpert platforms will improve TB case finding in high-risk populations and improve detection of MDR-TB. Targeted capacity development will ensure improved clinical diagnosis of smear-negative and extra-pulmonary TB cases at Central, District and selected CHAM hospitals following an MOH assessment of X-ray equipment in the country. Radiology services will thus be strengthened through procurement and commissioning of seven X-ray machines at hospitals with non-functional X-ray equipment. The sample transportation gap is addressed in the HSS component of this Concept Note. Above allocation resources will also cover TA costs to support central reference laboratory strengthening. Additional sputum collection points will be set up and LED microscopes procured to facilitate the phase out of the light microscopes in high-burden facilities for relocation to low burden sites. An additional above allocation amount of USD 1,583,803 is being requested by PR for case detection and diagnosis activities for extended period of grant implementation July-December 2017.

**Expected Outcome:** With within resource allocation of USD 5,382,929, the NTP expects to detect and diagnose 53,052 cases in the two years of the grant implementation. The increase in case detection will contribute to the reduction in TB transmission and disease burden.

With full implementation of the planned activities under the **above allocation**, the NTP will be able to identify and diagnose an additional 17,744 TB patients, which is 25% of the targeted 70,000 in the NSP for the first two years. With availability of additional above allocation amount of USD 1,583,803 for the period July-December 2017, we expect to detect and treat 50% (23,118 cases) of the NSP target for 2017.

## Treatment

**Budget Allocation** – within allocation is USD 3,302,176 and above allocation is USD 2,492,241.

**Intervention and Rationale** – The within allocation funding will support two key activities. 1) Procurement of quality assured anti-TB drugs and; 2) Facility upgrades for the establishment of new TB registration sites. NTP will continue to decentralize TB registration sites aiming to achieve a density of one registration site per 35,000 – 40,000 general population in order to improve access to treatment services for improved outcomes. A thorough assessment will be conducted using set criteria that will include availability of HIV services, TB diagnostic capacity, adequate infrastructure, TB caseload and human resources. Based on the assessment results, the facilities will be capacitated to undertake the functions of a TB registration site.

With the **above allocation** amount of USD 1,031,472 for year 1 and 2 grant implementation, 53,052 TB patients are expected to be initiated on treatment achieving a treatment success rate of 85% or above.

An additional amount of USD 1,460,769 above allocation amount is being requested by PR for treatment activities for the extended period of grant implementation, July-December 2017.

**Expected Outcome and Impact:** Within allocation resources will be used to treat all the 53,052 to be diagnosed in the two years of the grant implementation. Treatment success rate among smear-positive new cases is expected to increase to 90% from the current 84%.

With above allocation resources, 40,863 TB patients will be initiated on treatment; achieving similar treatment success as within allocation.

## Prevention

**Budget Allocation** – Total within allocation is USD 557,536 and total above allocation is USD 202,044.

**Intervention and Rationale** - The target population will be patients visiting health facilities that are targeted for TB Infection Control (TB IC); 400 facilities are expected to benefit from general infection control practices through PEPFAR financial support resulting in reduced transmission. PEPFAR partners will work to improve administrative and managerial interventions to improve TB IC. TB IC will be assessed in all health facilities, presence of Infection Control Plans as well as implementation frameworks. Monitoring mechanisms will be regularly ensured through supportive supervision. Based on the assessment, action points will be revised and health care workers will benefit from integration of TB IC into Infection Prevention (IP). IP committees at the district level will be better able to manage and oversee IP. Isoniazid preventive therapy will be provided to contacts of PTB patients who are eligible for IPT as per guidelines. Contact investigation of pulmonary TB cases will be strengthened to ensure early detection and treatment initiation. Other activities include advocacy for streamlining TB infection control policies into Malawi's Infection Prevention Program (IP) at different levels of service delivery. Personal protective equipment will be procured and be available for health workers.

The above allocation funding will be used to support facilities in further expanding contact tracing activities such as contact investigation and procurement of PPEs, given the increased number of cases diagnosed with above allocation funding in case detection.

Of the total above allocation USD 39,017 will be used for prevention activities within the first two years of grant implementation and USD 163,027 will be used for the extended period of grant implementation, July-December 2017.

**Expected Outcomes and Impact:** Contribution to reduced transmission of Tuberculosis and improved quality of life.

## Community TB Care

**Budget Allocation** – Total within allocation is USD 284,698; total above allocation amount is USD 4,036,330.

**Intervention and Rationale** – The provisional results of the TB Prevalence Survey 2014<sup>151</sup> indicated that 65% of prevalent smear-positive TB cases are being missed. Awareness, health-seeking behaviour for TB and out of pocket expenditures related to a long diagnostic pathway are major barriers to access services<sup>152, 153</sup> especially for the poor. The focus will be on the review, printing and dissemination of guidelines for Community TB Care along with tools for monitoring, supervision and reporting. The NTP at zonal and district levels will provide TOT training and oversight to umbrella CSOs. These organizations in turn will train and oversee implementation of interventions by community-based organizations to deliver a package of services that includes increasing community awareness of TB and TB/HIV, decreasing stigma and discrimination, creating demand for services and treatment adherence. Systems will be put in place to ensure linkages between CSOs, health facilities and community networks to support patients and their families to mitigate the impact of TB and TB/HIV. The NTP will support them to establish a system to monitor the community TB interventions. Community system strengthening (module) has all the resources to implement community TB interventions. More than USD 2,000,000 is allotted for community system strengthening to implement community TB interventions. The allotted amount (USD 32,862) will be used by the NTP to oversee implementation.

USD 3,165,979 above allocation has been dedicated to the two years of grant implementation while an additional USD 870,351 has been allotted for the period July-December 2017.

**Expected Outcomes and Impact** - This intervention is envisioned to enhance community engagement to deliver a package of care that includes enhancing awareness of TB and TB/HIV, reducing stigma, creation of demand for services, facilitation of referrals and treatment adherence activities including linking patients to community networks that will facilitate addressing of social and economic hardships from TB and TB/HIV. Specific M&E tools will be developed to capture the contribution of CSOs in TB services.

## Vulnerable and At-Risk Populations

**Budget Allocation** – within allocation is USD 1, 306,977 and above allocation is USD 2,896,619.

**Intervention and Rationale** – Vulnerable and at-risk populations for TB include PLHIV, (those under 5 and over 55 years of age), persons with co-morbidities such as diabetic patients and miners exposed to silica, HCW and correctional facility inmates and

<sup>151</sup> Banda R. Malawi National Prevalence Survey Provisional Results. Presentation 2014 UNION Conference, Barcelona

<sup>152</sup> GoM. Ministry of Health. TB-HIV Training Manual for Community Volunteers. Malawi. First Edition, February 2013

<sup>153</sup> Kemp J et al. Can Malawi's poor afford free tuberculosis services? Patient and household costs associated with a tuberculosis diagnosis in Lilongwe. Bulletin of World Health Organization, 2007.85:580–58

staff and urban poor. Vulnerable and at-risk populations for TB disease require focused attention to reduce barriers to diagnosis, treatment and care. Undiagnosed cases of TB may have lower access to services, and thus remain in communities for lengthy periods, propagating disease transmission, unnecessary morbidity and mortality. The mobile screening service using the mobile van with on-board diagnostics (digital X-ray and mini-laboratory with GeneXpert and microscopy) will cover hotspot areas such as the urban poor, prisons, mining communities and those aged 55 years and above who do not seek service. Scheduled visits will be made to targeted areas at least once a year, staying an average of one week at each site. The team will work extended hours to get working men who may not seek care during regular hours for fear of losing their daily wage. Information regarding mobile screening services will be provided through different local media and CSOs working in the area before the screening service dates in each target area. This intervention will require well-coordinated social mobilization and CSOs will be critical for this.

**Within allocation:** This funding will help to procure two mobile vans fitted with on board digital radiography and mini laboratory comprising GeneXpert and microscope. Active case finding strategy will be undertaken by deploying mobile teams to areas or settings where there is a high TB burden (urban and high-risk population) as informed by the TB prevalence survey and epi-assessment. Sputum collection points will be established in urban and high-risk areas. Prior to the mobile screening, there will be intensive social mobilization including house-to-house interfaces in order to improve participation. The capacity of health workers to deal with diagnosis and management of childhood TB will be enhanced.

Regular and systematic TB screening will be done for prisoners using symptomatic TB screening and X-ray (wherever available). Regular screening of TB and surveillance systems will be introduced, encompassing other health conditions. In the absence of a policy for mandatory screening for TB among health workers assigned to TB wards, MDR-TB clinics, laboratories and other high-risk areas, health workers will be encouraged to voluntarily access TB screening through wellness centres. Equally, health workers with comorbidities that increase the risk of TB (HIV, chemotherapy) will be advised to work in other service outlets. Personal Protective Equipment (PPEs) will be procured and made available to all health workers working in high-risk areas.

The above allocation total amount of USD 2,896,619 will support active case finding: An additional five mobile vans fitted with digital radiography and a mini laboratory (microscopy and GeneXpert) will be procured and deployed to each of the five zones to sustain regular outreach screening services. Through this allocation provision will also be made for running and maintenance costs of the mobile van. Mobile outreach will be extended to other high-risk groups such as mining communities. Zonal level meetings will be conducted to train Champion HCW on expansion of Wellness Centres (Care for Caregivers clinics) that include services for TB and HIV.

The above allocation amount of USD 2,514,403 is for the two years of grant implementation, while USD 382,217 is for the period July-December 2017.

**Expected Impact and Outcome:** These interventions are expected to add to the system 15% of all notified TB cases. Addressing the needs of these populations is likely to improve case detection, treatment outcomes (reduce rate of treatment interrupters and defaulters) and reduce transmission in the population.

The expected impact of the above allocation: 6,129 TB patients are going to be detected using the above allocation resource.

### **Program Management of Tuberculosis (Including Monitoring and Evaluation)**

**Budget Allocation** – within allocation is USD 1,767,143 and above allocation is USD 1,191,305.

**Intervention and Rationale:** The focus will be on strengthening NTP leadership (program staff at the central, zonal and district levels, including laboratory staff) of the NTP to provide strategic guidance, more efficient and effective partner coordination, ensuring adequate supplies of quality assured medicines, improving information systems, generation of new evidence and measurement of progress through operational research. Almost 80% of this intervention supports four key activities: Coordination of public and private sector partners at all levels, including improved linkages with communities (23%); M&E including regular monitoring meetings (31%); establishment of a case-based electronic surveillance database and implementation of a second Drug Resistance Survey (DRS) (27%); supply chain management ensuring adequate quality-assured medicines, laboratory and other supplies and materials (19%).

**Above allocation:** The total above allocation funding of USD 1,191,305 includes USD 717,911 to be used in the two years of grant implementation an additional USD 473,394 above allocation for the extended grant implementation period of July-December 2017.

**Expected Impact and Outcome:** Evidence based decision-making which in turn will contribute to program efficiency.

### **ii) Multidrug-Resistant TB (MDR-TB)**

## Case Detection of MDR-TB

**Budget Allocation** – within allocation is USD 860,028 and above allocation is USD 4,449, 200.

**Intervention and Rationale** - An aggressive approach to case detection of DR-TB is required to prevent a further burden to the patients, families and communities. The current estimated burden of MDR-TB is based on DRS done 5 years ago. The EH–RH shift which was implemented after the DRS survey is expected to change the resistance pattern for Rifampicin. There is potential for increased MDR-TB with an all-Rifampicin-based regimen, hence the need for vigilance to monitor and promptly determine above-threshold resistance levels in order to trigger regimen change. Scaling up strategies to address the most at-risk populations will ensure early detection and rapid treatment initiation, limiting transmission. The following activities will be implemented:

Capacity building of HCW: the PMDT training module will continue to be part of overall TB prevention and control training to improve awareness and knowledge of HCW. This will ensure fast tracking of those at risk of MDR-TB for further diagnostic services. In-service training and refresher training will sensitize HCW to improve the utilization of GeneXpert. Sufficient supplies of GeneXpert cartridges will also be ensured through this allocation.

Laboratory strengthening: The capacity of the Central Reference Laboratory (CRL) will be strengthened to confirm MDR-TB with rapid molecular tests (LPA & MGIT). Staff in the reference laboratories will be trained and the required supplies for culture and DST will be procured.

Surveillance of retreatment cases: all retreatment cases will have access to GeneXpert, culture and DST.

Feedback of laboratory information results of will be improved through building on current SMS platforms already in place through TBREACH. Laboratory information will be sent through to a treating facility to facilitate better management and treatment monitoring.

Central Reference and regional laboratories: In addition to further expansion of Quality Management Systems for diagnostics, first-line DST will be strengthened and second-line DST will be introduced.

For the above allocation, main activities include procurement of LPA machines for the CRL and one reference laboratory; Sentinel surveillance of new smear-positive cases will be established in selected high volume sites where  $\pm 50\%$  of current Pulmonary TB notifications occur. This will require additional genotypic and phenotypic assays (additional MDR-TB cases detected are  $\pm 20$ ). If above allocation is approved for case detection, it is expected to garner 750 additional TB cases that will be tested for MDR-TB.

The total above allocation amount includes USD 3,274,182 for the two-year grant implementation period and an additional USD 1,175,018 for the extended implementation period July-December 2017.

**Expected Impact and Outcome** - Within allocation resources will enable the NTP to detect 186 MDR-TB patients as well as improve turnaround time for sample transportation and results.

Above allocation resources will enable NTP to detect 63 MDR-TB patients and an additional 107 MDR-TB patients with the additional above allocation resources covering the period July-December 2017.

## Treatment of MDR-TB

**Budget Allocation** – within allocation is USD 1,445,828 and above allocation is USD 4,010,984.

**Intervention and Rationale** - The mainstay of MDR-TB control is early detection and prompt treatment resulting in decreased morbidity, mortality and on-going transmission. Those presumptive MDR-TB patients with GeneXpert/RR result on two separate sputum samples (GeneXpert) will be started on MDR-TB treatment until the DST result is available. To ensure uninterrupted supply of second-line anti-TB drugs, drugs will be procured for all MDR-TB cases through this mechanism. Training will target HCW in all MDR-TB treatment facilities, and members of the District Health Teams to ensure coordinated and efficient approaches to PMDT services. Patients who are unstable or with underlying medical conditions will be admitted for short duration to ensure they are stabilized.

The existing community-based MDR-TB management will be strengthened. Community service delivery points will be supervised and supported by referral hospitals. Patients will also have regular visits to referral hospitals for clinical, biochemical and bacteriological evaluation. An appropriate sputum sample referral system will be established (a detailed plan is available in the laboratory strengthening of HSS section in the Concept Note). Adherence to treatment and patient follow-up will be strictly followed. Adequate training will be provided to HCW at receiving health units to provide the necessary follow-up. There will be close monitoring of MDR-TB patients through to treatment completion and evaluation.

The above allocation funds will be used for case detection of TB and MDR-TB. Then these additional MDR patients will need to be treated.

The total above allocation amount of USD 4,010,984 includes USD 2,624,647 for the two-year grant implementation period and an additional USD 1,386,338 for the extended implementation period of July-December 2017.

**Expected Impact and Outcome:** Within allocation resources will enable the NTP to treat 186 MDR-TB patients as well as to improve turnaround time for sample transportation and results.

Above allocation resources will enable NTP to treat 63 MDR-TB patients and an additional 107 MDR-TB patients with the additional above allocation resources covering the period July-December 2017.

## **MDR-TB Prevention**

**Budget Allocation** – within allocation is USD 259, 236 and above allocation is USD 228,778.

**Intervention and Rationale** - Interruption of transmission of TB and MDR-TB is essential and the main activities will focus on implementing the FAST (Finding TB cases, Actively, Separating Safely, and Treating Effectively) approach in healthcare settings. In addition, all health facilities providing care and treatment follow-up to MDR-TB cases will update and implement TB infection control plans. Infrastructure improvements and renovations will be supported in the three MDR referral centres. Personal protective equipment will be procured and distributed for health workers in all MDR-TB in-patient services and surgical masks for MDR-TB patients will also be made available. Eight district hospitals will be supported to create and maintain one isolation room for each facility.

The total above allocation amount of USD 228,778 includes USD 126,149 for the initial two years of the grant and an additional USD 102, 629 for the extended implementation period July-December 2017.

**Expected Outcome and Impact:** Reduced nosocomial transmission MDR-TB.

### **2.3.c TB/HIV Collaborative Activities**

**Budget Allocation** – within allocation is USD 691,554 and above allocation is USD 1,520,887.

**Intervention and Rationale** - The generalized HIV and TB prevalence in Malawi requires joint actions at all levels of the system to address morbidity and mortality, improve efficiencies, leverage resources and build on experiences and lessons learned from both programs. The focus will be on reducing the burden of TB in people living with HIV, reducing the burden of HIV in TB patients and strengthening mechanisms for collaborations at different levels. This will be implemented in line with the national TB and HIV implementation framework and WHO guidance for implementation of TB/HIV collaborative activities. Early diagnosis and treatment initiation of co-infected patients will be ensured. INH will be procured. Rifabutin will be procured and provided TB /HIV co-infected patients. Cross cutting activities including capacity building of health workers and integrative supervision and review meeting are dealt in the HSS module of this application.

The above allocation resources will be used to improve screening for TB in ART and PMTCT clinics, conducting national review meeting and printing of self-administered questionnaires with illustrations to be introduced in these care settings (ART and PMTCT clinics). Since this is a new innovation, implementation will be closely monitored to ensure that the initiative is contributing to increased TB case identification among PLHIV.

The total above allocation amount of USD 1,520,887 includes USD 1,113,431 for the initial two years of the grant and an additional USD 407,456 for the extended implementation period July-December 2017.

**Expected Outcome and Impact:** Joint implementation will result in more efficient use of resources; expanded implementation of one-stop services; increased early case detection and treatment of TB in PLHV with decreased mortality rates, and improved TB IC across all services including HIV services.

The above allocation funding is expected to increase the proportion of presumptive TB cases among PLHIV to 35,000 from the current 16,000.

### **2.3.d Health System Strengthening (HSS)**

#### **i) Procurement and Supply Chain Management (PSM)**

**Budget Allocation** – WTP is USD 5.75 million.

Above allocation is USD 1.96 million.

**Intervention and Rationale** - The key focus of strengthening PSM will be laboratory and medicines logistics management; information systems including medicines management supervision and mentoring functions; implementation of an electronic

stock management system for medicines and supplies resulting in better quality logistics data; health facility storage infrastructure as a key intervention leading to improved quality of logistics data and secured storage of medicines including HIV /TB commodities. Interventions under PSM aim to support the availability of medicines and medical supplies for patients on ART and TB patients while catering to the needs of the general population of people living with HIV/AIDS and TB across the country.

**Expected Outcome** – The key interventions will lead to improved storage conditions which will in turn lead to improved stock management and hence better quality of data reported through the Logistics Management Information System (LMIS).

## **ii) Human Resource Management**

**Budget Allocation** – within allocation is USD 2.85 million and above allocation is USD 2.29 million (WTP is USD 2.5 million).

**Intervention and Rationale** – Numerous partners are collaborating to address the human resources for health (HRH) crisis in Malawi and these investments complement their efforts. The HRH request from within the allocation is for four specific activities that support cross-cutting TB, HIV, and malaria programs. The Public Health Act requires a process of updating to address the changing realities of infectious diseases in Malawi, including HIV, TB, and malaria. In-service trainings are necessary to update health care workers on current standards of practice, including HIV/TB integration. Additional training of TB staff on how to administer ART for HIV is necessary. In addition, the MoH would like to support an orientation for all new HCW and a semi-annual refresher training. The cost of these trainings and activities totals USD 2.85 million.

The Government of Malawi HRH interventions under willingness to pay will focus on four key areas to holistically support HRH development in relation to delivering the TB and HIV/AIDS program in Malawi: Support for quality training institutions; support for pre-service education scholarships to supplement those from other development partners; support for an in-service mentorship program; and support for scaling up the Integrated Human Resources Information systems (IHRIS) for tracking production, deployment and retention of health care workers.

The Global Fund request also includes USD 2.29 million above the allocation. USD 1.45 million would be used for bursary support to train additional health care workers. USD 0.5 million would be used to provide water and electricity at government-provided accommodation in remote rural hard-to-fill posts in areas of high HIV and TB prevalence. An additional USD 0.3 million is requested to cover the district clinical review meetings for TB/HIV from July to Dec 2017.

**Expected Outcome** – All staff will be trained in current management of TB and HIV. 100 medical assistants, 50 clinical officers, 50 pharmacy assistants, and 50 laboratory assistants will be newly trained. 24 clinical officers will be upgraded to bachelor's degrees. Fifty HCW accommodations in remote and hard-to-fill posts will have water and electricity.

## **iii) Service Delivery**

**Budget Allocation** –above allocation is USD 0.63 million (WTP is USD 3.1 million).

**Intervention and Rationale** – A range of partners including PEPFAR and USAID collaborate on service delivery issues. The above allocation request of USD 0.635 million supports current Government of Malawi commitments to strengthening lab services by expanding service and maintenance contracts. Efforts funded by PEPFAR will help lab services but will not provide full coverage of lab services and fall short of meeting total lab needs.

The Government of Malawi has committed to using USD 3.1 million as part of WTP funds to strengthen lab and quality assurance services. Namely, investing in maintenance service contracts for lab equipment, increasing sample transport, ensuring drugs are appropriate and effective when supplies reach the country and assuring quality lab services through blind checks and proficiency tests for personnel.

The Global Fund request for above allocation monies of USD 0.63 million is to expand and support maintenance service contracts as current funds committed by Government of Malawi do not fully meet demand.

**Above Allocation Expected Outcome** – As greater service contracts can be fulfilled on an as-needed basis, it is expected that the number of functioning lab equipment will rise.

## **iv) Policy and Governance**

**Budget Allocation** – within allocation is USD 21,581.

**Intervention and rationale** – The Public Health Act (currently undergoing revision) requires a process of updating to address the changing realities of infectious diseases in Malawi, including HIV, TB, and malaria. When appropriately incorporated into the

Public Health Act, institutions now have a mandate to support the Act. The within allocation amount of USD 21,581 will be used to ensure an appropriate infectious disease component in the revised Public Health Act.

**Within Allocation Expected Outcome** – An appropriate and valid infectious disease control component in the Public Health Act that results from consultations with relevant TB and HIV personnel.

### **2.3.e Community System Strengthening (CSS)**

The role of community structures in this TB/HIV CN will be:

- Managing and delivering community-level TB, HIV and TB/HIV services including TB Screening and TB contact tracing.
- Supporting PLHIV, TB patients, key populations, women and young people, and other vulnerable groups to access quality TB/HIV services.
- Promoting networking and linkages amongst CSOs and with other service providers.
- Strengthening capacity of community organizations and structures to deliver quality TB/HIV community services.
- Mobilizing community players to implement TB/HIV.
- Mobilizing CSOs, police, judiciary, health care workers to community players to implement MSM, FSW HIV/TB programming including human rights and gender.
- Monitoring and advocating for protection and promotion of human rights, gender and better access to TB and HIV services.
- Monitoring and reporting on TB/HIV community level programs and interventions.

### **Advocacy for Social Accountability**

**Budget Allocation** - within allocation is USD 242,552 and above allocation is USD 151,200 (USD 85,745 for years 1 and 2 combined; USD 64,455 for the extended semester of year 3).

**Intervention and Rationale** - The intervention will support protection of human rights and removal of legal barriers for key and vulnerable populations. Key and vulnerable populations will be encouraged to access HIV/AIDS services if their rights and confidentiality are protected and there is no stigma and discrimination related to sexual orientation or means of making a living.

#### **Within Allocation**

The target population and scope for within allocation includes national, district, and community level.

Advocacy meetings on a range of critical topics will be conducted at zonal and national levels. Community orientations for faith leaders on human rights protection for MSM, female sex workers, women and girls will be conducted. Zonal meetings on social accountability will be undertaken with decision makers and service providers. Together with human rights experts and Key Populations themselves, we will conduct an assessment of laws, policies that negatively impact key populations. We will share the results of the assessment with representatives of key and vulnerable population, organizations working with these groups, and local, zonal and national political and faith leaders.

The within allocation is USD 242,552.

#### **Above Allocation**

The above allocation will support the process of engaging with stakeholders in developing a common policy agenda and prioritize policy issues to be addressed. This support will also identify the national deliberative bodies and individuals to target for policy change.

Appropriate tools, policy briefs and guidelines for advocating on these negative laws will be developed and activities using them conducted. Target groups for these policy briefs and activities will be parliamentarians, policy makers, and judiciary.

The above allocation is USD 151,200 (USD 85,745.27 for year 1 and 2 combined; USD 65,454.54 for the extended 6-month period of year 3).

#### **Expected Outcome:**

Within allocation will support the dissemination of the assessment report of policies and laws that negatively impact key populations to government representatives to enable them draft rights laws and policies. The assessment will also be shared with people living with and affected by the diseases as well as key populations will also be shared with the assessment. These will be disseminated at community and zonal meetings and leaders at these respective levels will be invited to receive and discuss the results.

The expected impact of the above allocation is an understanding by the Key Populations, community leaders and members of the exact laws and policies that will need to change and the development of tools and plans to advocate for the change.

#### **Social Mobilization, Building Community Linkages, Collaboration and Coordination**

**Budget Allocation** – within allocation is USD 1,349,708 and above allocation is USD 4,788,318.(USD 4,091,412 for years 1 and 2 combined; USD 696,906 for the extended 6-month period of year 3)

**Intervention and Rationale** - The intervention will focus on promoting and expanding capacity for Service provision of HTC, STI Screening and provision of condoms and lubricants for key and vulnerable populations in places and schedules suitable for the target groups. A key strategy that will be employed to ensure increased uptake of HTC and STI screening by key and vulnerable populations is Moonlight Services.

The intervention will also focus on promotion of integration of TB/HIV, gender and human rights in TB/HIV programming and mitigating the impact of HIV/AIDS for key and vulnerable populations through capacity building for and provision of vocational skills training.

Another area of support will be the provision of legal support/litigation in cases of human rights violations for key and vulnerable populations by integrating community paralegals to provide legal aid services.

#### **Within Allocation:**

The target population and geographic scope will be peer educators, village health committees, community health care workers, community and faith leaders in priority areas nationwide. Zonal trainings and community meetings involving local leaders and peer educators will be conducted. This will include:

- the training of community volunteers as TB DOT supporters;
- the training of 75 community workers to deliver community-based/outreach and Moonlight testing services;
- training and supporting mother groups in TB/HIV;
- training faith leaders and community leaders on adherence to ART and TB drugs;
- training clinic navigators/expert patients or peer educators to conduct healthcare referrals,
- Provision of bicycles for peer educators operating community TB sputum collection points,
- Advocacy,
- Peer education and community dialogue on availability and access to male and female condoms and lubricants in rural hotspots and trading centres
- targeted community dialogue and interpersonal discussion with community leaders and faith leaders on key populations
- conducting biannual coordination meetings between healthcare providers and community-based workers

The within allocation amount is USD 1,349,708.

#### **Above Allocation**

The target for the above allocation are health care workers, faith and community leaders and communities in priority areas nationwide. The interventions will focus on citizen engagement and community dialogue on key populations rights, PMTCT, TB services and gender issues. The activities will include:

- Creation of community structures to implement TB/HIV interventions carry out local dialogues, disseminate information on various topics to reduce stigma, condom usage, Family Planning and STI Screening.
- orientation meetings of HCW on rights of KP including issues of rights in PITC; Moonlight testing services at 225 hotspots throughout Malawi); community TB sputum collection points;
- training for male and female care givers in gender sensitive and rights based TB/HIV care (300 Care Givers will undergo 7 days training);
- formal and informal vocational trainings; quarterly interface meeting for Community Score Card; quarterly interface meeting for FSW/MSM alliances; capacity building for FSW/MSM alliances in networking and coordination;
- integrating community para- legal services into health outreach services by training of volunteers as lay legal to provide legal aid support and services that reach key populations;
- support for legal services through telephone hotline for key populations
- awareness-raising campaigns that raise legal literacy by providing information about rights and laws related to HIV through media e.g. TV, radio, print, internet; radio listening club training;

The above allocation is USD 4,788,318. (USD 4,091,412 for years 1 and 2 combined; USD 696,906 for the extended 6-month period of year 3)

**Expected Outcome:** These interventions within allocation will increase access to and use of HIV, TB and other health services by key and vulnerable populations; reduced new HIV infections.

The above allocation will expand demand creation for community TB detection and testing services. Specifically the key populations will be reached with services. The expected impact of the above allocation is that access to legal services for key populations will be improved because legal firms and institutions which have officers in many districts will be hired to provide specialised legal services to key populations. Increased reporting of well-documented human rights violations; increased actions taken against violators; improved human rights environment.

### **Community-Based Monitoring**

**Budget Allocation** - within allocation is USD 117,196 and above allocation is USD 382,668 (USD 376,794 for years 1 and 2 combined; USD 5,874 for the extended 6-month period of year 3).

**Intervention and Rationale** - The intervention will support capacity building of community volunteers and CSOs to document and report human rights violations. In addition, M&E visits will also be used to take stock of human rights violations so that such issues are dealt with in a timely and effective manner.

**Within Allocation:** The target population and geographic scope of this intervention is a nationwide network of volunteers who will be trained in use of community based monitoring.

The activities will include

- additional training on the use of community score card training for volunteers in 75 hot spots
- conducting of M&E technical visits to programs nationwide.

The within allocation amount is USD 117,196.

### **Above allocation**

- The activities for above allocation are nationwide zonal training meetings in M&E and research for gender, human rights, CSS for TB/HIV, and HIV/TB reporting, hiring of a technical assistant for CSOs advocating for private sector involvement and financing of TB/HIV. Budget advocacy will be undertaken to track spending on TB/HIV, gender, young people and key populations in national and donor funded budgets & advocate for government support for HIV/AIDS- ART, and HSS.

The above allocation is USD 382,668 (USD 376,794 for years 1 and 2 combined; USD 5,874 for the extended 6-month period of year 3).

**Expected Outcome** - The outcome of these within allocation interventions will be increased participation of volunteers in community based monitoring of case detection, ART adherence, and mobilisation for VMMC.

The outcome of the above allocation will add to community involvement in financing and budget advocacy.

### **Capacity Building**

**Budget Allocation** - within allocation is USD 833,519 and above allocation is USD 2,087,903 (USD 1,820,034 for years 1 and 2; USD 267,870 for the extended 6-month period of year 3)

**Intervention and Rationale** - This intervention will focus on capacity building for CSOs to plan and implement TB/HIV activities including incorporating issues of gender and human rights so that TB/HIV activities adequately address issues of gender and human rights. In addition, the intervention will focus on building the capacity of duty bearers, e.g., law enforcers, police, prison departments, teachers, and healthcare workers, and also CSOs on GBV prevention, stigma and human rights for key populations.

#### **Within Allocation:**

The target population includes CSOs, health care workers, teachers and police and prison personnel (i.e. service providers as duty bearers).

The main activities for the CSOs, HCW, police and teachers are to strengthen institutional human resources; develop strong guidelines and action plans to serve as basis for advocacy and implementation of specific programs; Meetings will be conducted with key government decision makers to gain support.

Specific activities include:

- scale up youth friendly HIV/TB interventions with a rights based approach and gender and address aspects of literacy, employment and skills development;
- training for prison personnel regarding the prevention, health care needs and human rights of prisoners living with or at risk of HIV and TB infection in order to reduce discrimination and stigmatisation, and strengthening of referral systems for prisoners upon release to the community;
- training for teachers on age-appropriate gender transformative rights based sex and sexuality education in and out of school;
- Orientation of CSOs, Police and Health Care Providers on GBV prevention, stigma and human rights for key populations; developing and disseminating gender transformative and rights based guidelines on confronting stigma and discrimination;
- Provide training for police, judges, officials, and/or health workers in legal literacy and the importance of appropriately addressing domestic and sexual violence cases in the context of HIV; and the negative consequences of illegal police activity on justice and on the HIV response
- Build the technical and programmatic capacity of CSO to serve the key populations
- disseminate evidence and good practices on TB/HIV and enabling factors;
- Baseline Survey (formative research about KPs);
- Capacity building for FSW alliances

The within allocation amount is USD 833,519.

#### **Above Allocation:**

A mapping exercise for CSOs working in TB/HIV, gender, human rights, for young people and key populations will be conducted to complement and fill in gaps of other mapping that may be carried out with non-Concept Note resources. The interventions then target strengthening the capacity of CSO who programme for key and vulnerable populations namely girls, women, boys, young people, MSM and FSW, prisoners. Since these are few, furthermore, mainstreaming CSOs will be oriented in Key and vulnerable population HIV/TB programming.

Specific capacity building interventions will be:

- The development & implementation of BCC and IEC programmes in the public sector programs targeting specific key and vulnerable populations;
- develop and disseminate TB HIV action plans and guidelines on gender, human rights, key populations, girls, women and men and boys to combat GBV, early child marriage, intergenerational and transactional sex, masculinity and culture;

- establishing and maintaining synergies between TB/HIV/SRH and other sectoral issues of gender, education, nutrition;
- conducting operational research on CSS related TB/HIV and enabling factors; training for health CW in gender and human rights

The above allocation is USD 2,087,903 (USD 1,820,034 for years 1 and 2; USD 267,870 for the extended 6-month period of year 3)

**Expected Outcome** – With within allocation, the expected impact of these interventions is the improved provision of integrated TB/HIV, gender and human rights activities; improved legal, human rights and health care environment from key duty bearers namely, health care workers, teachers and police and prison personnel. Engagement of relevant stakeholders on issues of key populations and rights through orientation of Health Care Workers on Rights of key populations and sensitization of police on importance of reaching out to key populations will increase number of organisations aware and working on issues of Key Populations thereby the bottleneck of having a limited number of organisations will be addressed.

In order to address the bottleneck of a limited number of organisations working with key populations, the within allocation includes the capacity building of key 2 AIDS service organisations per district to mainstream key population programming in their HIV interventions. The capacity of FSW alliances will also be build so that they can advocate .

The above allocation addresses further the issue of a limited number of organisations working with key populations. The main intervention is the mapping of CSOs to identify those that can most strategically mainstream key populations in their programming. Furthermore, direct capacity building will be provided by human rights experts to those organisations that are already championing key populations programming.

### **3.3.f Principal Recipient Programme Management**

This section provides an overview of the four program management functions and combined budget request for the two Principal Recipients (PRs), the Government PR, the MoH, and the non-government PR, ActionAid Malawi (AAM). A combined total of USD 4,128,623 within allocation is requested for the PRs to support the joint programme management role.

#### **Policy/Planning/Coordination and Management**

This activity will be carried out by both PRs. For the grant period, a total of USD 528,667 within allocation is being requested. At the beginning of the programme to allow integration and synergy building there will be joint planning for both diseases. Appropriate mechanisms for policy influencing will be supported by both PRs. For effective coordination of grant implementation per disease, the PRs will setup an executive committee to oversee implementation of related activities by the two PRs and subsequent sub-recipients (SRs). The committee will also monitor and support implementation of planned activities; timely submission of PUDRs; addressing conditions precedent attached to each PR and also addressing bottlenecks for effective grant implementation. Similarly there will be subcommittees within the disease split to provide oversight for program implementation. The MoH, in the context of HSS, will sign service contracts with appropriate providers for services such as specimen transportation and maintenance of medical equipment.

#### **Grant Management**

This activity will be carried out by both PRs. For the grant period, a total of USD 2,190,594 within allocation is being requested. As the PR and part of the management of program's activities to be financed by the Global Fund under the New Funding Model, MoH will establish a lean, efficient and cost-effective dedicated unit (the Global Fund Program Implementation Unit) which will be responsible for managing and supervising grant implementation and reporting to the Global Fund through the Secretary for Health. The Unit will be responsible to the Global Fund for all aspects of the NFM implementation, including technical vision, partner relations, MOH Departmental collaboration, program performance, and fiscal/resource management. The unit will be located in the Planning and Policy Development Department within the Ministry of Health and its members will work with all relevant Directorates and Departments in the implementation of the NFM. The Unit will have an independent Account Section and will be audited separately. The Ministry of Health, as PR, will be responsible for providing the periodic and annual progress reports as specified in the Grant Agreement. In addition, the Unit will develop capacity for financial management of Global Fund Grant resources in all the MOH Cost Centres in all the 29 Health districts and five (5) Zones.

The Unit will have three full time dedicated staff namely Program Manager, Program Management Specialist and Program Accountant. The Program Manager will be at a Principal Secretary level and will lead the Unit. He/she will be responsible for day to day running of the Unit and supervising all PIU staff. The Program Manager will report to the Secretary for Health. The Program Management Specialist and Program Accountant will be at Director level and will report to the Program Manager. The staff will be entitled to motor vehicle transportation, fuel and phone airtime as per Government of Malawi policy. The Unit will also have other dedicated staff who will be seconded to the Unit and their salaries will be funded through the Government of Malawi. These will include Accountant, two Accounts Clerks, and two Monitoring & Evaluation Officers. The Secretary for Health, Chief of Health Services and Director of Planning and Policy Development will dedicate their time and effort to the PIU and will be financially compensated for their time and power through Government of Malawi top up allowance. The Government of Malawi salary top-up will be part of the Willingness-to-Pay contribution. The Global Fund Coordinator will continue providing technical assistance to the PIU to ensure adherence to Global Fund Policies and procedures. The MOH Health Informatics Technical Assistant will be part of the PIU and will lead the implementation of all M & E activities for the PIU.

To effectively manage the Global Fund programme and undertake the responsibilities of PR, ActionAid Malawi will establish a core Programme Management Unit (PMU) composed of staff who will be 100 percent dedicated to the programme. This core team will be further assisted by several support staff and functions from ActionAid Malawi. The PMU will play a central management role in the implementation of the programme. This unit will take on the tasks of ensuring (i) programme coordination, (ii) contract management with SRs and consultants, (iii) project supervision, (iv) monitoring and evaluation, (v) budget tracking, (vi) communications, (vii) programme accounting and (viii) procurement.

ActionAid will engage SRs with requisite competencies to undertake specific activities within its scope of work. This will be done through competitive and transparent processes comprising a call for expressions of interest, review of submissions and capacity assessment. The process will align with Global Fund requirements for selecting SRs. Successful SRs will be managed as follows: SRs will sign contractual agreements with the PR and will develop work-plans based on the implementation arrangement. Performance frameworks will also be developed with clear indicators and deliverables for monitoring SR performance. Approval for SR disbursement requests will be dependent on achievement of pre-determined targets and timely remittance of accurate financial and activity reports. Based on the agreement entered with the Global Fund, the PRs and SRs will be expected to undertake an audit of their financial management systems. The PR will also conduct regular spot checks on SRs to ensure financial prudence.

### **Support Procurement and Supply Management**

This activity will be carried out by both PRs. For the grant period, a total of USD 686,807 within allocation is being requested. The procurement of goods and services such as consultancies will be guided by established procurement procedures that exist within the two PRs. Procurement requires justification and approval by the Line Managers. The selection criteria are transparent and documented. The process will be conducted by the procurement committee who make recommendation to the approving authority for approval. Clear terms of reference are agreed with the consultant/s when procuring the services of consultants, the following minimum guidelines apply: Fees and rates are paid in line with agreed rates in specific Policy document. A signed contract between PRs and service providers will be put in place which clearly details the following: -

- Duration of the contract
- Maximum contract value
- Payment arrangements
- Expected output
- Monitoring and evaluation arrangements

Dedicated teams from the two PRs will be responsible in managing the supply chain and ensuring effectiveness of the whole procurement and delivery system.

### **Monitoring and Evaluation**

This activity will be carried out by both PRs. For the grant period, a total of USD 722,555 within allocation is being requested. The program will set up the necessary mechanisms for measuring program efficiency and effectiveness and provides the reference for program monitoring and evaluation. Key M&E components will include: (i) Assessment of change and performance on a consistent and systematic basis across diseases; (ii) Continuous feedback to the various stakeholders involved in the project both at district and national level through regular reports as per agreed schedule and /or meetings; (iii) Ensuring information is used to assess progress and provide corrective action and mitigation strategies where needed; and (iv) Documentation and dissemination of lessons learned from the existing project and using them for proposed expansion.

The monitoring process will be carried out using a participatory approach and the results of collected data will be shared with all stakeholders. These processes include monitoring and field visits, periodic evaluations with communities and focus group discussions with relevant stakeholders. Information obtained will be collated to provide an overall profile on the program performance, which not only afford insight to the program successes, but also provide information to the PRs and other stakeholders, allowing them to make sound decisions related to the program delivery mechanism and expected outcomes. Based on the results of M&E activities, successful models will be identified that can be replicated and scaled up to a wider area to ensure maximum and beneficial coverage.

<b>PR Program Management Total Combined Budget (MoH &amp; AAM)</b>	
<b>Policy/Planning/Coordination and Management</b>	<b>\$528,667</b>
<b>Grant Management</b>	<b>\$2,190,594</b>
<b>Support Procurement and Supply Management</b>	<b>\$686,807</b>
<b>Monitoring and Evaluation</b>	<b>\$722,555</b>
<b>Total</b>	<b>\$4,128,623</b>

## IMPLEMENTATION ARRANGEMENTS AND RISK ASSESSMENT

### 3.1. Overall Funding Landscape for Implementation Period

#### a. Justification for not adopting a dual-track financing arrangement

The implementation arrangement for Malawi reflects a dual-track financing arrangement. The Malawi Country Coordinating Mechanism (CCM) has nominated the Ministry of Health (MoH) to be the Government Principal Recipient (PR) and ActionAid to be the non-government PR for the joint TB/HIV grant.

#### b. Coordination between PRs

The MoH will implement the biomedical component of the grant which will include the following: quantification, procurement, storage and distribution of medicines and other commodities, HIV and TB services delivery at primary, secondary and tertiary facilities. In addition, the MoH will be responsible for the capacity building and Health Systems Strengthening (HSS) component of the grant. On the other hand, ActionAid will be responsible for the non-biomedical interventions, such as community TB care, engagement and networking of CBOs, contribution to TB case finding at the community level, support for treatment adherence, and impact mitigation for both TB and HIV at the community level, and community mobilisation and demand creation for TB and HIV services.

For effective coordination of grant implementation per disease, the PRs will setup an executive committee to oversee implementation of related activities by the two PRs and subsequent SRs. The committee will also monitor and support implementation of planned activities; timely submission of PUDRs; addressing conditions precedent attached to each PR and also addressing bottlenecks for effective grant implementation. Similarly there will be subcommittees within the disease split to provide oversight for program implementation. The MoH, in the context of HSS, will sign service contracts with appropriate providers for services such as specimen transportation and maintenance of medical equipment.

#### c. Sub-recipient management arrangements

It is envisaged that the non-governmental PR (ActionAid) will engage sub-recipients (SR) with requisite competencies to undertake activities within its scope of work. This will be done through competitive and transparent processes comprising a call for expressions of interest, review of submissions and capacity assessment. The process will align with Global Fund requirements for selecting SRs. Successful SRs will be managed as follows:

SRs will sign contractual agreements with the PR and will develop work-plans based on the implementation arrangement. Performance frameworks will also be developed with clear indicators and deliverables for monitoring SR performance. Approval for SR disbursement requests will be dependent on achievement of pre-determined targets and timely remittance of accurate financial and activity reports.

Based on the agreement entered with the Global Fund, the PRs and SRs will be expected to undertake an audit of their financial management systems. The PR will also conduct regular spot checks on SRs to ensure financial prudence.

#### d. Coordination between PR and SRs

The successful sub-recipients will sign contract agreements with the PR. The agreements will guide the relationship between the PR and SRs including the coordination mechanism. SRs will submit quarterly work plans and technical and financial reports to the PR for consolidation into PR reports for onward transmission to the CCM and the Global Fund.

#### e. Participation of women's organizations, people living with the two diseases and other key populations

Representative groups for women's organizations, people living with HIV and former TB patients as well as umbrella bodies for key affected populations were engaged in the development of the concept note and will participate actively in the grant implementation primarily as SRs. These organizations will be engaged in such activities as community mobilization,

identification and referral of presumptive cases, treatment/care retention as well as awareness and demand creation for TB and HIV services. Members of these representative groups will also be engaged as key informants during respective program reviews.

#### 4.2 Ensuring Implementation Efficiencies

Currently the Malawi CCM is overseeing three Global Funds grants, namely HIV SSF, TB TFM Grant and Round 9 Malaria Grant. The HIV and Malaria grants will phase out at the end of June 2015 while the TB grant will end in December 2015. These are summarised in below:

*Table 17: Portfolio of GFATM grants in Malawi showing overlap with NFM*

Grant Number	Principal Recipient (PR)	Year					
		2012	2013	2014	2015	2016	2017
MLW-H-NAC	National AIDS Commission	USD 265,315,984					
MLW-708-G06-T	Ministry of Health	USD 11,653,620					
MLW-911-G08-M	Ministry of Health	USD 80,799,803					

This grant is expected to start in July 2015 and will build on the gains made by the existing TB and HIV grants. The grant will essentially continue supporting activities currently supported by the HIV SSF and TB TFM grants. It will also support HSS activities, which will catalyse implementation of activities in this and the malaria concept notes. Therefore, there will be no overlapping or duplication of activities with the existing grants.

From a program management perspective, components of the three disease programs managed by MoH are coordinated under two directorates, namely HIV and Preventive Health Services. There is a synergistic approach between TB and HIV in the joint TB/HIV funding request in terms of training, monitoring and evaluation and supportive supervision to health facilities. The non-government PR will conduct activities in this concept note in close collaboration with MoH.

#### 4.3 Minimum Standards for Principal Recipient (PR) and Program Delivery

PR 1 Name	Ministry of Health	Sector	Government
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
Minimum Standards	CCM assessment		
1. The Principal Recipient demonstrates effective management structures and planning	The PR has described a comprehensive management structure outlining functions of various technical and administrative levels. The PR also describes establishment of a lean, efficient and cost-effective dedicated unit responsible for managing and supervising grant implementation and reporting to the Global Fund through the Secretary for Health.		

<b>2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)</b>	The PR has mentioned SRs that it supports and a brief description of how the support is provided.
<b>3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud</b>	The PR has described a robust internal control system with seven commonly accepted control objectives. It provides assurance that, if properly implemented, this can prevent and detect misuse and fraud.
<b>4. The financial management system of the Principal Recipient is effective and accurate</b>	The PR has a financial management system composed of a series of tools and processes that permit the control, conservation, allocation and investment of the organization's or program's resources. For management of the Global Fund grants, the PR maintains a SUN System Accounting software that records transactions and balances, making clear reference to the budget and work plan of the grant agreements.
<b>5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products</b>	Given the increasing need for storage based on the planned program scale-up, the PR embarked on a competitive procurement process for a third-party logistics provider (3PL) hence storage and distribution functions will be outsourced during the implementation period. A two-year contract (commencing on 1 <sup>st</sup> Oct, 2014) was signed with Bollore Africa Logistics, who have further partnered with Central Medical Stores Trust (CMST). Two insured central warehouses manage receipt, inventory, and dispatches directly to all health facilities on a bimonthly schedule. Both warehouses have been licensed by the Pharmacy Medicines and Poisons Board (PMPB).
<b>6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions</b>	Distribution function was outsourced to Bollore Africa Logistics collaborating with CMST to ensure that all HIV commodities are distributed to all health facilities on a bimonthly basis. The distribution is insured up to the point of delivery to the health facility.
<b>7. Data-collection capacity and tools are in place to monitor program performance</b>	Standardized M&E tools have been developed and are available at over 700 health facilities. These are used to collect data at all health facilities and are a source of data during the data collation process.
<b>8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately</b>	The Department of HIV/AIDS has a functional integrated M&E system built on quarterly supportive site supervision visits to over 700 health facilities. Site visits are coordinated by the HIV Department and carried out by district and zonal program staff, supported by implementing partners.
<b>9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain</b>	Poisons Board (PMPB) of Malawi is the country's regulatory authority responsible for product registration, site inspection, import control and post-marketing surveillance for health commodities. Given that the PMPB National QC laboratory is neither WHO-prequalified nor ISO-certified, this function will be outsourced to four laboratories that were selected in 2014 through an RFQ procurement process. The PMPB is currently at advanced stages of signing contracts with the selected

		laboratories. This will be reinforced once the MOU with the PR is finalized.	
<b>PR 2 Name</b>	ActionAid	<b>Sector</b>	<b>Non Governmental</b>
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<b>Minimum Standards</b>		<b>CCM assessment</b>	
<b>1. The Principal Recipient demonstrates effective management structures and planning</b>		<p>The PR has a two-tier governance structure: the General Assembly and a National Board. The General Assembly is the highest decision-making organ comprising representatives of communities including the poor and marginalized as well as professionals in law, finance and marketing. The Board of Directors governs and administers affairs of ActionAid Malawi (AAM) through the Country Leadership Team (CLT) comprising head of functions such as programs and policy, fundraising and communication, finance, HROD/Administration and internal audit.</p> <p>The PR will set up a Program Management Unit (PMU) composed of staff dedicated full time to management of the Global Fund grant. These will be assisted by the finance, audit, human resources and program effectiveness units.</p> <p>The PMU will be responsible for program coordination; contract management with sub-recipients and consultants; grant supervision; monitoring and evaluation; budget tracking; communications, program accounting and procurement.</p>	
<b>2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)</b>		<p>The PR manages several SRs both at national and community levels. This is largely dependent on the outcome of SR capacity assessment results. The PR uses different tools to provide SR support and adequate oversight throughout the grant period. The tools include partnership capacity assessment tool (PICA), general conditions of grant agreement, operational manual, program monitoring and evaluation framework and risk management policy.</p>	
<b>3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud</b>		<p>The PR has an Internal Audit department that operates under an internal Audit Procedures and Manual. The department is responsible for internal and SR audits. It is also responsible for initial pre-external audit processes.</p> <p>This function is sufficiently independent of mainstream ActionAid Malawi activities and reports directly to the National Board. There is strict observance of ethics to avoid conflict of interest for effective prevention and detection of misuse or fraud.</p>	
<b>4. The financial management system of the Principal Recipient is effective and accurate</b>		<p>AAM's accounting policies follow the generally accepted standard accounting principles and guidelines in line with the current international standards.</p> <p>There are financial monitoring systems to supervise programs and projects in line with the Financial and Procedures Manual. This manual sets out detailed operational aspects of accounting and internal control systems of the organization. The PR operates a SUN accounts database which links the Head Office and field input</p>	

	system (FIS) in local communities. The system is able to generate periodic performance reports for timely decision-making and performance monitoring.
<b>5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products</b>	
<b>6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions</b>	
<b>7. Data-collection capacity and tools are in place to monitor program performance</b>	The PR has specific tools aligned with indicators in the results framework that are agreed with all stakeholders. The tools, including focus group discussion, are used for data collection. Data collection is done at both district and national levels by district officers and extension workers.
<b>8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately</b>	<p>The PR has a coordinated reporting system that follows a particular schedule. All indicators are entered into an information system that is used for data management, which includes storage, aggregation, collation and retrieval.</p> <p>The PR also employs data quality assurance, control and management to ensure that data are free of inconsistencies and anomalies. This helps to maintain data validity and reliability in alignment with the common data quality frameworks maintained by a number of donors and development partners. The organization has a data quality plan that stipulates the levels, tools and methodologies for conducting data quality assurance, control and management at every level.</p>
<b>9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain</b>	

#### 4.4 Current or Anticipated Risks to Program Delivery and PR(s) Performance

Description of risk	Proposed risk-mitigation measures
Potential issues with the eligibility of the CCM of Malawi	The Malawi CCM has been constituted in compliance with the New Funding Model (NFM) requirements. Grants Management Solution (GMS) has been engaged to help build the capacity of the CCM and improve on its eligibility. A Performance Improvement Plan (PIP) was developed and is being implemented with monthly reporting cycles on achievement of milestones.
Financial performance Issues raised in MoH audit report	<p>The Ministry of Health will establish a Global Fund Implementation Unit which shall ensure that all the transactions are properly authorized by the Team Leader, ensure that all the payments being made are within the budget and according to budget, ensure that request for funding is done in a timely manner, and also ensure that the next cheque is issued upon getting receipts and delivery notes for the previous transactions.</p> <p>The Implementation Unit shall involve an internal auditor to check if every transaction is in order.</p> <p>The Implementation Unit shall see to it that all documents are properly filed by serial number.</p>
High volume of advances and cash based payments	<p>The Implementation Unit shall see to it that officers assigned to disburse cash shall be accompanied by an internal auditor at the beginning phase of the program, and at other times depending on the amount of cash the officer shall be disbursing.</p> <p>The Implementation Unit shall see to it that cash shall be disbursed according to an activity calendar, with a sizable amount of cash.</p> <p>The Implementation Unit shall see to it that the internal auditor has done a pre-audit of all the liquidations before the main audit by external auditors.</p>
Inadequate implementation of policies related to non- health procurement	The Implementation Unit shall contact the procurement unit to make a request to ODPP for a waiver to purchase from suppliers other than Central Medical Stores.
Lack of compliance with Global Fund Audit arrangements	Since a discrete account will be opened for the Global Fund grant, the Implementation Unit shall ensure that the audit is done in time as there shall be only one audit. The delays in audit were due to the fact that there is a swap audit for the entire Ministry, which involves all cost centres requiring long periods of consultations with many stakeholders.
Issues raised by the OIG audit report for MOH	The Global Fund Program Implementation Unit will ensure that strong internal controls are in place to avoid ineligible and unsupported expenses. The Team Leader will work with the Ministry and Finance and Procurement Technical Working Group to ensure implementation of the OIG Audit recommendations.
Budget burn rate of existing grants	Non-disbursements and delays in processing of activity requests were some of the causes of low burn rate of the grants. The Program Implementation Unit will ensure implementation of the Grant Implementation Plan and Financial Management Improvement Plan to ensure timely resolution of the outstanding issues on the grants and ensure timely implementation of activities. Quarterly program work plans will be developed and implemented. Program review meetings will be conducted monthly to track progress on activity implementation and to resolve implementation bottlenecks.

Potential challenges in coordination of PSM services	The PR will lead implementation of all PSM functions including quantification, procurement planning, commodity monitoring and accountability at all levels including providing quality monitoring of outsourced PSM functions. The functions to be outsourced include procurement, storage and distribution. The PR has also established a CMST Reform Monitoring Committee to monitor the implementation of the CMST reform plan. The committee is composed of representatives from the CCM, MOH, USAID, Health Donor group, CHAM, and CMST. The committee's TORs will be reviewed to include monitoring PSM services in the country and ensure appropriate PSM coordination.
Inappropriate procurement process followed by existing PRs for procurement of non-health products and services	The PR will assign a dedicated procurement officer in its Procurement Unit to ensure timely procurement of Global Fund related non-health products. He or she will ensure procurement plan development, follow up with procurement approval processes and report any bottlenecks to the Program Implementation Unit in a timely manner.
Pharmaceutical and Health Product Management  Weak PSM capacity and PSM arrangements at program level  Delay in contracting a WHO prequalified laboratory for Quality Control Services Non-availability of a strong PSM coordination	Two drug management and logistics officers continue to support drug and commodity management at national level.  Procurement of WHO prequalified laboratory is a work in progress and will be concluded by the end of the year. This arrangement will improve QC.
Inaccuracy of TB data reported by PR on some of the indicators	The program M&E section will benefit from the availability of an M&E Technical Assistant provided through I-Tech.
Inadequate performance of MDR-TB case management manifested by high mortality among MDR-TB cases	The NTP is in the process of enforcing adherence to National PMDT guidelines by providers and use of SMS technology to transmit MTB-RIF results.
Delays in uploading drugs and health product deliveries in the price quality reporting (PQR) system	The NTP is working towards improving coordination with the CMST and PMPB to facilitate timely drug and health product quality checks and price quality reporting in the context of identifying a WHO prequalified laboratory.