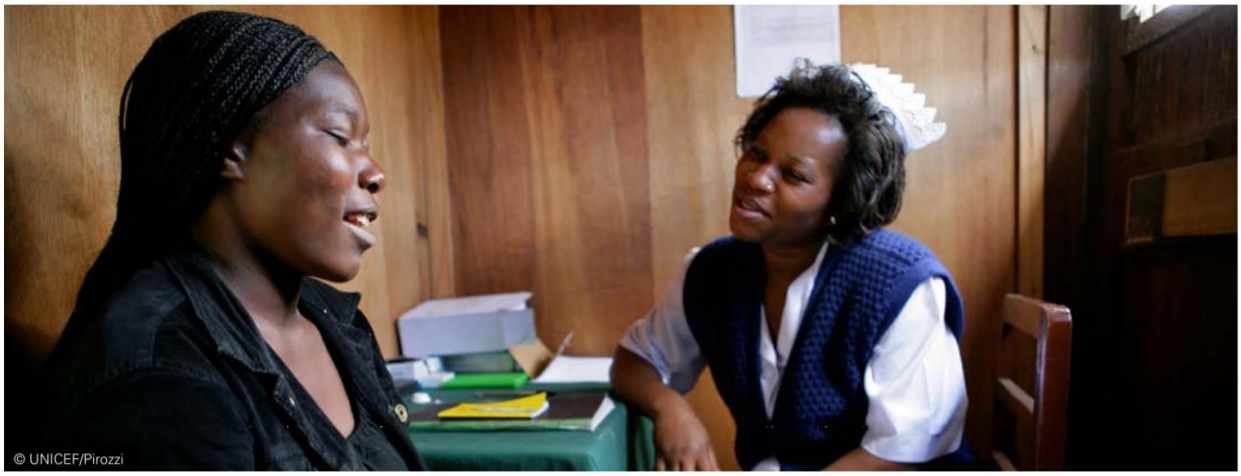
DESK REVIEW STUDY REPORT
FOR

CONSULTANCY TO CARRY OUT A BUDGET ASSESSMENT TO ANALYZE SUFFICIENCY OF TPT FUNDING i.e., INH, 3HP and 3HR



May 2021

Submitted by:
Mr. Kingsley Rex Chikaphupha (MSc)
Individual Consultant, C/O P.O. Box 1597,
Lilongwe, Malawi
Phone: +265 999 958 909
Email: kchikaphupha@gmail.com

Submitted to:
The Internal Procurement Committee
Facilitators of Community Transformation (FACT)
2nd Floor, Creswell House
Area 18 Along M1 Road
P.O. Box 30407, Lilongwe.
Email: admin@factmw.org

Contents

Acronyms

AGYW	Adolescent Girls and Young Women
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ATT	Anti-Tuberculosis treatment
COP	Country Operational Plan
CSO	Civil Society Organisation
DR-TB	Drug-resistant Tuberculosis
DTG	Dolutegravir
FACT	The Facilitators for Community Transformation
GDP	Gross Domestic Product
GoM	Government of Malawi
HBC	High-Burden Countries
HIV	Human Immunodeficiency Virus
HRH	Human Resources for Health
HSSP	Health Sector Strategic Plan
IMF	International Monetary Fund
LTBI	Latent Tuberculosis Infection
MDR-TB	Multidrug-Resistant Tuberculosis
MoH	Ministry of Health
NAF	National HIV and AIDS Action Framework
NCDs	Non-Communicable Diseases
NSP	National Strategic Plan
NTP	National Tuberculosis Control Programme
PE	Personal Emoluments
PEPFAR	President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
PMTCT	Prevention of Mother to Child Transmission of HIV
SEED	Secondary Education Expansion for Development
TAG	Treatment Action Group
TB	Tuberculosis
TPT	Tuberculosis Preventive Therapy
TST	Tuberculin Skin Test
UNHLM	United Nations High Level Meeting
UNICEF	United Nations Childrens Fund
USAID	United States Agency for International Development
VMMC	Voluntary Male Medical Circumcision
WHO	World Health Organisation

Introduction

The Facilitators for Community Transformation (FACT) received funding from TAG to implement a project called: "Strengthening CSO Engagement on TB Preventive Therapy (TPT) Supply Chain Management in Malawi". The project aims to reduce incidences of TB in Malawi by 2021 through increased political will and meaningful engagement of communities on the roll-out of TPT. The project, further, specifically focuses to influence the allocation of sufficient TB funding and implementation of effective TPT Supply Chain policies and processes for effective rollout to ensure 94, 000 people are on TPT by 2021 as stipulated in Malawi's United Nations High Level Meeting (UNHLM) TPT targets[1].

It is envisaged that by the end of the project, access to TPT (INH, 3HP and 3HR) drugs for PLHIV and the general population with TB in Malawi will have increased; and that there will be increased implementation of TB policies and guidelines, national budgetary allocation on TPT, including PEPFAR COP21.

FACT envisions a developed, gender-sensitive, just society that is free from poverty and human suffering through working with a network of over 60 Community Based Organizations on five thematic areas: Health, Agriculture, Women and Girls, Education, and Socio-Economic Development. FACT hosts the National TB CSO Network that was formed through technical assistance awarded by Global Fund Community Rights and Gender Department through the Strategic Initiatives. FACT is also providing organizational support to the Malawi Parliamentary TB Caucus. It is represented on the Global Fund Country Coordinating Committee TB Constituency seat, through its Executive Director, who is also a Coordinating Board member of the Stop TB Partnership.

This report is presented out of an assignment that was aimed to conduct a desk review of the existing evidence regarding the sufficiency of TPT funding i.e., INH, 3HP and 3HR in Malawi. The consultant pooled together available literature/documentation and conducted a budget assessment to analyse the sufficiency of TPT funding with the aim of comparing funding for TPT against the number of people that need TPT. An assessment was also made to ascertain if the funding can support the procurement of TPT drugs for its effective rollout in Malawi.

Objectives of the assignment

The specific objective of the consultancy was to:

- Understand if the funding towards TPT is effective in improving the capacity levels, programming and community practices leading to comprehensive TPT services scale-up in Malawi.
- Use the prevailing WHO estimates and guidelines to understand the relevance, effectiveness, and sustainability of comprehensive TPT services in the country.

[1] http://www.stoptb.org/assets/documents/global/advocacy/unhlm/UNHLM%20on%20TB%20-%20Preventive%20Therapy%20Targets.pdf Malawi's UNHLM Targets document

Methodology

Data collection methods

This was a desk review study. The study used google search engine to collect documents. Terms such as; "TPT studies in Africa", "TPT guidelines for Malawi", "WHO guidance on TPT", "Malawi national budget", "CSO advocacy around TPT", "National TB control programme in Malawi" "National Health Accounts" "Malawi introduces 3HP" and many others were used. Through the search process, websites such as the; https://www.auruminstitute.org, https://www.isglobal.org/en/-/whip3tb, http://www.croiwebcasts.org, and many others were also explored and very insightful data were collected from those websites. Available reports, PowerPoint presentations, articles were all collected and analysed to come up with this report. Generation of evidence from Malawi and across the globe was critical in this assignment to inform how CSO advocacy around the mode of delivery of 3HP interventions, feasibility and cost-effectiveness can be carried out.

This study was summative and dwelt much on understanding health financing mechanisms in the Malawian health sector by among other things; conducting a budget analysis especially funding to the health sector as a whole extracted from the national budget documents, including zeroing down to the specific budget by the national TB control programme. Then a cost-effective analysis followed to help generate evidence that will help FACT build a case for policy advocacy for sustained and/or increased funding towards TPT in Malawi. Documentation of the successes and challenges of funding TPT in the country was done by comparing what was planned and what was achieved in as far as TPT funding is concerned in Malawi. Documents such as WHO guidelines, project reports, journal articles, key TB websites' updates were reviewed to allow for triangulation of the findings thereby helping to explain the trends towards TPT programming in both monetary and qualitative terms.

Findings from the desk review

Background

Tuberculosis (TB) is currently the leading cause of death from a single infectious disease agent worldwide. The World Health Organization (WHO) End Tuberculosis strategy aims to substantially reduce tuberculosis incidence by 90% and mortality by 95% compared with the 2015 baselines of 142 cases per 100 000 population and 5.3 to 19 cases per 100 000 (depending on human immunodeficiency virus (HIV) status), respectively (WHO, 2017; Uplekar et al, 2015). Achieving this goal requires successful management of latent tuberculosis infection, which serves as a reservoir for new tuberculosis cases (Getahun et al, 2015). In high-income countries which already have a low incidence of tuberculosis, management of latent infection can contribute to the elimination of the disease (WHO, 2014). A review of treatment regimens found that treatment of latent tuberculosis can reduce the risk of disease reactivation by 60% to 90% (Lobue & Menzies, 2010). A recent randomized controlled trial in a high tuberculosis burden country showed that the benefits of preventive treatment/management of latent TB in people living with HIV can last for more than 5 years (Badje et al, 2017; Danel et al, 2017). The WHO recommends tailored latent tuberculosis infection management based on tuberculosis burden and resource availability (Getahun et al, 2016).

Despite some progress, particularly over the last decade, the scale-up of tuberculosis preventive treatment remains suboptimal globally. The 161 740 children started on tuberculosis preventive treatment in 2016 represented only 13% of the 1.3 million children estimated to be eligible for treatment (WHO, 2017). The total number of people living with HIV who were started on tuberculosis preventive treatment in 2016 was at least 1.3 million (WHO, 2017). Data for other risk groups are not available or very limited. Barriers to the scale-up of tuberculosis preventive treatment include the absence of national policies and a lack of monitoring and evaluation systems (Hamada et al., 2016).

Tuberculosis, a disease already known since ancient times, remains the number one killer among infectious diseases, affecting men, women and children, while drug-resistant TB (DR-TB) poses the greatest global threat in antimicrobial resistance for the 21st century. Although TB is a curable disease from an individual biomedical perspective, HIV, poverty and social exclusion still drive the TB epidemic. Lack of simple tools for prevention, diagnosis and treatment at the first level of care make management of TB a complex public health intervention. Front-line health workers and TB programs lack both the tools and resources that would allow them to effectively combat the disease

In March 2018, the World Health Organization (WHO) published updated and consolidated guidelines for programmatic management of latent tuberculosis (TB) infection (LTBI)[2]. These guidelines recommend expansion of TB preventive treatment services beyond the target populations of people living with HIV (PLHIV) and child household contacts of TB patients, to all household contacts in high TB burden countries. They also recommend shorter preventive treatment regimens and testing options for LTBI. These recommendations complement the Political Declaration from the first-ever UNHLM on TB on 26 September 2018, where Member States committed to providing TB preventive treatment to at least 30 million individuals by 2022. However, in 2017, fewer than one million PLHIV (36%) and about 250 000 household contacts of TB patients (23%) received TB preventive treatment in reporting countries. The UN High-Level Meeting ON TB Political Declaration states:

> *"Commit to prevent TB for those most at risk of falling ill through the rapid scale-up of access to testing for TB infection, according to the domestic situation, and provision of preventive treatment, with a focus on high-burden countries so that at least 30 million people, including 4 million children under five years of age, 20 million other household contacts of people affected by TB, and 6 million people living with HIV and AIDS, receive preventive treatment by 2022, with the vision to reach millions more…"*

To this end, in 2020, the World Health Organization (WHO) issued updated guidelines on TB preventive treatment (module 1 of 2020 WHO consolidated guidelines on TB), which include updated recommendations for HBCs (WHO, 2020). The guidelines comprise recommendations for targeted testing and treatment of people living with HIV (PLHIV), adults and children under 5 years of age who are household contacts of pulmonary TB cases, and HIV-negative risk groups such as patients with silicosis,

[2] *See https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en*

those on dialysis, or those receiving organ or hematological transplants (WHO, 2020). Importantly, as these groups are at increased risk of progression to active TB disease, the updated guidelines recommend targeting these groups for LTBI screening and treatment in all settings, independent of TB prevalence (WHO, 2020). Moreover, the 2020 guidelines state that systematic LTBI testing and treatment can also be considered in other risk groups, such as healthcare workers, prisoners, or the homeless, regardless of TB burden (as opposed to primarily in low-burden settings as indicated in the 2018 LTBI management guidelines) (WHO, 2020). Given the limitations of current evidence regarding optimal LTBI management, national policies regarding testing and treatment remain varied and inconsistently implemented. In particular, a review of 98 countries (including both high and low burden countries) found that algorithms for LTBI testing were inconsistently implemented, as were procedures for excluding active TB before initiating preventive treatment (Jagger et al, 2018). While active TB continues to be a high priority for high-burden countries (HBCs), these countries are starting to roll out TB preventive therapy.

However, there are a myriad of challenges associated with both diagnosing and treating LTBI (Pai et al, 2016; Pai et al, 2014), particularly in the HBC context, including the logistical barriers associated with requiring patients to return for Tuberculin Skin Test (TST) results to be read (Ginderdeuren et al, 2019), and widespread Bacille Calmette-Guérin (BCG) vaccination in HBC countries leading to high numbers of false-positive TST results (Zwerling et al, 2011). Further challenges include a lack of new funding for LTBI programs, infrastructure requirements WHO, 2020). Shortages of products such as purified protein derivative (PPD) (Tebruegge et al, 2016), the unavailability of newer LTBI drugs (e.g., Rifapentine) in some countries (Pai M, 2018; CSOs, 2019), and the unavailability of child-friendly LTBI treatment formulations (Kebede et al, 2018). In light of the abovementioned persisting challenges for LTBI screening and treatment in HBCs, it is of interest for Malawi as a country to investigate the extent to which it is currently planning or able to implement the WHO's updated guidelines on LTBI management, and which barriers are being faced or envisaged to be faced once the guidelines start being implemented.

Health financing in Malawi

The Malawian health sector relies heavily on funding from external sources. The National HIV program is almost entirely funded through international donors (95%). Based on 2019 preliminary HIV expenditure data, PEPFAR contributed 49% of total available HIV resources, the Global Fund contributed 45% while other external and domestic resources contributed 6% and 0.1% respectively. Between 2018 and 2019, multilateral donor contributions to the HIV response dropped from $9 million to approximately $1.9 million. Public funds also decreased during the 2015-2018 period, from 25% of total health expenditure to 23.9%. Additionally, the country's contribution to the Abuja Declaration fell short of the 15% promised. While Malawi has limited fiscal space, the Government of Malawi (GoM) is commended for investments in health systems strengthening including Human Resources for Health (HRH), health infrastructure, essential medicines, and prevention efforts. The Global Fund finances the procurement of health products, paying for 99% of all HIV-related commodities. Since 2004, PEPFAR has invested over $1 billion in HIV service provision to efficiently identify PLHIV, ensuring all newly diagnosed PLHIV are immediately linked to treatment, retained on treatment, and are virally suppressed. In partnership with the GoM, PEPFAR and USAID Education are currently implementing the Secondary Education Expansion for Development (SEED) project, a $90 million initiative to build up to 200 new secondary schools where

educational access has been limited. In COP20, PEPFAR Malawi will invest over $195 million, continuing its support to the HIV program implementation and maintaining epidemic control.

The trend in Total Health Expenditure for the past 2015-2018 financial years shows that, in nominal terms, total health expenditure increased from MWK 429.1 billion in 2015/16 to MWK 502.8 billion in 2017/18 (MoH, 2020). In real terms[3], however, total health expenditure fell during the three-year period, from MWK 171.2 billion in 2015/16 to MWK 147.8 billion in 2017/18. Nominal average per capita total health expenditure for the period was USD 39.8, which was slightly higher than the USD 39.2 that was recorded for the preceding three-year period (2012/13–2014/15) *Ibid*. Realized per capita total health expenditure for Malawi (USD 39.8) was comparable to per capita total health expenditure in low-income countries, which was USD 41 per year (WHO, 2019).

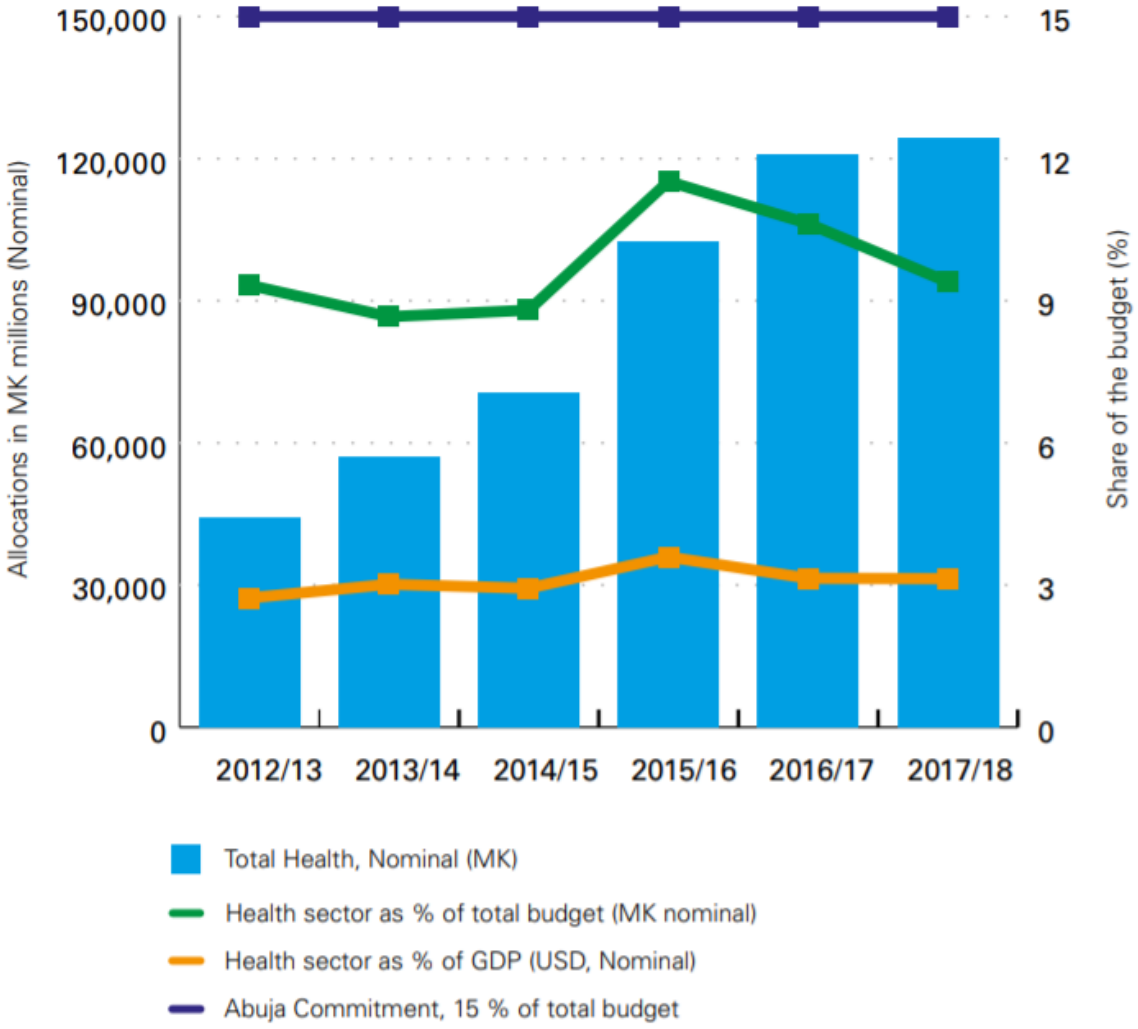
The health sector received the fourth-highest share of the 2017/18 total budget (9%) after education, agriculture and debt repayment. In total, the sector was allocated MK124 billion up from MK120 billion in the financial year 2016/17. This amounts to a 2.84% increase in nominal terms and a 13% decline in real terms. The education sector received 18% of the total budget followed by Agriculture at 15.5% and debt repayment at 15%. Compared to 2016/17, the total health sector budget increased at a lower rate (2.84%) in nominal terms than the general government budget which went up by 16.34%.

In Malawi, health sector budgets are far below what is required to implement all approved health sector policies and strategies. For example, the 2017/18 total health sector allocation (US$170 million) was almost 3 times less than the projected cost estimates in the Health Sector Strategic Plan (HSSP II). The five-year cost of the HSSP Il was estimated to be US$2.6 billion and costs were forecasted to increase from US$504 million in the financial year 2017/18 to US$540 million in 2021/22. The total cost per capita each year was expected to remain constant at about US$30. In the financial year 2017/18, the government allocated US$9 per person to the health sector. The total cost of providing high-quality community health services to all people in Malawi from 2017-2022 was estimated at US$407 million, or US$81 million each year and about US$3.9 in recurrent costs per Malawian each year by year five (MoH, 2017). Currently, per capita recurrent costs to District Councils average MK800, which is slightly over US$1.

The total budget allocation to the health sector is nearly six percentage points below the Abuja commitment. Malawi, being one of the African Union member states, committed itself to allocate at least 15% of its total government budget to the health sector. Unfortunately, since 2012/13, the government has, on average, allocated 9% of its annual budget to health. The 2017/18 health budget was approximately 3% of the Gross Domestic Product (GDP) of Malawi. This figure has remained relatively constant since 2012/13 as depicted in Figure 1 below:

[3] *2010 Consumer Price Index was set at 100 (World Bank, 2019). This implies that all nominal total health expenditures were adjusted for inflation with 2010 as a base year*

Figure 1: Health Sector Spending Trends



Source: UNICEF Calculations based on Estimates in the 2017/18 budget

Malawi spends a higher proportion of its GDP on health than many countries in sub-Saharan Africa. Data from the World Bank shows that in 2014, for example, Malawi spent an equivalent of 6% of its GDP on health when the sub-Saharan average was 3.9%. Malawi's neighbours – Mozambique and Tanzania spent 2.3% and 2.6%, respectively. Although Malawi dedicates a relatively higher percentage of its GDP on health, its total per-capita health expenditure is one of the lowest in the sub-Saharan region. In 2014, Malawi spent US$93 per person when the sub-Saharan average was US$201, with Zambia spending US$195. The per capita spending reflects the low GDP of the country. Malawi is a relatively small economy, mainly dependent on agriculture.

Further analysis of elements that comprise the health sector budget, UNICEF, found that the Ministry of Health (MoH), is the main beneficiary of the health sector budget. The ministry was allocated MK74 billion, which is almost 60% of the 2017/18 health sector budget. District Councils got the second-largest share

(40%), of which 25% was for personal emoluments (PE). Kachere Rehabilitation Centre and the Health Services Regulatory Authority[4], the only two subvented organizations under the health sector, got less than 1% of the health budget. Altogether, these two organizations received MK647 million which is approximately 0.52% of the total health sector budget. The allocation to the MoH declined from MK101 billion to MK74 billion because salaries and wages for district-level staff will now be transferred directly to District Councils. Nearly half of the MK74 billion allocated to the Ministry is for supporting service delivery, with approximately 35% going to management and administration. Approximately 63% of the health sector budget allocated to District Councils (MK31 billion) was for Personal Emoluments. The combined ORT budget to District Councils was composed of MK10.2 billion for drugs (presented as primary health care under the National Local Government Finance Committee) and MK7.9 billion for other medical supplies and services. The combined ORT budget (MK18.1 billion) was slightly lower than the MK18.9 billion allocated in 2016/17 by 2.4% in nominal terms and 17% in real terms. In nominal terms, the primary health care budget to District Councils barely changed since 2014/15 despite high inflation between 2014 and 2017.

From the analysis above, the realized nominal per capita total health expenditure fell short of the World Health Organization's recommended threshold of USD 86 per capita per year for the implementation of a minimum set of cost-effective interventions in low-income countries (WHO, 2015). The amount was also far lower than the 2016 Southern Africa Development Cooperation average of USD 200.8 per capita. Due to this gap, Malawi may not be able to provide all key essential services to its people. In addition, countries in the Southern Africa Development Cooperation region that have lower maternal mortality rates tend to have relatively high per capita spending, which implies that Malawi, with its higher maternal mortality rate, will likely struggle to bring down the maternal mortality rate without increasing per capita spending (MoH, 2020).

Private health expenditure, which consists of household out-of-pocket expenditure, medical insurance, and other corporate funds, rose from an average of 13.4% of total health expenditure between 2012/13 and 2014/15 to 17.5% of total health expenditure by 2018 (MoH, 2020). The major source of increases in private expenditure was the rise in household out-of-pocket expenditures on health, from an average of 8.6% of total health expenditure between 2012/13 and 2014/15 to 12.6% by 2018. This suggests that the sustainability of healthcare financing in Malawi is relatively weak as it relies on a high percentage of funds from external sources and high out-of-pocket expenditure. Increases in out-of-pocket expenditure are of significant concern as this implies a lack of risk pooling across the population, as well as a lack of financial risk protection for patients. Over-reliance on donors is equally concerning, because there is hardly any information on whether off-budget health expenditures by partners/donors are equitable. This is partly because most development partners, including NGOs, have not been submitting health expenditure information to the Aid Management Platform. Reports from partners, however, seem to suggest that off-

[4] *The Health Services Regulatory Authority has budgetary independence from the MoH to reinforce its policy independence. Kachere mainly provides rehabilitatory health services to people with disabilities*

budget resources are mostly earmarked and sometimes not equitably distributed, as some Districts receive more donor support than others.

There are also parallel health financing mechanisms in Malawi, which are not effectively coordinated, thereby generating some inefficiencies. It is, therefore, important that the government should institute and enforce good financial management systems to ensure Malawians especially the poor in rural areas are not subjected to catastrophic lifestyles as a result of accessing health care. Evidence shows that Malawians are spending more on health care due to the unavailability of essential medicines or commodities in public facilities, which forces individuals to buy medicines themselves and/or seek care elsewhere where they pay out-of-pocket (MoH, 2020). The situation is not in line with the World Health Organization's health financing policy recommendations for universal health coverage, which recommends that countries move toward predominantly prepaid funds to provide financial protection to the poor.

Furthermore, the pattern of health spending per function shows that curative and rehabilitative care and preventive care have the highest spending as a percentage of total health expenditure. Significant resources are also spent on governance and administration, averaging 26.2% of total health expenditure between 2015-2018. A higher share of curative care spending implies potential inefficient spending as preventive interventions are typically more cost-effective (WHO, 2014). It is therefore important to re-orient healthcare service spending toward preventive and/or primary healthcare functions to gain efficiencies. The relatively high share of spending on governance and administration is largely due to the pooling fragmentation of non-state actors. Stronger public financial management should provide more confidence in government systems and—ideally—increase the adoption of these systems by donors.

The policy and programmatic response in Malawi

Malawi remains one of the countries with the highest HIV burden in Southern Africa: prevalence among adults 15 years and above is 9.3% and over one million people are living with HIV (PLHIV). Disaggregated by sex, prevalence is 10.8% for women and 7.7% for men (MoH/UNAIDS,2019). However, Malawi has made great strides towards epidemic control through a well-coordinated multi-sectoral response, including the adoption of several policies such as the rapid scale-up of ART through the universal test and treat in 2016, continued to scale up of Option B+ for prevention of mother to child transmission of HIV (PMTCT), introduction of HIV self-testing in 2018, the transition to Dolutegravir-based regimens in 2019 and strengthened efforts to increase voluntary male medical circumcision (VMMC). Malawi has also implemented primary prevention and structural interventions for adolescent girls and young women (AGYW) and key populations in selected districts. As of December 2019, over 850,000 people were on ART. These efforts have contributed to a dramatic decline in the number of new infections from 111,000 in 1992 to 33,000 in 2019 and AIDS deaths from 71,000 in 2004 to 13,000 in 2019 (MoH/UNAIDS, 2019). This new NSP focuses on sustaining these tremendous gains and accelerating progress through adoption of the latest evidence-based interventions (MoH/UNAIDS, 2019).

The strategy is aligned to various global frameworks including, but not limited to, the Sustainable Development Goals, the UNAIDS Fast Track Strategy, and the 2017 Global HIV Prevention Road Map. The

strategy is also linked to local frameworks including, but not limited to, the Constitution of the Republic of Malawi, the HIV and AIDS (Prevention and Management) Act, the Malawi Growth & Development Strategy 2017-2022, the National Health Policy, the Health Sector Strategic Plan 2017-2022, and the National Gender Policy 2012-2017. In addition to these policies, Malawi has also a number of other health sector policies and plans including: Health Sector Strategic Plan (HSSP II), (2017-2022) Essential Health Package, (2017-2022), Every Newborn Action Plan, (2016-2020), Sexual and Reproductive Health Policy, (2017-2022), Health Sector Quality Management Policy, (2017-2022), National Health Information Policy, (2015-2020), Child Health Strategy, (2015-2020) Community Health Strategy, (2017-2022), Health Sector Quality Management Strategy, (2017-2022) Country Multiyear Plan-EPI, (2017-2021). Evidence shows that in spite of the existence of all these frameworks and plans, implementation of the policies continues to face inadequate financing which hinders their full success.

The NSP prioritises game-changing strategies including the inclusion of 3HP that will make a key contribution to Malawi's health and development goals, with an impact beyond SDG Target 3.3 to end the AIDS epidemic by 2030. Malawi developed the first comprehensive National HIV and AIDS Strategic Framework for the period 2000-2004. Malawi followed this with the National HIV and AIDS Action Framework (NAF) 2005-2009, the Extended NAF 2010-2012, the NSP 2012-2016, and then the NSP 2015-2020. Malawi has used these strategic plans to guide the national response to the HIV and AIDS epidemic and mobilize resources for the effective implementation of interventions. In pursuit of a healthy and prosperous nation free from HIV and AIDS, this new NSP provides the rationale and direction for key interventions that stakeholders and funding agencies should prioritize.

The Malawi National Strategic Plan (NSP) for HIV and AIDS 2020–2025 is the guiding document for the multi-sectoral response to the HIV epidemic for the next five years. It succeeds the 2015-2020 HIV NSP, building on previous achievements and addressing areas that need improvement with the goal of meeting 95:95:95 targets and eliminating HIV as a public health threat by 2030. Implementation of the previous NSP contributed to the dramatic decline in the number of new infections from 111,000 in 1992 to 33,000 in 2019 and the decline in AIDS deaths from 71,000 in 2004 to 13,000 in 2019.1 As of September 2019, progress on the 90:90:90 UNAIDS Fast-Track targets was 93:84:92. The vision of the new strategy is "A health and prosperous nation free from HIV and AIDS."

HIV Infections In Malawi

The latest epidemiological model estimates show that the number of new infections increased exponentially from 1980 and reached a maximum of around 111,000 in 1992.19 From 1994, new infections started to decline by approximately 3,000 each year reaching approximately 33,000 in 2019. The incidence decline started several years before prevention interventions reached any meaningful scale and before the introduction of free ART. This decline was likely driven by the saturation of high-risk networks and changes in sexual behaviour that is not well documented. Epidemiological models predict a continued, although slowing decline through 2025 and beyond. The projected decline shown in Figure 1 implies that Malawi may miss the UNAIDS target of a 75% reduction in new infections between 2010 and 2020 – the latest estimates show a 45% reduction of new infections from 56,000 in 2010 to 33,000 in

2019. An extrapolation of the current trend predicts around 17,000 new infections in 2030, which is equivalent to a 70% decline from the 2010 baseline. This suggests that the 90% UNAIDS target for the reduction of new infections might only be reached with a significant scale-up of ART and other effective prevention interventions.

Since the start of the epidemic in the 1980s, an estimated 1.2 million Malawians have died of AIDS shows the number of annual AIDS deaths among men, women, and children between 2007 and 2017. The AIDS death wave peaked at 71,000 in 2004 and started to decline rapidly with the introduction of free ART later that year. Malawi's rapid and successful scale-up of ART between 2004 and 2019 averted an estimated 500,000 AIDS deaths and gained 4.1 million life-years, primarily among young adults in their peak productive life period. As shown below, the Institute for Health Metrics and Evaluation estimated that AIDS mortality decreased by 72% between 2007 and 2017 but remained the leading cause of death in Malawi in 2017.

Malawi's population is projected to increase by 2.7 million in this NSP period, from 19 million in 2020 to 21.7 million in 2025 (MoH, 2019). Due to this rapid population growth, HIV incidence and prevalence have declined much more rapidly than the absolute number of new infections and PLHIV. The growing (HIV-negative) population potentially at risk of HIV infection from PLHIV not on ART will pose a considerable challenge for primary prevention interventions as the declining number of new infections will be "hidden" in a large and growing HIV negative population.

The latest epidemiological models estimate that the annual number of deaths among PLHIV will increase and reach over 20,000 in 2025. Over 95% of these deaths will be among patients in care. This is due to the aging of the ART patient cohort, bringing about long-term treatment complications: delayed diagnosis of treatment failure from adherence problems and emerging drug-resistance leading to deaths from opportunistic infections such as TB, cryptococcal meningitis, bacterial sepsis, and malignancies such as cervical cancer. A significant mortality burden is exacted by undiagnosed and poorly managed noncommunicable diseases (NCDs) such as hypertension, dyslipidemia and diabetes. In order to curb this second wave of deaths in the next 5 years and beyond, it will be critical for Malawi to ensure the availability of basic medical commodities and services and increase staffing numbers, clinical expertise, and diagnostic capacity.

The status of TB/PLWHIV in Malawi

PEPFAR is a dominant source of funding for HIV programs and health systems strengthening in many countries, seconded by the Global Fund. As TB is the leading global killer of people living with HIV, TB programming must be prioritized and integrated within life-saving bilateral efforts such as PEPFAR. It is critical that PEPFAR funding is put to the best possible use, in accordance with community needs. The COP process that PEPFAR conducts provides a critical opportunity for activists to ensure that the latest developments in TB treatment, prevention and diagnostics are implemented within PEPFAR countries. Malawi is one biggest PEPFAR funding recipient.

A quarter of the world's population is infected with latent TB – they have no symptoms, are not contagious and most do not know they are infected. Without treatment, 5% to 10% of these people – 85 million to 170 million people globally – will develop active TB, the form which makes people sick and can be transmitted from person to person. HIV infection makes people up to 37 times more likely to fall ill with the active TB disease. Close to 1.5 million people die of TB every year.

Previously, preventive TB therapy took 6 to 36 months and uptake was low. A Rifapentine-based regimen shortens treatment to 12 weekly doses in combination with another medicine, Isoniazid. The World Health Organization (WHO) recommends the use of this regimen for the treatment of latent TB infection in people living with HIV and contacts of TB cases of any age. Research shows that patients are far more likely to complete shorter treatment courses. The "IPT only" era is over!!!! Short course TPT regimens include: 3HP= 12 once-weekly doses of Rifapentine (P) + Isoniazid (H) 3HR = three months of daily Rifampicin (R) + Isoniazid (H) 4R = four months of daily rifampicin (R) IPT — given daily for 6 months (6H), 9 months (9H), or up to 36 months (continuous IPT), or as a fixed-dose combination with cotrimoxazole and vitamin B6 in a product called Q-TIB.

TB-HIV Co-Infection

Tuberculosis (TB) is the most common co-infection in PLHIV and the most common cause of HIV-related death. Forty eight percent (48%) of TB cases in Malawi are also HIV-positive; hence, systematic symptom screening for TB is a cornerstone of the HIV care package. The NSP 2015-2020 set a target that 83% of the HIV+ TB patients should be on ART and that 85% of the TB patients should have their HIV status ascertained. By December 2018, Malawi achieved both indicators at 93% and 97%, respectively. In 2019, 99% of new TB patients had their HIV status ascertained. Ninety five percent (95%) of those found HIV-positive were already on ART at the time of TB initiation. The proportion of new ART initiations during TB treatment is 7%. Total ART coverage among co-infected patients at the end of TB treatment has consistently been more than 99%. Almost all (99%) patients on ART were screened for TB during their last visit, and 2% classified as presumptive TB cases. While 2020 targets for TB-HIV co-infection have been achieved, challenges remain including delayed diagnosis of TB, delays in providing results due to high workloads in microscopic laboratories and absence of microscopy, GeneXpert platforms and Urine LAM in most facilities and the limited skills among service providers in screening for TB.

TB remains a major public health problem in Malawi. Malawi has an estimated TB burden of 27,000 cases (WHO, 2020). In 2019, of these cases, 16,902 (63 percent) were notified to the national TB control programme (NTP) and enrolled on treatment (WHO, 2020). In 2019, 40 percent of the notified cases came from two urban districts: Lilongwe (24 percent) located in the central region and Blantyre (16 percent) located in the southern region of the country (MoH, 2019). Additionally, drug-resistant TB (DR-TB) is an emerging issue in Malawi, with an estimated 750 incident cases of rifampicin-resistant TB (RR-TB) and multidrug-resistant TB (MDR-TB); however, only 104 DR-TB cases were reported in 2019; it is estimated that 2.3 percent of new and 6.1 percent of previously treated cases are drug-resistant (WHO, 2020). In the National Strategic Plan (NSP) for TB 2021-2025, the NTP set the ambitious goals to reduce TB incidence by 50 percent, TB mortality by 75 percent, and catastrophic costs due to TB to less than 20 percent of the annual income by 2024 (MoH, 2021).

In 2019, MoHP embraced TB prevention therapy (TPT) using Isoniazid-Rifapentine (3HP). The 2020-2025 NSP will increase adherence support and toxicity monitoring of TPT in these groups. The priorities for the TB/HIV program are to strengthen TB/HIV collaboration at all levels. The TB/HIV operational framework will be used to guide this collaborative work. Priorities include increasing case finding and diagnosis for TB and HIV among PLHIV or persons with TB; improving the coverage of high-quality treatment to all HIV/TB co-infected people and scaling up TPT to all people starting ART.

3HP Evidence and the need to respond

The progression from latent TB infection (LTBI) to active TB disease among the 1.7 billion population infected with TB (Houben & Dodd, 2016), continues to add to the existing number of TB patients every year. Several scientific studies suggest that a major driving force behind both occurrence and recurrence of TB may be the reactivation of LTBI. A systematic review of 11 studies of South-East Asia revealed that 24.4% to 69.2% of children under 15 years of age who were exposed to TB in their households were infected with TB and 3.3% to 5.5% had developed active TB (Triasih et al, 2012). A hospital-based Persons with latent TB infection (LTBI) have in his/her body TB bacteria that are alive but not causing disease. Do not feel unwell and do not have symptoms. Usually have a positive skin test or blood test result indicating TB infection but may have a normal chest X-ray and a negative sputum test and negative Xpert MTB/RIF® test. Without treatment, 5–10% of infected persons will develop TB disease at some time in their lives.

About half of those people who develop TB will do so within the first two years of infection. For persons whose immune systems are weak, especially those with HIV infection, malnutrition, on anti-cancer therapy, or on dialysis, the risk of developing active TB disease is considerably higher than that for persons with normal immune systems. The risk of progression to active TB in people living with HIV (PLHIV), and household contacts of infective patients with TB can be reduced by providing them with TB preventive treatment (TPT). South-East Asia Regional Action Plan on the Programmatic Management of Latent Tuberculosis Infection study in a major chest hospital of China showed that 64% of recurrent TB cases were due to reactivation of latent infection (Zong et al, 2018). A similar study in Spain showed that only 50% of the recurrent cases were due to reinfection whereas the remaining were due to reactivation (Millet et al, 2013). The host factors increase an individual's risk of progression to active pulmonary disease after LTBI. Host-related determinants of risk for disease include HIV infection, diabetes, smoking, excess alcohol use and malnutrition.

A Unitaid-funded study that was carried out in South Africa by Unitaid grantee Aurum Institute and the Johns Hopkins University Center for TB Research as part of the IMPAACT4TB project found that 3HP, a new, shorter preventive therapy for tuberculosis, is safe for people who also take the HIV drug dolutegravir. The study also found that people who take 3HP do not require a higher dose of dolutegravir (DTG), and that all viral loads were suppressed while the patients were taking 3HP. The study also, found that weekly administration of Rifapentine and Isoniazid (3HP) for three months in adults with HIV taking DTG was well-tolerated, with no need for dose adjustment. The findings put to rest fears of potential drug interactions with DTG and paved the way for scale-up of the 3HP regimen in 12 high-burden TB countries

across three continents. The 12 high-burden countries include: Brazil, Ghana, Ethiopia, Kenya, Tanzania, Malawi, Zimbabwe, Mozambique, South Africa, India, Cambodia and Indonesia. Together, these countries represent 50 percent of the global TB burden. The project will prioritize 3HP for people living with HIV and children under five, and subsequently all those in close contact with TB patients.

3HP is a 12 once-weekly dose of Rifapentine (P) + Isoniazid (H) 900 mg P | 900 mg H. It comes with a shorter duration than IPT; it has less liver toxicity than IPT; Higher completion rates than IPT; Similar efficacy as IPT in preventing TB. 3HP can be used to prevent TB in: HIV-negative adults; Adults with HIV who are taking ARVs with acceptable drug-drug interactions; Children and adolescents age 2–17; 3HP has not yet been studied in children under age 2—that trial should start soon. 3HP is not yet recommended for use in pregnant women, because of insufficient data (but research is underway). 3HP has not yet been studied in people taking OST (e.g., Methadone).

The results marked a critical milestone for countries and funding partners seeking to expand preventive TB therapy[5]. The evidence that 3HP was safe to use with dolutegravir was critical because, in today's most advanced HIV treatment, the scale-up of short-course preventive therapy for TB is paramount. TB kills some 340,000 people living with HIV every year and accounts for about a third of HIV-related deaths. TB preventive therapy protects people already infected with TB bacteria from falling ill with the active disease and shields those at risk of exposure. A third of the world's population is infected with latent TB, and HIV infection makes them much more likely to develop active TB.

Despite the successful clinical trials on new 3HP therapy's (a Rifapentine-based regimen known as 3HP, requires only once-weekly treatment for 12 weeks, compared to the 6-to-36-month daily regimen required under the older standard of care, Isoniazid preventive therapy) safety and efficacy, countries were still unsure of its adoption due to high costs associated with the drugs. Another great news to quell these fears was announced by Unitaid in 2018 again, that a landmark agreement was reached between the Global Fund to Fight AIDS, Tuberculosis and Malaria and global biopharmaceutical company Sanofi (the sole manufacturer of Rifapentine) that Sanofi would significantly lower the price of Rifapentine, a critically important drug used to prevent tuberculosis (TB). The deal aimed to bolster efforts to treat latent TB infection – currently estimated to affect 1.7 billion people worldwide – by broadening access to better preventive therapy.

The volume-based agreement entailed a discount to the price of a three-month treatment course of Rifapentine by nearly 70%, from approximately US$45 to US$15 in the public sectors of 100 low- and middle-income countries burdened by TB and TB/HIV coinfection. The agreement's expectation was that political commitment to adopt the WHO guidelines on 3HP would be transformed into tangible action. It also envisaged that such an approach would be a sustainable commercial approach that will widen access

[5] See *https://www.auruminstitute.org/component/content/article/28-blog/aurum-news/364-generating-evidence?Itemid=101*

to the new standard of care for latent tuberculosis infection. Through this Global Health initiative, the agreement would also allow the main development partners supporting TB prevention, such as the Global Fund, PEPFAR, USAID and the Stop TB Partnership's Global Drug Facility, to make 3HP much more widely available through their programs with governments in low- and middle-income countries. South Africa, one of the countries with a high burden of TB, pioneered the scale-up of Rifapentine-based TB preventive therapy in 2020 with a mix of domestic financing and support from the Global Fund and PEPFAR. This price discount will enable that scale-up, saving thousands of lives, and realize millions of dollars in savings.

In 2019, in its COP19, PEPFAR renewed focus on TB preventive treatment; TPT for all PLHIV (including pregnant women and children) ensuring that these were scaled- up as an integral and routine part of the HIV clinical care package. PEPFAR argued that "the evidence base for TPT is clear." Stressing that the use of shorter Rifapentine-based regimens (e.g., 3HP) was associated with lower risk for adverse events and higher completion [than IPT]; it should be the preferred regimen for PEPFAR-supported patients for whom appropriate dosage is available. PEPFAR expected that countries would fully scale up TB preventive therapy within adolescents over the next two years, by which time they should have provided TPT to all eligible patients and should be routinely providing it to newly enrolling patients who do not have TB symptoms (or as secondary prevention after TB treatment).

PEPFAR advocates countries should follow the WHO guidance and create ambitious TPT scale-up plans and that there should be well-defined budgets for TPT commodities, including Rifapentine. This followed findings that showed that when talking of TPT, countries were still focused on IPT or INH/Cotrimoxazole and not 3HP. PEPFAR wants all countries to switch to 3HP. No country should only be using IPT, rather countries need to introduce shorter, safer TPT regimens based on Rifapentine. These shorter, safer Rifapentine-based TPT regimens should be offered to adults, young people, and children >2. PEPFAR programs should budget for contact investigations—if someone is diagnosed with TB, offering TPT to their household contacts once active TB is ruled out.

Discussion

Accelerating efforts to End TB by 2030 is a Regional Flagship Priority. To make a real dent in the TB epidemic, preventive treatment must become a key priority, in addition to accelerating TB case-finding and treatment. To align with the xvi South-East Asia Regional Action Plan on the Programmatic Management of Latent Tuberculosis Infection global commitments made at the UNHLM on TB in September 2018 by the Member States, Malawi needs to reach and treat at least 374,334 people with LTBI by 2022. This will require urgent and rapid scaling up of access to TB preventive treatment (TPT). Treating this pool of people living with recently acquired TB infection will help to reduce the incidence of TB tremendously leading to ending TB targets in the nearest future possible.

As the global community gears up to meet the ambitious targets for reduction (90% reduction in TB incidence by 2035) and even elimination of TB (less than 1 incident case per 1 000 000 population per year) by 2050 in some countries, the ability to address the LTBI reservoir will be critical in all the efforts

to succeed in the absence of vaccines and other preventive interventions that can be scaled up in the short term.

Persons with latent TB infection (LTBI) have in their body TB bacteria that are alive but not causing disease. They do not feel unwell and do not have symptoms. Usually, they have a positive skin test or blood test result indicating TB infection but may have a normal chest X-ray and a negative sputum test and a negative Xpert MTB/RIF® test. Without treatment, 5–10% of infected persons will develop TB disease at some time in their lives. About half of those people who develop TB will do so within the first two years of infection. For persons whose immune systems are weak, especially those with HIV infection, malnutrition, on anti-cancer therapy, or on dialysis, the risk of developing active TB disease is considerably higher than that for persons with normal immune systems. Risk of progression to active TB in people living with HIV (PLHIV), and household contacts of infective patients with TB can be reduced by providing them with TB preventive treatment (TPT).

Conclusion

In Malawi, TB policies still reflect the IPT regimen as TB/HIV preventive therapy. However, this review failed to find a documented budget line for 3HP TPT for example as drawn by the NTP. This is because the health sector budget is presented as a consolidated budget from all directorates and programmes within MoH towards the overall national budget. Furthermore, the design of the study had limitations considering that there is poor documentation and access to information in Malawi. Perhaps if the design had included Key informant interviews and other modes of data collection, some missing information in this study would have been elicited. One thing that comes out clear though, is that the country does not have, within the MoH budget a budget line on 3HP TPT. Only the national HIV and AIDS 2020-2025 strategic plan has included 3HP exclusively highlighting it as the new TPT regimen that must be implemented as a matter of commitment by the government. The language in the 2021-2025 NTP strategic plan is somewhat vague as TPT is mentioned generally without specific mention of the 3HP. It can only be assumed that this is in reference to 3HP and not IPT. PEPFAR COPS 2019 and 2020 show a detailed plan for 3HP implementation. These are opportune areas for the country to start a conversation about how the 3HP regimen can be scaled up. Being one of the HBCs, Malawi stands to benefit from the reduced 3HP costs, therefore, the NTP and MoH in general needs to embark on partnership conversations with partners such as PEPFAR and global fund to ensure that national documents such as the national budget reflect 3HP drugs as new TPT regimen for the country. This is also an opportunity for FACT and the TB-CSO network to identify influential partners (PEPFAR & Global fund) in their advocacy to ensure 3HP gets all the attention it requires for the country to not only implement the WHO guidelines but to also ensure that it is geared to implement and achieve its targets as presented to the UNHLM in 2018.

HIV programs can't afford to ignore TB prevention anymore. TPT is a routine part of HIV clinical care that should be planned and budgeted for in all TB/HIV programs across all countries. The world has now a shorter, safer alternative to IPT, the 3HP regimen. This 3HP is a preferred regimen for all lead donors including PEPFAR, Global Fund, USAID and the Global Drug facility especially now that there is a competitive price for rifapentine and confirmation that it's safe to use 3HP with DTG. All countries need

to set ambitious annual TPT targets. Countries should use 3HP to meet a portion of their TPT targets. As 3HP price comes down, countries should transition from IPT to 3HP to meet annual targets.

Currently, the MoH budget continues to be minimally funded as a proportion of the national budget - with a mixed outlook of better performance indicators in some specific functions such the drugs and other supplies budget line courtesy of huge parallel donor funding mechanisms; and blurred performance indicators in others for example between curative and preventive care where curative services get higher funding compared to the well-known cost-effective preventive services. In Malawi, health sector budgets are far below what is required to implement all approved health sector policies and strategies. A situation that is overall, presented as perpetual inadequate funding towards the health sector by all evaluations that get conducted in the country. However, MoH must adopt the 3HP because evidence shows that it is cost-effective more with the globally agreed reductions in costs, it will save more money as well as more lives in the short and long terms respectively. After all, TPT is not a stand-alone activity; rather it should be implemented within the overall package of services of the national TB control programme (NTP) and using the resources within the health system. This is the only realistic, feasible and cost-effective option to scale up TPT.

In terms of achieving the objectives of this assignment, an advocacy area/gap is hereby being recommended to FACT and the TB-CSO network in Malawi to ensure that 3HP becomes a national agenda and that the TPT narrative completely shifts in the country's policies and frameworks including the national budget. See annex 1 for a detailed recommendation on 3HP advocacy in Malawi.

ANNEX 1

Advocating for the 3HP budget line item in the national budget

Introduction

CSO & Government partnership

In Malawi, CSOs can potentially play an important role in overseeing health expenditures at the district level, monitoring what is spent by district governments or local health facilities and using these findings to call for changes in how government funds are allocated and spent. Yet formal recognition of civil society's role in the health budgeting process is limited. A public consultation stage is included in the budget process. However, the role of CSOs perse is not made explicit. Beyond these consultations, the officially recognised role of civil society is largely limited to community sensitisation and mobilisation to support budget implementation. For the past decade or so, the International Monetary Fund (IMF) has pushed for the involvement of CSOs in its consultations with the government of Malawi regarding the national budget (Scholte, 2009).

Advocacy is a systematic succession of actions designed to persuade those in power to bring a change to a specified issue of public concern. Advocacy is a deliberate process to deliver particular messages to decisionmakers who develop laws or policies or distribute resources that affect people's lives.

Using this definition, it is hereby suggested that FACT and the TB CSO network should consider the following to embark on advocacy for 3HP in Malawi:

• ***Systematic***—Carefully plan to achieve clearly defined goals, following specific steps in planning and execution. *Tip: Know that the Introduction of the 3HP budget line into the national budget or MoH budget is strategic thinking as the issue borders on public health and human rights of the people of Malawi*

• ***Goals***—This advocacy plan should seek to achieve a clearly defined change. The recommended goal states: "introduction of a budget line to purchase 3HP drugs" in the MoH budget as part of the national budget.

• ***Process***—Plan for longer-term engagement with decision makers and not a one-time meeting or engagement. *Tip: Advocacy is a deliberate process carried out over time, not a one-time intervention. Successful advocacy requires persistence and sustained engagement.*

• ***Targets***—Set a timeline by which the budget line is introduced within the national budget. As the situation is at present, engagements should start now aiming at the inclusion of the same during the mid-term review of the budget sometime in December 2021 or in the 2022-2023 national budget. *Tip: Know that Advocacy aims to influence the actions of key decisionmakers (politicians, government officials).*

• ***Persuasion***—Use evidence from this review to present to decision makers to make a case and persuade them*. Tip: Advocates use evidence to craft convincing messages and strategies to convince the target audience(s) to make the change(s) desired.*

Problem statement

Malawi experiences a dual high burden of TB and HIV and features among the 30 high burdened countries in the world. Despite registering tremendous progress in HIV and TB treatment, the country still needs to double its efforts to completely end HIV and TB. In 2019, MoH expressed the desire to transition from the IPT regimen for TB to the 3HP regimen which treats PLHIV and all those with latent TB infections. Despite this, the government budget has never included any allocation for 3HP procurement until now when the 2021-2022 budget sitting of parliament is in progress. Currently, Government is relying exclusively on donors' multilateral agencies to provide 3HP commodities and services.

Goal: Increase government allocation to 3HP commodities and services by introducing a specific 3HP budget line within the MoH budget.

Specific Objectives:

1) Create a budget line item for 3HP within the MOH budget.
2) Secure funding for the 3HP budget line item.
3) Increase funding for the 3HP budget line item.

Rationale for 3HP advocacy:

A 3HP budget line item will provide FACT and TB-CSO network with a way to easily track the allocation and use of government resources. It is an advocacy issue that is specific, timely and meaningful in terms of the needs of the health sector in Malawi. This is the most critical step within the long-term advocacy for 3HP and subsequent securing of increased government investment in 3HP goods and services. The WHO guidelines on latent TB infection do not require a test for infection before starting PLHIV or child household contacts. Countries are now required to report on TB screening of patients on ART, and the two mutually exclusive clinical decisions made from that screening: initiation of TB treatment, or 2) initiation and completion of TPT. Most countries can access RPT through the Global Drug Facility.

The benefit of preventing individuals from progressing to active TB, especially those at high risk of reactivation, is widely accepted today. Well-designed clinical trials have validated several regimens as effective and safe ways to prevent progression to TB disease. In low-incidence settings, management of latent infection can contribute to the elimination of the disease. A review of treatment regimens found that the treatment of latent TB can reduce the risk of disease reactivation by 60% to 90% (Uplekar et al, 2015). A recent randomized controlled trial in a high TB-burden country showed that the benefits of preventive treatment in people living with HIV (PLHIV) can last for more than 5 years (WHO, 2018). TB preventive treatment (TPT) provides not only individual protection against active TB disease but also regular treatment to the at-risk people. These include essentially the household contacts and PLHIV – which will help in reducing the burden of TB infection in the community, especially in high TB-incidence settings; subsequently lowering the progression of active TB and in turn the new and relapse TB cases. Prevention of active TB disease by treatment of LTBI is a critical component of the WHO End TB Strategy (6). WHO has published updated and consolidated guidelines for programmatic management of LTBI in 2018 and 2020, which offer recommendations for preventive treatment, including with newer drugs that need shorter treatment durations, are well tolerated and thus have better efficacy due to improved

adherence. The End TB targets, as committed to by the Member States, cannot be achieved without addressing LTBI at scale. However, prevention has received little priority due to multiple supply- and demand-side barriers.

Dye et al. (Dye et al, 2013) conclude that eliminating TB requires a simultaneous attack on two components of the Mtb life-cycle:

- cutting transmission by treating active cases
- Neutralizing the reservoir of latent infection, by preventing activation in high-risk groups

This study by Dye et al., presumes mass preventive treatment based on a biological marker of progression, a tool that is not yet available. However, this provides indirect evidence that preventive treatment should be offered to at least high-risk groups using the current tools to reap the benefits of available treatments. To summarize, the targets of ending TB can be achieved only by combining the effective treatment of active TB, which involves early case detection, with high cure rates to interrupt transmission, along with methods to prevent new infections and to neutralize existing latent infections using preventive treatment.

TPT is not a stand-alone activity; rather it should be implemented within the overall package of services of the National TB Control Programme (NTP) and using the resources within the health system. This is the only realistic, feasible and cost-effective option to scale up TPT. A recently notified TB patient and his/her household contacts including children should be regarded as one whole unit of beneficiaries of NTP services where those with active disease should be initiated on anti-TB treatment (ATT) and the rest commenced on TPT. The monitoring of treatment adherence can be done together for all of them in the unit by using the same resources to ensure successful completion of ATT by the patient/s with TB and TPT by the healthy, yet infected contacts. On similar lines, PLHIV must have access to TPT services as part of their continuum of care at the ART (antiretroviral treatment) centres, counseling centres and existing community-based HIV projects.

Who will be the decision-makers to engage?

• Ministry of Health (Planning dept, NTP, HIV Unit budget directors if any)
• Ministry of Finance (Budget director, Minister if possible)
• Members of Parliament (Influential ones that can add voice)
• Parliamentary Committee on Health
• PEPFAR
• Global Fund

What advocacy methods and processes to use?

This advocacy campaign can be both ad hoc as well as systematically planned, designed to take advantage of an opportunity created by the inclusion of 3HP in the 2020-2025 national HIV strategy in Malawi; taking advantage of the evidence produced in South Africa on the safety and efficacy of 3HP to support the efforts; and the desire by MoH to transition to 3HP. Also taking advantage of the complete change of focus by PEPFAR to ensure 3HP is rolled out across the country. PEPFAR has a costing tool that can also be used to present clear costs for the 3HP in Malawi.

What will be the main advocacy messages?

- Need for Increased case finding and diagnosis for TB and HIV among PLHIV or persons with TB
- Need to improve the coverage of high-quality treatment to all HIV/TB co-infected people
- Scaling up TPT to all people starting ART and under 5 child household contacts including prisoners
- Until budget allocations for 3HP drugs are made and matched with the anticipated need, Latent TB infections will continue to rise, threatening a rise in active TB cases in the country
- The government should create a budget line in the FY2021/2022 or FY2022/2023 as a 3HP drugs budget with a substantial amount that can be complemented by partners

TIPS

Budget process: *Advocates must understand the budget process, know which government institutions are responsible for shaping budget policy, and be aware of the entry points through which they can influence the budget.*

Key players: *What institutions are involved in shaping budget policy? This group can include government officials, interest groups, the media, and others. CSOs must account for all of these actors when developing budget advocacy strategies.*

Political and power dynamics: *In addition to understanding the formal budget process, CSOs need to understand how political and power dynamics can shape the budget process. What power relationships and political dynamics exist among the individuals and institutions described above? How might these affect which individuals and institutions wield influence, and how? Political and power dynamics affect how budget processes play out "in the real world," which may look different from budget processes on paper. Learning to understand and navigate these dynamics is an important skill that advocates can improve over time. In the beginning, more experienced advocates and friendly insiders can help CSOs find their way*

References

1. Badje AD, Moh R, Gabillard D, Guehi C, Kabran M, Menan H, et al. (2017). Six-month IPT reduces mortality independently of ART in African adults with high CD4. Abstract Number: 78. In: Conference on Retroviruses and Opportunistic Infections, 13–16 February 2017, Seattle, United States of America. San Francisco: CROI Foundation; 2017.
2. CSOs, (2019). Civil society statement on Rifapentine price discount. A lower price for Rifapentine is just a start—communities need more than discounts to access TB preventive therapy. Hyderabad, India; 2019. http://www. tbonline.info/media/uploads/documents/Rifapentine_price_discount_-_ civil_society_statement_-_final.pdf. Accessed March 25, 2021.
3. Danel C, Moh R, Gabillard D, Badje A, Le Carrou J, Ouassa T, et al. (2015). TEMPRANO ANRS 12136 Study Group. A trial of early antiretrovirals and Isoniazid preventive therapy in Africa. N Engl J Med. 2015 Aug 27;373(9):808–22. http://dx.doi.org/10.1056/NEJMoa1507198 PMID:26193126
4. Dye C, Glaziou P, Floyd K, Raviglione M. (2013). Prospects of tuberculosis elimination. Annu Rev Public Health. 2013; 34:271–86.
5. Faust L, Ruhwald M, Schumacher S, Pai M. How are high burden countries implementing policies and tools for latent tuberculosis infection? A survey of current practices and barriers. Health Sci Rep. 2020;3: e158. https:// doi.org/10.1002/hsr2.158
6. Getahun H, Matteelli A, Abubakar I, Hauer B, Pontali E, Migliori GB. Advancing global programmatic management of latent tuberculosis infection for at risk populations. Eur Respir J. 2016 May;47(5):1327–30. http://dx.doi.org/10.1183/13993003.00449-2016 PMID:27132266
7. Getahun H, Matteelli A, Chaisson RE, Raviglione M. (2015). Latent Mycobacterium tuberculosis infection. N Engl J Med. 2015 May 28;372(22):2127–35. http://dx.doi.org/10.1056/NEJMra1405427 PMID:26017823
8. Hamada Y, Sidibe A, Matteelli A, Dadu A, Aziz MA, Del Granado M, et al, (2016). Policies and practices on the programmatic management of latent tuberculous infection: global survey. Int J Tuberc Lung Dis. 2016 Dec;20(12):1566–71. http://dx.doi.org/10.5588/ijtld.16.0241 PMID:27931330
9. Houben RM, Dodd PJ. (2016) The global burden of latent tuberculosis infection: a re-estimation using mathematical modelling. PLoS Med. 2016;13: e1002152.
10. Jagger A, Reiter-Karam S, Hamada Y, Getahun H. National policies on the management of latent tuberculosis infection: review of 98 countries. Bull World Health Organ. 2018; 96:173-184F.
11. Kebede BA, Fekadu L, Jerene D. Ethiopia's experience on scaling up latent TB infection management for people living with HIV and under-five child household contacts of index TB patients. J Clin Tuberc Other Mycobactin Dis. 2018; 10:29-31
12. Lobue P, Menzies D. (2010). Treatment of latent tuberculosis infection: An update. Respirology. 2010 May;15(4):603–22. http://dx.doi.org/10.1111/j.1440- 1843.2010.01751.x PMID:20409026
13. Millet JP, Shaw E, Orcau A, Casals M, Miró JM, Caylà JA; (2013). Barcelona Tuberculosis Recurrence Working Group. Tuberculosis recurrence after completion treatment in a European city: reinfection or relapse? PLoS One. 2013;8: e64898.
14. MoH, (2019). National TB Control Program. Annual National TB Program Report, 2019.
15. MOH, (2020). Malawi National Heath Accounts. Report for Fiscal Years 2015/16–2017/18. Lilongwe, Malawi: Ministry of Health, Department of Planning and Policy Development.

16. MoH, (2021). Ministry of Health and Population. National TB and Leprosy Control Programme Strategic Plan 2021-2025
17. MoH. (2019). DHA Program Projections.
18. MoH/UNAIDS. (2019). 2020 Malawi Spectrum Model.
19. Pai M, Behr M, Dowdy D, et al. Tuberculosis. Nat Rev Dis Primers. 2016; 2:16076.
20. Pai M, Denkinger CM, Kik SV, et al. Gamma interferon release assays for detection of Mycobacterium tuberculosis infection. Clin Microbiol Rev. 2014;27(1):3-20.
21. Pai M. To scale-up TB preventive therapy, we need to bundle tools & improve access. Nature Research Microbiology Community, 2018. https://naturemicrobiologycommunity.nature.com/users/20892-madhukarpai/posts/41136-to-scale-up-tb-preventive-therapy-we-need-to-improveaccess-to-a-bundle-of-tools. Accessed April 28, 2021.
22. Scholte, J. (2009). IMF Interactions with Member Countries: The Civil Society Dimension. Washington, DC: Independent Evaluation Office of the International Monetary Fund, IEO Background Paper
23. Tebruegge M, Buonsenso D, Brinkmann F. European shortage of purified protein derivative and its impact on tuberculosis screening practices. Int J Tuberc Lung Dis. 2016;20(10):1293-1299.
24. Triasih R, Rutherford M, Lestari T, Utarini A, Robertson CF, Graham SM. (2012). Contact investigation of children exposed to tuberculosis in South East Asia: a systematic review. J Trop Med. 2012; 2012:301808.
25. Uplekar M, Weil D, Lonnroth K, Jaramillo E, Lienhardt C, Dias HM et al. (2015). WHO's new End TB Strategy. Lancet. 2015; 385:1799–801.
26. Uplekar M, Weil D, Lonnroth K, Jaramillo E, Lienhardt C, Dias HM, et al.; for WHO's Global TB Programme. WHO's new end TB strategy. Lancet. 2015 May 2;385(9979):1799–801. http://dx.doi.org/10.1016/S0140-6736(15)60570- 0 PMID:25814376
27. Van Ginderdeuren E, Bassett J, Hanrahan C, Mutunga L, Van Rie A. Health system barriers to implementation of TB preventive strategies in South African primary care facilities. PLoS One. 2019;14(2): e0212035.
28. WHA, (2018). General Assembly resolution 73/3. Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis, A/RES/73/3; 2018. https://www.un.org/en/ga/search/view_doc. asp? Symbol=A/RES/73/3. Accessed April 26, 2021.
29. WHO, (2014) Framework towards tuberculosis elimination in low-incidence countries. Geneva: World Health Organization; 2014.
30. WHO, (2014). The Case for Investing in Public Health: A Public Health Summary Report for EPHO 8. Geneva: World Health Organization.
31. WHO, (2015). Raising Revenues for Health in Support of UHC: Strategic Issues for Policy Makers. World Health Organization. Geneva
32. WHO, (2017). Global tuberculosis report. Geneva: World Health Organization; 2017.
33. WHO, (2018). World Health Organization. Latent tuberculosis infection: updated and consolidated guidelines for programmatic management. Geneva, 2018.
34. WHO, (2019). World Health Organization (WHO). 2019. Public Spending on Health: A Closer Look at Global Trends. Geneva: WHO.
35. WHO, (2020). WHO Consolidated Guidelines on Tuberculosis: Module 1: Tuberculosis Preventive Treatment. Geneva: WHO; 2020 https://www.who.int/publications-detail/who-consolidated-guidelines-on-tuberculosis-module-1-prevention-tuberculosispreventive-treatment. Accessed March 26, 2021.
36. WHO, (2020). World Health Organization. Global Tuberculosis Report, 2020.

37. Zong Z, Huo F, Shi J, Jing W, Ma Y, Liang Q et al. (2018). Relapse versus reinfection of recurrent tuberculosis patients in a national tuberculosis specialized hospital in Beijing, China. Front Microbiol. 2018; 9:1858.
38. Zwerling A, Behr MA, Verma A, Brewer TF, Menzies D, Pai M. The BCG world atlas: a database of global BCG vaccination policies and practices. PLoS Med. 2011;8(3):e1001012.