

**LIU LATHU MU
COP21
OUR VOICE
MALAWI**

COMMUNITY PRIORITIES

PEPFAR COUNTRY OPERATIONAL PLAN 2021



Photo: Lameck Luhanga

INTRODUCTION

Malawi has an estimated 1.1 million people living with HIV and in 2019 alone the country registered 33,000 new infections. In terms of the UNAIDS 95-95-95 targets, Malawi's progress has been 91%-87%-94%, translating into 79% of people living with HIV receiving ART and 74% being virally suppressed, respectively. Whilst much progress had been made towards achieving epidemic control, the onset of the COVID-19 pandemic has significantly impacted the HIV and TB programmes, with fewer people able to access HIV, TB and other health services. This is in part due to the first in a series of circulars issued by government in April 2020, related to COVID-19 and HIV services.



The circular outlined a slate of service suspensions, where the following services classified as non-essential as a result of COVID-19 were suspended:

1. Voluntary medical male circumcision.
However, post-op follow-up visits for recently circumcised men should be provided.
2. New initiation of Pre-exposure prophylaxis for HIV (PrEP) and TB Preventive Therapy (TPT). However, patients who have already been on IPT for at least 3 months without any side effects may be given IPT to complete their 6 months' course.
3. Condom distribution to walk-in clients. Condoms may be accessed through pharmacies and supermarkets by those clients. Note that condoms dispensed to clients on ART or those attending family planning or STI clinics will continue.
4. Routine scheduled viral load monitoring for stable adult patients.
5. Teen clubs and other patient support groups that involve gathering of people (IPs may continue providing support through virtual means to the teens).
6. Active tracing involving community visits, such as index testing, "defaulter" tracing. Use phones whenever possible
7. VCT, group pre-test education, active partner notification, HIV recency testing, community HIV testing and audits for the Rapid Testing and Continuous Quality Improvement project.

The barriers and disruptions in HIV services created by COVID-19 — confirmed by community-led monitoring — need to be urgently addressed to maintain the gains made in the HIV response.

The establishment of a community-led monitoring mechanism in Malawi has allowed us to more systematically document these and other challenges in health centres across the country. In January 2021, teams monitored the following health centres:

- + Bwaila Hospital, Kawale Health Centre, and Area 25 Health Centres (Lilongwe);
- + Matawale Health Centre and Naisi Health Centre (Zomba);
- + Bulala Health Centre, Kafukule Health Centre and Mzuzu Health Centre (Mzimba North).

Further, focus group discussions were held with PLHIV, women living with HIV, AGYW, transgender people, men who have sex with men, and sex workers to better understand the challenges they face in accessing HIV and TB prevention and treatment services.

The recommendations of this year's "**Liu Lathu Mu COP21**"¹ were developed using the data from the community-led monitoring, analysis of PEPFAR data, MoH HIV programme performance data, as well as through consultation with people living with HIV, the Civil Society Advocacy Forum (CSAF) and other health activists.

1. "Liu Lathu Mu COP21" is Chichewa for "Community Voices on COP21"

COMMUNITY PRIORITY INTERVENTIONS FOR COP21

This table reflects the 2021 community priorities for inclusion in COP21. Some are priorities that have been included in past People's COPs but have not yet been fully implemented.

PRIORITY INTERVENTIONS	TARGET	WHAT YEARS DID WE ASK FOR IT?	DO WE HAVE IT?
1. Funding	COP21 Target: COP21 (FY22) budget is maintained at \$184,034,169.	COP21	No
2. Expert Clients	COP21 Target: Provide civil society with the current number of Expert Clients paid for by PEPFAR in COP20.	COP21	No
	COP21 Target: 500 additional Expert Clients are recruited and trained to support with defaulter tracing and provision of adherence services. This should include 20% KP and AGWY specific Expert Clients.	COP20, COP21	In part
	COP21 Target: PEPFAR Implementing Partners (IPs) consult PLHIV organisations before recruiting Expert Clients in communities to ensure that the Expert Clients have come from the same geographical area.	COP21	No
	COP21 Target: Funding provided for the formulation of National Volunteer Guidelines for efficient management of Expert Clients by different IPs in the districts.	COP21	No
3. COVID-19	COP21 Target: Cloth reusable masks have been procured and distributed to all PEPFAR supported sites to be provided to any healthcare user arriving at the facility to access services who does not have access to a mask in COP21 and the remainder of COP20.	COP21	No
	COP21 Target: Personal Protective Equipment (PPE) including N-95 respirator masks, aprons, gloves, sanitizer, and face shields have been procured and distributed to all PEPFAR supported health centres for use by healthcare workers, community healthcare workers, and expert clients to protect them against COVID-19, in COP21 and the remainder of COP20.	COP21	No
	COP21 Target: Viral load testing, Teen Clubs, Support Groups, VMMC, PrEP, and other HIV prevention services are resumed in a safe manner in COP21 and the remainder of COP20.	COP21	No
	COP21 Target: No healthcare user is required to explain where in the health centre they are going or what services they are seeking on entry at the health centre during the COVID-19 screening process in COP21 and the remainder of COP20.	COP21	No
	COP21 Target: All PEPFAR supported facilities are observing COVID-19 prevention measures properly including COVID-19 screening, mask use, hand hygiene, and physical distancing in COP21 and the remainder of COP20.	COP21	No
4.1 6MMD	COP21 Target: All stable PLHIV are able to collect a 6 month supply of ARVs by end of COP21.	COP21	In part
4.2 Community ART Clubs (CACs)	COP21 Target: 50% of all eligible PLHIV are receiving their HIV treatment, care and support within functional Community ART Clubs as outlined in the Liu Lathu MuCOP21.	COP19, COP20, COP21	No
	COP21 Target: CACs are integrated for collection of TPT and contraceptive commodities and for screening and treatment of diabetes and hypertension.	COP21	No
4.3 Health centre opening hours	COP21 Target: All PEPFAR supported health centres have extended opening hours from 5am to 7pm on weekdays and 8am to 4pm on Saturdays — and PLHIV are able to use these extended opening times to pick up their medication from internal pick up points. Whilst healthcare workers are expected to spend limited time at the facility due to COVID-19 restrictions, arrangements should be made to work in shifts.	COP21	No

PRIORITY INTERVENTIONS	TARGET	WHAT YEARS DID WE ASK FOR IT?	DO WE HAVE IT?
4.4 Healthcare worker attitudes	COP21 Target: All healthcare workers are trained to improve their attitudes towards all PLHIV (including PLHIV returning to care after a treatment interruption), young people, key populations (including transgender people, men who have sex with men, sex workers, and people who use drugs).	COP20, COP21	In part
	COP21 Target: Fund community-led organisations to provide health rights literacy to community members to ensure as public healthcare users they understand their right to access dignified and quality healthcare services. Too often community members feel helpless, unaware of where and how to report grievances for redress and so accept the status quo as normal.	COP20, COP21	No
	COP21 Target: Fund trained and independent Hospital Ombudsman where PLHIV can report cases of maltreatment by healthcare providers at 100% of PEPFAR supported facilities. Experience has shown assigning this role to Health care workers makes it hard for them to objectively respond to the health users grievances as they are equally guilty.	COP20, COP21	No
4.5 HIV and TB treatment & prevention literacy	COP21 Target: PLHIV and KP groups develop PLHIV and KP friendly community-led HIV and TB treatment and prevention literacy materials and implement country-wide capacity building training using adequate PEPFAR funding.	COP20, COP21	No
	COP21 Target: PLHIV and KP led groups mobilise communities around U=U messaging that ensure uptake of viral load testing services, through a PEPFAR funded social mobilisation campaign.	COP20, COP21	No
	COP21 Target: Community-led HIV and TB treatment & prevention literacy materials are distributed by PEPFAR to all support groups and ART clinics to reduce information gaps and misinformation.	COP20, COP21	No
	COP21 Target: Health worker led health talks take place at all PEPFAR-supported health centres to provide information to patients waiting for services including (but not limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, cervical cancer screening, that ensure uptake of these services.	COP20, COP21	No
4.6 PLHIV identification + tracing	COP21 Target: Resume community-based tracing whilst observing COVID-19 prevention measures by increasing the number of expert clients to 500 and equipping them with bicycles for mobility and strengthening support groups for peer support.	COP21	No
5. Viral load	COP21 Target: 100% of PLHIV on ART receiving an annual viral load test with results delivered to PLHIV in a maximum of 10 days.	COP19, COP20, COP21	In part
	COP21 Target: PEPFAR Malawi institutes a system to monitor turnaround time from viral load test to results being in hand with the PLHIV.	COP21	No
	COP21 Target: Integration of COVID-19, TB and HIV testing to deal with the backlog of TB, EID and viral load samples at all the molecular labs.	COP21	No
	COP21 Target: Resolve all systemic issues delaying viral load sample collection at health facilities i.e. challenges related to logging into CommCare.	COP21	No
6.1 Index testing	COP21 Target: Only certified sites carry out index testing.	COP21	In part
	COP21 Target: No index testing targets on the proportion of new diagnoses that come from index testing enforced in COP21 or the remainder of COP20.	COP21	No
	COP21 Target: Before contacting the sexual partners of PLHIV, all healthcare providers ask if the individual's partners have ever been violent and no contacts who have ever been violent or are at risk of being violent should ever be contacted in order to protect the individual.	COP21	In part
	COP21 Target: After contacting the contacts, the healthcare providers check with the individual if they faced any violence due to contacting and refer them to intimate partner violence (IPV) services including psychosocial support if the answer is yes.	COP21	In part
	COP21 Target: Prior to (re-)implementing index testing in any facility, there are adequate IPV services with sufficient capacity available for PLHIV at the facility or by referral and all PLHIV who are screened should be offered this information. Referrals must be actively tracked to ensure those referred actually get the services they require.	COP21	In part
	COP21 Target: All implementing partners (IPs) understand (through training) that index testing is always voluntary, for both sexual contacts and children, where individuals are not required to give the names of their sexual partners or children if they don't want to, and this is explained to all PLHIV.	COP21	In part
	COP21 Target: All adverse events are monitored through a proactive adverse event monitoring system capable of identifying and providing services to individuals harmed by index testing.	COP21	In part
	COP21 Target: Index testing will not continue at the facility for any population where an IP cannot meet the above demands.	COP21	No

PRIORITY INTERVENTIONS	TARGET	WHAT YEARS DID WE ASK FOR IT?	DO WE HAVE IT?
6.2 HIV Self-testing	COP21 Target: All PEPFAR supported facilities are offering HIVST in a more targeted manner. For test kits distributed in the community, PEPFAR will ensure there is proper documentation and recording of tests distributed, disaggregated by age and sex, and a follow up mechanism to ensure that all those with a reactive self-test are reporting back to the facility for a confirmatory test.	COP21	No
6.3 PrEP	COP21 Target: PEPFAR in consultation with GoM to share an expedited roll out plan for PrEP with a clear strategy for meeting FY22 targets.	COP19, COP20, COP21	No
6.4 Dapivirine Vaginal Ring	COP21 Target: Launched National Process to review regulatory dossiers for Dapivirine Vaginal Ring (DVR) and eventually, long-acting cabotegravir for prevention (CAB-LA) whilst simultaneously starting work to identify programme models, provider training needs, and civil society roles in leading, communications and programme design.	COP21	No
7. Dolutegravir	COP21 Target: PEPFAR institutes tracking of weight gain amongst PLHIV, especially as more people transition or start on DTG. Where problematic weight gain is identified, clinicians refer PLHIV to a dietician in order to properly support the individual. Further the PLHIV is screened for other NCDs associated with obesity.	COP21	No
	COP21 Target: In conjunction with meaningful inputs from PLHIV, people friendly materials and topics are developed to help people in diet and nutrition, and rolled out across PEPFAR supported clinics, support groups and Community ART Clubs.	COP21	No
8.1 TB Preventive Therapy (TPT)	COP21 Target: All eligible PLHIV including children and adolescents be initiated and complete TPT within COP21, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient. Of these, at least 70% should receive 3HP and 30% should be on IPT.	COP20, COP21	In part
	COP21 Target: All contacts of PLHIV with TB, including children and adolescents, should be traced and 100% of those eligible should be initiated on TPT.	COP20, COP21	No
	COP21 Target: TPT must be incorporated within DSD models of HIV service delivery (including Community ART Clubs).	COP21	No
	COP21 Target: COP21 should set aside funds for refurbishing storage facilities in PEPFAR supported sites to address the issue of increasing CPNP levels in 3HP resulting from increased shelf life, humidity and high temperatures.	COP21	No
8.2 TB screening and testing	COP21 Target: 100% of PLHIV, including CLHIV, are screened for TB upon presentation to care at every clinical encounter.	COP20, COP21	In part
	COP21 Target: 100% of PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings receive both urine-LAM and rapid molecular testing (including the use of stool samples among CLHIV) upon their first presentation to care.	COP20, COP21	In part
	COP21 Target: 100% of PLHIV, including CLHIV, with positive urine-LAM results immediately initiate TB treatment, while awaiting confirmatory rapid molecular test results.	COP20, COP21	In part
	COP21 Target: 100% of PLHIV, including CLHIV, who are co-infected with TB receive confirmatory diagnostic test results and are linked to TB treatment in less than five days after their first presentation to care.	COP20, COP21	In part
	COP21 Target: Procurement quantities of commodities required for urine-LAM and rapid molecular testing should each exceed 34,000, the estimated number of PLHIV, including CLHIV, expected to present to care at PEPFAR-supported sites with advanced HIV disease in COP21 (according to PEPFAR data [individuals newly testing positive for HIV] and WHO estimates that 1 in 3 PLHIV present to care with AHD).	COP20, COP21	In part
8.3 Hypertension + Diabetes	COP21 Target: Diabetes and hypertension screening and treatment is incorporated within DSD models for HIV treatment.	COP21	No

PRIORITY INTERVENTIONS	TARGET	WHAT YEARS DID WE ASK FOR IT?	DO WE HAVE IT?
9. Cervical cancer	COP21 Target: 500 additional healthcare workers trained and equipped to provide cervical cancer screening and treatment services to address the existing gap.	COP20, COP21	No
	COP21 Target: Cervical cancer screening and treatment for pre-invasive lesions is available in 130 PEPFAR supported facilities in order to reach an additional 100,000 by end September 2022.	COP20, COP21	In part
	COP21 Target: PEPFAR and Ministry of Health work hand in hand to ensure that cervical cancer services are fully integrated with HIV services. In facilities where cervical cancer screening is being offered, screening is conducted on ART Clinic day. Where gaps in HRH, infrastructure, and/or equipment exist, PEPFAR will fill those gaps.	COP20, COP21	No
	COP21 Target: PEPFAR and Ministry of Health work hand in hand to ensure there are clear referral pathways and mechanisms in place to monitor and trace women referred to services outside the Health Centre (including where no services are offered, or for further treatment) for funding.	COP20, COP21	No
10.1 KP funding + targets	COP21 Target: PEPFAR increases the KP budget to be at least proportionally in line with other African countries (3.16% of total budget based on COP20 Budgets). From the Planning Letter Level of \$175,785,000 that would be a minimum of \$5,554,806 for KP programming.	COP21	In part
	COP21 Target: Programming is not limited by the existing/non-existent size estimates. A process is put in place to work with KP CSOs to establish the potential expansion of KP programming based on community data.	COP21	No
10.2 KP friendly services	COP21 Target: In collaboration with KP led organisations, review the healthcare worker curriculum and incorporate updated modules to support learning around KP issues.	COP21	No
	COP21 Target: Funding is increased to KP led organisations to carry out regular trainings to sensitise healthcare workers at PEPFAR supported sites on provision of key population friendly services (for sex workers, people who use drugs, men who have sex with men, and transgender people).	COP20, COP21	No
10.3 KP specific services	COP21 Target: A minimum package of services is provided for each key population group to meet their needs, as outlined above, at all health centres and site assessment should be carried out to ensure that all facilities are equipped with the essential services to key populations.	COP21	No
	COP21 Target: 20% of the 500 Expert Clients are recruited to support key populations specifically.	COP20, COP21	In part
	COP21 Target: Lubricant is made available at all PEPFAR supported sites, alongside male and female condoms, and is not labelled as a key population commodity. Healthcare workers are trained to have comprehensive knowledge on lubricant to avoid stigmatising key populations.	COP21	No
	COP21 Target: Introduce 10 clinics run by KP led organisations as a pilot which are flexible to address the needs of KPs and where KPs will be able to receive comprehensive services.	COP21	No
10.4 KP support groups	COP21 Target: Increase funding to KP led organisations to establish and maintain functional support groups specific for key populations linked to all PEPFAR supported sites.	COP21	No
11. DREAMS	COP21 Target: DREAMS interventions are expanded to 50 additional facilities/SNUs as per the recommendation from COP Guidance.	COP19, COP20, COP21	No
	COP21 Target: PEPFAR will analyse DREAMS data to determine if saturation has been achieved, that is 75% of AGYW in a given SNU has completed the appropriate package of interventions. Once SNUs achieve saturation, expansion to additional SNUs should take place (matching the number of SNUs reaching saturation). PEPFAR will include CSOs in the process.	COP19, COP20, COP21	No
12.1 Paediatric ART optimisation	COP21 Target: Optimisation of all eligible children to DTG based regimens, with full transition taking place no later than end of FY22 Q1.	COP21	No
12.2 Paediatric point of care testing	COP21 Target: POC EID is scaled up to reach all HIV exposed infants.	COP21	No
13. Community-led monitoring	COP21 Target: Funding is scaled up to \$1 million for community-led monitoring in Malawi to monitor 55 high burden sites across 11 districts Malawi.	COP21	YES!

COMMUNITY PRIORITY INTERVENTIONS FOR COP21

1. Funding

This year, the Malawi PEPFAR programme is facing a cut of nearly \$20 million, from \$195,577,167 to \$175,785,000. This is of concern, not least because of the added burden of the COVID-19 pandemic that is creating additional barriers to accessing quality HIV and TB services. Malawi will require more resource support, rather than less, to ensure that people living with HIV and key populations are supported in accessing HIV prevention and to support long term ART retention and viral suppression.

Malawi will require more resource support, rather than less, to ensure that people living with HIV and key populations are supported in accessing HIV prevention and to support long term ART retention and viral suppression.

COP21 Target: COP21 (FY22) budget is flatlined at \$184,034,169.

2. Expert Clients

In 2021, Malawi's health system continues to face a major human resource shortage, largely due to financial constraints and a shortage of skilled labour. This crisis makes the health system fragile and constantly in need of support. COVID-19 has only served to worsen this dire situation. According to government statistics at the time of writing, ten healthcare workers have died following COVID-19 exposure and another 900 are currently in quarantine. Critical healthcare worker posts have been repurposed away from their existing functions, to perform activities specifically related to COVID-19. As the surge in new COVID-19 cases continues, it is likely that both these factors will continue to worsen the situation.

Community-led monitoring confirmed this gap in staffing levels at a number of health centres. Healthcare workers at all 8 facilities monitored reported too few staff to meet the needs of patients. Healthcare users confirmed this, reporting shortages of staff at 5 out of 8 of the health centres monitored. For example, at Area 25 Health Centre (Lilongwe), the facility serves more than 20,000 patients each month with a complement of only 29 healthcare workers (**3 Clinical Officers, 3 Medical Officers, 2 Medical Assistants, 2 Lab Technicians, 2 Lab Assistants, 3 Nursing Officers, 12 Nurse Midwife Technician, 2 Pharmacy Technicians and 3 CMA**).

The Government of Malawi plans to recruit 1,380 more healthcare workers to address the current shortage as the country deals with the surge in COVID-19 cases. However this will still not be enough to cover for the long standing gap in human resources. More support towards recruitment and training of additional human resources will be needed. The major gap that has been identified and prioritised by the community for COP21 is to increase the number of Expert Clients to support with the adherence and retention services.

Malawi introduced the Expert Client model in 79 Health Centres in 9 districts across the country from 2011-2014. The Expert Client model is well accepted by healthcare

workers (HCWs). At most Health Centres, Expert Clients are viewed as an integral part of the multidisciplinary team. Whilst Expert Clients were specifically recruited to assist with providing health education and defaulter tracing, their presence has reduced workload and stress for salaried HIV service providers through the performance of many additional tasks and by simply being "an extra pair of hands." Though originally positioned to report to the senior Health Surveillance Assistant (HSA), Expert Clients are actually best supported and supervised by the clinical service provider in-charge of either HIV services specifically (in bigger facilities) or the facility in-charge (at smaller health centers).

Furthermore, there is evidence that the deployment of Expert Clients in health facilities resulted in several benefits, including the following:

- + Increased demand for HIV prevention, testing and treatment services;
- + Streamlined patient flow and service delivery;
- + Accelerated retrieval of "missed appointments" and improved retention of patients in care;
- + A strengthened functional referral system between facility and community;
- + Increased male involvement in prevention of mother-to-child transmission (PMTCT).

Task-shifting has been proposed as a feasible alternative for improving HIV service delivery in resource-constrained settings². Much of the evidence relating to task-shifting through a peer-based model comes from Swaziland, Zambia, Botswana, Uganda and South Africa³. Successes of these task-shifting programmes included saving nurses several hours of time each month, increased access to HIV services and ART, improved patient flow, re-orientation of clinician focus from record-keeping tasks to patient care, decreased virologic failure rates and reduced loss to follow-up⁴. Studies also reported that these models are leading to increasing acceptance of HIV at the community level, less expensive follow-up care of comparable quality and long-term monetary savings⁵. Of importance to note was that clinic staff reported that the peer-based adherence support programmes improved the overall care of patients. Patients who talked to someone living positively with HIV, such as an Expert Client, before initiating ART had a better understanding of the importance of adherence and less fear of disclosure⁶.

Expert Clients⁷ can be found in a variety of roles and settings where they assist with individual and group treatment literacy sessions, HIV testing and counseling (HTC) and referral, individual adherence counseling, and tracing PLHIV who have missed appointments or have disengaged from care. Expert Clients—also known as lay cadre⁸ by WHO—provide the uniquely relevant approach that can only be offered by a peer from within the same community, willing to use his or her own experience of living with HIV as a tool to establish credibility and rapport. Perhaps most importantly, this cadre frees up skilled HCWs, enabling them to focus on the more complex, technically challenging patients in HIV service areas and patients in the general population. Given the shortage of HCWs in the country, this is incredibly important.

The role of Expert Clients is as relevant today as it were 12 years ago. To this date Expert Clients play a number of multifaceted roles including providing health education talks about HIV at the facility and undertaking on-the-spot counseling and psychological support for patients who come for review and ART refills. They also trace ART patients who miss appointments and actively pursue all contacts of index testing to encourage HIV testing.

Additionally, Expert Clients check patients' weights; improve patient flow at the Health Centre; pull master cards (patient's records of HIV care and treatment) for expected patients and file them after each visit; pack medications in preparation for distribution; and distribute nets, soap and buckets to antenatal mothers. Expert Clients also guide patients to various departments within health facilities and identify very sick patients from the outpatient department to ensure they are fast-tracked for service. Each of these tasks serves to reduce staff workload and address congestion and distress amongst patients. Conversely, Expert Clients in some facilities are assigned menial

tasks such as sweeping, mopping, dusting and running errands. Whilst they don't mind to help out occasionally, this type of misuse has become a pattern in some poorly run facilities.

In a study by Catholic Relief Services (CRS), HCWs and managers communicated profound satisfaction with the extent to which Expert Clients are providing services to patients. Most HCWs interviewed expressed heartfelt appreciation for the commendable work done by Expert Clients and recognised that their presence has helped tremendously to improve the delivery of HIV services. In particular, they reported that the health education talks and psychosocial counseling Expert Clients provide resonate deeply with patients because Expert Clients pull from personal experiences. This openness and honesty motivates many people to get tested, and it reduces the worries they have about being HIV positive.

A further strength of the model is that the Expert Clients are recruited from the facility's catchment area. This brings local language fluency and in-depth familiarity with customs and local context. Expert Clients thus have a distinct advantage in their ability to develop relationships and credibility with patients.

"I went for defaulter tracing, tracing someone who had stopped taking ARVs in 2018. My finding after discussion is that she stopped taking ART due to death of her husband. She decided to not take ARVs anymore. Even after my counselling she said enough is enough. She said she could not reverse her decision, but I disclosed my status to her so that she could be convinced. She asked why I [had] disclosed my status to her. I said I wanted to save her life and for her to take care of the three children and let the children to take care of her too. I also did psychosocial counselling, and worked on stress management and self-stigma... She told me to call her last born daughter and she told her all we had been discussing. She asked her to escort her to the hospital on her pill pick up day. And the daughter accepted to escort her starting from Monday 8th February 2021. It was tough counselling which lasted almost 1 hour 47 minutes. During our discussions, we maintained social distance and discussed personal hygiene, putting on masks, washing hands and avoiding public gatherings. We also talked about signs and symptoms of COVID19"

— Expert Client in Mzimba South reporting on 6th February 2021 to a PLHIV Forum facilitated by African Community Advisory Board (AFROCAB) in conjunction with Civil Society Advocacy Forum on HIV and Related Conditions (CSAF).

The government circular issued on 3 April 2020 suspended all active and physical tracing of PLHIV who miss appointments and/or disengage from care, relying entirely on telephone tracking instead. Healthcare workers and PLHIV interviewed through community-led monitoring both agree, this is having a negative impact on finding people and bringing them back to care.

2. WHO, 2008

3. Shroufi, 2013; Kim, 2012

4. Tenthani, 2012; Belmans, 2010; Yaya 2013; Kim, 2012; Torpey, 2008; Arem, 2011

5. Ledikwe, 2013; Kiweewa, 2013

6. Arem, 2011; Chang, 2008

7. They are known as Community Referral Agents, Model Clients, Adherence Support Workers, Mentor Mothers Community Facilitators and lay cadres.

8. Any health worker who performs functions related to healthcare delivery; was trained in some way in the context of the intervention; but has received no formal professional or paraprofessional certificate or tertiary education degree (Lewin 2005) as cited by WHO in an article titled: Cadre definitions used in the project - WHO Recommendations: Optimizing Health Worker Roles to Improve Access to Key Maternal and Newborn Health Interventions Through Task Shifting - NCBI Bookshelf



Photo: Lameck Luhanga

According to PEPFAR Q3 data, at Tisungane Health Centre in Zomba, 71% of PLHIV who had missed their clinic appointments required physical tracing and because of the restrictions in the Government Circular, tracing was never attempted, and seen through high proportions of PLHIV disengaging from care, for example 47.2% at Mpala Health Centre in Mulanje and 47.02% at Lungwena Health Centre in Mangochi.

Peer-led models to trace PLHIV who disengage from care are critical to improving long term retention and viral suppression. Despite recommendations last year for PEPFAR to fund an additional 1,500 Expert Clients in COP20, there was no specification in the SDS as to how many will be recruited and for which target populations⁹. The SDS states “PEPFAR will recruit and deploy additional HCWs and lay cadres (e.g. patient supporters/ expert clients) to reduce waiting times and address psychosocial needs” (page 4). Community-led monitoring this year again highlighted the need for more Expert Clients to address the issue of PLHIV who miss appointments or disengage. Further focus group discussions in Mzuzu urban (Lilongwe) and Matawale (Zomba) revealed the need for population specific Expert Clients to meet the needs of key populations (KPs) and adolescents girls and young women (AGYW).

COP21 Target: Provide civil society with the current number of Expert Clients paid for by PEPFAR in COP20.

COP21 Target: 500 additional Expert Clients are recruited and trained to support with defaulter tracing and provision of adherence services. This should include 20% KP and AGYW specific Expert Clients.

COP21 Target: PEPFAR Implementing Partners (IPs) consult PLHIV organisations before recruiting Expert Clients in communities to ensure that the Expert Clients have come from the same geographical area.

COP21 Target: Funding provided for the formulation of National Volunteer Guidelines for efficient management of Expert Clients by different IPs in the districts.

9. <https://healthgap.org/wp-content/uploads/2020/03/Liu-Lathu-Mu-COP20-Malawi.pdf>



3. COVID-19 service disruptions + barriers to care

COVID-19 has created barriers and disruptions in accessing HIV, TB and other health services at health centres across Malawi, including many components of quality HIV and TB prevention and care services being deemed not essential. Community-led monitoring has confirmed a number of challenges that urgently need to be addressed.

Firstly, people are not allowed into health centres without masks which we agree is an important measure to curb the spread of COVID-19. However, many people (including PLHIV, key populations, and those attempting to access HIV prevention) cannot afford to buy masks, meaning that they are restricted from accessing the health centres, and cut off from service delivery—including collecting ART refills, TB treatment, or HIV prevention and testing, impacting the overall success of the HIV and TB response.

Secondly, there is a shortage of personal protective equipment (PPE) for healthcare workers. It is critical that healthcare workers have the PPE they need to safely engage in healthcare provision. Instead, and without the PPE they need, they are being put at risk of COVID-19 infection. One focus group respondent told us that **“in the consultation rooms the providers no longer have adequate time with us because they also are afraid that we might have COVID-19”**.

Thirdly, following the issuing of Government circular on guidance on provision of HIV services in response to COVID several services have been suspended or restricted including Teen Clubs, defaulter tracing, Support Groups, VMMC services, and HIV prevention (PrEP initiation and condom and lubricant distribution).

Fourth, through community-led monitoring it has been reported that on arrival at the health centre, healthcare users are asked to state which services they are seeking, therefore having to at times disclose their HIV status, or that they are a member of a key population, deterring people from seeking healthcare. One focus group respondent told us **“At facilities we are being asked where we are going and it’s always crowded, then you have to mention Lighthouse in front of everyone thereby involuntary disclosure takes place. Many PLHIV just turn back without accessing services.”**

Community-led monitoring also revealed that due to overcrowding in some facilities, COVID-19

prevention measures are not being observed such as hand hygiene and physical distancing.

COP21 Target: Cloth reusable masks have been procured and distributed to all PEPFAR supported sites to be provided to any healthcare user arriving at the facility to access services who does not have access to a mask in COP21 and the remainder of COP20.

COP21 Target: Personal Protective Equipment (PPE) including N-95 respirator masks, aprons, gloves, sanitizer, and face shields have been procured and distributed to all PEPFAR supported health centres for use by healthcare workers, community healthcare workers, and expert clients to protect them against COVID-19, in COP21 and the remainder of COP20.

COP21 Target: Viral load testing, Teen Clubs, Support Groups, VMMC, PrEP, and other HIV prevention services are resumed in a safe manner in COP21 and the remainder of COP20.

COP21 Target: No healthcare user is required to explain where in the health centre they are going or what services they are seeking on entry at the health centre during the COVID-19 screening process in COP21 and the remainder of COP20.

COP21 Target: All PEPFAR supported facilities are observing COVID-19 prevention measures properly including COVID-19 screening, mask use, hand hygiene, and physical distancing in COP21 and the remainder of COP20.

4. ART Continuity

According to PEPFAR's 2020 data, whilst 90,889 people were initiated on treatment (TX_NEW) during the year, treatment rolls increased by only 6,706 (TX_NET_NEW) by the end of quarter 4—meaning 84,183 people stopped treatment, were lost, or died during the year, pointing to worrying continuity of care challenges.¹⁰ Nearly all implementing partners failed to meet targets in COP19, as noted in the planning letter stating that *“During FY20, almost all scale-up districts in Malawi did not achieve their TX_CURR or TX_New targets. There is a need to regain the losses in treatment, especially among children and men.”*

Community-led monitoring data reveals several reasons for this poor continuity of care including:

- + Long distances PLHIV face in order to get to the health centre;
- + Lack of access to transport or transport money;
- + Long queues at the health centre and other time inconveniences/deterrents;
- + Limited times to collect ART refills;
- + Being shouted at or treated badly by healthcare workers;
- + Lack of or misinformation on treatment adherence (including to PLHIV with no symptoms);
- + Poor tracing of PLHIV who disengage from care, including PLHIV working outside of Malawi;
- + Faith healing and false identities by PLHIV perpetuated by a disconnect between facilities and communities.

The planning letter agrees stating that *“Maintaining epidemic control, as measured by the proportion of PLHIV with viral suppression, will require long-term, continuous adherence to ART for an adult population that is asymptomatic—and for whom HIV treatment is easily interrupted by drug side effects, inconvenience, lack of time, poor customer service, stigma and discrimination, or life circumstances.”*

The planning letter prioritises the implementation of *“a new and refocused strategy to increase... treatment retention and viral load suppression among pediatrics, adolescents and men”* and further it highlights a priority in *“Ensuring 15-35-year-old asymptomatic clients are maintained on treatment and virally suppressed.”* It lastly states that *“Maintaining long-term viral suppression necessitates planning and implementing services that are free, fit the lives of the clients, and empower clients to on ART to stay the course.”* Below are key interventions needed to improve long term retention and viral load suppression in Malawi.

4.1. 6MMD

We welcome the push towards 6MMD by PEPFAR and encourage a rapid scale up to all eligible PLHIV. The SDS commits that *“PEPFAR will... support the implementation of multi-month prescriptions and the transition to 90 pills per bottles for around two-thirds stable PLHIV”* (page 53) and the planning letter states that *“All PEPFAR supported sites are implementing 6MMD.”* However most PLHIV interviewed through community-led monitoring reported receiving shorter refills of 2 or 3 months' supply.

It is important to reiterate that 6MMD should not be used **instead** of differentiated service delivery models (DSD), especially those offering critical peer and psychosocial

support like Community ART Clubs. Rather 6MMD should be offered **within** any of the DSD models together with psychosocial support. It is simply one component.

COP21 Target: All stable PLHIV are able to collect a 6 month supply of ARVs by end of COP21.

4.2. Community ART Clubs

Community ART Clubs (CACs) are a client-centered approach to HIV treatment collection where PLHIV access ARVs outside of their local health centre. When functional, CACs should simplify and adapt ART refill collection to both serve the needs of PLHIV better and reduce unnecessary burdens on the health system. CACs should be much easier, quicker, and more accessible systems than travelling long distances to health centres only to wait in long queues. CACs also provide important opportunities for PLHIV to get much-needed treatment literacy information and support to remain adherent to their treatment.

Page 33 of the SDS commits to *“improving retention on ART through differentiated service delivery models”*. However, we know that CACs have not yet been rolled out and scaled up effectively. Further, community-led monitoring reveals that many participants were not familiar with DSD models in general and several did not even know that Community ART Clubs were an example of a DSD model.

It is also important to note that PLHIV receiving their HIV treatment, care and support within DSD models for HIV treatment (including community ART clubs), may also have other health needs that can be addressed with the DSD model. For example, PLHIV within a DSD model may also need to be receiving TB preventive therapy (as outlined in section 6.2), contraceptive care commodities or other medications (such as for hypertension and diabetes, see below section 6.4). Wherever possible, refill durations of other chronic care medications should be aligned with the refill duration of ART to support efficient collection of all medications.

COP21 Target: 50% of all eligible PLHIV are receiving their HIV treatment, care and support within functional Community ART Clubs as outlined in the Liu Lathu MuCOP21.

COP21 Target: CACs are integrated for collection of TPT and contraceptive commodities and for screening and treatment of diabetes and hypertension.

10. <https://mer.amfar.org/location/Malawi/treatment>



Photo: Isabel Corthier

A FUNCTIONAL COMMUNITY ART CLUB

- + Adherence clubs are run by a Community ART Nurse who understands treatment adherence information and who is trained to identify people with psycho-social and other mental health challenges who need referral for further support;
- + The meetings take place in a venue in the community where participants discuss issues concerning them and their group members;
- + Members should have a basic clinical check-up, conducted by the Community Nurse;
- + Members should collect six months' supply of ARVs (once at 6MMD);
- + To qualify for the adherence club, patients must be clinically stable (6-months on treatment, evidence of treatment success);
- + One club consists of a maximum of 30 people living with HIV who meet every three to six months and are reminded of their appointment by SMS the day before;
- + TB symptom screening will occur at each session and TPT collection will be available through clubs;
- + Contraceptive care commodities collection will be available through clubs;
- + Diabetes and hypertension screening and treatment is incorporated within clubs;
- + In contrast to clinic visits which can take hours or even a full day, adherence club members must be in and out of their club visit in between one and two hours.
- + Clubs are not simply a collection point, they must include discussion on issues of treatment literacy and adherence information which members have to attend, as well as other topics including those around diet based on the issue of weight gain as people start or transition to DTG;
- + Some clubs should be specific to target populations based on gender, age, or if part of a key population; such as male clubs, teen clubs, KP clubs etc.

4.3. Health centre opening hours

It is well known that each time someone is asked to spend an extended time at a clinic, simply to collect ART refills, there is an increased risk of that person disengaging from care. Long waiting times also affect the quality of services provided as healthcare workers have little time to provide adequate information or care to PLHIV.

As stated in the planning letter, *“maintaining long-term viral suppression necessitates planning and implementing services that... fit the lives of the clients”*. In addition to longer refills and options to collect closer to home, one way to ensure that ART collection can fit the lives of PLHIV is to extend health centres opening hours and ensure PLHIV can collect ART refills Monday to Saturday.

Patients interviewed through community-led monitoring reported health centres opening between 7:00am and 8:30am, with closing times around 4pm. Several facilities were reported as open during the weekend, but for shorter hours between 8am and 12pm. Further it was often reported that ART refills can only be collected on allocated days.

It is important to note that the gains we have made in the HIV response should not now be lost during COVID-19. Where staff are meant to spend reduced time at the facility, arrangements should be made to work in shifts to allow for extended opening times, whilst also respecting staff needing to spend limited time at the facility.

COP21 Target: All PEPFAR supported health centres have extended opening hours from 5am to 7pm on weekdays and 8am to 4pm on Saturdays — and PLHIV are able to use these extended opening times to pick up their medication from internal pick up points. Whilst healthcare workers are expected to spend limited time at the facility due to COVID-19 restrictions, arrangements should be made to work in shifts.

4.4. Healthcare worker attitudes

It is commonly reported that people who miss appointments and/or stop taking their treatment are sometimes treated badly by healthcare workers when they return into care. This fear of being reprimanded discourages people from going back to the health centre to seek help and restart treatment.

The SDS notes that one key intervention to bring PLHIV back to care will be to *“create a more friendly and enabling environment for clients to interface with at site and community level. PEPFAR will also work with the MoH to address HRH related barriers such as poor HCW attitudes towards clients returning back to care”* (page 54). However, there is no clear outline as to how this friendlier environment will be delivered.

Community-led monitoring in January 2021 reveals that staff attitude remains a major barrier—with reports of staff reactions to patients who missed a facility visit for ARV collection that continue to be unwelcoming, unfriendly, and/or lacking in support. Whilst some focus group participants did report staff being friendly, others had a more negative experience receiving unfriendly and unwelcoming services at sites, particularly after a treatment interruption as a PLHIV.

One FGD participant from Mtsiriza township (Lilongwe) said, ***“after defaulting treatment, most people do not take an initiative to go back to their ART clinic because of fear of healthcare providers’ reaction after a missed appointment. Instead they go to other hospitals, get tested and be initiated there as a new person while leaving a gap at their former ART clinic”***. The participant gave an example of Bwaila Health Centre where five support group members disengaged from treatment and re-tested in Area 18 and ABC, starting as PLHIV newly initiated on ART.

One woman living with HIV told us that after missing an appointment and returning to the facility the next day ***“I arrived at the facility at around 7am on the next day and the providers punished me for missing my appointment by being made to wait for 3 hours before I can begin the refill process. I was allowed to start the process at 10am and left the facility at 3pm”***.

COP21 Target: All healthcare workers are trained in COP21 to improve their attitudes towards all PLHIV (including PLHIV returning to care after a treatment interruption), young people, key populations (including transgender people, men who have sex with men, sex workers, and people who use drugs).

COP21 Target: Fund community-led organisations to provide health rights literacy to community members to ensure as public healthcare users they understand their right to access dignified and quality healthcare services. Too often community members feel helpless, unaware of where and how to report grievances for redress and so accept the status quo as normal.

COP21 Target: Fund trained and independent Hospital Ombudsman where PLHIV can report cases of maltreatment by healthcare providers at 100% of PEPFAR supported facilities.

4.5. HIV + TB prevention, AHD and treatment literacy

By becoming as informed as possible, PLHIV are empowered to take control of their own health and sex lives. Treatment literacy improves linkage and retention rates as PLHIV understand the importance of adhering to treatment effectively. When individuals do not understand the importance of starting and staying on ART and other medications including those to prevent TB, or the importance of an undetectable viral load, the likelihood of poor adherence, high viral load, treatment fatigue and stopping treatment altogether plus morbidity and mortality increases.

Through community-led monitoring, one focus group respondent told us ***“I am feeling ok, therefore I can stop the medication”*** pointing to a lack of treatment literacy information leading to PLHIV disengaging from care. Others told us that starting HIV treatment is not taken seriously when one is ***“feeling healthy and full of life”***—

only when they become sick is medication taken seriously. One woman living with HIV at Kafukule bemoaned having lost two brothers after each one of them stopped taking treatment because after feeling better and getting well they thought they no longer needed treatment.

Of PLHIV interviewed at clinics, knowledge about viral load and viral load testing was generally low, with a range of 50% to 67% who could not explain what viral load is despite them appreciating its value on their health. Both AGYW and PLHIV explained that viral load testing is all about getting tested to know the level of HIV virus in your body. They said if the viral load is low it means your body is healthy and entails that you are adhering to medication. Importantly, in addition to understanding the impact of being undetectable on your health, it is critical and empowering for PLHIV to understand the impact of being undetectable on transmission too.

The SDS commits to “*Intensified national treatment literacy efforts: PEPFAR will work through civil society and government platforms to disseminate “Messages of Hope” to improve treatment literacy at the individual, community and national level.*” (page 4) — and the planning letter states that “*U=U messaging is integrated into the Faith and Community Initiative component of Finding Men messaging*” and “*PEPFAR Malawi is supporting national treatment literacy campaigns including funding for CSO demand creation and coordination via NAC.*”

However, more needs to be done regarding ensuring PLHIV understand U=U messaging as well as broader HIV & TB prevention and treatment literacy efforts that will improve continuity in care and viral load suppression. Whilst PEPFAR understands the value of this intervention, and PLHIV and KPs role in peer led capacity building, no additional funds are being made available. Whilst money has gone to FBOs to engage in demand creation for viral load services, more money should be given to PLHIV and KP groups where impact can easily be seen; missed by the current initiative in order to expand this demand creation amongst people outside of the religious sector.

Further, despite commendable progress in scaling up ART in Malawi, a significant number of people living with HIV continue to present late for treatment with advanced HIV disease (AHD). Individuals with AHD are at higher risk of mortality and morbidity especially if they are not started on treatment immediately. Studies have also shown that a high proportion of individuals presenting to facilities with advanced HIV and dying of HIV related complications had been previously initiated on treatment, suggesting the need for improved retention interventions¹¹. Further, according to a presentation made by the Department of HIV at the QUIN annual meeting in July 2020, in 2019 alone 11% (18,183) of PLHIV newly initiated on ART presented with AHD.

Some of the notable reasons for presenting late for treatment also observed through community-led monitoring include; faith healing, low treatment literacy, drug and alcohol abuse by people on ART, poor nutrition, as well as stigma and discrimination discouraging people from accessing HIV testing services to know their status.

Lastly, as outlined in more detail in the section on dolutegravir below, we recommend that in conjunction with meaningful inputs from PLHIV, people friendly materials and topics are developed to help people in diet and nutrition. This is based

on emerging evidence around weight gain during the rollout of DTG. These materials would then be rolled out across PEPFAR supported clinics, support groups and Community ART Clubs. We outline this in more detail in the section below.

COP21 Target: PLHIV and KP groups develop PLHIV and KP friendly community-led HIV and TB treatment and prevention literacy materials and implement country-wide capacity building training using adequate PEPFAR funding.

COP21 Target: PLHIV and KP led groups mobilise communities around U=U messaging that ensure uptake of viral load testing services, through a PEPFAR funded social mobilisation campaign.

COP21 Target: Community-led HIV and TB treatment & prevention literacy materials are distributed by PEPFAR to all support groups and ART clinics to reduce information gaps and misinformation.

COP21 Target: Health worker led health talks take place at all PEPFAR-supported health centres to provide information to patients waiting for services including (but not limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, cervical cancer screening, that ensure uptake of these services.

4.6. PLHIV identification and tracing

As noted in the SDS, COP20 will commit to “*return patients back to care through responsive measures to identify missed appointments and establish tracing outcomes within a 30-day period*” (page 33). Further the planning letter notes a success in that “*Quality client-centered patient care was also possible for greater numbers of people by expanding the availability of an electronic medical record (EMR) system to health providers across the 27 districts*” and that “*PEPFAR Malawi is using EMRS and active tracing systems for PLHIV who missed their appointments or defaulted from care to monitor morbidity and mortality outcomes.*”

However, the government circular issued on 3 April 2020 suspended all active physical tracing of PLHIV who miss appointments and/or disengage from care, relying entirely on telephone tracing instead. Healthcare workers and PLHIV interviewed through community-led monitoring both agree, this is having a negative impact on finding people and bringing them back to care.

COP21 Target: Resume community based tracing whilst observing COVID-19 prevention measures by increasing the number of expert clients by 500 and equipping them with bicycles for mobility and strengthening support groups for peer support.

11. 2021 HIV and AIDS Spectrum Estimates as presented during the COP21 National Dialogue from 4th - 5th February by DHA.



Photo: Isabel Cortthier

5. Viral load

It is critical for the long term health of PLHIV (as well as to reduce the risk of transmission) to receive and understand viral load test results in a maximum of 10 days, with subsequent follow up clinical actions for those who may be virally unsuppressed. However, despite commitments in the SDS (page 89) to ensure “100% access to... annual viral load testing and results delivered to caregiver within 4 weeks”, turnaround time of viral load results to PLHIV remains a challenge as identified in recent community-led monitoring. This problem was compounded as routine viral load monitoring was suspended in the April government circular.

The Planning Letter states that “As of Q4 FY20, OU has achieved 61% VL coverage, 92.3% viral load suppression” and commits to “Expand coverage through patient education/literacy efforts” and “Reduce TAT from 13.6 days to 10 days.”

In COP20, we know that routine viral load monitoring was affected as one of the suspended services in the April 2020 circular compounded by stockouts of the reagents due to supply chain challenges affected by COVID-19 on air transport.

According to community-led monitoring data, respondents told us that viral load test results can take a long time to be returned. A focus group with women living with HIV in Lilongwe revealed that women are told that their viral load test results will be ready on the next appointment, yet when they return, their results are still not ready. PLHIV in Mzimba North told us results came back in 3 to 4 months, and key populations in the same area pointed to longer turnaround time of on average 5 and a half months. Turnaround times were reported as even longer in Lilongwe and Zomba, as long as 6 months by focus group participants.

As a result of the long turnaround time, it is reported that PLHIV feel demotivated to return to the facility and track their viral suppression at all. One focus group participant told us that “**last time the healthcare worker told me that I should not worry if my results are not coming back, then it means that I am doing fine**”, pointing to a major challenge and misinformation—giving PLHIV the message that viral load is not important. Another highlighted the importance of getting results back saying “**I felt good and encouraged to remain on treatment when the healthcare worker informed me about the outcome of my viral load test**”.

Models such as the Kenya viral load database, show that viral load samples can be collected and returned to PLHIV within a turnaround of 10 days. The database’s remote login functionality enables facilities to log and register samples at the facility level onto the testing laboratory information management system (LIMS), monitor testing progress, view results and retrieve historical results.¹²

The current turnaround time only tells us the length of time from a viral load test to the results being delivered back to the facility—however it is critical that PEPFAR also tracks the length of time until that result is with the PLHIV, because that is what is important. In Kenya, where power outages are also common, lab technicians are able to access the database using remote logins on their phones in order to ensure an SMS is sent in time even when there is no electricity. Malawi should adopt a similar model.

COP21 Target: 100% of PLHIV on ART receiving an annual viral load test with results delivered to PLHIV in a maximum of 10 days.

COP21 Target: PEPFAR Malawi institutes a system to monitor turnaround time from viral load test to results being in hand with the PLHIV.

COP21 Target: Integration of COVID-19, TB and HIV testing to deal with the backlog of TB, EID and viral load samples at all the molecular labs.

COP21 Target: Resolve all systemic issues delaying viral load sample collection at health facilities i.e. challenges related to logging into CommCare

12. <https://www.aphl.org/aboutAPHL/publications/Documents/GH-2018Dec-Kenya-Remote-Login.pdf>

6. Prevention

6.1. Index testing

Whilst index testing has the ability to help identify individuals who may have been exposed to HIV earlier, thereby protecting their health and interrupting onward transmission of HIV, if implemented in ways that cause harm to individuals, undermine their rights to consent, privacy, safety and confidentiality, it erodes communities' trust of healthcare providers.

We welcome language in the SDS that prioritises consent, safety and confidentiality within index testing modalities.

We note in the SDS the following positive language:

- + *"Adherence to the 5Cs (consent, confidentiality, counseling, correct test results and connection to prevention/treatment) will be a key requirement to index testing modalities, in addition to, site certifications, intimate partner violence (IPV) screenings and referrals".* (page 5)
- + *"PEPFAR will work with the MoH and CSOs to establish an adverse event monitoring system and response as part of index testing implementation. Index clients who screen positive in intimate partner violence screenings will be linked to supportive post-violence care services within the district."* (page 32)
- + *"PEPFAR Malawi will work with the MoH to develop and implement a site certification to prevent IPV and adverse events associated with index testing modalities".* (page 52):

Further the planning letter prioritises the implementation of *"a new and refocused strategy to increase case finding ... specifically ensuring the expected shift from PITC to quality index testing."*

However, community-led monitoring reveals certain challenges around this modality. Firstly, we monitored a site that is not certified to conduct index testing, yet it was doing so—Kafukule Health Centre. How many others are engaging in uncertified index testing across the country? It is critical where protocols are in place to maintain the safety of index testing as a modality, such as site certification, that these are rigorously upheld.

We are also concerned that the high targets set for the index testing programme, along with expectations of high positivity rates resulting from index testing, will violate human rights, PLHIV confidentiality and put people at risk of violence. In FY19 only 9% of new cases were found through index testing, and 15% in FY20. The target for FY21 is to have 57% of new cases diagnosed through index testing—3.5 times more cases. Concurrently, there is to be a massive targeted reduction (88%) in PITC of 1.8 million fewer tests, from 67% of the testing done to just 13%. Scaling programming that carries with it such inherent risks of GBV, confidentiality, privacy, voluntarism, and informed consent and that requires very clear and thorough training for all participating HCWs and site readiness certifications is dangerous and could undermine trust in the health care system - particularly amongst key populations being forced to out themselves (by disclosing their contacts) in public health facilities and adolescent girls and young women who already face significant stigma in these facilities. How will PEPFAR Malawi ensure people's safety, confidentiality and human rights in this huge increase in targets?

In addition, it is critical that before contacting the partners of PLHIV, all healthcare providers ask if the individual's partners have ever been violent and no contacts who have ever been violent or are at risk of being violent should ever be contacted in order to protect the individual. Oftentimes, index testing proceeds once an individual agrees they are ok with it. However, whilst that individual may have extracted themselves from the violent partner, the violent partner in question may be in a new relationship, and may be being violent in that new relationship.

There is no way to be sure that such violence will not occur in the new relationship as a result of index testing. No adverse event monitoring system will ever pick up that harm thus the proper course of action is to proceed in the most conservative fashion, and not contact any partner who screens positive for violence.

Community-led monitoring has further shown the impact of index testing on key populations—in increasing stigma and discrimination. One transgender woman told us how she gave a contact for her partner for testing, only for the healthcare workers to subject her to ridicule.

Finally, where PLHIV are shown to have faced or are facing violence, it is critical that they are made aware of and referred to appropriate gender based violence case reporting and redress mechanisms. It is critical that referrals for GBV services be tracked and that there are systems in place to ensure that the sites being referred to are actually accessible to the client. There should also be tracking of the rate of clients actually taking up these referral services. However, through community-led monitoring, we found one clinic that implements index testing without being able to provide GBV services. How many more countrywide?

COP21 Target: Only certified sites carry out index testing.

COP21 Target: No index testing targets on the proportion of new diagnoses that come from index testing enforced in COP21 or the remainder of COP20.

COP21 Target: Before contacting the sexual partners of PLHIV, all healthcare providers ask if the individual's partners have ever been violent and no contacts who have ever been violent or are at risk of being violent should ever be contacted in order to protect the individual.

COP21 Target: After contacting the contacts, the healthcare providers check with the individual if they faced any violence due to contacting and refer them to intimate partner violence (IPV) services including psychosocial support if the answer is yes.

COP21 Target: Prior to (re-)implementing index testing in any facility, there are adequate IPV services with sufficient capacity available for PLHIV at the facility or by referral and all PLHIV who are screened should be offered this information. Referrals must be actively tracked to ensure those referred actually get the services they require.

COP21 Target: All implementing partners (IPs) understand (through training) that index testing is always voluntary, for both sexual contacts and children, where individuals are not required to give the names of their sexual partners or children if they don't want to, and this is explained to all PLHIV.

COP21 Target: All adverse events are monitored through a proactive adverse event monitoring system capable of identifying and providing services to individuals harmed by index testing.

COP21 Target: Index testing will not continue at the facility for any population where an IP cannot meet the above demands.



Photo: Lameck Luhanga

6.2. HIV self testing

The Planning Letter notes that the “*Exponential growth in self-testing must also be applauded.*” However, community-led monitoring data revealed that HIV self testing is not known to be available across facilities. Focus groups in Zomba with AGYW and PLHIV reported that they are unaware if Matawale Health Centre and Naisi Health Centre make HIV self testing services available. Whilst KP focus groups participants in Mzimba (Kafukule) told us that the service is not available.

Further, part of the reason why there has been that increased uptake in HIV self testing is because implementing partners

are distributing without proper targeting leading to few people reporting back to the facility for a confirmatory test. HIVST should be seen as a recruitment tool for testing.

COP21 Target: All PEPFAR supported facilities are offering HIVST in a more targeted manner. For test kits distributed in the community, PEPFAR will ensure there is proper documentation and recording of tests distributed, disaggregated by age and sex, and a follow up mechanism to ensure that all those with a reactive self-test are reporting back to the facility for a confirmatory test.



6.3. PrEP

PrEP was another service suspended in the April 2020 government circular and has had significant delays in roll out in COP19. The planning letter highlights this “significant delay in PrEP rollout for populations at high risk” in Malawi and that “while there were more clients initiated on PrEP in FY20 Q4 compared to FY20 Q2, PrEP targets were not achieved.” The target for PrEP_NEW was 6549, and 189 was reached — less than 3%.

The planning letter goes on to state that there should be a “Scale up the rollout of the evidence-based prevention intervention PrEP, including in DREAMS districts” and “National expansion of PrEP beyond the demonstration projects expected by end of FY21 and must occur. FY21 targets for PrEP ~18,080 including AGYW, PBFW, high-risk HIV negative partners and key populations.”

The planning letter outlines that “In COP 2021, PrEP should continue to be made widely available with a focus on getting PrEP, (including possible new PrEP options) to the people that need it. Groups to be prioritized for PrEP include HIV negative partners of index cases key populations including sex workers, men who have sex with men, transgender persons, people in prisons and other closed settings, people who inject drugs, adolescent girls and young women and, pregnant and breastfeeding women, in areas with high HIV incidence or with higher risk partners, and other identified serodifferent couples.”

However certain questions remain unanswered:

- + How will PEPFAR expedite the roll out plan for PrEP during COVID-19?
- + How will targets be met, when they could not be in COP19? What will be different in COP20?

Further we found through community-led monitoring that key populations, especially transgender people, are finding it difficult to access PrEP due to the strict criteria set to be eligible for initiation.

COP21 Target: PEPFAR in conjunction with GoM to share an expedited roll out plan for PrEP with a clear strategy for meeting FY22 targets.

6.4. Dapivirine Ring (DVR)

Thanks to research, two new HIV prevention tools will soon be available on the market for use. The Dapivirine Ring (DVR) which received EMA positive opinion in July 2020, has now been recommended by the World Health Organisation as an additional prevention choice for women at substantial risk. Malawi is one of the ten countries planned for initial introduction of the ring. The International Partnership for Microbicides is expected to submit a dossier for regulatory approval in Malawi in 2021, being one of the countries where clinical trials for the ring were conducted. COP21 should therefore support rapid scale up of the oral PrEP programme, addressing the gaps and challenges highlighted in the PrEP section above. COP21 should also lay out concrete steps to prepare for a broader PrEP programme. COP21 should include the technical, and where necessary financial, support for policy development and guidelines review to support:

1. Regulatory review of licensure applications for Dapivirine Ring and Long Acting Cabotegravir; and
2. Design of pilot projects and communications campaigns with active engagement of Civil Societies emphasising individual choice and not prioritising specific groups of specific strategies (i.e. on the basis of adherence requirements).

COP21 Target: Launched National Process to review regulatory dossiers for Dapivirine Vaginal Ring (DVR) and eventually, long-acting cabotegravir for prevention (CAB-LA) whilst simultaneously starting work to identify programme models, provider training needs, and civil society roles in leading, communications and programme design.

7. Dolutegravir

Last year activists globally were raising concerns regarding clinical trial results pointing to significant weight gain associated with first line dolutegravir (DTG) and Tenofovir alafenamide (TAF) usage as witnessed in the ADVANCE and NAMSAL trials. It seemed to indicate that DTG and TAF were a direct cause of weight gain amongst, predominantly, black women. Since then, increasing data has been released that now presents a different picture—although there is still considerable debate. Now, it seems that in fact, PLHIV who metabolised efavirenz more slowly developed a build up of the drug in their bodies, blunting weight gain. In addition, it seems that tenofovir disoproxil fumarate also blunts weight gain.

As these PLHIV are moving to DTG now, the gain in weight would therefore be a return to their normal weight trajectory, a result of stopping EFV. Much more still needs to be understood about this evidence, however one thing is clear, some PLHIV are putting on significant weight leading to clinical obesity and the risk of numerous non-communicable diseases (NCDs) associated with obesity.

COP21 Target: PEPFAR institutes tracking of weight gain amongst PLHIV, especially as more people transition or start on DTG. Where

problematic weight gain is identified, clinicians refer PLHIV to a dietician in order to properly support the individual. Further the PLHIV is screened for other NCDs associated with obesity.

COP21 Target: In conjunction with meaningful inputs from PLHIV, people friendly materials and topics are developed to help people in diet and nutrition, and rolled out across PEPFAR supported clinics, support groups and Community ART Clubs.

8. Comorbidities

8.1. TB Preventive Therapy

Given that PLHIV are 19 times more likely to develop active TB¹³ and that TB is the leading cause of death amongst PLHIV, TB preventive treatment (TPT) is an integral and routine part of the HIV clinical care package for all eligible PLHIV and children 5 years and younger. Unfortunately the TPT programme continues to underperform, even with scaled-up integration of HIV/TB service delivery through DSD models. Whilst PEPFAR dramatically decreased the TPT targets from 232, 282 in COP19 to 46,891 in COP20, the TPT/IPT programme only achieved a 50.53% (23,693) of the target.¹⁴ This is still a drop in the ocean compared to the number of eligible PLHIV in the country. These results are also way below the FY21 targets of 415,568 outlined in the planning letter, and Malawi's cumulative UN HLM targets for TPT being 343,050 (2018-2020 cumulative) and the country having a 89,300 target for 2021.¹⁵

Furthermore, the rollout of TPT is likely impacted by the COVID-19 pandemic, as less people are accessing HIV and TB services. According to PEPFAR Global Guidance *"In many countries, TPT initiations slowed or were delayed in the wake of COVID-19; these countries will need to implement aggressive TB "catch-up" plans in order to achieve full TPT coverage"* (pg 366).

In addition, the reality revealed through community-led monitoring is that a number of people do not adhere to IPT due

to a lack of treatment literacy on the benefits of TPT. Community members have also reported side effects of using Isoniazid Preventive Therapy (IPT) currently being offered for TPT — and there is poor clinical management of patients facing such side effects. PEPFAR COP21 Global Guidance strongly recommends that *"completion of TB treatment and TPT should be assured for those who are started through provision of psychosocial, nutritional, and adherence support, as needed"* (pg 354).

The SDS states that *"PEPFAR implementing partners will mentor health facility staff in managing adverse events arising from TB and HIV treatment and TB preventive Therapy, monitor treatment completion, and completion of the associated data as per PEPFAR requirements"* (pg 35). However, communities have reported that some PLHIV reported stopping IPT courses altogether due to the negative side effects they experience. Whilst some healthcare facilities are not initiating IPT due to shortages of Vitamin B6 supplies. Community led monitoring asked PLHIV if they were aware of TPT services. A much smaller proportion said they had been on TPT in 2020. AGYW had even less knowledge of TPT services presently or in the past. PEPFAR supports inclusion of vitamin B6 in INH-containing TPT regimens, lack of vitamin B6 has been cited by communities as a major barrier to acceptance of TPT regimens and additional local contributors. Lack of availability or delays in procurement of vitamin B6 alone should never be a reason to discontinue or prevent initiating TPT in otherwise eligible PLHIV (pg 370 of COP21 Guidance).

13. "Tuberculosis - World Health Organization." 17 Oct. 2019, <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>. Accessed 13 Feb. 2020.

14. Information available at mer.AMFAR. https://mer.amfar.org/location/Malawi/TB_PREV (Accessed 27 January 2021)

15. STOP TB Partnership, Country UN HLM on TB, TB Preventive Therapy Targets, at page 3. Available at http://www.stoptb.org/assets/documents/global/advocacy/unhlm/PTTargets_November_2019.pdf (Accessed 27 January 2021)

Given the complications people face in adhering and completing IPT-based TPT, 3HP — the newer, less toxic, shorter, and more patient friendly dual TB preventive therapy — should be the preferred regimen for the country replacing IPT. PEPFAR Malawi should work closely with the government in order to transition from lifelong IPT to 3HP. In Q4 of COP20, TPT/ 3HP was initiated in the following districts; Mzimba north, Mangochi, Chikwawa, Nsanje and Mulanje, through the IMPAAC4TB pilot project. The COP21 planning letter states that *“Five TB/HIV high burden districts are already implementing 6H and 3HP. By the end of FY21, all 28 districts are expected to have TPT rolled out.”* In accordance with the 3HP forecasting update, we understand that the Global Fund will procure close to 129,306 doses of 3HP of the Sanofi and MacLeods products, throughout Q1 and 26 789 in Q4 of 2021. The second consignment of 115,223 doses will be received through the IMPAACT4TB project between May and October 2021. Whilst this is commendable progress, these figures are still not enough to saturate those eligible, which means more PLHIV will continue to be exposed to TB and/or IPT.

Given the challenges presented by the nitrosamine impurities found in both the Sanofi and MacLeods products, there is a need for expedited initiation of 3HP. The amount of nitrosamines can sometimes increase as products sit and/ or is near the end of shelf-life. The Global Fund has been very proactive in working with the DHA, to monitor the nitrosamine levels in the batches that were distributed in Q4 of COP20. A circular was disseminated in December 2020, advising of these the impurity and installation of an early warning system, to ensure that batches coming from the medical stores to the facilities, are effectively monitored. The rolling out of 3HP (both Sanofi and McLeods products) should happen without delays or periods of keeping products at the central warehouse. This vigilance is required especially for the MacLeods fixed dose combination products, which are temperature sensitive and need to be initiated within short timeframes. To ensure effective monitoring and community-led responses throughout the TPT roll-out, it is recommended that PEPFAR implementing partners work closely with the Malawi’s community-led monitoring team to ensure effective monitoring of the supply chain of 3HP and that those working towards the HIV/TB response received resource allocation along with the other CLM teams.

If PLHIV are enrolled in a DSD programme for ART, TB treatment or TPT should also be integrated into DSD. TPT should also be dispensed in multi-month refills that align with ART refills. This is supported by the planning letter, which notes the importance that *“TB/HIV services must be integrated, including DSD and MMD models for both TB and TB preventive treatment (TPT)... TPT is considered routine HIV care, and all country programs must have offered TPT to all PLHIV on treatment by the end of COP21; targets have been set accordingly. Countries should budget for full coverage, and plan to use optimal regimens (3HP) as supply allows.”*

COP21 Target: All eligible PLHIV including children and adolescents be initiated and complete TPT within COP21, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient. Of these, at least 70% should receive 3HP and 30% should be on IPT.

COP21 Target: All contacts of PLHIV with TB, including children and adolescents, should be traced and 100% of those eligible should be initiated on TPT.

COP21 Target: TPT must be incorporated within DSD models of HIV service delivery (including Community ART Clubs).

COP21 Target: COP21 should set aside funds for refurbishing storage facilities in PEPFAR supported sites to address the issue of increasing CPNP levels in 3HP resulting from increased shelf life, humidity and high temperatures.

8.2. TB screening and testing

One key driver of excess morbidity and mortality amongst people living with HIV (PLHIV) is that symptoms of TB or other risk factors are often overlooked by clinics and healthcare workers, and that the opportunity for early TB diagnosis and treatment is missed.

In COP20, PEPFAR Malawi committed to *“intensify the implementation of the national guidelines to conduct urine LAM... in district and central hospitals”* (pg. 35), *“detect TB cases early and effectively through systematic symptomatic screening”* (pg. 35), and ensure that *“all symptomatic patients are promptly referred for TB diagnostic work-up at sites with efficient laboratory diagnostic tools such as GeneXpert and LF-LAM”* (pg. 35).

In COP21, Malawi should expand its commitment to reduce preventable morbidity and mortality amongst PLHIV and their close contacts by implementing TB screening at every clinical encounter followed by TB diagnostic testing using urine-LAM and rapid molecular testing according to WHO guidelines and algorithms. As such, Malawi should ensure that urine-LAM is universally available in all inpatient and outpatient settings where PLHIV present to care, and that rapid molecular testing for TB is available at or near the point of care for rapid turnaround times to results, with sufficient quantities of urine-LAM and rapid molecular test commodities procured.

To improve rates of TB detection amongst PLHIV in the PEPFAR programme in Malawi in COP21, clinics, hospitals, and other PEPFAR sites should universally screen PLHIV, including children living with HIV (CLHIV), at every clinical encounter for TB symptoms and other risk factors, using the WHO four-symptom screen or other WHO-recommended screening tools including chest X-ray, C-reactive protein (CRP), or rapid molecular tests (Xpert MTB/RIF Ultra or Truenat MTB Plus and MTB-RIF Dx). PEPFAR Guidance states that *“All PLHIV must be screened at every clinical encounter for TB symptoms and using available technologies consistent with international guidelines”* (pg. 354).

PEPFAR Guidance also states that *“For individuals who screen positive for TB symptoms, a WHO-recommended rapid molecular diagnostic test (e.g., Xpert MTB/RIF Ultra, Truenat MTB Plus and Truenat MTB-Rif) should be used in conjunction with LF-LAM, if appropriate,”* and that *“LF-LAM should be performed in parallel to molecular diagnostic tests”* (pg. 348-349). Clinics, hospitals, and other PEPFAR sites should ensure that both urine-LAM and rapid molecular testing is available on-site and implemented upon first presentation to care for all PLHIV, including CLHIV, with TB signs and symptoms, who are seriously ill, or who have low CD4 counts <200 cells/mm³, in both inpatient and outpatient settings. In line with WHO guidance, TB treatment should be initiated immediately following positive urine-LAM results, while awaiting confirmatory results from rapid molecular testing. Whenever an individual is believed to be at risk of or is



Photo: Isabel Corthier

diagnosed with TB, PEPFAR Malawi should ensure contact tracing is conducted amongst their household and other close contacts.

In COP21, PEPFAR Malawi should support training for healthcare workers on TB symptom screening and the use of other WHO-recommended screening tools; and on sample collection and preparation for urine-LAM and rapid molecular testing with Xpert MTB/RIF Ultra or Truenat MTB Plus and MTB-RIF Dx, including stool sample processing for CLHIV. PEPFAR Guidance states that “Where appropriate, programs should ensure WHO-recommended rapid molecular TB diagnostic testing for children is done using both sputum and non-sputum specimen types (including stool) according to the WHO policy guidance for each test type” (pg. 359). Where TB tests are inconclusive but risk factors and likelihood of TB are high, especially amongst children, PEPFAR Malawi should support clinical/empirical TB diagnosis and treatment initiation. Additionally, PEPFAR Malawi should commit to positioning rapid molecular testing platforms (GeneXpert, Trueprep/Truelab) as close as possible to the point of care at peripheral health centers in order to ensure rapid turnaround times to results and rapid linkage to appropriate TB treatment within five days of first presentation to care.

To ensure that TB screening and both urine-LAM and rapid molecular testing are being implemented in all settings where PLHIV present to care in COP21, PEPFAR Malawi should set ambitious targets for TB screening and testing amongst PLHIV. PEPFAR Guidance states that “Procurement quantities of LF-LAM should exceed the number of PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings, and sufficient budget should be allocated accordingly” (p361). The PEPFAR planning letter reiterates this, stating that “Countries should budget adequately for commodities including urinary LAM” (pg. 17). PEPFAR Malawi should allocate sufficient budget to support the procurement of commodities required for urine-LAM testing (e.g., TB LAM urine assays, urine cups, pipettes, pipette tips, timers) and rapid molecular testing (e.g., test cartridges/chips, sample cups, sample processing kits including stool processing kits for children, pipettes, and pipette tips), in quantities that each exceed 34,000, the number of PLHIV, including CLHIV, estimated to present to care at PEPFAR-

supported sites with advanced HIV disease in COP21. If a more sensitive urine-LAM assay becomes available and receives WHO endorsement during COP21, PEPFAR Malawi should support its use. PEPFAR Guidance states that “In the meantime, programs should scale-up and implement the currently available LF-LAM test” (pg. 361), Abbott’s Determine TB LAM Ag test.

COP21 Target: 100% of PLHIV, including CLHIV, are screened for TB upon presentation to care at every clinical encounter.

COP21 Target: 100% of PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings receive both urine-LAM and rapid molecular testing (including the use of stool samples among CLHIV) upon their first presentation to care.

COP21 Target: 100% of PLHIV, including CLHIV, with positive urine-LAM results immediately initiate TB treatment, while awaiting confirmatory rapid molecular test results.

COP21 Target: 100% of PLHIV, including CLHIV, who are co-infected with TB receive confirmatory diagnostic test results and are linked to TB treatment in less than five days after their first presentation to care.

COP21 Target: Procurement quantities of commodities required for urine-LAM and rapid molecular testing should each exceed 34,000, the estimated number of PLHIV, including CLHIV, expected to present to care at PEPFAR-supported sites with advanced HIV disease in COP21 (according to PEPFAR data [individuals newly testing positive for HIV] and WHO estimates that 1 in 3 PLHIV present to care with AHD).

8.3. Hypertension + diabetes

A growing number of PLHIV are also living with non-communicable diseases including hypertension and diabetes. With an increased risk of cardiovascular morbidity and mortality amongst PLHIV and the aging of ART cohorts, addressing the comorbidities of hypertension and diabetes is an essential component of a comprehensive package of care.

WHO recommends all PLHIV should be screened for cardiovascular disease risk, however this is not systematically implemented. Once diagnosed, integration of comorbidities

such as hypertension and diabetes into their DSD for HIV model should benefit both the client and health system. The PEPFAR COP21 guidance includes an important new provision to support comprehensive person-centered health services for people living with HIV and indicates a possible opportunity to support integrated services, including screening, diagnosis and treatment of hypertension and diabetes, in high-performing districts/provinces/sub-national units.

COP21 Target: Diabetes and hypertension screening and treatment is incorporated within DSD models for HIV treatment.

9. Cervical cancer

According to BMC Public Health (2016), Malawi has the highest cervical cancer incidence and mortality in the world, with an age-standardised rate (ASR) of 75.9 and 49.8 per 100,000 population respectively. The Malawi National Sexual and Reproductive Health Rights (SRHR) Policy 2017-2022 observes that women living with HIV are four to six times more likely to contract human papillomavirus (HPV) which causes cervical cancer. Yet despite these alarming figures, access to cervical cancer services amongst women living with HIV remains a huge challenge.

Community-led monitoring revealed that 1 facility did not offer cervical cancer screening, and 2 out of 8 facilities monitored did not offer any cervical cancer services including screening and treatment of pre-invasive lesions, largely due to lack of trained personnel and a shortage of equipment. Kafukule Health Centre in Mzimba offers cervical cancer screening but not treatment. Women from Kafukule are therefore referred to Mzuzu Central Hospital which is almost 60km away. Community-led monitoring further revealed that the facilities not offering cervical cancer screening usually do not because of a lack of trained personnel. Bulala Health Centre reported that cervical cancer screening has not been done since September 2020 because the trained provider left for school, whilst Naisi Health Centre does not have the space or human resources.

The SDS commits to “further improve access to cervical cancer screening and treatment services by scaling up to an additional 41 sites, bringing the number of PEPFAR supported cervical cancer sites to 80, while reaching 50% of WLHIV aged 25-49 years”. Although this is highly commendable, the gap to saturation is quite significant. In COP21 PEPFAR should scale up service well beyond the 80 facilities.

Furthermore, where cervical cancer screening is being offered, community-led monitoring has revealed a lack of integration between cervical cancer and HIV services. Integration of HIV and Cervical Cancer services has been proposed as an effective way of improving access to cervical cancer screening especially in areas of high HIV prevalence as well as lower resourced settings. Yet, in 6 Health Centres monitored—where cervical cancer services are actually being offered—cervical cancer screening is conducted on a different day to the ART clinic. This means women who attend the clinic to collect ART refills, and who are also in need of cervical cancer screening/treatment services, are asked to return to the health centre on another day for cervical cancer services.

8 Health Centres monitored reported that they do not have any trained staff to screen and treat women for cervical cancer. As a result, women are referred to different facilities to access cervical

cancer services. This adds both a burden onto women who must travel to another site at the cost of additional time and money, and at times can mean they are entirely lost in the process.

The lack of trained staff to screen and treat women for cervical cancer results in women having to be referred to different facilities to access cervical cancer services. This adds both a burden onto women who must travel to another site at the cost of additional time and money, and at times can mean they are entirely lost in the process. As a result many women do not return and are lost to follow up.

COP21 Target: 500 additional healthcare workers trained and equipped to provide cervical cancer screening and treatment services to address the existing gap.

COP21 Target: Cervical cancer screening and treatment for pre-invasive lesions is available in 130 PEPFAR supported facilities in order to reach an additional 100,000 by end September 2022.

COP21 Target: PEPFAR and Ministry of Health work hand in hand to ensure that cervical cancer services are fully integrated with HIV services. In facilities where cervical cancer screening is being offered, screening is conducted on ART Clinic day. Where gaps in HRH, infrastructure, and/or equipment exist, PEPFAR will fill those gaps.

COP21 Target: PEPFAR and Ministry of Health work hand in hand to ensure there are clear referral pathways and mechanisms in place to monitor and trace women referred to services outside the Health Centre (including where no services are offered, or for further treatment) for funding.

10. Key populations

10.1. KP Funding & targets

For the last 2 years, Malawi has benefited from funds from the Key Population Investment Fund (KPIF) that have enhanced the quality of services provided to key populations and supported a host of innovative community interventions and activities that would not ordinarily be funded by the traditional COP process. These interventions had great value in increasing the quality of services for key populations. Organisations that would not have been funded under the traditional PEPFAR process had their capacity strengthened through KPIF resources and were certified as organisations that would qualify to access PEPFAR funding. Organisations were also able to test more key populations across the constituencies and offer more KP specific services.

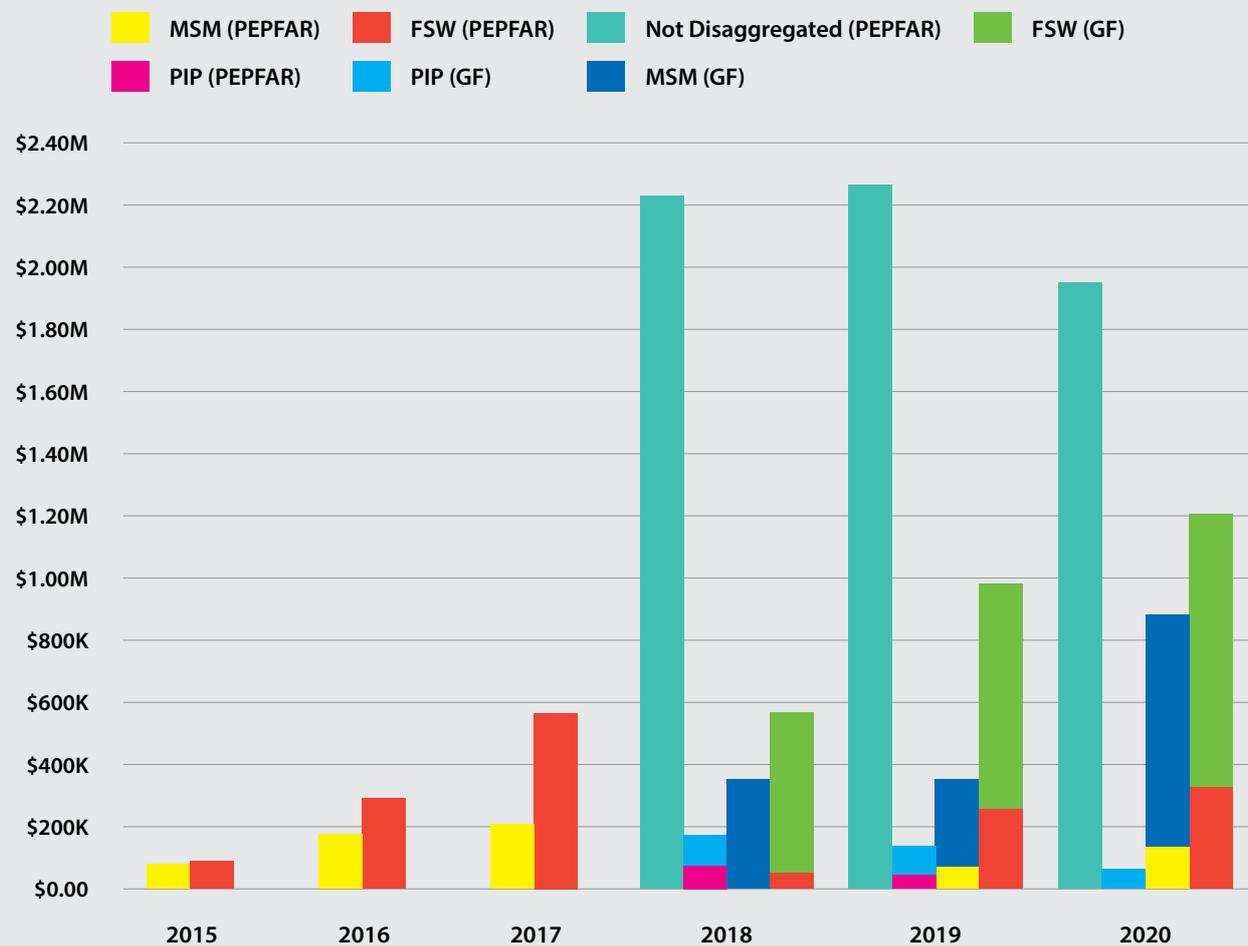
The planning letter highlights an overarching issue as “supporting key populations with prevention and treatment services”. Whilst it

praises the KPIF community programme for “demonstrating the effectiveness and resilience of peer-led KP programming efforts... that leveraged CSO-led online platforms, navigators and educators and showed an effective approach that should be scaled up”.

Given that the funding under KPIF is soon coming to an end, PEPFAR needs to provide clear written guidance on the plans to incorporate KPIF activities into the COP. Activities funded under the KPIF must be absorbed into the COP to ensure continuity of the successes in the KPIF. It is critical that there is a smooth transition, where the lessons of KPIF implementation are integrated into the COP and where funding is maintained at COP/ KPIF levels to ensure no interruption of services.

Moreover, Malawi’s KP COP funding is below the average of PEPFAR countries. In COP19, only 2.34% of COP funding was budgeted for KP programming compared with 3.82% across

PEPFAR and Global Fund KP Funding (2015-2020)
Total funding in US\$



all countries. Worse, in COP20, Malawi's COP budget for KP programming is only 0.72% of all COP funding compared to 5.29% across all countries. Malawi is dramatically under-investing in KP programming compared to other countries. For reference, 5.29% of Malawi's COP20 budget would be \$10.3 million. Based on Malawi's Planning Letter notional budget of \$175,785,000, to bring Malawi's KP funding in-line with PEPFAR overall would indicate funding levels between \$6.7 million (3.82%) and \$9.3 million (5.29%).

Further, Malawi's low or no size estimates for KPs are highly problematic and may directly be leading to low targets and underfunding and underprioritising interventions and programmes for HIV prevention and treatment that specifically target the additional vulnerabilities that KPs face. Currently there are no size estimates for transgender people or PWIDs in Malawi, other than a transgender formative study in Global Fund districts. Furthermore, the size estimates for sex workers and men who have sex with men show low percentages compared to the average in Africa and — for MSM — is far below the WHO and UNAIDS recommendation of a minimum of 1% of men aged 15-49.¹⁶

COP21 Target: PEPFAR increases the KP budget to be at least proportionally in line with other African countries (3.16% of total budget based on COP20 Budgets). From the Planning Letter Level of \$175,785,000 that would be a minimum of \$5,554,806 for KP programming.

COP21 Target: Programming is not limited by the existing/non-existent size estimates. A process is put in place to work with KP CSOs to establish the potential expansion of KP programming based on community data.

10.2. KP friendly services

One major barrier to HIV prevention and treatment services for key populations is being discriminated against at the facility. Most of the stigma and discrimination experienced by key populations is perpetrated by the police and healthcare workers. Transgender people, men who have sex with men, and sex workers in Malawi face many challenges especially in accessing healthcare services. In many cases we get reports that key populations can be referred to the police and get arrested for impersonation, and as a result fail to get treatment.

Criminalisation of LGBTIQ people, limited knowledge on SOGIE, negative perceptions, and bad attitudes of healthcare workers, all increase the barriers to accessing healthcare services for key populations. In many circumstances key populations are denied healthcare services and chased away from the hospitals. Focus group discussion with key populations highlighted the issues that many key populations face when accessing HIV, TB and other healthcare services. Participants reported that there were a lack of staff at clinics trained in KP friendly services.

COP21 Target: In collaboration with KP led organisations, review the healthcare worker curriculum and incorporate updated modules to support learning around KP issues.

COP21 Target: Funding is increased to KP led organisations to carry out regular trainings to sensitise healthcare workers at PEPFAR supported sites on provision of key population friendly services (for sex workers, people who use drugs, men who have sex with men, and transgender people).

Most recent size estimates and HIV prevalence data:

MSM		FSW		PWID		TG	
Size Estimate:		Size Estimate:		Size Estimate:		Size Estimate:	
PEPFAR	10,376 (2020)	PEPFAR	27,312 (2020)	PEPFAR	NA (NA)	PEPFAR	NA (NA)
GF	NA (NA)	GF	NA (NA)	GF	NA (NA)	GF	NA (NA)
KP Atlas	42,600 (2017)	KP Atlas	36,400 (2018)	KP Atlas	NA (NA)	KP Atlas	NA (NA)
Per Male Pop (15-49)		Per Female Pop (15-49)		Per Pop (15-49)		Per Pop (15-49)	
PEPFAR	0.24%	PEPFAR	0.6%	PEPFAR	NA%	PEPFAR	NA%
GF	NA%	GF	NA%	GF	NA%	GF	NA%
KP Atlas	1.03%	KP Atlas	0.83%	KP Atlas	NA%	KP Atlas	NA%
Comparative Regional Population Proportions		Comparative Regional Population Proportions		Comparative Regional Population Proportions		Comparative Regional Population Proportions	
Global Average	1.99%	Global Average	1.23%	Global Average	0.48%	Global Average	0.23%
Africa	0.92%	Africa	1.49%	Africa	0.22%	Africa	0.06%
Americas & Europe	3.17%	Americas & Europe	1.46%	Americas & Europe	0.76%	Americas & Europe	0.14%
Asia	1.43%	Asia	0.53%	Asia	0.45%	Asia	0.07%
HIV Prevalence:	14.0%	HIV Prevalence:	15.0%	HIV Prevalence:	NA%	HIV Prevalence:	NA%

16. WHO/UNAIDS, Recommended Population Size Estimates of Men who have Sex with Men: https://www.unaids.org/sites/default/files/media_asset/2020-recommended-population-size-estimates-of-men-who-have-sex-with-men_en.pdf

10.3. KP specific services

Community-led monitoring revealed that a limited number of facilities responded affirmatively to providing some services for key populations—with Kawale Health Centre providing extended hours ART collection for female sex workers and men who have sex with men. However, when probed further into the specifics of what services are provided, it is apparent that very few facilities provide comprehensive key population services.

Community-led monitoring highlights the need for much more to be done to ensure better access to HIV and TB services for key populations. Most facilities do not have KP friendly corner or one stop centres where key populations are able to access services. The current system of using specific trained healthcare workers as a focal point of key populations when accessing services is problematic as key populations are not able to access care in events that the person is transferred, is absent from work or has been moved to other departments. Further, interviews with peer navigators showed the benefit of peer to peer engagement at health centres on long term retention and viral suppression. One told us **“through peer counselling some KP have gone back to treatment. They are not only fit but also healthy”** and another said that **“the few clients that I am responsible for have gone back to ART. They are now able to follow all the steps”**. Within the cadre of Expert Clients to be recruited (as outlined in Section 1 of Liu Lathu), it is critical that a special allocation of this cadre is towards KP Expert Clients to support key populations.

The planning letter notes that *“Condoms are key to a successful combination HIV prevention approach and are a cost-effective tool for preventing other sexually transmitted infections and unintended pregnancies. PEPFAR’s goal is to ensure high levels of use, equitable access to, and sustained demand for condoms and lubricants among key and priority populations and low-income groups.”*

However, in all health facilities that we visited lubricant was not being provided. Further focus group discussions revealed that key populations access lubricants using parallel systems and that lubricant is not available at the hospital. Where lubricant was available one individual told us that **“there is only one type of lubricant available and so there is no choice/variety”**. Additionally, lubricants are stigmatised, though the commodity is essential to key populations but to have it attached to them makes it difficult for them to access for fear of having to come out.

COP21 Target: A minimum package of services is provided for each key population group to meet their needs, as outlined above, at all health centres and site assessment should be carried out to ensure that all facilities are equipped with the essential services to key populations.

COP21 Target: 20% of the 500 Expert Clients are recruited to support key populations specifically.

COP21 Target: Lubricant is made available at all PEPFAR supported sites, alongside male and female condoms, and is not labelled as a key population commodity. Healthcare workers are trained to have comprehensive knowledge on lubricant to avoid stigmatising key populations.

COP21 Target: Introduce 10 clinics run by KP led organisations as a pilot which are flexible to address the needs of KPs and where KPs will be able to receive comprehensive services.

SPECIFIC SERVICE PROVISION FOR SEX WORKERS, MSM AND TRANSGENDER PEOPLE:

SEX WORKERS

- + Sex worker outreach services
- + Sex worker friendly HIV testing and counseling
- + HIV care and treatment
- + Access to PrEP
- + Access to lubricant
- + Access to contraception
- + Information packages for sexual and reproductive health services
- + Sex worker friendly STI testing & treatment
- + Cervical cancer screening
- + Peer navigators

MEN WHO HAVE SEX WITH MEN

- + MSM outreach services
- + HIV care and treatment
- + MSM friendly HIV testing and counseling
- + Access to PrEP
- + Access to lubricant

- + Information packages for MSM sexual health services
- + MSM friendly STI testing & treatment
- + Peer navigators

TRANSGENDER PEOPLE

- + Transgender outreach services
- + HIV care and treatment
- + Transgender friendly HIV testing and counseling
- + Access to PrEP
- + Information packages for transgender sexual and reproductive health services
- + Transgender friendly STI testing & treatment
- + Hormone therapy
- + Peer navigators

ALL KPS

- + Peer educators/navigators at the facility level
- + Support groups to improve continuity in care
- + Access to GBV services



Photo: Lameck Luhanga

10.4. KP Support groups

Support groups linked to each health centre are critical to provide counselling and support services to people prior to testing, post testing, pre-treatment, and those struggling on treatment or re-engaging in care. This is especially true for key populations who are at higher risk of facing stigma and discrimination in this process. There continues to be a high number of key populations who

disengage from care, become “treatment fatigued”, stop ARVs, and even die. Much more needs to be done to provide counselling, psycho-social support and other mental health services to prevent this “pill fatigue” from taking place.

COP21 Target: Increase funding to KP led organisations to establish and maintain functional support groups specific for key populations linked to all PEPFAR supported sites.

11. DREAMS

Prevention of new HIV infections amongst adolescent girls and young women (AGYW) remains a critical challenge. According to the NSP, in 2019 alone AGYW accounted for 25% of all new HIV infections in Malawi. Despite considerable progress made under DREAMS and other AGYW interventions in HIV prevention and care, including the availability of counselling on HIV risk reduction, promotion of consistent condom use, and, more recently, oral pre-exposure prophylaxis (PrEP) to reduce the risk of HIV infection, coverage of DREAMS intervention remains very low.

Recent data presented at the last Joint Annual Review shows that coverage for 28% of AGYW nationally are being reached with AGYW interventions either through the Global Fund AGYW programme or the DREAMS programme. There are 1,952,000 females aged 15-24 in Malawi, representing 10% of the total population (NSP).

COP21 Target: DREAMS interventions are expanded to 50 additional facilities/SNUs as per the recommendation from COP Guidance.

COP21 Target: PEPFAR will analyse DREAMS data to determine if saturation has been achieved, that is 75% of AGYW in a given SNU has completed the appropriate package of interventions. Once SNUs achieve saturation, expansion to additional SNUs should take place (matching the number of SNUs reaching saturation). PEPFAR will include CSOs in the process.

12. Paediatric HIV

12.1. Paediatric ART optimisation

Inappropriate, suboptimal treatment options have contributed to low treatment coverage, viral load suppression and retention for infants and children living with HIV. COP21 minimum requirements recommends rapid optimisation of ART by transitioning to DTG-based regimens for children who are ≥ 4 weeks of age and who weigh ≥ 3 kg and removal of all NVP- and EFV-based ART regimens. The planning level letter also requires programmes to move forward with the introduction and broad use of paediatric DTG formulations in FY21 (COP20), with full implementation expected to occur during the first quarters of FY22 (COP21). COP21 must ensure that all eligible children are offered optimised treatment regimens. Treatment literacy led by HIV positive caregivers and other directly impacted communities also should be provided for mothers of children living with HIV and other caregivers to improve case finding, treatment adherence and retention to care.

COP21 Target: Optimisation of all eligible children to DTG based regimens, with full transition taking place no later than end of FY22 Q1.

12.2. Paediatric point of care testing

There remains a large gap in the treatment cascade with high rates of mortality for infants who are not diagnosed with HIV. Without immediate access to treatment and the comprehensive support they need to be retained in care, approximately 50% of HIV-positive children die before two years of age.¹⁷ Point of care (POC) Early Infant Diagnosis (EID) dramatically shortens the turnaround time in HIV test results being received by caregivers and increases rates of treatment initiation as well as retention in care.¹⁸ PEPFAR should also scale up proven models of peer-led community support such as mentor mothers who are paid a living wage to ensure continuous care for HIV positive children and their caregivers, as well as working with healthcare workers at the facility and communities of women living with HIV to increase early visits to the clinic, treatment and retention support for pregnant women living with HIV.

COP21 Target: POC EID is scaled up to reach all HIV exposed infants.

13. Accountability

Community-led monitoring has a critical role to play in identifying local-level problems at health centres and advocating for solutions. CLM in Malawi will systematically collect information and translate that into informed community accountability efforts that hold authorities accountable for providing high-quality HIV and TB care and support.

The planning letter agrees stating that *"community-led monitoring must raise visibility and appropriate response to the needs of populations already vulnerable before COVID"* and that *"collaboration with community groups, civil society organizations and patients/beneficiaries can help PEPFAR programs and health institutions diagnose and pinpoint persistent problems, challenges, and barriers to effective service and client outcomes at the site level."*

During 2020 the community-led monitoring project has begun to be developed in Malawi. When at scale, it will take

place across 11 districts and 55 facilities. Progress has been made in designing and testing a number of monitoring tools as well as recruiting the national project team. Technical support is being provided by Health GAP, amfAR, AVAC and the O'Neill Institute for National and Global Health Law.

COP21 Target: Funding is scaled up to \$1 million for community-led monitoring in Malawi to monitor 55 high burden sites across 11 districts Malawi.

17. Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis

18. Effect of point-of-care early infant diagnosis on... : AIDS

14. Government and Global Fund

Achieving epidemic control requires concerted efforts from PEPFAR, Global Fund and the Government of Malawi to shape the HIV response to the unique needs of different populations. The table below highlights existing gaps in funding, policy and service delivery that must be addressed by both the Global Fund and Government of Malawi to allow for a successful implementation of COP21.

ISSUE	CURRENT GAP(S)	ASK
PrEP	Despite the existing funding gap for PrEP no funding analysis has been done to highlight specific areas that need additional funding.	Government should come up with a PrEP funding gap analysis with details on specific components that require additional funding.
HIV/AIDS management act	Knowledge gap on HIV and AIDS management Act.	NAC should develop a strategy with clear timeframes for dissemination and education of communities about the new HIV and AIDS management act by end of September 2021
AGWY	Low representation of AGYW in existing decisions making governance structures at the health facility.	Government, through the Department of Community Services, should ensure that all governance structures at the facility level have an AGWY representative.
Cervical Cancer	Some facilities offer mandatory screening for cervical cancer as a pre-condition for accessing viral load and ART services by WLHIV. Community-led monitoring exercise revealed that in some facilities cervical cancer screening is mandatory.	Government should ensure that cervical cancer screening is being offered on a voluntary basis across all facilities.
Supply Chain	Weak and parallel supply chain systems leading to frequent drug stockouts and expiry of some drugs.	Global Fund should work with PEPFAR to strengthen the supply chain management and procurement system and ensure there is uninterrupted supply.
Drug and commodity stockout	Stockouts of drugs reported at (100%) of facilities visited during community-led monitoring. Drugs reported out of stock include; gentamicin, captopril, omeprazole, simvastatin, benzathine, penicillin, doxycycline. Other commodities reported out of stock include TB Lam Urine Assays, timers, urine cups and pipettes.	Global Fund should fully fund procurement of all essential drugs.

SPECIFIC LANGUAGE REQUESTED IN COP21

	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	1. Funding		
	<p>"The PEPFAR Country Operational Plan (COP 2021) notional budget for Malawi is \$175,785,000 inclusive of all new funding accounts and applied pipeline." planning letter pg. 3</p>	<p>COP21 (FY22) budget is flatlined at \$184,034,169.</p>	<p>COP21 Target: COP21 (FY22) budget is flatlined at \$184,034,169.</p>
PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	2. Expert Clients		
	<p>"PEPFAR will recruit and deploy additional HCWs and lay cadres (e.g. patient supporters/ expert clients) to reduce waiting times and address psychosocial needs." - pg. 4</p> <p>"Implementation of proven retention and adherence strategies (e.g. active defaulter tracing and adherence support through lay providers such as Expert Clients)" - pg. 32</p> <p>"As part of this intervention [case management], patient supporters, such as Expert Clients and Community Health Workers, will provide group and individual counseling, reminders for clinic appointment, as well as link clients to community care services." - pg. 34</p> <p>"Current high-level PEPFAR data show a good HRH alignment between TX_CURR and site volume in PEPFAR target sites, but granular data analysis revealed that there are inconsistencies with insufficient numbers of health diagnostic assistants (HDAs) and Expert Clients at larger sites and some smaller sites with larger numbers." - pg. 72</p> <p>"To rectify the underlying HRH issues at site level, PEPFAR investments in COP20 will optimize staffing allocation (right-size Expert Client to patient staffing ratios)" - pg. 73</p> <p>"Besides rationalization of existing HRH, PEPFAR will add more psycho-social counselors (or comparable cadres), Expert Clients, and Community Health Workers (CHWs) to support client retention in care in the high-volume sites." - pg. 73</p> <p>"Currently funding over 1,500 expert clients" and there is a "Plan to increase the number of expert clients in COP20" - pg. 92</p>	<p>In COP21, PEPFAR will recruit and deploy an additional 1,000 Expert clients, including key populations and AGYW focused Expert Clients, across PEPFAR sites to the existing 1,500 Expert Clients funded. Expert Clients will support active defaulter tracing, provide adherence support, provide group and individual counseling, reminders for clinic appointment, as well as link clients to community care services.</p>	<p>COP21 Target: Provide civil society with the current number of Expert Clients paid for by PEPFAR in COP20.</p> <p>COP21 Target: 500 additional Expert Clients are recruited and trained to support with defaulter tracing and provision of adherence services. This should include 20% KP and AGWY specific Expert Clients.</p> <p>COP21 Target: PEPFAR Implementing Partners (IPs) consult PLHIV organisations before recruiting Expert Clients in communities to ensure that the Expert Clients have come from the same geographical area.</p> <p>COP21 Target: Funding provided for the formulation of National Volunteer Guidelines for efficient management of Expert Clients by different IPs in the districts.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	3. COVID-19		
	<p>"In addition to multi-month dispensing, differentiated models to improve retention and treatment outcomes include teen clubs, male friendly clinics, pediatric clinics, and nurse-led community ART clinics (a community outreach model). Ambition Funding resources will be used to expand teen clubs for adolescents living with HIV (ALHIV) in Nsanje, Chikwawa, and Lilongwe districts." - pg. 31</p> <p>"PEPFAR will continue to support teen clubs and other youth-friendly approaches to ensure ALHIV have the support they need to stay in care and achieve durable viral suppression." - pg. 34</p> <p>"Peace Corps Volunteers and their counterparts will also support adolescents living with HIV (and their caregivers) through teen clubs that provide guidance on nutrition and well-being, life skills, ART adherence, hygiene, and psychosocial support" - pg. 40</p> <p>"COP20 will continue to prioritize and target the 9-14 age group (at least 50,000 to be reached in COP20) with age-specific evidence-based curricula with skills building components such as Families Matter!, Sinovuyo Teens, and Grassroots Soccer" - pg. 41</p>	<p>To support ART continuity and access to HIV prevention, PEPFAR will procure PPE to be distributed to all PEPFAR supported sites including N-95 respirator masks, aprons, gloves, sanitizer, and face shields for use by healthcare workers. Further PEPFAR will procure cloth reusable masks to be provided to patients without masks to be able to access health services. PEPFAR will work together with GoM to ensure that all supported sites observe COVID-19 prevention measures properly including screening, mask use, hand hygiene, and physical distancing in COP21 and the remainder of COP20. No facility will require a healthcare user to explain where in the health centre they are going or what services they are seeking on entry at the health centre during the COVID-19 screening process, to avoid discrimination and people to avoid accessing health services. PEPFAR will work with GoM to ensure that viral load testing, Teen Clubs, Support Groups, VMMC, PrEP and other HIV prevention services are resumed to support ART continuity and HIV prevention efforts.</p>	<p>COP21 Target: Cloth reusable masks have been procured and distributed to all PEPFAR supported sites to be provided to any healthcare user arriving at the facility to access services who does not have access to a mask in COP21 and the remainder of COP20.</p> <p>COP21 Target: Personal Protective Equipment (PPE) including N-95 respirator masks, aprons, gloves, sanitizer, and face shields have been procured and distributed to all PEPFAR supported health centres for use by healthcare workers, community healthcare workers, and expert clients to protect them against COVID-19, in COP21 and the remainder of COP20.</p> <p>COP21 Target: Viral load testing, Teen Clubs, Support Groups, VMMC, PrEP, and other HIV prevention services are resumed in a safe manner in COP21 and the remainder of COP20.</p> <p>COP21 Target: No healthcare user is required to explain where in the health centre they are going or what services they are seeking on entry at the health centre during the COVID-19 screening process in COP21 and the remainder of COP20.</p> <p>COP21 Target: All PEPFAR supported facilities are observing COVID-19 prevention measures properly including COVID-19 screening, mask use, hand hygiene, and physical distancing in COP21 and the remainder of COP20.</p>
	4.1 6MMD		
	<p>"PEPFAR will also support the implementation of multi-month prescriptions and the transition to 90 pills per bottles for around two-thirds stable PLHIV." - pg. 50</p> <p>"To optimize client centered care, differentiated service delivery modalities including 6MMD, pharmacy fast-tracking and nurse-led community ART clubs (see Appendix E for additional information on CACs)." - pg. 52</p> <p>"All PEPFAR supported sites will implement MMD6. Technical assistance will be provided to MOH to support differentiated service delivery models in non-PEPFAR supported facilities." - pg. 88</p>	<p>In COP21, PEPFAR will support GoM to roll out multi-month dispensing including 6 month supply to all eligible patients, whether within a DSD model or not, across Malawi.</p>	<p>COP21 Target: All stable PLHIV are able to collect a 6 month supply of ARVs by end of COP21.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	<p>4.2 Community ART Clubs (CACs)</p> <p>“To optimize client centered care, differentiated service delivery modalities including 6MMD, pharmacy fast-tracking and nurse-led community ART clubs (see Appendix E for additional information on CACs).” - pg. 52</p> <p>“Differentiated models to improve retention and treatment outcomes include teen clubs, male friendly clinics, pediatric clinics, and nurse-led community ART clinics (a community outreach model). Ambition Funding resources will be used to expand teen clubs for adolescents living with HIV (ALHIV) in Nsanje, Chikwawa, and Lilongwe districts” - pg. 31</p> <p>“PEPFAR will continue to support teen clubs and other youth-friendly approaches to ensure ALHIV have the support they need to stay in care and achieve durable viral suppression.” - pg. 34</p> <p>“PEPFAR will intensify enrollment of children and adolescents living with HIV ages 10–17 (especially those with high viral load or newly enrolled on ART) into Y+ (Youth Living Positively with HIV) support groups based in the communities and the facility based adherence clubs in COP20.” - pg. 40</p> <p>“Adoption and implementation of differentiated service delivery models for clinically stable clients that ensures choice between facility and community ART refill pick-up location and individual or group ART refill models. All models should offer patients the opportunity to get 6 months of medication at a time without requiring repeat appointments or visits.” - pg. 91</p> <p>In COP19, “By the end of COP19, PEPFAR will support implementation of community ART models in all 10 scale up districts” (COP19, pg. 53-54)</p>	<p>In order to improve ART continuity and to reduce the burden on health facilities, PEPFAR will continue to scale up implementation of functional Community ART Clubs (CACs) to ensure 50% of eligible PLHIV are accessing treatment from this model by the end COP21 (and remaining eligible are decanted to an alternative DSD model). CACs will be integrated for collection of TPT and contraceptive commodities and for screening and treatment of diabetes and hypertension in COP21.</p>	<p>COP21 Target: 50% of all eligible PLHIV are receiving their HIV treatment, care and support within functional Community ART Clubs as outlined in the Liu Lathu MuCOP21.</p> <p>COP21 Target: CACs are integrated for collection of TPT and contraceptive commodities and for screening and treatment of diabetes and hypertension.</p>
	<p>4.3 Health centre opening hours</p> <p>“In COP20, additional male-friendly integrated strategies will be implemented in major cities to promote reach with HTS, including male friendly clinics, HIVST, and extended clinic hours” pg. 31</p> <p>“Successful strategies to improve the uptake of VMMC services among older men will be scaled in COP20, including: flexible hours for services (weekends and after hours), enhancing linkage to VMMC from other services like STI and HTS clinics, using client centered demand creation approaches, and improving collaboration with private clinics.” pg. 51</p>	<p>PEPFAR will provide the staffing and other needs to support sites to extend opening hours to 5:00 -19:00 on weekdays and 8:00-16:00 on Saturdays. ART refill collection will be available on any day of the week during these extended opening hours at all PEPFAR supported sites. Whilst healthcare workers are expected to spend limited time at the facility due to COVID-19 restrictions, arrangements will be made to work in shifts.</p>	<p>COP21 Target: All PEPFAR supported health centres have extended opening hours from 5am to 7pm on weekdays and 8am to 4pm on Saturdays — and PLHIV are able to use these extended opening times to pick up their medication from internal pick up points. Whilst healthcare workers are expected to spend limited time at the facility due to COVID-19 restrictions, arrangements should be made to work in shifts.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	<p>4.4 Healthcare worker attitudes</p> <p>“As the PEPFAR program fully transitions to a direct service delivery model, key programmatic shifts will include increased investments in both professional and lay HCWs to address retention, decongest facilities, offer an increased menu of differentiated service delivery models and, create a more friendly and enabling environment for clients to interface with at site and community level.” pg. 54</p>	<p>Together with GoM, PEPFAR will ensure that all clinical and non clinical staff at PEPFAR supported sites are trained to provide a friendly and welcoming environment for all patients whether accessing HIV prevention, accessing ART, or, most especially, returning to care after a treatment interruption. Where PLHIV may have had a treatment interruption or have missed an appointment, staff will treat those returning respectfully and with compassion. Working with GoM, PEPFAR will ensure that no PLHIV will be sent to the back of the queue if they miss an appointment. Further where staff are found to reprimand clients, disciplinary measures will be taken against the relevant staff member.</p> <p>PEPFAR will fund community-led organisations to provide health rights literacy to community members to ensure as public healthcare users they understand their right to access dignified and quality healthcare services. Too often community members feel helpless, unaware of where and how to report grievances for redress and so accept the status quo as normal.</p> <p>To further support accountability efforts at local level, PEPFAR will fund an independent Hospital Ombudsman where PLHIV can report cases of maltreatment by healthcare providers at 100% of PEPFAR supported facilities.</p>	<p>COP21 Target: All healthcare workers are trained in COP21 to improve their attitudes towards all PLHIV (including PLHIV returning to care after a treatment interruption), young people, key populations (including transgender people, men who have sex with men, sex workers, and people who use drugs).</p> <p>COP21 Target: Fund community-led organisations to provide health rights literacy to community members to ensure as public healthcare users they understand their right to access dignified and quality healthcare services. Too often community members feel helpless, unaware of where and how to report grievances for redress and so accept the status quo as normal.</p> <p>COP21 Target: Fund trained and independent Hospital Ombudsman where PLHIV can report cases of maltreatment by healthcare providers at 100% of PEPFAR supported facilities.</p>

COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
4.5 HIV and TB treatment & prevention literacy		
<p>"With Malawi estimated to have achieved 93-80-92 of the 95-95-95 UNAIDS goals, the PEPFAR Malawi program will need to reach 160,000 people living with HIV (PLHIV) with antiretroviral therapy (ART), retain the over 800,000 clients currently in care with client centered services and prevent transmission through accelerated treatment literacy efforts and scale high impact prevention programs." - pg. 3</p> <p>"Intensified national treatment literacy efforts: PEPFAR will work through civil society and government platforms to disseminate "Messages of Hope" to improve treatment literacy at the individual, community and national level." - pg. 4</p> <p>"Over \$1 million will be allocated in COP20 to support community-led monitoring, treatment literacy, advocacy, and oversight efforts to ensure that recipients of care have access to client-friendly services, a feedback loop to report stigma, discrimination, and support district-level coordination efforts." - pg. 19</p> <p>\$300,000 is specifically allocated for treatment literacy - pg. 22</p> <p>"Treatment Literacy Mechanism: USAID CSO Prime</p> <p>PEPFAR Malawi will support civil society to implement education and treatment literacy efforts related to the science of HIV/TB and related medicines, treatment adherence, the importance of early treatment initiation, treatment adherence to achieve an undetectable viral load, and mental health issues. Any developed materials will need to align with MoH guidelines and will be disseminated within communities." - pg. 23</p> <p>"Treatment literacy: Through individual and group approaches, PEPFAR Malawi will ensure clients are reached with key treatment literacy messages focused on adherence" - pg. 33</p> <p>"U=U messaging is integrated into the Faith and Community Initiative component of Finding Men messaging. COP20 will include funding for national treatment literacy campaigns including funding for CSO demand creation and coordination via NAC" - pg. 90</p>	<p>In COP21, PEPFAR will fund an aggressive expansion of HIV and TB prevention and treatment literacy across all PEPFAR supported districts run by, and for, communities living with HIV and key populations. This will include a community lead component (material development and dissemination to all PEPFAR sites, adherence clubs, support groups as well as trainings, and social mobilisation campaigns at community level) and a healthcare worker component (through health talks, adherence clubs, when providing viral load test results, and in any other patient consultations). Topics will include (but not be limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, cervical cancer screening, that ensure uptake of these services. PEPFAR will fund five community led PLHIV organisations to engage with the general population and five key populations led organisations to target those groups more specifically. PLHIV and KP led groups will mobilise communities around U=U messaging that ensure uptake of viral load testing services, through a PEPFAR funded social mobilisation campaign.</p>	<p>COP21 Target: PLHIV and KP groups develop PLHIV and KP friendly community-led HIV and TB treatment and prevention literacy materials and implement country-wide capacity building training using adequate PEPFAR funding.</p> <p>COP21 Target: PLHIV and KP led groups mobilise communities around U=U messaging that ensure uptake of viral load testing services, through a PEPFAR funded social mobilisation campaign.</p> <p>COP21 Target: Community-led HIV and TB treatment & prevention literacy materials are distributed by PEPFAR to all support groups and ART clinics to reduce information gaps and misinformation.</p> <p>COP21 Target: Health worker led health talks take place at all PEPFAR-supported health centres to provide information to patients waiting for services including (but not limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, cervical cancer screening, that ensure uptake of these services.</p>
4.6 PLHIV Identification + tracing		
<p>"Use of unique IDs: PEPFAR Malawi will work the Ministry of Health to use unique IDs for the HIV program. Unique IDs will complement other retention interventions by enabling tracking of movement of patients across sites in the national program. Understanding patient movement across sites will help the program grasp the number of "true defaulters" and channel tracing efforts to those groups, as opposed to "silent transfers." - pg. 14</p> <p>"In COP19, PEPFAR Malawi is intensifying efforts to prevent missed appointments, early loss to follow up, as well as, return clients back to care." - pg. 30</p> <p>Figure 4.2.3 presents a Stratified Approach to Case Management to Improve Early Retention, including a package for facilities with a 13% risk for 6 month LTFU, 20% risk and 30% risk. - pg. 32</p> <p>"This will include ensuring the use of National IDs as unique identifiers to track patient movements and outcomes, including mortality, to better quantify default, loss to follow up, and the current cohort on ART." - pg. 70</p>	<p>PEPFAR will resume and intensify efforts to prevent missed appointments, early loss to follow up, as well as, return clients back to care including through Expert Clients who will be formally paid, trained, capacitated, and equipped with communications equipment and reliable transportation needed to be effective.</p>	<p>COP21 Target: Resume community-based tracing whilst observing COVID-19 prevention measures by increasing the number of expert clients by 500 and equipping them with bicycles for mobility and strengthening support groups for peer support.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	5. Viral load		
	<p>"Another major achievement in FY19 was the reduction in [VL] turnaround times from 21 days in FY19 Q1 to 13 days by FY20 Q1 (from sample collection to dispatch from the molecular lab), as shown in Figure 4.9.2." - pg. 64</p> <p>"In FY19 going into FY20, sample transportations optimization will continue. A pull system using SDS phone messaging will reduce unnecessary trips by couriers improving the efficiency of results return, per Figure 4.9.3. The Bill and Melinda Gates Foundation has committed to funding a SMS results alter pilot in Malawi in 2020 which will be sustained, improving turnaround time and empowering PLHIV to know and receive their viral loads in a timely manner." - pg. 65</p> <p>"Completion of Diagnostic Network Optimization activities for VL/EID, TB, and other coinfections, and ongoing monitoring to ensure reductions in morbidity and mortality across age, sex, and risk groups, including 100% access to EID and annual viral load testing and results delivered to caregiver within 4 weeks." - pg. 89</p> <p>"Commitment from BMGF to develop SMS results alerts to further reduce TAT</p> <ul style="list-style-type: none"> + Monitor VL counseling and concerns from PLHIV through CSO monitoring and hotline + Institute VL/EID POC at sites for sample tracking and patient communication" - pg. 92 	<p>PEPFAR will ensure 100% of PLHIV on ART access viral load testing in COP21. The program will work with GoM to ensure that transportation of viral load samples take a maximum of 10 days between sample collection to return the results to the client.</p>	<p>COP21 Target: 100% of PLHIV on ART receiving an annual viral load test with results delivered to PLHIV in a maximum of 10 days.</p> <p>COP21 Target: PEPFAR Malawi institutes a system to monitor turnaround time from viral load test to results being in hand with the PLHIV.</p> <p>COP21 Target: Integration of COVID-19, TB and HIV testing to deal with the backlog of TB, EID and viral load samples at all the molecular labs.</p> <p>COP21 Target: Resolve all systemic issues delaying viral load sample collection at health facilities i.e. challenges related to logging into CommCare.</p>

COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
<p>6.1 Index testing</p>		
<p>“Adherence to the 5Cs (consent, confidentiality, counseling, correct test results and connection to prevention/treatment) will be a key requirement to index testing modalities, in addition to, site certifications, intimate partner violence (IPV) screenings and referrals” pg. 5</p> <p>“Active index testing has been rolled out in all sites in scale-up districts while expansion to high volume sites in sustained districts is currently underway. All facilities implementing index testing will be reassessed after certification criteria are established to ensure compliance with the 5Cs, effective 29 Page adverse event monitoring, and adequate training. Remediation plans will be put in place for sites that do not meet criteria until they are able to meet certification standards.” pg 28</p> <p>“PEPFAR will work with the MoH and CSOs to establish an adverse event monitoring system and response as part of index testing implementation. Index clients who screen positive in intimate partner violence screenings will be linked to supportive post-violence care services within the district.” pg. 32</p> <p>“Malawi will work with the MoH to develop and implement a site certification to prevent IPV and adverse events associated with index testing modalities while ensuring implementing partners and providers are both familiar and trained on the 5Cs.” pg. 52</p>	<p>PEPFAR will not enforce index testing targets in COP21 and index testing targets as a percent of all new HIV positive diagnoses will not be communicated to implementing partners.</p> <p>All sites will undergo a certification process, and no sites will implement index testing without certification. Implementing partners will fully comply in screening all clients for a risk of violence before contacting partners. No contacts who have ever been violent or are at risk of being violent will ever be contacted in order to protect the individual and other partners the contact may have that are unknown. Further, index testing is always voluntary, for both partners and children, and this is explained to all PLHIV. Post contacting the contacts, healthcare providers will follow-up with the individual after a reasonable period to assess whether there were any adverse events—including but not limited to violence—and refer them to the IPV services if the answer is yes. If no IPV services are available either at the facility or by referral, index testing will not be (re-) implemented. All referrals will be actively tracked to ensure individuals access them and referral sites have adequate capacity to provide services to the individual. All adverse events are monitored through a proactive adverse event monitoring system capable of identifying and providing services to individuals harmed by index testing. Comment boxes and other passive systems are necessary but inadequate. Index testing will not continue at the facility for any population where an IP cannot meet these demands.</p>	<p>COP21 Target: Only certified sites carry out index testing.</p> <p>COP21 Target: No index testing targets on the proportion of new diagnoses that come from index testing enforced in COP21 or the remainder of COP20.</p> <p>COP21 Target: Before contacting the sexual partners of PLHIV, all healthcare providers ask if the individual's partners have ever been violent and no contacts who have ever been violent or are at risk of being violent should ever be contacted in order to protect the individual.</p> <p>COP21 Target: After contacting the contacts, the healthcare providers check with the individual if they faced any violence due to contacting and refer them to intimate partner violence (IPV) services including psychosocial support if the answer is yes.</p> <p>COP21 Target: Prior to (re-) implementing index testing in any facility, there are adequate IPV services with sufficient capacity available for PLHIV at the facility or by referral and all PLHIV who are screened should be offered this information. Referrals must be actively tracked to ensure those referred actually get the services they require.</p> <p>COP21 Target: All implementing partners (IPs) understand (through training) that index testing is always voluntary, for both sexual contacts and children, where individuals are not required to give the names of their sexual partners or children if they don't want to, and this is explained to all PLHIV.</p> <p>COP21 Target: All adverse events are monitored through a proactive adverse event monitoring system capable of identifying and providing services to individuals harmed by index testing.</p> <p>COP21 Target: Index testing will not continue at the facility for any population where an IP cannot meet the above demands.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	<p>6.2 HIV Self-testing</p> <p>“HIV testing services at the site level will become more streamlined through the consolidation of provider-initiated testing counseling (PITC) testing points, expansion of HIV self-testing (HIVST), continued validation of screening tools, and task-shifting of HDAs to identify high risk clients and reduce over testing.” - pg. 5</p> <p>“Mapping and social networking approaches will be scaled to reach untested key populations while strengthening the continuum of care for KP living with HIV to include orientation for health workers, law enforcement, and communities to address stigma and discrimination, and institutional strengthening of KP-led networks.” - pg. 19</p> <p>“HIV prevention programs will prioritize HIVST distribution as its primary modality for HIV testing.” - pg. 29</p> <p>“Assisted HIVST distribution will be promoted in DREAMS, KP, and VMMC programs.” - pg. 29</p> <p>“Self-testing blends well in the social network strategy aimed at reaching MSM in particular.” pg. 46</p>	<p>In COP21, PEPFAR supported facilities will offer HIVST in a more targeted manner to those in need (e.g. key populations, AGYW, men etc). For test kits distributed in the community, PEPFAR document and record tests distributed — disaggregated by age and sex — and establish a follow up mechanism to ensure that all those with a reactive self test are reporting back to the facility for a confirmatory test.</p>	<p>COP21 Target: All PEPFAR supported facilities are offering HIVST in a more targeted manner. For test kits distributed in the community, PEPFAR will ensure there is proper documentation and recording of tests distributed, disaggregated by age and sex, and a follow up mechanism to ensure that all those with a reactive self-test are reporting back to the facility for a confirmatory test.</p>
	<p>6.3 PrEP</p> <p>“PEPFAR Malawi will also increase access and demand for Pre-Exposure Prophylaxis (PrEP) which will be provided to 16,000 new clients including AGYW, pregnant and breastfeeding women, sero-discordant couples, and KP.” - pg. 4-5</p> <p>“The roll-out plan will include investments in multi-level communications that promote PrEP messages validated by civil society” - pg. 35</p> <p>“In COP20, PEPFAR Malawi aims to reach 4,493 DREAMS AGYW with PrEP.” - pg. 36</p> <p>“Findings from the PrEP pilot conducted among AGYW in Lilongwe demonstrate high uptake and retention across a six-month period and lessons learned from this pilot will inform the implementation and outreach strategy. Community and facility partners will work together to improve awareness, generate demand, and facilitate PrEP screening and initiation for those who are eligible.” - pg. 36-37</p> <p>“Partners will also engage peer educators and DREAMS Ambassadors to build awareness of and generate demand for PrEP” - pg. 37</p> <p>“Direct and immediate assessment for and offer of prevention services, including pre-exposure prophylaxis (PrEP), to HIV-negative clients found through testing in populations at elevated risk of HIV acquisition (PBFW and AGYW in high HIV-burden areas, high-risk HIV-negative partners of index cases, key populations and adult men engaged in high-risk sex practices” - pg. 89</p> <p>“Implementation and reach will increase from 8 to 11 Districts (Balaka, Blantyre, Chikwawa, Chiradzulu, Lilongwe, Machinga, Mangochi, Mulanje, Mwanza, Mzimba, Phalombe, Thyolo and Zomba) reaching over 16,000 clients.” - pg. 89</p> <p>COP20 expresses targets of 21,362 for PREP_NEW, and 14,006 for PREP_CURR, disaggregated by key population - pg. 56-61</p>	<p>PEPFAR will develop a PrEP rollout plan to ensure vigorous promotion of PrEP to meet PrEP targets in FY22. Key priorities will include integration of PrEP into mainstream health services provision, orientation of facility staff, demand creation, training, capacity building and mentorship, and data capture, monitoring, and reporting. Community sensitization to reduce myths and misconceptions around PrEP and to increase demand among all eligible populations will also be enhanced.</p>	<p>COP21 Target: PEPFAR in conjunction with GoM to share an expedited roll out plan for PrEP with a clear strategy for meeting FY22 targets.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	6.4 Dapivirine Vaginal Ring		
	No mention	PEPFAR will launch a National Process to review regulatory dossiers for Dapivirine Vaginal Ring (DVR) and eventually, long-acting cabotegravir for prevention (CAB-LA) while simultaneously starting work to identify programme models, provider training needs, and civil society roles in leading, communications and programme design.	COP21 Target: Launched National Process to review regulatory dossiers for Dapivirine Vaginal Ring (DVR) and eventually, long-acting cabotegravir for prevention (CAB-LA) while simultaneously starting work to identify programme models, provider training needs, and civil society roles in leading, communications and programme design.
	7. Dolutegravir		
		A greater focus will be placed upon ensuring that all PLHIV are offered TLD within the context of informed choice and are provided with all the information before transition. PEPFAR will institute tracking of weight gain amongst PLHIV. Where problematic weight gain is identified, clinicians will refer the PLHIV to a dietician in order to properly support the individual, further the PLHIV will be screened for other NCDs associated with obesity. In conjunction with meaningful inputs from PLHIV, people friendly materials and topics will be developed to help people in diet and nutrition, to be rolled out across PEPFAR supported clinics, CACs and support groups.	COP21 Target: PEPFAR institutes tracking of weight gain amongst PLHIV, especially as more people transition or start on DTG. Where problematic weight gain is identified, clinicians refer PLHIV to a dietician in order to properly support the individual. Further the PLHIV is screened for other NCDs associated with obesity. COP21 Target: In conjunction with meaningful inputs from PLHIV, people friendly materials and topics are developed to help people in diet and nutrition, and rolled out across PEPFAR supported clinics, support groups and Community ART Clubs.
	8.1 TB Preventive Therapy (TPT)		
	<p>“Scale-up of TB Preventive Therapy using the MoH preferred TB Preventive Regimen of 3HP when it is available in-country” - pg. 32</p> <p>“Strengthened M&E through a TPT dedicated register, including adverse event tracking” - pg. 32</p> <p>“Prevent TB among PLHIV: optimize TPT and IC practices</p> <ul style="list-style-type: none"> - Scale-up TPT nationwide - Optimize TPT for pregnant women, CLHIV, u5C contacts, prisoners - Strengthened M&E through a TPT dedicated register, including adverse event tracking” - pg. 33 <p>“Five districts already implementing 6H (six-month INH). TPT commodities are expected to be delivered in June (IPT) and July (3HP). Relocation of excess IPT from the five initial districts is underway. Scale up will be intensified as soon as commodities are available. All 28 districts will be rolling out TPT mostly 3HP in COP20” - pg. 88</p> <p>“All eligible PLHIV, including children, should complete TB preventive treatment (TPT) by end of COP20, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient.” - pg. 88</p>	Implementing partners will be expected to scale up TB preventive therapy to reach 89,300 PLHIV including children and adolescents — of these, at least 70% should receive 3HP and 30% should be on IPT. All contacts of PLHIV with TB, including children and adolescents, should be traced and all those eligible will be initiated on TPT. TPT will be incorporated within DSD models of HIV service delivery, even with IPT/TPT. Where indicated, cotrimoxazole will be fully integrated into the HIV clinical care package at no cost to the patient.	<p>COP21 Target: All eligible PLHIV including children and adolescents be initiated and complete TPT within COP21, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient. Of these, at least 70% should receive 3HP and 30% should be on IPT.</p> <p>COP21 Target: All contacts of PLHIV with TB, including children and adolescents, should be traced and 100% of those eligible should be initiated on TPT.</p> <p>COP21 Target: TPT must be incorporated within DSD models of HIV service delivery (including Community ART Clubs).</p> <p>COP21 Target: COP21 should set aside funds for refurbishing storage facilities in PEPFAR supported sites to address the issue of increasing CPNP levels in 3HP resulting from increased shelf life, humidity and high temperatures.</p>

COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
8.2 TB screening and testing:		
<p>"In COP20, PEPFAR Malawi will build on FY20 interventions to intensify the implementation of the national guidelines to conduct urine LAM and cryptococcal antigen screening in district and central hospitals (currently not available universally) to patients with advanced HIV (i.e. CD4 < 200, WHO Stage III/IV, "seriously ill" patients). In smaller health centers, access to these services will depend on a functional referral system to district hospitals and of other referral facilities that have the required diagnostic and treatment capacities." - pg. 35</p> <p>"TB/HIV: PEPFAR implementing partners will implement a three-pronged TB strategy at site level aiming to: detect TB cases early and effectively through systematic symptomatic screening using a dedicated cadre; optimize TB/HIV care by ensuring all symptomatic patients are promptly referred for TB diagnostic work-up at sites with efficient laboratory diagnostic tools such as GeneXpert and LF-LAM, with those diagnosed with TB or HIV initiated on appropriate treatment regimens; and scale-up of TB Preventive Therapy using the MoH preferred TB Preventive Regimen of 3HP when it is available in-country." - pg. 35</p> <p>"Malawi has a total of 92 GeneXpert Machines with 48 available for EID and VL testing at sites eligible for TB/HIV integration (with integrated testing beginning in FY20). National policies are already in place to decentralize EID and targeted VL testing at the district level utilizing GeneXpert. Currently, POC EID is only being done at selected high-volume facilities including central hospitals. As the National TB program moves towards the WHO recommendation of using GeneXpert as the primary test for all presumptive TB patients, an increase in TB testing is expected." - pg. 68</p> <p>"All PLHIV must be routinely screened for TB and have access to molecular diagnostic testing and/or point of care tests such as LF-LAM." - pg. 16 planning letter</p> <p>"The advanced disease package of care should be fully integrated into clinical care and includes diagnostics and therapeutics for tuberculosis and cryptococcal meningitis as well as cotrimoxazole. Countries should budget adequately for commodities including urinary LAM, CrAg, amphotericin B and flucytosine. Please see section 6.5.2 of the COP guidance." - pg. 17 planning letter</p>	<p>In COP21, PEPFAR Malawi will build on FY20 interventions to intensify the implementation of the national guidelines to conduct urine LAM and cryptococcal antigen screening in all inpatient and outpatient settings where PLHIV present to care to patients with TB signs and symptoms or advanced HIV (i.e. CD4 < 200, WHO Stage III/IV, "seriously ill" patients), and ensure immediate TB treatment initiation following positive LAM results while awaiting confirmatory rapid molecular test results. In all health centers, access to these services will be made universally available.</p> <p>TB/HIV: PEPFAR implementing partners will implement a three-pronged TB strategy at site level aiming to: detect TB cases early and effectively through systematic screening at every clinical encounter using WHO-recommended screening tools and algorithms, and using a dedicated cadre; optimize TB/HIV care by ensuring all symptomatic patients immediately receive both LF-LAM testing and rapid molecular testing with GeneXpert or Truenat, including the use of stool samples among children living with HIV, with those diagnosed with TB or HIV initiated on appropriate treatment regimens in less than five days of first presentation to care; and scale-up of TB Preventive Therapy using the MoH preferred TB Preventive Regimen of 3HP when it is available in-country."</p> <p>Malawi has a total of 92 GeneXpert Machines with 48 available for EID and VL testing at sites eligible for TB/HIV integration (with integrated testing beginning in FY20). National policies are already in place to decentralize EID and targeted VL testing at the district level utilizing GeneXpert. Currently, POC EID is only being done at selected high-volume facilities including central hospitals. As the National TB program moves towards the WHO recommendation of using GeneXpert or Truenat as the primary test for all presumptive TB patients, an increase in TB testing is expected, and Malawi will ensure that GeneXpert or Truenat testing is available at or near the point of care for rapid turnaround times for results.</p> <p>PEPFAR Malawi will fully scale-up and roll-out both TB-LAM (accessible as a POC test at primary facilities in both inpatient and outpatient settings) and GeneXpert/Truenat in quantities that each exceed 34,000, the estimated number of PLHIV, including CLHIV, expected to present to care at PEPFAR-supported sites with advanced HIV disease in COP21.</p>	<p>COP21 Target: 100% of PLHIV, including CLHIV, are screened for TB upon presentation to care at every clinical encounter.</p> <p>COP21 Target: 100% of PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings receive both urine-LAM and rapid molecular testing (including the use of stool samples among CLHIV) upon their first presentation to care.</p> <p>COP21 Target: 100% of PLHIV, including CLHIV, with positive urine-LAM results immediately initiate TB treatment, while awaiting confirmatory rapid molecular test results.</p> <p>COP21 Target: 100% of PLHIV, including CLHIV, who are co-infected with TB receive confirmatory diagnostic test results and are linked to TB treatment in less than five days after their first presentation to care.</p> <p>COP21 Target: Procurement quantities of commodities required for urine-LAM and rapid molecular testing should each exceed 34,000, the estimated number of PLHIV, including CLHIV, expected to present to care at PEPFAR-supported sites with advanced HIV disease in COP21 (according to PEPFAR data [individuals newly testing positive for HIV] and WHO estimates that 1 in 3 PLHIV present to care with AHD).</p>
8.3 Hypertension + Diabetes		
<p>No mention in SDS</p>	<p>Diabetes and hypertension screening and treatment is incorporated within DSD models for HIV treatment.</p>	<p>COP21 Target: Diabetes and hypertension screening and treatment is incorporated within DSD models for HIV treatment.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	<p>9. Cervical cancer</p> <p>“PEPFAR Malawi implemented cervical cancer screening and treatment for pre-cancerous lesions for WLHIV in FY19 at 39 high-volume ART facilities and reached 39,235 women with screen and treat (representing 92% achievement of the FY19 target of 42,827).” - pg. 63</p> <p>“In FY20 Q1, Malawi’s cervical cancer program continued its strong performance with an achievement of 25% of the annual CXCA_SCRN target (101,507 WLHIV).” - pg. 50</p> <p>“PEPFAR will continue working with the MoH to introduce LEEP services to all district hospitals (secondary referral level), strengthening referral networks for WLHIV in need of LEEP and specialized care for those presumed to have cervical cancer. In COP20, PEPFAR Malawi will further improve access to cervical cancer screen and treat services by scaling up to an additional 41 sites, bringing the number of PEPFAR supported cervical cancer sites to 80, while reaching 50% of WLHIV aged 25-49 years. PEPFAR aims to screen 103,650 WLHIV in COP20 from the 80 designated facilities.” - pg. 63</p> <p>“PEPFAR Malawi strengthened service delivery through in-service training of providers and deploying at least one cervical cancer lead per site to coordinate screening and treatment services.” - pg. 63</p> <p>“PEPFAR will expand cervical cancer screening in 41 additional sites, for a total of 80 facilities in 24 districts” - pg. 93</p>	<p>PEPFAR will support the HRH, infrastructure and equipment needs to ensure cervical cancer screening and treatment for pre-invasive lesions at 130 PEPFAR supported sites in order to reach an additional 100,000 by end September 2022. 1,500 additional healthcare workers will be trained and equipped to provide cervical cancer services to address the existing gap. PEPFAR and GoM will work hand in hand to ensure that cervical cancer services are fully integrated with HIV services. In facilities where cervical cancer screening is being offered, screening is conducted on ART Clinic day. Clear referral pathways and monitoring mechanisms will be put in place to trace women referred to services outside the Health Centre (including where no services are offered, or for further treatment).</p>	<p>COP21 Target: 500 additional healthcare workers trained and equipped to provide cervical cancer screening and treatment services to address the existing gap.</p> <p>COP21 Target: Cervical cancer screening and treatment for pre-invasive lesions is available in 130 PEPFAR supported facilities in order to reach an additional 100,000 by end September 2022.</p> <p>COP21 Target: PEPFAR and Ministry of Health work hand in hand to ensure that cervical cancer services are fully integrated with HIV services. In facilities where cervical cancer screening is being offered, screening is conducted on ART Clinic day. Where gaps in HRH, infrastructure, and/or equipment exist, PEPFAR will fill those gaps.</p> <p>COP21 Target: PEPFAR and Ministry of Health work hand in hand to ensure there are clear referral pathways and mechanisms in place to monitor and trace women referred to services outside the Health Centre (including where no services are offered, or for further treatment) for funding.</p>
	<p>10.1 KP funding + targets</p> <p>“The timely introduction of Key Population Investment Funds (KPIF) in COP19 has been a great resource for capacity building of these KP-led organizations and enabled them to provide comprehensive prevention and treatment services to KP in two additional districts: Phalombe and Balaka. The Diversity Forum is a KP-led organization coordination structure which ensures that there are coordinated efforts in the KP programming with PEPFAR, the Global Fund, UNAIDS, MoH, NAC, and all other relevant stakeholders. PEPFAR consults with the Diversity Forum and will aim for quarterly meetings in COP20 to improve quality services for KP, including indicator performance, especially in testing strategies, ART adherence, treatment as prevention, and tracking of mobile FSW wherever they may be. High-level stakeholder engagement continues to improve with increased dialogue at national, district, and local levels” pg. 48</p> <p>Total KP_PREV target for FY21 is 55,831 - pg. 53-55</p>	<p>In COP21, PEPFAR will integrate the lessons of KPIF implementation into how COP funding is allocated and programmed. KP programming will not be limited by the existing/non-existent size estimates. A process will be put in place to work with KP CSOs to establish the potential expansion of KP programming based on community data.</p>	<p>COP21 Target: PEPFAR increases the KP budget to be at least proportionally in line with other African countries (3.16% of total budget based on COP20 Budgets). From the Planning Letter Level of \$175,785,000 that would be a minimum of \$5,554,806 for KP programming.</p> <p>COP21 Target: Programming is not limited by the existing/non-existent size estimates. A process is put in place to work with KP CSOs to establish the potential expansion of KP programming based on community data.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	10.2 KP friendly services		
	<p>“Mapping and social networking approaches will be scaled to reach untested key populations while strengthening the continuum of care for KP living with HIV to include orientation for health workers, law enforcement, and communities to address stigma and discrimination, and institutional strengthening of KP-led networks.” - pg. 5</p> <p>“Key approaches include well-trained health care workers to provide KP-friendly and sensitive clinical services, KP lay personnel (peer educators and HIV positive peer navigators), and direct service delivery to beneficiaries.” - pg. 45</p> <p>“Provision of HCW KP sensitive trainings will continue in COP20 to ensure the existence of KP friendly facilities. HCW trainings are key to PEPFAR’s 5As KP program model of implementing KP centered and focused program.” - pg. 47</p>	<p>The program will fund and coordinate with KP communities to review the current HCW curriculum and offer HCW sensitization training (including clinical and non clinical staff) at all PEPFAR supported sites to expand behavioral and biomedical understanding of key populations at facilities, ensuring the provision of friendly and dignified integrated KP services.</p>	<p>COP21 Target: In collaboration with KP led organisations, review the healthcare worker curriculum and incorporate updated modules to support learning around KP issues.</p> <p>COP21 Target: Funding is increased to KP led organisations to carry out regular trainings to sensitise healthcare workers at PEPFAR supported sites on provision of key population friendly services (for sex workers, people who use drugs, men who have sex with men, and transgender people).</p>
	10.3 KP specific services		
	<p>“To complement retention efforts, COP20 will expand implementation of high impact prevention interventions targeting men, key populations (KP) including men who have sex with men (MSM), female sex workers (FSW), male sex workers (MSW), transgender persons, and adolescent girls and young women (AGYW).” - pg. 4</p> <p>“Peer-led activities increase self and community efficacy to adopt healthy behaviors and access services addressing the continuum of care for HIV positive individuals. Through direct, referrals, or service-providing centers, the comprehensive KP package will include: condoms/lubricant, quarterly HIV testing, STI screening and treatment, family planning, cervical cancer screening and treatment services, TB, PMTCT, and post-GBV services treatment and care. PEPFAR will continue to provide these services through the KP platform including targeted HTS, condoms, and prevention messages to clients of FSW.” - pg. 45</p> <p>COP mentions it will “address leakages in the clinical cascade” for key populations - pg. 46</p> <p>“Well-trained and trusted peers will reach MSM, male sex workers and transgender people with expanded services” - pg. 46</p>	<p>The PEPFAR-supported KP program provides a comprehensive package of biomedical and behavioral services for prevention, diagnosis, and treatment of HIV, TB, sexually transmitted diseases, sexual and reproductive health, as well as all other services outlined in the Liu Lathu MuCOP21. KP led clinics and drop in centres are established in all PEPFAR supported key populations districts.</p> <p>As in Section 1: In COP21, PEPFAR will recruit and deploy an additional 1,000 Expert clients, including key populations and AGYW focused Expert Clients, across PEPFAR sites to the existing 1,500 Expert Clients funded. Expert Clients will support active defaulter tracing, provide adherence support, provide group and individual counseling, reminders for clinic appointment, as well as link clients to community care services.</p>	<p>COP21 Target: A minimum package of services is provided for each key population group to meet their needs, as outlined above, at all health centres and site assessment should be carried out to ensure that all facilities are equipped with the essential services to key populations.</p> <p>COP21 Target: 20% of the 500 Expert Clients are recruited to support key populations specifically.</p> <p>COP21 Target: Lubricant is made available at all PEPFAR supported sites, alongside male and female condoms, and is not labelled as a key population commodity. Healthcare workers are trained to have comprehensive knowledge on lubricant to avoid stigmatising key populations.</p> <p>COP21 Target: Introduce 10 clinics run by KP led organisations as a pilot which are flexible to address the needs of KPs and where KPs will be able to receive comprehensive services.</p>
	10.4 KP support groups		
	<p>No mention in SDS.</p>	<p>The PEPFAR team will scale up KP-led support groups in PEPFAR supported sites and ensure that newly diagnosed KPs, KPs returning to care, or KPs struggling with adherence are provided with the option to be linked to these support groups.</p>	<p>COP21 Target: Increase funding to KP led organisations to establish and maintain functional support groups specific for key populations linked to all PEPFAR supported sites.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	11. DREAMS		
	<p>"In COP20, HIV primary prevention will guide efforts to ensure that individuals facing a substantially higher risk for HIV infections are reached with PrEP, VMMC, OVC, KP and DREAMS programs and services in high burden SNU" pg. 37</p> <p>"Data from the 2019 World AIDS Day modeling highlights that all DREAMS districts in Malawi have demonstrated a >30% reduction in new diagnoses among AGYW between 2015-2019, with an over 40% decline observed in Blantyre. Ensuring AGYW receive a full prevention package based on their unique needs and vulnerabilities is key to reaching and maintaining epidemic control." pg 38</p> <p>"In COP20, the DREAMS budget has been increased from \$8.5 million to \$20 million to expand and saturate interventions, hire DREAMS Ambassadors, further develop the DREAMS database to monitor layering of services, and to address implementation challenges in the three districts (Blantyre, Machinga, and Zomba) where DREAMS is currently being implemented." pg. 89</p>	<p>PEPFAR will expand DREAMS interventions to 50 additional facilities/SNUs in COP21. PEPFAR will analyse DREAMS data to determine if saturation has been achieved (75% of AGYW in a given SNU has completed the appropriate package of interventions). Once SNUs achieve saturation, expansion to additional SNUs should take place (matching the number of SNUs reaching saturation). PEPFAR will include CSOs in this process.</p>	<p>COP21 Target: DREAMS interventions are expanded to 50 additional facilities/SNUs as per the recommendation from COP Guidance.</p> <p>COP21 Target: PEPFAR will analyse DREAMS data to determine if saturation has been achieved, that is 75% of AGYW in a given SNU has completed the appropriate package of interventions. Once SNUs achieve saturation, expansion to additional SNUs should take place (matching the number of SNUs reaching saturation). PEPFAR will include CSOs in the process.</p>
	12.1 Paediatric ART optimisation		
	<p>"ART optimization: PEPFAR Malawi will build upon COP19 successes in ARV optimization to ensure adult and pediatric clients have access to the most efficacious regimens in line with national guidelines. Over 75% of the ART cohort is on tenofovir/lamivudine/dolutegravir (TLD), though 57% of children were still on a nonnucleoside reverse transcriptase inhibitors (NNRTI) as of February 2020. These optimized ARVs will contribute to better viral suppression, especially among CLHIV. Clinicians will be mentored and supervised to ensure compliance with national guidelines. The transition to optimal ARVs will be supported through training and mentorship of providers, deployment of clinical staff, and close monitoring of progress and timely resolution of issues." pg. 36</p> <p>"PEPFAR will support implementation for pediatric ART optimization as recommended by WHO and will support the country to optimally use Global Fund resources to ensure a seamless transition and availability of HIV/AIDS commodities." pg. 53</p>	<p>COP21 will ensure that all eligible children are offered optimised treatment regimens through rapid transition to DTG based regimen for all infants and children who are ≥ 4 weeks of age and who weigh ≥ 3 kg and remove all NVP- and EFV-based ART regimens. Treatment literacy led by HIV positive caregivers and other directly impacted communities will be funded by PEPFAR to be provided for mothers of children living with HIV and other caregivers to improve case finding, treatment adherence and retention to care.</p>	<p>COP21 Target: Optimisation of all eligible children to DTG based regimens, with full transition taking place no later than end of FY22 Q1.</p>
	12.2 Paediatric point of care testing		
	<p>"Timely transmission of viral load/early infant diagnosis (EID) results: PEPFAR Malawi will collaborate with the Bill and Melinda Gates Foundation to establish an electronic results transmission system for viral load and EID results. This system will transmit an alert with the availability of results from labs directly to sites and clients simultaneously. Timely receipt of viral load and EID results by providers and clients will assist appropriate actions to be taken immediately in the event of a high viral load or positive EID result." pg. 14</p> <p>"Global Fund proposed investments for the next funding cycle will cover ARV, lab, point of care and EID commodities, programming for AGYW, sexual and reproductive health service integration, STI drugs and essential medicines, in addition to, systems strengthening investments which will compliment PEPFAR COP20 activities" pg. 19</p>	<p>COP21 will support and fast track funds to implementing partners to ensure a sufficient early infant diagnosis point of care diagnostic program.</p>	<p>COP21 Target: POC EID is scaled up to reach all HIV exposed infants.</p>

PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS • PRIORITY INTERVENTIONS	COP20, PLANNING LETTER & MER DATA	LANGUAGE TO INCLUDE IN COP21	TARGET
	<p>13. Community-led monitoring</p> <p>“PEPFAR will also directly fund civil society organizations to conduct community-led monitoring of HIV services with the intent of identifying and addressing challenges clients face in accessing care.” - pg. 4</p> <p>“Community-led monitoring: PEPFAR will provide funding to civil society organizations (CSOs) for community-led monitoring of the national HIV/AIDS response in line with national and PEPFAR strategic priorities. PEPFAR Malawi will work with CSOs to establish effective feedback mechanisms that enable timely resolution of problems and/or broader application of good practices.” - pg. 14</p> <p>“Over \$1 million will be allocated in COP20 to support community-led monitoring, treatment literacy, advocacy, and oversight efforts to ensure that recipients of care have access to client-friendly services, a feedback loop to report stigma, discrimination, and support district-level coordination efforts.” - pg. 19</p> <p>\$725,000 is allocated to: COP20 CSO Community-led Monitoring Mechanism: UNAIDS PEPFAR will provide funding to CSOs for community-led monitoring of the HIV/AIDS response in 11 PEPFAR scale-up districts. In line with the national and PEPFAR strategic priorities, monitoring of client-centered care at the site- and community-levels will be central to this effort. CSOs will analyze and collect quantitative and qualitative data about HIV services with a focus in getting input from recipients of care. PEPFAR Malawi will work with CSOs to establish effective feedback mechanisms that enable timely resolution of problems and/or broader application of good practices.” - pg. 22</p> <p>“PEPFAR Malawi will work with CSOs to establish effective feedback mechanisms that enable timely resolution of problems and/or broader application of good practices.” - pg. 22</p> <p>“In COP20, PEPFAR Malawi will fund CSOs for community-led monitoring to help PEPFAR to diagnose and pinpoint persistent problems and barriers to effective services and client outcomes at the site level.” - pg. 85</p>	<p>PEPFAR will continue to directly fund civil society organizations to conduct community-led monitoring of HIV services with the intent of identifying and addressing challenges clients face in accessing care.</p>	<p>COP21 Target: Funding is scaled up to \$1 million for community-led monitoring in Malawi to monitor 55 high burden sites across 11 districts Malawi.</p>

