LIU LATHU MU COP20 OUR VOICE MALAWI

COMMUNITY PRIORITIES

PEPFAR COUNTRY OPERATIONAL PLAN 2020

INTRODUCTION

About 1,070,896 people are currently living with HIV in Malawi—with a prevalence rate of 9.2% amongst adults (15–49 years)1. Although progress has been made towards the 90-90-90 targets, only 818,446 (76%) of people living with HIV (PLHIV) have access to ARVs. This means nearly a quarter of PLHIV have no access to lifesaving treatment. We commend the 120% (88% achievement in 2019) increase in the number of viral load tests in Q4 but would still like to note that the overall viral load testing is low. The program needs to provide a viral load test for every person living with HIV on treatment. Lost to follow up rates are high due to lack of accessibility of healthcare services, poor attitudes and lack of information from healthcare workers, and challenges with psycho-social and other support. In 2018, 13,000 people died of AIDS related illnesses—and a further 38 000 acquired HIV. Malawi has a significant TB/HIV co-infection rate. 48% of people with TB also have HIV. 16% of individuals newly initiated on ART start treatment with advanced HIV disease.

PEPFAR's own data from FY19 Q3 and Q4 shows challenges in:

+ **Slow pace of scale up of multi month dispensing**. Whilst the policy direction was approved in March 2019, Q3 results shows that between Q1 and Q3, the number of facilities offering 6-month refills only increased from 0 to 23 out of the largest facilities with TX_CURR of 179,145 representing 22% of 810,245 PLHIV on ART nationally (MOH quarterly report).
+ **Poor viral load suppression**: Of those not virally suppressed, 21% are unaware of their status, 50% are aware and not on ART, and 28% are on ART and not virally suppressed. The data shows the suppression rates to even be much lower amongst children.

These recommendations were developed by people living with HIV, the Civil Society Advocacy Forum (CSAF) and other health activists through analysis of FY19 and FY20 data, community focus groups as well as community-led monitoring in January 2020 to 12 PEPFAR-supported facilities in 3 high burden districts namely: Chitera Health Centre, Chimwawa Health Centre, Malavi Health Centre, Namadzi Health Centre in Chiradzulu, Kapire Health Centre, Monkey bay Health Centre, Nangalamu Health Centre, Makanjira Health Centre in Mangochi and Manyamula Health Centre, Khosolo Health Centre, Ehehleni Health Centre, Chikangawa Health Centre in Mzimba North. This monitoring aimed to assess the quality of HIV and TB service delivery and hear from PLHIV about the challenges they face in getting access to and staying on treatment.

1. UNAIDS. Malawi. https://www.unaids.org/en/regionscountries/countries/malawi. Accessed 11 Feb. 2020.

PRIORITY INTERVENTIONS FOR COP20

1. Increase funding for human resources for health by funding an additional 1,500 Expert Clients, 50 Lab Assistants, 50 Community Health Nurses and incentivise 800 Sputum Collectors.

With an overall vacancy rate of 48% in public facilities and 51% in CHAM facilities, the lack of adequate, committed, qualified, motivated, and equally distributed health workforce remains a significant challenge to the provision of essential and quality HIV and TB services in the country to achieve 95-95-95.[2]

Community-led monitoring in January 2020 revealed the impact of the lack of sufficient human resources for health on the delivery of HIV and TB services across different facilities. Data was captured from both the perspective of healthcare providers and healthcare users. In 9 out of the 14 facilities visited, understaffing emerged as one of the major challenges affecting the delivery of services. For example at Nangalamu Health Centre in rural Mangochi, staff indicated a shortage of 2 Medical Assistants, 2 Community Healthcare Workers, 2 HDAs, 2 Security Guards, 1 Nurse, 1 Ground Worker and 1 Hospital Attendant.

Shortages of staff were also highlighted as a major contributing factor leading to long waiting hours and congestion at facilities. Waiting times varied across facilities depending on the severity of the shortage, with some facilities registering 7 hours of waiting time — as explained by one of the participants interviewed at Monkey Bay Community Hospital who stated: "I have been at the facility since 7am in the morning. Now it is 2pm and I still haven't been served".

Shortages of staff also contribute to compromised quality of services, when it was revealed that at times certain tasks are carried out by untrained professionals. For instance at Chimwawa Health Centre in Chiradzulu a ground worker was assisting with HIV and Malaria testing (laboratory work).

Due to a shortage of Expert Clients as well as a lack of tools, resources and motivation for them to perform their work, most facilities are experiencing an increase in the number of PLHIV who are lost to follow up. During community monitoring we found that 8 out of the 14 facilities visited had recorded increased numbers of PLHIV lost to follow up by the end of December 2019. For example, Manyamula Health Centre in Mzimba recorded 162 PLHIV lost to follow up out of 606 on treatment at the site, whilst Nangalamu Health Centre in Mangochi recorded about 330 PLHIV lost to follow up against 1073 on treatment at the site.

TB case finding has also been negatively impacted by shortage of HRH. Almost all facilities visited had a shortage of Sputum Collectors. In Manyamula Mzimba, only 3 Sputum Collection points were functioning with only 8 out of the 30 trained Sputum Collectors active largely due to lack of incentives and other materials to carry out their work. This has resulted in an increased turnaround time for diagnostic results, where in some instances people never receive results at all.

Civil society organisations in Malawi acknowledge PEPFAR's support towards training and recruiting additional healthcare workers, with 13,066 healthcare workers supported in COP18, and an additional 550 healthcare workers committed in COP19[3]. However, the current figures are still inadequate to implement quality targeted HIV service delivery. COP20 must therefore fund additional healthcare workers to fill the gaps highlighted above.

COP20 must fund 1,500 Expert Clients to support tracing of HIV and TB clients who have been lost to follow up—prioritising sites with recurrent high rates of lost to follow up. COP20 must also fund 50 Community Health Nurses to support the expansion and maintenance of the Community Adherence Clubs committed in COP19. In order to increase and improve active TB case finding, COP20 must incentivise 800 Sputum Collectors across the 11 districts and provide them with training to administer rapid urine-LAM tests to PLHIV with signs and symptoms of TB or who are seriously ill to improve rates of TB diagnosis among PLHIV and to bring TB screening and diagnosis closer to the point of care. COP20 must also fund 50 Lab Assistants to support HIV case finding and viral load access.

2. PEPFAR. 2019. Malawi Country Operational Plan 2019 Strategic Direction. Accessed 11th February 2020 https://www.state.gov/wp-content/uploads/2019/09/Malawi_COP19-Strategic-Directional-Summary_public.pdf. Accessed 11 Feb. 2020.
3. PEPFAR. 2019. Malawi Country Operational Plan 2019 Strategic Direction. Accessed 11th February, 2020https://www.state.gov/wp-content/uploads/2019/09/Malawi_COP19-Strategic-Directional-Summary_public.pdf

Photos: Isabel Corthier

2. Improve linkage and retention rates by expanding access to Community Adherence Clubs, establishing a welcoming environment for PLHIV in and returning to care, and financing a widespread treatment literacy programme.

2a. Maintain Community ART with Community Adherence Clubs as established in COP19 and expand to ensure at least 50% of eligible PLHIV access services through this differentiated service delivery model.

Communities commend PEPFAR's commitment in COP19 to support the establishment of Community Adherence Clubs (CACs). Adherence clubs are a client centered approach to HIV services which provides PLHIV access to ARVs outside of their local health centre, thus reducing the need to travel long distances to collect their medications. Adherence Clubs also provide important opportunities for PLHIV to get much-needed treatment literacy information and support to remain adherent to their treatment. Not only do the clubs promote better adherence but they also relieve the burden on health facilities that are already stretched to capacity.

Whilst there are clear benefits for PLHIV in participating in Community Adherence Clubs, community-led monitoring revealed that many PLHIV have limited access to these clubs and continue to travel long distances to access their ARVs. The lack of Community Adherence Clubs to support eligible PLHIV was reported as a key reason for increased lost to follow up numbers. In Khonsolo, Mzimba, PLHIV on average travel for as many as 28km, usually by foot, to get to the facility. In almost all the facilities visited, PLHIV reported that it usually takes more than 2 hours on average before one gets assisted by a healthcare worker, sometimes taking the whole day at the facility. In Monkey Bay, one interviewee reported that she had arrived at the facility at 7am and had yet to be assisted by 2pm—a 7 hour wait at the time of interview. At both Ndamera Health Centre and Nsanje District Hospital, PLHIV indicated that they would prefer to access ART through Community Adherence Clubs due to long distances and long waiting times.

By end COP19, PEPFAR committed to "support implementation of community ART models in all 11 scale up districts. The model will use the PEPFAR COP18 and COP19 funded Community Health Nurses (CHNs) and Health Surveillance Assistants (HSAs) to distribute ART once every six months at select sites".

However it is still unclear what exactly is meant by "select sites". How many sites in total will be part of this model—and how many PLHIV will be decanted? In COP20 PEPFAR must go further to support increased staffing, transportation and other needs to ensure that at least 50% of eligible/stable PLHIV are able to collect their ARVs through Community Adherence Clubs.

COP20 should maintain existing Community Adherence Clubs as established in COP19 and expand this model to ensure at least 50% of eligible PLHIV are decanted in this differentiated service delivery model—with other eligible/stable PLHIV decanted to other DSD models. This should include recruitment of additional staff to support the expansion.

2b. Establish a welcoming environment for PLHIV in and returning to care by addressing poor healthcare worker attitudes.

During community-led monitoring, there were multiple reports of poor staff attitude across several facilities especially towards PLHIV, youth, men and key populations. These groups report challenges with getting tested for HIV as well as treatment initiation and retention due to stigma and discrimination from unfriendly staff. Further, we heard that PLHIV who miss appointments and/or stop taking their treatment can be treated badly by health workers when they return into care. In Nsanje young female sex workers reported being denied access to condoms and being treated badly by healthcare workers. This fear of being mistreated and/or reprimanded discourages people from returning to the health centre in the first place and/or going back to the facility to seek help and restart their treatment if they stop.

Whilst the SDS 2019 references the need for "Back to Care" services, there is limited focus on addressing poor healthcare worker attitudes which continues to be a barrier towards people's continued uptake of services. We note five ways to address this challenge and its impact on retention:

Firstly, the programme should utilise Expert Clients to act as a bridge between clinicians and clients (as outlined in COP19).

Secondly, all health workers should also be trained to change staff attitudes towards PLHIV (including men, youth and key populations) as well as towards PLHIV upon return after treatment interruption, providing individualised counseling to clients, and referring people to optionally join support groups.

Thirdly, PEPFAR should support the revamping (those that are not functioning) and strengthening of existing Health Centre Management Committees (HCMC) by providing financial support to ensure that these committees meet monthly, have a community representative, and that all members understand their roles and responsibilities. Functional HCMCs should timely address each individual complaint made by a healthcare user when accessing services at health facilities. PEPFAR should work with community-led groups in order to develop this programme.

Fourthly, PEPFAR should 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 we speak to community members who have lost hope and have accepted the status quo of people being treated poorly.

Lastly, PEPFAR should fund the establishment and implementation of a community run hotline that community members can call, SMS, whatsapp, or send a please call me, to report cases of poor health worker attitude. The hotline should be advertised through the health literacy campaign, dissemination of posters and other communication tools at facility and community level. Cases reported will be documented and reported to both the DHA and PEPFAR on a regular basis for a rapid response. This mechanism, together with the others highlighted above will empower service beneficiaries to report cases of poor health worker attitude.

In addition to addressing health worker attitudes, tracking and identifying clients (using the EMRS system) provision of a psychosocial package of support and a medical package of care will be critical, given that many clients returning into care may do so with low CD4 counts, and AIDS related co-infections such as TB. These medical interventions will be outlined in Section 5.

COP20 must ensure that healthcare providers are trained to provide friendly services to PLHIV (including key and marginalised populations). COP20 should track if PLHIV returning to care are treated with dignity and respect as they return into care. Further, COP20 should assist in strengthening accountability measures including the functionality of Health Centre Management Committees—and rolling out a community-led programme of health rights literacy and watchdogging through a nationwide hotline. COP20 should also fund an independent Hospital Ombudsman where PLHIV can report cases of maltreatment by healthcare providers.

2c. Fund widespread community and peer led prevention and treatment literacy efforts.

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, treatment fatigue and stopping treatment altogether increases. Community-led monitoring at Ndamera Health Centre and Nsanje District Hospital both reported that treatment fatigue is contributing to a worsening of lost to follow up rates.

Achieving 95% viral load suppression amongst PLHIV on treatment and national roll out of TPT will therefore require getting more people to understand why they need to start and stay on treatment. In addition, it will require a client proper understanding of why they are switching regimens and the interpretation of viral load results. The limited time the few health workers spend with clients impact on the access to quality, up-to-date information by clients not part of a support group structure.

Despite existing support group regular meetings across the country, these lack to up to date and accurate treatment literacy information leads to treatment information gaps for their members. Support group facilitators are yet to be oriented on the latest developments and information such as the shift to the DTG based regimen, annual viral load testing and its importance, PrEP and other issues. This gap in information is a major missed opportunity given the thousands of PLHIVs accessing information through over 2500 support groups across the country.

Whilst dolutegravir (DTG) is set to become the backbone of Malawi's HIV programme, there is limited information being provided during the transition. Dolutegravir offers many important clinical benefits to PLHIV, however, evidence from new studies shows that first-line DTG is associated with rises in body weight for PLHIV, especially amongst women and that it also causes obesity in men and women. PLHIV must therefore be informed about the pros and cons of switching to or starting on a dolutegravir-based regimen through targeted social mobilisation campaigns and health talks on treatment literacy.

In COP19 PEPFAR Malawi loosely committed to improve retention and viral load suppression rates through the rollout of DTG and annual viral load testing, "coupled with treatment literacy messaging through existing and emerging platforms". There are no further mentions of treatment literacy education in the final SDS, despite requests in Liu Lathu Mu COP19 for adequate financing for an expansion of this critical intervention.

In addition, key elements of the T=T campaign have yet to take off. Currently information being provided by healthcare workers on viral load is not comprehensive. PLHIV are often times not given adequate information on what it means to have unsuppressed or undetectable viral loads and how that can be fixed or maintained. The messaging in the original T=T campaign only emphasises increased health outcomes—"better health"—leaving out the critical element of reducing new HIV infections (undetectable=untransmittable). Community-led monitoring revealed that PLHIV interpret an undetectable viral load as being "cured", due to inadequate counselling offered leading to them stopping ARVs altogether.

COP20 must financially and otherwise support efforts to design and implement a widespread quality community-led treatment literacy programme that complements and supports the provider initiated counselling services by funding at least 15 community and PLHIV lead organisations across the country in Malawi to:

i. Design and develop accurate, informative, accessible and easily understandable prevention and treatment literacy materials 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 — PEPFAR should then ensure the dissemination of these materials to all PEPFAR supported health facilities;
iii. Implement a country-wide training of trainers programme to improve treatment literacy levels in the general population and amongst key and marginalised populations through trainings in the community as well as localised social mobilisation campaigns at a community level in all PEPFAR supported districts;
iv. Disseminate all materials amongst support groups to reduce information gaps and ensure they are able to provide the most up to date, accurate and relevant treatment literacy information especially with regard treatment regimen changes and the importance of maintaining an undetectable viral — in addition to providing training where necessary;
v. Run subsequent trainings and health talks at facility level to provide information to patients waiting for services as well as healthcare providers.

In addition, PEPFAR should work with DHA to ensure the inclusion of prevention and treatment literacy topics in the training and scope of work of all healthcare workers, including (but not limited to): nurses, community nurses, expert clients, peer navigators, and outreach workers.

Photo: Isabel Corthier

3. COP20 must ensure that all PLHIV receive an annual viral load test and receive test results within a maximum of 15 days.

Despite Malawi's recent shift to annual viral load testing, turnaround time of viral load results to clients remains a challenge. Yet it is critical for clients' long term health and risk of transmission of the virus to receive and understand these results in a timely manner with subsequent follow up clinical actions for those unsuppressed.

Currently it can take more than two months for PLHIV to receive results. In some cases, such as in Mangochi, viral load samples are sent to Mangochi DHO with results taking as long as three months to be returned, and sometimes they are reported as never coming back to the facility at all. During community monitoring, missing viral load samples where results are never returned to the facility were reported in all 14 facilities that were visited. 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.

Further in all facilities visited it was observed that Intensive Adherence Counselling is only carried out by implementing partners. This is a missed opportunity for government healthcare workers to build capacity in this area.

Models such as the Kenya viral load system, show that viral load samples can be collected and returned to PLHIV within 9 days. The PEPFAR Malawi programme should adopt similar systems that include a viral dashboard that allows clinicians to be able to see viral load results in real time as they are uploaded to the dashboard, and receive a text message from the lab with the results in areas without access to the internet.

In COP20 PEPFAR should support effective annual viral load testing by:

i. Supporting the transport and other costs to ensure a rapid turnaround of viral load results within 15 days of a test being taken — and ensure that no results are lost in this process.
ii. Ensuring that all results returned to facilities are logged and relayed to PLHIV within 15 days of an initial viral load test. To add HRH and space where necessary to carry out this function.
iii. Ensuring all results are properly explained to PLHIV including the benefit of a suppressed viral load on long term health and transmission of HIV through sexual intercourse ("undetectable=untransmittable") — including through ensuring that all healthcare providers have the knowledge to provide this information.

Photos: Isabel Corthier

4. Fund local level community and PLHIV led groups to monitor the state of service provision at PEPFAR supported sites & escalate issues of poor performance.

Community-led monitoring carried out by Civil Society Advocacy Forum (CSAF) members at PEPFAR supported sites in 2019 and 2020 highlights a range of challenges that detrimentally impact on people's ability to access HIV & TB prevention, treatment and care services. These include: long waiting times, long distances to facilities, poor staff attitudes, shortages of healthcare workers, lack of treatment and adherence information provisions, discrimination and stigma against PLHIV, men, AGYW, and KPs, and stockouts and/or shortages of diagnostics and treatment, just to mention a few.

Data collected has been utilised to formulate community recommendations for the 2019 and 2020 PEPFAR Country Operational Plans as well as highlight where challenges in the PEPFAR programme exist. This has covered both the general population of PLHIV as well as key populations and other marginalised groups. However, to date due to limited resources and capacity, community monitoring efforts have so far been carried out annually as an exercise to find out the key challenges ahead of COP reviews. A more systematic and regular collection of data would allow us to highlight challenges, make recommendations to facilities, district health offices, DHA and PEPFAR in real time, and monitor the implementation of these recommendations to ensure accountability and subsequent improvement in quality of HIV service delivery.

In COP20 Global Guidance PEPFAR states that *"In COP20 all PEPFAR programs are required to develop and support and fund a community led monitoring platform in close collaboration with independent civil society organizations and host country governments."*

COP20 must set aside resources to ensure that community-led monitoring can be more consistently rolled out and maintained and that issues identified can be addressed and resolved in a timely and satisfactory manner. In Malawi, we propose a system of community-led monitoring using community treatment observatories in the following manner:

+ Consistent quarterly monitoring of selected PEPFAR supported facilities to collect robust data using standardised observational, patient/PLHIV, and healthcare worker surveys.
+ Ad hoc fact-finding missions to assess the state of other facilities less consistently monitored where issues are brought to our attention that need follow up.
+ Surveys to monitor the quality of HIV and TB service provision at the facility, waiting times, staffing complements and shortages, staff attitudes, stockouts & shortages of health technologies (including diagnostics, treatments, and prevention methods), facility cleanliness and the state of infrastructure, TB infection control at the facility, as well as other key issues related to HIV and TB.
+ Monitoring results to be collated, cleaned, coded and published in a simple data dashboard for tracking the state of service delivery.
+ Monitoring results to be linked to a model of accelerated response from the facility, district health offices, DHA, PEPFAR and implementing partners to address issues outlined. Widespread and repeating issues to be presented at national level meetings in order to attempt to generate systemic solutions.

To fully implement the above an amount of US$1 million will be required. Specifically the resources will cover trainings, staffing, field data collection visits, communication, data analysis and documentation, and other costs to allow HIV led community groups to carry out the monitoring at site level, document and upload results, and escalate any issues at facility, district, national level as well as with donors and other programme implementers on a quarterly basis.

COP20 should allocate US$1 million to fund local level community and PLHIV led groups to quarterly monitor the state of service provision at PEPFAR supported sites in all districts & escalate issues including (but not limited to) poor performance, poor quality of services, poor health worker attitudes, health and rights violations, and stockouts and/or shortages of diagnostics and treatment. The results of monitoring must be linked to a model of accelerated response from DHA, PEPFAR and implementing partners to address the issues identified in order to ensure they are rapidly rectified. Widespread or repeating issues identified should be discussed at national level in order to attempt to generate systemic solutions.

5. Expand access to critical prevention and diagnostic tools and treatments to lower morbidity and AIDS related deaths amongst PLHIV.

The WHO estimates that in Malawi there were 33,000 people with TB in 2018 — with Malawi being in the top 20 countries with the highest TB/HIV burden globally[4]. In COP19 PEPFAR outlines that *"National program data shows that approximately 16% of new ART clients start treatment are either in WHO stage three or four. PLHIV with advanced HIV have a higher likelihood of opportunistic infections and early mortality, especially due to TB co-infection."*

PEPFAR has made clear commitments in COP19 around scaling up access to TB LAM in all district and central hospitals, supporting with the rollout of 60,000 courses of 3HP, and by deploying lay cadres to provide more systematic screening for TB and increase contact tracing of contacts of PLHIV with TB. However, much more needs to be done and a number of challenges remain.

5a. Support scale up of TB preventive therapy to all people living with HIV and initiate access to 3HP for 40% of PLHIV eligible for TPT.

Given that PLHIV are 19 times more likely to develop active TB[5] 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. Whilst PEPFAR has increased TPT targets to 46,896 in COP20 from 28,948 in COP19 — this is still a drop in the ocean compared to the number of eligible PLHIV in the country. In addition, the reality revealed through community-led monitoring is that a number of people suffer 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. Some PLHIV reported stopping IPT courses altogether due to the negative side effects they experience.

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. We understand that about 120,000 non-Fixed Dose Combination packs and 240,000 Fixed Dose Combination packs of 3HP are expected in the country by May 2020 and in Q3 2020 respectively. We are also aware that the 3HP implementation study will start rolling out in May this year in 5 districts. 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. PEPFAR should therefore come up with an ambitious target commensurate with the existing gap. COP20 should increase the 3HP target from 28,948 to 100,000. According to the planning letter *"only about 250,000 of nearly 1.1 million PLHIV have received TB preventive therapy, due to restriction of TPT policy to 5 of 28 districts".*

COP20 should scale up access to TPT for all eligible PLHIV and close contacts of people with TB including those in prisons settings which have very high rates of latent TB (preliminary data shows over 65% in Chichiri in Blantyre). PEPFAR must start transitioning those eligible for TPT and initiate at least 60% of PLHIV on 3HP, pending adequate global supply of rifapentine. TPT and, in particular 3HP, must be incorporated within DSD models of HIV service delivery (including Community Adherence Clubs) and 3HP scale-up should be linked. All contacts of PLHIV with TB should be traced and 100% of those eligible should be initiated on TPT. COP20 must further scale up TPT coverage to all PEPFAR districts.

5b. Scale-up systematic TB screening across all PEPFAR sites

Whilst PEPFAR has committed to scaling up TB screening, community-led monitoring in January revealed that rates of screening remain low. This is a major missed opportunity to find TB cases. One key driver of TB is people with symptoms being missed and remaining undiagnosed.

In COP20, all PEPFAR supported Health Centres should routinely and universally screen people for TB upon arrival at the facility. People with symptoms should be referred for testing with both urine-LAM and Xpert MTB/RIF Ultra, and separated from other people waiting at the facility to avoid further transmission. Tissues and masks should be provided to people coughing.

5c. Improve TB testing amongst PLHIV by supporting better placement of GeneXpert and urine-LAM tests and training for health workers at all PEPFAR funded sites

The urine-LAM test is the only test available that can rapidly and easily diagnose active TB in people living with HIV/AIDS, and the only TB test shown to reduce deaths.[6] Using urine-LAM and Xpert MTB/RIF Ultra testing together increases the overall diagnostic yield and the chance of detecting TB amongst PLHIV, compared to the individual use of either

4. WHO Global TB report 2019. Available at: https://apps.who.int/iris/bitstream/handle/10665/329368/9789241565714-eng.pdf
5. "Tuberculosis - World Health Organization." 17 Oct. 2019, https://www.who.int/news-room/fact-sheets/detail/tuberculosis. Accessed 13 Feb. 2020.
6. Peter JG, Ziejenah LS, Chanda D, et al. Effect on mortality of point-of-care, urine-based lipoarabinomannan testing to guide tuberculosis treatment initiation in HIV-positive hospital inpatients: a pragmatic, parallel-group, multicountry, open-label, randomised controlled trial. Lancet [Internet]. 2016 Mar 19 (cited 2020 Jan 22);387(10024):1187–97. Available from: https://doi.org/10.1016/S0140-6736(15)01092-2.

test.[7] PEPFAR Malawi should make urine-LAM and Xpert MTB/RIF Ultra testing available in all settings where PLHIV present for care, including both inpatient and outpatient settings.

PEPFAR Malawi should support training in the use of urine-LAM including sensitisation of healthcare workers on the utility of urine-LAM and its place in the TB diagnostic algorithm, in accordance with the latest evidence and PEPFAR COP Guidance. Task sharing should be considered as the test is easy enough to be conducted by nurses, and should be deployed as close to the point of care as possible. PEPFAR should also support training and equipment necessary to obtain specimen samples for urine-LAM and Xpert MTB/RIF Ultra testing and culture from children and from adults, including those with possible extrapulmonary TB.

COP20 must make urine-LAM and Xpert MTB/RIF Ultra testing available in all settings where PLHIV present for care, including both inpatient and outpatient settings. PEPFAR Malawi should use urine-LAM and Xpert MTB/RIF Ultra together as first line to diagnose all PLHIV with signs and symptoms of TB, who are seriously ill, or who have advanced HIV disease in both inpatient and outpatient settings. Where tests are inconclusive, especially in children, PEPFAR Malawi should support clinical/empirical TB diagnosis and treatment initiation.

5d. Support TB diagnostics procurement and placement to improve detection at all PEPFAR funded sites.

To expand TB diagnoses and reduce TB-related morbidity and mortality amongst PLHIV, PEPFAR Malawi should ensure adequate budget is appropriated to support the procurement of commodities required for urine-LAM (e.g., TB LAM Ag urine assays, urine cups, pipettes, pipette tips, timers) and Xpert MTB/RIF Ultra testing. Urine-LAM tests and commodities should be procured in quantities that at minimum match the number of people projected to present to care in COP20 with advanced HIV disease (16% of new ART clients start treatment either in WHO stage three or four). PEPFAR Malawi should support the use of more sensitive TB urine LAM tests, should they become available and receive endorsement by the WHO within COP20; however, in the meantime, PEPFAR Malawi should not wait for more sensitive urine-LAM assays and instead, procure and implement the already available Abbott Determine TB LAM Ag test.

As urine-LAM and Xpert MTB/RIF Ultra produce the highest diagnostic yield when used together, PEPFAR Malawi should procure and distribute Xpert MTB/RIF Ultra test cartridges to supplement those procured by the Global Fund. Total quantities of Xpert MTB/RIF Ultra cartridges procured by PEPFAR Malawi should at minimum match the number of urine-LAM assays (based on the number of people projected to present to care with advanced HIV disease), as these tests should be given together.

PEPFAR partners should ensure systems are in place to monitor the performance and usage of the GeneXpert devices and supply stocks, to ensure sample transport and rapid linkage of all diagnosed PLHIV to treatment, and to capture TB/HIV indicators. In addition to optimising the use of GeneXpert for TB and strengthening sample transportation networks, PEPFAR Malawi should also commit to positioning GeneXpert testing platforms as close as possible to the point of care (not only in laboratories), in order to ensure that rapid Xpert MTB/RIF Ultra testing is readily available in combination with urine-LAM testing in all inpatient and outpatient settings where PLHIV present for care. Where sample transport is required for Xpert MTB/RIF Ultra testing, the turn-around time for results and linkage to appropriate treatment should be less than five days.

COP20 must procure urine-LAM and Xpert MTB/RIF Ultra test cartridges in total quantities that at minimum match the number of people projected to present to care with advanced HIV disease in COP20 plus the number of PLHIV projected to present to care with signs and symptoms of TB. PEPFAR must also ensure that PEPFAR funded GeneXpert cartridges are exempt from pre-export validation checks which are costly, time-consuming and lead to stockouts and monitor use of geneXperts performance and usage and ensure the rapid turn-around time of results from Xpert MTB/RIF Ultra testing in less than 5 days.

5e. Scale up access to other diagnostics and treatments for advanced HIV disease.

HIV advanced disease (AHD) is an emerging area in Malawi that currently lacks demand creation to provoke interest and need among beneficiaries. We commend PEPFAR for recognising AHD as a critical area that needs attention in SDS19. However, there is no mention of scaling up access to other key diagnostics for PLHIV with AHD, and also there is reported a lack of point of care diagnostic equipment at health centres and hospitals including CD4 testing, TB-Lam and CrAg screening. CD4 is essential for diagnosing AHD. Clinical staging/symptom screening on its own misses half of people with AHD at entry and re-entry into care, according to the REALITY study . Further cryptococcal meningitis (CM) remains a common AIDS-defining illness in Africa. Globally; WHO observes that 18% of HIV related deaths of hospitalised adults are due to Cryptococcal meningitis. In Malawi according to DHA a ward at QECH recorded a CrAg positivity rate of 13% in July 2019. Early diagnosis and treatment is paramount to reducing CM-related mortality. CM is a subacute meningitis in which the polysaccharide CrAg is detectable in serum a median of 3 weeks prior to onset of clinical symptoms. Other AHD related interventions that should be further supported in terms of diagnostics, training and treatment (OI medication) to reduce mortality include for severe bacterial infections, Kaposi sarcoma and PCP . Currently there is also need for improved hospital care for AHD (due to high mortality when people present late), as well as need for improved referral systems from community to HC/hospital, as well as need for strengthened post-discharge follow up (also high rates of mortality post-discharge).

COP20 should fund CD4 baseline testing for all new initiations or PLHIV returning to care; targeted CD4 for people who are clinically sick or have a detectable viral load (VL >1000 copies/mL). CD4 results should be available within 7 days of testing. COP20 should also fund CrAg screening for cryptococcal meningitis as recommended by the WHO in all PLHIV with CD4<200. COP20 should also fund the procurement of optimal cryptococcal meningitis CM drugs, flucytosyne, liposomal amphotericin B, and fluconazole. COP20 should fund community groups to engage in demand creation activities for those needing AHD related services.

7. Lawn S, Kerkhoff A, Burton R, et al. Diagnostic accuracy, incremental yield and prognostic value of Determine TB-LAM for routine diagnostic testing for tuberculosis in HIV-infected patients requiring acute hospital admission in South Africa: a prospective cohort. BMC Med. 2017;15:67. doi: 10.1186/s12916-017- 0822-8.

Photo: Isabel Corthier

6. Invest in comprehensive key population service delivery and increase the service delivery target of key populations supported by PEPFAR to access services.

Key populations (KPs) are disproportionately affected by HIV and have low rates of access to HIV testing and treatment services compared to the broader population. Catering to the specific needs of each KP (including men who have sex with men, sex workers, people who use drugs, prisoners, and transgender people) increases service acceptability, quality and coverage. Implementation of community-based and lay provider administered HIV testing and treatment services reduces barriers and reaches more people than facility-based services.

In Malawi, AGYW sex workers face double discrimination, legal barriers, high rates of infection and challenges accessing care at the facilities. Prisoners and sex workers have no access to six month refills despite the policy change allowing key populations access to the service. Further key populations still face challenges accessing STI and PEP due to stigma, discrimination and poor health worker attitudes which include asking personal questions and and requirement to show proof of rape to access PEP.

6a. Increase the target numbers of key populations reached with services by PEPFAR

In FY 2019, PEPFAR set a target of 27,238 key populations to be reached with services and exceeded that target by 58% (43,060). Whilst the programme should be commended for these efforts, the results also highlight the great need for services for key populations who are currently not being captured by the system due to low target setting. To reach a majority of key populations with services, the programme needs to adjust the target to reflect the true number of key populations in need of services. MSM for example make up 1% of the male population of every country which results in 99,026 men in Malawi. PEPFAR must support another place study to come up with realistic targets for different KP groups.

COP20 must increase the key population target by 50% of FY 2019 results and support a new target of 64,590.

6b. Support increased access to self-test kits and outreach testing to increase numbers of key populations with knowledge of positive status.

Long distance to facility, stigma and discrimination towards key populations are some of the key barriers to accessing services at the facility. Self-testing has the capacity to greatly increase knowledge of status amongst key populations most of whom would shy away from facility testing. Existing data suggest that HIV self-testing results in high yield and reach amongst men and youth. PEPFAR should support access to self-test kits at easy to access points for key populations to increase testing. Support of increased community outreach by peers and testing is also key

Photo: Isabel Corthier

to increasing access to services at community-level and should be scaled up. New innovations such as social network testing strategies that use the networks of positive key populations to find new, undiagnosed key populations should also be used to increase access to testing services amongst key populations.

COP20 must ensure that 50% of key populations have access to HIV self-testing services, and that 90% of key populations are accessing HTS through outreach testing services as well as introduce a social network strategy to reach more key populations. Peer educators/ navigators must be trained to distribute the kits in the community and provide counselling. PEPFAR must also strengthen linkage after self-testing.

6c. Support adherence and retention amongst key populations

For sex workers and other mobile populations (migrants), because of high mobility there is a need for longer multi month ART refills to support adherence. The current service delivery structure neither provides long refills nor emergency refills when not in their home/original district. A one stop approach—as being implemented by MSF in Nsanje—can facilitate better access to healthcare for mobile populations and ensure a comprehensive package of care (HIV, TB, and SRH) when the individual reaches the health facility.

COP20 must support scale up routine KP friendly DSD models in all districts, which provides one stop comprehensive care and services (STI, GBV, HTS, PEP, TB, PrEP, psycho-social support, legal support or referral).

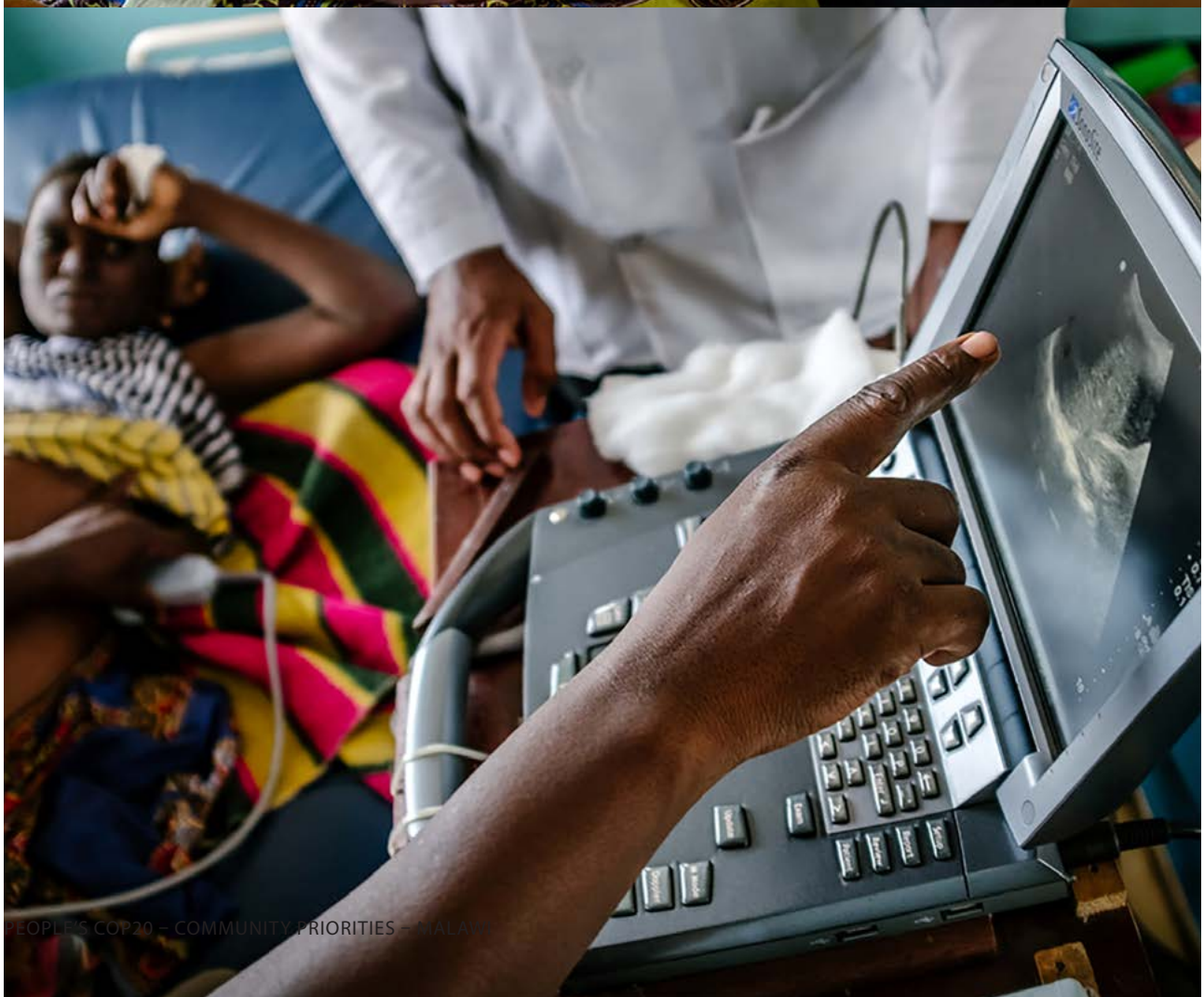
i. Provision of support for transport;
ii. Provide for implementation of a one stop approach to provision of services;
iii. Fund and support KP Peer navigators including their training and allowance to provide basic services in community (HTC, STI testing, family planning, health education, referral to HC, emergency contraceptive, first doses PEP, patient tracing) in all 11 districts;
iv. Roll out/full implementation with proper M&E of 6 month refills in all districts for KPs; and
v. Scale up KP support groups in all 11 districts.

6d. Address structural barriers to HIV and TB services for key populations.

We commend PEPFAR's support to key populations through the KPIF fund currently covering the following districts: Balaka, Phalombe, Blantyre, Lilongwe, Mzuzu and Mangochi. However some critical gaps still exist. One area not being adequately addressed by KPIF are the structural barriers to accessing services for KPs. KPIF activities are focused on biomedical interventions and do not address the underlying factors that prevent KPs from accessing services. Addressing the existing barriers to services will require implementation of targeted interventions for different stakeholders including religious leaders, healthcare workers, the police, and the community gatekeepers and the media. PEPFAR must fund and support the sensitisation of the above mentioned stakeholders.

PEPFAR must commit to address structural barriers to services by ensuring that COP20:

i. Provide financial and other support for community-led sensitisation and training of religious leaders, healthcare workers, the police, community gatekeepers, and media in all 11 districts.
ii. Empower and orient communities on human rights and where to report human rights violations.
iii. Work with government and civil society to disseminate the national guidelines on stigma elimination.



Photos: Isabel Corthier

7. Increase access to prevention, treatment and retention amongst adolescents and young women (AGYW).

7a. Support adolescent specific teen clubs to increase adherence amongst young people.

The net number of people added to treatment in FY 2019 was 89,725, a 35% achievement on a target of 249,950 highlighting programme challenges in retaining those newly enrolled to treatment.

In Malawi, young people have high rates of infection, poor adherence, high lost to follow up rates and difficulty adhering and are especially difficult to retain as age of consent to services, access to services whilst juggling school, and stigma remain barriers.

Support groups for young people have been proven to increase linkage to treatment and adherence amongst young people. For example the operation triple zero (OTZ) clubs in Kenya[8] increased the retention of young people to 96%. In Malawi, there is an inadequate number of teen clubs at the facility due to lack of financial support and many young people lack comprehensive youth friendly services at the health service delivery points.

To improve adherence, the program must support and implement peer models for youth by training in and out of school peer educators and include community based distribution agents to support community outreach, clinic and services. The programme also needs to train/sensitise health workers, community leaders, parents, teachers on the need to support youth right to health/access services, implement and integrate youth friendly health services in youth centres and develop youth friendly IEC materials with modern technology. Specific attention should be given to AGYW engaged in sex work — a highly vulnerable population.

COP20 must support the establishment of youth teen clubs in all scale up districts/sites to increase retention and adherence amongst youth including adolescent girls and young women (AGYW). Priority should be given to hard to reach areas.

8. Reduce new infections in Malawi by increasing access to HIV prevention tools.

In Malawi, the rate of new HIV infections remains high, necessitating the need for a comprehensive HIV prevention package tailored to the specific needs of different populations. In 2019, more than 38,000 people were acquired HIV.

8a. Fund PrEP access, awareness and retention programmes

It is well known that oral PrEP is highly effective for preventing HIV transmission, as it allows people who are HIV negative to be in control of their HIV status. National PrEP roll out—which was initially planned to start on 1st October 2019—has been delayed due to prolonged development of implementation and monitoring tools, costing, target setting and other processes. COP19 committed to supporting PrEP access for sex workers, MSM, high-risk AGYW, and serodiscordant couples even though specific targets for each population are not mentioned in the SDS.

Despite PEPFAR Q4 data showing high acceptability amongst AGYW and FSW enrolled in demonstration studies, national roll out is yet to commence. COP20 should therefore scale up funding for PrEP access for 6,700 FSW, MSM, high-risk AGYW, and serodiscordant couples about half of the national target. The Global Fund to fight AIDS, TB and Malaria, also must commit to fund the other half.

Experience shows that despite significant progress made with the rollout of PrEP in other countries— access, adherence and retention remain ongoing challenges due to limited awareness of PrEP as an HIV prevention tool amongst the population. During community-led monitoring in January, the majority of the people interviewed had no or limited knowledge about PrEP including how PrEP works and its potential impact. In Mangochi out of the 13 LGBTQIA+ members interviewed, only 2 had knowledge about PrEP. Whilst in Nsanje out of the 14 female sex workers interviewed, only 1 had knowledge about PrEP. Experience has shown that treatment literacy is key for access and uptake of any given intervention—and this is no different for PrEP.

COP20 should therefore fund community-led organisations to design and implement PrEP awareness and adherence programmes targeting sex workers, MSM, high-risk AGYW, and serodiscordant couples.

COP20 should maintain and fund PrEP access for 6,700 sex workers, MSM, MSW, Transgender, high-risk AGYW, and serodiscordant couples in PEPFAR focus districts. PEPFAR should maintain support for both commodities and fund user-centered design awareness and retention programmes. This should include community-outreach and AGYW/KP-friendly service delivery models that support both initiation and retention. COP20 should also provide PrEP and PEP access to students in tertiary institution campus clinics.

8. https://www.pepfarsolutions.org/solutions/2018/10/30/operation-triple-zero-empowering-adolescents-and-young-people-living-with-hiv-to-take-control-of-their-own-health

9. Improve access to SRHR services

9a. Eradicate STI medicine stockouts and improve healthcare worker attitude to increase uptake of STI diagnostics and treatment.

Early diagnosis and treatment of STIs must remain a priority both for the HIV and SRHR programmes. There are high rates of STIs in Malawi especially amongst key populations. In addition, high incidence rates have been reported even in those districts with increased condom distribution and uptake. FY18 Q2 PEPFAR POART data reported 24% STI incidence amongst female sex workers and 4% amongst MSM.

Reports from community-led monitoring point to ongoing stockouts and shortages of STI medicines as well as poor healthcare worker attitude towards people attempting to access STI services. This is a major contributing factor towards high STI incidence rates especially amongst key populations. For example in Mangochi, STI medicine stockouts/shortages were reported in 3 out of the 4 facilities visited. At Nangalamu Health Centre ciprofloxacin had been out of stock for 2 months whilst metronidazole and doxycycline had been out of stock for 2 weeks. In terms of staff attitude, key populations continue to face stigma when accessing healthcare for STIs, especially when they present with anal STIs, this despite PEPFAR's efforts in training healthcare workers on new national STI management guidelines. As a result, most opt out of treatment leaving the majority of the cases untreated, fuelling more infections. Positively, community-led monitoring also revealed that in facilities where trained providers exist the environment is more friendly for key populations.

A further challenge is that antenatal care services funded by PEPFAR at CHAM facilities are delivering services in a discriminatory manner, as women who do not bring their partners for testing are charged user fees for ANC services. This practice is unacceptable, discriminatory and must end immediately.

COP20 must support the health worker, staffing, transportation, commodities and other needs to ensure that facilities are adequately stocked. This should include:

i. Funding the procurement of STI commodities
ii. Ensuring that all facilities in the 11 districts have at least 90% fill rate for STI medicines all the time.
iii. Ensure at least two healthcare providers are STI trained at each site.
iv. Ensure intensified pharmacovigilance for STI medicines. Based on emerging evidence, as reported in most recent prevention technical working group, there is growing resistance to existing STI medicines.

9b. Fund comprehensive cervical cancer services including training of healthcare workers and purchase of services.

Malawi is one of the countries with the highest cervical cancer incidence and mortality in the world with age-standardised rate (ASR) of 75.9 and 49.8 per 100,000 population respectively[9]. According to the Malawi Human Papillomavirus and Related Diseases Summary Report 2018 about 4,163 new cervical cancer cases are diagnosed annually and 2,879 die from the disease in the country. In COP19, PEPFAR committed to support cervical cancer screening services with an aim to reach 101,507 women living with HIV. Reaching this target will require availability of adequate tools and human resources to provide the services. Community-led monitoring revealed that some facilities such as Chikangawa Health Centre and Ehleheni Health Centre in Mzimba neither trained providers nor have screening equipment available — and thus clients are sent back or sometimes referred to other facilities with no follow up to confirm if they accessed the service or not. It was further observed in community-led monitoring that cervical cancer services are not being integrated with other SRHR essential services.

COP20 must increase financial investment in cervical cancer services to reach 150,000 women living with HIV—50% more than the COP19 target. PEPFAR must support integration of cervical cancer services with other SRHR services. COP20 must also fund training of healthcare workers and ensure that at least each facility in the 11 districts has at least 1 trained provider and equipment for screening and management of precancerous lesions. COP20 must ensure that SRHR/HIV/TB/ANC/FP/UFC services are integrated and properly linked in the 11 districts and ensure WLHIV access these services at one go to avoid missed opportunities.

9. "Cervical cancer screening uptake and challenges in ... - NCBI." 17 Aug. 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4989288/. Accessed 17 Feb. 2020.

Photo: Isabel Corthier

10. Expand PEPFAR priority districts to include Nsanje.

Nsanje is a rural remote district in the southern region with HIV prevalence of 12.1% compared to national 9.2% average. Nsanje is characterised by high rates of AHD. HIV-related mortality in Nsanje district hospital is attributed as follows: 50% for TB and 17.8% bacterial infections. People still die at home from AHD due to distance to health facilities and socio-economic barriers that impede access. TB & HIV co-infections are very high at approximately 52%. There are 21,908 people on ART for a population of 299,168 in the district

Bordering Mozambique, many PLHIV move back and forth between the two countries in search of work. Further support of DSD programmes, including fast-track, 6-months refill, teen clubs, and CAGs, are needed to improve retention. Challenges of distance and poor financial capacity means that patients only return to care when they are very ill, often with opportunistic infections, mostly TB. 85% of those hospitalised in Nsanje in 2018 had previously been on ART. Additionally, there is great need for key & vulnerable populations interventions for sex workers, including adolescent girls engaged in sex work, fishermen & migrants who travel between Malawi & Mozambique including case finding for testing and provision of PrEP.

Given the climate and isolated location, the human resources for health in the district cover only 38% of the established cadres filled; with only 32% and 20% of medical & nursing/midwifery cadres filled respectively.

Currently, the only partners present and focused on HIV care in the district are MSF & Partners in Hope (PIH). Since 2011, MSF investments have contributed to reduced AHD mortality in IPD, from 35%-27% to currently consistently below 15%. However, MSF is exiting Nsanje this year. Upon MSF departure, PEPFAR prioritisation of the district could be significant in sustaining the gains already realised. To continue reducing mortality rates, additional funds and support is needed at community, health centre, hospital, and district levels. Through USAID/PEPFAR health system strengthening activities, there is potential to build from MSF investments and infrastructure development to yield greater HSS outcomes.

Upon MSF departure, PEPFAR prioritisation of the district could be significant in sustaining the gains already realised.

In COP20 PEPFAR must add Nsanje as one of the scale up districts in order to maintain gains made through MSF investments.

SPECIFIC LANGUAGE REQUESTED IN COP20

COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
1. Increase funding for human resources for health by funding an additional 1,500 Expert Clients, 50 Lab Assistants, 50 Community Health Nurses and incentivise 800 Sputum Collectors.		
Although there is significant support for HRH in Malawi, inadequate HRH remains a challenge at all levels of the HIV response. As clarified below in Section 6.1.1, in COP19, PEPFAR will maintain surge salary support for HCWs, provide scholarships to enrolled students, strengthen HRH planning and management, and recruit additional community HCWs (HSAs and HDAs) including community nurses to work on the frontline of the HIV response. (SDS 2019 pg 18) Where human resources are a significant challenge, PEPFAR is supporting the recruitment of relevant staff to help meet the PEPFAR targets. (SDS 2019 pg 90)	In COP20, PEPFAR will fund additional 1500 Expert clients, 50 Lab Assistants, 50 Community Health Nurses and incentivise 800 Sputum Collectors across PEPFAR sites. Human resources for health management approaches will include site level HRH units support to ensure efficient health workforce utilization at community and facility level, health workforce training to ensure quality of service providers.	**Target:** PEPFAR will fund an additional 1,500 Expert clients, 50 Lab Assistants, 50 Community Health Nurses and incentivise 800 Sputum Collectors.
2a. Maintain Community ART with Community Adherence Clubs as established in COP19 and expand to ensure at least 50% of eligible PLHIV access services through this differentiated service delivery model.		
"In alignment with MOH and DHA guidelines, PEPFAR will continue to deploy frontline ART providers, such as community HIV nurses, to provide ART in community settings, through programs like the facility-linked, nurse-initiated community ART approach. Expert clients and psychosocial counsellors will also support PLHIV enrolled in adherence clubs and support groups, which will be entry points for scaling up DSD." (SDS 2019 pg 39) "Work with MOH to scale up differentiated service delivery models, such as six-monthly multi-month dispensing, Community Adherence Clubs (CACs), and teen clubs, across priority sites. AGYW who participate in teen clubs have better viral suppression than those who are not teen club members. These interventions will offer peer support, significantly reduce the frequency of facility visits, and save clients travel time and cost which will lead to better adherence and retention. The resulting reduction in PLHIV volume at the ART clinics will enable providers to spend more time on PLHIV with advanced HIV." (SDS 2019 pg 47) **"4.1.5 Community ART with Adherence Clubs** - In COP18, PEPFAR partners are implementing nurse-led community ART distribution in Lilongwe, Mangochi, Machinga, and Chikwawa. This service package includes refills for ARVs and cotrimoxazole, adherence support, screening for TB and other opportunistic infections, access to contraceptives, index testing, and screening for hypertension. PEPFAR IPs will scale this up to other locations where PLHIV have to travel long distances to ART clinics and in the catchment areas of high volume sites in urban locations to improve adherence and reduce patient volumes and waiting times. At the community level, IPs will continue to strengthen and link PLHIV to existing support groups. By the end of COP19, PEPFAR will support implementation of community ART models in all 10 scale up districts. The model will use the PEPFAR COP18 and COP19 funded Community Health Nurses (CHNs) and Health Surveillance Assistants (HSAs) to distribute ART once every six months at select sites (however, CAC members may meet more frequently for ongoing adherence counseling and peer support which will be facilitated by Expert Clients). In addition to ART dispensing, CHNs will provide other clinical services (e.g., TB screening, viral load sample collection) as needed during their visits to the targeted clubs. Where they exist, support groups will serve as platforms for community adherence clubs. PEPFAR will work with expert clients and other community cadres to establish new adherence clubs where these support structures are not functional. Client-demand will guide implementation with sites farther from ART clinics prioritized for CAC roll-out. The MOH DSD task force, in consultation with other key stakeholders, will develop criteria for site selection and the tailoring of interventions for specific PLHIV groups. PEPFAR funded HDAs, HSAs, and/or expert clients will help facilitate the clubs and recruit people into them. CHNs would collect drugs from either a Village Health post or Health Centre for delivery to communities and use MOH registers to reconcile the commodities. Some of the adherence clubs will be specific to target populations based on gender, age, or key population groups. Complementary services currently in place include: • HSAs have a clearly defined population and most of them stay within the communities; • Most HSAs have either a bicycle or motorcycle; • HSAs are already within the government establishment and on government payroll; • MOH will soon construct Village Health posts through GAVI grant; and, • CHNs are within the government establishment". (SDS 2019 pg 53/54)	By start COP20, all PEPFAR sites will have functional Community Adherence Clubs that at least 50% of all eligible PLHIV on ART decanted into clubs (and remaining stable PLHIV decanted into other DSD models).	**Target:** 50% of all eligible PLHIV on ART decanted into Community Adherence Clubs (with other PLHIV decanted into other DSD models).

COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
2b. Establish a welcoming environment for PLHIV in and returning to care by addressing poor healthcare worker attitudes.		
"41% are aware of their HIV status, but not on ART: Evidence-based case management strategies will improve linkage to care to >95% and reduce 12-month ART loss to follow-up to 1% This involves standardized counseling for those newly diagnosed to ensure linkage and retention on ART and back to care counseling for those who initiated treatment, but struggle with adherence." p3 "In COP19, PEPFAR Malawi will intensify efforts to retain PLHIV on treatment through a comprehensive approach across the "retention cascade" as shown in Figure 4.1.8 below. These interventions will aim to reduce missed appointments and loss to follow-up as well as bring those lost to follow-up back to care." p32 "Strengthen the back-to-care program including tracing of PLHIV who miss their appointments through roll out of SOPs and monitoring and evaluation tools, and deployment of Expert Clients" p47 "Interventions planned for COP19 address the whole continuum of care starting with quality counselling at diagnosis, interventions during care, including DSD, peer support, tracking appointments, and interventions to bring back those that have defaulted (an expansion of the back-to-care program)" p61 "These interactions between the expert clients and newly diagnosed clients should include face-to-face counseling sessions, emphasizing the importance of early ART and retention, facilitating active index testing, providing follow-up support calls, sending appointment reminders, and facilitating back-to-care tracing. Expert clients should escort new clients during their first facility visit, with expedited registration, and treatment navigation services during the first 6 – 12 months of ART." p71 "Back-to-Care program: Since 2006, some IPs have implemented tracing of clients lost to follow- up at some facilities, achieving some success. More recently, IPs have used missed appointments as an earlier trigger. Currently, about 75% of clients who have stopped ART and then found are returned to ART. Improvements in the Expert Client intervention (described above) and the EMRS scale-up plan will also help implement the back-to-care program and ensure each site has accurate data on who needs to be traced due to a missed appointment." p72	COP20 will invest in creating a welcoming environment for PLHIV to ensure people who have interrupted treatment are re-engaged into care to achieve stable outcomes and, where necessary, are quickly switched to appropriate regimens of care (i.e. 2nd line or 3rd line treatment). The components of the "Welcome Services" will include: • Identifying patients (counsellors to trace patients; digital 'single patient viewer' to track movement of patients through health system); • Medical package of care (provide point of care diagnostic tools to allow CD4 detection allowing patients to be assigned to care depending on whether their CD4 count is above or below 200 cells/ul); and provide TB LAM and Gene Xpert testing among PLHIV (1) with TB signs and symptoms, (2) who are seriously ill, or (3) have advanced HIV disease (AIDS); incorporate evaluation for eligibility to receive a course of TB preventive therapy); • Psychosocial package of support (training in helping change staff attitudes to patients upon return after interruption, provide individualised counseling to patients, peer-led patient navigators acting as a bridge between clinicians and patients, mapped networks of referral services, and optional support groups.)	**Target:** <90% of enrolled patients return for follow up visit to the health centre and are appropriately linked to care.
2c. Fund widespread community and peer led prevention and treatment literacy efforts.		
"27% are on ART but not virally suppressed: Accelerating the transition to Dolutegravir-based regimens and the adoption of an annual viral load testing policy both create an enabling environment to empower clients to achieve and maintain a suppressed viral load. Coupled with treatment literacy messaging through existing and emerging platforms, Malawi will not only provide better treatment to those in existing care, but will also create a demand through knowledge around the health benefits of viral suppression." p3 "PEPFAR renews our commitment toward the national T=T campaign and will leverage the networks of faith-based organizations and community-based organizations to increase awareness of the T=T strategy." p39 "PEPFAR will integrate viral load messaging into communication and demand creation strategies and will expect implementing partners supporting HIV case finding and linkage to treatment to support clients to know their viral load status (including programming targeting key populations)." p83	COP20 will fund scale up of treatment literacy across all PEPFAR supported districts run by, and for, communities living with HIV and key populations. This will include both a community led component including: material development and dissemination to 100% of PEPFAR sites, training of trainers & subsequent trainings, social mobilisation campaigns at community level, as well as a healthcare worker component ensuring that community and facility-based health workers understand HIV and TB fully to offer up to date prevention and treatment literacy information—and offer HIV and TB education in facilities, community adherence clubs and beyond. PEPFAR will fund at least 15 community led PLHIV and KP organisations to increase retention of people on treatment.	**Target:** People friendly treatment literacy materials—developed by PLHIV and KPs—developed and disseminated to PLHIV across the country through trainings, health talks and localised social mobilisation campaigns. **Target:** Healthcare workers deliver high quality treatment literacy to 80% of people living with HIV.

COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
3. COP20 must ensure that all PLHIV receive an annual viral load test and receive test results within a maximum of 15 days.		
"27% are on ART but not virally suppressed: Accelerating the transition to Dolutegravir-based regimens and the adoption of an annual viral load testing policy both create an enabling environment to empower clients to achieve and maintain a suppressed viral load. Coupled with treatment literacy messaging through existing and emerging platforms, Malawi will not only provide better treatment to those in existing care, but will also create a demand through knowledge around the health benefits of viral suppression." p3 "Among children, viral load suppression is extremely low, suggesting the need for urgent transition to Lopinavir and ritonavir (LPV-r)-based regimens and rapid scale-up of viral load monitoring in these populations." p6 "Sub-optimal implementation of lab mechanisms to effectively and efficiently utilize lab resources and inadequate laboratory infrastructure to meet viral load scale-up goals for COP18" p6 "Malawi recently approved policies - self-testing, oral pre-exposure prophylaxis (PrEP), multi--month scripting (six months), annual viral load etc. - in line with the World Health Organization (WHO) guidelines to ensure epidemic control. In COP19, there is a need for continued engagement with stakeholders and MOH/Department of HIV/AIDS (DHA) to ensure scale-up of these polices nationally." p17/18 "PEPFAR is also working closely with the Global Fund to accelerate the transition to Dolutegravir (currently underway) and to ensure funding for key investment areas, such as annual viral load platforms (including reagents) and other key commodities required for program implementation." p21 "is support includes increased investment where the HIV burden, particularly the gap to viral load suppression, is the highest with key interventions at all sites, including but not limited to: clinical mentoring to ensure quality programming and care; provision and funding of HIV staff (e.g., HDAs); sample transport for viral load tests; quarterly supportive supervision; electronic medical record systems and data monitoring; and technical support to the national and district level response at sites." p24 "**Viral Load Monitoring**: Annual viral load testing and the T=T strategy (Tizirombo Tochepa= Thanzi or less virus equals more health) will be critical to improving treatment outcomes and will contribute to achieving epidemic control, as depicted in Figure 4.1.13 below. This figure reflects the power of the DTG transition to a better, more effective drug leading to viral load suppression where people can live long and healthy lives with virtually no risk of onward HIV transmission to sexual partners. The more people that understand these benefits, the more likely they are to want to know their status or re-engage in care to utilize the new, more powerful drug. PEPFAR renews our commitment toward the national T=T campaign and will leverage the networks of faith-based organizations and community-based organizations to increase awareness of the T=T strategy." "**Annual Viral Load Implementation and Use of the Results:** Given excellent performance against viral load volume targets, and the evidence base supporting the need for an annual viral load since the release of the 2013/2014 WHO guidelines, MOH approved an annual viral load policy for implementation starting in April 2019 onwards. This will result in a substantial increase in the required volume of viral load tests implemented in COP19." p73 "In addition, significant strengthening of the cascade is needed to ensure that health care workers returns viral load results to the clients living with HIV and informs them of their optimized care. PEPFAR plans these investments through increased HRH investments, optimized HRH management, better data systems and better supervision." p74 "**4.8 Viral Load and Early Infant Diagnosis Optimization** - In March 2019, Malawi adopted the WHO Annual Viral Load Testing (VLT) policy. This requires an increase in the number of viral load tests done from the COP18 level of 610,574 to 1,111,586 total tests (including repeat tests) resulting in 965,624 individuals receiving a viral load test in COP19. The strategy for the remainder of COP18 and COP19 is to strengthen and scale.	COP20 will ensure 100% of PLHIV on ART access viral load testing. The program will work with MOH Malawi to ensure that transportation of viral load samples take a maximum of 15 days between sample collection to return the results to the client.	**Target:** 100% of PLHIV on ART receive annual viral load test and receive results within a maximum of 15 days.

COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
In COP19, lab activities will focus on scaling viral load monitoring and EID, including strengthening sample transportation systems, building the capacity of labs for VL/EID tests, QA/QI for quality control, implementing results reporting via EMRS and hubs (district Health Offices) digitization to reduce the turnaround time, minimizing transcription errors, managing records, and enabling timely clinical decision-making. This investment will be accompanied by community and site-level demand for VL and EID services. In accordance with national guidelines, PEPFAR works to ensure that PLHIV are informed about VL, receive a VL at six and 12 months, with more attention to pediatric PLHIV and pregnant mothers. All exposed infants are tested at two and 24 months to confirm positivity. PEPFAR will support strengthening cascade milestones and significantly scale up services to manage annual testing demand. The VL cascade, depicted in Figure 4.8.1 below, shows each step along the cascade." p91 **"Sample transportation:** In COP17, FY18 Riders for Health transported 419,530 samples from across the country, of which, 82.5% were viral load, 11% EID, 6% TB, and 0.5% others. They visited 662 sites in all the 28 districts of the country. PEPFAR will continue to support national transportation of samples at all health facilities and will strengthen the system to be able to support the phased switch to plasma samples in urban areas and annual testing scaled up DBS volume for VL and EID." p93 **"Improving Viral Load Return of Results through Hub Digitization:** As part of reducing TAT, PEPFAR will support plans to build capacity at district sample hubs for electronic return of results by procuring and installing digitization equipment. This will include workstations, printers, and barcode scanners in hubs, in addition to integrating hubs with laboratory information management systems (LIMS) to allow for remote sample login and results return to be decentralized to the hubs. This will decrease time needed to log samples in the lap upon receipt, eliminate results loses, and decrease transportation time of results." p94 "Sample transportation is effective and has coverage of 662 sites in all 28 districts of the country. However, this is not adequate to meet 100% demand considering the new annual viral load testing policy. In COP19, this system will be empowered to strengthen samples and results tracking to contribute towards reduction of losses. The system will be optimized to improve turn-around time (TAT) from the current 46 days for viral load to less than half and, 30 days for EID to less than half and less than 5 days for TB (*URC ST report, 2017*). The introduction of annual viral load testing is expected to double the workload, hence PEPFAR will continue to support sample transport optimization to cope." p106		
4. Fund local level community and PLHIV led groups to monitor the state of service provision at PEPFAR supported sites & escalate issues of poor performance.		
No mention.	COP20 will fund local community and PLHIV groups to monitor the state of service provision at PEPFAR supported sites & escalate issues including (but not limited to): poor performance, poor quality of services, poor health worker attitudes, health and rights violations, and stockouts/shortages of diagnostics and treatment. The results of monitoring will be linked to a model of accelerated response from PEPFAR and partners to address the issues identified in order to ensure they are rapidly rectified. Widespread or repeating issues identified will be discussed at national level in order to attempt to generate systemic solutions.	**Target:** Issues affecting HIV and TB service delivery at site level are rapidly addressed by PEPFAR and implementing partners through an accelerated response mechanism.

COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
5a. Support scale up of TB preventive therapy to all people living with HIV and initiate access to 3HP for 40% of PLHIV eligible for TPT.		
The government of Malawi has ambitious plans to introduce short-course, rifapentine-based TPT regimens (e.g., 3HP) and will submit one of the largest orders for 3HP among countries under the Unitaid-negotiated deals with 3HP suppliers Sanofi and Macleods. In COP19, PEPFAR pledged to "continue supporting isoniazid-based TPT services in five high burden TB districts. PEPFAR will collaborate with KNCV through UNITAID funding to implement 3 month isoniazid rifapentine (3HP) in five additional districts. IPs will also support the integration of 3HP in DSD models. The goal is to reach all PLHIV with TPT (preferably 3HP, pending price reductions) in COP20." (2019 SDS, p11) "With the exciting determination that three-month rifapentine/isoniazid regimen (3HP) has no negative interactions with DTG, there is an opportunity to scale 3HP in Malawi." (2019 SDS, p52) The COP20 planning letter acknowledge this opportunity, calling for TPT to be scaled to 23 new districts in order to achieve national targets. In practice, however, TPT scale-up has fallen short of these ambitious goals. In COP19, only 28,948 people initiated and completed a course of TPT (through Q4), only 12.46% of the target of 232,282. Not a single district met its target and only one district (Lilongwe) reached 25% of its TPT target. Of concern, TB_PREV significantly lags TX_NEW in all districts except Lilongwe. All PLHIV newly diagnosed and initiated on ART (TX_NEW) are eligible for TPT if they screen negative for TB disease. And PLHIV on stable ART should receive TPT at least once. So in most areas, we would expect TB_PREV to approach or even exceed TX_NEW during the national scale-up phase of TPT implementation. For example, in Blantyre, TB_PREV = 6,979 but TX_NEW = 17,129. Anyone initiating ART who screens negative for TB and is not placed on TPT represents a missed opportunity to prevent TB. In 2018, Malawi did not report the percentage of PLHIV newly enrolled in HIV care who started TPT to WHO.	<u>TPT for adults and adolescents:</u> PEPFAR will support the MOH scale-up 3HP as the TPT regimen of choice in 23 new districts (beyond the initial five selected in COP19) to reach national scale. PEPFAR will continue to work closely with the MOH to transition the TPT program from lifelong IPT to 3HP on a national scale pending adequate supply and drug availability. Major concerns cited in COP19 about 3HP (price/affordability and compatibility with TLD) have now been resolved. • **Re. price**: Rifapentine is now available for $15/patient-course of 3HP from Sanofi, and a fixed-dose combination of 3HP with a lower pill burden will become available from Macleods at $15/patient-course within COP20 implementation. • **Re. 3HP and TLD:** 1) for PLHIV already on ART: the DOLPHIN-1 study completed in 2019 demonstrated that 3HP can safely be given to PLHIV on TLD without compromising viral suppression; 2) for PLHIV starting ART: PEPFAR notes that based on SPRING-1 trial data, "it seems reasonable to start 3HP and TLD simultaneously in treatment-naive patients." <u>TPT for children:</u> PEPFAR will support contact investigation for all PLHIV diagnosed with active TB disease. Children of PLHIV with TB identified by contact investigations will be offered TPT with the regimen determined after considering HIV status, ARV regimen, pill burden, and availability of child-friendly TPT formulations. Per the PEPFAR COP20 guidance: • For HIV-negative children, the preferred TPT regimen is 3HR. • For HIV-positive children, the preferred regimen is 6H until 3HP becomes available in child-friendly dosages and formulations (expected after COP20). 3HR may be given to any child with HIV on efavirenz-based ART. <u>TPT and DSD integration:</u> TPT should be integrated within DSD models, including models for multi-month prescriptions; fast-track drug refills; community ART groups; and those called for elsewhere in this Peoples COP. This integration will be especially important as Malawi begins to implement 6-month multi-month dispensing services. PEPFAR should link the scale-up of 3HP to TLD transition. In particular, 3HP and TLD should be started simultaneously in anyone newly diagnosed with HIV started ART (based on SPRING-1 and DOLHPIN-1 trials). In PLHIV on ART switched from EFV to TLD, 3HP can be started 2–4 weeks after making the TLD switch. Training, adherence support, pharmacovigilance, adverse event monitoring, and reporting systems associated with TLD transition should incorporate 3HP. <u>Human rights and stigma:</u> PEPFAR will ensure that TPT implementation respects human rights and minimizes stigma. In particular, that TPT initiation is always voluntary and introduced with full information and proper counselling on risks/benefits. Contact investigations should be carried out in a way that minimizes the impact of stigma in the community (e.g., by avoiding identifying a household as having TB or disclosing the TB or HIV status of a person without their consent).	**Target:** 47,000 PLHIV initiate and complete TPT within COP20. Of these, at least 60% should receive 3HP instead of IPT, pending adequate global supply of rifapentine. **Target:** 100% of PLHIV diagnosed with active TB (TX_TB) receive household contact investigation of family and close contacts. **Target:** All children identified through household contact investigation (TX_TB x 2) screened for TB, and either initiate TB treatment or TPT.
5b. Scale-up systematic TB screening across all PEPFAR sites		
To facilitate early TB detection and improve the quality of TB screening, PEPFAR partners will deploy, mentor, and supervise lay cadres to provide systematic TB symptom screening to clients accessing HIV services in high TB/HIV burden facilities. The lay cadres will also conduct tracing of contacts of PLHIV with bacteriologically confirmed pulmonary TB disease to provide TB and HIV screening, as well as TB preventive therapy, as per local guidelines. (2019 SDS, pg 51)	PEPFAR Malawi will integrate TB screening into HIV case finding, and ensure that 100% of people presenting for care are screened for TB using the TB symptom screen.	**Target:** 100% of people presenting for care screened for TB using TB symptom screen

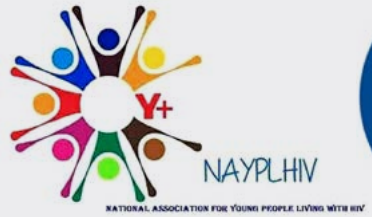
COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
5c. Improve TB testing amongst PLHIV by supporting better placement of GeneXpert and urine-LAM tests and training for health workers at all PEPFAR funded sites		
In COP19, PEPFAR Malawi achieved 88% of its TB testing target– this amounted to 16,518 diagnoses of PLHIV with new or relapsed TB in 2019 compared to the target of 18,740 diagnoses of PLHIV with new or relapsed TB. "Treatment for Late Presenters: National program data shows that approximately 16% of new ART clients start treatment either in WHO stage three or four21. PLHIV with advanced HIV have a higher likelihood of opportunistic infections and early mortality, especially due to TB co-infection. In COP19, PEPFAR Malawi will support the implementation of the national guidelines to conduct urine-LAM and cryptococcal antigen screening in districts and central hospitals (currently not available universally) to PLHIV with advanced HIV (i.e., CD4 < 200, WHO Stage III/ IV, "seriously ill" PLHIV). In smaller health centers, access to these services will depend on a functional referral system to district hospitals and other referral facilities that have the required diagnostic and treatment capacities. Implementation of proven retention and adherence strategies (e.g., active defaulter tracing and adherence support through lay providers such as Expert Clients) will be key to reduce the number of PLHIV on ART failing on treatment. This model will include a case management component for active follow-up." (2019 SDS, p39) "To facilitate early TB detection and improve the quality of TB screening, PEPFAR partners will deploy, mentor, and supervise lay cadres to provide systematic TB symptom screening to clients accessing HIV services in high TB/HIV burden facilities. The lay cadres will also conduct tracing of contacts of PLHIV with bacteriologically confirmed pulmonary TB disease to provide TB and HIV screening, as well as TB preventive therapy, as per local guidelines. Additionally, these lay cadres will extended TB screening, integrated with HIV screening, to contacts of bacteriologically confirmed pulmonary TB PLHIV. PEPFAR will support use of sensitive molecular testing for TB including Xpert MTB/RIF Ultra through procurement and distribution of test cartridges to supplement those procured by the Global Fund. PEPFAR partners will maintain a contract for GX alert system with System-One to help monitor the performance and usage of the Xpert devices, ensure linkage of all diagnosed PLHIV to treatment, more so for MDR and HIV PLHIV, help capture TB/ HIV indicators, and finally, facilitate provision of supplies as it provides data on stock status of test cartridges. PEPFAR will continue to support the hub and spoke Xpert network to optimize access and utilization of the available Xpert platforms through strengthening of the national sample transportation and results reporting system." (2019 SDS, p51/52) **PEPFAR Malawi also planned to improve the utilization of GeneXpert, including plans to improve turn-around times for Xpert TB testing:** "In COP19, this system will be empowered to strengthen samples and results tracking to contribute towards reduction of losses. The system will be optimized to improve turn-around time (TAT) from the current 46 days for viral load to less than half and, 30 days for EID to less than half and less than 5 days for TB (URC ST report, 2017). The introduction of annual viral load testing is expected to double the workload, hence PEPFAR will continue to support sample transport optimization to cope." (2019 SDS, p106)	While the number of registered cases of new and relapsed TB diagnoses among PLHIV in Malawi has increased steadily since 2016, TB diagnoses fall short of targets, and there are other indicators important to measuring PEPFAR Malawi's progress in reducing TB-related morbidity and mortality among PLHIV. These include indicators to track: progress in scaling up and implementing urine-LAM testing; the placement of GeneXpert platforms in relation to the point of care; and turn-around times for Xpert MTB/RIF Ultra results and linkage to treatment. **Improving TB screening and testing among PLHIV** In COP20, PEPFAR Malawi should use urine-LAM and Xpert MTB/RIF Ultra together to screen all people living with HIV with signs and symptoms of TB, who are seriously ill, or who have advanced HIV disease in both inpatient and outpatient settings. To facilitate early TB detection using urine-LAM and Xpert MTB/RIF Ultra, PEPFAR Malawi should expand and improve the quality of its TB screening efforts, including by training and deploying lay cadres to systematically conduct TB symptom screening and urine-LAM testing in high TB/HIV burden facilities and to conduct contact tracing when a PLHIV is diagnosed with TB. **TB diagnostics procurement and placement** To expand TB diagnoses and reduce TB-related morbidity and mortality among PLHIV, PEPFAR Malawi should ensure adequate budget is appropriated to support the procurement of commodities required for urine-LAM (e.g., TB LAM Ag urine assays, urine cups, pipettes, pipette tips, timers) and Xpert MTB/RIF Ultra testing. Urine-LAM tests and commodities should be procured in quantities that at minimum match the number of people projected to present to care in COP20 with advanced HIV disease (16% of new ART clients start treatment either in WHO stage three or four). PEPFAR Malawi should also commit to positioning GeneXpert testing platforms as close as possible to the point of care (not only in laboratories), in order to ensure that rapid Xpert MTB/RIF Ultra testing is readily available in combination with urine-LAM testing in all inpatient and outpatient settings where PLHIV present for care. Where sample transport is required for Xpert MTB/RIF Ultra testing, the turn-around time for results and linkage to appropriate treatment should be less than five days. **PEPFAR Malawi COP20 targets for TB diagnoses among PLHIV** PEPFAR's COP20 Guidance calls on implementing teams to "make the [urine-LAM] test available in all in-patient settings that admit PLHIV with advanced disease as well as outpatient settings where PLHIV are evaluated for TB symptoms or may present with advanced disease" (p290). To achieve this, it is essential that PEPFAR Malawi set specific targets for the procurement and implementation of urine-LAM. At minimum these targets should match the number of people projected to present to care with advanced HIV disease. To more fully match implementation with the latest evidence and PEPFAR COP20 Guidance, PEPFAR Malawi targets for implementing urine-LAM should match the number of people living with HIV projected to present to care with advanced HIV, plus the number of people living with HIV projected to present to care with signs and symptoms of TB. PEPFAR Malawi reported in its COP20 Planning Letter that plans to improve the utilization of GeneXpert testing platforms for the combined testing for TB, EID and VL are underway with a current 50% utilization rate at the start of 2020. It further reported that the optimization of sample transportation for TB remains one of the outstanding issues hindering implementation, which has led to a proposed shift in strategy in 2020 from a "push" to a "pull" collection schedule (p14). Rapid and accurate TB testing among PLHIV is essential to reducing mortality, especially among people with advanced HIV disease, who are most at risk of dying of TB. Rather than tracking just the utilization of GeneXpert testing platforms, PEPFAR Malawi should also track how close GeneXpert platforms are to the point of care, and report on results turn-around times and linkage to TB treatment.	**Target:** 10,000 registered cases of new and relapsed TB diagnoses amongst PLHIV. **Target:** 100% of people presenting to care with TB symptoms, serious illness or advanced HIV receive urine-LAM and Xpert MTB/RIF Ultra testing for TB. **Target:** 16% of new ART clients (percentage expected to present with advanced HIV) receive urine-LAM and Xpert MTB/RIF Ultra testing for TB. **Target:** 100% of Xpert MTB/ RIF Ultra results turned-around in less than 5 days. **Target:** 60% of GeneXpert testing platforms situated at the point of care.

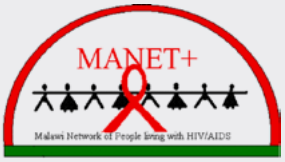
COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
	100% of newly diagnosed people with HIV are initiated on 3HP if they screen negative for TB; 50% of PLHIV already receiving ART (and eligible for TPT) are initiated on 3HP; 75% of all those eligible for TPT (including HIV negative people) are initiated on 3HP; and that 100% of people living with HIV diagnosed with active TB disease (TX_TB) should receive household contact investigation of family and close contacts, with close contacts and should be initiated on 3HP (or 3HR or 6H if a child less than 2 years of age or a child taking ART).	
5d. Support TB diagnostics procurement and placement to improve detection at all PEPFAR funded sites.		
In its 2019 COP, PEPFAR Malawi planned to scale up the use of urine-LAM testing as a point of care diagnostic test for PLHIV with advanced HIV disease: "Additionally, PEPFAR will procure and scale-up the use of urine lipoarabinomannan (urine-LAM) assay as a rapid point of care diagnostic of disseminated TB for PLHIV presenting with advanced HIV disease." p52 **However, these plans did not include specific procurement or implementation targets against which to monitor this progress.**	PEPFAR will support the procurement of commodities required for urine-LAM (e.g., TB LAM Ag urine assays, urine cups, pipettes, pipette tips, timers) and Xpert MTB/RIF Ultra testing. Urine-LAM tests and commodities will be procured in quantities that at minimum match the number of people projected to present to care in COP20 with advanced HIV disease (16% of new ART clients start treatment either in WHO stage three or four). PEPFAR targets for the procurement and implementation of urine-LAM will match the number of people projected to present to care with advanced HIV disease plus the number of people living with HIV projected to present to care with signs and symptoms of TB. PEPFAR will support rapid and accurate TB testing among PLHIV to reduce mortality, especially among people with advanced HIV disease, who are most at risk of dying of TB.	**Target:** TB diagnostics including commodities required for urine-LAM (e.g., TB LAM Ag urine assays, urine cups, pipettes, pipette tips, timers) and Xpert MTB/RIF Ultra testing are procured for 16% of PLHIV presenting to care in COP20 with advanced HIV disease (16% of new ART clients start treatment either in WHO stage three or four).
5e. Scale up access to other diagnostics and treatments for advanced HIV disease.		
"Additionally, PEPFAR will procure and scale-up the use of urine lipoarabinomannan (urine-LAM) assay as a rapid point of care diagnostic of disseminated TB for PLHIV presenting with advanced HIV disease. PEPFAR Malawi has been a consistent advocate for TB Preventive Treatment (TPT) and partners with MOH to offer life-long isoniazid preventive therapy (IPT) in five districts." (2019 SDS, pg 52)	COP20 will fund CD4 baseline testing for all new initiations or PLHIV returning to care; targeted CD4 for people who are clinically sick or have a detectable viral load (VL >1000 copies/mL). CD4 results should be available within 7 days of testing. COP20 will also fund CrAg screening for cryptococcal meningitis as recommended by the WHO in all PLHIV with CD4<200. COP20 will fund the procurement of optimal cryptococcal meningitis CM drugs, flucytosyne, liposomal amphotericin B, and fluconazole. COP20 will fund community groups to engage in demand creation activities for those needing AHD related services.	**Target:** Fund CD4 baseline testing for all new initiations or PLHIV returning to care; targeted CD4 for people who are clinically sick or have a detectable viral load (VL >1000 copies/mL). **Target:** CD4 results should be available within 7 days of testing. **Target:** Fund CrAg screening for cryptococcal meningitis as recommended by the WHO in all PLHIV with CD4<200. **Target:** Fund the procurement of optimal cryptococcal meningitis CM drugs, flucytosyne, liposomal amphotericin B, and fluconazole. **Target:** Fund community groups to engage in demand creation activities for those needing AHD related services. **Target:** Fund improved hospital care and referral systems to reduce AHD mortality.

COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
6a. Increase the target numbers of key populations reached with services by PEPFAR.		
"Utilizing the latest programmatic data, PEPFAR Malawi will expand key populations programming into two new districts with hot spots of high HIV transmission due to transportation routes and seasonal agricultural or other trading opportunities, as well as newly aligned (to ensure no overlap) Global Fund programming The package of services includes HIV oral self-testing for residents of informal settlements, including sex workers and their clients, most of whom do not interface regularly with the health system." "Targeted community testing focusing on children of key populations, OVC, and high-risk adolescents."(2019 SDS, p50) "Some of the adherence clubs will be specific to target populations based on gender, age, or key population groups." (2019 SDS, p53) "In COP19, strengthened linkages with implementers serving key populations will reach more children of female sex workers through the OVC program." (2019 SDS, p58)	The PEPFAR program has had great success in reaching key populations and even exceeded the 2019 targets. In COP20 the program will increase the number of key populations reached with services to 64,590 to ensure that more communities have access to HIV services	**Target:** 64,590 key populations reached in COP20.
6b. Support increased access to self test kits and outreach testing to increase numbers of key populations with knowledge of positive status.		
In COP18, PEPFAR supported quantification and supply planning of HIV/AIDS commodities and procurement of Oraquick self-test kits ($450,000), lab reagents ($805,010), VMMC commodities ($2,906,740), condoms, and lubricants ($1,419,700) for key populations. (2019 SDS, p81)	The PEPFAR program will increase access to self-test kits among key populations to increase knowledge of HIV status among communities who are not frequently visiting the facility. At a minimum of 50% of key populations will have access to HIV self test kits and 70% and 90% will have access to testing through community outreach and social network strategies.	**Target:** 50% of key populations have access to HIV self-testing services **Target:** 90% of key populations access HTS through community outreach. **Target:** Social network strategy in place to increase case finding amongst key populations
6c. Support adherence and retention amongst key populations		
In COP19, PEPFAR implementing partners will continue to scale up the differentiated service delivery (DSD) model for stable PLHIV. Six-month prescribing and dispensing of ART is expected to have the greatest impact in decongesting high- volume ART clinics. (SDS 2019 pg 39) FSWA is one of the main stakeholders for PEPFAR's female sex workers program. PEPFAR consults with on how to improve indicator performance, especially in testing strategies, ART adherence, treatment as prevention, and tracking of the mobile FSW (2019 SDS, p66)	In COP20, the programme will increase retention amongst key populations by increasing partnership with community led organisations. The program will invest in communities to ensure that peers have access to services. Innovations such as 6 MMD will be extended to key populations because they are highly mobile and longer prescriptions allow them to remain on treatment .	**Target:** Transition all stable key populations to multi month scripting.
6d. Address structural barriers to HIV and TB services for key populations		
No Mention	In COP20, PEPFAR will address barriers to access for key populations by investing in training for health workers, religious leaders, the police and the community on key population to reduce stigma with reduces the number of key population accessing services	**Target:** 10 community-led organisations supported to sensitise and train religious leaders, healthcare workers, the police, community gatekeepers, and media in all 11 districts. **Target:** Support dissemination of the national guidelines on stigma elimination.

COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
7a. Support adolescent specific teen clubs to increase adherence amongst young people.		
Work with MOH to scale up differentiated service delivery models, such as six-monthly multi-month dispensing, Community Adherence Clubs (CACs), and teen clubs, across priority sites. AGYW who participate in teen clubs have better viral suppression than those who are not teen club members (2019 SDS, p47)	PEPFAR will support youth teen clubs across the country to increase retention. The program will replicate successful models such as the OTZ in Kenya that increased retention to 96%.	**Target:** Fund the OTZ model to scale up adherence among young people in the country **Target:** Support the establishment of youth teen clubs in all scale up districts/ sites to increase retention and adherence amongst youth including adolescent girls and young women.
8a. Fund PrEP access, awareness and retention programmes		
"As PrEP was included in the Malawi national HIV prevention guidelines in December 2018, the Malawi DREAMS program will incorporate PrEP as a secondary DREAMS intervention in FY20, expanding on FY19 implementation among this population in Lilongwe. AGYW PrEP implementation will expand to all three DREAMS districts (Blantyre, Zomba, and Machinga), as well as four other priority districts (Thyolo, Mzimba, Lilongwe, and Chiradzulu) as part of PEPFAR Malawi's larger PrEP roll-out program targeting other eligible individuals such as key populations and sero-discordant couples. The overall AGYW PrEP target is 1,452, with the greatest reach in the DREAMS districts. PEPFAR DREAMS implementers will identify and monitor potentially eligible AGYW through community partners in Blantyre, Thyolo, Mzimba, and Chiradzulu. Through an active referral system and following an eligibility assessment, facility staff will initiate clients onto PrEP until national policy permits community initiation of ART. Facilities will integrate PrEP into youth-friendly health services, ANC, STI, and other service delivery points that AGYW often access. Finally, partners will engage peer educators to build awareness of PrEP and promote retention."(2019 SDS, p56/57)	COP20 will scale up funding for PrEP access for 6,700 FSW, MSM, high-risk AGYW, and serodiscordant couples about half of the national target. To ensure increasing demand for those at risk, PEPFAR will also fund access, awareness and retention program for PrEP in COP 2020	**Target:** 6,700 people access PrEP.
9a. Eradicate STI medicine stockouts and improve healthcare worker attitude to increase uptake of STI diagnostics and treatment.		
In COP16, PEPFAR facilitated the establishment of a dedicated supply chain of public sector condoms and lubricants (single-use packaging) to key populations and community partners to reduce stock outs for these priority populations. (2019 SDS, p47) In COP19, PEPFAR will continue supporting quantification, supply planning, and monitoring of stock availability of TLD and other HIV commodities to avoid stock outs, overstocks, and expirations. (2019 SDS, p81) In COP19, PEPFAR intends to ensure that stock outs of key commodities do not exceed five percent through investment in continued targeted site level monitoring and supervision, which address key bottlenecks in the supply chain. (2019 SDS, p110)	PEPFAR will support forecasting and quantification of medicines to reduce stockouts and shortages occurring. The programme will also prioritise the forecasting of STI medication to ensure people coming for services will also have access to STI treatment.	**Target:** All patients presenting with STIs are treated with medicines available at PEPFAR sites.

COP19 & DATA	LANGUAGE TO INCLUDE IN COP20	TARGET
9b. Fund comprehensive cervical cancer services including training of healthcare workers and purchase of services.		
In FY19, PEPFAR Malawi started supporting screening and treatment services for precancerous lesions for WLHIV in 39 high-volume ART facilities. In COP19, PEPFAR Malawi will intensify its cervical cancer interventions and aims to reach 101,507 WLHIV with screening services. In addition to treatment of precancerous lesions, PEPFAR partners will also establish referral network-to-district and referral hospitals where specialized care is available for PLHIV with advanced stages of cervical cancer. (2019 SDS, p43) As part of COP18, PEPFAR Malawi received a planning level of up to $5.4 million to support cervical cancer screening and treatment of precancerous lesions among women living with HIV/AIDS (WLHIV). As of Q2 in FY19, PEPFAR Malawi had scaled up cervical cancer activities to 39 high- burden health facilities spread across 22 districts with an intention to reach 42,825 women by the end of COP18, representing 50% of WLHIV 25-49 years old in these facilities.(2019 SDS, p89)	PEPFAR will fund Cervical cancer service for an increased number of women living with HIV. The program will target 150,000 women and integrate cervical cancer service with other services including SRHR to increase demand. Health workers will also be trained in the provision of these services in 11 districts. At a minimum, the 11 district will have 1 trained health provider trained to provide cervical cancer screening	**Target:** Reach 150,000 women living with HIV—50% more than the COP19 target with cervical cancer services. **Target:** Integrate cervical cancer services with other SRHR services. **Target:** train healthcare workers and ensure that at least each facility in the 11 districts has at least 1 trained provider and equipment for screening and management of precancerous lesions. **Target:** Integrate SRHR/HIV/TB/ ANC/FP/UFC services to the cancer screening
10. Expand PEPFAR priority districts to include Nsanje.		
National program data shows that approximately 16% of new ART clients start treatment either in WHO stage three or four21. PLHIV with advanced HIV have a higher likelihood of opportunistic infections and early mortality, especially due to TB co-infection. In COP19, PEPFAR Malawi will support the implementation of the national guidelines to conduct urine-LAM and cryptococcal antigen screening in districts and central hospitals (currently not available universally) to PLHIV with advanced HIV (i.e., CD4 < 200, WHO Stage III/IV, "seriously ill" PLHIV). In smaller health centers, access to these services will depend on a functional referral system to district hospitals and other referral facilities that have the required diagnostic and treatment capacities. Implementation of proven retention and adherence strategies (e.g., active defaulter tracing and adherence support through lay providers such as Expert Clients) will be key to reduce the number of PLHIV on ART failing on treatment. This model will include a case management component for active follow-up In COP19, PEPFAR Malawi will intensify efforts to retain PLHIV on treatment through a comprehensive approach across the "retention cascade" as shown in Figure 4.1.8 below. These interventions will aim to reduce missed appointments and loss to follow-up as well as bring those lost to follow-up back to care.	By expanding programs into Nsanje District, PEPFAR shall support access to Advance disease service package – including OI screening, prophylaxis and treatment – to be fully integrated into HIV patient management for 16% of all ART clients projected to present to the health facility with advanced disease.	**Target:** PEPFAR shall expand operations into Nsanje District and provide care and treatment services, including for all patients projected to present to the health facility with advanced HIV disease (this includes the 16% of all new ART clients who present with AHD, and ART-experienced AHD patients) .





Photographs by Isabel Corthier, courtesy of Médecins Sans Frontières