Once every year, PEPFAR convenes different stakeholders in PEPFAR recipient-countries to input into its annual Strategic Direction summary also known as the Country Operational Plan (COP). Civil Society and Communities are one of the key stakeholders to this process as they provide lived experiences and insights on program successes and best practices as well as the existing gaps and challenges in services delivery and quality.

Liu Lathu (Our Voices) is a consolidation of community priorities for the national HIV and TB program and facility level services developed out of a nexus of CSO and community-led consultation processes including; community-led monitoring and stakeholder engagement at community, facility, district and national level.

Liu Lathu aims at amplifying the voices of people living with HIV (PLHIV) and key populations (KPs) in regarding their priorities and needs. The purpose of this document is to inform and influence the PEPFAR COP process to address the needs of those directly affected by HIV service quality and HIV program activities.

Who is the target audience for this document
Ending the AIDS epidemic will require a comprehensive response through concerted efforts from different stakeholders. PEPFAR’s COP development process provides a unique opportunity for different stakeholders and players in the HIV response to jointly plan, coordinate and strategize on the most viable interventions. The target audience for this document are all stakeholders involved in the COP planning process including PEPFAR, Global Fund and Ministry of Health, Department of HIV/AIDS and Hepatitis B with the expectation that the community priorities outlined in this document and categorized by stakeholder would be addressed accordingly by all relevant stakeholders.
INTRODUCTION

Malawi is one of the PEPFAR supported countries on the verge of achieving epidemic control. According to 2022 Naomi estimates, by the end of December 2021, there were 981,844^1 people living with HIV in Malawi.

The new MPHIA 2020-21 survey results shows that Malawi has made remarkable progress in prevention and treating HIV. Progress towards the 95-95-95 targets is currently at 88:98:97. HIV prevalence continues to decline and is now at 8.2%. Despite the progress, gaps still remain in a number of HIV epidemic indicators. After missing the 2020^2 HIV prevention targets to reduce new HIV infections from a baseline of 32,000, (2016) to 11,000 by the end of 2020, the pace of progress in reducing new HIV infections continues to slow down. In 2021, there were 15,300 adults (15+) newly acquired HIV, a slight decline from the previous year. Despite the huge investments and tremendous efforts by different partners Blantyre and Lilongwe remain the worst performing districts contributing highest numbers of new HIV infections with more undiagnosed PLHIV.

PEPFAR FY 21 Q4 data^3 shows improvement in selected program indicators; by the end of Q4, the overall rate of treatment continuity increased to 96%; there was a slight reduction in treatment interruption from 5.5% in FY20 Q4 to 5% in FY21 Q4. PEPFAR data also showed commendable progress in DREAMS enrollment targets, with 101,845 AGYW enrolled against a target 81,264. However, gaps still remain across a number of program indicators:

+ **Slow progress in scaling up of PrEP:** By the end of Q4, only 33% of the PrEP NEW target was achieved. PEPFAR Q4 dat highlights the following as some of the contributing factors to slow scale up of PrEP; the phased in scale up approach to only those sites with laboratory capacity, inadequate Lab capacity for creatinine and Hepatitis B testing, low adherence and lack of follow up and lack of decentralized PrEP delivery i.e Community PrEP distribution.
+ **Poor ART linkage among key populations:** despite the overall increase among the general population, ART linkage among key populations remains a challenge, 66% among MSM and 69% among FSW, largely due to lack of National KP database and KP mobility.
+ **Retaining mother infant pairs by 24 months** is also one of the challenges posing a threat to the country’s goal of achieving elimination of mother to child transmission.
+ **Poor viral load coverage among KPs:** Q4 data also shows poor viral load coverage among KP, especially those accessing services in Drop-in Centres.
+ **Low VLS among children and pediatric:** Viral load suppression rates among adolescent and pediatric remains suboptimal.

As Malawi celebrates progress made towards achieving epidemic control, it is important to acknowledge that the fight against HIV is far from over. Achieving epidemic control should go beyond the general population and take into consideration the heterogeneity of needs among different sub-populations masked within the general population. Achieving epidemic control should not leave anyone behind, especially the key and vulnerable populations.

With more than 19,000 people getting infected with HIV annually, the need for renewed efforts and commitment towards HIV prevention cannot be overemphasized.

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1. 2022 HIV Epidemiological Estimates for Malawi Spectrum, Naomi, Shiny90
2. HIV prevention 2020 roadmap
3. PEPFAR Malawi Q4 POART
4. Kippax, S., & Stephenson, N. (2012). Beyond the distinction between biomedical and social dimensions of HIV prevention through the lens of a social public health
THE DEVELOPMENT OF LIU LATHU MU COP22

Community-led monitoring (CLM) by CSOs and HIV and TB affected communities continues to play a pivotal role in identifying gaps and challenges in service delivery and access. Through quantitative and qualitative data collection, analysis and interpretation, civil society and communities are able to bring to light the challenges behind different program outcomes as well as provide recommendations for program improvement.

Liu Lathu mu COP22 was developed out of a series of data collection exercises under the PEPFAR funded CLM program targeting PLHIV, AGYW, Key Populations and other affected populations, followed by engagement with different stakeholders at community, district and national level.

In total there were three rounds of data collection at community and facility level conducted between January and September 2021 followed by facility, district and national level stakeholder consultation to discuss findings and recommendations.

Priorities and recommendations included in the document were also informed by findings from two other CLM programs namely; the Treatment Community Observatory and COMPASS CLM program. Development of the Liu lathu was also informed by analysis of policy documents and reports including; the SDS 20&21, PEPFAR POART Q4 data, PEPFAR Planning Level Letter, the Global Fund Funding request, MOH HIV program data and other national policy documents.

The process of developing COP22 priority areas and recommendations

- Liu lathu CLM Qualitative and quantitative data collection and analysis Interpretation of results
- CTO Qualitative and quantitative data collection and analysis Interpretation of results
- Compass CLM Qualitative and quantitative data collection and analysis Interpretation of results

Merging of results

Drafting of COP22 priorities and recommendations
## PRIORITY INTERVENTIONS FOR COP22

### 1. Routine Viral Load

<table>
<thead>
<tr>
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<th>WHICH YEARS DID WE ASK FOR IT?</th>
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</tr>
</thead>
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<td>COP22 Target: PEPFAR should fund procurement of additional viral load machines, especially for those districts that are using viral load platforms for COVID-19 testing.</td>
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<tr>
<td>COP22 Target: 100% of PLHIV on ART receiving an annual viral load test with results delivered to PLHIV in a maximum of 14 days.</td>
<td>COP20, COP21, COP22</td>
<td>SDS commitment but not fully implemented</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR should fund a viral load cascade assessment to understand the bottlenecks that are contributing to long turnaround time and missing viral load results.</td>
<td>COP22</td>
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</tr>
<tr>
<td>COP22 Target: PLHIV and KP groups develop PLHIV and KP friendly community-led HIV and TB treatment and prevention literacy materials and implement country-wide capacity building training using adequate PEPFAR funding.</td>
<td>COP20, COP21, COP22</td>
<td>SDS commitment but not fully implemented</td>
</tr>
<tr>
<td>COP22 Target: Community-led HIV and TB treatment &amp; prevention literacy materials are distributed by PEPFAR to all support groups and ART clinics to reduce information gaps and misinformation.</td>
<td>COP20, COP21, COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR should support efforts to improve modes of communication of VL results including interpretation of results i.e. using mobile phones and SMS (mHealth). PEPFAR must leverage on the viral load results utilization program being funded by Bill and Melinda gates foundation and scale it up to more districts.</td>
<td>COP22</td>
<td>No</td>
</tr>
</tbody>
</table>

### 2. ART Retention/Treatment continuity

<table>
<thead>
<tr>
<th>TARGET</th>
<th>WHICH YEARS DID WE ASK FOR IT?</th>
<th>DO WE HAVE IT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>COP22 Target: PEPFAR should support the recruitment of additional staff to ensure uninterrupted services at all times.</td>
<td>COP19, COP20, COP21, COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR to work with GoM to ensure that all PEPFAR-supported health facilities have service charters clearly pasted at the facility and healthcare providers to follow this service charter.</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR should work with GoM to expand DSD options to accommodate the needs of the different population groups, including through the establishment of community-driven Community ART Groups.</td>
<td>COP19, COP20, COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: 40% of all eligible PLHIV are receiving their HIV treatment, care and support within Community ART Groups.</td>
<td>COP19, COP20, COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: All PEPFAR supported health centers have extended opening hours from 5am to 7pm on weekdays and 8am to 4pm on Saturdays — and PLHIV are able to use these extended opening times to pick up their medication from internal pick-up points.</td>
<td>COP21, COP20</td>
<td>In part</td>
</tr>
</tbody>
</table>

### 3. Stockouts

<table>
<thead>
<tr>
<th>TARGET</th>
<th>WHICH YEARS DID WE ASK FOR IT?</th>
<th>DO WE HAVE IT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>COP22 Target: PEPFAR to allocate funding for Drug Buffers in health facilities.</td>
<td>COP22</td>
<td>No</td>
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</table>

### 4. HIV Prevention

<table>
<thead>
<tr>
<th>TARGET</th>
<th>WHICH YEARS DID WE ASK FOR IT?</th>
<th>DO WE HAVE IT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>COP22 Target: PEPFAR should fund PrEP awareness and adherence support interventions.</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: Everyone eligible should be offered PrEP including but not limited to AGYW, key populations, and those in sero-discordant couples.</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: Implement DSD for PrEP to simplify service delivery including community collection of PrEP refills.</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP 22 Target: Fund the development of DVR policy and guidelines.</td>
<td>COP22</td>
<td>No</td>
</tr>
</tbody>
</table>
### 5. Services for Key and Vulnerable Population

<table>
<thead>
<tr>
<th>TARGET</th>
<th>WHICH YEARS DID WE ASK FOR IT?</th>
<th>DO WE HAVE IT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>COP22 Target: PEPFAR should fund the training of all clinical and non-clinical staff at health facilities on SOGIE and provision of KP friendly services to ensure a welcoming and safe environment for all KPs at all times. KP must be involved in the implementation of these training modules.</td>
<td>COP20, COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: Any reports of poor staff attitude, privacy violations, verbal or physical abuse/harassment and/or of services being restricted or refused should be urgently investigated by DHA/PEPFAR and disciplinary action taken where appropriate.</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: Post sensitisation training, PEPFAR should complete follow up to assess the quality of KP service provision at site level (to show the success of the sensitisation programme).</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR and the Global Fund should strengthen the lubricant and condom supply chain to ensure that condom compatible lubricants and both male and female condoms are easily available at all public health facilities (not only upon request or in public spaces that make it difficult to pick them up).</td>
<td>COP21, COP22</td>
<td>SDS commitment but not fully implemented</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR should scale-up KP specific service availability across all PEPFAR supported facilities including but not limited to KP friendly HIV prevention, testing, treatment and care; gender affirming care; outreach services, peer navigators, HCV/HBV services; easily accessible condoms and lubricants; psycho-social support; harm reduction services.</td>
<td>COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR should allocate US$ 100,000 for planning and coordination activities for the Diversity Forum.</td>
<td>COP22</td>
<td>No</td>
</tr>
</tbody>
</table>

### 6. Comorbidities

<table>
<thead>
<tr>
<th>TARGET</th>
<th>WHICH YEARS DID WE ASK FOR IT?</th>
<th>DO WE HAVE IT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>COP22 Target: 100% of PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings receive both urine-LAM and rapid molecular testing (including the use of stool samples among CLHIV) upon their first presentation to care.</td>
<td>COP20, COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: Procurement quantities of commodities required for urine-LAM and rapid molecular testing should each exceed the estimated number of PLHIV, including CLHIV, expected to present to care at PEPFAR-supported sites with advanced HIV disease or TB signs and symptoms in COP22.</td>
<td>COP20, COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: 100% of healthcare workers at PEPFAR-supported sites are trained to perform TB screening, urine-LAM, and rapid molecular testing among PLHIV in accordance with WHO recommendations and algorithms and appropriate approach for sputum scarce symptom positive but rapid molecular negative patients.</td>
<td>COP20, COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR to work with GoM and Global Fund to train 100% of community sputum collectors</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: All eligible PLHIV and all eligible contacts of a person with pulmonary TB, including children and adolescents, should be traced and initiated on TPT. All people considered for TPT should undergo clinical evaluation (symptom check and physical examination) and be tested with GeneXpert (Xpert), even without having any symptoms.</td>
<td>COP20, COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: All eligible PLHIV including children and adolescents be initiated and complete TPT within COP22, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient. Of these, at least 70% should receive 3HP and 30% should be on IPT.</td>
<td>COP20, COP21, COP22</td>
<td>SDS commitment but not fully implemented</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR to fund “cold” storage of the fixed-dose 3HP products for TPT to avoid impurities.</td>
<td>COP21, COP22</td>
<td>In part</td>
</tr>
<tr>
<td>COP22 Target: Point of care diagnostic tools provided at all PEPFAR supported sites allow CD4 detection, to allow patients to be assigned to care depending on whether their CD4 count is above or below 200 cells/ul.</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR should ensure the provision of L-AmB for all facilities that currently provide infusions and fluconosine for inpatient and outpatient facilities for follow-up oral treatment together with fluconazole in order to reduce overall mortality.</td>
<td>COP22</td>
<td>No</td>
</tr>
<tr>
<td>COP22 Target: PEPFAR and GoM should ensure clear quantification and monitoring of cryptococcal meningitis (CM) including annually how many PLHIV: 1) develop CM; 2) receive optimal treatment for CM; 3) survive CM; 4) die of CM; 5) receive preventive treatment for CM; 6) receive a CD4 test; 7) CRAG + getting lumbar puncture (LP); 8) LP negative getting fluconazole prophylaxis.</td>
<td>COP22</td>
<td>No</td>
</tr>
</tbody>
</table>

### 7. Community-Led Monitoring

<table>
<thead>
<tr>
<th>TARGET</th>
<th>WHICH YEARS DID WE ASK FOR IT?</th>
<th>DO WE HAVE IT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>COP22 Target: USD 1.08 million for CLM to expand in COP22 to 50 high burden sites across Malawi including to gather evidence, analyze data, generate solutions and engage with duty bearers to see swift corrective action.</td>
<td>COP21, COP22</td>
<td>In part</td>
</tr>
</tbody>
</table>
1. Routine Viral Load

Evidence shows that viral load testing in PLHIV who are on ART, is an important measure of treatment outcome and critical for the long term health of PLHIV (and reduction of transmission). However this depends on PLHIV actually receiving and understanding VL test results, and uptake and utilization of the results for clinical actions for those who may be virally unsuppressed. While the Government of Malawi recommends annual viral load testing for adults and children, the return of these results for clinical and personal action have not been an emphasis of HIV programming in Malawi. For the past few years, long turnaround time and missing VL results have been a major area of concern for CSOs and communities have repeatedly recommended that these challenges be addressed in PEPFAR’s COP and the Global Fund Funding request. CSOs acknowledge the efforts by both Global Fund and PEPFAR to improve access to viral load testing, however several gaps still exist.

In COP21, PEPFAR acknowledged “effective viral load sample transportation with significant reduction in turnaround time” (SDS 2021, pg 30) as a top priority. The need for expanded capacity was also captured by PEPFAR’s commitment to refurbish two district hospital laboratories in COP21 (SDS 2021, pg 59). Another effective solution, according to community feedback, was the scale up of Expert Clients/ Patient Supporters (a COP20 commitment) to provide support and reminders for VL testing action.

However, CLM data show that between July and September 2021 (quarter 4), only 85% of PLHIV reported having a VL test. Further 82 % of PLHIV interviewed (n = 147) reported receiving their results late, i.e. more than one month from the time of testing. Alarmingly, 1 in 5 PLHIV (22%) reported receiving their VL from 6 months or longer, and 23% reported never receiving their results.

How long did it take to receive your results?

<table>
<thead>
<tr>
<th></th>
<th>Patients Surveyed: 147</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 weeks</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>1 month</td>
<td>17 (12%)</td>
</tr>
<tr>
<td>2 months</td>
<td>14 (10%)</td>
</tr>
<tr>
<td>3 months</td>
<td><strong>46 (31%)</strong></td>
</tr>
<tr>
<td>6 months</td>
<td>25 (17%)</td>
</tr>
<tr>
<td>Over 6 months</td>
<td>7 (5%)</td>
</tr>
<tr>
<td>Never received the results</td>
<td>34 (23%)</td>
</tr>
</tbody>
</table>

At the health facility level, the following were stated as reasons for VL results being delayed and/or missing:

+ Limited testing centers and availability of testing equipment at the district level.
+ Testing centers and equipment diverted for COVID-19.
+ Shortages of trained staff to perform VL testing at facility level.

Experientially, the expanding of testing equipment through the Global Fund COVID-19 efforts has had little effect on reducing the strain on equipment as equipment diversion was listed as a top reason for VL result delay. This could be due to little overlap between sampled CLM districts and those districts funded by Global Fund.

It is possible to reduce TAT. Models such as the Kenya viral load database, show that viral load samples can be collected and returned to PLHIV within a turnaround of 10 days. The database’s remote login functionality enables facilities to log and register samples at the facility level onto the testing laboratory information management system (LIMS), monitor testing progress, view results and retrieve historical results. CLM also identified a persistent need of care for higher viral load literacy and understanding of the importance of VL results among PLHIV. There is also a greater need for better training of healthcare workers to explain VL results, provide turnaround-time (TAT) estimations, and guide PLHIV with information on what to do once they receive their results.

Long TAT for viral load test results or results that are lost or go missing put PLHIV at higher risk of poor treatment outcome, as it delays necessary interventions if an individual has an unsuppressed VL and treatment is failing. Long TAT and missing or lost VL test results can also result in PLHIV losing trust in the public health system and feeling demotivated to return to the health centre. This failing has had a detrimental effect on PLHIV.

“I, for example, leave home at 8am to get my viral load sample collected for testing but will not be assisted until noon. As a result myself and other recipients of care leave the facility out of frustration.” — Interview with AGYW in February 2022, Bvumbwe Health Centre, Thyolo

“I have had my viral load sample collected for testing three times yet I have never received my results.” — Interview with FSW in February 2022, Zingwangwa Health Centre, Blantyre

“I got my first test and received my results. However, I did not receive my results the second time. I am currently waiting for my results from my third test which was done in October, 2021.” — Interview with WLHIV in February 2022, Chilomoni Health Centre, Blantyre

“They don’t call to tell you the results but they wait till you come for the next refill even if the results are in.” — Interview with WLHIV in February 2022, Nathenje Health Centre, Lilongwe

“The doctors/counsellors assuming that increased viral load is due to sexual activity is offensive” — Interview with PLHIV in February 2022, Nathenje Health Centre, Lilongwe

“I was tested in June 2021, but my results did not come out, then I went again for the second time the same happened, now I went again to test for the third time in December, 2021, I am waiting for the results now. I was told that there are many tests that have to be done that is why the results are missing.” — Interview with FSW in February 2022, Namasalima Health Centre, Zomba

Recommendations for PEPFAR

+ **COP22 Target**: PEPFAR should fund training for more laboratory technicians to assist with viral load testing.

+ **COP22 Target**: PEPFAR should collaborate with GoM to increase VL screening sites to avoid VL sample congestion at testing sites

+ **COP22 Target**: PEPFAR should fund procurement of additional viral load machines, especially for those districts that are using viral load platforms for COVID testing.

+ **COP22 Target**: 100% of PLHIV on ART receiving an annual viral load test with results delivered to PLHIV in a maximum of 14 days.

+ **COP22 Target**: PEPFAR should fund a viral load cascade assessment to understand the bottlenecks that are contributing to long turnaround time and missing VL results.

+ **COP22 Target**: PLHIV and KP groups develop PLHIV and KP friendly community-led HIV and TB treatment and prevention literacy materials and implement country-wide capacity building training using adequate PEPFAR funding.

+ **COP22 Target**: Community-led HIV and TB treatment & prevention literacy materials are distributed by PEPFAR to all support groups and ART clinics to reduce information gaps and misinformation.

+ **COP22 Target**: Health worker-led health talks take place at all PEPFAR-supported health centres to provide information to patients waiting for services including (but not limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, cervical cancer screening, that ensure uptake of these services.

+ **COP22 Target**: PEPFAR should support efforts to improve modes of communication of VL results including interpretation of results i.e. using mobile phones and SMS (mHealth). PEPFAR must leverage on the viral load results utilization program being funded by Bill and Melinda gates foundation and scale it up to more districts.

Recommendations for MoH, DHA

+ Government, with support from the Global Fund, must reduce turnaround time for viral load test results to 14 days.

Recommendations for Global Fund

+ Global Fund should fund the procurement of additional viral load machines.
2. ART Retention/ Treatment Continuity

As more PLHIV get to know their status and initiate on ART, more facility and community based interventions are needed to support long-term ART retention. Achieving low levels of viral suppression among PLHIV has wider public health benefits, given that it has the potential to stop onward transmission of HIV.

Despite efforts to retain the majority of PLHIV in care, Malawi continues to experience high rates of treatment interruption/disengagement from care. According to PEPFAR's 2021 data, while 78,551 people were initiated on treatment (TX_NEW) during the year, treatment rolls increased by only 45,098 (NET_NEW) by the end of quarter 4 — meaning 33,453 people stopped treatment, were lost, or died during the year. While the overall loss to follow up rate is not high, these numbers still point to concerning ART continuity challenges.

Treatment interruptions can lead to increased risk of treatment failure, viral rebound, and drug resistance. Hence to reduce mortality, PLHIV need to be encouraged to remain in care. Several strategies and interventions have been implemented to increase ART retention, including differentiated service delivery (DSD) options, improved treatment literacy, and increased follow up of PLHIV who have missed clinic appointments/interrupted treatment by Expert Clients.

Implementation of DSD models of care have proven effective to better serve the needs of PLHIV and reduce the unnecessary burden on the health system, especially in low resource limited settings where the health system is already strained. Malawi adopted the use of DSD models of care in 2006 followed by an endorsement of DSD policy by the Ministry of Health in 2019. Malawi's current DSD Policy recommends implementation of five models of care; 3 facility-led and 2 community-based. However, despite their demonstrable potential to improve ART retention, the majority of these models are healthcare provider-led. This means that implementation and scale-up requires significant investment in human resources. Implementation of nurse-led Community ART groups (N-CAGs) has tremendously increased ART retention, however, this model is expensive and currently there is limited implementation.

More community-based and community-led interventions such as Community ART Groups (CAGs) are needed to fully address the needs of different populations. A cohort study by Decroo,T et.al on the effect of CAGs on retention in care showed that PLHIV enrolled in CAGs achieved higher retention in care than PLHIV in individual models of care, confirming that patient driven ART distribution achieves better results.

Community-based ART collection reduces the frequency of health facility visits, thereby reducing transportation costs or long walks to the facility. Long distances to get to health facilities remains one a major barrier to accessing health services, especially among the most vulnerable houses. A recent geospatial analysis exercise showed that over 200,000 PLHIV travel more than 60 minutes to get to the nearest health facility, and over 70,000 travel for more than 90 minutes.

This corresponds with CLM data which revealed that a significant number of PLHIV travel long distances just for ART refills. CLM data further reveal that 57% of PLHIV would like to collect ARVs closer to home, pointing to a clear need for more community ART collection points.

If it was an option, would you like to collect your ARTs closer to home?

Patients Surveyed: 172

- Yes: 57%
- No: 40.7%
- Don’t know: 2%

Recipients of care interviewed strongly recommend community distribution of ART as the most effective way to address long distance to the facility.

“Though as sex workers we prefer not going to the facility ourselves to collect ART hence a woman who looks after us takes oir health passports on oir behalf to collect the drugs. Sex workers have their leader and as those with HIV they formed a group where this leader collects ART on their behalf (Namasalima). The service provider once in a while comes to our place of residence where they bring services right at the place of residence, they bring condoms and tests them for viral load. FSW prefer not going to the facility on a Thursday that is put in place for ART. We go to the facility but when we are failing or have no transport our leader takes for us.” — Interview with FSW in February 2022, Namasalima Health Centre, Zomba

“In October 2021, I was at General, where I was delivering my child. I sent someone to go and collect meds for me. The providers refused to give him, hence was sent back.” — Interview with AGYW in February 2022, Naisi Health Centre
Flexible and extended facility operating hours is another promising strategy for reducing the risk of PLHIV disengaging from care. In SDS21 PEPFAR acknowledges flexible clinic hours as one of the key strategies for ensuring continuity of treatment. However evidence from CLM shows that there are some facilities that are still using the conventional operating hours thereby not fully addressing the needs of all populations.

“I went to the health facility on 26th December for my ART refill. Unfortunately I was told the facility is not operating and the staff are on holiday yet that is the date I was given. I was then given ART and bactrim for 8 days and told to return on January 8th, 2022 when they resume operation. I was very unhappy” — Interview with AGYW in February 2022, Chingale Health Centre, Zomba

CLM data also reveal that protocols are not always being followed and concerningly 46% of PLHIV interviewed who had missed an appointment said they are not contacted by the clinic.

If you miss a facility visit to collect your ARTs which of the following happens?

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Get an SMS from healthcare worker</td>
<td>8</td>
<td>14%</td>
</tr>
<tr>
<td>Visited by a healthcare worker</td>
<td>16</td>
<td>27%</td>
</tr>
<tr>
<td>Get a phone call</td>
<td>8</td>
<td>14%</td>
</tr>
<tr>
<td>You are not contacted by the clinic</td>
<td>27</td>
<td>46%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>4</td>
<td>7%</td>
</tr>
</tbody>
</table>

Recommendations for PEPFAR

+ **COP22 Target:** PEPFAR should support the recruitment of additional staff to ensure uninterrupted services at all times.
+ **COP22 Target:** PEPFAR to work with GoM to ensure that all PEPFAR-supported health facilities have service charters clearly pasted at the facility and healthcare providers to follow this service charter.
+ **COP22 Target:** PEPFAR should work with GoM to expand DSD options to accommodate the needs of the different population groups, including through the establishment of community-driven Community ART Groups.
+ **COP22 Target:** 40% of all eligible PLHIV are receiving their HIV treatment, care and support within Community ART Groups.
+ **COP22 Target:** All PEPFAR supported health centres have extended opening hours from 5am to 7pm on weekdays and 8am to 4pm on Saturdays — and PLHIV are able to use these extended opening times to pick up their medication from internal pick-up points.

Recommendations for the Government of Malawi

+ Government should work with CSOs to move forward with the launch of the T=T campaign.
+ Government to ensure that all health facilities have service charters that are clearly pasted at the facility and healthcare providers follow the service charter.
+ Government and PEPFAR should increase/expand DSD options to accommodate the needs of the different population groups, including with the establishment of Community ART Groups.
3. Stockouts

Despite efforts by the Ministry of Health to improve the availability of medicines and medical supplies at all levels of the public health delivery system in Malawi, medicine stockouts at the facility level remains a major challenge. CLM data collected in quarter 4 reveal that 95% of facilities monitored faced stockouts.

CLM data reveal stockouts of gentamicin, benzathine penicillin, palliative care drugs, CPT, TPT, and ceftraxzone. Out of the 19 facilities visited in quarter 4, 95% facilities reported stockouts of medicines.

We commend the effort by MoH in pushing for recapitalization of Central medical stores to support the implementation of the Master Supply Chain Transformation Plan (MSCTP) 2021-2026 — a long-term plan for addressing the challenges in the supply chain system. However, while we appreciate that implementation of the MSCTP is the way to go to sustainably address the existing challenges in the supply chain system, urgent efforts are needed to address the ongoing medicine and commodity stockouts which continue to place a financial burden on poor households and could potentially result in people disengaging from care.

CLM data reveal stockouts of gentamicin, benzathine penicillin, palliative care drugs, CPT, TPT, and ceftraxzone. Out of the 19 facilities visited in quarter 4, 95% facilities reported stockouts of medicines.

“I went to the facility in November, 2021 and I was told there is no bactrim, amoxicillin, panado and aspirin.” — Interview with WLHIV in February 2022, Namasalima Health Centre, Zomba

Recommendations for PEPFAR
+ **COP22 Target:** PEPFAR to allocate funding for drug buffers in health facilities.

Recommendations for Government
+ GoM to increase the national health budget to a minimum of 15% (as per the Abuja Declaration).
+ GoM to allocate (increase) a certain percentage of drug budget to districts to cushion gaps with CMST supplies.
+ GoM to provide drug store management training including improvement in stock reporting (digitalisation of drug stock reporting)

Recommendations for Global Fund
+ Global Fund to allocate funding for drug buffers in health facilities.

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**Did the facility experience drug stock-outs in the previous month?**
Facility Staff Surveyed: 20

- Yes: 95%
- No: 5%

**Which drugs were out of stock in the last month?**
Facility Staff Surveyed: 19

- Gentamicin: 14 (74%)
- Benzathine Penicillin: 9 (47%)
- Palliative care drugs: 6 (32%)
- CPT: 4 (21%)
- TB Preventive Therapy: 6 (32%)
- Ceftraxzone: 8 (42%)
- Other: 7 (37%)

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PEOPLE’S COP22 – COMMUNITY PRIORITIES – MALAWI

13
4. HIV Prevention

HIV primary prevention in Malawi remains underfunded and is usually not a top priority during budget and resource allocation. Oftentimes HIV primary prevention resource needs compete with HIV treatment and care commodities budgets. As such Malawi has been very slow in adopting and rolling out new HIV prevention tools.

In 2018, Malawi adopted the Oral PrEP Policy. Since then, PrEP rollout has been very slow, largely due to a delay in the development of guidelines and SOPs for implementation, lack of funding for procurement of drugs and commodities and health system strengthening including training of healthcare workers, as well as low uptake due to medicalization of delivery models which are largely facility based. By the end of FY21 Q4, only 33% of the PrEP_NEW target had been achieved. Due limited laboratory capacity for Creatinine and Hepatitis B testing, PrEP has only been rolled out to 86 facilities across the country.

In addition, the Dapivirine Ring could be a game changer for HIV prevention programming for women. The ring received scientific positive opinion from the European Medicines Agency (EMA) in July 2020. In January 2021 WHO recommended the ring as an additional HIV prevention option for women at substantial risk of HIV prevention. For a long time women have bemoaned the lack of agency and choice in the existing HIV prevention tool box, which limit their ability to be in control of their sexual health. The Dapivirine ring is a discreet/women-controlled vaginal ring that slowly releases an antiretroviral (ARV) drug, dapivirine, in the vagina for up to 1 month.

Communities have repeatedly noted the importance of “choice” in the toolkit as different options work for different people at different times of their lives. Women want HIV prevention options that are discreet, long-acting, and that can be used without partner cooperation. Not all women would prefer oral or injectable PrEP; and similarly not all women would prefer Dapivirine ring. Hence the need for providing a wide range of choices cannot be overemphasized.

Recommendations for PEPFAR

- COP22 Target: PEPFAR should fund PrEP awareness and adherence support interventions.
- COP22 Target: Everyone eligible should be offered PrEP including but not limited to AGYW, key populations, and those in sero-discordant couples.
- COP22 Target: Fund the development of DVR policy and guidelines

Recommendations for the Department of HIV

- GoM should allow for decentralization of PrEP delivery i.e DSD models including community distribution of PrEP.
- GoM to fast-track the issuance of Guidelines on Creatinine and Hepatitis B testing to align with WHO Guidance.
- DHA to work with civil society to advocate for regulatory approval of DVR.
5. Services for Key & Vulnerable Populations

5.1. Key Populations (KPs)

KP Friendly and Specific Services

Malawi has made tremendous strides in improving access to quality HIV prevention and treatment services for KPs. However, gaps and challenges still exist, and KPs are being left behind in attainment of the UNAIDS 95-95-95 targets. PEPFAR’s COP Guidance states that “PEPFAR remains committed to its affirming ‘do no harm’ principle that emphasizes voluntary, confidential, non-judgmental, non-coercive, and non-discriminatory services” (COP Guidance, page 425). Yet KPs continue to be treated very poorly, facing abuse, humiliation, harassment, privacy violations, discrimination and even risk of arrest, negatively impacting KPs access to and uptake of HIV and other health services.

“In December 2021, I was raped by one of my clients, when I went to a mobile clinic to seek for services the nurses told me that a FSW can never be raped, there was a mission there so we can’t help you.” — Interview with FSW in February 2022, Mlambe Health Centre, Blantyre

“One nurse told us that when we write bad or incriminating things about a service provider, they check the suggestion boxes and remove such complaints.” — Interview with FSW in February 2022, Bwaila Health Centre

“I want to be able to come to the facility and be assisted without being asked why I chose to be transgender.” — Interview with a trans* person in February 2022, Namasalima Health Centre, Zomba

“Sometimes KPs are in fear of discrimination and being mocked by healthcare providers when they have STIs. As a result, some return home without seeking medical help.” — Interview with a KP in February 2022, Zomba

At friendlier sites, or where KPs are able to tolerate ill-treatment, oftentimes, specific services to meet their needs are not available. It is critical that KPs can access specific services to meet their specific needs. Catering to the specific needs of each KP can increase service acceptability, quality and coverage.

Yet KPs often struggle to access basic prevention tools like male and female condoms and especially lubricants remain out of reach. Condoms and lubricants should always be available at facilities, and could easily be placed in the toilets or other areas of the clinic where people could take them without the fear of judgment.

KP Coordination and Representation in Different Forums

A careful mapping of the needs, opinions and visions of local KP communities is critical for successful design and implementation of KP programs.

PEPFAR’s COP Guidance, under KP minimum program requirements, states that “Establishment of an independent PEPFAR-funded KP community consortium where/if it does not already exist, in collaboration with diverse stakeholders; emphasis should be on avoiding the creation of duplicative or parallel systems, and on ensuring there is regular engagement with KP communities in the geographies where PEPFAR works and with the national program” (COP Guidance, page 425).

In May 2019, KP groups in Malawi established the Diversity Forum, a KP coalition which brings together LGBTQI+-led organizations operating in and registered in Malawi. The coalition was created to unite KP voices around issues that affect them as well as coordinate and facilitate representation of the KP communities in different decision making platforms. The coalition meets every quarter to discuss emerging issues from the field, plan, strategize and coordinate KP representation and engagement in different fora. However, due to inadequate funding, participation in the quarterly meetings and other national level stakeholder engagement meetings is only limited to capital based KP members, leaving out critical voices from the community. More resources are needed to increase and strengthen representation of wider KP community members.

Specifically additional resources are needed to:

+ Increase participation of local KP community members in quarterly planning and coordination meetings and other national level engagement activities;
+ Beyond the quarterly meetings, there is need for more KP community consultations and strategizing meetings during the COP Planning processes to consolidate cross cutting KP priority areas to inform the development of the People’s COP;
+ Advocacy engagement meetings with different stakeholders to discuss cross cutting KP issues.

Yet KPs often struggle to access basic prevention tools like male and female condoms and especially lubricants remain out of reach. Condoms and lubricants should always be available at facilities, and could easily be placed in the toilets or other areas of the clinic where people could take them without the fear of judgment.
Adolescent girls and young women (AGYW) account for 74% of new HIV infections among all adolescents in Sub-Saharan Africa. CLM data reveal that AGYW struggle with disclosure due to the underlying stigma and discrimination in the community as well as at health facilities. In addition to this, lack of privacy in health facilities remains a barrier to the uptake of services for AGYW.

The DREAMS program, through layering of interventions and provision of a comprehensive package of services, has been instrumental in addressing the complex needs of AGYW which puts them at risk of HIV. PEPFAR Q4 POART data shows remarkable progress with enrollment of AGYW into the DREAMS program. By the end of 2021, 101,845 AGYW were enrolled in the DREAMS program against a target of 81,264. However, geographical coverage for the DREAMS program remains low. Currently DREAMS is only being implemented in 3 districts across the country. Expansion of DREAMS interventions to additional districts is therefore needed in order to further reduce HIV incidence among AGYW.

As PEPFAR plans to scale up interventions to additional districts, successful implementation of the DREAMS program will require meaningful involvement of AGYW in the design, planning, implementation and monitoring of the DREAMS interventions. PEPFAR COP Guidance acknowledges the importance of meaningful engagement of AGYW and recommends that “country teams must establish or work with existing mechanisms to enable meaningful AGYW participation in DREAMS. For example, DREAMS mentors and ambassadors, AGYW-led organizations and/or an AGYW-led advisory council should participate in the design, implementation, and monitoring of DREAMS” (COP Guidance).

Currently there are no clearly defined channels and mechanisms for AGYW participation and engagement in the design and implementation of the DREAMS interventions. Engagement of AGYW is usually ad hoc and not systematic. In the absence of clearly defined channels and mechanisms, engagement can be tokenistic. In COP22, PEPFAR should support the development of an engagement mechanism to facilitate systematic engagement of AGYW during planning, implementation and monitoring of DREAMS interventions. Thorough consultations with AGYWs must be done prior to rolling out DREAMS interventions in additional districts.

5.2. AGYW

Adolescent girls and young women (AGYW) account for 74% of new HIV infections among all adolescents in Sub-Saharan Africa. CLM data reveal that AGYW struggle with disclosure due to the underlying stigma and discrimination in the community as well as at health facilities. In addition to this, lack of privacy in health facilities remains a barrier to the uptake of services for AGYW.

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6. Comorbidities

TB deaths remain high partly due to lack of timely diagnosis and linkage to treatment. TB LAM tests are an affordable rapid POC TB tests for use among PLHIV that are proven lifesaving. TB LAM tests can be administered at every level of the healthcare system and results are returned in just 25 minutes. Trained non-laboratory personnel (e.g., nurses, HTC counselors) can perform TB LAM tests.

In the SDS, it was stated that “PEPFAR will continue to build capacity and increase demand at site level on the use of Urine-LAM tests and support the supply chain management” (page 54, COP21 SDS) and that “Access to urine-LAM (part of the AHD service) is dependent on MOH plans and GF resources” (page 83, COP21 SDS). However, CLM data reveal that TB LAM testing is not provided in 12 facilities (Chingale Health Centre, Namasalima Health Centre, Naisi Health Centre, Limbe Health Centre, Mangunda Health Centre, Makhuwira Health Centre, Zingwangwa Health Centre, Nchalo Health Centre, Zilindo Health Centre, Sucoma Health Centre, Chilomoni Health Centre, Mikolongwe Health Centre) out of 20 facilities monitored.

PEPFAR should allocate sufficient budget to support the procurement of commodities for Urine Lam testing and ensure that all supported sites universally screen PLHIV, including children living with HIV (CLHIV), at every clinical encounter for TB symptoms and other risk factors, using the WHO four-symptom screen or other WHO-recommended screening tools including chest X-ray, C-reactive protein (CRP), or rapid molecular tests. Bi-directional screening for TB and COVID-19 should be implemented at every clinical encounter.

While ART greatly reduces the risk of developing TB disease, TB preventive therapy (TPT) can further reduce TB sickness and deaths. In the SDS, PEPFAR committed that “IPs will continue to accelerate TPT scale-up to newly on ART patients and engage the MOH leadership to devise TPT delivery models that align ART provision with TPT dispensing schedules IPs will explore the use of DSD models, including the use of digital technologies to boost adherence to TPT and monitor adverse events” (page 54, SDS COP21).

PEPFAR further committed that “All eligible PLHIV, including children, should complete TPT by end of COP20, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient” (page 72-73, SDS COP21). However, CLM data reveal that the volunteers working at sputum collection points are not well trained and 18 facilities out of 25 monitored were still not providing TPT (3HP).

PEPFAR further committed to “work with DHA and CSOs to generate demand for TB Prevention. This will include… commodity quantification, distribution, and ensuring supporting the GoM in managing “cold” storage of the fixed-dose 3HP products, to ensure adequate, expeditious and equitable supply of newer rifapentine-based products in Malawi” (page 4, SDS COP21).

Advanced HIV disease (AHD), or AIDS, is a major challenge that needs addressing for people starting treatment late, or re-engaging after a treatment interruption. It is estimated by WHO that 1 in 3 PLHIV present to care with AHD.

CD4 testing is essential for diagnosing (especially asymptomatic) AHD. The provision of point of care (POC) diagnostic tools to allow CD4 detection allows PLHIV to be assigned to care depending on whether their CD4 count is above or below 200 cells/ul. This can lead to getting PLHIV onto an effective HIV treatment regimen ASAP to improve viral load suppression including rapid restart or rapid switch to second line treatment. POC CD4 tests are available and affordable. The VISITECT CD4 Advanced Disease test is a semi-quantitative POC rapid diagnostic test (RDT) that costs US$3.98 per test.

Cryptococcal meningitis is the second leading cause of death for PLHIV, causing headaches, deafness, and blindness. If CM is not successfully diagnosed and treated it causes “cerebral herniation” – where the brain gets pushed down into the spinal canal due to increased intracranial pressure. PEPFAR should ensure the provision of flucytosine for inpatient and outpatient facilities for follow-up oral treatment together with fluconazole in order to reduce overall mortality.

8. Gupta-Wright et al, Lancet, July 2018
9. Carmona et al, Clinical Infectious Diseases, March 2018
Recommendations for PEPFAR

+ COP22 Target: 100% of PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings receive both urine-LAM and rapid molecular testing (including the use of stool samples among CLHIV) upon their first presentation to care.

+ COP22 Target: Procurement quantities of commodities required for urine-LAM and rapid molecular testing should each exceed the estimated number of PLHIV, including CLHIV, expected to present to care at PEPFAR-supported sites with advanced HIV disease or TB signs and symptoms in COP22.

+ COP22 Target: 100% of healthcare workers at PEPFAR-supported sites are trained to perform TB screening, urine-LAM, and rapid molecular testing among PLHIV in accordance with WHO recommendations and algorithms and appropriate approach for sputum scarce symptom positive but rapid molecular negative patients.

+ COP22 Target: PEPFAR to work with GoM and Global Fund to train 100% of community sputum collectors

+ COP22 Target: All eligible PLHIV and all eligible contacts of a person with pulmonary TB, including children and adolescents, should be traced and initiated on TPT. All people considered for TPT should undergo clinical evaluation (symptom check and physical examination) and be tested with GeneXpert (Xpert), even without having any symptoms.

+ COP22 Target: All eligible PLHIV including children and adolescents be initiated and complete TPT within COP22, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient. Of these, at least 70% should receive 3HP and 30% should be on IPT.

+ COP22 Target: PEPFAR to fund “cold” storage of the fixed-dose 3HP products for TPT to avoid impurities.

+ COP22 Target: Point of care diagnostic tools provided at all PEPFAR supported sites allow CD4 detection, to allow patients to be assigned to care depending on whether their CD4 count is above or below 200 cells/ul.

+ COP22 Target: PEPFAR should ensure the provision of L-AmB for all facilities that currently provide infusions and fluycytosine for inpatient and outpatient facilities for follow-up oral treatment together with fluconazole in order to reduce overall mortality.

+ COP22 Target: PEPFAR and GoM should ensure clear quantification and monitoring of cryptococcal meningitis (CM) including annually how many PLHIV: 1) develop CM; 2) receive optimal treatment for CM; 3) survive CM; 4) die of CM; 5) receive preventive treatment for CM; 6) receive a CD4 test; 7) CRAG+ getting lumbar puncture (LP); 8) LP negative getting fluconazole prophylaxis.

Recommendations for Government

+ Government, PEPFAR and GF to collaborate in provision of enablers and training of community sputum collectors.

+ Government to increase TB registration sites.

+ Government to scale-up TPT (3HP) nationwide.

Recommendations for Global Fund

+ Government, PEPFAR and GF to collaborate in provision of enablers and training of community sputum collectors

+ GF to scale-up availability and use of TB diagnostic tools including TB LAM.

+ PEPFAR/GF to fund cold/storage rooms for TPT to avoid impurities.
7. Community-Led Monitoring

In COP22, PEPFAR should sufficiently increase funding for CLM to expand to 50 sites across 7 districts. Data will continue to be uploaded through a data collection platform to allow for centralisation of information for ease of access and review. Information will be fed back to duty bearers at relevant levels on a quarterly basis to ensure swift corrective action can take place.

PEPFAR Malawi should continue to fund CLM to ensure that PLHIV and KPs have the ability to monitor the quality of service provision and escalate performance problems — an indispensable strategy for enabling Malawi to meet and sustain the 95-95-95 targets.

Recommendations for PEPFAR

+COP22 Target: USD 1.08 million for CLM to expand in COP22 to 50 high burden sites across Malawi including to gather evidence, analyze data, generate solutions and engage with duty bearers to see swift corrective action.
## COP22 Specific Recommendations

### COP21 Language

1. **Routine viral load**

   "Expanded treatment literacy (TL): For clients to start and stay on HIV treatment (and TB), they need to understand the benefits and challenges associated with HIV treatment (and TB) and must be equipped to overcome those challenges. To this end, health facilities and community-level treatment literacy interventions play an important role. PEPFAR Malawi will continue its treatment literacy activities at health facilities through clinical partners. Community-level TL activities through CSOs including MANASO and MANARELLA, and other PEPFAR implementing partners will be expanded." - pg. 46

   "In COP20, lessons from the Faith and Community Initiative and other TL initiatives will be considered to inform the expansion of community-level TL activities in Lilongwe, Blantyre, and Mulanje districts. PEPFAR IPs will actively engage in the planned national roll out of the T=T campaign that also benefits from the ongoing "Flip the Script" work supported by the BMGF." - pg. 46

   "Among the minimum program requirements in the COP are “Completion of Diagnostic Network Optimization activities for VL/EID, TB, and other co-infections, and ongoing monitoring to ensure reductions in morbidity and mortality across age, sex, and risk groups, including 100% access to EID and annual viral load testing and results delivered to caregiver within 4 weeks.” - pg. 73

   "In response to this community ask, PEPFAR said "PEPFAR is supporting real time monitoring of sample transport and result return using a START application dashboard and a GPS system. This will help monitor TAT and make corrective actions in a timely manner for areas that need improvement. A barcode scanner will be used to reduce multiple entries of patient information and avoid loss of samples." - pg. 80

2. **Testing & prevention literacy**

   To scale-up access to viral load testing services, in COP22, PEPFAR will fund the training of additional laboratory technicians to assist with viral load testing. PEPFAR will collaborate with GoM to further decentralize viral load testing services and increase screening sites to avoid sample congestion. With some viral load testing platforms currently being used for COVID-19 testing, PEPFAR will procure additional viral load machines across those districts.

   In COP22, 100% of PLHIV on ART will receive an annual viral load test with results delivered to PLHIV in a maximum of 14 days. PEPFAR will fund a viral load cascade assessment to understand the bottlenecks that are contributing to long turnaround time and missing viral load results.

   In COP22, PLHIV and KP groups will be funded to develop PLHIV and KP friendly community-led HIV and TB treatment and prevention literacy materials and implement country-wide capacity building training using adequate PEPFAR funding. Community-led HIV and TB treatment & prevention literacy materials will be distributed by PEPFAR to all support groups and ART clinics to reduce information gaps and misinformation. Health worker-led health talks will take place at all PEPFAR-supported health centres to provide information to patients waiting for services including (but not limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, cervical cancer screening, that ensure uptake of these services.

### Language to include in COP22

- COP22 Target: PEPFAR should fund training for more laboratory technicians to assist with viral load testing.
- COP22 Target: PEPFAR should collaborate with GoM to increase VL screening sites to avoid VL sample congestion at testing sites.
- COP22 Target: PEPFAR should fund procurement of additional viral load machines, especially for those districts that are using viral load platforms for COVID-19 testing.
- COP22 Target: 100% of PLHIV on ART receiving an annual viral load test with results delivered to PLHIV in a maximum of 14 days.
- COP22 Target: PEPFAR should fund a viral load cascade assessment to understand the bottlenecks that are contributing to long turnaround time and missing viral load results.
- COP22 Target: PLHIV and KP groups develop PLHIV and KP friendly community-led HIV and TB treatment and prevention literacy materials and implement country-wide capacity building training using adequate PEPFAR funding.
- COP22 Target: Community-led HIV and TB treatment & prevention literacy materials are distributed by PEPFAR to all support groups and ART clinics to reduce information gaps and misinformation.
- COP22 Target: Health worker-led health talks take place at all PEPFAR-supported health centres to provide information to patients waiting for services including (but not limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, cervical cancer screening, that ensure uptake of these services.
### COP21 language

<table>
<thead>
<tr>
<th>2. ART Retention/ Treatment Continuity</th>
<th>Language to include in COP22</th>
<th>COP22 Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>“The contributions of current and previous expert clients have been instrumental in mitigating treatment gaps and PEPFAR will continue to leverage lessons learned to recruit, deploy and train lay cadres to meet client needs.” - pg. 21</td>
<td>In COP22, PEPFAR will fund additional staffing in health facilities to ensure uninterrupted provision of services.</td>
<td>COP22 Target: PEPFAR should support the recruitment of additional staff to ensure uninterrupted services at all times.</td>
</tr>
<tr>
<td>“PEPFAR will resume and intensify efforts to prevent missed appointments, early loss to follow up, as well as, return clients back to care through the use of lay cadres including expert clients and patient navigators who will be formally paid, trained, capacitated, and equipped.” - pg. 46</td>
<td>PEPFAR will work with GoM to ensure that all PEPFAR-supported health facilities have service charters clearly pasted at the facility and healthcare providers to follow this service charter.</td>
<td>PEPFAR should work with GoM to expand DSD options to accommodate the needs of the different population groups, including through the establishment of community-driven Community ART Groups.</td>
</tr>
<tr>
<td>“PEPFAR will continue to engage the MOH to implement health care worker led community ART distribution or outreach models with integrated services including SRH. Current policy restrictions limit implementation of peer led community ART clubs and PEPFAR will continue to engage MOH and stakeholders for ongoing conversation on these models.” - pg. 48</td>
<td>PEPFAR will fast track implementation of new WHO Guidance on Simplified adherence support interventions.</td>
<td>PEPFAR should fund PrEP awareness and adherence support interventions.</td>
</tr>
<tr>
<td>Out of about 450 DSD sites, only about 75 will offer community ART distribution in COP21 - pg. 48</td>
<td>Everyone eligible will be offered PrEP including but not limited to AGYW, key populations, and those in sero-discordant couples.</td>
<td>COP22 Target: Everyone eligible should be offered PrEP including but not limited to AGYW, key populations, and those in sero-discordant couples.</td>
</tr>
<tr>
<td>“PEPFAR Malawi expects to fully implement retention-related PEPFAR Minimum Program Requirements at every PEPFAR-supported site, as these have a known impact on continuity of ART. Implementing partners will be assessed on site level implementation of the below four elements: [...] Adoption and implementation of differentiated service delivery models for clinically stable clients that ensures choice between facility and community ART refill pick-up location and individual or group ART refill models. All models should offer patients the opportunity to get 6 months of medication at a time without requiring repeat appointments or visits.” - pg. 77</td>
<td>PEPFAR will work with GoM to ensure that all PEPFAR-supported health facilities have service charters clearly pasted at the facility and healthcare providers to follow this service charter.</td>
<td>COP22 Target: PEPFAR to support extension of opening hours at all PEPFAR-supported health centres from 5am to 7pm on weekdays and 8am to 4pm on Saturdays — and PLHIV will be able to use these extended opening times to pick up their medication.</td>
</tr>
</tbody>
</table>

### 3. Stockouts

“PEPFAR continues to support viral load and EID tests in both high throughput and point of care testing (POCT) laboratories. In FY20, laboratories encountered high turnaround time and high VL sample backlogs due to reagent stockouts, staff shortage, equipment and supplies coproduction for COVID-19 tests. In COP21, to reduce service interruption due to stockouts, e-LMIS will be upgraded to monitor laboratory supply chain at national level and facility level; additionally, an existing laboratory stock module will be activated in iBLIS that will help the Diagnostic Department and laboratories to track and monitor the current laboratory reagents and supplies at any given time and provide forecasting to avoid stockouts and overstocks at the laboratory-level.” - pg. 58

In COP22, PEPFAR will fund additional staffing in health facilities to ensure uninterrupted provision of services. PEPFAR will work with GoM to ensure that all PEPFAR-supported health facilities have service charters clearly pasted at the facility and healthcare providers to follow this service charter. PEPFAR will support the expansion and scale-up of DSD models such as flexible/extended clinic hours and Community ART Groups to accommodate the needs of different populations. At least 40% of all eligible PLHIV on ART will be enrolled in Community ART Groups in COP22. In COP22, PEPFAR will support extension of opening hours at all PEPFAR-supported health centres from 5am to 7pm on weekdays and 8am to 4pm on Saturdays — and PLHIV will be able to use these extended opening times to pick up their medication.

**COP22 Target:** PEPFAR to allocate funding for procurement of drug buffers for health facilities.

### 4. HIV Prevention

“In anticipation of the Dapivirine Vaginal Ring (DVR) licensure which is likely to happen later this year, PEPFAR Malawi will work with the MOH and other stakeholders to assess health system requirement and guideline revisions.” - pg. 22

“PEPFAR Malawi will procure PrEP commodities for 6,000 clients in COP21 which will ensure that the country has enough commodities to reach the overall COPs21 PrEP CURR targets at approximately 19,000.” - pg. 36

8 key priorities for PrEP are expressed on pg. 36-37, which include the promotion of PrEP and expansion of PrEP services.

“Key priorities for COP21 will include: [...] Integration of PrEP into mainstream health services provision through orientation of facility staff, demand creation, training, capacity building and mentorship, and data capture, monitoring, and reporting.” - pg. 36-37

“Key priorities for COP21 will include: [...] Community sensitization to reduce myths and misconceptions around PrEP and to increase demand among all eligible populations will also be enhanced.” - pg. 36-37

In COP22, PEPFAR will work with the government to decentralize PrEP delivery in order to increase uptake of PrEP. This will include implementation of DSD for PrEP to simplify service delivery including community collection of PrEP refills. Everyone eligible will be offered PrEP including but not limited to AGYW, key populations, and those in sero-discordant couples. PEPFAR will also fund PrEP awareness and adherence support interventions. PEPFAR will fast track implementation of new WHO Guidance on Simplified PrEP Implementation and fund the development of policy and guidelines for dapivirine ring.

**COP22 Target:** PEPFAR should fund PrEP awareness and adherence support interventions.

**COP22 Target:** Everyone eligible should be offered PrEP including but not limited to AGYW, key populations, and those in sero-discordant couples.

**COP22 Target:** Implement DSD for PrEP to simplify service delivery including community collection of PrEP refills.

**COP22 Target:** Fund the development of DVR policy and guidelines.
### COP21 language

#### 5.1. Key Populations

“...To holistically meet the needs of KP, flexible hours at drop-in centers and hybrid facilities, individualized microplanning, and other activities previously supported through the Key Populations Investment Fund (KPIF) will be scaled in COP21. PEPFAR remains committed to closely collaborating with the Key Populations Diversity Forum (including quarterly meetings) to achieve more responsive and representative services.” - pg. 4-5

“PEPFAR Malawi will continue to coordinate with KP communities and the MoH to offer HCW sensitization training (including clinical and non-clinical staff) at supported sites to facilitate the provision of friendly and dignified integrated KP services.” - pg. 30

“The KP program is implemented in the nine high-burden districts of Blantyre, Machinga, Zomba, Mangochi, Lilongwe, Chikwawa, Chiradzulu, Mwanza, and Mzimba. The program continues to provide a cascade of comprehensive HIV prevention, care, and treatment services through eighteen drop-in centers, mobile hotspot outreach, and supported KP-friendly public facilities.” - pg. 30

In total, $5,172,196 is planned for investment in KP programming in 2022. - pg. 33

“PEPFAR partners will support the health facilities to integrate PrEP in STI clinics, family planning clinics, antenatal clinics, HIV testing and counselling, ART clinics, youth friendly health services clinics, gynecology clinics, and drop-in centers for key populations.” - pg. 35-36

“Together with GoM, PEPFAR will utilize CLM findings to guide trainings targeting clinical and non-clinical staff at PEPFAR supported sites to provide a friendly and welcoming environment for all patients (whether accessing HIV prevention, accessing ART, or, most especially, returning to care after a treatment interruption).” - pg. 46

“In COP20, PEPFAR supported quantification, supply planning, and monitoring of HIV/AIDS commodities and procurement of VMMC commodities ($2,022,735), condoms, and lubricants ($804,046). In COP21, PEPFAR will leverage the Commodity Fund ($785,000) to support PEPFAR prevention programs by continuing to fund Malawi’s lubricant needs for KPs, socially-marketed Chishango condoms, and public sector female condoms to prevent gaps in condom supplies.” - pg. 67

PEPFAR will fund the training of all clinical and non-clinical staff at health facilities on SOGIE and provision of KP friendly services to ensure a welcoming and safe environment for all KPs at all times. KPs will be involved in the implementation of these training modules. Post sensitisation training, PEPFAR will complete follow-up assessments to review the quality of KP service provision at site level (to show the success of the sensitisation programme). For the remainder of COP21 and in COP22, PEPFAR will work with DHA to investigate any reports of poor staff attitude, privacy violations, verbal or physical abuse/harassment and/or of services being restricted or refused and ensure that disciplinary action is taken where appropriate.

In COP22, PEPFAR will work with the Global Fund to strengthen the lubricant and condom supply chain to ensure that condom compatible lubricants and both male and female condoms are easily available at all public health facilities (not only upon request or in public spaces that make it difficult to pick them up).

PEPFAR will scale-up KP specific service availability across all PEPFAR supported facilities including but not limited to KP friendly HIV prevention, testing, treatment and care; gender affirming care; outreach services, peer navigators, HCV/HBV services; easily accessible condoms and lubricants; psycho-social support; harm reduction services. PEPFAR will allocate US$ 100,000 for planning and coordination activities for the Diversity Forum.

#### 5.2. AGYW

“PEPFAR Malawi will expand DREAMS eligibility to young women in institutions of higher learning, will rely upon the fully functional DREAMS database to track layering services and completion of the primary package, and roll-out the Historically Black Colleges and University (HBCU) initiative that will complement efforts to increase formal economic opportunities for DREAMS AGYW.” - pg. 4

“In COP21, the program will continue to scale up DREAMS activities in the existing districts (Machinga, Zomba, and Blantyre) to ensure full district saturation. Saturation (75% of AGYW in a given SNU has completed the appropriate package of interventions) is expected by the end of COP 21. Once SNUs achieve saturation, expansion to additional SNUs will take place in consultation with CSOs and GoM. AGYW. Prev targets have been set for the very first time and the target for Malawi is 56,204 as the numerator and 88,121 as the denominator.” - pg. 23

In response to this ask, PEPFAR said: “PEPFAR Malawi plans to maintain the number of districts but expand within the districts and work towards saturation across the age bands.” - pg. 84

In COP22, PEPFAR will expand DREAMS interventions to 2 additional districts. PEPFAR should clearly define and support engagement mechanisms for AGYW in all DREAMS districts.

### Language to include in COP22

PEPFAR will fund the training of all clinical and non-clinical staff at health facilities on SOGIE and provision of KP friendly services to ensure a welcoming and safe environment for all KPs at all times. KPs will be involved in the implementation of these training modules. Post sensitisation training, PEPFAR will complete follow-up assessments to review the quality of KP service provision at site level (to show the success of the sensitisation programme). For the remainder of COP21 and in COP22, PEPFAR will work with DHA to investigate any reports of poor staff attitude, privacy violations, verbal or physical abuse/harassment and/or of services being restricted or refused should be urgently investigated by DHA/PEPFAR and disciplinary action taken where appropriate.

PEPFAR should clearly define and support engagement mechanisms for AGYW in all DREAMS districts.

### COP22 Target

PEPFAR will fund the training of all clinical and non-clinical staff at health facilities on SOGIE and provision of KP friendly services to ensure a welcoming and safe environment for all KPs at all times. KPs will be involved in the implementation of these training modules.

PEPFAR and the Global Fund should strengthen the lubricant and condom supply chain to ensure that condom compatible lubricants and both male and female condoms are easily available at all public health facilities (not only upon request or in public spaces that make it difficult to pick them up).

PEPFAR should scale-up KP specific service availability across all PEPFAR supported facilities including but not limited to KP friendly HIV prevention, testing, treatment and care; gender affirming care; outreach services, peer navigators, HCV/HBV services; easily accessible condoms and lubricants; psycho-social support; harm reduction services.

PEPFAR should allocate US$ 100,000 for planning and coordination activities for the Diversity Forum.

PEPFAR should clearly define and support engagement mechanisms for AGYW in all DREAMS districts.
6. Comorbidities

“Point of care diagnostic tools will be provided at all PEPFAR supported sites to allow CD4 detection on site, to allow patients to be assigned to care depending on whether their CD4 count is above or below 200 cells/ul. In COP22, PEPFAR will ensure the provision of L-AmB for all facilities that currently provide infusions and fluconazole for inpatient and outpatient facilities for follow-up oral treatment together with fluconazole in order to reduce overall mortality.

In COP22, PEPFAR will ensure that all PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in patient and outpatient settings receive both urine-LAM and rapid molecular testing (including the use of stool samples among CLHIV) upon their first presentation to care. PEPFAR will ensure that procurement quantities of commodities required for urine-LAM and rapid molecular testing should each exceed the estimated number of PLHIV, including CLHIV, expected to present to care at PEPFAR-supported sites with advanced HIV disease or TB signs and symptoms in COP22.

COP22 Target: 100% of healthcare workers at PEPFAR-supported sites are trained to perform TB screening, urine-LAM, and rapid molecular testing among PLHIV in accordance with WHO recommendations and algorithms and appropriate approach for sputum scarce symptom positive but rapid molecular negative patients.

COP22 Target: PEPFAR to work with GoM and Global Fund to train 100% of community sputum collectors.

COP22 Target: All eligible PLHIV and all eligible contacts of a person with pulmonary TB, including children and adolescents, should be traced and initiated on TPT. All people considered for TPT should undergo clinical evaluation (symptom check and physical examination) and be tested with GeneXpert (Xpert), even without having any symptoms. All eligible PLHIV including children and adolescents will be initiated and complete TPT within COP22, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient. Of these, at least 70% should receive 3HP and 30% should be on IPT. PEPFAR will fund “cold” storage of the fixed-dose 3HP products for TPT to avoid impurities.

Point of care diagnostic tools will be provided at all PEPFAR supported sites to allow CD4 detection on site, to allow patients to be assigned to care depending on whether their CD4 count is above or below 200 cells/ul. In COP22, PEPFAR will ensure the provision of L-AmB for all facilities that currently provide infusions and fluconazole for inpatient and outpatient facilities for follow-up oral treatment together with fluconazole in order to reduce overall mortality.

COP22 Target: PEPFAR and GoM should ensure clear quantification and monitoring of cryptococcal meningitis (CM) including annually how many PLHIV: 1) develop CM; 2) receive optimal treatment for CM; 3) survive CM; 4) die of CM; 5) receive preventive treatment for CM; 6) receive a CD4 test; 7) CRAG+ getting lumbar puncture (LP); 8) LP negative getting fluconazole prophylaxis.
<table>
<thead>
<tr>
<th>COP21 language</th>
<th>Language to include in COP22</th>
<th>COP22 Target</th>
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<tr>
<td><strong>7. Community-led monitoring</strong></td>
<td>In COP22 PEPFAR will increase the CLM budget from the current $694,898 to $1.08 million to allow for expansion of CLM interventions to 50 additional high burden sites in 7 districts.</td>
<td><strong>COP22 Target:</strong> USD 1.08 million for CLM to expand in COP22 to 50 high burden sites across Malawi including to gather evidence, analyze data, generate solutions and engage with duty bearers to see swift corrective action.</td>
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<td>“In COP21, PEPFAR will continue providing funding to CSOs for community-led monitoring of the HIV/AIDS response in the 11 scale-up districts.” - pg. 20 Amount for CLM = $694,898 pg. 21</td>
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