Malawi Country Operational Plan 2021

Strategic Direction Summary

May 19, 2021

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1.0 Goal Statement

PEPFAR Malawi's Country Operational Plan (COP) 2021 reflects a culmination of strong interagency collaboration between the PEPFAR Malawi team, Government of Malawi (GoM), and civil society organizations (CSOs) to mitigate the devastating impacts of COVID-19 and sustain progress achieved over the last two decades towards HIV epidemic control. At the conclusion of the March 2020 Johannesburg Regional Planning Meeting, the PEPFAR Malawi team presented a COP20 surge strategy to improve client-centered care, mitigate treatment disruption, scale prevention programs to key and vulnerable populations, and strengthen national health systems. Following this meeting, the first three COVID-19 cases were reported in Malawi and immediately thereafter, adaptations to the COP20 strategy became imperative to deliver safe, client-centered care.

PEPFAR Malawi's COP21 strategy is designed to accelerate delayed interventions (due to the COVID-19 pandemic) outlined in the COP20 Strategic Direction Summary (SDS), repair prevention programs which experienced significant setbacks due to national policy restrictions, and "Build Back Our Programs Better" - leveraging the smart adaptations developed in response to COVID-19 to improve the resiliency of HIV programs against the backdrop of dual pandemics.

Building upon the COP20 back-to-care surge strategy, PEPFAR Malawi remains committed to actively addressing barriers clients face by increasing service delivery access points and extending operational hours for client convenience. We are implementing integrated service delivery models to reduce waiting times and telehealth to maximize spacing of in-person visits. PEPFAR Malawi will capacitate District Health Offices to oversee and implement programs currently supported by international partners, reinforcing the GoM's decentralization plans and paving the way for PEPFAR programming to transition to government and local entities.

In COP21, PEPFAR Malawi will continue to adapt the MenStar Strategy to the Malawian context to reach men in the 25-39 age band, accelerate six multi-months dispensing, and continue the recruitment of lay and on-establishment healthcare workers to provide advanced HIV disease (AHD) care and psychosocial support. Epidemic control cannot be sustained without treatment and viral load literacy. PEPFAR Malawi will work through civil society and government platforms to disseminate "Messages of Hope" to improve treatment literacy at the individual, community, and national level and will integrate central investments through the existing Faith and Community Initiative (FCI) into base activities. Market research and data generated from the Bill and Melinda Gates Foundation (BMGF), the Ministry of Health (MoH), Johnson & Johnson and PEPFAR "Flip the Script" public-private partnership will also be leveraged to ensure literacy and educational messages are impactful.

PEPFAR Malawi works across government ministries and closely with the Department of HIV and AIDS (DHA), implementing partners (IPs), and other civil society entities to reduce stigma and ensure safe and ethical implementation of case-finding modalities, including index testing. By standardizing IPs' reporting on key indicators related to safe and ethical testing and providing

feedback for all newly diagnosed people living with HIV (PLHIV), PLHIV not on antiretroviral treatment (ART), and children/adolescents of PLHIV aged 19 years and below, benefit. In COP21, a validated screening tool will be in used across PEPFAR IPs for outpatient departments to improve efficiency of HIV testing services and HIV self-testing targeting men, adolescent girls and young women (AGYW), and key populations (KP) will be expanded. Although recency testing was suspended due to COVID-19 for most of calendar year 2020 and quarter one of 2021, PEPFAR Malawi will rapidly scale its use to inform hotspot targeting and monitor new infections.

To increase access to cervical cancer screening and treatment services, 47 additional sites across all 28 districts will be capacitated to deliver services to 107,078 women living with HIV (WLHIV) in COP21. PEPFAR Malawi will strengthen referral networks and continue to support LEEP, visual inspections with acetic acid and cervicography (VIAC), capacitate histopathology labs, as well as introduce human papillomaviruses (HPV) DNA testing. In an effort to scale TB preventative therapy (TPT) following a six-month COVID-19-related suspension and Rifapentine recall due to nitrosamine impurities, PEPFAR Malawi will work with the MOH and civil society to finalize TPT/3HP rollout plans in COP21. In the interim, PEPFAR Malawi will work with DHA and CSOs to generate demand for TB Prevention. This will include adherence counseling for those currently receiving TPT (including IPT), treatment literacy on the importance of TPT, 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. PEPFAR Malawi will work with DHA and CSOs to generate demand for TPT, promote adherence among PLHIV, and support commodity quantification, distribution, and storage to ensure adequate supply.

Due to the COVID-19 pandemic, many PEPFAR programs were either suspended, paused, or scaled-down in order to reduce the risk of transmission and protect the safety of PEPFAR-supported staff and beneficiaries. Recognizing that many PEPFAR programs are also crucial to saving lives and preventing HIV transmission, COP21 will make up for lost ground by shifting demand creation activities for pre-exposure prophylaxis (PrEP), voluntary medical male circumcision (VMMC), and other community-based prevention programs through a combination of virtual, one-on-one, and small group approaches. 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.

A virtual case management approach for orphans and vulnerable children (OVC) will be incorporated into family centric models with an increased priority to enroll 90% of children living with HIV (CLHIV) into OVC programs in PEPFAR-supported sites as a strategy to increase viral load coverage and suppression rates. COP21 will also see a major focus on pediatric treatment optimization including the transition to pediatric Dolutegravir 10mg. 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.

Lastly, PEPFAR Malawi will invest in laboratory, health management information (i.e., electronic medical records), supply chain, human resources for health (HRH), and community-led monitoring (CLM) to sustain epidemic control goals. Investments in CLM will continue in COP21 to ensure implementation fidelity and inform programmatic shifts based on client feedback. PEPFAR Malawi has also started reactivating surveillance activities including recency, birth defects, HIV drug resistance, and mortality, which were all suspended due to the COVID-19 pandemic. In COP21, full implementation of these surveillance activities is expected. PEPFAR Malawi will also continue efforts to use government-to-government (G2G) agreements to sustainably recruit and deploy critical HRH, and to promote governance, oversight, accountability, and policy implementation.

PEPFAR Malawi's systems investments are foundational to client-centered care and preventing new HIV infections. A multi-pronged approach will be utilized in COP21 to more intentionally engage district leadership in PEPFAR programs, in addition to, aligning the distribution of HRH cadres with site level client volume. To increase viral load coverage and strengthen laboratory systems strained by COVID-19 demands, PEPFAR Malawi will leverage the American Rescue Plan, Global Fund New Funding Model (NFM3), and the COVID-19 Response Mechanism (C19RM) grant application to scale the use of plasma for viral load testing, support waste management, infection prevention and control measures, in addition to, optimizing sample transportation pull systems. PEPFAR Malawi will continue to prioritize investments for continuous quality improvement of Malawi's laboratory networks, module development, and system upgrades to the point of care electronic medical records (EMR) system for patient management.

In COP21, PEPFAR Malawi will address commodity gaps by procuring ARVs and lab reagents for PrEP, viral load and AHD care, VMMC commodities, HIV self-test kits, and condoms. PEPFAR Malawi will also enhance the functionality of logistics management information systems (LMIS), support surveillance, pharmacovigilance, forecasting, and quantification efforts to minimize commodity insecurity.

Although COP21 reflects a reduced planning level investment and is unable to financially respond to all the recommendations and priorities received by civil society and external stakeholders, COP21 reflects a concerted effort to address gaps and challenges shared by beneficiaries, implement sustainable solutions that can be transitioned to the GoM, and efficiently leverage donor resources to support Malawi's national HIV response. As Malawi will likely reach epidemic control before or during COP21, mapping changes for the new operational context will be essential.

2.0 Epidemic, Response, and Program Context

2.1 Summary Statistics, Disease Burden, and Country Profile

Malawi is a low-income country (GNI: 380 per capita[1]) with a population of 19 million people[2]. Although a small country, Malawi's HIV prevalence, at 5.6% overall and 9.1% among adults, is among the highest in the world[3].

An estimated 1.06 million Malawians are living with HIV, of which, 63% are women, 37% men, and 6% are children under 15 years old. Malawi has made good progress toward reaching the 95-95-95 UNAIDS goals, and at the end of September 2020, an estimated 92% of all PLHIV knew their HIV status, 84% of PLHIV with known status were on ART, and 93% of PLHIV on ART were virally suppressed (see Table 2.1.2 below). Despite the progress, some critical disparities by geography and populations persist and the greatest gaps to reaching 90% ART coverage are in Blantyre, Lilongwe, and Zomba districts.

Within Malawi, results from the Malawi Population-based HIV Impact Assessment (MPHIA) 2015-16 show HIV prevalence varies widely by region, with prevalence among adults ranging from 4.9% in the Central-East regions to 17.7% in Blantyre City. Prevalence is highest in the urban centers of Blantyre and Lilongwe (14.2% among adults aged 15-64 years with urban residence) and differs significantly by age and sex. HIV prevalence is nearly twice as high among females 15-24 years old (3.4%), and nearly three times as high among females 25-29 years old (13.6%) than among males in the same age brackets (1.5% and 4.7%, respectively). Prevalence peaks among females at 40-44 years old at 24.6% and among males 45-49 years old at 22.1% (see Table 2.1.1 for more details). The migration of youth to urban centers, a growing youth population bulge, and sub-optimal levels of viral suppression in urban areas have contributed to higher incidence and prevalence among young people.

[1] World Bank. GNI per capita, Atlas method (current USD$). https://data.worldbank.org/indicator/NY.GNP.PCAP.CD?locations=MW. Accessed May 3, 2021

[2] Government of Malawi National Statistical Office. 2018 Population and Housing Census: Main Report. http://www.nsomalawi.mw/images/stories/data_on_line/demography/census_2018/2018%20Malawi%20Population%20and%20Housing%20Census%20Main%20Report.pdf. May, 2019.

[3] Spectrum 2021 third-quartile estimates, for 2021

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Table 2.1.1 Host Country Government Results

	Total		<15				15-24				25+				*Source, Year*
			Female		Male		Female		Male		Female		Male		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Total Population	19,010,635	100	3,963,962	21	3,973,800	21	2,070,183	11	1,906,438	10	3,760,338	20	3,335,914	17	Naomi 2021 estimates, for 2021
HIV Prevalence (%)		5.6		0.8		0.8		3.8		2.1		15.1		9.6	Naomi 2021 estimates, for 2021
AIDS Deaths (per year)	10,857		740		746		737		586		4,157		3,894		Spectrum 2021 estimates, for 2021
# PLHIV	1,063,626		30,150		30,186		78,115		39,683		566,190		319,302		Naomi 2021 estimates, for 2021
Incidence Rate (Yr)		0.39		NA		NA		0.40		0.05		0.61		0.42	MPHIA, 2015-16
New Infections (Yr)	19,753														Spectrum 2021 estimates, for 2021
Annual births	638,145	100													Spectrum 2021 estimates, for 2021
% Pregnant Women with at least one ANC visit		99.4		NA				99.6				99.2			MPHIA, 2015-16
Pregnant women needing ARVs	41,574	NA													Spectrum 2020 estimates, for 2020
Orphans (maternal, paternal, double)	1,085,900		NA		NA		NA		NA		NA		NA		OVC rates from MDHS 2015-16 applied to 2019 projection of the population (2010 population census projections).
Notified TB cases (Yr)	16,791		NA		NA		NA		NA		NA		NA		National TB Program Quarterly Data, FY2019

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% of TB cases that are HIV infected	7,878	47	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	National TB Program Quarterly Data, FY2019
% of Males Circumcised	503,934 (0-64)	9.2 (adults 15+)			123,753	3.2			207,232	12.8			172,949	6.9	MPHIA, 2015-16
Estimated Population Size of	23,200														IBBS Report, 2020
MSM HIV Prevalence		12.8													IBBS Report, 2020
Estimated Population Size of FSW	36,100														IBBS Report, 2020
FSW HIV Prevalence		49.9					NA	NA			NA	NA			IBBS Report, 2020

Table 2.1.2 95-95-95 Cascade: HIV Diagnosis, Treatment, and Viral Suppression

Epidemiologic Data					HIV Treatment and Viral Suppression			HIV Testing and Linkage to ART Within the Last Year		
	Total Population Size Estimate (#)	**HIV Prevalence (%)**	**Estimated Total PLHIV (#)**	**PLHIV diagnosed (#)**	**On ART (#)**	**ART Coverage (%)**	**Viral Suppression (%)**	**Tested for HIV (#)**	**Diagnosed HIV Positive (#)**	**Initiated on ART (#)**
Total population	19,010,635	5.6%	1,063,626	976,594	839,205	79%	93%	3,186,677	103,332	91,483
Population <15 years	7,937,762	0.8%	60,336	46,976	43,493	72%	72%	no data	no data	5,250
Men 15-24 years	1,906,438	2.1%	39,683	32,877	16,253	41%	84%	no data	no data	3,159
Men 25+ years	3,335,914	9.6%	319,302	290,645	249,418	78%	94%	no data	no data	30,128
Women 15-24 years	2,070,183	3.8%	78,115	63,839	44,344	57%	89%	no data	no data	14,822
Women 25+ years	3,760,338	15.1%	566,190	542,257	466,377	82%	95%	no data	no data	36,171
MSM	14,245	12%	1,744		688	39%	91%	2,987	445	279
FSW	22,809	49%	11,282		3,835	34%	96%	15,548	2,771	1,953

Source: COP21 Data Pack, Panorama

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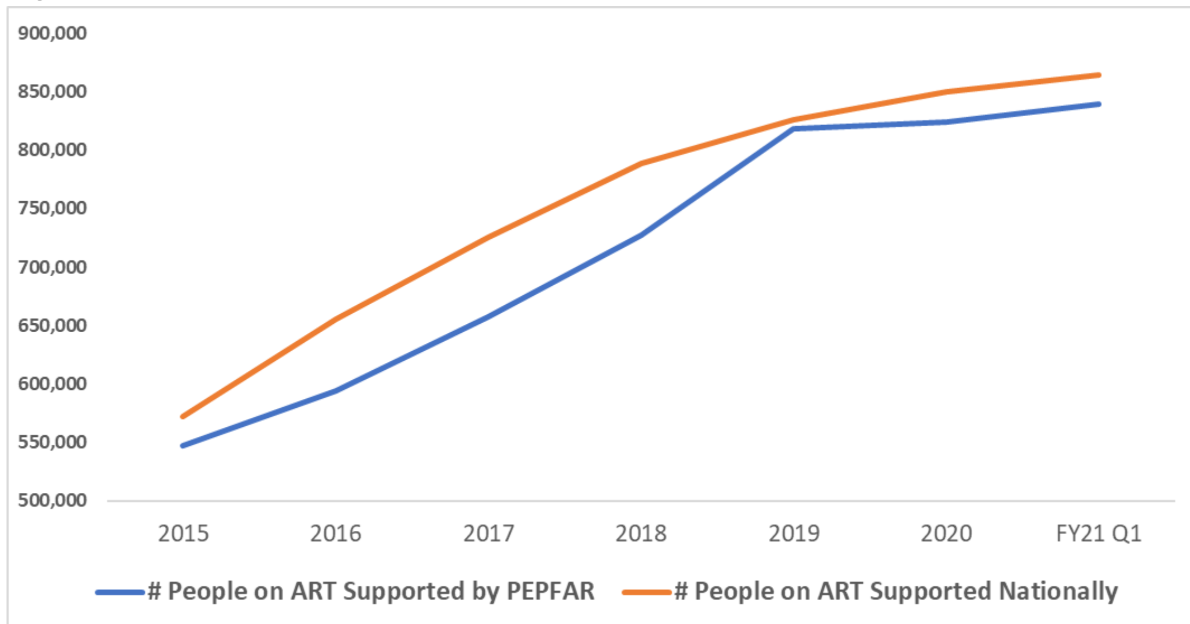
Figure 2.1.3 Updated National and PEPFAR Trend for Individuals Currently on Treatment



Source: DATIM, Panorama, DHA data

Figure 2.1.3 compares the number of clients on ART as reported by PEPFAR compared with the number of clients on ART as reported by the national program. Although PEPFAR supports all sites that provide ART services in the country, the number of people on ART reported nationally by the MOH is higher than those reported by PEPFAR. This is largely due to the differences in the definition of "loss to follow-up"; the MOH uses a 60-day definition whereas PEPFAR uses a 30-day definition. If the MOH and PEPFAR were using same definition, the data of the number of clients on ART would more closely match.

Figure 2.1.4 Updated Trend of New Infections and All-Cause Mortality among PLHIV

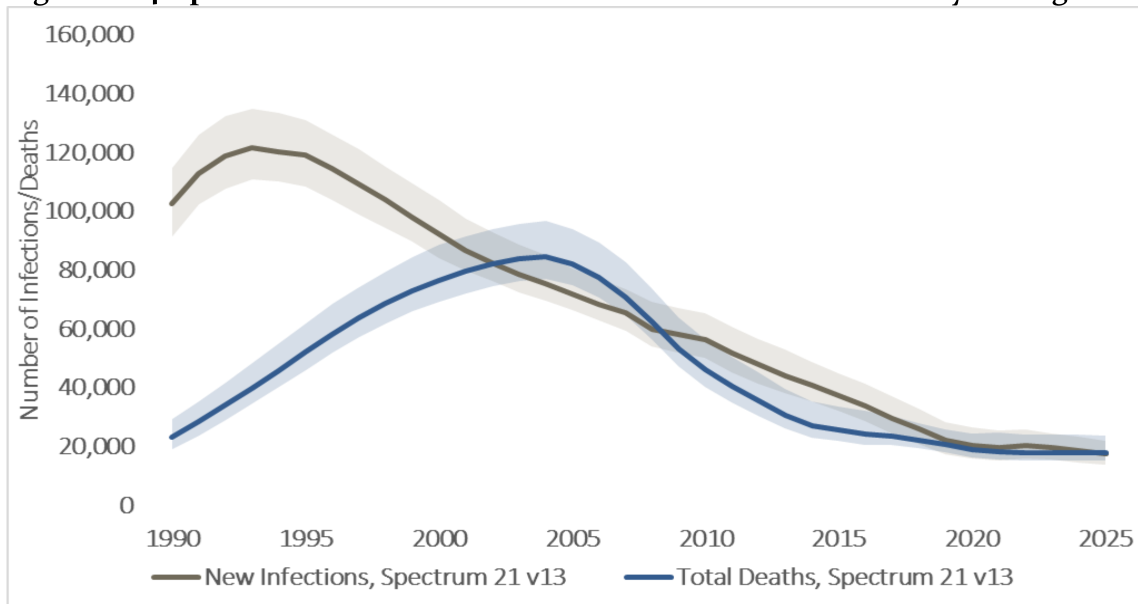


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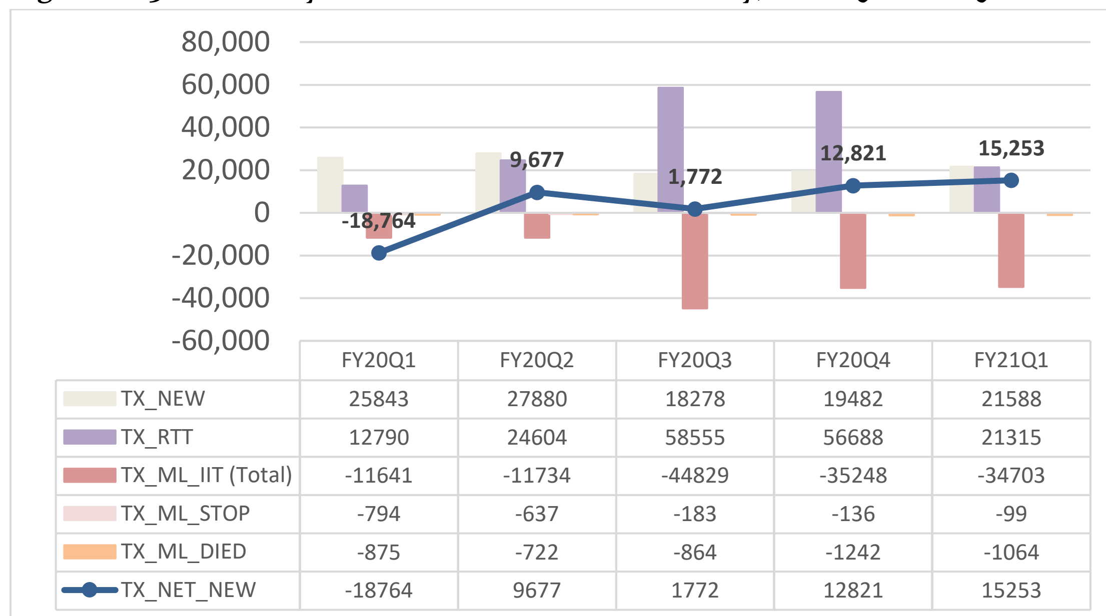
Figure 2.1.4 reflects the HIV estimates from Spectrum (2021) and shows that Malawi has reached epidemic control based on the number of new infections converging with the number of deaths in the HIV population. The figure also indicates considerable overlap between the uncertainty bounds. However, considering uncertainties with Spectrum, the PEPFAR Malawi team with guidance from S/GAC, used the third quantile of the Naomi model, which gave a higher PLHIV number while also indicating a gap to the 95-95-95 achievements. These will be confirmed once PEPFAR Malawi has the MPHIA results later this year and may necessitate revision to the COP21 targets.

Figure 2.1.5 Continuity of Treatment Annual Summary, FY20 Q1- FY21 Q1



	FY20Q1	FY20Q2	FY20Q3	FY20Q4	FY21Q1
TX_NEW	25843	27880	18278	19482	21588
TX_RTT	12790	24604	58555	56688	21315
TX_ML_IIT (Total)	-11641	-11734	-44829	-35248	-34703
TX_ML_STOP	-794	-637	-183	-136	-99
TX_ML_DIED	-875	-722	-864	-1242	-1064
TX_NET_NEW	-18764	9677	1772	12821	15253

Source: ICPI Continuity in Treatment Dashboard, FY21 Q1

Figure 2.1.5 represents PEPFAR's continuity of treatment data from FY20 Q1 to FY21 Q1. Increases in overall TX_NET_NEW were observed since FY20 Q3, and although there are high numbers of clients returning to care, the program is still working to reduce treatment interruptions and increase ART coverage for optimal program outcomes.

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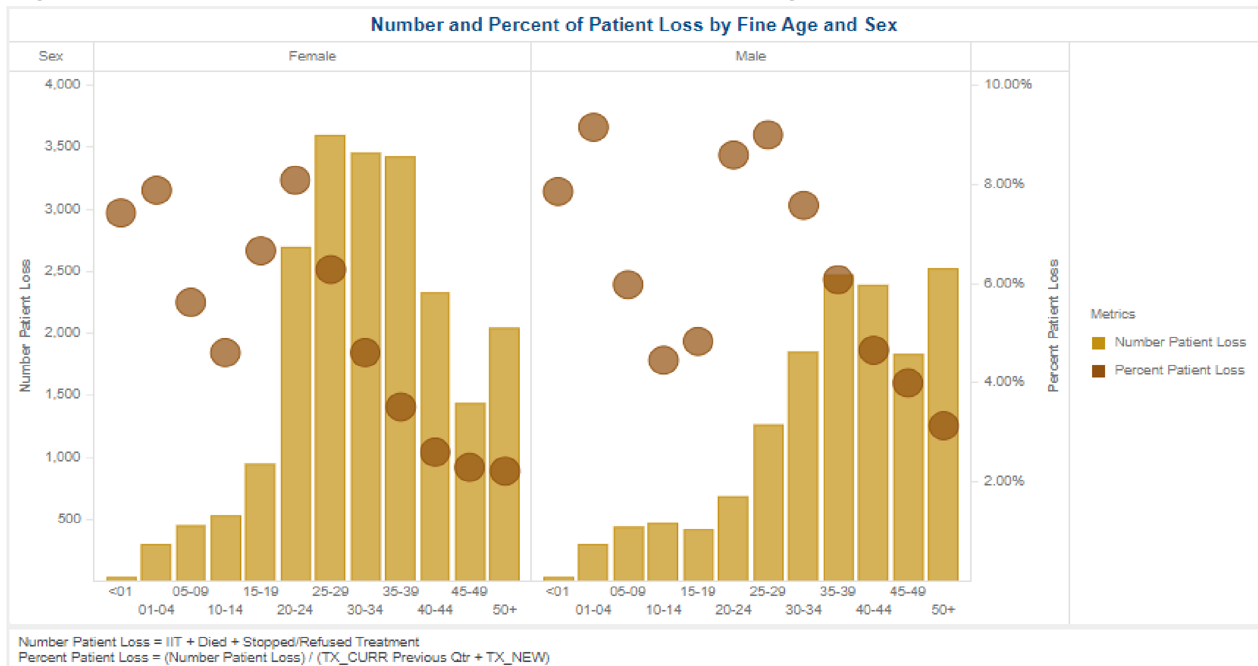
Figure 2.1.6 Number and Percent of Client Loss by Fine Age and Sex, FY21 Q1



Source: Panorama, FY21 Q1

Figure 2.1.6 represents client loss by age and sex, with the highest percentages of loss observed in pediatrics and males between the ages of 20-29 years. In COP21, the PEPFAR program will strive to reduce treatment interruptions within these subpopulations.

Figure 2.1.7 Epidemiologic Trends and Program Response

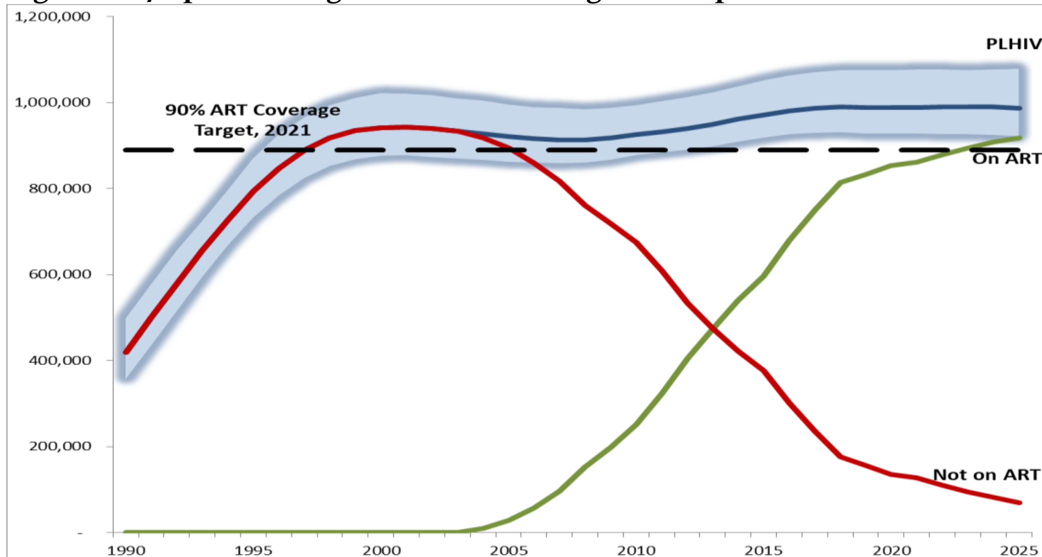


Figure 2.1.7 presents trends of ART coverage among PLHIV and PLHIV on ART. Overtime, ART coverage has steadily increased with the gap to ART coverage closing significantly. The above figure shows the operating unit (OU) is on course to achieve ART 90% coverage within COP21; that is if not already achieved, pending the MPHIA results later this year.

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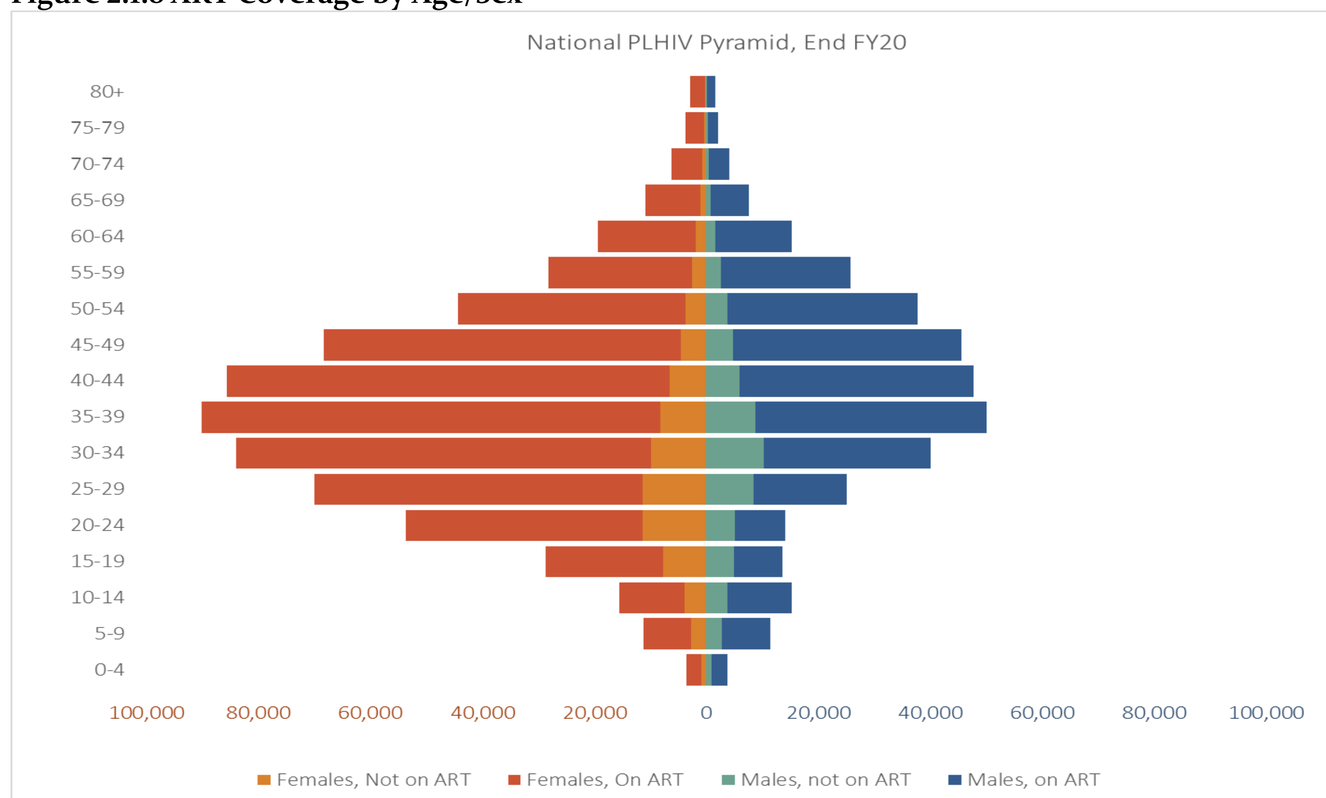
Figure 2.1.8 ART Coverage by Age/Sex



Source: Spectrum 21 v13, Fine age/sex calibrated Naomi output

Figure 2.1.8 shows that based on modelled ART coverage, the largest treatment coverage gaps are observed in the pediatric population, males aged 15-29 years, and females between the ages of 15-24 years.

2.2 Investment Profile

The Malawian health sector relies heavily on funding from external sources; the national HIV program is 95% funded by international donors for various programming components. The Global Fund finances the procurement of health products, paying for 99% of all HIV-related commodities. While Malawi has limited fiscal space, PEPFAR commends the GoM for increasing its investments in health systems strengthening including HRH, health infrastructure, essential medicines, and prevention efforts. Malawi has demonstrated initial efforts to continue the national dialogue and plans to take up some of the costs of anti-retroviral therapy in the future. With the backdrop of the COVID-19 pandemic, the growing debt, lower domestic revenue (as compared to prior years), and depreciation of the exchange rate, all of these factors potentially threaten the country's ability to meet domestic resource mobilization goals and the 2022 Global Fund co-financing requirement.

Since 2004, PEPFAR has invested over $1 billion in HIV service provision and prevention to efficiently identify PLHIV, ensuring all newly diagnosed PLHIV are immediately linked to treatment, retained on treatment, and are virally suppressed. In COP21, the PEPFAR Malawi

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program will invest over $181 million, continuing its support to the HIV program implementation and maintaining epidemic control. In a unique and catalytic partnership with the GoM, PEPFAR and USAID Basic Education are currently implementing the Secondary Education Expansion for Development (SEED) project, a $90 million initiative to build up to 200 new secondary schools where educational access has been limited and expand classroom space in crowded urban center secondary schools. This initiative will ensure thousands of AGYW have the opportunity to complete additional years of secondary school, which has been shown to decrease the lifetime risk of HIV acquisition among AGYW.

The COP21 development cycle provided an opportune time for PEPFAR and the Global Fund (GF) to reaffirm commitments to support the national HIV response and for development partners to rethink how we interact, deliver services, and support the GoM. Leveraging investments and approaches for keeping both healthcare providers and clients living with HIV/AIDS safe remains paramount while mitigating the effects of COVID-19 on the HIV, TB, and Malaria programs through a focus on high impact interventions and multi-stakeholder coordination in the current New Funding Model III grant. As the 2022 COVID-19 Resource Mechanism application process continues, the US Government team is actively engaged in ensuring the proposed interventions and investments serve those most affected by the three diseases and at highest risk of co-mortalities and morbidities. PEPFAR's significant investment in service delivery, including human resources and technical assistance where gaps exist, and these Global Fund grants ensure a secure commodity supply chain, namely for ARVs, lab monitoring, and HIV tests. Close coordination between PEPFAR, the Global Fund, and other donors will maximize use and impact of resources to combat HIV/AIDS to the fullest extent possible.

Table 2.2.1 Malawi Annual Investment Profile (Budget Allocation) for HIV Programs, 2021

Table 2.2.1 Malawi Investment Profile (Budget Allocation) for HIV Programs, 2021					
	Total	**Domestic Gov't**	**Global Fund**	**PEPFAR**	**Other Funders**
	$	%	%	%	%
Care and Treatment	$115,289,971	0%	28%	72%	0%
HIV Testing Services	$6,872,125	0%	19%	81%	0%
Prevention	$45,481,886	0%	9%	91%	0%
Socio-economic (incl. OVC)	$8,752,139	0%	5%	95%	0%
Above Site Programs	$27,495,927	0%	41%	59%	0%
Program Management	$36,373,767	0%	10%	90%	0%
Total (incl. Commodities)	**$244,827,828**	**2%**	**22%**	**76%**	**0%**
Commodities Only	**$28,294,323**	**0%**	**93%**	**7%**	**0%**

Source: HIV Resource Alignment. Domestic Gov't and Other Funders data included where available

Table 2.2.2 Malawi Investment Profile (Budget Allocation) for HIV Commodities, 2021

Table 2.2.2 Malawi Investment Profile (Budget Allocation) for HIV Commodities, 2021					
	Total	**Domestic Gov't**	**Global Fund**	**PEPFAR**	**Other Funders**
	$	%	%	%	%
Antiretroviral Drugs	$17,395,864	0%	100%	0%	0%
Laboratory Supplies and Reagents	$214,213	0%	100%	0%	0%
Medicines	$2,986,239	0%	100%	0%	0%
Consumables (condoms, Rapid Test Kits, VMMC kits and supplies)	$2,734,254	0%	43%	57%	0%
Health Equipment	$765,653	0%	100%	0%	0%
PSM Costs	$4,198,100	0%	89%	11%	0%
Total Commodities Only	**$28,294,323**	**0%**	**93%**	**7%**	**0%**

Source: HIV Resource Alignment. Domestic Gov't and Other Funders data included where available

Table 2.2.3 Annual USG Non-PEPFAR Funded Investments and Integration

Funding Source	Total USG non-PEPFAR resources	Non-PEPFAR Resources Co-Funding PEPFAR IMs	# Co-Funded IMs	PEPFAR COP Co-Funding Contribution	Objectives
USAID MNCH	17,500,000	3,029,000	4	1,623,735	To reduce maternal and child morbidity and mortality, and strengthen health systems to deliver primary health care services.
USAID TB	3,500,000	1,200,000	1	510,574	To strengthen TB screening prevention, diagnosis, and treatment among PLHIV, including IPT delivery.
USAID Malaria	24,000,000	360,000	1	211,765	To strengthen health systems to deliver primary health care services.
Family Planning	11,000,000	1,800,000	4	1,097,353	These co-funded mechanisms provide support to strengthen health systems to deliver primary health care services.
Nutrition	7,000,000	700,000	4	417,147	To strengthen health systems to deliver primary health care services.
DRG	1,867,285	625,000	1	157,776	To strengthen democracy and community participation in district assemblies.
Other (COVID)	1,500,000	300,000	1	500,000	To support dissemination of risk communication, community engagement, and implementation of infection prevention and control measures at community level.
Total	66,367,285	8,014,000	16	4,518,350	

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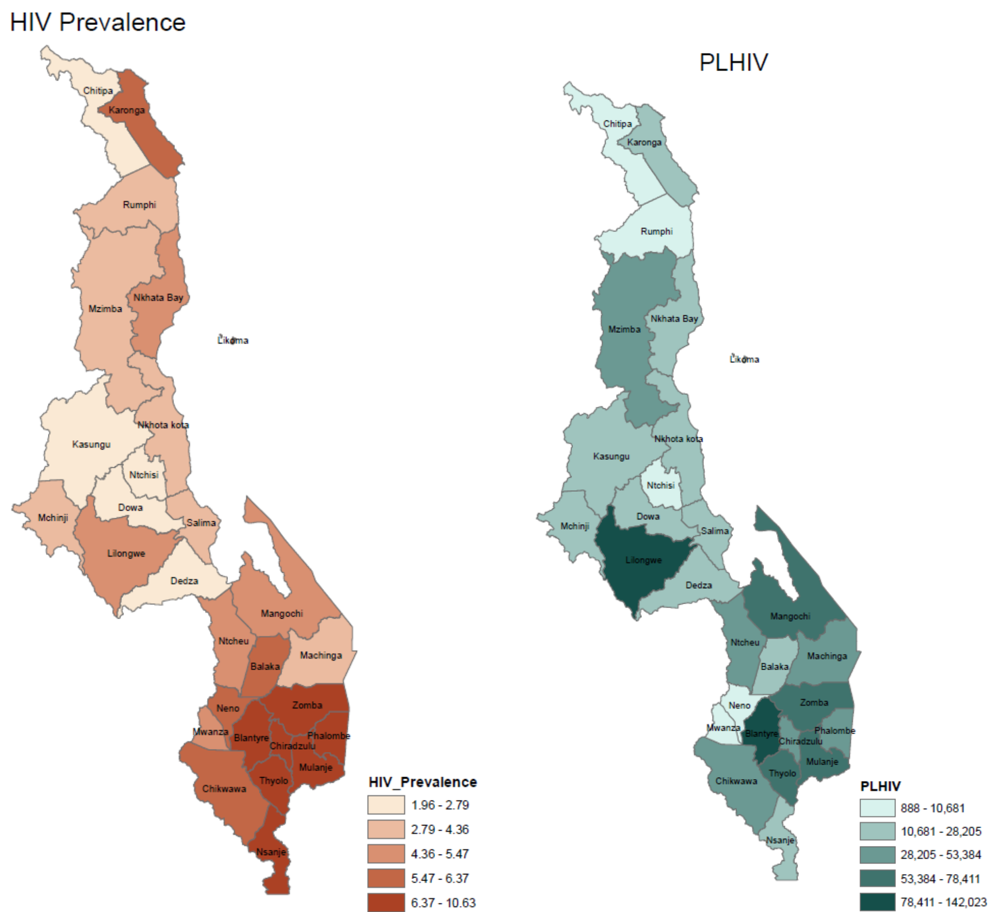
2.3 Alignment of PEPFAR Investments Geographically to Disease Burden

Figure 2.3.1 below outlines HIV prevalence and district-level HIV burden. While PEPFAR invests in all districts throughout Malawi, PEPFAR most strategically focuses investments in high-burden, scale-up districts. In COP21, PEPFAR will focus on the 11 scale-up districts with the greatest PLHIV burden and largest remaining gaps to 95% ART coverage in Blantyre, Chikwawa, Chiradzulu, Lilongwe, Machinga, Mangochi, Mulanje, Mzimba, Phalombe, Thyolo, and Zomba.

Figure 2.3.1 HIV Prevalence and People Living with HIV

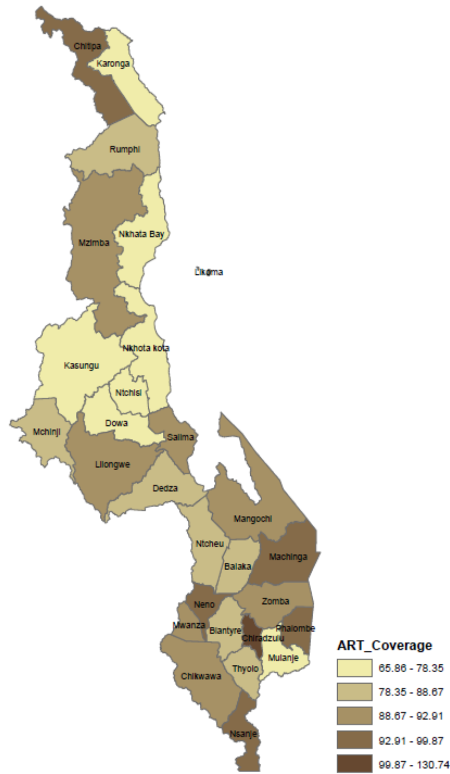


Source: Spectrum 21 v13, Fine age/sex calibrated Naomi output

Figure 2.3.2 FY21 Q1 ART Coverage, COP21 ART Coverage, COP21 Viral Load Coverage

ART Coverage, FY21 Q1

ART Coverage, COP 21



Viral Load Coverage, COP 21

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3.0 Global Fund, Government of Malawi, and Civil Society Stakeholder Engagement

COP21 development included continuous dialogue, planning, and prioritization of areas for investment and attention with various stakeholders. Key virtual meetings with the PEPFAR interagency team provided a space for discussions and feedback loops with civil society, implementing partners, the Government of Malawi, bilateral, and multilateral partners amid the COVID-19 pandemic:

- **May 28, 2020**: Key Populations Diversity Forum enabled KP representatives to share challenges affecting LGBTI interventions and offer recommendations.
- **September 8, 2020**: CSOs presented CLM findings to MOH and stakeholders who exchanged feedback and agreed on a way forward.
- **February 4-5, 2021**: This virtual stakeholder retreat kicked off the COP21 planning process with MOH, multilateral institutions, implementing partners, and CSOs to arrive at:
    - National priorities and gaps presented on the TB/HIV grants with requests for COP21 funding consideration;
    - The presentation of the People's COP21 by CSOs and feedback informed revisions; and
    - Follow-up actions identified to increase district-level planning and engagement.
- **February 12, 2021**: This CSO-led forum presented a revised draft of the People's COP21.
- **March 4, 2021:** This CLM field findings consultative meeting included CSOs, IPs, UNAIDS, the PEPFAR interagency and focused on:
    - An update on defaulter rates/tracing and availability of cervical cancer screening services in each district;
    - Discussion and exchange of strategies for reducing defaulter rates in health centers; and
    - Sharing and wider implementation of strategies to scale up cervical cancer screening services in health centers currently not covered.
- **March 24, 2021:** CSOs presented the final People's COP21 informed by prior feedback.
- **March 25, 2021**: This stakeholder discussion covered FY21 Q1 POART highlights and COP21 resumption plans with MOH, multilaterals, implementing partners, and CSOs.
- **March 29, 2021**: This HIV testing services (HTS) partner meeting stimulated discussion of current and new approaches to improve testing efficiency with HTS IPs.

- **April 15, 2021**: PEPFAR-led virtual stakeholder meeting allowed for discussion of the COP21 strategy with the virtual Regional Planning Meeting delegation and the PEPFAR interagency.

- **April 15, 2021**: This HRH interagency consultative meeting with IPs resulted in:

    - The introduction to draft the proposed roadmap and agreement on an initial vision for standardization of key cadres and remuneration with PEPFAR Malawi; and
    - Early stage formation of the USG-IP HRH Taskforce to carry work forward.

- **April 20, 2021:** This COP21 briefing with the Secretary for Health included an overview of the COP21 draft strategy and highlighted critical issues to jointly track and support with the MOH leadership and the PEPFAR interagency.

- **April 22, 2021:** PEPFAR Interagency followed up with RPM external partners (UNAIDS, WHO, MOH, CSO's, GF-PIU, GF) to provide updates on the target-setting process.

In addition to the above, PEPFAR actively participated in national dialogues with stakeholders and targeted technical meetings for intensifying coordination and planning efforts.

- **March 18 & April 15, 2021:** PEPFAR and the HIV/AIDS Donor Group discussed the COP21 strategy, CLM, and COVID-response related funding.

- **March 5 & April 30, 2021:** DHA-led discussions highlighting progress and gaps in the TB/HIV grant and Government of Malawi's health systems strengthening priorities.

- **April 9 & April 15, 2021:** the Global Fund and MOH Program Implementation Unit (PIU) held an Allocation Letter review call with the CCM; convened a C19RM national dialogue; and, followed by a later stakeholder review on the 2021 draft Funding Request. These participatory discussions and consultations informed the prioritization of interventions and investments that mitigate the impact of COVID-19 with civils society, donor and development partners, and the PEPFAR interagency.

- **April 21-May 14, 2021**: PEPFAR representatives supported COVID-19 Response Mechanism writing teams and joint strategy discussions (TB, HIV, HRH, Lab, commodities and budget experts, Project Implementation Unit) to inform prioritization of TB-HIV activities, assure HIV and COVID-19 commodities security and build consensus on key content for mitigation activities across the three diseases in non-PEPFAR districts and nationally.

CSO Community-Led Monitoring (CLM)

In COP21, PEPFAR will continue providing funding to CSOs for community-led monitoring of the HIV/AIDS response in the 11 scale-up districts. In line with the national and PEPFAR strategic

priorities, monitoring of client-centered care at the site and community-level will be central to this effort. CSOs will analyze and collect quantitative and qualitative data about HIV services with a focus on getting inputs from recipients of care. PEPFAR Malawi will work with CSOs to establish effective feedback mechanisms that enable timely resolution of problems and broader application of good practices. The COP20 CLM evaluation informed the Peoples' COP21.

The following were some of the important CLM recommendations considered for COP21: recruitment and training of expert clients; training of additional cervical cancer service providers; continuation of KP-led programs after phasing out the KPIF; resumption of community-based tracing and strengthening of peer support groups; integration of cervical cancer screening services with other HIV-related services; and optimization of all eligible children to Dolutegravir (DTG)-based regimens. Currently, there are no plans to recruit additional expert clients in COP21. Based on poor TX_RTT performance, partners have shifted from using expert clients with low-level education to cadres with school certificate qualification. It is believed that preventing treatment interruptions can be improved with treatment literacy and accurate treatment information. With this background, additional cadres that have been recruited to support retention are: Adherence support officers: 488; HSAs: 50; Psycho social counselors: 12; and replaced 300 expert clients with patient supporters; KP and AGYW (DREAMS) do not use expert clients for their programs. KP has enough peer educators, but working conditions need to be changed from part time to full time employees. DREAMS uses a cadre with diploma and Malawi school certificate of education who are not necessarily at the same level with expert clients. 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. Going forward, the CLM in COP21 will increase to cover 25 more facilities while engaging with relevant stakeholders to influence policy changes using the evidence generated from COP20 implementation. Non-PEPFAR resources will be leveraged to increase CLM focus on HIV and sexual and reproductive health (SRH) services for AGYW.

Figure 3.0.1 COP21 CSO Funding Allocation

Amount	Activities
$694,898	**COP21 CSO Community-led Monitoring** **Mechanism: CDC/UNAIDS** PEPFAR will continue providing funding to CSOs for community-led monitoring of the HIV/AIDS response in 11 PEPFAR scale-up districts. In line with the national and PEPFAR strategic priorities, monitoring of client-centered care at the site- and community-levels continues to be central to this effort. CSOs will collect and analyze quantitative and qualitative data about HIV services with a focus in getting input from recipients of care and other relevant stakeholders. PEPFAR Malawi will work with CSOs to establish effective feedback mechanisms that enable timely resolution of problems and/or broader application of good practices.

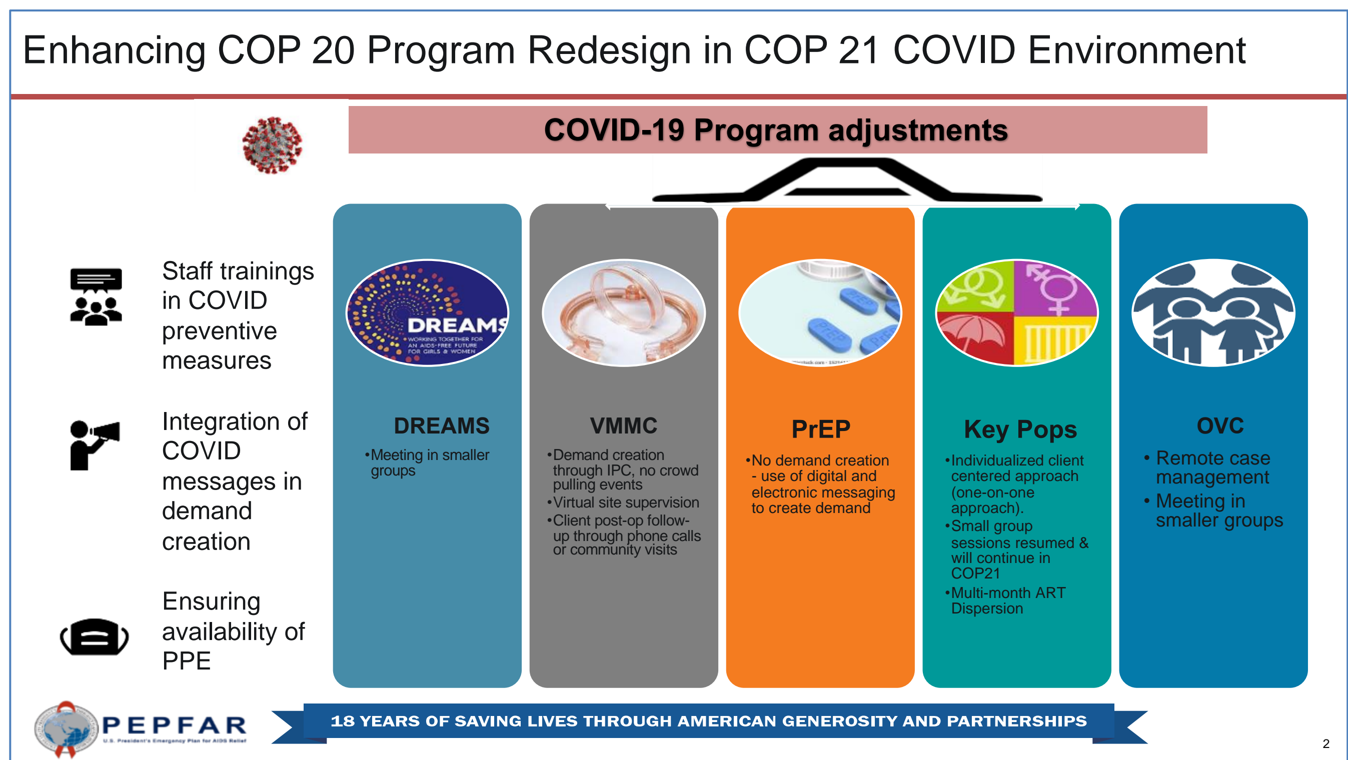
4.0 Prevention Updates for Epidemic Response and Program Context

Prevention and Vulnerable Populations Priorities Summary

HIV prevention programs remain integral in reaching and maintaining HIV epidemic control. In COP21, individuals with substantial risk to HIV will be reached with PrEP, KP, VMMC, OVC, and DREAMS program services in the high burden subnational units (SNUs).

COVID-19 greatly affected implementation of HIV prevention programs in Q3 and Q4 of FY20 and Q1 to Q2 of FY21. In FY20 Q3, most activities were paused due to national policy directives and services slowly resumed in Q4. Program adjustments were made to ensure the safety of clients and service providers. All IP staff were trained in COVID-19 preventive measures and IPs procured personal protective equipment (PPE) for staff. Messages for community awareness and service demand creation activities were updated to include COVID-19 prevention messages. Activities that required larger group formats were minimized to small group or one-on-one. For example, DREAMS club meetings were limited to ten or less girls per session, while the OVC program implemented remote case management. 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 asses health system requirement and guideline revisions.

Figure 4.0.1 COP21 Programming Redesign in a COVID-19 Environment



4.1 HIV Prevention and Risk Avoidance for AGYW and OVC

The GoM remains committed to addressing the disproportionate effect of HIV on adolescent girls and young women (AGYW) compared to their male peers through the operationalization of Malawi's National AGYW Strategy. National coordination structures have been established and district coordination structures are being established in 11 districts across the country. Recently, through the national AGYW Secretariat in collaboration with other stakeholders (including PEPFAR and its implementing partners), the AGYW minimum service package was developed for donors and referral and linkage tools are being piloted in two districts. The PEPFAR team continues to work with other donors and stakeholders through the AGYW Strategy Secretariat, Core Team, and sub-technical working group to support the implementation of the National AGYW Strategy and ensure PEPFAR programming aligns with the goals and objectives of the strategy. PEPFAR also routinely engages with the Global Fund in its implementation of its own AGYW program in Mulanje, Thyolo, Chikwawa, Mangochi, and Lilongwe districts. PEPFAR and the Global Fund routinely share implementation challenges, solutions, joint learning, COVID-19 programming innovations with one another, and coordinate with Malawi's national technical working groups. PEPFAR Malawi continues to advocate and provide technical assistance to Global Fund partners for the harmonization of the minimum package of services for AGYW programming across the Global Fund and PEPFAR investments.

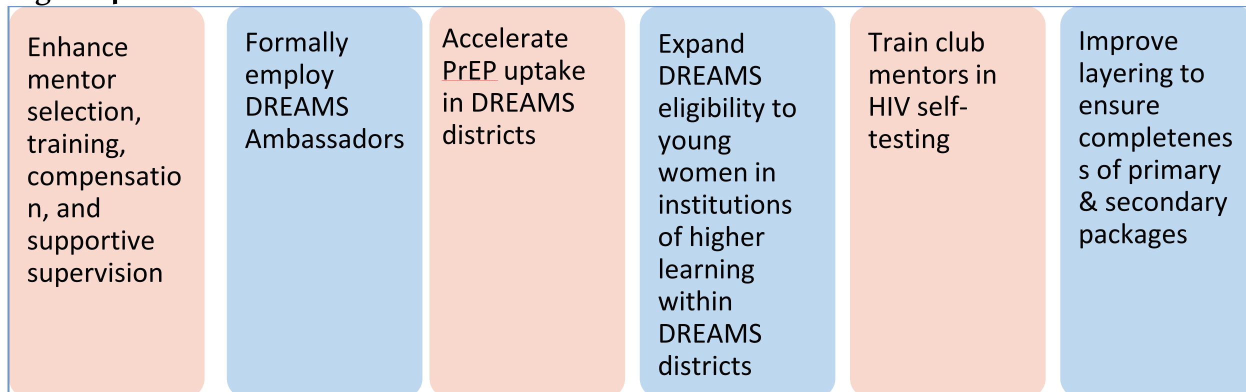
DREAMS

In FY20, the DREAMS screening tool was revised to include vulnerabilities specified in the COP21 guidance. Completion of the DREAMS primary package has been a challenge for the Malawi program. At FY20 Q4, only 18% of AGYW had completed the primary package. This was largely because the Malawi-specific DREAMS toolkit took around twelve months to complete. To compensate for the delay, the DREAMS toolkit was revised to reflect age-specific curricula, subsequently reducing the completion timeframe. The revised toolkit now takes 7.7. months for 10 – 14 years olds to complete, 7.5 months for 15 – 19 years old to complete, and 5.5 months for 20 – 24 years olds. DREAMS completion rates are expected to reach at least 50% by the end of Q4 in FY21. Additionally, PEPFAR Malawi is implementing the Siyankha model for comprehensive economic strengthening and education support tailored to the needs of specific individuals. The DREAMS database, which is fully operational, ensures all individual AGYW enrolled in the program are tracked for layers of the primary package and additional secondary interventions.

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. In the 10–14-year age band, 13,519 beneficiaries will be enrolled, with 57,947 beneficiaries in the 15-19 year age band, and 16,655 enrollees in the 20-24 year age band. PEPFAR Malawi believes DREAMS is closer to reaching

saturation in the 10-14 age band than in the 15-19 age band, which is why more enrollments are expected in the older cohort. Based on the assumptions that were used during target setting, PEPFAR Malawi anticipates reaching 75% saturation or greater across all age bands in the three existing districts by the end of FY22.

Figure 4.1.1 DREAMS Priorities in COP21



PEPFAR Malawi's COP21 DREAMS strategy will respond to COP21 guidance and country-specific objectives for district saturation and improvement of layering in the following ways:

- Mentor selection, training, and supportive supervision will be streamlined across all club partners to ensure selection is based on the minimum set criteria. All club mentors will continue to receive standard, initial, and refresher trainings in the delivery of the DREAMS toolkit. All club mentors will receive supportive supervision from their supervisors which will involve observation of the delivery of club sessions followed by feedback to the club mentor to help them improve their delivery skills. Fidelity checklists will also be updated per the streamlined approach.
- DREAMS Ambassadors will continue to be selected from existing DREAMS beneficiaries. In COP21, they will be formerly employed as opposed to the voluntary role they have held in previous years. Roles for the Ambassadors will include district coordination and other tasks as agreed upon by the implementing partner and DREAMS Ambassador, in consultation with the PEPFAR DREAMS technical team and Peace Corps Volunteers.
- PrEP education and information will be part of the primary package, while screening for 15–24-year-olds eligible and interested will be referred to youth friendly health services since community initiation is not currently permitted in Malawi's national policy. In COP20, PEPFAR Malawi aims to newly initiate 4,524 DREAMS AGYW on PrEP. Community and facility partners will work together to improve awareness, generate demand, and facilitate PrEP screening and initiation for those who are eligible and interested. Health facilities will initiate PrEP until national policy permits community initiation. Partners will also engage peer educators and DREAMS Ambassadors to build awareness of and help generate demand for PrEP, in a non-coercive manner.
- DREAMS eligibility will be expanded to include young women at high risk attending institutions of higher learning within the DREAMS districts. This is a priority in response to feedback from stakeholders, in particular from DHA and the National AIDS Commission

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(NAC). As this demographic differs from the demographic PEPFAR typically engages in the community, the curriculum used with them will be different to support their HIV-risk reduction needs.

- Club mentors will be trained in HIV self-testing**.** This will help to improve HTS screening and uptake of HTS services among AGYW enrolled in DREAMS. All AGYW who test positive will receive a conventional test for confirmation and be linked to ART initiation if confirmed HIV positive.

In light of COVID-19, DREAMS has made some adjustments, such as meeting in open spaces, weather permitting, with small groups of up to ten AGYW. The program will continue to be flexible and make necessary adjustments, such as allowing groups of up to 20 people to gather, as the COVID-19 situation continues and evolves.

In COP21, Peace Corps Response Volunteers, once back in country, will continue to coordinate with District AIDS coordinators and counterparts to ensure continued collaboration among all AGYW stakeholders and implementers. Peace Corps will place Health and Education Volunteers in DREAMS districts to support education and health services for youth, with a focus on AGYW. Three Education Specialists will help headmasters in the SEED and AMAA schools to set up administrative and management systems and introduce gender-sensitive pedagogy to create gender equitable learning opportunities.

DREAMS District Coordinator Ambassadors will be hired to work alongside Peace Corps Response Volunteers at the district level to strengthen programming and coordination across partners; ensure DREAMS AGYW are receiving the complete package based on their unique needs; and facilitate collaboration with district health office counterparts and other stakeholders. These District Coordinators will be supported by the PEPFAR DREAMS interagency team.

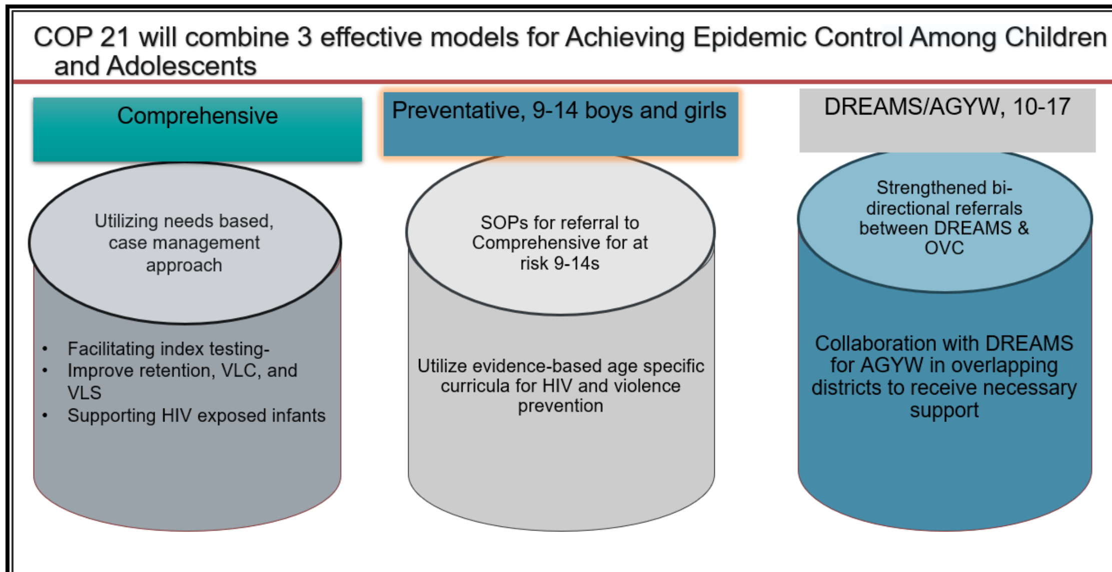
In COP21, the Health Resources and Services Administration (HRSA) will continue to build on the Historically Black Colleges and Universities (HBCUs) pathway to employment through the community health worker training activity for DREAMS AGYW. An initial analysis of the HRH gaps in DREAMS districts and education level of DREAMS participants demonstrates a strong need for Health Surveillance Assistants (HSAs). Engagement with the Ministry of Health (including the community health unit), NAC, and the AGYW Secretariat has provided direction for development and implementation of a training program that will capitalize on the unique perspective and community of AGYW. The program will focus on producing trained AGYW ready to be absorbed into the formal workforce as HSAs and sustained by the GoM; providing economic stability for AGYW while supporting more accessible and client-focused health services.

OVC Program

Building off COP20, PEPFAR Malawi will provide HIV impact mitigation, prevention, and treatment services to 158,440 OVC ages 0-17 years and their households to address contributing factors to vulnerability with particular focus on: 1) actively facilitating testing for all children at risk of HIV infection; 2) facilitating linkage to treatment, support for continuity of treatment, and viral

suppression, and providing case management for vulnerable children and adolescents living with HIV; and 3) reducing risk for adolescent girls in high HIV-burden areas and providing HIV and sexual violence prevention for the 9-14 year-old girls and boys. Activities will be implemented in 138 high burden health facility catchment areas in nine districts, including Machinga, Mangochi, Zomba, Blantyre, Chikwawa, Phalombe, Mulanje, Thyolo, and Lilongwe. These catchment areas have the highest numbers of TX_CURR <19 and the sites are split evenly between CDC and USAID at 69 sites each.

Figure 4.1.2 COP21 OVC Models for Achieving Epidemic Control



The target of 83,478 children will be reached through the comprehensive model targeting enrollment of children and adolescents in priority sub-populations, including children and adolescents living with HIV (C/ALHIV), HIV exposed infants, sexual violence survivors, children of HIV+ mothers, children of HIV+ female sex workers (FSW), at risk AGYW, child-headed households, and their caregivers.

COP21 will strengthen efforts to ensure at least 45% of the OVC_SERV <18 cohort are C/ALHIV, while ensuring 90% of TX_CURR <19 at the 138 facilities in the OVC catchment area are offered enrollment into the OVC comprehensive program. Priority enrollment will be given to newly identified C/ALHIV, C/ALHIV with poor viral suppression, and those who have experienced interruption in treatment. Further, using its community network and through household visits and support, OVC frontline providers will also: identify siblings of C/ALHIV, link children of index clients, conduct HIV risk assessments, facilitate access to testing, and ensure linkage to and continuation of treatment for those living with HIV. Achieving treatment literacy for all household will be a priority focus. Through the case management approach, the program will provide age and need-appropriate activities as needed, including psychosocial support, promotion of positive parenting and norms change, child protection and GBV services, savings and loans groups, work readiness, and market-based income-generating activities. Emphasis will be given to supporting parents and caregivers living with HIV to remain in care and economically viable. Strengthened collaboration with health facilities through MOUs between clinical and OVC IPs, placement of

OVC staff at health facilities, including roving social workers, facility-based case management, and case conferencing, will lead to improved outcomes for C/ALHIV. The facility-based OVC cadre is trained to assess, recruit, and ensure referral completion of C/ALHIV into the OVC program. Viral load monitoring services will be scaled up, to reach all the C/ALHIV enrolled in the program to ensure viral suppression.

Activities will continue to cover four main domains of healthy, safe, stable, and schooled, coordinated through tailored, comprehensive family-centered case management efforts. PEPFAR will increase enrollment of C/ALHIV into age-appropriate support groups based in the communities and the facilities. These provide high-quality social support and age-appropriate information about HIV infection, treatment, adherence, HIV status disclosure, positive living and life skills needed for growing into healthy adults. Treatment literacy interventions will be extended to the caregivers and guardians of C/ALHIV through various activities, including positive parenting. COP21 will emphasize support to mothers/caregivers and HIV-exposed children 0–24 months old to assure early diagnosis, adherence, and retention on treatment, and provide holistic parenting support to optimize HIV-exposed children's developmental outcomes. Treatment literacy will be prioritized for improved treatment outcomes and linkages with implementers serving KPs being strengthened to reach more children of FSW through the OVC program. PEPFAR will also support keeping children in school through community mobilization and intensifying household economic strengthening so caregivers and guardians are able to pay school fees. Peace Corps Volunteers (PCVs) and their counterparts will support ALHIV and their caregivers through teen clubs. The activities will include information on good nutrition, life skills, treatment adherence, hygiene, cooking demonstrations, home gardens and more. Deliberate efforts will be made to ensure Peace Corps Volunteers are placed at facilities being reached by the OVC program.

The OVC target of 32, 369 children will be reached under the preventive model. Preventing sexual violence and HIV for the 9-14-year old girls and boys and reducing risk for AGYW in non-DREAMS districts through leveraging schools, community groups, and faith-based networks will be a key focus in COP21 in line with Malawi's National Intervention Framework. This model focuses on preventing sexual violence and HIV risk to help youth reduce risk or consequences of exposure to risk. For the 9-14 age group, activities will focus on primary prevention and for the 15-17 age group, activities will focus on a combination of preventing and reducing risk. The program will use age-specific evidence-based curricula with skills building components such as Families Matter, Sinovuyo Teens, and Grassroots Soccer. PEPFAR will intensify collaboration with faith-based organizations and community-based organizations through community mobilization and norms change interventions (like SASA! Faith and Coaching Boys into Men). Implementation will be sensitive to sexual violence and other factors shaping adolescent sexual behaviors. PCVs will target the 10-14 year old youth with interventions that address sexual violence, HIV prevention, and early sexual debut by utilizing the Grassroots Soccer curriculum, which has been adapted for school and community settings. PEPFAR will ensure IPs have standard operating procedures to refer beneficiaries reached under the preventive model for services under the comprehensive model when necessary and fidelity checks will be used during site visits.

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In COP21, PEPFAR Malawi will continue to work with the Ministry of Gender to reinforce a strong national case management system and professionalization of the community-based social welfare workforce will remain a key priority. In partnership with GoM training institutions, PEPFAR Malawi will train social workers and continue to inject much needed, qualified social workers into the on-establishment child protection system. Since the OVC program is expanding to an additional 17 facilities in COP21, the number of case workers will be increased by at least 10%. The expansion is possible due to efficiencies created within the program. The OVC program will continue to support the strengthening of case management through G2G support directly to the Zomba District Council.

OVC and DREAMS Collaboration

The OVC and DREAMS programs overlap in three districts (Blantyre, Machinga, and Zomba). The OVC program will not implement activities targeting AGYW 10-17 years in these districts, as they will be reached through DREAMS programming. Referrals between OVC and DREAMS programs will be strengthened to achieve enhanced outcomes for the AGYW. To promote efficiencies, OVC and DREAMS will implement joint planning where appropriate, to reach the target of 42,593 AGYW.

Table 4.1.3 Targets for OVC and Linkages to HIV Services

SNU/District	Estimated # of Orphans and vulnerable children **	Total OVC_SERV	Target # of OVC served in comprehensive Program (FY22 target) OVC_SERV	Target # of OVC Receiving Prevention Interventions (FY22 target) OVC_SERV	Target # of OVC served in DREAMS (FY22 target) OVC_SERV	Target # of Active beneficiaries receiving support from PEPFAR OVC programs whose HIV status is known in the program files (FY22 target) OVC
Blantyre	70,852	42348	15143	4131	23074	11356
Chikwawa	34,399	6942	5160	1782		3870
Lilongwe	118,143	24657	15387	9270		11540
Machinga	41,533	16721	5751	2882	8088	4313
Mangochi	70,852	14006	9750	4256		7313
Mulanje	44,615	11081	8604	2477		6454
Phalombe	27,580	7424	5846	1578		4384
Thyolo	46,979	9960	7346	2614		5508

Zomba	49,468	24999	10489	3078	11432	7868
Balaka *	27657	60		60		
Dedza *	50,557	60		60		
Neno *	7866	60		60		
Ntcheu *	40,696	60		60		
Salima *	27,583	60		60		
Totals	658,780	158438	83476	32368	42594	62606

*Peace Corps-only districts **Malawi Population and Housing census Report, 2018

4.2 Key Populations

COP20 has been a challenging year due to COVID-19, yet the KP program has remained resilient. The COVID-19 pandemic provided an opportunity for developing and implementing new innovations to ensure KPs and their families continue accessing health care services amidst a restrictive operating environment. The peer educator microplanning approach enabled PEPFAR Malawi to provide client-centered services since each KP is assigned to a peer educator who provides or refers them to KP-friendly service providers. Some activities halted to reduce COVID-19 exposure among KPs and service providers. These included: outreach testing activities, new PrEP initiations (as per Ministry of Health guidance), group sessions facilitated by peer cadres at hotspots, and outreach testing activities. The following services continued with all COVID-19 precautionary measures observed: drop-in centers and KP-friendly testing and treatment; small group meetings and one-on-one education sessions; peer educator mentorship; and HIV, TB, sexually transmitted infections (STI), and cervical cancer services in PEPFAR-supported prisons (including integrating COVID-19 preventive measures for inmates and staff). Multi-month ART scripting was enhanced with SMS and call reminders as a strategy for ensuring KP stayed on treatment. Health care worker trainings on COVID-19, screening and case management were conducted while PPE were provided to all service providers as part of an integrated approach of piggybacking on HIV interventions. Social network strategies, coupled with HIV self-testing, were scaled up and enhanced, contributing to a 23% positivity rate. These will be the main testing and case finding strategies going forward into COP21. Any scale-up in Index Testing among KPs will carefully consider matters of privacy and safety, including implementation of training protocols for healthcare worker staff. The Diversity Forum will be consulted, as well as, engaged at quarterly meetings about progress and updated about any adverse events.

PEPFAR's KP Services Prioritization and Interventions

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. Key approaches include: ensuring facilities have well-trained and supervised health care workers to provide KP-friendly and sensitive clinical services; using KP lay personnel, such as peer educators and HIV positive peer navigators, to reach KPs; and providing direct service delivery to beneficiaries. 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. Peer-led activities increase self and community efficacy to adopt healthy behaviors and access to services addressing the continuum of care for HIV positive individuals. The PEPFAR team will continue to support KP-led support groups and ensure that newly diagnosed KPs, KPs returning to care, or KPs struggling with adherence, are provided with differentiated service delivery options. Apart from the nine PEPFAR-supported KP program districts, two other districts, Phalombe and Balaka, were supported by the Key Population Investment Fund (KPIF), bringing the total of KP program districts to eleven. Through the KPIF, six new KP-led organizations were registered at the end of FY19 to increase access to HIV prevention and treatment service delivery for KPs - especially for the hardest to reach and in districts where PEPFAR previously and the Global Fund did not have a presence. The timely introduction of the KPIF in COP19 provided well-targeted capacity building of KP-led organizations and enabled them to provide comprehensive prevention and treatment services to KPs in these two districts. With the completion of the KPIF in COP20, continued support for KP programming in Phalombe and Balaka districts will be incorporated into COP21 funding.

After a rigorous COP21 planning and consultative process internally and externally, KP size estimation remains a top priority. Other COP21 priorities include accelerated access to PrEP, effective viral load sample transportation with significant reduction in turnaround time, reaching children of FSW through coordination between the OVC program and pediatric HIV clinical services providers, and engaging CSOs in the evaluation of KP programs. In consultation with KP clients and drop-in center staff, consideration will be given to the inclusion of clinical services to children of KP. Understanding the population size of KPs will help set realistic targets for different KP groups and help evaluate if all KPs are being reached. NAC, with support from the Global Fund, conducted a biobehavioral survey in 2019-2020 which only included five PEPFAR districts. The Transgender study on assessing HIV risk factors, access to health services, and population size estimates was supported by GIZ (a German development agency). While a results validation meeting occurred with stakeholders, the final report is not yet available. There are also plans by the same organization to conduct a formative study on people using injectable drugs in COP20.

In COP21, PEPFAR will continue to provide a package of prevention and treatment services to approximately 14,000 prison inmates in 19 prisons across scale-up and sustained districts. The package includes HIV/TB, COVID-19, STI screening at entry and again at emerging symptoms, COVID-19 prevention supplies, cervical cancer screenings for eligible female inmates, as well as,

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VMMC for eligible male inmates. Prevention information and counseling is provided continuously during imprisonment and additional screening for symptoms is done upon leaving prison. Suspected, as well as, confirmed TB and COVID-19 positive inmates are isolated and their symptoms managed accordingly. Sustained districts were included because the increased risk of HIV for prison inmates is the same regardless of prison geographical location (situational men having sex with other men, or MSM). COVID-19 prevention, screening, case identification, and management remain priorities due to overcrowding in Malawi prisons.

Figure 4.2.1 KP Best Practices and Strategies to Achieve and Maintain Epidemic Control

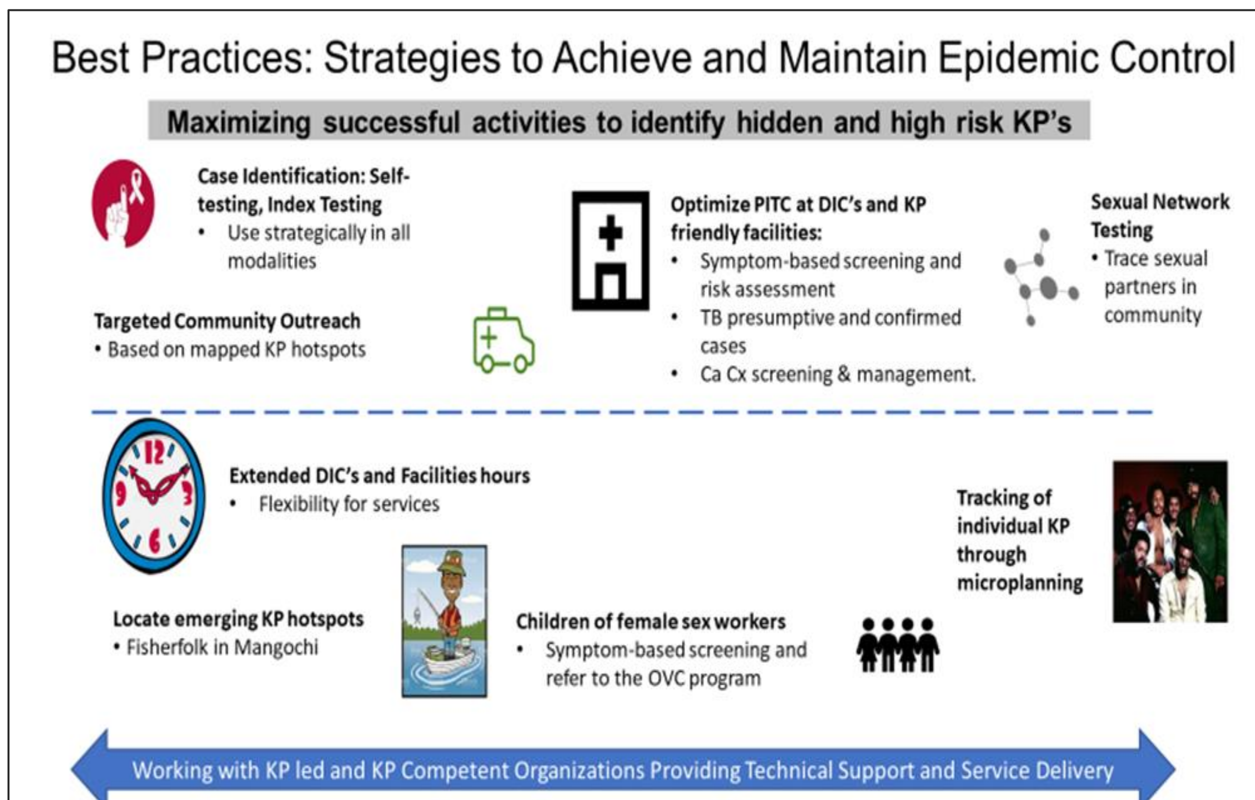

Table 4.2.2 Key Population Prevention Interventions to Facilitate Epidemic Control

District	Indicator	Target Population	Population Size Estimate	Coverage Goal (in FY22)	FY22 Target
Blantyre	KP_PREV	FSW	2700	95%	2565
		MSM	2300	95%	2185
		TG	200	95%	190
		People in prisons and other enclosed settings	2500	100%	2500
Balaka	KP_PREV	FSW	589	95%	560
		MSM	475	95%	451

Chikwawa	**KP_PREV**	**FSW**	1350	95%	1283
		MSM	925	95%	879
Chiradzulu	**KP_PREV**	**FSW**	615	95%	584
		MSM	375	95%	356
Lilongwe	**KP_PREV**	**FSW**	5400	95%	5130
		MSM	5500	95%	5225
		TG	300	95%	285
		People in prisons and other enclosed settings	5600	95%	5600
Machinga	**KP_PREV**	**FSW**	2550	95%	2423
		MSM	450	95%	428
Mangochi	**KP_PREV**	**FSW**	1900	95%	1805
		MSM	1300	95%	1235
Mwanza	**KP_PREV**	**FSW**	600	95%	570
		MSM	100	95%	95
		Prisons	330	95%	330
		TG			
Mzimba	**KP_PREV**	**FSW**	5150	95%	4893
		MSM	950	95%	903
		TG	70	95%	67
		People in prisons and other enclosed settings	1400	100%	1400
Phalombe	**KP_PREV**	**FSW**	755	95%	717
		MSM	270	95%	257
Zomba	**KP_PREV**	**FSW**	1200	95%	1140
		MSM	1600	95%	1520
		TG	67	95%	64
		People in prisons and other enclosed settings	4000	100%	4000
Thyolo	**KP_PREV**	**People in prisons and other enclosed settings**	718	100%	718
Dedza	**KP_PREV**	**People in prisons and other enclosed settings**	300	100%	300
Ntchisi	**KP_PREV**	**People in prisons and other enclosed settings**	360	100%	360
Ntcheu	**KP_PREV**	**People in prisons and other enclosed settings**	379	100%	379

Rumphi	KP_PREV	People in prisons and other enclosed settings	336	100%	336
	KP_PREV	People in prisons and other enclosed settings		100%	
Neno	KP_PREV	People in prisons and other enclosed settings	85	100%	85
Nkhatabay	KP_PREV	People in prisons and other enclosed settings	290	100%	290

Figure 4.2.3 Malawi KP Budget FY21-22

MALAWI KP BUDGET FY21-22
Excludes M&O

OU	Agency ..	Mechanism ID-Name	KP Budget 2021	KP Budget 2022	Total Planned Funding 2021	Total Planned Funding 2022
Malawi	Grand Total		5,789,720	5,172,196	36,263,780	34,947,996
	CDC	Sub Total	1,340,000	966,508	25,617,118	23,831,501
		14441-Center of Excellence for Comprehensive Integra..			7,586,145	7,300,707
		18025-Achieving HIV Epidemic Control through Scaling up Qu..			8,560,373	7,485,859
		18244-Addressing unmet need in HIV Testing Services (HTS)..	1,340,000	966,508	9,470,600	9,044,935
	USAID	Sub Total	4,449,720	4,205,688	10,646,662	11,116,495
		18063-GHSC-PSM		142,800	3,672,734	4,926,375
		70190-Local Capacity KP	1,217,511	1,053,036	1,734,700	1,665,456
		81759-Meeting Targets and Maintaining Epidemic Control (EpiC)	2,461,796	2,280,639	4,269,259	3,595,895
		81764-PROTECT	770,413	729,213	969,969	928,769

4.3 Voluntary Male Medical Circumcision (VMMC)

PEPFAR Malawi will add Mulanje to the three high priority ART districts (Blantyre, Chikwawa, and Lilongwe), including military facilitie,s with high HIV exposure, incidence, and unmet VMMC needs. PEPFAR will work with the Global Fund and the GoM to ensure the VMMC program is in line with the revised National Strategic HIV Plan for 2020-2025, which gives priority to VMMC in twelve districts with the aim of providing coverage for 50-80% in males aged 15-49 years, with an emphasis on 25-39 year age band. A target of 131,000 has been set for the four districts and military settings, which includes men over the age of 15 years old. The target setting process considered the incidence of HIV in men and anticipation of Blantyre reaching 80% saturation in the 15-29 age group.

The GoM continues to prioritize VMMC as part of their biomedical prevention strategy, as noted in the revised NSP 2020-2025. The NSP emphasizes the need to prioritize those under 25-39 years for VMMC as the incidence of HIV among sexually active men in this age group is increasing. The revised NSP also prioritizes VMMC services for men aged 15-49 in districts with high levels of HIV. This is highly consistent with PEPFAR's guidelines that boys under 15 years of age should not be circumcised, and the national plan should use survey data to prioritize VMMC targeting men with the highest HIV infection rates.

The updated Decision Maker Program Planning Tool (DMPPT) has been integrated into Spectrum and shows these four districts (Blantyre, Chikwawa, Lilongwe, and Mulanje) will reach different VMMC saturation levels for males older than 15 years by the end of COP21 (see Table 4.3.1). This is due to denominator variance, VMMC efficiency rates, and HRH availability.

Despite the COVID related suspension of VMMC services, the VMMC program continued to gain momentum and the number of circumcisions in FY21 Q1 and Q2 was 55,744 (35%) of the annual target. Overall, the VMMC performance in FY21 Q1 and Q2 were better than in previous quarters. Results were achieved through the use of innovative methods to generate demand, customer planning, and remote monitoring. The country has taken COVID-19 precautions to ensure the VMMC program keeps up with the momentum. Preventative measures and limitations of COVID-19 require the VMMC program to reduce the number of teams and community mobilizers in static, outreach, and mobile locations, while maintaining performance. PEPFAR partners will continue to carry out activities for continuous quality improvement and implementation of fidelity checks in order to ensure compliance with standards and avoid adverse events.

The Department of HIV/AIDS will regularly monitor VMMC sites and conduct annual external quality assurance activities. PEPFAR will continue to work with implementation partners and the Ministry of Health to ensure well-trained and supervised providers participate in the program and complete virtual refresher training for service delivery teams. In FY21, a total of 13,776 men were circumcised using the Shang Ring device and all clients had the removals within the window period. There were six device displacements that resulted in device suspension. The program has successfully provided Shang Ring providers with refresher trainings and anticipates the resumption of device use before the start of COP21. All PEPFAR partners switched to reusable toolkits starting in FY19 and continued to conduct staff training and procurement. InCOP21, PEPFAR will no longer buy single-use kits, but will increase the number of circumcisions performed with reusable kits (40%) and with Shang Ring (60%).

Key COP21 activities will include:

- Providing a minimum essential service package, including age-appropriate risk reduction counseling, sexually transmitted infection screening and treatment, HIV screening and testing, and links to ART for people who test positive, condom promotion and distribution, and postoperative follow-up activities including adverse event management.

- Offering a comprehensive, age-appropriate sex education for children aged 10-14 who are not eligible for VMMC.
- Enhancing client-centered design for VMMC communication and demand generation.
- Scaling up use of Shang Ring devices and reusable kits.
- Tracking of referrals of clients testing positive in VMMC settings using ART linkage registers.
- Linking HIV-negative men to VMMC services through collaboration among testing, treatment, and VMMC partners. Priority will be given to high-risk facilities such as STI clinics.
- Providing integrated services tailored for men in selected static VMMC locations, like general medical examination, STI detection and treatment, HIV self-testing, and sexual and reproductive health services.
- Continuing with COVID-19 mitigation measures, including: the provision of essential measures for risk reduction in accordance with the national standards inclusive of spacing of service provision, social distancing, hand washing, and providing masks for clients. All VMMC partners have established procedures to identify and triage clients and staff who may be exposed or sick due to COVID-19. All suspected cases are referred to designated case management sites and facilities.

Table 4.3.1 VMMC Coverage and Targets by Age Bracket in Scale-Up Districts

SNU	Target Populations	Population Size Estimate (SNUs)	Current Coverage (FY21)	*VMMC_CIRC* (in FY22)	Expected Coverage (in FY22)
Blantyre	>15 years	413,410	55%	28,000	61%
Chikwawa	> 15 years	165,473	43%	26,299	58%
Lilongwe	>15 years	849,862	31%	68,306	39%
Mulanje	>15 years	195,137	54%	15,261	62%

Source: DMPPT2, Spectrum

4.4 PrEP

National PrEP guidelines were approved by MoH senior management on December 14, 2020. COVID-19 partly affected the finalization of the PrEP guidelines and other associated tools necessary for rollout. Prior to the approval of the guidelines, MOH in collaboration with PEPFAR implementing partners, conducted trainings for the service providers and site readiness assessments. PrEP roll out started in March 2021 in a few facilities in the eleven PEPFAR priority districts while other sites continue to train providers and finalize the site-specific roll-out plans.

Malawi's PrEP guidelines prioritize KPs (FSW, MSM, MSW and TG), AGYW, and sero-discordant couples. Pregnant and breastfeeding women are not among the prioritized population for PrEP in Malawi. PEPFAR Malawi, in collaboration with other stakeholders, will continue to advocate for inclusion of PBFW as a priority population group for PrEP initiation. As per the national PrEP guidelines, 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.

In FY20, PEPFAR implementing partners conducted two implementation science projects which to assess acceptability and feasibility of PrEP services among AGYW and FSW. Lessons from these projects informed the roll-out of PrEP, including the use of demand creation and peer support to increase PrEP acceptance and uptake among high-risk populations. Both implementation science projects were facility-based as this is the only approach currently approved.

In COP21, PrEP services will be implemented in eleven PEPFAR scale-up districts to reach a target of 17,720 clients newly initiated on PrEP and a PrEP CURR target of 19,195. The population groups to be reached are in line with the national guidelines with the exception of PBFW. Capacity of facilities to conduct creatinine tests is a limiting factor for scaling up PrEP more largely. Currently, only sites within a 30-kilometer radius of a laboratory with the capacity to conduct creatinine laboratory tests have been prioritized to provide PrEP services. These facilities include district hospitals, rural hospitals, some mission hospitals, and a few health facilities. The mission hospitals, however, charge a fee for the laboratory test which poses as a barrier for PrEP access. PEPFAR continues to advocate with the MoH to ensure the Ministry's MOU with CHAM states that CHAM should provide all HIV-related services free of charge.

The annual PrEP targets in the NSP (2020-2015) are lower than the ambitious targets set by PEPFAR, resulting in a commodity gap. The Global Fund's support for commodities is based on the NSP targets, set at 7,000 in FY22. PEPFAR Malawi will procure additional PrEP commodities (ARVs, lab reagents, and supplies) to minimize any gap in COP21. In June 2021, PEPFAR Malawi expects to receive a PrEP ARV donation from Gilead to reach 6,000 AGYW, which will also help to fill the commodity gap and accelerate PrEP implementation. The delay in start of PrEP implementation also means that some commodities purchased by Global Fund for FY21 may carry over to FY22; it is anticipated that approximately 6,000 PrEP ARV drugs and associated laboratory reagents will be carried over to FY22. This carry over will be added to the 7,000 Global Fund PrEP commodities for FY22 leading to a total of 13,000. 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.

Key priorities for COP21 will include:

- Scaling up PrEP services to high-risk groups, including KP, AGYW, and SDC.
- Strengthening demand creation services (the KP program will use peer educators, DREAMS will use DREAMS Ambassadors).
- Strengthening referrals to PrEP from other prevention programming.
- Linking identified HIV positive clients to treatment.
- Routinely inquiring about gender-based violence among people accessing PrEP and referring suspected cases to post-GBV services.
- Continuing to advocate for community PrEP implementation and inclusion of PBFW as priority population group with the GoM.

- 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.
- Community sensitization to reduce myths and misconceptions around PrEP and to increase demand among all eligible populations will also be enhanced.

Table 4.4.1 Overall Target Populations for Prevention Interventions

District	Indicator	Target Population	FY22 Target
Blantyre	AGYW_PREV (N)	AGYW	36194
	AGYW_PREV (D)	AGYW	54956
	PP_PREV	AGYW	41734
		Non-Disaggregated	9275
	GEND_GBV-Physical emotional	AGYW	1681
	GEND_GBV-Sexual	AGYW	859
	PrEP_NEW	FSW	394
		MSM/TG	713
		AGYW	3344
		Non-Disaggregated	51
	PrEP_CURR	FSW	513
		MSM/TG	713
		AGYW	4347
		Non-Disaggregated	51
Balaka	PP_PREV	Non-Disaggregated	65
	PrEP_NEW	FSW	102
		MSM/TG	142
	PrEP_CURR	FSW	102
		MSM/TG	142
Chikwawa	PrEP_NEW	FSW	234
		MSM/TG	276
		Non-Disaggregated	424
	PrEP_CURR	FSW	234
		MSM/TG	276
		Non-Disaggregated	424
Chiradzulu	PrEP_NEW	FSW	117
		MSM/TG	112
		Non-Disaggregated	98

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	PrEP_CURR	FSW	117
		MSM/TG	112
		Non-Disaggregated	98
Lilongwe	PP_PREV	Non-Disaggregated	390
	GEND_GBV-Physical emotional	Non-Disaggregated	181
	GEND_GBV-Sexual	Non-Disaggregated	124
	PrEP_NEW	FSW	954
		MSM/TG	1793
		Non-Disaggregated	1367
	PrEP_CURR	FSW	954
		MSM/TG	1793
		Non-Disaggregated	1367
Machinga	AGYW_PREV (N)	AGYW	8492
	AGYW_PREV (D)	AGYW	14153
	PP_PREV	AGYW	5656
	PP_PREV	Non-Disaggregated	10498
	GEND_GBV-Physical emotional	AGYW	1113
	GEND_GBV-Sexual	AGYW	794
	PrEP_NEW	FSW	422
		MSM/TG	134
		AGYW	631
		Non-Disaggregated	200
	PrEP_CURR	FSW	422
		MSM/TG	134
		AGYW	820
		Non-Disaggregated	200
Mangochi	PP_PREV	Non-Disaggregated	195
	GEND_GBV-Physical emotional	Non-Disaggregated	105
	GEND_GBV-Sexual	Non-Disaggregated	62
	PrEP_NEW	FSW	355
		MSM/TG	336
		Non-Disaggregated	919
	PrEP_CURR	FSW	355
		MSM/TG	336
		Non-Disaggregated	919
Mwanza	PrEP_NEW	FSW	94

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		MSM/TG	30
	PrEP_CURR	FSW	94
		MSM/TG	30
Mzimba	GEND_GBV-Physical emotional	Non-Disaggregated	73
	GEND_GBV-Sexual	Non-Disaggregated-	44
	PrEP_NEW	FSW	883
		MSM/TG	305
		Non-Disaggregated	1088
	PrEP_CURR	FSW	883
		MSM/TG	305
		Non-Disaggregated	1088
Phalombe	PrEP_NEW	FSW	140
		MSM/TG	81
	PrEP_CURR	FSW	140
		MSM/TG	81
Zomba	AGYW_PREV (N)	AGYW	11518
	AGYW_PREV (D)	AGYW	19012
	PP_PREV	AGYW	8899
	PP_PREV	Non-Disaggregated	10696
	GEND_GBV-Physical emotional	AGYW	1345
	GEND_GBV-Sexual	AGYW	714
	PrEP_NEW	FSW	220
		MSM/TG	515
		AGYW	549
		Non-Disaggregated	340
	PrEP_CURR	FSW	220
		MSM/TG	515
		AGYW	714
		Non-Disaggregated	340
Thyolo	PREP_NEW	Non-Disaggregated	162
	PREP_CURR	Non-Disaggregated	162
Mulanje	PrEP_NEW	Non-Disaggregated	198
	PrEP_CURR	Non-Disaggregated	198
Ntcheu	PP_PREV	Non-Disaggregated	65
Dedza	PP_PREV	Non-Disaggregated	65

Salima*	PP_PREV	Non-Disaggregated	65
Neno*	PP_PREV	Non-Disaggregated	65

*Peace Corps-only districts

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5.0 Client-Centered Clinical Activities for Epidemic Control

Clinical Services Summary

COP21 will build on the comprehensive COP20 strategy focusing on client-centered care to sustain the large cohort on treatment and efficient case finding, while ensuring service resilience within the on-going context of the COVID-19 pandemic. COP21 will respond to inputs from stakeholders and will expand Community-led Monitoring to address barriers being faced by clients, especially populations yet to reach epidemic control (children under five years and young men and women). Specific client-centered approaches to be scaled up in COP21 include: decentralized ART delivery, family-focused approaches to client care, and Advanced HIV Disease models. Continuity of HIV services is critical in the context of the COVID-19 pandemic. COP21 will ensure services can continue to be offered safely, with necessary measures, protocols, commodities, equipment for infection prevention and control, continued efforts to decongest and reduce visits, and leveraging virtual contacts (with clients and facilities) where feasible. In COP21, PEPFAR will also continue to scale up TB preventive therapy and access to integrated cervical cancer screening and treatment for women living with HIV.

5.1 Case Finding: Finding the Missing, Getting and Sustaining them on Treatment

PEPFAR Malawi is standardizing proven HIV testing strategies across all IPs that find HIV positive men, key populations, adolescents, and children who do not yet know their status and link them to treatment. Active index testing has been rolled out in all sites in scale-up districts and expansion to high volume sites in sustained districts is currently underway. Towards the end of FY20, all facilities implementing index testing in scale-up districts were assessed for compliance with the WHO's 5Cs (consent, confidentiality, counseling, correct results, and connection), availability of effective adverse event monitoring, and appropriate training and supervision. Remediation plans were put in place for sites that did not meet criteria. Key gaps included: incomplete community feedback systems; few staff trained on gender-based violence/intimate partner violence; lack of adverse event reporting from index testing; lack of client communication materials, such as information on how patients can report violations of their rights and how to obtain support; and lack of lockable cabinets for storing client data at some sites.

PEPFAR Malawi continues to support universal testing at prevention of mother-to-child transmission (PMTCT), TB, and STI settings. Outpatient department (OPD) testing, other provider-initiated testing and counseling (PITC), and voluntary counselling and testing (VCT) contributes to most of the new cases identified, albeit at lower HIV positivity rates than expected. PEPFAR implementing partners are working together to validate and implement screening approaches to increase yield and reduce testing volumes. In addition to the use of screening tools in OPD settings, testing and treatment literacy efforts will minimize repeat testing among individuals seeking care.

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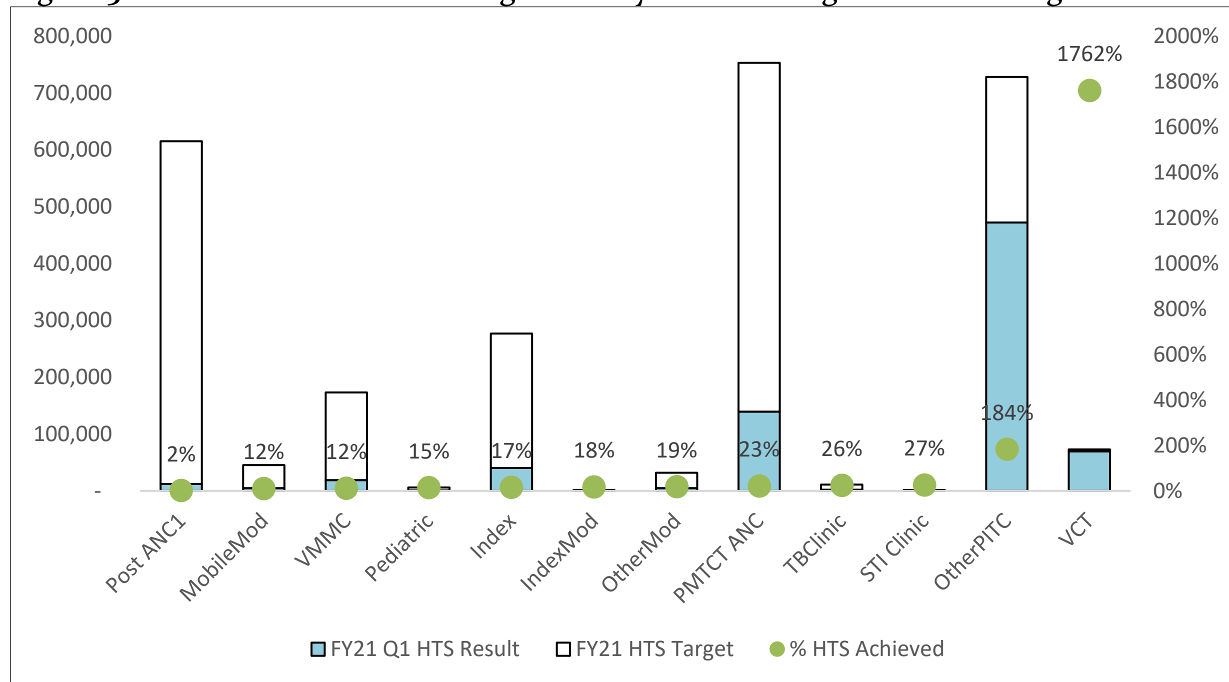
Figure 5.1.1 Other PITC & VCT are Significantly Contributing to Over-Testing



Some clients who never initiated ART or who previously dropped out of care utilize retesting as a route back into treatment. Efforts will be employed to ensure clients ready to return back to care do not face additional obstacles. For example, in COP21, PEPFAR Malawi's HTS investments will be focused on supporting efficient HTS strategies. PEPFAR Malawi's HTS investments are similar to COP20 with a slight increase in COP21; $5,598,488 and $5,697,556 respectively. Figure 5.1.2 summarizes COP21 testing modalities, targets, yield, and proportional contribution to new cases identified. Compared to COP21, testing targets are similar to COP20 with a slight decrease (from 1,956,679 in COP20 to 1,947,081 in COP21). This increase in funding despite the decrease in targets is due to index testing being more expensive that PITC. Index testing has the highest contribution (41%) to the overall target of new positives to be identified.

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Figure 5.1.2 COP20 HTS Targets per Modality and Expected Yield

TESTING MODALITY		HTS_POS	HTS_TST	YIELD	% of positives from modality
		FY22 Target	FY22 Target	FY22 Target	
Index Testing	Community Index	4,105	15,727	26%	5.2
	Facility Index	28,375	139,666	20%	36.1
Community-Based Testing	Mobile	603	6,698	9%	0.8
	Other	4,400	6,900	64%	5.6
Facility-Based Testing	Pediatric	58	2,686	2%	0.1
	PMTCT ANC1	7,739	603,401	1%	9.8
	PMTCT Post-ANC1	1,984	555,364	< 1%	2.5
	TB	381	8,448	5%	0.5
	VMMC	253	13,603	< 2%	0.3
	VCT	10,922	264,197	4%	13.9
	STI	74	2,465	3%	0.1
	Other PITC	17,393	264,182	7%	22.1
	Inpatient	2,329	63,744	4%	3.0
Total target		**78,616**	**1,947,081**		**100.0**

Implementing partners will use the projected contribution of various HIV testing modalities to find PLHIV and guide the COP21 work plan development with index testing as the dominant strategy. The development of index testing certification processes with an emphasis on the WHO's 5Cs principle is complete in all scale-up districts and plans to expand index testing to high volume sites in sustained districts are underway. Supportive supervision and monitoring with fidelity checklists will be improved.

Men

Spectrum Malawi 20 v6 reports sub-optimal reach of men (especially 15-40-years old) with testing and treatment services. FY21 Q1 program data showed a similar report (see Figure 5.1.3). This continues to fuel the HIV transmission cycle. In COP21, additional male-friendly integrated strategies will be implemented in high-volume facilities to promote reach with HTS, including male friendly clinics that implement a core basic package of services, HIV self-testing (HIVST), and extended clinic hours. Currently, PEPFAR Malawi is working with partners to clearly define a core package using MenStar strategies at high-volume sites with a TX_CURR of 2,000 and above. Targeted mobile testing to reach MSM through social network strategies (SNS) will continue in COP21. Moreover, clients of FSW in geographic hotspots will be reached through secondary HIVST distribution and index testing services.

Figure 5.1.3 Low Treatment Coverage among Younger Men under 40 Years of Age, FY21 Q1

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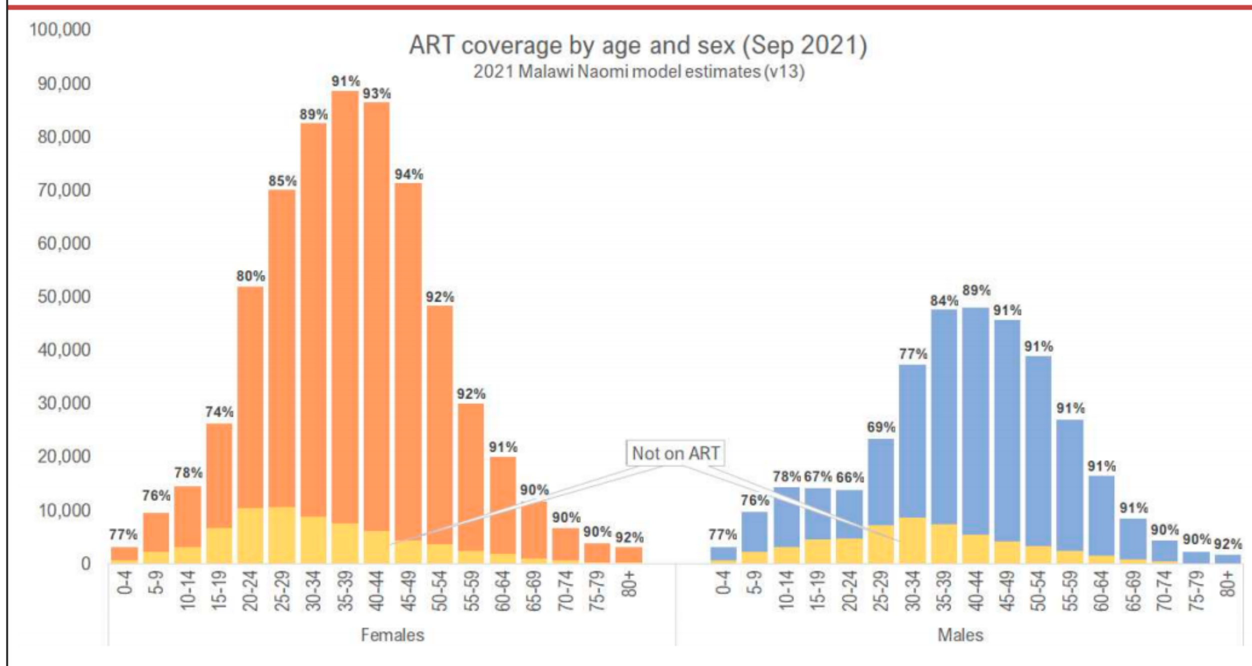

Implementing Active Index Testing with Fidelity

As previously reported, PEPFAR partners strategically shifted HIV diagnostic assistants (HDAs) from low yield OPD testing to active index and recency testing in COP20. PEPFAR HRH support and assignment to entry points will regularly be evaluated vis-à-vis HIV new case finding performance. This may address some concerns about ignoring some key entry points. PEPFAR will work with the MoH and CSOs to standardize adverse event monitoring systems and response as part of index testing implementation. The national program currently uses a standard incident reporting form for all HTS modalities, that was developed when index testing was not yet an adopted policy in Malawi. Index clients in intimate partner violence situations screenings are linked to supportive post-violence care services within the district and/or catchment area. The MOH also leads the development and piloting of standardized index testing registers, and reporting tools have been rolled out across the country.

HIV Self-Testing (HIVST)

HIV prevention programs will prioritize HIVST distribution as its primary modality for HIV testing. Assisted HIVST distribution will be promoted in DREAMS, KP, and VMMC programs. As the Global Fund will not be purchasing HIVST kits, American Rescue Plan funds have been allocated to provide commodities for the noted programs. Integration of HIVST into active index testing targeting sexual partners will continue being implemented in COP21. HIVST kits will also be distributed to HIV negative pregnant women with partners of unknown status as secondary distribution. Primary HIVST distribution will also target men in hotspots (marketplaces, plantations, etc.) and at the community level. The PEPFAR team will advocate for sourcing other

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funds for test kits to cover these distribution points. All individuals screening positive will be referred to ART facilities for confirmatory tests prior to ART initiation, in accordance with national guidelines. PEPFAR partners will ensure active linkage of all clients screening HIV positive.

Table 5.1.4 ART Targets by Prioritization for Epidemic Control

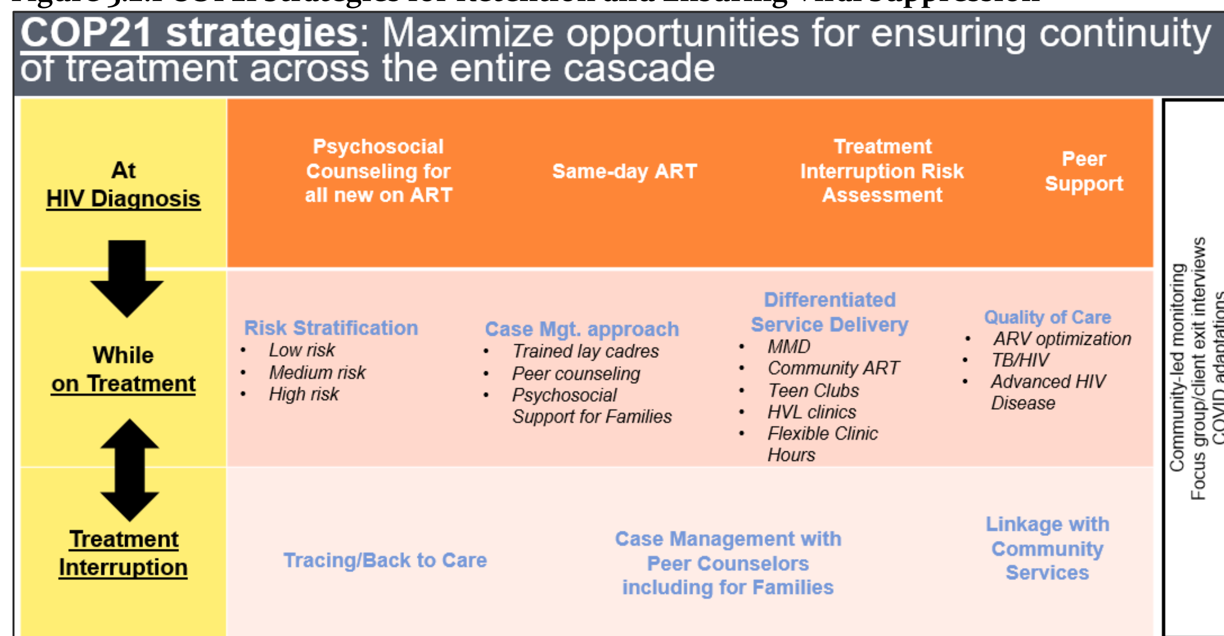
Prioritization Area	Total PLHIV	Expected current on ART (APR FY21)	Additional patients required for 80% ART coverage	Target current on ART (APR FY22) *TX_CURR*	Newly initiated (APR FY22) *TX_NEW*	ART Coverage (APR 22)
Scale-Up Saturation	767,630	643,453	0	696,807	61,184	91%
Sustained	295,996	235,981	0	248,932	15,948	84%
Total	1,063,626	879,434	0	945,739	77,132	89%

*Military not included

5.2 Retaining Clients on Treatment and Ensuring Viral Suppression

Ensuring continuity of treatment remains a key priority for PEPFAR Malawi and a critical strategy for achieving and sustaining HIV epidemic control. Building on COP20 strategies and in collaboration with stakeholders, including the MOH, Global Fund, and CSOs, PEPFAR Malawi will roll out comprehensive continuity of treatment interventions proven to be effective and address challenges across the retention cascade. Preventing treatment interruptions will be a major priority of these interventions accompanied by reengagement of clients whose treatment was interrupted.

Figure 5.2.1 COP21 Strategies for Retention and Ensuring Viral Suppression



Key COP21 actions will include:

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- 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 facility 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. Topics will include (but not limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, and cervical cancer screening to ensure uptake of these services.
- PEPFAR will fund five community led PLHIV organizations to engage with the general population and five key populations led organizations to target those groups more specifically. 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.
- 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.
- 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). Where PLHIV may have had a treatment interruption or have missed an appointment, staff will treat those returning respectfully and with compassion.

Table 5.2.2 PEPFAR Malawi's TL Activities both at the Health Facility and Community Levels

Implementation Mechanisms	Key Activities	District *(* star shows new districts)*
Clinical Service Delivery Partners (Site Level)	Health education Individual and group counseling (in-person/using video counseling) IEC materials	Mangochi, Machinga, Mulanje, Phalombe, Balaka, Salima, Lilongwe, Nkhotakota, Dowa, Kasungu, Karonga, Nsanje, Chikwawa, Chitipa, Blantyre, Zomba, Thyolo, Chiradzulu, Neno, Mwanza, Dedza, Ntcheu, Mchinji, Ntchisis, Mzimba, NKhatabay, Rumphi

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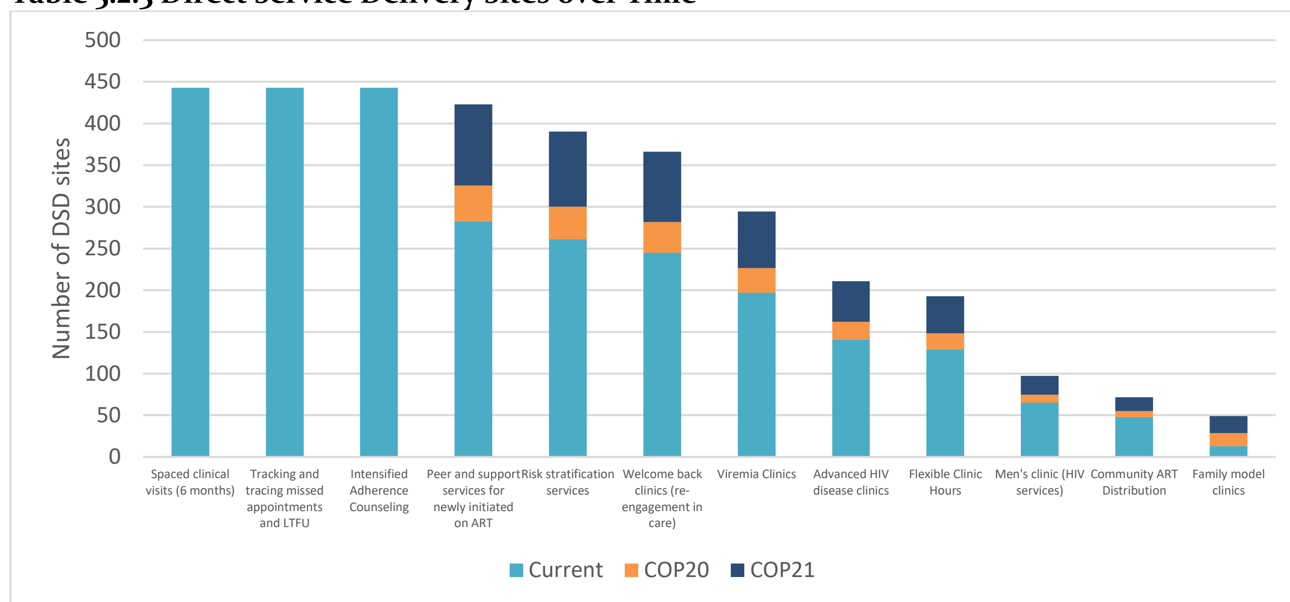
MANASO award (Community Level)	Community health education PLHIV support group led awareness campaigns Treatment literacy awareness sessions in health facilities and in communities	Blantyre, Zomba, Lilongwe, and Mulanje
Faith and Community Initiative: IPs: MANARELLA, World Relief, six religious mother bodies via HP+ (Community Level)	Dissemination of new messages of hope within faith communities for supporting HIV treatment adherence and retention among men, families, and youth Expansion of HIV testing/linkage and retention among men	Chikwawa, Nsanje, Lilongwe, Kasungu, Dowa, Nkhotakota, Blantyre, Zomba, Thyolo, Chiradzulu, Mzimba, Mangochi*, Machinga*, Mulanje*
OVC Programs (Community Level)	Household case management, support groups, positive parenting	Lilongwe, Machinga, Mangochi, Blantyre, Chikwawa, Zomba, Phalombe, Thyolo, Mulanje
COWLHA/ WOCACA Cervical Cancer (Community Level)	Community Information dissemination (through existing networks) and referrals for screening and treatment services for cervical cancer	Lilongwe, Machinga, Mangochi, Blantyre, Zomba,

Continued scale up of differentiated models: PEPFAR Malawi supports the expansion of several differentiated, client-centered treatment service delivery models both at the facility and community levels. As of FY21 Q1, all PEPFAR direct service delivery sites offer multi-month dispensing with 92% of treatment clients on three-plus-multi-month dispensing. In COP21, PEPFAR will continue its support to accelerate uptake of six-month multi-month (MMD6) dispensing. The ongoing adoption of MenStar strategies will inform our scale up of service models in COP21 to address the barriers that men experience in accessing services. Individual- and family-centered models will be expanded to improve continuity of treatment, especially among men. PEPFAR Malawi will apply lessons from the COP20 private sector Decentralized Drug Distribution (DDD) demonstration project to strengthen current private sector activities, as well as, explore further expansion. In order to improve ART continuity and to reduce the burden

on health facilities, 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.

Table 5.2.3 Direct Service Delivery Sites over Time



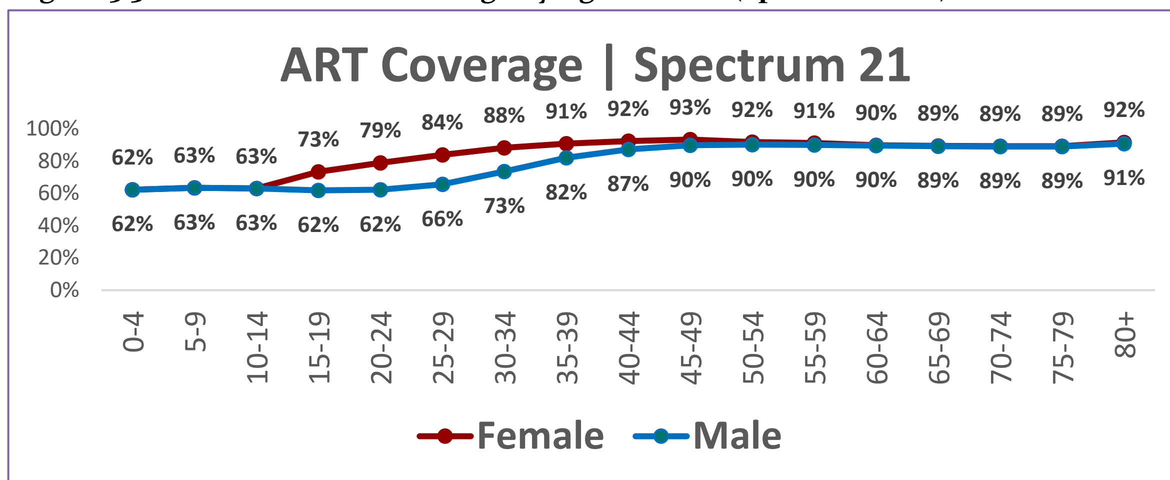
Data use (back-to-care App): In COP20, PEPFAR Malawi's health information system partner is collaborating with the MoH and clinical partners to develop a digital tool to facilitate identification and follow-up of PLHIV who interrupted their treatment. In COP21, this tool will be deployed to all PEPFAR supported sites and will play a critical role in the timely identification and reengagement of clients back to care.

COVID-19: Concerted effort by implementing partners and other stakeholders has been required to ensure COVID-19 and related service disruptions do not negatively affect the continuity of treatment and viral suppression. As part of the national COVID-19 response, PEPFAR implementing partners are supporting site-level efforts to reduce transmission and mitigate the impact of COVID-19. Some of the key interventions in COP21 will include expansion of MMD6 uptake, flexible clinic hours, phone reminders, virtual counseling support, and expansion of phone tracing for those who interrupted their treatment, or had a positive early infant diagnosis or high viral load results.

5.3 Reaching and Retaining Adolescents and Pediatrics

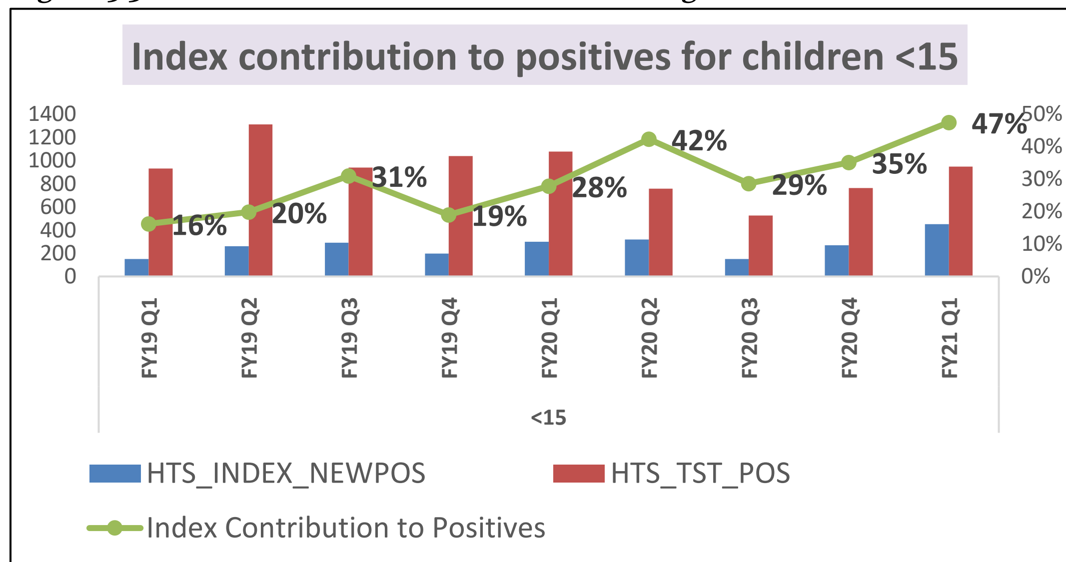
According to 2021 Spectrum data, the estimated number of children living with HIV aged 0–14 (CLHIV) in Malawi is 72,883. An estimated ART coverage for CLHIV is currently at 63% (see Figure 5.3.1). For older adolescents living with HIV (15-19 years), their estimated coverage is 68% (73% for female ALHIV and 62% for male ALHIV). Estimates of CLHIV have varied over the past five years based on assumptions used each year.

Figure 5.3.1 Estimated ART Coverage by Age and Sex (Spectrum 2021)



Case finding remains a bottleneck for both children and adolescents. PEPFAR Malawi will continue to prioritize finding these populations and putting them on treatment. Building on COP20, efforts to reach 100% of biological children of PLHIV remain the priority for COP21. Necessary tools have been finalized to help with regular monitoring of coverage and index testing for biological children continues to improve. COP19 through COP20 found progressive increases in the number of CLHIV diagnosed through index testing and the overall contribution of index testing to total positives identified. In FY21 Q1, almost half (47%) of all newly diagnosed HIV positive children were from index testing (see Figure 5.3.2). However, only 59% of the elicited children were reached and tested. COP21 will realize continued improvement in active index testing of biological children as the key case finding strategy.

Figure 5.3.2 Overall Contribution of Index Testing to the Total Positives among 0-14 Years



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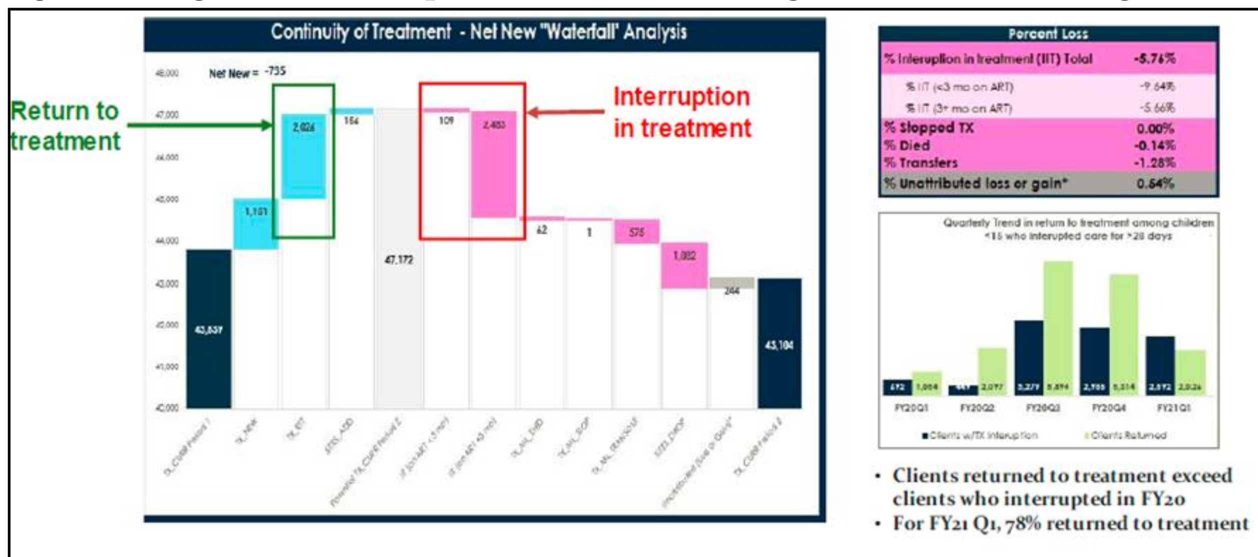
In COP21, PEPFAR Malawi will continue to implement trainings of health care workers, supervision, mentorship, and leveraging the OVC program to reach families. PITC in high yield entry points will continue to be supported as well as risk-based testing in OPD. In addition, PEPFAR will continue to ensure high EID coverage with POC testing for immediate results and linkage to treatment, and ascertainment of final status among HIV exposed infants (HEI) at PEPFAR supported sites.

Viral load (VL) suppression rates are still sub-optimal among children and adolescents but significantly improving across all age groups. The improvement is mainly attributed to the transition to optimized regimens (LPV/r and DTG-based) and continued adherence support by implementing partners and the OVC case management approach to support facilities has been important. According to the MOH program data, 0–4-year-olds had the lowest VL suppression with only 66% females and 60% males suppressed in FY21 Q1. They are also the main population on the challenging LPV/r formulations and have not yet transitioned to DTG regimens. The transition started on a small scale in COP20 as Malawi made a catalytic procurement of DTG 10mg. Transition plans to DTG 10mg are on track with the first shipment expected to arrive in FY21 Q3. In COP21, Malawi will rapidly transition all children weighing less than 20 kilograms to a more pediatric-friendly DTG 10mg regiment. Through the OVC program, treatment literacy efforts will be incorporated to enable HIV positive caregivers and other directly impacted communities to care for children living, improve case finding and mitigate treatment disruption.

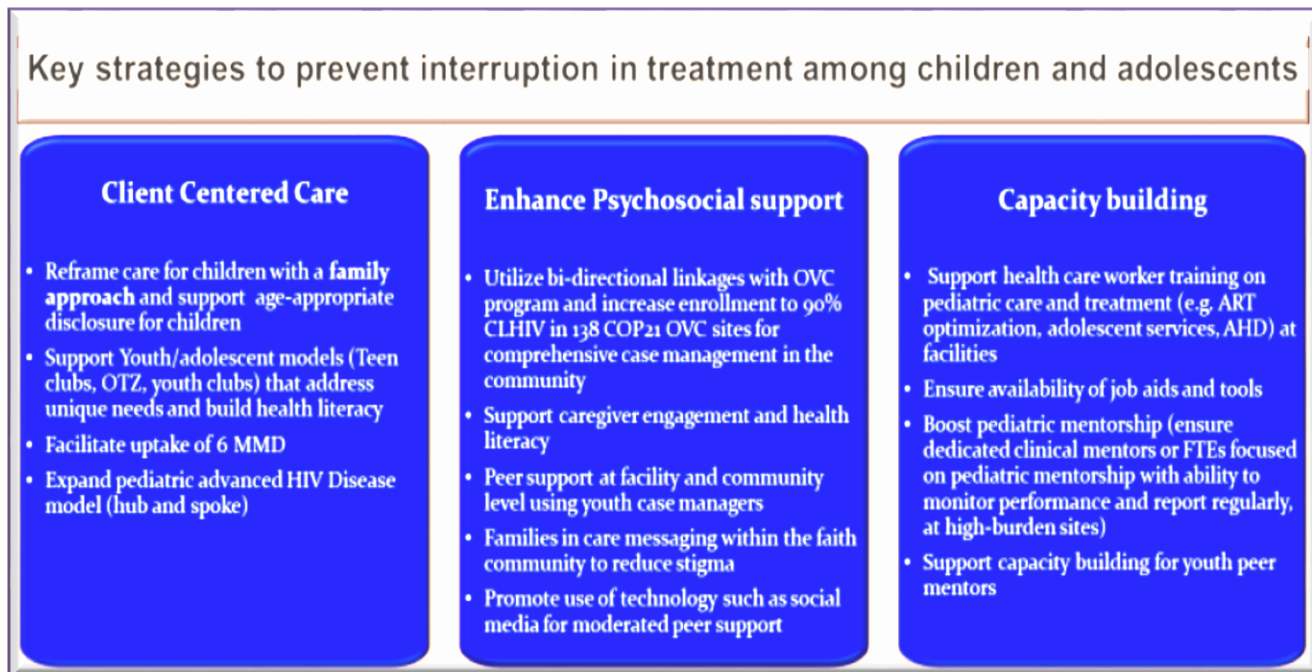
Malawi continues to observe significant interruptions in treatment among CLHIV (0-14 years). In FY21 Q1, 6% of CLHIV enrolled on ART interrupted treatment. More interruptions (9.6%) were observed among newly enrolled (< 3 months on ART) than those >3 months on ART (6.7%). However, return to treatment rates were high at 78% in FY21 Q1; this highlights the need to focus on preventing interruptions in COP21.

Figure 5.3.3 Significant Interruption in Treatment but High Rate of Return among CLHIV



For adolescents 15-19 years old, 6.8% of females interrupted treatment compared to 4.8% of males in FY21 Q1. Women had higher rates of both early and late interruptions and better rates of return to treatment (60% at FY21 Q1). These adolescents not only had lower interruption rates but also lower return to treatment rates (2.6%). Table 5.3.4 below outlines the interventions PEPFAR Malawi will implement to address interruptions in treatment among children and adolescents.

Table 5.3.4 Key Strategies to Prevent Interruption in Treatment among Children and Adolescents



During COP21 planning, PEPFAR Malawi and stakeholders agreed to strengthen client-centered care, overall capacity building of healthcare workers, and psychosocial support. An agreement was made to reframe care for children with a family-centered approach. PEPFAR implementing partners are already implementing family models at some clinics currently, and with promising results in terms of continuity of treatment and VL suppression. In COP21, this approach will be scaled up to high burden sites in order to support families holistically. Coordination with communities of families to encourage families in care messaging will be continued to reduce HIV-related stigma.

Strong linkages with the OVC program have been established for case management and will continue to be utilized at 138 OVC-supported sites in COP21, targeting at least 90% of C/ALHIV. For adolescents, age and sex appropriate peer supporters will also be capacitated to offer community level adolescent psychosocial support. COP21 will also strengthen access to AHD and MMD6 for young people who are stable and eligible, which the OVC program will reinforce.

5.4 Cervical Cancer Program Updates

Cervical cancer is the number one cancer killer in sub-Saharan Africa. Women living with HIV (WLHIV) are four to five times more likely to develop persistent precancerous lesions that progress to cervical cancer, often with more aggressive forms and with higher mortality. PEPFAR leverages Global Fund resources for the procurement of key equipment and consumables and also works closely with the MOH to ensure equipment distribution is rationalized. PEPFAR has also supported a revision of monitoring and evaluation tools to align with PEPFAR clinical reporting requirements and emerging issues in cervical cancer. Strengthened service delivery through in-service training of providers and deploying at least one cervical cancer lead per site to coordinate screening and treatment services will also be a priority in COP21.

Between FY19 and FY20, PEPFAR seconded two technical advisors (one Program and one M&E) to the MOH to strengthen coordination and improve the quality of data collection, analysis, and utilization. Standard operating procedures for quality assurance were also developed. However, the availability of the loop electrosurgical procedure (LEEP) for treatment of large lesions is limited across the country. This has resulted in women travelling very long distances to access services where they often encounter challenges as other emergency surgical procedures are often given priority.

By the end of FY20 Q4, a total of 81,672 WLHIV were screened for cervical cancer at the 39 high volume sites where PEPFAR was supporting screen-and-treat services. This represents an achievement of 80.5% against the target of 101,507 women. In FY21 Q1, Malawi's cervical cancer program successfully scaled up the number of sites from 39 to 80, per COP20 plans, and continued its strong performance with an achievement of 31,888 (31%) of the annual CXCA_SCRN target (103,671 WLHIV). Same-day treatment of precancerous lesions has improved from 85% in FY20 Q1 to 91% in FY21 Q1. PEPFAR implementing partners have also introduced systems to provide logistical support and track women who are referred to other sites due to large lesions.

In COP21, PEPFAR will continue working with the MOH to introduce LEEP services to all district hospitals (secondary referral level) and strengthen referral networks for WLHIV in need of LEEP and specialized care for those presumed to have cervical cancer. To ensure that specimens coming from LEEP are evaluated, PEPFAR also plans to strengthen histopathology services. PEPFAR Malawi will further improve access to cervical cancer screen-and-treat services by scaling up to an additional 47 sites, bringing the number of PEPFAR supported cervical cancer sites to 127 while reaching 55% of WLHIV aged 25-49 years. PEPFAR aims to screen 154,787 WLHIV. To meet this target, PEPFAR will provide both static and outreach services including the use of rechargeable thermocoagulators which allows for a same day screen and treat in outreach facilities. PEPFAR also plans to leverage other partners to scale up screening using HPV DNA-PCR.

PEPFAR and GoM will work hand in hand to ensure that cervical cancer services are fully integrated with HIV services. In facilities where cervical cancer screening is being offered, screening is conducted on ART Clinic day. Clear referral pathways and monitoring mechanisms will be put in

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place to trace women referred to services outside the Health Centre (including where no services are offered, or for further treatment).

To beef up local level information dissemination and awareness training, PEPFAR Malawi will work with CSOs such as the Coalition of Women Living with HIV and AIDS (COWLHA) and the Women's Coalition Against Cancer (WOCACA) to ensure that targeted communities around the PEPFAR sites receive information about related PEPFAR-supported cancer services and how to access these.

COWLHA, WOCACA **Cervical Cancer** **(Community Level)**	Community Information dissemination (through existing networks) and referrals for screening and treatment services for cervical cancer	Lilongwe, Machinga, Mangochi, Blantyre, Zomba,

Table 5.4.1 Status of Integrated Cervical Cancer Services in COP20 and Plans for COP21

	COP 20 ACTION ITEM	COP 21 VISION
# of Sites	Increased from 39 to 80 (**41 new sites**)	**47 new sites** – for a total of **127 sites** • All 28 districts covered • 43 spoke sites for outreach activities covered by 26 hub sites
Screening target	Increased from 42,000 in COP 18 to 103,360 in COP 20	Increased to 154,787
Referral systems	• IPs developed tools for referral tracking and reporting • Logistical support to recipients of care for transportation • Scaling up LEEP to all districts	• Strengthen utilization of tracking tools and referral networks • Continue with referral logistical support • Continue to support LEEP trainings, mentorship, and service delivery
Other	• Initial and refresher trainings for providers	• Capacitate Histopathology Labs • Introduction of HPV-DNA testing for VIA triaging • Initial and refresher trainings for providers

5.5 TB and HIV Program Updates

In COP21, one of PEPFAR Malawi's top priority will be to maintain TB/HIV program successes in the context of COVID-19; including making TPT available through client-centered direct service delivery (DSD) and multi-month dispensing (MMD) models. Ending HIV-associated TB is possible through a combination of: rigorous TB screening of PLHIV at each encounter with the health system, optimizing GeneXpert diagnostics for all PLHIV, supporting widespread optimized

ART coverage, TB preventive therapy, early and optimal TB and HIV treatment for co-infected clients; and effective infection prevention and control. PEPFAR implementing partners will implement a multi-pronged TB strategy at site and community levels. 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.

Finding TB among PLHIV: Integration with COVID-19 Case Finding

PEPFAR IPs will strive to improve the quality of TB and COVID-19 screening and strengthen and optimize the use of recommended diagnostic tools. In particular, IPs will ensure all PLHIV who screened positive for TB and COVID-19 have 1) a specimen collected, 2) the specimen is sent for WHO recommended diagnostic testing (e.g., GeneXpert), and 3) results are reported and utilized in time. To ensure the WHO-recommended diagnostic assays are used as the initial diagnostic test for TB in all PLHIV with TB symptoms, IPs will facilitate sample transportation from sites that do not have GeneXpert platform to the diagnostic hubs. IPs will also provide dedicated and trained lay personnel at selected high TB burden health facilities to administer a TB (including COVID-19) screening questionnaire before clients are seen by a clinician and conduct contact investigation for pulmonary TB patients. IPs will continue to use dedicated TB and COVID-19 integrated algorithms to optimize resources for case finding both at the facility and community levels.

Maintain High Levels of HIV Testing among TB and Presumptive TB Patients and ART Linkage for HIV Positive TB Patients

HIV ascertainment among TB (99%) and presumptive TB (>90%) patients and linkage to ART (99%) are very high in the Malawi TB and HIV programs. In COP21, IPs will ensure these rates are maintained or improved.

Preventing TB among PLHIV: Optimize TPT and Infection Control Practices

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.

Optimizing TB Treatment and ART for TB/HIV Co-Infected Patients in the Context of COVID-19

The aim will be to minimize patients' visits to the health facilities in order to decongest them, minimize transmission of COVID-19 and TB, and to ensure TB patients are able to complete their treatment. IPs will work with the MoH to implement flexible service delivery models to ensure uninterrupted availability of TB and ARV drugs for all co-infected patients. IPs will work with health facility staff and TB/HIV program leadership to ensure multi-month TB drug dispensing is aligned with ART dispensing where possible. Where appropriate, IPs will support implementation

of active treatment monitoring through regular phone calls to individuals on treatment or passive monitoring by encouraging patients to call back and report any arising issues.

Diagnostic Network Optimization (DNO) and Multiplex Use Considerations

Through the Global Fund and COVID-19 resources, the number of GeneXpert platforms in Malawi has markedly increased to cater for COVID-19, TB, HIV, EID, and viral load testing. This will ensure the integrated testing on these platforms is performed systematically to avoid compromising diagnostics for any of the services requiring the GeneXpert facilities. Clinical partners will optimize GeneXpert and other WHO approved molecular methods as endorsed by the MoH for all PLHIV (including the use of stool samples among children living with HIV).

Infection Prevention and Control (IPC)

IPC is an important aspect of controlling TB, COVID-19, and other communicable infections. PEPFAR-supported sites had IPC committees, SOPs, and equipment before the COVID-19 pandemic. However, the pandemic generated a significant improvement in multisectoral coordination, resource mobilization, and equipment utilization for IPC. PEPFAR IPs will build on these best practices beyond COVID-19 and amid any future health epidemics.

6.0 Systems Strengthening Updates for Epidemic Control

Systems Strengthening Summary

The HIV program in Malawi has evolved from a crisis in the early 2000s to approaching epidemic control. However, the program continues to face barriers that will make it difficult to sustain the gains made so far, including: (1) the evolving and suboptimal policy environment; (2) health information systems that require infrastructure and sustained investment; (3) inadequate human resources for health for HIV and health service delivery; (4) limited host country institutional capacity; (5) limited commodity management and storage capacity; and, (6) inadequate optimization of laboratory mechanisms. Each of these barriers requires particular attention during COP21 given their potential to stall implementation of HIV interventions across the cascade.

The 2019 Sustainability Index Dashboard (SID) identified technical and allocative inefficiencies, commodity insecurity and supply chain issues, epidemiology and health data, insufficient laboratory commodities as posing the greatest threats to the country's progress and ability to sustain epidemic control. In conjunction with the SID, information and insights gleaned from MER and SIMS data all point to the need for PEPFAR investments to focus on improved service delivery and broader health systems strengthening, including right-sizing the number of skilled professional cadres; advancing the quality and depth of national, district, and site-level governance and accountability; bolstering the management of HIV services; and recognizing that

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data ecosystems inform rational decision-making and demonstrate the gains made in HIV prevention, treatment, and viral load interventions.

6.1 Human Resources for Health

In FY21, a key focus for HRH was ensuring the remaining 50% of supported health care workers (HCWs) are fully absorbed into the MOH establishment, per the signed MOU. This has been achieved, and all 224 HCWs were smoothly transitioned to the government payroll, a crucial first step in ensuring sustainability of the healthcare workforce by the MoH. In FY21, PEPFAR has continued to provide support to the Malawi MoH by funding 10,920 HCWs for HIV direct service delivery through G2G and other service delivery mechanisms. The G2G mechanism is also strengthening governance, program, and financial accountability challenges through systems improvements and provision of supportive tools. Other key achievements in FY21, thus far, include building capacity of mid-level training institutions through provision of learning equipment in the select labs and supporting 77 mid-level HCWs with scholarships. PEPFAR also provided scholarships to ten students at the College of Medicine for the HIV Medicine Diploma, seven scholarships in Physician Specialists, three in family medicine, and four in internal medicine. PEPFAR is also working closely with the Ministry of Local Government, the Department of Human Resources Management and Development, and the MoH to review the functions of Lilongwe, Zomba, and Blantyre district offices to determine appropriate numbers and cadres of HRH to meet the needs of PEPFAR and non-PEPFAR services.

Not unexpectedly, some PEPFAR-supported healthcare workers who tested positive for COVID-19 and were isolated, creating fear, anxiety, and stress. Healthcare workers reported abuse by the public that would not allow them to board public transport due to fear of spreading COVID-19. The pandemic increased demand for services and reduced resources for service delivery. There were strikes and demands for more personal protective equipment and allowances. The pandemic reduced the productivity of healthcare workers and affected their social, physical, and mental well-being. Partners adopted virtual supportive supervision and mentoring, task shifting and sharing to maximize resources and implement COVID-19 prevention measures.

While progress was made, the COVID-19 pandemic caused disruption to HRH programs and strategy. All training colleges were closed, which affected anticipated graduation students. Physical supportive supervision was suspended, delaying completion of functional reviews of Blantyre, Lilongwe, and Zomba health sectors. Turnaround time in molecular labs for VL results increased from ten days to 52 days due to the high demand for COVID-19 testing and insufficient numbers of laboratory staff and testing resources. To mitigate the effects of COVID-19, PEPFAR has supported schools to develop an e-learning curriculum, pivoted to virtual supportive supervision, and conducted virtual meetings with district health management teams to finalize functional review reports. Additionally, 20 laboratory staff and ten data clerks were recruited to optimize testing services for HIV, EID, TB, and COVID-19.

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In FY22, PEPFAR will continue to maintain surge salary support for 374 HCWs through the CHAM cooperative agreement and 10,926 HCWs through the G2G and service delivery mechanisms. PEPFAR will recruit an additional 51 Lab technicians and 71 data clerks to maintain 16-hour shifts in molecular laboratories, ensuring full utilization and optimization to meet testing demands. One hundred fifty scholarships for laboratory staff will be offered, who upon graduation, will be deployed to district and central labs to support strengthening laboratory capacity. Peace Corps will recruit five Health Professionals to support pre-service training through mainstreaming HIV/AIDS in the Nursing and Medicine curriculum.

Furthermore, PEPFAR will continue to support the training institutions to strengthen e-learning to avoid disruptions during the pandemic in COP21. In-service training and monitoring has been a major challenge; therefore, PEPFAR, in consultation with Districts Health Offices and DHA, will identify knowledge and skills gaps among the workforce and design in-service training using standardized lay cadres' training curriculum. Performance will be measured regularly for continuous improvement. Additionally, STI screening and family planning services are already provided in many ART clinics. More focused mentorship on integrated services and strengthened linkage and referral systems will be undertaken in COP21. Cervical cancer screening and treatment is also available in a subset of ART clinics. Partners supporting SRH and HIV will coordinate service provision in shared site locations. Lastly, data analysis has shown that there has been a positive relationship between increased lay workers and increased NET_NEW. However, to achieve more positive outcomes, PEPFAR, in collaboration with Global Fund and the Ministry of Health, will support standardization and professionalization of lay cadres, which will focus on roles, level of effort, naming of cadres, remuneration, and training.

Adding more staff or right-sizing staff are not the only solutions to addressing the gaps in HRH. In FY22, PEPFAR will document the full HRH landscape, including staff employed in both public and private sectors. In partnership with the MoH, the College of Medicine, and WHO, PEPFAR is enumerating and gathering critical information on the cadres employed in private facilities, which until now, have been a large data gap affecting the development of a comprehensive HRH strategy. The findings from the aforementioned private facilities enumeration, with data from the PEPFAR HRH Data Inventory, the MoH, and the Global Fund, will provide the most comprehensive overview of HRH in Malawi and allow an assessment of needs and optimization to support an HRH strategy for post-epidemic control. Lastly, engagement with district-level leadership to improve HRH planning and management capacities will continue in COP21 to better equip district level leadership to sustain implementation and oversight of the HIV program. Sustainability of PEPFAR site-level HRH investments is dependent on the success of public sector reforms and decentralization, and the capacity of the health sector to plan, attract, motivate, and retain capable healthcare workers.

Table 6.1.1 COP21 Malawi HRH Strategy

COP21 Malawi HRH Strategy: Applying HRH inventory and national staffing data to refine and execute the DSD-driven strategy and lay the foundation for transition planning for sustainability as we reach epidemic control in the context of COVID-19.

- PEPFAR Malawi HRH inventory and analysis of site-level data demonstrated both data gaps and valuable insights to guide how we arrive at the needed evidence-base, rethinking staffing decisions and recommendations for HRH in Malawi. MoH, Global Fund, and private facility HRH data collection underway now were unavailable at the time of analysis during COP21 preparations. To fully assess the current HRH needs for healthcare service delivery, a more accurate assessment will be completed, as PEPFAR-supported staff are only one part of the larger HRH picture. Activities planned for COP21 include:
  - Acquiring more granular data on the cadres employed by MoH (supported by Global Fund); enumerating and describing the cadres employed at private facilities; and engaging in joint planning to share and assess HRH pipeline across Malawi more routinely,
  - Carrying out lay cadre standardization through a multi-partner Task Force to understand the differences in lay cadre duties and compensation across the health sector.
- As part of completion of this analysis during COP21, PEPFAR, in consultation with the MOH and other partners, plans to map and set criteria to guide the requisite streamlining of key types and numbers of cadres working throughout Malawi, as well as conduct an optimization exercise that would help to operationalize the HRH strategy 2.0 for COP22 and beyond.

The end result will be the implementation of PEPFAR Malawi's HRH Roadmap – a transparent, consensus- and data-driven plan that describes the landscape of current HRH in Malawi and details a whole-of-government approach for efficient use and support of limited human resources. Working across technical teams and areas, COP21 will "reset" how we support and engage IPs in preparation for determining what is required to sustain gains and transition HRH investments in phases that ensure quality HIV services continue.

6.2 Laboratory, Viral Load, and Early Infant Diagnosis Optimization

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 competition 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. This module is complementary to the EMR stock management module at the clinical facility-

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level, and the OpenLMIS stock management module, which is a supply chain module to track commodities between facilities and central warehouses. 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, a module will be added to LIMS/iBLIS that will help laboratories to manage their stock. PEPFAR will continue to support the MoH in procuring reagents and laboratory supplies for viral load and EID testing in high throughput and POCT laboratories when there are critical needs. To ensure continuous testing and reduce breakdown of equipment, PEPFAR, in consultation with MoH and Global Fund, will support repairs and maintenance of lab equipment and work to replace the older platforms with advanced technology devices. More laboratory technologists for molecular laboratories and data entry clerks will also be recruited to fill gaps (see Section 6.1 for more detail). PEPFAR will continue to support laboratory infrastructure improvement to maintain laboratory practices and biosafety.

Following the MoH policy change, in June 2020, EID was decentralized to POCT laboratories using GeneXpert and m-PIMA devices. Currently, 48 GeneXpert devices are being used for multiplex testing for EID, TB, targeted VL, and COVID-19. Among the 48 GeneXpert devices, the overall annual utilization rate in FY20 was at 44%, showing there is additional capacity for implementation of more laboratory tests, including AHD, PBFW, and infants and adolescents viral load tests. To achieve this expanded testing in COP21, PEPFAR is planning to refurbish two district hospital laboratories to ensure adequate space to accommodate the additional workload needed and for storage of reagents and specimens.

Diagnostic network optimization (DNO) plays a key role to maximize efficient utilization of limited resources through integrated sample transportation systems, multiplex testing using high throughput and POCT platforms, strengthening laboratory information management systems, and optimization of working hours by introducing extra shifts and increasing the duration of shifts. In collaboration with the MoH and other stakeholders, the DNO will be continuously reviewed using PEPFAR-approved tools to standardize the hub and spoke network and to optimize the workload and supply utilization. At national and district levels, technical assistance and human resource support will be provided to the MoH and district health officers on policy and guideline development, dissemination, implementation and monitoring.

In COP21, PEPFAR will expand the pull sample transportation system to all districts for efficient utilization of resources as well as to ensure samples that need immediate transportation are delivered in a timely manner to testing laboratories (i.e., PrEP, EID, targeted viral load, sputum and COVID samples). Replacing old motorbikes will also assist with ensuring that all facilities are reached.

Abbott platforms in the ten molecular laboratories and 48 GeneXpert platforms near POCT labs are being used for multiplex testing. Most of these platforms are aged and had frequent breakdowns; in COP21, PEPFAR will continue to support laboratories on regular equipment maintenance and services in collaboration with MOH and local engineers. Ancillary equipment, such as biosafety cabinets, fridges/freezers and pipettes, need regular calibration and will occur

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during COP21. PEPFAR will continue to support annual hematology, chemistry, and CD4 instrument services to make sure that these pieces of equipment remain functional and patients with AHD are monitored effectively.

PEPFAR will continue to strengthen the integrated laboratory information management system for all tests. The effort to integrate National LIMS, EID/VL LIMS and iBLIS at different levels and the automation of hub laboratories will be expanded to an additional 16 districts. Interfacing EMRs to National LIMS and iBLIS will facilitate transfer of results directly from testing laboratory to facilities. SMS patient notification will be used to enable clients to track their VL, EID, CD4, TB, and COVID-19 results. PEPFAR will continue to support laboratory waste management through transportation of hazardous liquid and solid waste from testing laboratories to cement factories for incineration. In addition, regular training of laboratory staff on appropriate waste management will continue in COP21.

Continuous quality improvement (CQI) is key to ensuring laboratories are producing reliable and accurate results for appropriate patient management. Since 2014, PEPFAR supported implementation of quality management systems in 34 laboratories through SLMTA/SLIPTA programs. In FY20, four laboratories achieved SADCAS ISO15189 accreditation for the HIV viral load test. Also, PEPFAR supported the HIV RT CQI program by institutionalizing a national assessment and certification program for both test providers and testing sites. Currently, 178 HIV rapid testing sites are enrolled in the HIV CQI program, and this will be expanded to an additional 209 sites. In COP21, POCT laboratories sites will be enrolled in SPI-POCT to improve quality of service, and this will be done in a stepwise manner, prioritizing high workload sites.

All high throughput molecular laboratories are participating in VL, EID, and COVID-19 EQA programs. Laboratories are also enrolled in hematology, chemistry, parasitology, serology, TB microscopy, and GeneXpert EQA programs provided by the National Health Laboratory Services (NHLS) in South Africa. PEPFAR supports the production, distribution, result collection, and corrective action implementation in all PEPFAR-supported testing sites. In COP21, NHRL and College of Medicine capacity will be built for local PT panel production to establish sustainability. PEPFAR will continue to advocate for the establishment of a biosafety level-3 laboratory at the national reference laboratory to handle emerging diseases and pandemics.

6.3 Supply Chain Management

Continuous availability of HIV commodities is key to the achievement of epidemic control goals and targets. With Global Fund resources and significant technical assistance from PEPFAR, Malawi is operating a well-functioning parallel supply chain for HIV/AIDS commodities, ensuring HIV commodity availability at service delivery points. In COP21, PEPFAR will promote sustainable supply chain strategies for HIV commodities by ensuring an increasingly government-led, self-reliant health supply chain that is integrated and optimized, leverages the private sector, and is able to supply quality products to all citizens. PEPFAR will also fill gaps for selected commodities for VMMC, PrEP, HIV self-test kits, and condoms to achieve PEPFAR targets. To facilitate timely

procurement of high quality and safe essential medicines for the VMMC program, PEPFAR will prequalify local pharmaceutical wholesalers.

In COP21, PEPFAR Malawi will increase supply chain data visibility and decrease risks in the supply chain. To increase data quality and timeliness, PEPFAR will support the expansion of direct data entry sites for OpenLMIS from the expected 260 sites to about 400 sites (over half of the ART sites), enhance OpenLMIS e-stock card and EMR dispensing module, and strengthen interoperability between the systems. PEPFAR will work with district and health facility staff to strengthen data use, reporting of inventory data into OpenLMIS, and improve accuracy of inventory records through mentorship and supportive supervision. This will increase visibility into inventory levels, consumption, and facilitate regular triangulation between clinical and logistics data at facility level at more regular intervals. In COP21, PEPFAR will also support introduction of GS1 serialization for tracking and tracing of HIV commodities following completion of the Product Master list and National Product Catalogue (NPC), which are catalytic for tracking and tracing. PEPFAR will decrease risks and improve effectiveness of the supply chains by proactively monitoring and mitigating risks through audits and security assessments.

PEPFAR will continue supporting ART optimization, including pediatric DTG 10 mg transition, and support implementation of PrEP, MMD, DDD, and promote the introduction of new products. In COP21, PEPFAR will ensure HIV commodities are safe, of good quality throughout the supply chain, and managed appropriately at the last mile by supporting post market surveillance, pharmacovigilance, supply chain supervision and mentorship, and maintenance of prefabricated commodity storage units at health facilities.

6.4 Health Information Systems and Surveillance

Health Information Systems (HIS)

To improve program monitoring and allowing for rapid strategic shifts at the district and site-level, successful program implementation requires near real-time individual-level data. PEPFAR Malawi has established different types of electronic information systems to facilitate availability of real time quality data. To ensure availability of near real-time individual-level data, PEPFAR will continue strengthening sustainable electronic solutions that include differentiated models based on the needs of the site and a centralized data repository (CDR), as well as systems for laboratory information management and mortality surveillance.

Electronic solutions in Malawi continue to evolve in response to the needs of the PEPFAR program and technological advances. At the facility level, PEPFAR is supporting a POC EMR system in 207 high and medium volume sites and an electronic HIV treatment system (eMasterCard) for retrospective data capture in 514 medium and low volume sites. The POC EMR has modules for ART, HTS, antenatal care (ANC), and outpatient services (OPD), as well as features that allow for the integration of laboratory information systems and ART tracking distribution. Smaller direct service delivery and technical assistance sites supported by PEPFAR

enter data retrospectively using the eMasterCard application, which captures the HIV testing and treatment cascade for patients ever registered at each site. Together, the systems cover 721 sites.

A key component to ensuring real-time access to individual level data for client-centered program management is the CDR. By consolidating patient-level databases across the country, greater insight into program effectiveness can be achieved. For example, deduplication can identify patients classified as defaulters but who have silently transferred to another facility. Leveraging the established connectivity from facilities to the CDR allows for daily syncing of patient-level data from all connected facilities. This data is further integrated, transformed, and made available in a secure analytic environment. As a main national data repository, the CDR also consolidates data from the National Laboratory Information Management System (NLIMS) and the Civil Registration and Vital Statistics system (CRVS). To support other external applications, the CDR will feed its data into the Ministry of Health's DHAMIS system and the DHIS2 system. Further integrations being implemented on the CDR in COP21 include the DREAMS and KP databases with external systems. Following implementation, these will be fully optimized.

In COP21, PEPFAR will continue to provide system level support by improving connectivity, replacing end-of-life hardware, strengthening monitoring systems (e.g., helpdesk, connectivity uptime) and providing short-term power backup systems at sites. PEPFAR will also maintain the software and expand reporting capabilities at site and central levels to facilitate program monitoring and resource allocation. PEPFAR will pilot a multi-platform POC EMR and eMasterCard system to support compatibility across devices. Furthermore, new applications for index testing and back to care tracing will be piloted. PEPFAR will strengthen existing modules (OPD, ANC, cervical cancer) and leverage CARES funding to build systems that support integrated disease surveillance (IDSR).

In COP21, PEPFAR will maintain its longstanding support for the MoH and other government entities to build and sustain these electronic solutions to maintain quality ART services and availability of individual-level data, while staying apprised of current and future Global Fund support to address the existing EMR system in 210 high burden facilities and other Health Management Information System (HMIS) investments. PEPFAR will implement full scale up and optimization for the multi-platform POC EMRs, index testing, and back-to-care applications. Regarding infrastructure, PEPFAR will support the MoH to capacitate District Information and Communications Technology (ICT) teams as helpdesk first line responders. PEPFAR will continue to support ongoing upgrades for systems for hardware, local connectivity, and power. With respect to CDR, in COP21, PEPFAR will optimize database systems to support daily syncing of data to all 721 facilities from the current 190 facilities. Furthermore, the CDR's hardware infrastructure, including servers and connectivity, will be optimized. PEPFAR will also implement and optimize a disaster recovery solution for the CDR, so the MoH can ably respond to a disaster or other emergency that affects proper operations of the CDR and related health information systems.

In addition to facility-based electronic systems (i.e., POC EMR and eMasterCard) installation, PEPFAR continues to address delays in reporting test results by improving and expanding electronic integration of the POC EMR and the NLIMS with other laboratory related systems, including the Viral Load/EID LIMS, private LIMS, and electronic tracking systems used by Riders 4 Health (R4H). This facilitates same or next day return of lab results to the facility and specimen tracking. In COP20, PEPFAR will continue with the scale up of laboratory systems integration and improving connectivity in molecular laboratories. In COP21, PEPFAR will support testing machine integration and optimization, improve NLIMS data quality and governance, and augment interoperability of all systems within the LIMS landscape.

PEPFAR will continue to utilize a DHIS2-based system to track the clinical cascade, prevention, and referral services provided to KP clients through a generated Unique Identifier Code (UIC). The system will track periodic repeat testing, linkage to treatment, referral to other supportive services, and facilitate real time monitoring of services accessed by this population.

With support from PEPFAR, the GoM, through the National Registration Bureau (NRB) and the MoH, established and rolled out a national birth and death registration system. Birth registration systems are in 583 health facilities in all 28 districts, of which 35 facilities have electronic birth registration systems (eBRS). NRB also installed eBRS in all district offices, which pushes data to the central database. The birth registration process is also integrated with the National ID system to ensure that each newborn is assigned an ID that will be printed on their National ID card when issued at the age of 16. Universal and compulsory facility-based electronic death registration systems (eDRS), including Medical Certification of Cause of Death (MCCoD), are implemented in 13 districts and community death registration in 12 districts. eDRS is being used in all 28 district registration offices and central hospitals, and the remaining districts register deaths on demand without MCCoD. By the end of COP20, a centralized architecture is expected to be implemented in all the 28 districts. In COP21, the focus will be on optimizing the centralized architecture, including integration of the applications with POC EMR and eMasterCard to reduce duplicative data entry and improve data quality.

Surveillance

In addition to the health information system activities described above supporting routine surveillance, PEPFAR Malawi will continue to support the MoH in conducting targeted sentinel- and survey-based surveillance to monitor HIV epidemiology and ART outcomes, including adverse birth outcomes. In COP21, PEPFAR Malawi will support mortality, recency, birth defects, case-based, drug resistance, and verbal autopsy surveillance. PEPFAR will also continue to support CDC's Field Epidemiology Training Program (FETP) to support quality data review, resolution, and emergency preparedness to respond to emerging diseases affecting PLHIV.

Recency

In COP17, PEPFAR supported early implementation of a recency study to estimate HIV incidence and detect recent infections among pregnant AGYW at ANC clinics in Blantyre, Lilongwe, Zomba, and Machinga. In COP18, the scope was broadened and established a surveillance system among newly diagnosed populations beyond AGYW to monitor recent HIV infection by age, sex, and geography, and multiple HIV testing service delivery points. The surveillance had a slow start, beginning with validation of testing kits to aid with the selection of the best testing kits for the Malawi program. After the validation exercise, Asante was selected and a surveillance system was established in April 2019 starting with Blantyre district. In COP19, recency surveillance expanded to 11 high burden districts, with the goal of eventually covering 80% of newly diagnosed PLHIV nationally in select health facilities across 27 districts. However, surveillance activities were paused in COP19 mid-year due to the COVID-19 pandemic. In COP20, recency surveillance is resuming following refresher trainings and site reactivation to reach 15 districts. In COP21, recency surveillance will expand to 12 new districts, while also responding to potential outbreaks to identify recent infections. The near real-time data from this surveillance system will help PEPFAR and the national program respond to clusters of infections with targeted HIV prevention and treatment efforts. The MOH and IPs will conduct data and hotspot analyses to identify areas with high prevalence of recent infections requiring further investigation; hotspots are areas where the prevalence of recent infections are higher than other areas in a specified geographic location and may signify ongoing or high risk of transmission. Findings from the investigations may guide targeted prevention, treatment, and retention interventions.

Drug Resistance

In January 2019, Malawi transitioned its first-line treatment combination from tenofovir/lamivudine/efavirenz (TLE) to TLD, due to exceptional performance of Dolutegravir-based regimens (DBR) in clinical trials. Malawi is one of the countries in Africa with high patient volumes of PLHIV taking DBR, although within the first six months of DBR introduction in MSF-supported districts, Malawi reported two cases of DTG resistance in patients with baseline NNRTI resistance. Currently, the country has registered about 1,800 patients taking DTG-based regimens with a persistent high viral load even after adherence counseling. It is unclear whether PLHIV with baseline NNRTI are prone to integrase resistance, and with limited data available on DBR resistance, Malawi presents a unique opportunity to address this and related urgent programmatic and epidemiological questions. In COP20, PEPFAR Malawi started implementation of drug resistance surveillance in selected sites. In COP21, DBR resistance surveillance work will continue and may scale-up to include children.

Birth defects

In COP17, Malawi began implementing birth defects surveillance to estimate the prevalence of birth defects in sentinel sites targeting four hospitals in Lilongwe, Blantyre, Mangochi, and

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Ntcheu. The study is also designed to examine the association of maternal use of ART and birth defects outcomes. In COP18, the protocol was modified to include the establishment of a pregnancy registry and monitoring of birth outcomes as required in transition plans for DTG. In COP19, birth defects surveillance continued to monitor birth outcomes as DTG scaled up; although, due to COVID-19, data collection paused in April 2020. In COP19, implementation of birth defects surveillance transferred from Malawi College of Medicine to International Training and Education Center for Health (I-TECH), and the transfer of data and materials continues in COP20. Under I-TECH, data collection will continue until the sample size to monitor the impact of DTG-based regimens on birth outcomes is achieved, and data analysis and dissemination of results will continue through COP20 and COP21.

Case Based Surveillance (CBS)

In COP18, I-TECH, in partnership with the MoH, piloted a CBS system in ten sites. To leverage routinely collected data from existing systems (like POC EMR), as well as, HIV recency and mortality surveillance, CBS is generating data for an individual-level, de-identified longitudinal cohort. Such a cohort allows for the tracking of sentinel events such as HIV diagnoses and ART initiations, as well as other individual-level health outcomes, and provides robust surveillance data on a real-time basis. In COP20 the CBS protocol was approved for scale up to all site in Malawi but there have been challenges expanding the system because MoH has persistently questioned the utility of CBS system, resulting in delays in rolling it out. In COP20 PEPFAR and implementing partners will continue to work with MOH to get them to understand the importance and utility of the system. In COP21, the CBS system will expand in accordance with central data repository (CDR) expansion to include all sites in Malawi and refined to improve report templates, data use and sustainability at all levels, including facility, district and central level.

Capacitation

Although increasing, Malawi has limited personnel with epidemiological skills to effectively monitor HIV programs. PEPFAR/CDC introduced FETP in 2016 as a three-month frontline in-service training to strengthen the capacity of healthcare workers to collect and analyze epidemiological and surveillance data. This capacity building facilitates timely responses to the HIV program needs, diseases, and events of public health importance. PEPFAR Malawi planned to train 48 people in COP20, however, due to pause in trainings caused by the COVID-19 pandemic, only 13 people were trained. During the first COP20 FETP cohort, a virtual training approach was adopted instead of the traditional in-person meeting to comply with safe COVID-19 measures. By the end of COP20, a total of 151 surveillance officers are expected to be trained in FETP. In COP21, the USG team plans to train an additional 48 healthcare workers in frontline FETP.

MPHIA

The 2020 Malawi Population-based HIV Impact Assessment (MPHIA 2020) is a cross-sectional bio-marker survey that will assess the prevalence of key HIV-related health indicators, such as HIV incidence, prevalence, viral load suppression, and risk behaviors and will describe the uptake of key HIV prevention, care, and treatment services. Data collection began in January 2020 and was paused in March 2020 due to the COVID-19 pandemic. Data collection resumed in March 2021, concluded in April 2021, and data cleaning is ongoing in COP20. The data are expected to show progress towards meeting the 90-90-90 goals, will support future HIV program planning, and will be incorporated into programmatic goal setting for COP21 and future COPs. It is expected that preliminary data will be available by July 2021 and will be used to adjust COP21 targets since the current targets were set above the estimated country PLHIV population to align with PEPFAR Malawi's COP21 Planning Level Letter.

Civil Registration and Vital Statistics (CRVS)

The Malawi CRVS system was established in 2015 under the National Registration Bureau (NRB). This system registers both births and deaths occurring in facilities and communities. PEPFAR/CDC supports the NRB to administer and scale-up the system with District Registration Offices (DRO) who manage district-level registrations and data entry. Birth and death registration forms are collected from facilities and communities by the DRO for retrospective entry and validation into an electronic birth registration system (eBRS) and an electronic death registration system (eDRS), respectively. The registration of birth is compulsory for all health facility births and the eBRS was in 38 facilities in COP19. In COP20, a system is being developed that integrates the electronic birth and death registration systems leveraging the EMR investments over the last few years. In COP21, it is expected that all facilities with electronic medical record systems will be facilitated to have birth, death, and cause of death electronic reporting. Community birth, death, and cause of death reporting has been rolled out in 13 districts and will expand to four more districts in COP21.

Mortality Surveillance

Leveraging the death registration system, the HIV program is able to conduct HIV mortality surveillance by analyzing HIV-related, cause-specific data generated by eDRS. This data potentially provides cause of death information to stakeholders to inform evidence-based programmatic changes in a timely manner. In COP20, the facility-based death registration was compulsory in 13 districts and on demand in 15 districts, while the community death registration was scaled up to nine districts. By the end of COP20, facility death registration and cause of death reporting will be scaled up to an additional four districts. COP21 will focus on improving timeliness and completeness of reporting so the data can effectively inform programing while expanding death and cause of death reporting to four new districts using central CDC COVID-19 CARES Act funding.

Verbal Autopsy

In COP20, PEPFAR Malawi will support the MoH and Public Health Institute of Malawi (PHIM), to pilot verbal autopsy (VA) in selected clusters in two districts. The project responds to the need to register the majority of deaths which occur outside the health system and are not recorded in the eDRS. In COP21, phase two of the project will be scaled to district-level representative sentinel clusters targeting 10 districts.

6.5 Commodities

Over 95% of key HIV/AIDS commodities are procured through the Global Fund and effectively managed by the MOH with support from PEPFAR technical assistance. 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. PEPFAR will also fill gaps in commodity needs for PrEP and VMMC programs.

There has been a significant increase in consumption of HIVST kits in 2020 following PEPFAR's support to the MoH to roll out implementation of HIVST from the beginning of COP20. This increased consumption, coupled with COVID-19 related increase in consumption of HIVST kits, has resulted in potential gaps for HIVST kits. As there is no other planned Global Fund HIVST kit procurement beyond the 600,000 kits arriving in FY21 Q2, there will be a stock out in early 2022. PEPFAR continues to engage the MOH to address this potential gap. PEPFAR is also planning to address gaps in PrEP commodities to achieve COP21 PrEP targets.

PEPFAR is also providing supply chain management support for COVID-19 control to mitigate the impact on HIV programs while leveraging existing resources and infrastructure, such as Open LMIS for visibility of PPEs and related commodities.

DTG Transition

Malawi began transitioning clients to DTG-based formulations in January 2019 and has since transitioned about 97% (over 800,000 PLHIV) of those on first-line ART. PEPFAR will continue supporting quantification, supply planning, and monitoring of stock availability of TLD and all other HIV commodities to avoid stock outs, overstocks, and expirations. PEPFAR support of the implementation of multi-month prescriptions and the transition to 90 pills per bottle for over two-thirds of stable PLHIV clients, remains essential. Beginning in FY21 Q3, PEPFAR will support the MoH in transitioning children to an optimal pediatric regimen, DTG 10 mg, which will begin to arrive in-country in May 2021 (starting with CHAI's catalytic procurement, followed by Global Fund shipments).

7.0 USG Operations and Staffing Plan to Achieve Stated Goals

USAID's PEPFAR Malawi budget for Management and Operations has been flatlined at COP20 levels. Any shifts needed to align with the COP21 program priorities, including managing government-to-government agreements and increased funding to local partner organizations, will come from funding efficiencies within the current agency staffing patterns. Increased time will be spent in the field monitoring implementation of activities and ensuring financial oversight as the number of awards and agreements with local entities increased in COP20.

CDC's staffing footprint is aligned towards supporting critical PEPFAR COP21 priorities. A staff complement of forty-five people has been maintained to provide leadership, technical assistance, and program management support in the key HIV/AIDS technical areas and to conduct the robust monitoring and data analysis required to responsively adapt the program to epidemic response priorities.

Long-term Vacant Positions

There were twenty-three vacancies as of March 2021 across the PEPFAR interagency. USAID and CDC have each eleven and eight vacancies respectively, and Peace Corps has two.

Recruitment for long-term vacancies at USAID for the Branch Chief for HIV Operations, KP Specialist, three Local Capacity Development Specialists, Senior Technical District Specialist, HSS Specialist, and M&E Specialist is in progress. Most of these positions are expected to be filled by COP21 implementation. The Deputy Division Chief for HIV will be filled by a USDH in FY20 Q4. The HIV HTS Specialist position will be reclassified as an HIV HTS Specialist. Some of the vacant positions were renamed to better reflect their responsibilities.

CDC's eight vacant positions previously approved are: Cooperative Agreement Specialist, Financial Specialist, Laboratory Specialist, Grants Finance Specialist, Epidemiologist, Executive Assistant, AGYW Specialist, and Administrative Assistant. Recruitment of the Cooperative Agreement Specialist is completed and the incumbent will start on May 10, 2021. Recruitment of the Laboratory Specialist and Grants Finance Specialist will be completed by end of Q3 of FY21. The applications for these positions are being shortlisted for interviews. The Epidemiologist, Executive Assistant, and Administrative Assistant will be recruited by mid Q4 of FY21. The positions have been advertised for applications. The recruitment of the Financial Specialist (long-term vacancy) is awaiting management decision on some elements of the position description. The AGYW Specialist is awaiting approval of the Chief of Mission. These two positions will be recruited by Q1 of the COP21 implementation period. There was no attrition in FY20 among technical staff, presumably due to an exceptional rate range (ERR) the Mission received in FY18 on selected technical series. The implementation of exceptional rate range has also facilitated recruitment of three technical staff due to improved competitiveness in recruiting highly qualified, technical locally engaged staff. Delays in classifying positions by the Department of

State is the major challenge CDC faces to maintain staff remunerated on local compensation plans and fill remaining vacant positions.

New Positions

There are no proposed new positions in COP21.

Cost of Doing Business (CODB)

USAID's PEPFAR funding for management and operations for COP21 will remain at COP20 funding levels. In COP20, the agency shifted to greater implementation through local entities, including increased government-to-government modalities. USAID's CODB will ensure adequate staffing to design, award, and effectively manage new implementing mechanisms. The budget includes resources to provide targeted technical assistance to support local organizations to meet rigorous PEPFAR results and expenditure reporting requirements, as well as USAID award compliance guidelines. USAID will continue to support staffing costs for three offshore hire positions in the PEPFAR Coordination Office in COP21.

CDC's budget for management and operations has increased by 7%, mainly due to a number of USDH who will be transitioning to the post in FY22. A total of 85% of the CODB is comprised of priority costs including salaries, benefits, capital security cost sharing, ICASS, and computers and IT services. CDC will continue to support staffing costs for one offshore hire position in the PEPFAR Coordination Office in COP21.

APPENDIX A - Budget Profile and Resource Projection

A1. COP21 Planned Spending in Alignment with Planning Level Letter Guidance

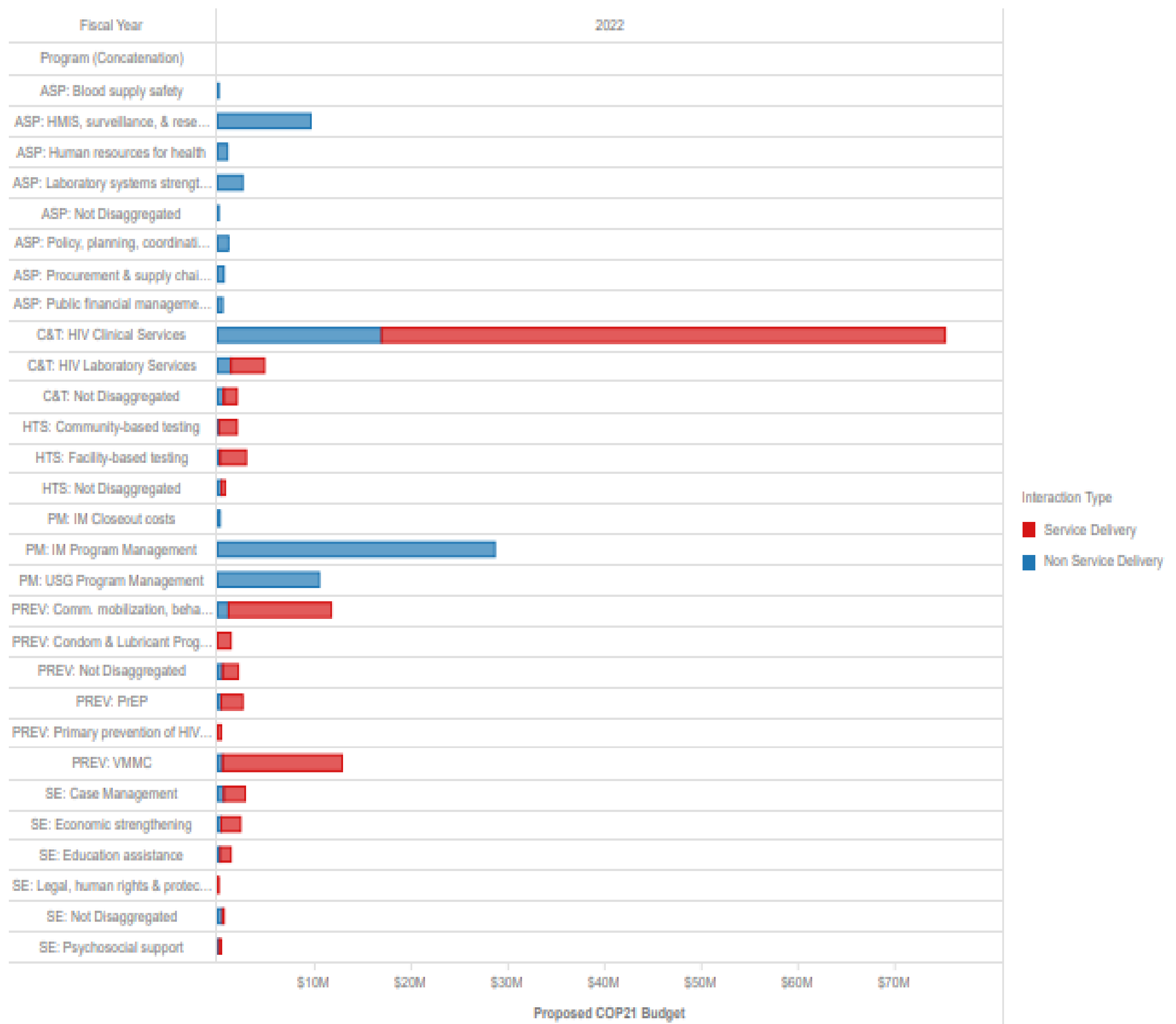

Table A.1.2 COP21 Total Planning Level

Fiscal Year	2022	2022	2022
Metrics	Proposed COP21 Budget		
Operating Unit	Applied Pipeline	New	Total
Total	**$8,402,915**	**$172,999,236**	**$181,402,151**
Malawi	$8,402,915	$172,999,236	**$181,402,151**

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Table A.1.3 COP21 Budget by Program Area

Program	Fiscal Year / Metrics / Subprogram	2022 Proposed COP21 Budget: Non Service Delivery	Service Delivery	Total	Percent of COP 21 Proposed Budget: Non Service Delivery	Service Delivery	Total
Total		$79,143,386	$102,258,765	$181,402,151	43.63%	56.37%	100.00%
C&T	Total	$18,866,521	$63,118,963	$81,985,484	23.01%	76.99%	100.00%
	HIV Clinical Services	$16,857,927	$58,335,868	$75,193,795	22.42%	77.58%	100.00%
	HIV Laboratory Services	$1,333,696	$3,475,276	$4,808,972	27.73%	72.27%	100.00%
	Not Disaggregated	$674,898	$1,307,819	$1,982,717	34.04%	65.96%	100.00%
HTS	Total	$756,650	$4,940,906	$5,697,556	13.28%	86.72%	100.00%
	Community-based testing	$150,000	$1,774,655	$1,924,655	7.79%	92.21%	100.00%
	Facility-based testing	$246,604	$2,765,074	$3,011,678	8.19%	91.81%	100.00%
	Not Disaggregated	$360,046	$401,177	$761,223	47.30%	52.70%	100.00%
PREV	Total	$2,522,006	$28,357,681	$30,879,687	8.17%	91.83%	100.00%
	Comm. mobilization, behavior & norms change	$1,106,781	$10,593,290	$11,700,071	9.46%	90.54%	100.00%
	Condom & Lubricant Programming		$1,313,326	$1,313,326		100.00%	100.00%
	Not Disaggregated	$475,391	$1,579,294	$2,054,685	23.14%	76.86%	100.00%
	PrEP	$385,121	$2,222,032	$2,607,153	14.77%	85.23%	100.00%
	Primary prevention of HIV and sexual violence		$415,944	$415,944		100.00%	100.00%
	VMMC	$554,713	$12,233,795	$12,788,508	4.34%	95.66%	100.00%
SE	Total	$1,913,000	$5,841,215	$7,754,215	24.67%	75.33%	100.00%
	Case Management	$666,000	$2,231,021	$2,897,021	22.99%	77.01%	100.00%
	Economic strengthening	$400,000	$2,004,710	$2,404,710	16.63%	83.37%	100.00%
	Education assistance	$250,000	$1,163,384	$1,413,384	17.69%	82.31%	100.00%
	Legal, human rights & protection		$50,000	$50,000		100.00%	100.00%
	Not Disaggregated	$497,000	$172,100	$669,100	74.28%	25.72%	100.00%
	Psychosocial support	$100,000	$220,000	$320,000	31.25%	68.75%	100.00%

Program	Fiscal Year / Metrics / Subprogram	2022 Proposed COP21 Budget: Non Service Delivery	Service Delivery	Total	Percent of COP 21 Proposed Budget: Non Service Delivery	Service Delivery	Total
ASP	Total	$15,622,647		$15,622,647	100.00%		100.00%
	Blood supply safety	$60,000		$60,000	100.00%		100.00%
	HMIS, surveillance, & research	$9,635,579		$9,635,579	100.00%		100.00%
	Human resources for health	$999,992		$999,992	100.00%		100.00%
	Laboratory systems strengthening	$2,613,016		$2,613,016	100.00%		100.00%
	Not Disaggregated	$100,000		$100,000	100.00%		100.00%
	Policy, planning, coordination & management of disease control programs	$1,092,408		$1,092,408	100.00%		100.00%
	Procurement & supply chain management	$652,428		$652,428	100.00%		100.00%
	Public financial management strengthening	$469,224		$469,224	100.00%		100.00%
PM	Total	$39,462,562		$39,462,562	100.00%		100.00%
	IM Closeout costs	$250,000		$250,000	100.00%		100.00%
	IM Program Management	$28,701,643		$28,701,643	100.00%		100.00%
	USG Program Management	$10,510,919		$10,510,919	100.00%		100.00%

APPENDIX B – Minimum Program Requirements

	Policy	Status for COP21 Implementation
Care and Treatment	1. Adoption and implementation of Test and Start with demonstrable access across all age, sex, and risk groups, with direct and immediate (>95%) linkage of clients from testing to treatment across age, sex, and risk groups.[4]	Test and Start services available in all 750 ART sites.
	2. Rapid optimization of ART by offering TLD to all PLHIV weighing ≥30 kg (including adolescents and women of childbearing potential), transition to other DTG-based regimens for children weighing ≥20kg, and removal of all nevirapine-based regimens.[5]	DTG transition completed in all Malawi ART sites. 98% of the national treatment cohort is on DTG-based regimen in FY21 Q1. Pediatrics ARV optimization: based on MOH data, as of FY21 Q1, only 1,300 (3%) children out of TX_CURR of 43,493 were still on nevirapine-based regimen (2P). They will be prioritized for pediatric DTG 10mg transition using early catalytic commodities procured through CHAI/UNITAID expected in May 2021. The rest of the children (receiving LPV/r) will be transitioned Q1 of COP21 following delivery of Global Fund commodities that were ordered in March 2021.
	3. Adoption and implementation of differentiated service delivery models, including six-month multi-month dispensing (MMD) and delivery models to improve identification and ARV coverage of men and adolescents.[6]	All PEPFAR supported sites will are implementing and will continue to implement 6MMD. Technical assistance will be provided to MOH including supply chain management to ensure availability of DTG 90-day bottles.
	4. All eligible PLHIV, including children, should complete TPT by end of COP20, and cotrimoxazole,	Malawi initially offered TPT in 5 of 28 districts, implementing 6H (six-month INH) starting in 2018. Over COP19 and Q1 of COP20, TPT has been scaled up to all the districts in the country. Due to COVID-19, this nation-wide scale up faced a 6-month delay but was fully in effect by Q1

[4] Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization, September 2015

[5] Update of recommendations on first- and second-line antiretroviral regimens. Geneva: World Health Organization, July 2019

[6] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization, 2016

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	where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient.[7]	of COP20. However, due to COVID-19, TPT has only been restricted to new ART initiations and PEPFAR will continue to work with the MOH and stakeholders to continuously review the situation. Malawi introduced of 3HP in 5 districts in Q1 of COP20. Malawi planned to transition to 3HP as the main TPT regimen due to a shorter course which could improve acceptability and completion rates. However, this introduction was curtailed due to CPNP impurities reported in the commodities globally by the manufacturer. All drugs were recalled from the facilities and pending orders cancelled. PEPFAR will continue to work with the MOH and stakeholders to support safe implementation of 3HP for TPT including ensuring adequate storage conditions for the drugs.
	5. Completion of Diagnostic Network Optimization activities for VL/EID, TB, and other coinfections, and ongoing monitoring to ensure reductions in morbidity and mortality across age, sex, and risk groups, including 100% access to EID and annual viral load testing and results delivered to caregiver within 4 weeks.	As of Q1 FY20, 70% VL coverage, 94% viral load suppression. Expand coverage through patient education efforts. Reduce TAT from 13.6 days to 10 days. Continue conventional lab optimization through current and additional Hologic and increased utilization of existing multiplex GeneXpert POC. Sample transportation optimization scaled and transition from URC to University of Maryland in progress. By COP20, 85% viral load coverage expected with 95% viral suppression. Additional Hologic devices will also be procured to increase lab capacity.
Case Finding	6. Scale up of index testing and self-testing, ensuring consent procedures and confidentiality are protected and assessment of intimate partner violence (IPV) is established. All children under age 19 with an HIV positive biological parent must be tested for HIV.[8]	Index testing policy adopted. MOH-led development of national index testing registers, reporting tools, and roll out is in progress. PEPFAR partners conducted an index testing assessment for all sites in scale up districts. Implementation of remediation plans is in progress in PEPFAR supported community and facility sites. LIVES trainings providing healthcare workers with skills to identify and provide first

[7] Latent Tuberculosis infection: Updated and consolidated guidelines for programmatic management. Geneva: World Health Organization, 2018

[8] Guidelines on HIV self-testing and partner notification. Supplement to consolidated guidelines on HIV testing services. Geneva: World Health Organization, 2016 https://www.who.int/hiv/pub/self-testing/hiv-self-testing-guidelines/en/

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		line responses to IPV are expected to be completed by end June 2021 as some sites faced delays due to COVID-19 prevention response. IPV screening is a standard practice in index testing. Individuals screening IPV positive are not offered index testing and are referred to appropriate services within respective districts. All children under the age of 19 born to PLHIV biological mothers are offered HTS.
Prevention and OVC	7. Direct and immediate assessment for and offer of prevention services, including pre-exposure prophylaxis (PrEP), to HIV-negative clients found through testing in populations at elevated risk of HIV acquisition (PBFW and AGYW in high HIV-burden areas, high-risk HIV-negative partners of index cases, key populations and adult men engaged in high-risk sex practices)[9] .Creatinine and Hep B testing could become a barrier to service delivery: WHO technical update on these tests will need an update for Malawi PrEP policy.	Implementation in 13 Districts (Balaka, Blantyre, Chikwawa, Chiradzulu, Lilongwe, Machinga, Mangochi, Mulanje, Mwanza, Mzimba, Phalombe, Thyolo, and Zomba) reaching over 16,000 new clients. National PrEP Guidelines were approved by MOH, guidelines printed, M&E tools printed, and trainings and capacity building are underway. 62 sites in 10 scale-up districts received the guidelines and M&E tools and 6 sites started initiating clients on PrEP. Status of commodities: Global Fund procurement for 6,000 clients in-country; Gilead procurement for 5,700 AGYW in progress.
	8. Alignment of OVC packages of services and enrollment to provide comprehensive prevention and treatment services to OVC ages 0-17, with particular focus on 1) actively facilitating testing for all children at risk of HIV infection, 2) facilitating linkage to treatment and providing support and case management for vulnerable children and adolescents living with HIV, 3) reducing risk for adolescent girls in high HIV-burden areas and for 9-14 year-old girls and boys in regard to primary prevention of sexual violence and HIV.	The OVC program is currently being implemented in 9 districts: Chikwawa, Blantyre, Lilongwe, Mangochi, Machinga, Mulanje, Phalombe, Thyolo, and Zomba. In COP21, the OVC program will continue to be implemented in the same 9 districts, reaching a population of over 158,000 OVCs including caregivers with services for C/ALHIV, AGYW who are also DREAMS recipients, and prevention services for OVC. The program will expand to an additional 17 (13 CDC and 4 USAID) high burden facilities to bring the total to 138 (69 CDC and 69 USAID). The expected number of additional TX_CURR <19 to be enrolled in COP21 is 12,572.

[9] Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization; 2015 (http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en).

Policy & Public Health Systems Support	9. Elimination of all formal and informal user fees in the public sector for access to all direct HIV services and medications, and related services, such as ANC, TB, cervical cancer, PrEP and routine clinical services, affecting access to HIV testing and treatment and prevention.[10]	Malawi's policy does not allow user fees to be charged for HIV services. GOM to expand SLA to include new elements of HIV services including TB treatment, cervical cancer screening and treatment, and GBV services at CHAM facilities where user fees for these services exist.
	10. OUs assure program and site standards are met by integrating effective quality assurance and Continuous Quality Improvement (CQI) practices into site and program management. CQI is supported by IP work plans, Agency agreements, and national policy.[11]	CQI will remain an integral approach to identifying and addressing bottlenecks that hamper Malawi's progress towards achieving and sustaining epidemic control.
	11. Evidence of treatment and viral load literacy activities supported by Ministries of Health, National AIDS Councils and other host country leadership offices with the general population and health care providers regarding U = U and other updated HIV messaging to reduce stigma and encourage HIV treatment and prevention.	U=U messaging is integrated into the Faith and Community Initiative component of Finding Men messaging. Building on COP20, COP21 will continue to include funding for national treatment literacy campaigns including funding for CSO demand creation and coordination via NAC.
	12. Clear evidence of agency progress toward local, indigenous partner direct funding.	COP20 will include three new government-to-government agreements with NAC, MOH, and Ministry of Finance (MOF), and two district councils to increase government capacity to implement and deliver HIV services. Mechanisms to directly fund civil society organizations will also increase in COP20 as funding shifts from international organizations.

[10] The practice of charging user fees at the point of service delivery for HIV/AIDS treatment and care. Geneva: World Health Organization, December 2005

[11] Technical Brief: Maintaining and improving Quality of Care within HIV Clinical Services. Geneva: WHO, July 2019

	13. Evidence of host government assuming greater responsibility of the HIV response including demonstrable evidence of year after year increased resources expended.	Through willingness to pay agreements as part of the Global Fund application process and investments in human resources for health via CHAM, the GOM continues to demonstrate an increasing commitment to investing in the HIV response. Malawi is expected to meet its Global Fund 2020-2022 co-financing requirement of $76,940,862. In FY20, the GOM also took responsibility for the salaries of 331 healthcare workers who previously were supported by a PEPFAR IP and have committed to absorbing HRH on establishment, who are currently being supported under the MOF G2G mechanism.
	14. Monitoring and reporting of morbidity and mortality outcomes including infectious and non-infectious morbidity.	There has been significant progress in establishing mortality surveillance systems as an integral part of the civil registration and vital statistics program. Mortality surveillance is being expanded through the National Civil Registration and Vital Statistics system (CRVS). Currently there are 13 districts where death and cause of death reporting has been established. In 9 of these districts, death reporting has been established in both facility and community levels. By the end of COP20, there will be a total of 17 districts reporting death and causes of death. In COP21, the emphasis will be on improving timeliness and completeness of reporting to ensure quality data that can inform programing. In addition, PEPFAR Malawi is using EMRS and active tracing systems for PLHIV who missed their appointments or defaulted from care to monitor morbidity and mortality outcomes.
	15. Scale-up of case-based surveillance and unique identifiers for patients across all sites.	There has been slow progress in scaling up case-based surveillance even though proof of concept was demonstrated in COP19. PEPFAR continues to work with the MOH to have them understand the importance and utility of these systems. Meetings to continue dialogue on this issue are planned once an agreement is reached with the MOH. The case-based surveillance system will be expanded using data from Central Data repository (CDR). The CDR continues to consolidate data from POC EMR and eMastercard sites. Case-based surveillance will be implemented using the framework of the CDR. As part of the EMR roll out, in COP20, the use of national ID in health will be piloted in 20 facilities.

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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:

Direct and immediate (>95%) linkage of clients from testing to treatment across age, sex, and risk groups.
Rapid optimization of ART by offering TLD to all PLHIV weighing ≥30 kg (including adolescents and women of childbearing potential), transition to other DTG-based regimens for children weighing ≥20kg, and removal of all nevirapine-based regimens.
Elimination of all formal and informal user fees affecting access to HIV testing and treatment and prevention in the public sector for access to all direct HIV services and medications, and related services, such as ANC, TB, Cotrimoxazole, cervical cancer, PrEP and routine clinical services.
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.

APPENDIX C – Stakeholder & CSO Recommendations for PEFPAR COP21 Strategy

Thematic Area		Stakeholder Recommendations	PEPFAR COP21 Feedback
HRH	HRH	COP21 Target: Fund trained and independent Hospital Ombudsman where PLHIV can report cases of maltreatment by healthcare providers at 100% of PEPFAR supported facilities. Experience has shown assigning this role to Health care workers makes it hard for them to objectively respond to the health users grievances as they are equally guilty.	All district and central hospitals have hospital ombudsman offices established. This has not been decentralized to the health centers yet. The Ombudsman operates under the HR departments and are appointed by the respective hospitals to serve in that capacity. Further discussion is needed with DHA to identify specific areas that the ombudsman functions could be leveraged to support PLHIV
		COP21 Target: Viral load testing, Teen Clubs, Support Groups, VMMC, PrEP, and other HIV prevention services are resumed in a safe manner in COP21 and COP 20.	PEPFAR IPs are following the DHA guidelines on resumption of services
		COP21 Target: No healthcare user is required to explain where in the health centre they are going or what services they are seeking on entry at the health centre during the COVID-19 screening process.	PEPFAR will work in collaboration with MOH at site level to ensure that access barriers are addressed
		COP21 Target: All PEPFAR supported facilities are observing COVID-19 prevention measures properly including COVID-19 screening, mask use, hand hygiene, and physical distancing in COP21 and the remainder of COP20.	PEPFAR IPs will continue to support the compliance to COVID related risk mitigation measures and have included interventions such as patient flow modifications, access to masks and enforcement of physical distancing. Requests have been made through the ARPA for PPEs for health workers and clients/ patients
Differentiated Service Delivery	6MMD	COP21 Target: All stable PLHIV are able to collect a 6 month supply of ARVs by end of COP21.	PEPFAR will continue supporting scale up of MMD6 in all its supported sites.
	Community ART Clubs (CACs)	COP21 Target: 50% of all eligible PLHIV are receiving their HIV treatment, care and support within functional Community ART Clubs.	PEPFAR will continue advocating with the MoH as currently implementation policies do not include community distribution of ART.
		COP21 Target: CACs are integrated for collection of TPT and contraceptive commodities and for	Recognizing that the enrollment into the various DSD models is at the patient's discretion, the 50% target requires further discussion.

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		screening and treatment of diabetes and hypertension.	The exisiting community-based ART distribution models integrate ARV refills and other essential medications, including family planning, and hypertension screening (BP checks).
	Health centre opening hours	COP21 Target: All PEPFAR supported health centres have extended opening hours from 5am to 7pm on weekdays and 8am to 4pm on Saturdays — and PLHIV are able to use these extended opening times to pick up their medication from internal pick up points. Whilst healthcare workers are expected to spend limited time at the facility due to COVID-19 restrictions, arrangements should be made to work in shifts.	The coverage of flexible hours is increasing. Currently, 129 out of 444 PEPFAR supported facilities provide flexible clinic hour services. All facilities may not necessarily need the extesnion of clinic hours and and increased enrollment into DSD models (at the patient's discretion) would require a case by case analysis of volume and gaps. The KP drop-in service centers will be expanding their hours of operation.The PEPFAR team is proposing a 15% increase in Q3/Q4 of COP 20 and a slightly higher increase in COP 21, but HRH and policy guidance needs to be considered as resource constraints remain.
Clinical Services	**HIV and TB treatment & prevention literacy**		
		COP21 Target: PLHIV and KP led groups mobilise communities around U=U messaging that ensure uptake of viral load testing services, through a PEPFAR funded social mobilisation campaign.	See above; Support to CSOs through the BMGF project and UNAIDS Co Ag can be coordinated to ensure inclusion of KP specific needs
		COP21 Target: Community-led HIV and TB treatment & prevention literacy materials are distributed by PEPFAR to all support groups and ART clinics to reduce information gaps and misinformation.	See above
		COP21 Target: Health worker led health talks take place at all PEPFAR-supported health centres to provide information to patients waiting for services including (but not limited to) prevention, testing, viral load, treatment adherence, advanced HIV, TPT, cervical cancer screening, that ensure uptake of these services.	DHA included the procurement of STI and COVID-19 case management OI drugs; the development and dissemination of STI treatment and antimicrobial resistance awareness messages in the presentation for the C19RM meeting on April 19th 2021
	AHD	COP 21 Target: Expand package of AHD services; current reach is limited	Expanding AHD services further using the hub ad spoke model is indeed planned for COP21. However, the extent of expansion will focus on high volume sites

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	PLHIV identification + tracing	COP21 Target: Resume community-based tracing whilst observing COVID-19 prevention measures by increasing the number of expert clients to 500 and equipping them with bicycles for mobility.	Community based tracing has resumed with the lifting of MOH- DHA suspended activities
	Viral load	COP21 Target: Adopt a viral load database (comparable to Kenya) 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, leading to 100% of PLHIV on ART receiving an annual viral load test with results delivered in to PLHIV via SMS within a maximum of 10 days.	In COP21, there is a plan to integrate EMRs to LIMS in both high throughput and POCT laboratories. Viral load results can be transferred from the testing laboratory directly to EMRs once the result is approved in the LIMS. Additionally, in COP21, there are plans to investigate building a system that allows ART results to be delivered via SMS to PLHIV. This will be addressed by the BMGF's Viral Load Result Project which is being implemented with DHA.
		COP21 Target: PEPFAR Malawi institutes a system to monitor turnaround time from viral load test to results being in hand with the PLHIV.	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.
	Dolutegravir	COP21 Target: PEPFAR institutes tracking of weight gain amongst PLHIV, especially as more people transition or start on DTG. Where problematic weight gain is identified, clinicians refer PLHIV to a dietician in order to properly support the individual. Further the PLHIV is screened for other NCDs associated with obesity.	Routine assessment of BMI is conducted at each clinical visit. IPs can reinforce clinical management on the basis of the national guidelines, which are undergoing revision. DHA included support for ART & NCD clinics with screening/diagnostic equipment, reagents & medicines (BP machines, Glucometers, Insulin infusers & other supplies, NCD drugs, hematology & biochemistry reagents) as one of the priorities in the C19RM presentation
		COP21 Target: In conjunction with meaningful inputs from PLHIV, people friendly materials and topics are developed to help people in diet and nutrition, and rolled out across PEPFAR supported clinics, support groups and Community ART Clubs.	Recommendation for the national TWG and ongoing discussions on the national clinical guidelines

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	Hypertension + Diabetes	COP21 Target: Optimisation of all eligible children to DTG based regimens, with full transition taking place no later than end of FY22 Q1.	For the pDTG roll out, transition is expected to occur in phases with the catalytic commodities expected to arrive in May (CHAI- ad hoc distribution) and subsequently in June, these commodities will be distributed to facilities. The consignment procured through NFM3 has an anticipated arrival in Q4 with full transition of eligible CLHIV expected to occur by 2022 Q1 (Jan- March 2022)
	Paediatric point of care testing	COP21 Target: POC EID is scaled up to reach all HIV exposed infants.	The Ministry has already transitioned EID to POC (or near POC) from towards the end of 2019 to the beginning of 2020. This is how the program is operating fully currently. Some sites use a hub and spoke model but at the very least samples are managed within the districts for EID. Update with numbes from most recent EID report from lab team to reflect EID numbers tested using POC (near POC)
HIV Testing Services	**Index testing**	COP21 Target: Only certified sites carry out index testing.	PEPFAR partners continue to implement quality assurance through direct observation during mentorship/supervision and client exit interview. PEPFAR will continue to engage with Districts and DHA to ensure safe implementation of index testing.
		COP21 Target: No index testing targets on the proportion of new diagnoses that come from index testing enforced in COP21 or the remainder of COP20.	S/GAC guidance and the design of the datapack requires the setting of index testing as the entry stream into the clinical cascade.
		COP21 Target: Before contacting the sexual partners of PLHIV, all healthcare providers ask if the individual's partners have ever been violent and no contacts who have ever been violent or are at risk of being violent should ever be contacted in order to protect the individual.	PEPFAR completed site assessments for safe and ethical index testing to identify gaps and trainings were conducted including avoiding coercion and ensure patient consent and IPV/GBV screening and response. IPV screening can be incorporated at various points in HIV service delivery
		COP21 Target: After contacting the contacts, the healthcare providers check with the individual if they faced any violence due to contacting and refer them to intimate partner violence (IPV). Prior to (re-)implementing index testing in any facility, there are adequate IPV services with sufficient capacity available for PLHIV at the facility or by referral and	Thank you for this recommendation, see above

		all PLHIV who are screened should be offered this information.	
		COP21 Target: All implementing partners (IPs) understand (through training) that index testing is always voluntary, for both sexual contacts and children, where individuals are not required to give the names of their sexual partners or children if they don't want to, and this is explained to all PLHIV.	This is in line with the WHO guidance, IPs will be monitored for compliance as part of the HTS quality assurance systems
	HIV Self-testing	COP21 Target: All PEPFAR supported facilities are offering HIVST in a more targeted manner. For test kits distributed in the community, PEPFAR will ensure there is proper documentation and recording of tests distributed, disaggregated by age and sex, and a follow up mechanism to ensure that all those with a reactive seft-test are reporting back to the facility for a confirmatory test.	Further discussion is needed with DHA about approaches for offering more targeted testing, noting that increased distribution occurred during the first wave of COVID when routine PITC services were suspended unless they were for clients at a higher risk of HIV. The national M and E tools have included this field to record if a patient has had an HIV ST, however in some instances clients may not be willing to disclose if they used an HIV ST kit, and may choose not to report back to the facility for a confirmatory test
TB	**TB Preventive Therapy (TPT)**	COP21 Target: All eligible PLHIV including children and adolescents be initiated and complete TPT within COP21, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient. Of these, at least 70% should receive 3HP and 30% should be on IPT.	The national TPT task force recommended a phased roll out of 3HP and the target of 70% may not be achieved in COP 21. Some of the challenges experienced in COP19-20 include a 6 months suspension of TPT scale-up due to COVID19; Commodity and Supply chain constraints including the withdrawal of 3HP commodities due to impurities; frequent stockouts and inadequate supplies of commodities (IPT & Pyridoxine) at sites. In COP 21, PEPFAR will work closely with CSOs to create demand for TPT and promote adherence among PLHIV. TA will be provided for commodity forecasting, quantification, distribution and storage to ensure adequate supplies at sites. Additionally, PEPFAR will collaborate with MOH to monitor the TPT program to optimize service delivery.
		COP21 Target: All contacts of PLHIV with TB, including children and adolescents, should be traced and 100% of those eligible should be initiated on TPT.	PEPFAR IPs will reinforce measured for contact tracing in line with the national guidelines and review data on a routine basis to identify any performance gaps
		COP21 Target: TPT must be incorporated within DSD models of HIV service delivery (including Community ART Clubs).	Inclusion of TPT in DSD models will be implemented in line with national guidelines and is an area for further discussion during the treatment guideline revision process

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	COP21 Target: COP21 should set aside funds for refurbishing storage facilities in PEPFAR supported sites to address the issue of increasing CPNP levels in 3HP resulting from increased shelf life, humidity and high temperatures.	Manufacturers are responsible for preventing the presence of unacceptable impurities and for developing and using suitable methods to detect and limit unacceptable impurities. Please refer to FDA guidance (https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications). Maintenance needs have been noted with the pharmacy/ storage in a box (SIAB) and this has been listed as a priority by DHA in the C19RP stakeholder meeting presentation on April 19th 2021
TB screening and testing	COP21 Target: 100% of PLHIV, including CLHIV, are screened for TB upon presentation to care at every clinical encounter.	Routine screening for TB at every visit is standard of care and will be reinforced through site level mentorship and data analyses
	COP21 Target: 100% of PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings receive both urine-LAM and rapid molecular testing (including the use of stool samples among CLHIV) upon their first presentation to care. COP21 Target: 100% of PLHIV, including CLHIV, with positive urine-LAM results immediately initiate TB treatment, while awaiting confirmatory rapid molecular test results.	The national roll out of advanced HIV disease services is phased: 108 facilities in phase 1 and 305 facilities in phase 2 (COP 20- into COP 21) Further expansion has been delayed due to commodity delivery and HRH (COVID related training suspensions in the first wave). The EGPAF BMGF-funded pilot will inform the implementation of the 2nd phase, which will involve 7 existing hubs and expand to 34 spokes. Access to urine-LAM (part of the AHD service) is dependent on MOH plans and GF resources. The roll out of AHD is being done in a phased manner. Investments are needed to ensure access to CD4 and improve the functionality of PIMA machines. Through the Global Fund, MOH is procuring Xpert machines and Xpert TB test Cartridges through NFM 3, the current Global fund COVID-19 grant. Through USAID TB funding, support to introduce NTP was offered; however, MOH policy guidelines have not formally approved NTP. Validation of using stool samples on GeneXpert has been approved and HQ TA is available.
Cervial Cancer	COP21 Target: Cervical cancer screening and treatment for pre-invasive lesions is available in 130 PEPFAR supported facilities in order to reach an additional 100,000 by end September 2022.	Further discussion is needed with the DHA and GF on the procurement of essential HIV commodities to address gaps and support the roll out plans
	COP21 Target: PEPFAR and Ministry of Health work hand in hand to ensure that cervical cancer services are fully integrated with HIV services.	In COP 21, 47 new sites, which will be a total of 127 PEPFAR supported sites. All 28 districts will be covered. The target has been increased to 109,608

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		COP21 Target: PEPFAR and Ministry of Health work hand in hand to ensure there are clear referral pathways and mechanisms in place to monitor and trace women referred to services outside the Health Centre (including where no services are offered, or for further treatment) for funding.	The aim is for cervical cancer screen-and-treat services to be integrated with HIV/ART/TB services provided at the facilities to reduce the risk of attrition and efficiencies. The various service delivery models will be guided by infrastructure and staffing availability, since specific trained cadres are required to provide the service, e.g., nurses providing cervical cancer screening may not be trained as ART providers.
Key Populations	**KP funding + targets**		
		COP21 Target: Programming is not limited by the existing/non-existent size estimates. A process is put in place to work with KP CSOs to establish the potential expansion of KP programming based on community data.	2019/2020 IBBS report is available for use. 8 districts are included in the report with Three KP population groups. TG study preliminary results were shared and waiting for the final report. NAC is planning to implement a formative PWIDU study. KP Validation Exercise underway in select districts in FY 21; funding for KP size estimation proposed in COP 21.
		COP21 Target: Funding is increased to KP led organizations to carry out regular trainings to sensitize healthcare workers at PEPFAR supported sites on provision of key population friendly services.	See comment above; Some districts have support groups up and running which had been halted because of the pandemic.
	KP specific services		
		COP21 Target: 20% of the 500 Expert Clients are recruited to support key populations specifically.	With the Peer Educator microplanning strategy, no expert clients are needed. Peer educators/navigators track each client through the service package and the number of Peer Educators/Navigators is determined using a ratio recommended by WHO
		COP21 Target: Lubricant is made available at all PEPFAR supported sites, alongside male and female condoms, and is not labelled as a key population commodity. Healthcare workers are trained to have comprehensive knowledge on lubricant to avoid stigmatizing key populations.	KP are mobile and commodities should not only be available at PEPFAR supported sites. They should be able to access commodities wherever when they are conducting their business
		COP21 Target: Introduce clinics run by KP led organizations which are flexible to address the needs of KPs and where KPs will be able to receive comprehensive services.	This is a policy discussion which require government on the table. Currently we have DIC's functional and running where DIC's act as a community clinic for KP's and most of the providers are either KP's themselves or well trained in providing KP's services. This is the same in the hybrid facilities as well.

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	KP support groups	COP21 Target: Increase funding to KP led organisations to establish and maintain functional support groups specific for key populations linked to all PEPFAR supported sites.	Some districts have support groups up and running, which have been halted because of the pandemic. We are proposing to use ARPA to expand this support.
Prevention	**DREAMS**	COP21 Target: DREAMS interventions are expanded to 50 additional facilities/SNUs as per the recommendation from COP Guidance.	PEPFAR Malawi plans to maintain the number of districts but expand within the districts and work towards saturation across the age bands.
		COP21 Target: PEPFAR will analyse DREAMS data to determine if saturation has been achieved, that is 75% of AGYW in a given SNU has completed the appropriate package of interventions.	Analysis done to project saturation at end of FY 22. At the end of COP 21, we will reach more than 75% saturation for all age groups in the three districts; district expansion will be considered depending on COP 21 performance. NFM3 covers combination HIV services for AGYW in Mulanje, Thyolo, Chikwawa, Mangochi, Lilongwe.
	PrEP	COP21 Target: PEPFAR in consultation with GoM to share an expedited roll out plan for PrEP with a clear strategy for meeting FY22 targets.	Funding for PrEP acceleration also included in NFM3 PEPFAR to cover commodities gap between NSP funded targets in Global Fund and COP 21 acceleration targets for PrEP.
Other	**Community-led monitoring**	COP21 Target: Funding is scaled up to $1 million for community-led monitoring in Malawi to monitor 55 high burden sites across 11 districts Malawi.	NFM3 covers support for community-based monitoring as part community systems strengthening and leadership development, including DHTs and CSOs. This is the first year of CLM implementation in Malawi, evaluation of the program implementation (outcome) and funds absorption may determine funding adjustment. CDC funding through UNAIDS for CLM will continue in COP21. USAID funding through MANASO for T=T work in three districts will continue in COP 21.

	Faith Based Programming and Literacy	COP21 Target: Fund community-led organisations to provide health rights literacy to community members to ensure as public healthcare users they understand their right to access dignified and quality healthcare services. Too often community members feel helpless, unaware of where and how to report grievances for redress and so accept the status quo as normal.	PEPFAR implementing partners are scaling up treatment literacy during pre-initiation counselling and psychosocial support for patients. Risk stratification approaches are being used to identify patients who are in greater need for support. The FCI is another approach used to increase treatment literacy through FBOs. To complement this, work is underway through the "Flip the Script" project. Funded jointly by the Bill and Melinda Gates Foundation, PEPFAR and Johnson and Johnson, the aim of this project is to develop a strategic marketing campaign that will “rebrand” ART, so that both PLHIV and their communities see being on treatment as something that restores a person’s normalcy.
	Monitoring & Evaluation	Maintenance for back-up power solutions and replacement of old EMR hardware	Blueprint for power and local area network (LAN) developed and shared with MoH in COP20. In COP21, there are plans to explore Public-Private partnership to support implementation of blueprint at HIS Centers of Excellence, maintenance of power backup system and LAN. New infrastructure prototypes will be piloted.
		Data Audit for POC and EMR	With the Central Data Repository (CDR) now processing data from all POC EMR sites, there is an opportunity in COP21 to establish a digital data governance policy covering effective data audits, data use and sustainability strategies. HIS partner has plans to implement these policies with guidance from MoH, DHA and other key stakeholders.
		Interoperability of DHAMIS and LIMS with DHIS2 Data Security Unit at CMED District Performance Quarterly Review Meetings	Integration of DHAMIS and DHIS2 was part of the work implemented by the kuunika interoperability project supported by BMGF. However, this work has since stalled. With PEPFAR support, HIS partner plans to implement integration of National LIMS with DHIS2 in COP21. There is also an opportunity to integrate DHAMIS with the Central Data Repository. Guidance needed with MOH regarding data security. Implementing partners can help facilitate district review meetings in coordination with NAC.

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APPENDIX D – The American Rescue Plan Act Summary

Purpose

The American Rescue Plan Act (ARPA) COVID-19 appropriation for PEPFAR designates $250,000,000 to the Department of State "to support programs for the prevention, treatment, and control of HIV/AIDS to prevent, prepare for, and respond to coronavirus, including to mitigate the impact on such programs from coronavirus and support recovery from the impacts of the coronavirus". PEPFAR Malawi is requesting **$8,789,250** (5% of the COP21 Planning Level Letter) of these funds to solely focus on mitigating the COVID-19 impact on PEPFAR programs and beneficiaries, and support program recovery from the impacts of coronavirus to date. COVID-19 continues to challenge the way services are delivered. This funding request represents PEPFAR Malawi's strategy to rethink how we interact, deliver services, and keep both our frontline healthcare providers and clients living with HIV safe. This proposal summarizes PEPFAR Malawi's strategy to sustain gains achieved over the last two decades and build back better a post-COVID system to be stronger, more effective, and more efficient.

I. Proposed strategies, interventions, approaches and activities to prevent, prepare for, and respond to coronavirus (including prevention of COVID-19 infection, illness, and death among PEPFAR beneficiaries and staff)

A. **Infection prevention and control programming (IPC)**

To facilitate the rapid identification and isolation of suspected COVID-19 cases among clients and healthcare workers in PEPFAR-supported facilities, PEPFAR Malawi is requesting IPC resources to improve infection prevention policies and procedures both at the facility and community level. Many program beneficiaries lack the required PPE necessary to access facility and community-based services and participate in community-led monitoring efforts. Communities have also expressed fear of accessing services and subsequently becoming exposed to COVID-19. Supplies are often procured during a COVID-19 surge, arriving late to facilities and leaving both beneficiaries and healthcare workers exposed. Proposed activities will include: the procurement of PPE for program beneficiaries (KPs, AGYW, and PLWHIV) such as disinfectant, surgical masks for clinical teams, and cloth mask production; dissemination of IEC materials targeted at HIV service delivery points to dispel misinformation on HIV and COVID; and, tents to increase shelter for effective screening and social distancing while program beneficiaries wait for HIV and other services at supported facilities, particularly needed in rural areas where vaccination uptake is minimal.

B. Services supporting COVID-19 vaccination access for staff at PEPFAR-supported sites and beneficiaries

Demystifying COVID-19 in Malawian communities is imperative for the scale-up and uptake of COVID-19 vaccinations and HIV services. Misinformation about the COVID-19 vaccine is

affecting service delivery and uptake of HIV services. Proposed activities will help address current funding gaps for supporting risk communication and vaccine administration, integrating screening for TB and COVID-19 (e.g., screening for TB, screening for non-communicable diseases and linkage to preventive and therapeutic services as appropriate according to MOH guidance), and, following MOH guidelines, increasing community sensitization, awareness of and readiness to receive the COVID-19 vaccine. Available data show that the high COVID-19 vaccine coverage will protect health care workers from severe COVID-19 disease and will minimize current disruptions to essential HIV services. However, MOH is not fully able to cover vaccine administration, especially inclusive of PLHIV in treatment. The African Union has a goal of reaching 60% of Africa's population with vaccination services by 2022, but each individual country of the 55 member African Union will approach this goal according to local government guidelines in close coordination with civil society.

C. Testing PEPFAR-supported staff and beneficiaries for COVID-19 and informing epidemiologic surveillance

Access to COVID-19 testing is a challenge, particularly at rural health facilities and in the surrounding communities given the lack of staff for COVID-19 contact tracing. PrEP scale-up plans and prevention programs targeting Key Populations and AGYW were significantly impacted by COVID-19 with most community-based activities suspended for the majority of 2020. Resources are requested to optimize contact tracing among vulnerable populations and train lay cadres and HIV surveillance assistants to deliver COVID-19 testing and generate demand for services. Resources will also be used to conduct social dialogue sessions with communities on COVID-19 testing, vaccine, and prevention methods to raise awareness and address misconceptions and mis-information.

D. Clinical management

The COVID-19 pandemic has exacerbated resource-constrained health facilities and illuminated the limited capacity of health care workers and national systems to respond to both COVID-19 and HIV. A review of the national response plan indicates funding gaps for patient screening and management (pillar 10) and linkage of eligible clients to COVID-19 testing and vaccination services. There is also a need for sustained availability of diagnostic and case management equipment. Demand for oxygen is significant and urgent, and funding will support critical procurements of oxygen cylinders and nebulizers to treat moderate and severe cases, prior to and during transit to a COVID-19 treatment unit. PEPFAR will coordinate closely with the Global Fund writing team to ensure oxygen related activities included in the C19RM proposal is not duplicative with the ARP.

II. Mitigate COVID-19 impact on PEPFAR programs and beneficiaries and support program recovery from the impacts of coronavirus

A. Extraordinary logistics and commodity costs to HIV programs associated with COVID-19

Military sites in Malawi were particularly affected by a temporary closure of barracks to beneficiaries, which led to large reductions in continuity of care. Returning these clients into care will require a quick and aggressive community effort using motorcycles as the reliance on the limited number of motor vehicles is also impractical due to social distancing measures. To revamp back-to-care contact tracing efforts and minimize treatment disruption among clients living with HIV, resources are requested to revamp and scale index testing, provide surge HRH, support increased transportation costs due to social distancing rules, and procure motorcycles to cover more ground during outreach.

B. Laboratory

PEPFAR's investments in laboratory strengthening over the last two decades has been invaluable to Malawi's national response to COVID-19. Nevertheless, the increased demands on an already stretched system has exponentially burdened viral load platforms which are dually used for PCR testing. Currently, there are limited COVID-19 cartridges in GeneXpert POC sites, improper management of liquid waste in molecular labs, limited laboratory technicians to keep up with demand of VL and SARS-CoV-2 testing, as well as other laboratory tests, and limited in-country experience with genomic sequencing. The latter has led to sequencing for SARS-CoV-2 and HIVDR being outsourced to a private laboratory in South Africa, leading to high costs and longer turnaround times. ARP resources will support the enhancement of biosafety and waste management in molecular labs, renovate labs to create space to accommodate COVID-19 testing, procure COVID-19 GeneXpert cartridges for screening HIV and TB patients, support COVID-19 sample transportation from border districts, including Chitipa, Karonga, Dedza, Mwanza, Mchinji (based on the country's policy, these people are supposed to be screened before being granted entry into the country). ARP resources will also allow for sequencing in-country (equipment and human resources) to identify circulating SARS-CoV-2 variants on a routine basis and to support HIVDR, which will reduce costs and decrease lag time that is crucial to outbreak response and patient management. Laboratory equipment, reagents, and consumables are also being requested to avoid service interruptions, in addition to resources to support overtime to lab personnel for extended testing hours and data clerks to do data entry.

C. "Repair of Program Injury" i.e., support for PEPFAR programmatic acceleration and recovery from adverse impacts on PEPFAR program performance due to COVID-19

The COVID-19 pandemic has adversely impacted VMMC service delivery in Malawi due to suspension of VMMC services as a non-critical service by the MoH. Support will be used to ramp up demand creation activities and provide PPE to participants. Case finding, particularly community index testing, was also suspended due to COVID-19. ARP funding will be used for community tracing to reach contacts of index clients with testing and reengage individuals who interrupted their treatment. Supplemental funding will enhance the engagement of OVC case care workers, KP, and other peer outreach workers to increase provision of virtual services by providing them with phones and airtime to allow socially distanced, virtual counseling and support. Clients also will be provided with airtime. Supplemental funding will increase access to

mental health support for facility health care workers who have endured the impacts of COVID-19 for over a year and are experiencing reduced productivity and vaccine hesitancy. Funding will support accelerated progress of MMD6 for KPs at drop-in centers (DICs), which were impacted by COVID-19 and train additional HRH on Advanced HIV Disease support, especially since declines in health facility visits during COVID-19 waves may result in significant increases in PLHIV presenting with AHD. Funding will also support expanding the provision of DDD, especially for KPs and priority populations, to reduce COVID-19 exposure and support MMD6 coverage, inclusive of DICs and private sector facilities.

APPENDIX E – PEPFAR Malawi COP20 SDS Link

https://www.state.gov/wp-content/uploads/2020/07/COP-2020-Malawi-SDS-FINAL.pdf