PEOPLE'S COPICS KENYA

COMMUNITY PRIORITIES

PEPFAR COUNTRY OPERATIONAL PLAN 2019



Today, there are an estimated 1.6 million people living with HIV in Kenya (a prevalence of 5.6%¹) - yet only 1 million of those people are taking life saving HIV treatment, leaving 37.5% of people without access². In 2018 alone, 28,000 people died unnecessarily from AIDS related illnesses—and a further 53,000 people newly acquired HIV.³ While Kenya is on track to reach the 90-90-90 targets and epidemic control, more needs to be done to bring an end to AIDS by 2030. We also note that results from the Kenya Population Based Impact Assessment (KENPHIA) are due this year that will provide much more accurate data on the HIV response as it stands today—giving better insight into the remaining gaps in the response and ways to fix them.

The most recent data from PEPFAR points to extremely poor programme performance in linkage and retention. FY18 quarter 4 data indicates that while 183,332 people tested positive, only 144,818 people had been newly enrolled on treatment in total during the year—just 79% of people were linked to treatment. Worse, on retention, the NET_NEW target stood at only 42,609 overall—or only 15.46%.⁴ In order to address these low linkage and retention rates, PEPFAR must focus on both the quantity of services delivered while drastically improving the quality of services people receive.

Key populations—including men who have sex with men (MSM), transgender people, people who use drugs (PWUD), and sex workers—continue to be at high risk and often are restricted from accessing services due to stigma, discrimination and criminalisation. Key population reach has been high with collaborative efforts between PEPFAR and key population led organisations. However, the achievements drop when key populations are linked to care at the general facility, resulting in low retention rates.

Men with HIV—for many reasons—remain less likely to get an HIV

test, to know their status, or to seek any treatment or care at the facility. Only 76% of men above 15 were linked to care in FY18.

Targeted testing, linkage and retention strategies are needed to improve uptake of services by these groups. Currently, PEPFAR is using VMMC and index testing to reach more men, but supporting community-based drug distribution and supporting group models of care specifically for men will increase retention rates.

In addition to HIV, Kenya faces a high tuberculosis (TB) burden. According to the World Health Organization (WHO), Kenya is among the highest TB burden countries globally for drug sensitive (DS) TB, TB/HIV co-infection and multi-drug resistant (MDR) TB. In 2017, of the 158,000 people reported to have TB, 45,000 were living with HIV; around 2 800 people had MDR TB; and nearly half of those with MDR TB were people never treated for TB before⁵. While the number of TB deaths among people living with HIV has reduced substantially in recent years, mainly as a result of the wider roll out of ARVs, it still remains the largest cause of death for PLHIV. This is something that PEPFAR must address.

Yet despite the TB emergency, the reality is that TB infection control is poor at primary healthcare level with human resource

^{1.} Kenya AIDS Strategic framework.

^{2.} POART data Q4

^{3.} UNAIDS

 $^{4.\ \} PEPFAR\ Monitoring, Reporting\ and\ Evaluation\ Database, Amfar.\ Available\ at:\ https://mer.amfar.org/location/Kenya$

^{5.} Global TB Report, 2018. World Health Organization (WHO). Available at: https://apps. who. int/iris/bitstream/handle/10665/274453/9789241565646-eng.pdf?ua=1



shortages and infrastructural issues leading to over congested clinics and long waiting times. The health system is lacking, and despite the achievement of getting 1 million people on treatment, most facilities are not equipped to be able handle the large numbers accessing HIV services. Most ART clinics are too full and unable to provide services with privacy, confidentiality and dignity contributing to poor linkage and loss of to follow up. Ongoing health worker strikes also affect HIV and TB service provision, including in large part PMTCT services in the facility⁶.

PEPFAR Kenya is currently faced with a 31% (\$120 million) cut in funding for Country Operational Plan 2019 (COP19)—this following a cut of \$57 million in the previous COP. This is a threat to the major gains made in the HIV and TB response to date. At a time when PEPFAR should be increasing investment to address challenges in finding currently undiagnosed people living with HIV and improve linkage and retention rates, the cuts will mean a scale back in service delivery and a regression in quality of services provided. In particular, it is likely the cuts will

reduce PEPFAR support for much needed healthcare workers at the frontline of the HIV and TB response, and to scale back on targeted services aimed at key and vulnerable populations. Already last year we saw results worsening for numbers of babies being born with HIV—rising from 8.3% in 2015 to 11.5% in 2017.

Given that Kenya will not take part in the COP19 planning meetings in Johannesburg, we are extremely concerned that civil society will be excluded entirely from the Nairobi-based COP19 planning to take place. While PEPFAR has opened up space for activists to input into the content of the COPs more broadly, this has seemingly been retracted in Kenya this year. This is inconsistent with PEPFAR minimum standards for good governance. KENPHIA preliminary results might be confidential, but that is no reason to obstruct multi-stakeholder engagement. The Office of the Global AIDS Coordinator (OGAC) must ensure civil society representation and meaningful engagement in the development of Kenya's COP19.

To support our input, we have developed the "People's COP"—outlining Kenya's community recommendations and priorities for COP19. These recommendations were developed by people living with HIV and health activists following a recent fact-finding mission in January 2019 to 7 PEPFAR supported facilities in three high buren counties including: Siaya (Siaya County Referral Hospital, Bondo District Hospital, and Ligala Community Health Centre), Homabay (Othoro Sub County Hospital and Rachuonyo District Hospital) and Kisumu (Jaramogi Oginga Odinga Referral and Teaching Hospital and the Lumumba Sub County Hospital).

This facility level monitoring aimed to assess the state and quality of HIV and TB service provision, through a series of questions targeting health providers and healthcare users at the facilities. The results of this fact-finding mission will be analysed in the narrative below. The People's COP has been further

shaped following a series of consultations held with people living with HIV, key populations, community based organisations (CBOs), Non-Governmental Organisations (NGOs), and Faith Based organisations (FBOs)—stakeholders with collective experience at the forefront of Kenya's HIV and TB response.

^{6.} Kenya Country Operational Plan 2018 Strategic Direction Summary. Available at: https://www.pepfar.gov/documents/organization/285861.pdf

PRIORITY INTERVENTIONS FOR COP19

- 1. Invest in increased quality programming to ensure better linkage and retention rates in the facility by funding additional 1,000 frontline professional healthcare workers and 5,000 outreach workers, and funding basic facility infrastructure improvements.
- 1a. Fund at least 1,000 additional frontline professional healthcare workers in PEPFAR priority counties.

People living with HIV have an expectation not just to access services at a health facility, but to access quality services. However, often at PEPFAR supported sites, the quality of service provision is poor or limited—as confirmed during our fact-finding mission that revealed human resource shortages and infrastructural space challenges—despite high numbers of people collecting ART.

Staff shortages: At all facilities (7 out of 7) major human resource shortages were reported—and healthcare workers reported being overburdened with work and overwhelmed by the large numbers of people living with HIV collecting ART. The WHO estimates at minimum 2.5 professional medical staff (physicians, nurses and midwives) per 1,000 people are needed to provide adequate coverage with primary care interventions⁷. However, the ratio of professional medical staff to patients in these sites was alarming. In Rachuonyo District Hospital, there was just one nurse (supplemented by four peer educators and one community healthcare worker) for 3,722 PLHIV collecting ART.

Linkage and retention results are closely impacted by the quality of HIV services provided. It is resource intensive to: provide HIV services and treatment at the facility; locate and reintegrate people who have defaulted back into care effectively; to provide adequate counselling and psycho-social support to individuals struggling to adhere; to provide information on HIV and medicines (especially in light of the TLD transition and the need to inform women on DTG for informed consent); ensure advanced HIV disease is adequately detected and acted upon; and reaching underserved communities with HIV services, for example. Without an adequate number of healthcare workers on the frontline of HIV service delivery, retention rates will remain low, and Kenya will not reach epidemic control.

COP19 should ensure that all human resources funded by PEPFAR are prioritised in districts with the highest HIV burden and the largest shortages of staff in order to fill capacity gaps. Currently funded health workers should be re-assigned to those PEPFAR priority districts and PEPFAR supported sites most in need. Finally, overburdened and overstretched healthcare workers reported being unable to attend trainings and improve their skills. PEPFAR Kenya should consider providing on-site training for clinical staff in high burden districts.

COP19 must fund 1,000 additional frontline professional healthcare workers at PEPFAR supported sites to ensure quality HIV and TB service delivery at a primary level. These healthcare workers should be prioritised in PEPFAR priority counties at sites with the greatest human resource shortages—and with a high burden of HIV. PEPFAR must provide a breakdown of healthcare workers employed, at what level, and in which facilities.

1b. Fund at least 5,000 additional outreach workers in the five highest burden PEPFAR supported counties to provide HIV and TB services in the community.

Community based non-professional health workers have the potential to bring health services closer to the community while reducing the burden on an already overstretched primary healthcare services. Community based workers have long been recognised as an important part of a primary healthcare system and Kenya has utilised many lay workers to support with HIV service provision, in the face of too few professional healthcare workers. PEPFAR has invested in outreach workers in a bid to provide services to an ever increasing number of people living with HIV.

The functions of outreach workers must include (but will not be limited to):

- + Understand HIV and TB fully to offer up to date prevention and treatment literacy information;
- + Promote HIV testing at a facility level and offer information to prevent sexual transmission of HIV;
- + Promote and provide HIV self-testing kits and/or finger prick tests to marginalised and hard to reach communities not currently accessing health services through the clinic, linking those who gain positive results to facility services;
- + Provide lay counselling and support services at facility and community level,, including through home visits and through facilitating community based adherence clubs;
- + Provide people living with HIV with treatment and adherence support, ensure people who access HIV treatment keep taking it and engage in defaulter tracing;
- Provide basic mental health assessments in particular for people living with HIV facing treatment fatigue, depression and other mental health challenges;
- + Improve linkage of people living with HIV between the facility and community HIV services;
- + Follow up with people living with HIV who have missed appointments (both through telephone calls and home visits);
- + Ensure quality implementation of index testing in a manner that protects the human rights of people with HIV and prevents criminalisation, stigma and violence; and
- + Trace people with TB or who are close to people with TB and ensure that they have access to, and take, treatment effectively.

^{7.} World Health Organisation. World Health Report 2006.

Another model that provides HIV testing and other services in the community is through funding community PLHIV led organisations. For example, PEPFAR Uganda supports community groups to engage in community outreach and testing in order to increase their positivity yield and increase retention. Community-based organisation JIACOFE is funded to work together with implementing partners to offer targeted testing and counselling services at community level, provide HIV starter packs to those newly diagnosed with HIV, and refer them to health facilities nearest to them. Bringing ART refills to the community and supporting facilities with adherence counselling has led to reduced travel burden for PLHIV and increased retention and viral suppression. COP19 needs to also support expert clients to provide ART refills, adherence support and basic health assessments. People living with HIV who are stable could be eligible for participation.

COP19 must fund at least 5,000 additional outreach workers to deliver HIV and TB services in the community and link people to care. These outreach workers should be prioritised in the five highest burden PEPFAR supported counties.

1c. Ensure 100% of PEPFAR supported sites have functional group models of care including Community ART Groups (CAGs), as well as fast track models of care such as Community Drug Distribution Points (CDDP) by end of COP19.

Waiting times: At all facilities (7 out of 7) monitored, healthcare users reported needing to arrive in the early hours of the morning—as early as 4 am at Rachuonyo District Hospital—in order to expect to access health services in a reasonable time. The majority of individuals interviewed indicated that waiting times lasted between one to six hours, depending on the number of people also waiting. This is hugely disruptive for people's lives—especially healthy people simply collecting ART refills. It is well known that each time an individual has to engage in care at the facility for lengthy periods it can increase the risk of them disengaging from care.

Long distances: In certain areas, people report walking long distances in order to get to healthcare facilities. This is certainly the case for places like Siaya—a vast County—where healthcare workers we spoke to also complained of poor retention in the rainy season, as well as during the planting season and market days. In such areas there is clearly a need for more decentralised services.

For PLHIV stable on ART and virally suppressed, DSD models such as Community ART Groups (CAGs), and fast track models such as community drug distribution points (CDDP) need to be scaled up. These models support long-term retention by providing aspects of peer support as well as speeding up the process of collecting ART refills more easily and closer to home. DSD models also subsequently ease the burden on overstretched healthcare workers at the facility, ensuring more time to provide quality services.

Community ART Groups (CAGs): For people who are stable on ART, there should be an option to utilise a CAG for faster,

more convenient and cheaper ART collection. With a more than 84.54% (Q4 2018) of people disengaging in care in FY18, it is critical for PEPFAR programmes to address retention rates with community supported approaches. In CAGs, which are managed by the recipients of care themselves, people living with HIV receive their ART refills in self-managed groups. The group usually meets outside of healthcare facilities and works on a roster system sharing pickup and distribution duties. It is made up of around six individuals.

This is not a new idea. CAGs have been piloted in Mozambique with benefits including increased peer support, reduced time and costs associated with collecting ART refills, and stronger engagement of the community in HIV care. In Zimbabwe, an adaptation to the model was implemented based on feedback from PLHIV. The Community ART Refill Group (CARG) was changed according to the local context (wherein members had access to three-month refills and yearly clinical consultations) and in line with PLHIV preferences for bigger groups. In Malawi, the CAG model reached more than 5 000 people living with HIV, with retention in care after two years of establishment at 96.8%

Community Drug Distribution Points (CDDP): By offering ART collection in the community CDDP will reduce the potential for missed appointments as services are brought closer to community members, becoming less time consuming, and easing challenges of transportation to the health facility. MSF's model of working with networks of people living with HIV to establish community ART distribution points, bringing medication delivery closer to people's homes will be vital to increasing retention.

By end COP19, PEPFAR must ensure 100% of sites in PEPFAR counties have Community ART Groups (CAGs) and Community Drug Dispensing Points (CDDP) in place. These will reduce the burden on health centres, provide better access to treatment and support, and improve overall linkage and retention rates.



^{8. &}quot;Engaging the Community to Reach 90:90:90". UNAIDS, NAC, MSF, and Mothers 2 Mothers. Available at: https://www.msf.org/sites/msf.org/files/engaging_the_community_to_reach_90-90-90.pdf

^{9.} Community ART Group Toolkit. Available at: https://www.msf.org/sites/msf.org/files/community_art_group_toolkit.pdf

2. Maintain investment in the Prevention of Mother to Child Transmission (PMTCT) programme to test 60,000 pregnant women for HIV in COP19.

Major gains in finding women living with HIV have been made through the robust Prevention of Mother to Child Transmission (PMTCT) programme in Kenya. According to the PEPFAR data on achievements, the number of women found through PMTCT services in the last four years has been 61,456 (in 2015), 68,867 (in 2016), 48,432 (in 2017), and 56,655 (in 2018)—resulting in an average of around 58,852 per year.

COP19 proposes an alarming reduction of targets for adult women from COP18 of 96,416 to COP19 of 39,594. It is through women that most of the targets on assisted partner notification (APN), DREAMS, and early infant diagnosis (EID) are being met. The programme needs to test enough women to find their male partners and reach children. Reducing funding and targets will hinder women's access to HIV services, and also pose a significant threat to the DREAMS programme, PMTCT programme, and APN. COP19 must review these targets or risk losing the gains made in reaching not only women but other populations.

Ongoing health worker strikes¹⁰ and reduced funding for health workers have greatly affected the PMTCT gains in the 2nd and 3rd 90. The quality of service delivery requires an investment in health workers to offer support treatment adherence. COP19 should invest in health workers to improve treatment outcomes for mothers enrolling on PMTCT services.

COP19 must maintain a minimum PMTCT target to reach 60,000 women in FY20—thus contributing to the success of DREAMS, APN and EID.

3. Invest in TLD transition for women of reproductive age to improve retention and treatment outcomes.

Dolutegravir (DTG) is the first integrase inhibitor that will be widely used by people living with HIV in the developing world. It is a critically important antiretroviral medicine that is set to become the backbone of many countries HIV programmes. Studies show that DTG represents an important improvement over existing treatments including that it is highly effective, well-tolerated, and easier to take; has fewer interactions with other medicines (although some exist); has a high barrier to resistance; and has the capacity to be produced more affordably. Adherence among PLHIV has been shown to improve when people face fewer side effects, given that DTG offers this, it has the potential of better retention and health outcomes.

While in May 2018, preliminary findings from an observational study in Botswana raised a potential safety concern about the use of DTG for women at the time of conceiving a child, subsequent findings as the study has progressed has revealed reduced risk of this being associated with DTG use. However, once the potential safety concern was identified, women of childbearing age in Kenya have been left behind in accessing the DTG based regimen (tenofovir-lamivudine-dolutegravir—TLD) that is already being widely offered to men.

Health talks at all facilities monitored focused solely on the disadvantages of DTG for women of reproductive age; they did not cover any of the benefits¹¹. All clinicians told us that they were only changing men to TLD and not any women of reproductive age. Most clinicians did not understand the need to provide information to women in order to allow them to make an informed choice to take TLD—despite being required to do this in national guidelines¹². Most did not know that the choice

of preferred regimen belonged to the women coming to the facility, and not the clinicians. Those who did understand that the choice belonged to women, still failed to offer it to them. Screening tools at all facilities had no indication of choice for the women of reproductive age to access TLD. In fact the tools actively excluded women from consideration for optimisation.

Without sensitisation and training, women of reproductive age will not be transitioned to TLD. COP19 must support re-training of healthcare workers providing ART to ensure women are appropriately counselled on the risks and the benefits of DTG. PEPFAR should urge the Government of Kenya to issue a circular to providers that reiterates that TLD as an option for all people including women, and that information on DTG should be provided for women of reproductive age to allow them to make an informed choice, thus ensuring treatment optimization for women as well.

In order to ensure TLD transition success, it will be critical

^{10.} Kenya Country Operational Plan 2018 Strategic Direction Summary. Available at: https://www.pepfar.gov/documents/organization/285861.pdf

^{11. &}quot;Let women decide whether they want to take dolutegravr", Health GAP. Available at: https://

healthgap.org/let-women-decide-whether-they-want-to-take-dolutegravir/

^{12.} National Department of Health New Guidelines. Available here: https://www.nascop.or.ke/?page_id=2431

to ensure people know about TLD as an option and are informed on the benefits and risks associated with it to make an appropriate ART choice. COP19 must financially and otherwise support community and PLHIV led efforts to improve treatment literacy levels in the country. Demand creation for new medicines, and preparedness for interim side effects, is another benefit of widespread treatment literacy programmes.

Finally, contraception demand among women of reproductive potential is likely to go up once clinicians start to offer TLD as an option. All PEPFAR supported facilities must be equipped with sufficient family planning commodities for all women who choose to utilise them. Forced and/ or coerced access to contraceptives by women living with HIV must not be tolerated with TLE to TLD transitioning.

COP19 must support full roll out of TLD optimization among women of reproductive age. Clinicians must be trained on the need to allow women to make an informed choice for TLD initiation/transition. COP19 must also support the staffing and commodities needed to ensure that all women have the option to utilise a family range of family planning options. COP19 must provide the financial and other resources necessary to ensure a major upscale of treatment literacy in the country. This must include: material development and dissemination to 100% of PEPFAR sites, training of trainers & subsequent trainings, social mobilisation campaigns at community level. PEPFAR must fund at least 5 community lead PLHIV organisations to carry out this work.

4. Improve timely diagnosis of perinatal HIV with point of care (POC) testing and scale up optimised HIV treatment for infants.

The EGPAF Early Infant Diagnosis (EID) point of care project led to increased initiation of treatment of children with HIV from 43% to 93%.

From July 2019, the programme will no longer be able to supply POC EID tests to sites currently offering them due to lack of funding. Without funding, the programme will have to revert to conventional EID, which is a sub-optimal diagnosis method in which mothers and their children must wait for results for months or may never receive them. 20% of children with HIV tested with conventional EID die before they even receive their test result. In order to avoid stockouts after July 2019, an order needs to be urgently made at the end of March 2019/early April

2019. The programme is expecting a gap of USD 302,500 from July to December 2019, and USD 605,000 annually thereafter.

COP19 must cover the gap of USD 302,500 from July to Dec 2019 and USD 605,000 annually from 2020 in EID point of care support and must fully fund an immediate scale up of lopinavir/ritonavir based ART for children <20kg and DTG based regimens for children >30kg.

5. Eliminate informal user fees at the facility for opportunistic infection (OI) treatment and biochemistry services affecting treatment and monitoring of patient response to ARV treatment.

Shortages of medicines for opportunistic infections were mentioned at every facility. People were instead given prescriptions to go to buy medicines for themselves at the pharmacy—creating a barrier to access.

In addition, only one facility provided biochemistry services to assess treatment resistance/success, due to the introduction of universal health coverage (UHC) in the county. However in most places, people were instead referred to clinics that were long distances away and with prohibitive costs associated with accessing the service. Referral to these services was not routine, and only provided to people who complained of complications. As the programme transitions from TLE to TLD, and increases quality services to retain people on treatment, COP19 must ensure people with advanced HIV

disease and treatment failure are quickly detected, and then adequately acted upon. Response to ART should then be monitored to ensure ongoing treatment success.

COP19 must support rollout of biochemistry services to the five highest burden clinics to monitor toxicity, resistance and improvement of people's health. COP19 must support monitoring of the medicine supply chain to reduce stockouts and shortages of medicines at the facility level.

6. Find more men with HIV and improve linkage and retention by funding men only treatment days, expanding flexible opening hours and weekend clinics, men specific DSD models, and other strategies targeting men at 100% of PEPFAR supported facilities.

Men are less likely to test for HIV than women. Studies¹³ and implementation data including Kenya's POART still show that men are lagging behind on testing, treatment and viral suppression. The facilities monitored relied on APN and VMMC as the only methods to find men for testing. To achieve the first 90 and reach populations like men, COP19 must fund HTS modalities beyond APN.

Only 2 out of the 7 facilities in our monitoring had targeted services for men. One innovation at Bondo District Hospital in Siaya was a professional men's support group, that meets on Saturdays, and offers adherence counselling and health talks for men. The facility also fast tracks men who had to go to work in the morning. All other facilities told us that they would like to offer services to attract men, but lacked the resources to do so. "We want to offer male medical camps screening for other diseases to attract men to the facility but we have no funding to do so", said a clinician at Othoro Sub County Hospital in Homabay. Facility operation hours, as observed during the fact-finding mission, were a clear indication of challenges in reaching and retaining men. All the facilities began clinical services at 8am and closed business at 5pm, which is a major challenge for the men who have to go to work all day. As noted above, healthcare users are forced to

wait many hours to be seen at the facility—arriving as early as 4am, and queueing for as long as six hours to see a clinician.

Extended opening hours for men will improve testing, linkage and retention rates, as men can better access HIV services at the facility, as well as increasing men's access to counselling and support at times that are most convenient to them. In addition men only support groups and CAGs, men only treatment days will also support increased linkage and retention.

COP19 must find more men with HIV and link and retain them in care through targeted services at 100% of PEPFAR supported sites including: flexible and weekend opening hours; men only treatment days; and men only adherence clubs and support groups. Men only drop in days should be established in the highest burden districts.

7. Invest in key population led comprehensive service delivery and bio behavioral surveillance.

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

In Kenya, community outreach and service delivery is the backbone of key population service delivery. Peer-driven interventions have been shown to be effective in engaging, recruiting and supporting KPs. KP led programmes employ peer navigators and other staff to provide case management, enrolment and/or re-enrolment in care and treatment services. The programme has been highly successful at reaching all key populations cohorts with an achievement of 93% and above for all communities according to Q4 POART data, however, the programme faces challenges with testing and retention of KPs.

The past three COPs have included recommendations from KP organisations for PEPFAR to support increase of the numbers of KP led organisations providing comprehensive services. However, while the programme has supported KP community led organisations (linkage and UNODC) to

reach peers at the community level, it has failed to support most community groups to offer testing and treatment. This results in referrals to the main facilities where retention is low and has consistently led to loss to follow up.

During our facility visits, all the staff at the service delivery points looked shocked at the mention of KPs visiting their clinics, despite most of the facilities being high volume sites. All clinicians responded along the lines of "I cannot tell you if key population come to our facility, if they come they do not say they are key populations". This is a clear indication that KP friendly spaces were missing at all monitored facilities. The programme should consider at a minimum having key population peer educators at general health facilities for the KPs currently receiving services at general facilities and an agreement between community led organisation and specific facilities

^{13.} Kenya HIV Estimates Report. Available at: https://nacc.or.ke/wp-content/uploads/2018/11/HIV-estimates-report-Kenya-20182.pdf

for referral to ensure quality treatment and viral load services. Community groups are also great with supporting peers with adherence to both treatment and prevention tools such as a PrEP. COP19 should prioritise funding communities to host support groups that incorporate social media and DSD models.

The medically assisted therapy service achievements continues to remain low and urgently needs community outreach to be successful. Communities have also continuously recommended funding for mobile outreaches for the MAT programme to increase uptake by people who use drugs (PWUDs) who are far from the facility. Community members still have to travel far and expensive distances to access services that have strict operating hours. Women who use drugs require even more services than just methadone access to ensure uptake, support for organisations such as MEWA that caters for women who use drugs will greatly increase retention and reach of women in the programme.

COP19, can also support in filling gaps in the minimum package offered to key populations. Shortages of lubricants for the last year and access of PrEP only in certain counties have left KPs without access.

Communities would like to reiterate their support for an IBBS process without biometrics in order to capture all the information necessary to programme for KPs. As we await the second phase of the IBBS, the first phase shared the

first target numbers for Kenya's transgender population at 4,000. COP19 must start providing services for transgender communities and increase the KP targets using the UCSF data with allows of increased targeting for KP service delivery.

For the programme to achieve its goal in KP prevention and service delivery, the reduction in funding for KP needs to be reviewed against the level of prevalence and incidence, gaps in service delivery, the new emerging data on transgender people, the successes of the programme (reaching the target of 29,000 MSMs despite fears of over programming) and the second phase of the IBBS. An increase back to the USD 16 million threshold plus an increase to allow for the expansion of the programme in necessary to achieve epidemic control among key population.

COP19 must fund transgender programming for a target of 4,000 people. The programme must increase the KP programme funding lines to USD 20 million to ensure quality and increased services for key populations. The programme must upgrade/ support 7 new key population led service delivery organisations to comprehensive service delivery units. The programme must fund mobile outreach for MAT clients in 3 MAT counties and one programme for women who use drugs to increase access. The programme must continue to fund an IBBS in order to capture all the data required for sufficient programming for KP service delivery.

8. Implement a system at 100% of PEPFAR sites to ensure that facilities can track patient transfers—including all medical records.

All facilities had test and start as a policy for all, but actual implementation of this for individuals newly diagnosed was dependent on the distance they live from the facility and the willingness of the individual to start treatment at the same facility where they were tested. Initiation to treatment and services was only immediate if the individual was being initiated at the same facility that testing took place in. Linkage became more complicated if the individual was tested but wanted to be linked to another facility—requiring a lengthy referral process. Ensuring the community testing strategies include the provision of an HIV starter pack, and allow those found positive to immediately be offered treatment as community health workers prepare to refer them to the facility, is key to ensuring immediate ART initiation to treatment for the willing.

Another challenge identified at the facility is self-transfers of patients, and the challenge of accessing services and doctors review when out of town on clinic due dates. Clinicians spoke of healthcare users accessing medicines at facilities other than their own, unknown to them unless they disclose that information to them. Strengthening of this referral system is critical to ensure that individuals are rapidly linked to care in an appropriate facility to meet their needs. Facility Electronic Medical Records (EMRs) need to be up to date and functional in order to ensure that facilities can keep track of transfers, and to ensure that people missing appointments or lost to follow up are not mistaken as self-transfers and are tracked on time.

COP19 must implement a system at 100% of PEPFAR sites to ensure that facilities can track patient transfers—including all medical records. This will allow better differentiation between transfer (and self transfer) and missed appointments due to loss to follow up.



9. Reduce TB mortality (the leading cause of death amongst PLHIV) by upscaling interventions aimed at preventing and diagnosing active TB cases - and reducing medicine stockouts.

9a. Improve TB infection control measures and ensure TB screening and testing in 100% of PEPFAR supported sites.

TB can be spread through the air when people with active TB disease cough or sneeze. However, various infection control measures can be taken to reduce the risk of TB transmission. TB infection control is critical to reduce the spread of TB and DR-TB in Kenya. The results of TB infection control assessment was variable, however some sites performed extremely poorly—with limited ventilation. "All 7 of us sit in this room and this is where we provide TB services even to MDR TB cases" said a nurse in Othoro Sub County Hospital. In Siaya county, people with MDR TB still have to travel to Kisumu and Homabay to access services due to the lack of an isolation room in the county.

PEPFAR must carry out a full audit of all PEPFAR funded health facilities to assess whether sufficient TB infection control measures are in place based upon WHO guidelines. PEPFAR must publish the audit results and use them to ensure turnaround plans in poorly performing sites. PEPFAR must:

- + Ensure that people are routinely and universally screened for TB symptoms upon arrival at the facility—people with symptoms should be referred for testing;
- + Procure and distribute masks and TB posters (explaining how to cover your mouth when coughing and what symptoms are related to TB) to all sites;
- + Ensure that TB infection control posters are displayed in visible places in the waiting area;
- + Ensure that all windows in all PEPFAR sites are kept open
- + Ensure that all healthcare users attending the facility are screened for TB symptoms on arrival—those with TB symptoms should be seen first to reduce the risk of transmission, and those coughing should be separated from those who are not while waiting;
- + People who cough a lot or who may have TB to be given tissues or TB masks.

GeneXpert MTB/RIF Ultra should be the initial TB test in all PLHIV and their household and other close contacts, including HIV-negative persons with TB symptoms. Training and equipment necessary to obtain specimen samples from children for ultra testing and culture, and to support clinical TB diagnosis among the 80% of children with TB in whom microbiological confirmation cannot be achieved, should also be supported by PEPFAR. Training and tools to rule out active TB disease should be supported by PEPFAR, especially for groups in which existing TB diagnostics have limited sensitivity (PLHIV and children)— this is especially important for initiating people at risk of TB on TPT (see section 9c).

GeneXpert platforms at PEPFAR sites can be used for TB

diagnosis, viral load monitoring, and early infant diagnosis. At sites where pregnant women, infants, and children present for care, it is important for PEPFAR to ensure ultra availability, given increased risk of TB among infants and children and the poor performance of symptom-based TB screening among pregnant women with HIV.

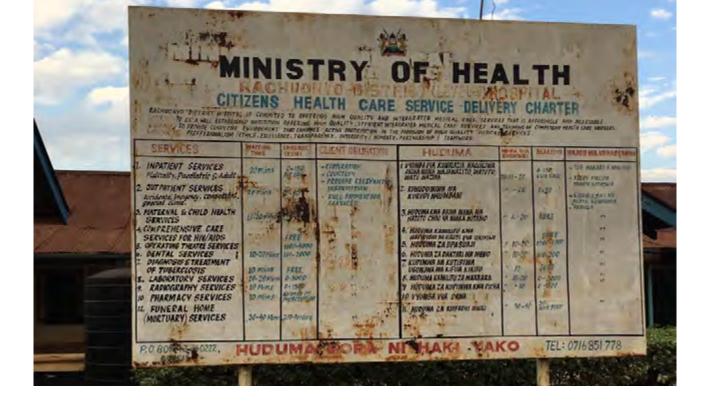
Diagnosis of TB was interrupted last year by a GeneXpert cartridge stockout that lasted several months. This was due to regulatory barriers caused by the new policy on preexport quality checks of manufacturing plants for each order and delays in ordering the cartridges¹⁴ supported by the Global Fund. As a result, the Government responded to the cartridge stock out by reverting back to microscopy for TB testing¹⁵; which is a significantly insensitive test, in comparison to GeneXpert, especially in people living with HIV and children leading to missed TB diagnosis. The stockouts affected high volume service delivery points such as Mbagathi District Hospital¹⁶ and lower level health facilities, further away from the capital. PEPFAR must ensure that all sites are fully stocked with GeneXpert cartridges to ensure all people with TB symptoms are able to access a TB test.

In COP19, PEPFAR must carry out a full audit of all PEPFAR funded health facilities to assess whether sufficient TB infection control measures are in place based upon WHO guidelines. Results must be published and used to ensure turnaround plans in poorly performing PEPFAR sites. COP19 should fill the human and other resource gap to ensure that 100% of PEPFAR sites screen every patient for TB upon arrival at the facility. People found to have TB symptoms should immediately be separated from those without TB, and provided with tissues and/or masks to prevent the spread of TB. People with TB symptoms should receive TB testing with GeneXpert MTB/RIF Ultra those diagnosed with TB should be started on treatment; people in whom active TB is ruled out should receive TPT.

9b. Scale-up access to TB LAM testing in outpatient settings at all hospitals in PEPFAR districts.

The TB LAM test is an affordable, quick and easy to use point of care TB urine test for people living with HIV. It requires no electricity or reagents and the results are ready in 25 minutes. Studies show that it allows earlier TB diagnosis in people with advanced HIV, and reduces TB mortality¹⁷. Although the WHO recommended TB LAM use in those with CD4≤ 100 cells/µL in 2015, TB LAM has also been

^{14.} Oketch A. Kenya: Alarm as TB Testing Gadgets Run Out of Stock in Public Hospitals. Daily Nation. [Newspaper online]. 2018 Nov 16 [Cited 2019 Feb 20]. Available from: https://allafrica.com/stories/201811160090.html
15. Saya M. Hospitals have cartridges for printing TB results, says ministry. The Star. [Newspaper online]. 2018 Nov 19 [Cited 2019 Feb 20]. Available from: https://www.the-star.co.ke/news/2018/11/19/hospitals-have-cartridges-for-printing-tb-results-says-ministry_c1852347
16. Michira M. Crisis at Nairobi's biggest public hospital. [Newspaper online]. 2019 Jan 10 [Cited 2019 Feb 20]. Available from: https://www.standardmedia.co.ke/article/2001308982/crisis-at-nairobi-s-biggest-public-hospital
17. "Effect on mortality of point-of-care, urine-based lipoarabinomannan testing to guide tuberculosis treatment initiation in HIV-positive hospital inpatients: a pragmatic, parallel-group, multicountry, open-label, randomised controlled trial". The Lancet. Available at: http://thelancet.com/journals/lancet/article/PIIS0140-6736%2815%2901092-2/fulltext



demonstrated to be effective in those with CD4<200 cells/ μ L and a separate prospective observational cohort study of both ambulatory and hospitalised HIV-positive adults in Kenya indicated the utility of expanding TB-LAM testing to people with CD4<200/mm3 to increase diagnostic yield¹⁸.

The Kenyan HIV guidelines recommend TB LAM LF for people living with HIV with advanced disease (including CD4<200 cells/ μ L) in both inpatient and outpatient settings. Recent national HIV¹⁹ and TB guidelines also recommend the use of TB LAM, and in November 2017 the Government of Kenya pledged to allocate USD 300 000 to roll out TB LAM²⁰—but the test has not been rolled out nationally. COP18 only procured limited stocks of TB LAM for hospitalised patients, despite the test being an important component of care for people living with HIV. Based on available evidence, COP19 should ensure that TB LAM test is available for use in all outpatient settings.

COP19 must fund for procurement of TB LAM and distribution of TB LAM tests and related commodities (including urine cups & pipettes) together with information on use to all PEPFAR sites. COP19 should also support monitoring of utilisation to ensure demand creation for TB LAM.

9c. Ensure access to 3HP for 20% of PLHIV eligible for TPT.

TB preventive therapy (TPT) is proven to reduce morbidity and mortality among PLHIV, including PLHIV on ART. For this reason, TPT should be considered a routine and integral part of the HIV clinical care package. The WHO recently recommended a short course-rifapentine and isoniazid based therapy (3HP), which is taken weekly for three

months for people living with HIV above 5 years old and for children less than 15 years in high TB-burden areas²¹.

All PLHIV should be screened for TB with the outcome of this screening one of two mutually exclusive clinical decisions:

1) diagnosis of active TB and initiation of TB treatment; or

2) initiation and completion of TB preventive therapy.

All PLHIV diagnosed with active TB should receive household contact investigation to identify TB in their families and among their close contacts, with TPT offered to household members who screen negative for TB. Household contact investigation is especially important for preventing TB in young children who living in the same household as an adult with TB.

PEPFAR Kenya should aim to put a significant proportion (suggested 20%) of PLHIV who receive TPT on 3HP. While currently more costly than IPT, the 3HP regimen is shorter, safer, easier for people to complete, and has been shown to be as effective in preventing TB as IPT. Generic producers of 3HP are expected to enter the market soon, making it important for PEPFAR Kenya to lay the groundwork for transitioning more PLHIV to rifapentine-based TPT as the cost of rifapentine comes down and information on the safety of its use with dolutegravir becomes available (expected March 2019).

In COP19 Kenya has a target of putting 138,951 people on TB Preventive Therapy (TPT). PEPFAR should fund the provision of 3HP for at least 20% of the TPT target and support a buffer stock of fixed dose combination of CTX-INH-B6, marketed as Q-TIB.

COP19 must fund 3HP for 20% for the TPT target. COP19 must also support household contact tracing and expand provision of TPT to eligible household contacts of PLHIV with active TB, with a special emphasis on reaching young children.

18. Huerga H, et al. Incremental Yield of Including Determine-TB LAM Assay in Diagnostic Algorithms for Hospitalized and Ambulatory HIV-Positive Patients in Kenya. PLoSOne. 2017 Jan 26;12(1):e0170976. doi: 10.1371/journal.pone.0170976 19. In a meeting with WHO, HIV department, they advised that we assume about 33% of people living with HIV will have a CD4<200 cells /μL) and we have used that percentage calculate the estimated need of LAM. 20. Suleiman K and Kibuchi E. A win for TB-HIV coinfected patients in Kenya. TBCAB. [Online]. 2017 Nov 24 [Cited 2019 Feb 18]. Available from http://www.tbonline.info/posts/2017/11/24/win-tb-hiv-co-infected-patients-kenya/ 21. WHO. Guidelines on the management of latent tuberculosis infection. [Online]. 2015 [Cited 2019 Feb 20]. Available from: https://apps.who.int/iris/bitstream/handle/10665/136471/9789241548908_eng.pdf?sequence=1

PRIORITY INTERVENTIONS

COP18 & DATA LANGUAGE TO INCLUDE IN COP19 TARGET

1a. Invest in at least 1,000 additional frontline professional healthcare workers in PEPFAR priority counties.

"Human Resources for Health (HRH): Kenya has inadequate capacity to meet all local staffing needs at facility and community level. HRH management capacity at national and county government levels remains limited for achievement of PEPFAR service delivery targets. Support to engage professional unions and strengthen capacity for negotiations is needed to minimize ongoing labor disputes and avoid disruption of services." (COP p18).

HRH_ Curr has seen a reduction from FY17 39,838 to 22,089. This may have been attributed to rationalisation measures proposed for FY18 and well as improvement in reporting. (POART Q4 2018)

In COP19, PEPFAR will fund the deployment of 1,000 professional healthcare workers across PEPFAR sites. Human resources for health management approaches will include county level HRH units support to ensure efficient health workforce utilization at community and facility level, health workforce training to ensure quality of service providers.

Target: Fund 1,000 additional frontline professional healthcare workers.

1b. Invest in an 5,000 additional outreach workers in the five highest burden PEPFAR supported counties to provide HIV and TB services in the community.

"Facility and targeted community outreach strategies will be used to identify individuals living with HIV among KP and other targeted groups (children <15 years, youth, and men 25+ years) through high yield HTS modalities, scale up of partner notification services and index client testing populations." (SDS p50) COP19 will fund an expansion of an additional 5,000 outreach workers, to increase community outreach and quality of adherence and retention of clients. These lay health workers will be formally paid, trained, capacitated, and equipped with communications and transportation needed to be effective.

Target: Fund 5,000 additional outreach workers in the five highest burden PEPFAR supported counties to provide HIV and TB services in the community.

1c. Ensure 100% of PEPFAR supported sites have functional group models of care including Community ART Groups (CAGs), as well as fast track models of care such as Community Drug Distribution Points (CDDP) by end of COP19.

"PEPFAR Kenya has been implementing differentiated service delivery models since 2017, which has reduced the transaction costs for patient travel to facilities, Increased peer support and community involvement, reduced workload form he health worker's perspective and has maintained and improves patient outcomes. As part of patient centered care, treatment literacy will continue to be offered to stable patients in differentiated models including multi-month prescription, fast tracked patient flows and the option of community ART pick up. PEPFAR will work to ensure there is adequate linkage between the facility and community for both data capture and referrals." (COP p19)

PEPFAR will support the establishment and functioning of community ART groups (CAGs) and community drug dispensing points (CDDP) in all PEPFAR sites to both ease the burden on health workers, and increase retention by reducing time spent at the facility and distance travelled by those stable on ART.

Target: 100% of PEPFAR sites will have CAGs and CDDP models for ART delivery as well as support groups running by end of COP19 and will report portion of patients in CAGs and CDDP for PLHIV stable on ART.

2. Maintain investment in the Prevention of Mother to Child Transmission (PMTCT) programme to test 60,000 pregnant women for HIV in COP19.

"In COP 2018 (FY19), PEPFAR will continue to provide technical support and direct PMTCT service delivery through implementing partners that cover 65% (3,728/5,769) of health facilities within the 47 counties. These health facilities provide antenatal care to 1,218,514 (74%) of the 1,656,858 expected pregnancies and 83% of the 79,477 HIV infected pregnant and breastfeeding women in Kenya. The majority (82%) of these women will be in the scale up counties. HIV testing and ART uptake will continue to be optimized, aiming to at least maintain 98% achieved in FY17." (SDS p39)

PEPFAR will maintain a minimum PMTCT target of 60,000 women to be reached in COP19. This will ensure ongoing success of the program in reaching women and contribute to the success of DREAMS, APN and EID.

Target: (At a minimum) reach 60,000 women through PMTCT in COP19.

3. Invest in TLD transition for women of reproductive age to improve retention and treatment outcomes.

"Roll out of DTG-containing regimens as the preferred first line ART will be introduced in FY18 and scaled up in FY19 for all eligible populations including children ≥ 10 years and ≥ 30 kilograms, DTG boosted TLD in HIV associated TB patients, pregnant and breastfeeding women. The first consignment of TLD is already in country in preparation for patient transition. It is expected that most patients on first line will have been transitioned to TLD within 8 months of the roll out." (SDS p47)

TLD Stock Status (1st Nov, 18)

- Received: 4,812,443 packs
- Issued: 338,616 packs

PRIORITY INTERVENTIONS.

• SOH: 4,428,827 packs (Source: KEMSA LMIS) (POART Q4)

COP19 will support full roll out of TLD optimization among women of reproductive age. PEPFAR will work with the Ministry of Health to ensure that a circular is shared to all health facilities on the implementation of guidelines, the benefit and risk of different regimens, and the requirement to provide women on a choice to transition to or initiate on TLD. Clinicians will be trained on the need to allow women to make an informed choice for TLD initiation/transition. COP19 will support the staffing and commodities needed to ensure that all women have the option to utilise a family range of family planning options upon request. COP19 must provide the financial and other resources necessary to ensure a major upscale of treatment literacy in the country. PEPFAR will fund at least 5 community lead PLHIV organisations to carry out this work.

Target: All women of reproductive age who choose TLD will be transitioned by end December 2019.

4. Improve timely diagnosis of perinatal HIV with point of care (POC) testing and scale up optimised HIV treatment for infants.

"There will be efficient utilization of existing equipment through the national laboratory network, and adoption of (near) point of care testing for EID using the GeneXpert machines in line with the national policy that is in development. COP 18 will support the ongoing discussion on the use of the GeneXpert platform for EID testing and capacity build PEPFAR supported sites on the testing and algorithm to ensure maximum utilization of the available testing capacity." (SDS p48)

The program will support and fast track funds to partners to ensure reduction in gaps in the EID POC program. COP19 will cover the gap of USD 302,500 from July to Dec 2019 and USD 605,000 annually from 2020 in EID point of care support. PEPFAR will also fully fund an immediate scale up of lopinavir/ritonavir based ART for children <20kg and DTG based regimens for children >30kg.

Target: Fund the cartridge gap of USD 302,500 from July to Dec 2019 and USD 605,000 annually from 2020.

Target: All children >20kg will get dolutegravir 50mg; all children >10kg can swallow whole tablets will get lopinavir/ritonavir 100/25mg tablets; all children <20kh will get lopinavir/ritonavir granules / tablets/syrup.

5. Eliminate informal user fees at the facility for opportunistic infection (OI) treatment and biochemistry services affecting treatment and monitoring of patient response to ARV treatment.

No reference.

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COP19 will support rollout of biochemistry services to the five highest burden clinics to monitor toxicity, resistance and improvement of people's health. COP19 will support monitoring of the medicine supply chain to reduce stockouts and shortages of medicines at the facility level.

Target: All high volume facilities in high burden counties are supported to provide biochemistry.

Target: Support monitoring of the medicine supply chain to reduce stockouts and shortages of medicines at the facility level.

6. Find more men with HIV and improve linkage and retention by funding men only treatment days, expanding flexible opening hours and weekend clinics, men specific DSD models, and other strategies targeting men at 100% of PEPFAR supported facilities.

"As part of retaining men in treatment, Kenya plans to enhance peer support through male support groups led by expert patients, especially for those newly enrolled as well as those who are experienced on treatment, and establishment of male friendly corners in health facilities, a model that has demonstrated good results in Lesotho. In addition, Kenya will strengthen the peer mentor model, building on the success demonstrated by flexible clinic hours for men and leverage clinical decision support technology to track defaulters and those lost to follow-up, especially in high burden counties." (COP p27)

Kenya will find more men with HIV and link and retain them in care through targeted services at 100% of PEPFAR supported sites including: flexible and weekend opening hours; men only treatment days; and men only adherence clubs and support groups. Men only drop in days should be established in the highest burden districts.

Target: 100% of PEPFAR supported sites have flexible and weekend opening hours; men only treatment days; and/or men only adherence clubs and support groups by end COP19.

Target: Men only drop in days should be established in the highest burden districts. PRIORITY INTERVENTIONS - PRIORITY INTERVENTIONS - PRIORITY INTERVENTION

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"The focus in COP18 for HIV prevention and treatment services among KP is on optimizing coverage, improving program quality and responses to loss in both prevention and treatment cascades." (SDS p41)

Services will be expanded to reach women who use drugs (PWIDs) that will be monitored through a separate target. COP19 will support KP organisations to offer comprehensive services to improve access, timely linkage, improving viral suppression and increase target numbers for key populations.

COP19 will also support community organisation to offer adherence support peers, literacy among service provider on KP programming and work with KP led organisation to link KPs to KP friendly sites with KP peers for services. COP19 will also fund gaps in lubricant, PrEP, and outreach for PWID service delivery. Transgender population services will also be offered in 2019. PEPFAR will work with transgender communities to create a minimum package of service and choose service delivery points.

Target: The programme will support an increase of 5,000 MSM, 10,000 FSW and 4,000 transgender people with services in COP19.

Support upgrade/ support seven new key population led service delivery organisations to comprehensive service delivery units, three mobile outreach for MAT clients in 3 MAT counties and one program for women who use drugs to increase access.The **IBBS** in order to capture all the data required for sufficient programming for key population service delivery. Fund the gap in **lubricant** in the kp program.

8. Implement a system at 100% of PEPFAR sites to ensure that facilities can track patient transfers— including all medical records.

"The strategic objectives under the information systems approach include: enhancement of the health information systems (HIS) to address the entire spectrum of HIV service delivery; improvement of HIS solutions and capacity building of stakeholders to undertake HIS use; and strengthening of data quality and utilization and enhancement of the human resources information system (HRIS) utilization for workforce planning and allocation." (SDS p58)

PEPFAR Kenya will implement a system at 100% of PEPFAR sites to ensure that facilities can track patient transfers—including all medical records. This will allow better differentiation between transfer (and self transfer) and missed appointments due to loss to follow up.

Target: 100% of PEPFAR sites to ensure that facilities can track patient transfers— including all medical records.

9a. Improve TB infection control measures and ensure TB screening and testing in 100% of PEPFAR supported sites.

"Resources will be set aside...maintain proper TB infection prevention in health care settings, conducting surveillance of TB among health care workers; support routine TB screening and contact tracing in HIV, MCH, prison clinics and other hospital settings, diagnostic work-up and appropriate management as per the national TB guidelines; and monitoring and evaluation, including integration of the TB electronic recording and reporting system (TIBU, which also means "to cure" in Swahili) with existing electronic medical record (EMR) systems and provision of tools." (SDS p26-p27)

"To improve case detection, PEPFAR will support the integration of active TB case finding in HIV testing at all service delivery points" (SDS pg26)

"The GeneXpert® mycobacterium TB and rifampicin resistance (MTB/RIF) test is the initial diagnostic test for people living with HIV presumed to have TB. A total of 157 GeneXpert® machines have been installed in laboratories spanning each county in Kenya and a specimen referral network has been established to cover all HIV treatment sites countrywide. Efforts are underway to optimize machine utilization from the current 50% to 80%." (SDS pg26)

"Investments will concentrate on strengthening and expansion of the specimen transport networks for GeneXpert® testing and drug resistant TB surveillance; expansion of continuous quality improvement to cover GeneXpert® assay, smear microscopy and TB culture through external quality assurance including proficiency testing will be bolstered" (SDS p26)

In COP19, PEPFAR will carry out a full audit of all PEPFAR funded health facilities to assess whether sufficient TB infection control measures are in place based upon WHO guidelines. Results must be published and used to ensure turnaround plans in poorly performing PEPFAR sites. COP19 will support the purchasing of N-95 respirators so that health workers are protected from TB and carry out bi-annual TB screening of health workers.

COP19 will use GeneXpert MTB/RIF Ultra as the initial TB diagnostic test for all people who screen with TB symptoms, and support training and equipment necessary to obtain specimen samples for Ultra testing and culture from adults with possible extrapulmonary TB and children for Ultra testing and culture, and to support clinical TB diagnosis in children.

COP19 will ensure that the outcome of TB screening results in one of two mutually exclusive decisions: 1) people diagnosed with TB should be started on treatment; 2) people in whom active TB is ruled out should receive TPT.,

In COP19 will ensure that PEPFAR funded GeneXpert cartridges are exempt from pre-export validation checks which are costly, time-consuming and lead to stockouts as observed in 2018.

Target: 100% of PEPFAR supported facilities will have good TB infection control measures in place, as found with spot checks, by end COP19.

Target: N-95 respirators are provided for all health and community workers that consult with TB patients; and all health workers will be screened for TB in COP19.

Target: 100% of people presenting for care screened for TB using TB symptom screen and, where indicated, chest X-ray.

100% of people with TB symptoms identified during screening tested for TB are tested using GeneXpert MTB/RIF Ultra, including children.

COP18 & DATA LANGUAGE TO INCLUDE IN COP19 TARGET

9b. Scale-up access to TB LAM testing in outpatient settings at all hospitals in PEPFAR districts.

"To improve case detection, PEPFAR will support the integration of active TB case finding in HIV testing at all service delivery points, procurement of limited stocks of TB urine lateral flow lipoarabinomannan assay (TB-LAM) for hospitalized patients and support the development and operationalization of a revised TB diagnostic algorithm that includes HIV testing of all presumed TB patients" (SDS p26)

COP19 will make LAM testing available in all settings where people living with HIV present for care, including both inpatient and outpatient settings. In inpatient, hospital settings, PEPFAR will use TB LAM as a screening test in all hospitalized patients with HIV. In outpatient, ambulatory setting will provide LAM testing to all people presenting to care with clinical signs of apparent serious illness, or, if CD4 testing is available, with CD4<200 cells/µL or with clinical signs of apparent serious illness. COP19 will support training in the use of TB

LAM and ensure the procurement of required commodities (TB LAM Ag urine assays, urine cups, pipettes, pipette tips, timers) within laboratory costs. PEPFAR Kenya will also support sensitization of health care workers on the utility of TB LAM and its place in the TB diagnostic algorithm. Task sharing should be considered as the test is easy enough to be conducted by nurses.

PEPFAR Kenya will preferentially support the use of more sensitive TB LAM tests, if they become available and are recommended by WHO within COP19.

The estimated cost of TB LAM in Kenya is USD 1.7 million (this excludes consumables and training), this will cover 429 000 TB LAM tests.

Target: LAM testing provided to 100% of people living with HIV who are hospitalised.

LAM testing provided to all people living with HIV presenting to care in outpatient settings with signs of advanced illness or with CD4<200 cells/µL or with signs of advanced illness [i.e., 33% of TX_NEW target].

9c. Ensure access to 3HP for 20% of PLHIV eligible for TPT.

"In COP18, PEPFAR will support provision of IPT to patients not previously on preventive therapy and initiate 90% of newly enrolled patients." (SDSpq26)

"PEPFAR will continue to support forecasting and quantification for IPT commodities, printing of tools and evaluation of the impact of IPT on the HIV-TB epidemic. To improve case detection, PEPFAR will support the integration of active TB case finding in HIV testing at all service delivery points, procurement of limited stocks of TB urine lateral flow lipoarabinomannan assay (TB-LAM) for hospitalized patients and support the development and operationalization of a revised TB diagnostic algorithm that includes HIV testing of all presumed TB patients. Investments will concentrate on strengthening and expansion of the specimen transport networks for GeneXpert® testing and drug resistant TB surveillance; expansion of continuous quality improvement to cover GeneXpert® assay, smear microscopy and TB culture through external quality assurance including proficiency testing will be bolstered." (SDS p26)

"In COP18, PEPFAR will support provision of IPT to patients not previously on preventive therapy and initiate 90% of newly enrolled patients. Concurrent efforts will build the capacity of site level staff on topics including the identification, management and reporting of adverse drug reactions and other events. In addition, PEPFAR will support the GF evaluation of IPT and TB screening cascades and outcomes in various TB-HIV integration models and use the results to improve the quality of services" (SDS p26)

TPT for adults: PEPFAR KE will support the GoK scale-up TB preventive therapy (TPT), ensuring that all people living with HIV newly enrolled into care who screen negative for active TB disease initiate and complete a course of TPT. All people living with HIV in PEPFAR KE programs newly diagnosed with active TB disease receive household contact investigations of their families and close contacts, with household contacts offered TPT.

PEPFAR KE will pilot the use of the short-course, rifapentine-based 3HP regimen as an alternative to isoniazid preventive therapy (IPT) for 20% of people living with HIV started on TPT, pending confirmation that rifapentine is safe to use with dolutegravir. Individuals receiving IPT will receive the fixed-dose combination of isoniazid/cotrimoxazole/B6 (Q-TIB).

TPT for children: PEPFAR KE will support contact investigations for all people living with HIV diagnosed with active TB disease. Children of people living with HIV with TB identified by contact investigations will be offered TPT with the regimen determined by HIV status. HIV-negative children will be offered the 3HR regimen, which is available as a child-friendly FDC. Children with HIV will be offered 3HR (if on EFV-based ART) or 6HIPT (if on nevirapine, lopinavir-ritonavir, or dolutegravir-based ART). 6H IPT is also available in a child-friendly dispersible tablet. (3HR = three months of daily isoniazid + rifampicin; 6H = six months of isoniazid preventive therapy)

PEPFAR KE will integrate training on TPT initiation and adherence support into preparations to rollout dolutegravir-based ART, recognizing that TB prevention is a routine and integral part of the HIV clinical care package.

Human Rights and Stigma: PEPFAR KE will

ensure that TPT implementation respects human rights and minimizes stigma. In particular, that TPT initiation is always voluntary, introduced with full information and proper counselling on the risk/benefits, and never mandatory. Contact investigations should be designed and carried out in a way that minimizes the potential impact of stigma in the community (e.g., identifying a household as having TB or disclosing the TB or HIV status of a people living with HIV without their consent).

Target: 138,951 people living with HIV initiate and complete TPT within COP19. Of these, at least 20% (27,790) should receive 3HP.

PEPFAR should fund at least USD 1.3 million for 3HP to be provided to people living with HIV and fund 100% of people living with HIV diagnosed with active TB disease (TX_TB) receive household contact investigation of family and close contacts.

All children <15 identified through household contact investigation (TX_TB x 2) screened for TB, and either initiate placed on TB treatment or initiated on TPT.









































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