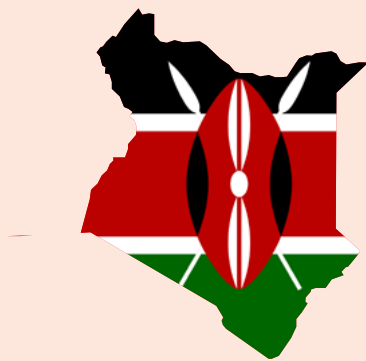


# PEOPLE'S COP20 KENYA

**COMMUNITY PRIORITIES**

**PEPFAR COUNTRY OPERATIONAL PLAN 2020**





# INTRODUCTION

In the second year of the People's COP, PEPFAR Kenya increased the number of people living with HIV identified by 175,858 and offered treatment to 142,330 (FY2019). However, the program continued to be plagued by linkage and retention challenges with only a net new of 59,018 people by the last quarter, a key indication of a need to invest in retaining people living with HIV on treatment.

In total, Kenya has an estimated 1.6 million people living with HIV (a prevalence of 4.7%)—yet only 1.1 million of those people are taking life saving HIV treatment, leaving 31.25% of people without access.<sup>1</sup> In 2018 alone, 25,000 people died unnecessarily from AIDS related illnesses—and a further 46,000 people newly acquired HIV.<sup>2</sup> While Kenya is on track to reach epidemic control, more needs to be done to address the remaining gaps in the 1st 90 for all the populations and the 3rd 90 for children especially as the country is witnessing an increase in mother to child transmission.

In 2019, the PEPFAR program cut over US\$100 million from the Kenya program in a bid to push toward efficiency and cost effectiveness, however, the cuts ended up having major negative impacts on sustaining and improving not only the reach of the program, but more importantly the level of quality of service delivery. These cuts ultimately ended up massively undermining progress made towards national targets. Indeed, civil society witnessed these negative impacts firsthand, most acutely around human resources for health, a critical component of the program and the healthcare system overall needed to support the retention of clients to treatment and key population service delivery.

The PEPFAR program's introduction of a targeted testing approach seemed to address only half the issue. The program aimed at identifying those at most risk, but now proposes to reduce support for test kits. If COP20 continues with this irrational approach, the program will do little to reach testing targets and get positives on to treatment. Also the more successful the program is in identifying new positives, the harder it becomes to identify the remaining people living with HIV. The program will need to create a minimum number of allowable tests to ensure that implementers are able to target tests but not cripple the testing program.

The Kenya Population Based Impact Assessment (KENPHIA)

data that would have greatly shaped the COP20 discussions and given better insight into the remaining gaps are still yet to be released, and as communities, we are concerned about the delays and most importantly the opportunities we are losing to respond to the epidemic with real time data. Anecdotal data from the KENPHIA shows that children between the ages of 0-14 have a testing rate of 78.9% and a viral suppression of 67.1%—both unacceptably low rates that require more attention and investment. Identification, testing, treatment and retention among children living with HIV and retention services need to be a core part of the interventions funded by PEPFAR in 2020.

In support of Kenya's goal to reach the 95-95-95 targets, we offer this "People's COP"—outlining Kenya's community recommendations and priorities for COP20. These recommendations were developed by people living with HIV and health activists through analysis of FY18 and FY19 data, community dialogues as well as community-led monitoring in December 2019 and January 2020 to four PEPFAR-supported facilities in four high burden counties: 1) Siaya (Bondo District Hospital), 2) Homabay (Rachuonyo District Hospital), 3) Kisumu (Lumumba Sub County Hospital), and 4) Nairobi (Mbagathi District Hospital). This mission aimed to assess the state and quality of HIV and TB service provision at the facility level, through a series of questions targeting health providers and service users. Community-led monitoring also assessed the implementation of COP19 following the cuts to the Kenya program budgets. The results of this data collection are described below and provide not only evidence of the reality of what's happening on the ground, but also justification for our community recommendations. The People's COP has been further shaped following consultation with PLHIV, key populations, community based organisations (CBOs), Non-Governmental Organisations (NGOs), and Faith Based organisations (FBOs)—all stakeholders with collective experience at the forefront of Kenya's HIV and TB response.

1. UNAIDS Kenya country factsheet 2018

2. Ibid

# PRIORITY INTERVENTIONS FOR COP20

## 1. Increase the budget for the overall PEPFAR program by US\$60 million to ensure quality service delivery across the program.

PEPFAR needs to invest more resources in the Kenya program to ensure that the country does not regress on successes previously achieved. Reduction in funding for test kits, and for programs for men, key populations and human resources will not allow the program to make progress. The gaps resulting from the reduction of funding in COP19 were visible for communities especially when retention officers and peer health workers offering support to programs to retain and link clients were fired. The key population program was not spared despite being the only program with an increased budget at the end of COP19 planning. Local key population-led organisations lost funding meant to fill in the key population program gaps to the general program. Key population led implementing partners are still yet to receive funding from the larger new implementing partners funded by COP19.

This year's planning letter reduces the amounts allocated to the key population program further down to US\$10 million from the previous US\$18.4 million further limiting the capacity of the implementers to subgrant funds to local organisations with the expertise and presence to reach KPs.

The Global Fund's investment in the country has risen but only provides support in three-year cycles and is still significantly lower than the investment by the PEPFAR program. The Global Fund is unable to absorb all the gaps being left behind by the current proposed PEPFAR program.

***COP20 must reverse funding cuts and increase funding by US\$60 million to the overall program to ensure the maintenance of current successes and to improve the quality of service delivery.***

### 1b. Revise the proposed reduction in test kits and support 7 million test kits and track self test kits to maintain the program capacity to identify undiagnosed people living with HIV.

The planning letter rightfully mentions missing communities including men and young people and the need for the program to find these populations, however, the planning

letter then restricts the purchase of test kits. Data across the country is showing an increase in mother to child transmission in counties including PEPFAR funded high burden counties eg. Nairobi.<sup>3</sup> Some of the mothers are potentially young people who ideally need to know their status before they are pregnant. Test kits will not be available for them. The implementers will also face challenges when the partners of the pregnant women come to the facilities for index testing and they do not have test kits. While the planning letter highlights investments in testing among pregnant mothers, linkage and adherence to medication to ensure a reduction in transmission and an increase in the diagnosis of children living with HIV will also be critical to ensuring mothers are supported across the cascade. The program needs an increase in test kits from the proposed numbers to ensure all populations are able to access testing. Overtesting is an issue but the current proposal greatly reduces the programs capacity to increase knowledge of HIV status among the undiagnosed.

Self test kits have been a great addition to reach people who are difficult to reach with services but tracking those returning to the facility after a positive outcome is difficult. Self test kit numbers should be disaggregated from normal test kits to ensure that targets are based on trackable numbers of test kits.

***COP20 must increase test kits from the current proposal of 3 million to 7 million test kits and only track positives for tests conducted using the normal routine test kits.***

3. <https://www.the-star.co.ke/counties/nairobi/2020-01-26-nairobi-hiv-mother-to-child-transmission-cases-rise-to-113-per-cent/>



## 2. Put in place measures to ensure that index testing does not lead to intimate partner or other violence, or forced disclosure of PLHIV's status'

Civil society in Kenya together with other partners across the world expressed concern that the high targets set for the index testing program, along with expectations of high positivity rates resulting from index testing, violated human rights, confidentiality and put people at risk of violence. Civil society also raised concerns that index testing programs do not have adequate measures in place to prevent and monitor adverse effects associated, including intimate partner violence (IPV).

In Kenya, our monitoring revealed that health workers only asked questions about violence before they tested the clients, and that reports of violence were often ignored in favour of targets. Once contacts were elicited and partners contacted, none of the facilities followed up with clients to track if they had faced violence as a result of reaching out to their partner.

Screening for violence and ignoring responses to a client's capacity to face violence is dangerous and unethical. In COP20, PEPFAR must implement index testing with rules that ensure the rights of people living with HIV are not violated.

"The SDS 2019 states that "Kenya is developing a guidance document for index testing expected in June 2019 that includes consent procedures and confidentiality are protected and monitoring of intimate partner violence (IPV) is ensured through a screening process. We do not test people with a risk of IPV." The guidance is yet to be finalised." Civil society must be involved in the development of the certification processes for restarting index testing and in the implementation of monitoring.

In theory, index testing has the ability to help identify individuals who may have been exposed to HIV earlier, thereby protecting their health and interrupting onward transmission of HIV by enrolling people into effective treatment. It can also be aggressively implemented in ways that can cause harm to individuals, undermine their rights to consent, privacy, safety and confidentiality, and can erode the trust of communities with healthcare providers.

**All index testing programs should be immediately paused** while risk mitigation and mediation efforts are put in place. Civil society rejects any PEPFAR guidance that only key

populations (KP) programs need to deal with this issue or that index testing is only halted for members of KPs. Many KPs test in general population health facilities where disclosing their partners may risk discrimination and violence. Cisgender women and adolescent girls and young women (AGYW) face equally high risk of adverse events related to index testing. Their needs will not be met by KP-specific interventions.

*COP20 must not contain any targets that a percentage of people newly diagnosed with HIV must come from index testing. COP20 must additionally ensure that before contacting the sexual partners of PLHIV, all healthcare providers ask if their client's partners have ever been violent and avoid contacting them if so in order to protect their client and after contacting the client's partner the healthcare providers must also check with the patient if they faced any violence due to the partner notification and refer them to the GBV centre if the answer is yes. Prior to (re-)implementing index testing in any facility, there must be adequate IPV services available for PLHIV at the facility or by referral and all patients who are screened should be offered this information. PEPFAR must ensure that index testing is always voluntary, for both sexual contacts and children, where clients are not required to give the names of their sexual partners or children if they don't want to. All PLHIV must understand that this is voluntary. Additionally, an adverse event monitoring system must be established that's capable of identifying and providing services to individuals harmed by index testing. If these demands are not or cannot be met by an implementing partner, index testing must not continue at the facility for any population.*

## 3. Increase funding for healthcare workers to ensure quality programming and better linkage. Fund an additional 6,000 outreach workers, transport reimbursements for community outreach and community support groups.

### 3a. Fund an additional 6,000 healthcare workers consisting of retention workers and community health volunteer workers to provide retention services at facilities and in the community.

As the program makes progress towards attaining epidemic control, investing in the quality of service delivery will be key to maintaining the success of the program. Healthcare workers are at the centre of that success.

In 2019, civil society recommended the increase of frontline health workers by 6,000 to improve the quality of services at the facility and community levels and increase retention. The program shared a US\$92 million spending budget for healthcare workers and committed to reducing testing staff by a third due to lesser numbers of PLHIV in need of testing, and to maintaining retention staff to ensure quality of service delivery.

Community monitoring found healthcare worker salaries declined by 26% (from US\$780 per month to US\$580 per month) by implementers in Kisumu, Siaya, and Homabay and an overall reduction in the number of healthcare workers previously

Version Aug. 2018



MINISTRY OF HEALTH

## MOH 731 PLUS PrEP SUMMARY REPORTING TOOL

County	NAROKI		
Sub-County	KIBERA		
Facility Name	BAGATHI		
MFL Code	12080		
Start Month/Year	JAN/2019	End Month/Year	

supporting retention. This is visible in PEPFAR's data as well. In FY18, the PEPFAR program in Kenya spent \$71.9 million on combined salaries for healthcare workers or contracted healthcare workers. In FY2019, such expenditures were reduced by 55% to \$32.7 million. This is before the \$100 million funding cut enacted as part of COP19 has even gone into effect. It is not news that Kenya faces one of the most serious human resource crises in the region, so the impact of these cuts around healthcare workers are felt intensely. Reduced salaries have demoralised and demotivated healthcare workers. Reduced numbers of healthcare workers means that less workers are taking on more, leading to overwhelmed and overburdened workers due to the increased workloads. Without an adequate number of healthcare workers who are paid a fair salary, good plans will be impossible to realise and targets unachievable.

We are particularly concerned about the reduction in retention staff at the facilities observed during the latest round of community monitoring. PEPFAR Kenya's main challenge is retention of those newly diagnosed and those on treatment as shown by quarterly data and reiterated in the planning letter. While not considered formal, professional healthcare workers, this group of workers serve as the glue between facilities, communities and individuals. They are an integral part of making the healthcare system work. Retention and community health volunteer workers not only serve to educate individuals and communities on HIV prevention and treatment (as well as TB), but they are also important agents for promoting testing, providing counselling and mental health assessments, linking PLHIV to services, finding those who have missed appointments and essentially filling gaps in tasks that facilities and facility staff do not have the resources, time and capacity to carry out. Kenya has utilised many outreach workers to supplement facility-based HIV service provision in the face of too few professional healthcare workers. PEPFAR has recognised their importance by investing in them as a way to provide services to an ever increasing number of PLHIV. Reduction of health workers who are at the frontline helping patients with their treatment only reduces the chances of increasing quality programming.

***COP20 must reverse funding cuts and increase funding to restore and increase health workers focused on retention. Implementers must restore salaries to their previous monthly amount particularly in districts with the highest HIV burden and the largest shortages of staff in order to fill capacity gaps and increase retention in the program.***

### **3b. Fund transportation for community outreach to find people living with HIV who are lost to follow up and require support to remain on treatment**

As the implementers responded to PEPFAR cuts, retention staff were greatly affected despite their importance in supporting outreach and finding those lost to follow up (LTFU). Community monitoring found that the seemingly small, but critical incentive for outreach workers are the minimal stipend they receive for finding people LTFU and bringing them to the facility. Prior to the cuts, these workers would receive a stipend of US\$2 for finding someone LTFU and providing some services (e.g education, counseling, reminders) even if the individual did not come to the facility; however, community health volunteers complained of no transport reimbursement and where there was transport reimbursement, monitoring revealed that these workers only get the stipend if those LTFU came to the facility. In some facilities, the outreach workers were not

reimbursed for months and had given up requesting for their money back and stopped doing outreach altogether. Some facilities provided bicycles, but either their outreach workers consisted of older women who are unable to use them or the geography covered by the facility were impossible to reach on bicycles. Communication for adherence counsellors to track those LTFU up is also varied across the implementing partners. Some provide funds to find those LTFU and others do not and volunteers have to use personal resources to find people.

For the program to ensure linkage, retention and quality programming PEPFAR needs to invest in adequate and appropriate transportation for outreach workers to be able to do their jobs properly and find people LTFU. The change in the stipend system has negatively impacted motivation among outreach workers resulting in less workers willing to continue to not be compensated and/or reimbursed. PEPFAR guidelines now consider a PLHIV "lost to follow up" after 30 days of missing an appointment representing a significant decrease from the previous guideline of 90 days. This change alone has therefore significantly increased the number of lost to follow up cases. Investment in finding clients is critical.

***COP20 must fund communication and transportation for workers supporting retention for at least four trips each month per retention staff. The funding must be standardised across the country to ensure that workers have enough resources to reach those lost to follow up. These workers should be rewarded for their hard work and contribution as an integral component of a functional healthcare system, ensuring linkage of PLHIV to care, treatment and other services and most importantly ensuring retention of PLHIV to treatment.***

### **3c. Invest in community support groups for people living with HIV at the community and facility levels.**

For the last 3 years, people living with HIV have been calling for funding for treatment literacy. The SDS made committed that "Partnerships will be fostered with PLHIV networks to roll-out Treatment Literacy focusing on the health benefits of 'early' HIV treatment and life-long adherence. This is because the majority of PLHIV who have disengaged from care or are LTFU have been clients new on ART." (SDS p39). However a number of questions remain on how and when this will be implemented.

No PLHIV or key populations organisations have been approached to date to implement community-led treatment literacy and support group interventions. Over the years, PLHIV have played a crucial role in supporting peers to remain on treatment. PLHIV-led community support groups have helped PLHIV to discuss challenges at the facility and to learn about new science and medication being provided at facilities all of which have increased demand and ensured retention. Our community monitoring supported community dialogues that yielded a wealth of information on challenges at the facility eg. lack of friendliness of staff, challenge with new initiatives such as UHC, reasons for dropping out of service etc. PEPFAR needs to invest in PLHIV community organisations that have been proven to successfully provide peer support to those on treatment.

***COP20 must fund 10 PLHIV community organisations to revive support groups for community members in need of education and support in at least five high burden regions of the country.***



## 4. Invest in key populations-led comprehensive service delivery by restoring funds from COP19 to the key population program and maintaining PEPFAR's Key Population investment for COP20 at US\$18.4 million

### 4a. Restore the US\$18.4 million investment to the key population program

After pushback from key populations (KP), last year's decision to not cut funding to KP programs and even increase the total amount over FY18 levels (by US\$2.4 million) brought on a huge relief to communities for and working with KPs. However, the supposed US\$18.4 million in dedicated funds to KP programs was not utilised as anticipated. In reality, community-led, on-the-ground monitoring efforts found that KP-specific programs only received about half or US\$9 million of total funding while the remaining US\$9.4 million was used to support general health facilities. PEPFAR bizarrely justified this split by assuming that KP programs would focus on finding cases and bringing them to the facility and then the facility would provide the rest of the services. As is evidenced across the world, KP-led programs are critical in reaching peers who do not have adequate access to HIV services due to stigma and discrimination they face from the formal healthcare system. In these many instances, KPs do not seek services from general facilities, but rather rely on KP-focused and -friendly programs to serve their needs. Community monitoring revealed similar shortcomings on KP service delivery in the general service delivery points where services still do not cater to KP and community members do not self identify at these points. All the facilities responded to questions on KP service delivery by stating that KPs reach service in KP sites and not that the general facility.

In COP19 not only did PEPFAR end up reducing much needed funding that KP community groups requested and needed to increase their reach into communities to find more KPs living with HIV, they also decreased the funding required to retain those who were already on treatment—while increasing the annual KP target, setting up an impossible task for implementers. Specifically, KP organisations serving MSM, sex workers, people who use drugs, and transgender people were defunded in COP19 in favor of larger implementers with little to no experience in finding and retaining KPs living with HIV and who refused to fund KP led organisations. These implementers claimed that they were not given authorisation to subgrant funds.

The PEPFAR planning letter for COP20 reduced the funding allocation for the key population program to US\$10 million. This reduction will lead to a further reduction in key population-led service delivery that is required for effective service delivery.

The reduced funding for KP programs has and will continue to result in less services for KPs, and a lack of achievement of targets. Most of the new positive client numbers are supposed to come from the MSM program as proposed in the 2020 planning letter and in COP19 targets, but since there is less money, targets will not be met.

**PEPFAR must increase KP program funding levels to US\$18.4 million to ensure that KP-led programs are able to get back on track with providing critical services to KP groups and meet targets.**

### 4b. Increase investment in community led service delivery, and community outreach.

The key population program must be allowed to program funds across the cascade to ensure a true tracking of achievements. Key population-led service delivery can achieve this. The current assumption that key populations once identified will be absorbed by the main healthcare system has been proven not to work and Kenya's health system is not equipped to track linkage and retention in the general health system without violating privacy and confidentiality and denying communities access to friendly services. The KP program is the only remaining stronghold of community-led service provision that is now being eliminated in favour of cheaper, less effective methods in order to save money in the program. The program risks losing all the gains made in the key population program and needs to reverse cuts urgently.

In Kenya, KP-led programs have been highly successful at reaching all KP groups with prevention and treatment, and maintaining HIV negative cohorts in a country where the KP prevalence is three times higher than in the general population. PEPFAR-requested improvements to reach HIV positive KP will only be realised if resources are given to community groups to reach and retain them.

**PEPFAR must keep its promise to key population communities and direct KP funds to KP -specific programs from the COP19 budget. KP-led organisations must be funded in COP20 to find and retain community members and show direct links to services for KP groups.**

### 4c. Increase investment in data protection and data on behaviour.

PEPFAR's efforts to ensure an ambitious program in Kenya despite a lack of current key population size estimates have proven successful and the team should be commended. However, the country needs the program to be focused on the epicentre of transmission and behaviour to ensure increased demand and access to services. A bio-behavioural study focused on behaviours and drivers of infection would be key to increasing demand among community members. The program should consider funding a study without the use of a biometric system after supporting policy on digital protections and data storage that protect the privacy and confidentiality of communities. The HIPAA Privacy Rule provides a great framework for this which includes training for all in the system, etc.

**COP20 must support data protection systems and after a bio-behavioural study for the key population program across the country without the use of a biometric system.**





**5. Ensure that women of reproductive age have access to TLD to improve retention and treatment outcomes and are able to make an informed decision to start/transition to a dolutegravir based regimen, and that PLHIV on DTG are tracked for weight gain and moved back to EFV if needed.**

DTG is a critically important antiretroviral medicine that is set to become the backbone of many countries HIV programs. 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. However, Evidence from new studies shows first-line DTG is associated with rises in body weight (mean change in weight at 96 weeks >5kg) for PLHIV on TAF/FTC+DTG, worse for women (mean change in weight at 96 weeks >10kg). Further it is associated with clinical obesity in men and women (ADVANCE and NAMSAL), and increased trunk and limb fat (ADVANCE). Further rises in body weight on TAF/FTC+DTG are progressive and do not plateau to 96 weeks in women (ADVANCE).

COP19 saw a shift in PEPFAR support for TLD in PEPFAR-funded countries. People living with HIV benefited from PEPFAR's push to change policy and the purchase of medication. Kenya also benefited from this change in policy, however, despite new guidelines being released in August 2019 and the PEPFAR 2020 planning letter recognising the country's change in policies to allow access to TLD, PEPFAR implementers are still yet to adopt and implement these policies. Community monitoring efforts and community dialogues revealed that PEPFAR implementers are still yet to offer TLD to women of reproductive age despite research showing that no new women have given birth to children with neural tube defects since

the 2018 observational study in Botswana. Women living with HIV stated that health workers and health talk experts are still telling women that the medicines are bad for their health.

PEPFAR must ensure the implementers allow women to access the new medication without discrimination, and while longer term follow-up and re-analysis of other studies is required to evaluate the consequences of weight gain and clinical obesity—in the interim PEPFAR should ensure that within its program, PLHIV are able to choose whether to start/or continue on an efavirenz based regimen or start/switch to a dolutegravir based regimen. Health workers must be trained on the need to allow PLHIV to make an informed choice for TLD initiation/transition. PEPFAR must also institute tracking of weight gain amongst PLHIV taking DTG and respond accordingly, including by returning people back to TLE (tenofovir-lamivudine-efavirenz) where necessary.

***COP20 must support full rollout of TLD among women of reproductive age. Clinicians must be trained on the need to allow women to make an informed choice for TLD initiation/transition. COP20 must support tracking of weight gain among women and respond accordingly, including by returning people back to an efavirenz based regimen where necessary.***

## 6. Invest in scale up of quality service for children living with HIV

### 6a. Improve timely diagnosis of perinatal HIV with point of care testing and scale up optimised HIV treatment for infants.

KENPHIA data shows a large gap in the treatment cascade for children who lag behind from knowledge of their status, to access to HIV treatment and finally retention. The PEPFAR planning letter also acknowledges the gaps in the cascade as areas of key concern in COP20.

Due to funding cuts from COP19, the PEPFAR program was unable to retain the EGPAF Early Infant Diagnosis (EID) point-of-care (POC) pilot that led to increased initiation of treatment of children with HIV from 43% to 93%. This pilot supported a system that enabled mothers to get test results for their babies within one hour of testing. Currently, data shared in the media and in government documents show there is a steady increase in new infections in the numbers of children in PEPFAR-funded and non-PEPFAR-funded areas. PEPFAR needs to support mothers across the country to adhere to treatment and reduce transmission. POC-EID will go a long way in diagnosing HIV positive babies and DTG access for children will ensure those with a positive diagnosis have access to quality treatment. PEPFAR should also work with healthcare workers at the facility and communities of women living with HIV to increase early visits to the clinic, treatment and retention support for pregnant women living with HIV.

***COP20 must fund the continuation of the pilot POC-EID system to improve early infant diagnosis across the country.***

### 6b. Make available optimised ARV for all infants and children living with HIV.

Inappropriate, suboptimal treatment options have contributed to low treatment coverage and retention for infants and children living with HIV. WHO recommends use of DTG based regimens for infants and children who meet the dosing criteria (>20kg) phasing out use of nevirapine based regimen for neonates and paediatrics. All the sites monitored had phased out nevirapine and the children were offered LPV/r-based regimens for infants and young children < 20 kg until DTG based regimens are readily accessible for them.

New paediatric formulations that are set to come out in 2020 will also ensure optimised treatment for paediatrics and children for whom approved DTG dosing is still unavailable. i.e those <20kg including the 4-in-1 granules ( contain ritonavir, lopinavir, abacavir and lamivudine) and DTG 10mg. We recommend in COP20 that in all infants and children are switched to DTG based regimens. Children <20kg should be initiated/switched on LPV/r-based regimens in the most friendly formulations, like LPV/r pellets or LPV/r granules or 4-in-1 as soon as this is available. Treatment literacy also should be provided for mothers of children living with HIV to improve case finding, treatment adherence and retention to care.

***COP20 must ensure DTG based regimens for all infants and children living with HIV within dosing criteria of >20kgs. LPV/r pellets must be made available for infants and children <20kgs who are struggling with taking the syrup. Health workers must be trained on the need to support treatment literacy for mothers of children living with HIV to improve case finding, treatment adherence and retention to care.***

## 7. Continue funding services for people living with HIV despite the proposed transition by the government to Universal Health Coverage

The Kenyan President has been championing Universal Health Coverage (UHC) and the government's goal to cover all associated costs internally without any donor or external funding. This is an ambitious goal that should be applauded. As a first step in transitioning to UHC, the government launched a pilot in four counties which came to an end in December 2019. Community monitoring found that for most of the counties, the pilot did not take off and was not fully implemented. In terms of HIV services, the only free service provided was consultation while for other critical services including laboratory services and treatment, PLHIV were referred to other facilities. Community monitoring also discovered that results citing its "success" were in fact not from the pilot but from Global Fund-supported services. No evaluation has been carried out yet to assess the pilot's results, effectiveness and impact. Without real evidence as to how the pilot was successful (or

not) in providing access to HIV services, communities believe that it is too premature for PEPFAR to consider it as a model for replication and/or expansion to other counties or for PEPFAR to shift funding away from core service needs for PLHIV. Kenya is not yet prepared to take on paying for the full needs of PLHIV, therefore PEPFAR should be encouraging that the pilot be fully implemented as intended. Community monitoring will continue to reveal where and how the pilot can be strengthened to ensure that PLHIV receive the full range of services needed.

***COP20 must continue to fund core services of PLHIV and to ensure PLHIV have uninterrupted access to the full range of services they need. The government pilot has not yet been proven to be a model of success and so PEPFAR shifting funds away from supporting core services is premature.***

## 8. Invest in TB service delivery including improving infection control in PEPFAR funded sites and scale up of 3HP for eligible PLHIV

### 8a. Support scale up of TB preventive therapy to all people living with HIV and initiate access to 3HP for 40% of PLHIV eligible for TPT

PEPFAR continues to recommend TB preventive treatment (TPT) as an integral and routine part of the HIV clinical care package for eligible PLHIV and children 5 years and younger. In COP19, PEPFAR scaled up TPT coverage, ensuring over 85% of PLHIV currently on ART received isoniazid preventive therapy (IPT) and increased TPT targets to 153,454 from 127,250. This increase shows a commitment by PEPFAR to ensure national scale up of TPT. However, Kenya still has a long way to go in improving TPT initiation and completion rates. In FY19, only 11 of 83 districts achieved or surpassed their TB\_ PREV target resulting in only 95,901 people completing a course of TPT out of a target of 153,454. In COP19, PEPFAR also noted that they were supporting policy change to facilitate access to the shorter, more patient friendly 3HP regimen among PLHIV in Kiambu county under the IMPACT4TB study but made little progress. This pilot is yet to begin.

The program needs to increase access to short-course, rifampentine-based TPT regimens (3HP, 1HP) as the preferred TPT regimens. As a result of the price reduction of 3HP from US\$45 to US\$15 per patient course, and the introduction of a second 3HP supplier to the market, PEPFAR is encouraged to increase the number of PLHIV to be initiated on 3HP to 40% of the overall TPT target.

*COP20 must ensure universal access to TPT for all PLHIV and eligible household contacts of PLHIV with TB disease, including children and all PLHIV complete a course of TPT. PEPFAR must start transitioning those eligible for TPT onto 3HP and initiate at least 40% of PLHIV on TPT/ 3HP. TPT and, in particular 3HP, must be incorporated within DSD models of HIV service delivery and 3HP scale-up should be linked to TLD transition.*

### 8b. Improve TB infection control measures and ensure TB screening and testing in 100% of PEPFAR supported sites.

One key driver of TB is people with symptoms being missed and remaining undiagnosed, a challenge faced by the PEPFAR program. Health centres, hospitals and PEPFAR sites should universally screen PLHIV for TB symptoms upon presenting for care. People with symptoms should receive testing with both urine-LAM and Xpert MTB/RIF Ultra, and should be separated from other people waiting at the facility to avoid further transmission. Tissues and masks need to be provided to people coughing.

*COP20 must carry out a full audit of all PEPFAR funded health facilities to assess TB infection control measures in accordance with WHO guidelines. Results must be published and used to ensure turnaround plans in poorly performing PEPFAR sites. COP20 must support the purchase of N-95 respirators so that health workers are protected from TB and carry out bi-annual TB screening of health workers.*

### 8c. Improve TB testing among PLHIV by supporting better placement of GeneXpert and urine-LAM tests and training for health workers at all PEPFAR funded sites

Despite the progress that has been made to diagnose and treat TB among PLHIV, low TB case detection and high (10%) TB/HIV case fatality remain a major concern. In COP 2019, PEPFAR Kenya pledged to support TB screening among PLHIV using GeneXpert and urine-LAM, and to strengthen and expand specimen transport systems to ensure rapid results of GeneXpert and culture testing. The urine-LAM test is the only test available that can rapidly and easily diagnose active TB in people living with HIV/AIDS, particularly those with advanced disease, and the only TB test shown to reduce deaths<sup>4</sup>. Using urine-LAM and Xpert MTB/RIF Ultra testing together increases the overall diagnostic yield and the chance of detecting TB among people living with HIV, compared to the individual use of either test<sup>5</sup>.

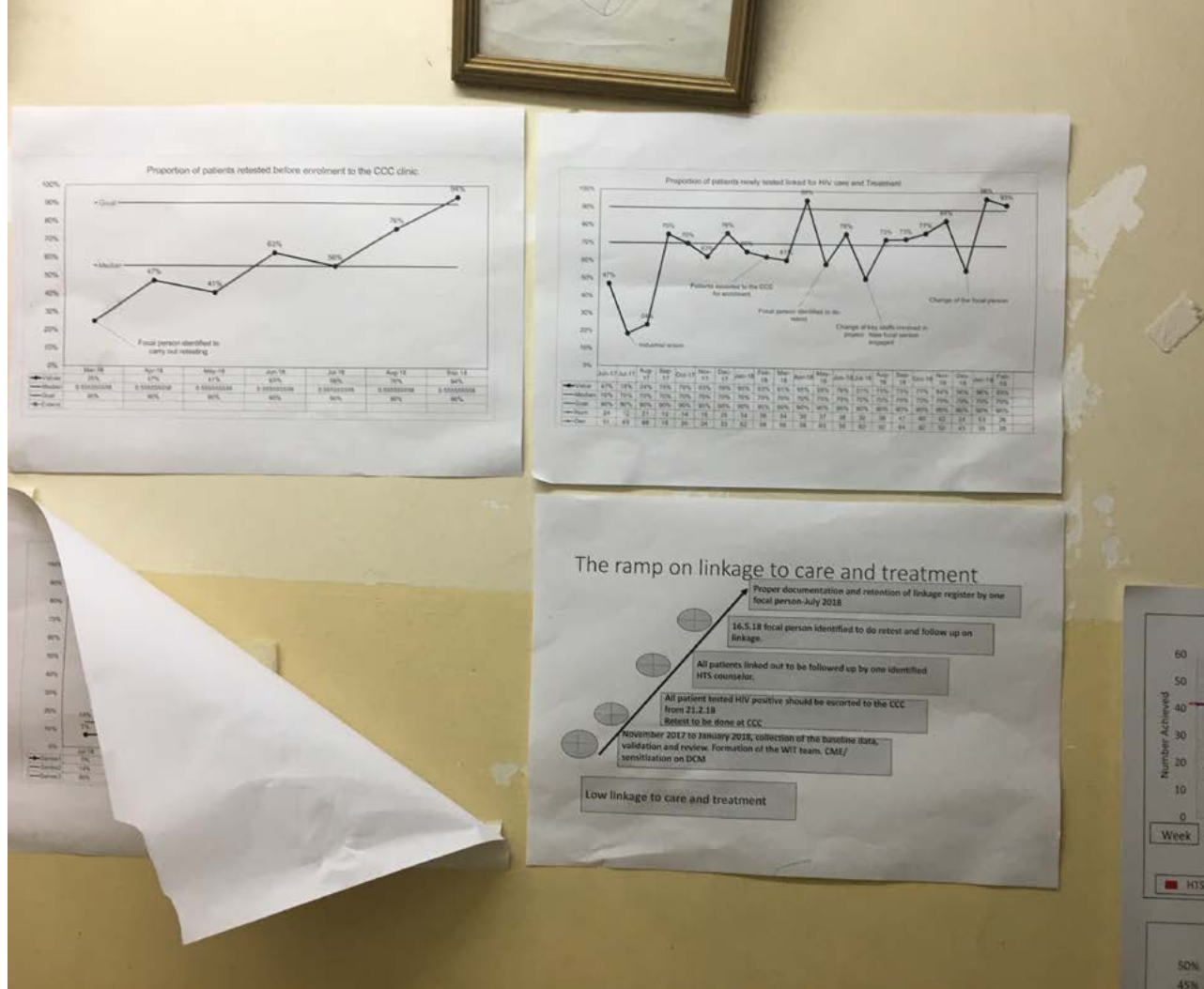
To facilitate early TB detection using urine-LAM and Xpert MTB/RIF Ultra, PEPFAR Kenya should expand and improve the quality of its TB screening efforts. PEPFAR Kenya should support training in the use of urine-LAM including sensitisation of health care workers on the utility of urine-LAM and its place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

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

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

5. Peter JG, Ziejenah LS, Chanda D, et al. Effect on mortality of point-of-care, urine-based lipoarabinomannan testing to guide tuberculosis treatment initiation in HIV-positive hospital inpatients: a pragmatic, parallel-group, multicountry, open-label, randomised controlled trial. Lancet [Internet]. 2016 Mar 19 (cited 2020 Jan 22);387(10024):1187–97. Available from: [https://doi.org/10.1016/S0140-6736\(15\)01092-2](https://doi.org/10.1016/S0140-6736(15)01092-2).





#### 8d. Support TB diagnostics procurement and to improve detection at all PEPFAR funded sites.

Kenya's COP20 planning letter highlighted the need for implementing teams to "make the [urine-LAM] test available in all in-patient settings that admit PLHIV with advanced disease as well as outpatient settings where PLHIV are evaluated for TB symptoms or may present with advanced disease". To expand TB diagnoses and reduce TB-related morbidity and mortality among PLHIV, PEPFAR Kenya should ensure ambitious targets and budget are appropriated to support the procurement of commodities required for urine-LAM (e.g., TB LAM Ag urine assays, urine cups, pipettes, pipette tips, timers) and Xpert MTB/RIF Ultra testing. PEPFAR Kenya should procure and distribute Urine-LAM tests and Xpert MTB/RIF Ultra test cartridges to supplement those procured by the Global Fund in quantities that at minimum match the number of people projected to present to care in COP20 with advanced HIV disease (16% of new ART clients start treatment either in WHO stage three or four). PEPFAR Kenya should also support the use of more sensitive TB urine LAM tests, should they become available and receive endorsement by the WHO within COP20; and in the meantime procure and implement the already available Abbott Determine TB LAM Ag test. PEPFAR Kenya should also 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.

PEPFAR Kenya reported in its COP20 Planning Letter that it has already completed "Diagnostic Network Optimization" activities for VL/EID, TB and other coinfections. Such optimisation activities

are aimed at improving the utilisation of GeneXpert testing platforms, but do not necessarily translate into improved access, particularly in the case of TB. Rather than tracking just the utilisation of GeneXpert testing platforms PEPFAR should track how close GeneXpert platforms are to the point of care, and report on results turn-around times and linkage to TB treatment. PEPFAR partners should ensure systems are in place to monitor the performance and usage of the GeneXpert devices and supply stocks, to ensure sample transport and rapid linkage of all diagnosed PLHIV to treatment, and to capture TB/HIV indicators. In addition to optimising the use of GeneXpert for TB and strengthening sample transportation networks, PEPFAR Kenya should also commit to positioning GeneXpert testing platforms as close as possible to the point of care (not only in laboratories), in order to ensure that rapid Xpert MTB/RIF Ultra testing is readily available in combination with urine-LAM testing in all inpatient and outpatient settings where PLHIV present for care. Where sample transport is required for Xpert MTB/RIF Ultra testing, the turn-around time for results and linkage to appropriate treatment should be less than five days.

**PEPFAR Kenya must procure urine-LAM and Xpert MTB/RIF Ultra test cartridges in total quantities that at minimum match the number of people projected to present to care with advanced HIV disease in COP 2020 plus the number of PLHIV projected to present to care with signs and symptoms of TB. PEPFAR must also ensure that PEPFAR funded GeneXpert cartridges are exempt from pre-export validation checks which are costly, time-consuming and lead to stockouts and monitor use of geneXperts performance and usage and ensure the rapid turn-around time of results from Xpert MTB/RIF Ultra testing in less than 5 days.**

## 9. Reduce viral hepatitis transmission and related mortality among people living with HIV by upscaling interventions aimed at preventing, diagnosing, and linking people to treatment and care, and ensuring full supply of HBV birth dose, HBV preventative vaccines, and pangenotypic direct-acting antivirals (DAAs).

Co-infections of HIV with HBV and HCV significantly contribute to morbidity and mortality within populations of people who are living with HIV. Addressing HIV/HCV co-infection among key populations is also important because HIV infection can lead to reduced spontaneous clearance of HCV, higher viral loads of HCV, and more rapid liver disease progression, which can cause advanced cirrhosis, liver cancer, and liver failure. In Kenya, HIV/HBV coinfection is reported as 5.7% prevalence, by some estimates. HIV/HCV coinfection is found as between 1.1% and 1.6% prevalence in different studies. There are gendered differences in HIV/HBV co-infection, which was found to be higher in women at 7.0% prevalence than in men at 3.8%. This could be related to condomless vaginal sex. By contrast, HIV/HCV coinfection was found to be higher in men at 1.9% prevalence compared to women at 1.4%. This could be related to men having more sexual partners or found to be more likely to engage in other high-risk activities, such as injection drug use. Yet due to limited data the prevalence could be under-estimated.

There are an estimated 1 million people living with chronic HBV; less than 50,000 are children under age 5. Kenya has an intermediate prevalence rate of 2.2 percent. The World Health Organization projects that HCV mono infection prevalence is at 0.2 percent, yet found to be much more prevalent in key populations, including people who use and inject drugs, MSM, and female sex workers (FSW), due to sharing of unsterile needles, other drug injection and non-injection equipment, and condomless sex. There is a low HCV antibody prevalence in the general population, however, reports have suggested that between 22% and 70% of people who inject drugs are anti-HCV positive. Data on HIV/HCV co-infection among PWID in Kenya are scarce, but according to some studies its prevalence appears to be 18–32%.

According to the WHO viral hepatitis scorecard for Kenya, the HBV birth dose is not implemented. There is progress in other areas with more than 90% coverage of the third dose of

the HBV preventative vaccine; this target is on track to being implemented and incorporated into the national program. There is no viral hepatitis plan but the clinical guidelines are used as a substitute. Another critical area is to scale up HBV and HCV testing, which are not on track to the 2020 targets. Further, there is no national hepatitis treatment program, but the Ministry of Health has access to sofosbuvir/ledipasvir (US\$596 or 60,000 shillings per treatment course), and there are possible negotiations with Egypt for generic, pangenotypic sofosbuvir/daclatasvir and sofosbuvir/velpatasvir.

*PEPFAR must play a critical role in eliminating viral hepatitis in PLHIV, which can catalyze a strategy for micro-elimination of HBV and HCV in Kenya. The program should integrate the administration of HBV birth dose in PEPFAR-funded perinatal clinics, as well as the HBV preventative vaccine and pangenotypic DAA treatment for HCV in health settings serving people living with HIV.*

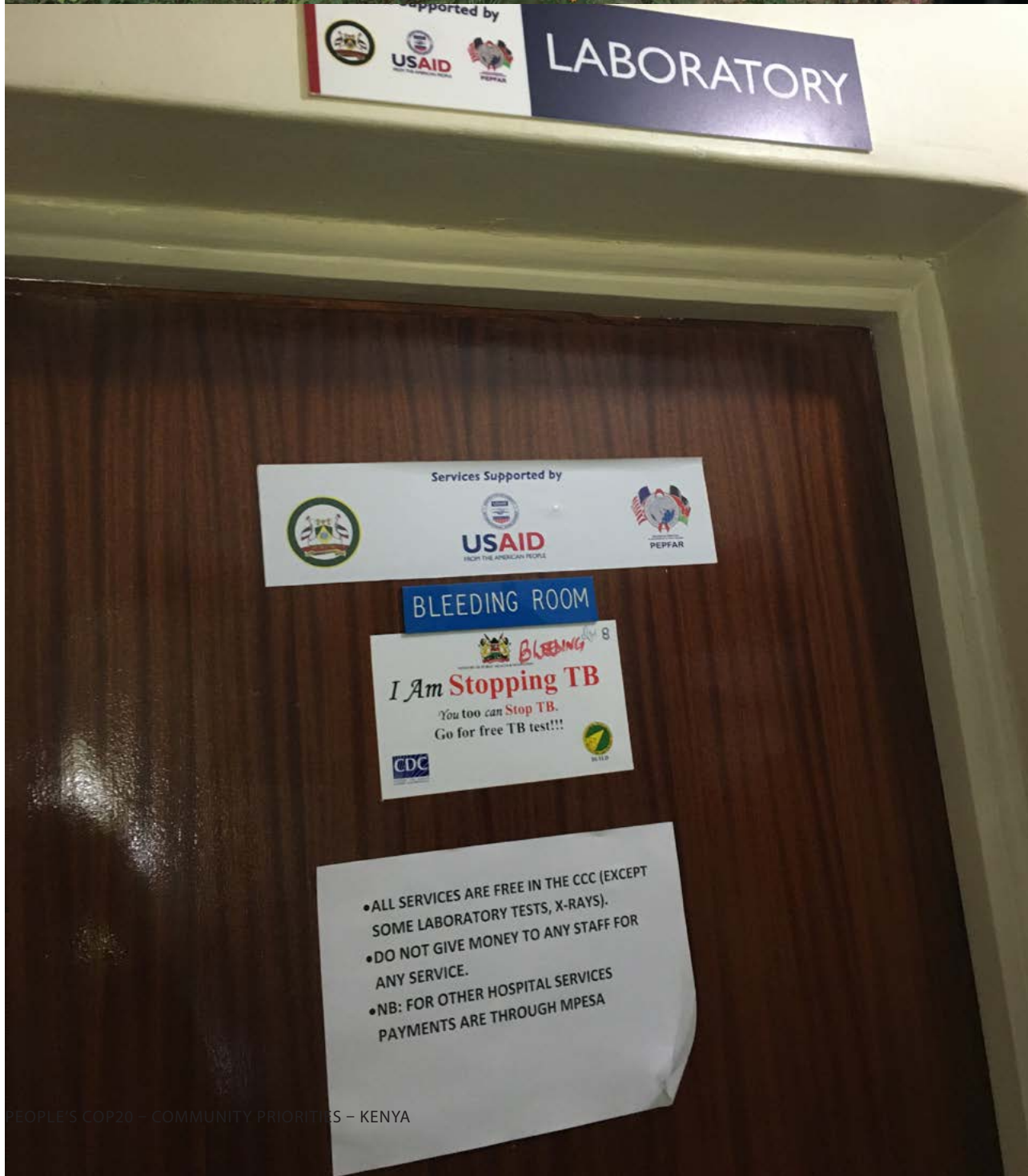
## 10. Fund local level community and PLHIV led groups to monitor the state of service provision at PEPFAR supported sites & escalate issues of poor performance.

The COP20 Guidance highlights the requirement by all PEPFAR programs to develop, support and fund a community-led monitoring activity through State Department Ambassador's small grants in close collaboration with independent, local civil society organisations and host country governments.

In Kenya, community-led monitoring has been carried out by Kenyan civil society members at PEPFAR supported sites in 2019 and 2020 and highlights a range of challenges that detrimentally impact on people's ability to access HIV & TB prevention, treatment and care services. These include: shortages of healthcare workers, lack of treatment

and adherence information provisions, stockouts and/or shortages of diagnostics and treatment to mention a few. Data collected has been utilised to formulate community recommendations to COP planning in 2019 and 2020 as well as to highlight where challenges in the PEPFAR programme need to be. This has covered both the general population







of PLHIV as well as key populations and other marginalised groups. However, to date due to limited resources and capacity, community monitoring efforts have so far been carried out annually as an exercise to find out the key challenges ahead of COP reviews. A more systematic and regular collection of data would allow communities working on TB and HIV to highlight challenges, make recommendations to MOH, the County and PEPFAR, and monitor the implementation of these recommendations to ensure accountability and subsequent improvement in quality of HIV service delivery.

COP20 must set aside resources to ensure that community-led monitoring can be more consistently rolled out and maintained and that issues identified can be addressed and resolved in a timely and satisfactory manner. The PEPFAR Kenya program must include communities in decision making as they build the community monitoring system as communities will be the people on the ground collecting the data. At least 100% of the funds allocated for community based monitoring should go to community groups for actual monitoring of PEPFAR funded sites. PEPFAR should fund a national reporting mechanism alongside the county based coordinating mechanism to ensure that information from the counties is also shared at a national level. Data collection and maintenance should be handled by community groups and put on a live website for reference by others who are not part of the monitoring but want to use the data. Data collection tools should be adopted from countries such as South Africa that have created and tested the tools to ensure community data collected across countries has the same baseline for review to track similarities across countries.

We propose a system of community-led monitoring in the following manner:

- + Consistent quarterly monitoring of selected PEPFAR supported facilities to collect robust data using standardised observational, patient/PLHIV, and healthcare worker surveys.
- + Ad hoc fact-finding missions to assess the state of other facilities less consistently monitored where issues are brought to our attention that need follow up.
- + Surveys will monitor: the quality of HIV and TB service provision at the facility, waiting times, staffing complements and shortages, staff attitudes, stockouts & shortages of health technologies (including diagnostics, treatments, and prevention methods), facility cleanliness and the state of

infrastructure, TB infection control at the facility, as well as other key issues related to HIV and TB.

- + Monitoring results to be collated, cleaned, coded and published in a simple data dashboard model for tracking the state of service delivery.
- + Monitoring results to be linked to a model of accelerated response by MOH and PEPFAR and implementing partners to address issues outlined. Widespread and repeating issues to be presented at national level meetings in order to attempt to generate systemic solutions.

Resources will be required for staffing, travel, communication, data analysis and documentation, and other costs to allow HIV led community groups to carry out the monitoring at site level, document and upload results, and escalate any issues at facility, district, national level as well as with donors and other program implementers.

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

***PEPFAR Kenya must:***

- + *Include communities in decision making on community led monitoring from conception to implementation by establishing a committee of non recipients monitoring.*
- + *Ensure 70+% of the monitoring money is spent on monitoring the sites.*
- + *Ensure the reporting is done at a national level to ensure inclusion of review by all stakeholders*
- + *Borrow data collection and storage tools from the South Africa model that has been tried and tested.*

## 11. Comply with the standards of collaboration with civil society.

Kenya's COP 2019 process was difficult to follow. Civil society was in the dark with very little information shared by the team on the direction of the COP until the last minute.

While we appreciate the inclusion of communities in the Washington DC meeting and the time taken by the team to meet civil society, civil society had little information on the content of the country's operational plan and the direction by PEPFAR. This was especially challenging in a COP where the country had a large reduction in funding and communities most affected

needed to be present as PEPFAR prioritised services. COP20 must include civil society as they make decisions on programs.

***PEPFAR must ensure civil society and communities of people living with HIV a fully included in the COP process.***

# PRIORITY INTERVENTIONS

PRIORITY INTERVENTIONS - PRIORITY INTERVENTIONS - PRIORITY INTERVENTIONS	COP19 & DATA , COP 2020 PLANNING LETTER	LANGUAGE TO INCLUDE IN COP20	TARGET
	<b>1a. Increase the overall PEPFAR allocation by \$60 million</b>		
	The PEPFAR Country/Regional Operational Plan (COP/ROP 2020) national budget is \$375,000,000 inclusive of all new funding accounts and applied pipeline.	COP20 will increase funding by an additional \$60 million to support the health system to improve the quality of service delivery.	<b>Target:</b> Fund an additional US\$60million for the overall program
	<b>1b. Revise the proposed reduction to test kits and support 7 million test kits and track self test kits to maintain the program capacity to identify undiagnosed people living with HIV.</b>		
	Per the funding letter part 1, test kit purchases are restricted to PMTCT and KP programs.	The program with support testing effort by supporting 7 million test kits that will be used to reach all populations with testing	<b>Target:</b> Fund 7 million test kits for the identification of PLHIV
	<b>2. Put in place measures to ensure that index testing does not lead to intimate partner or other violence, or forced disclosure of PLHIV's status'</b>		
	<p>"Six of the Evolve counties .....with a high and medium unmet need will be supported to rapidly increase the number of people on ART by scaling index testing, implementing efficient targeted facility testing, and self- testing for men and young people. In COP19, the counties will initiate a public health approach to index testing, which will be fully implemented in COP20 combining recency testing to hotspot mapping and mobilizing teams to identify the cases and engage them to treatment." (SDS pg30)</p> <p>"<i>Scale counties</i> are sixteen counties ..... These counties will be supported to scale up index testing, targeted testing and ART, in order to achieve &gt;80% ART coverage. Case identification will be done mainly through index testing, efficient targeted facility testing and self-testing for men and young people." (SDS Pg 30)</p> <p>"<i>Reboot counties</i> are twelve counties .... Rapid ART scale up will be supported in these counties to increase ART coverage, with case finding mainly done through index testing and efficient reduced facility testing." (SDS Pg31)</p>	<p>PEPFAR Kenya will not enforce ANY targets that a percentage of people newly diagnosed with HIV must come from index testing for the remainder of COP19 and COP20.</p> <p>PEPFAR Kenya will ensure that before contacting the sexual partners of any PLHIV, all healthcare providers should ask if their client's partners have ever been violent and avoid contacting them if so in order to protect their client. After contacting partners, healthcare providers will follow up to check if any PLHIV faced violence due to the contacting and refer them to the IPV centre if the answer is yes. Prior to (re-) implementing index testing in any facility, there must be adequate IPV services available for PLHIV at the facility or by referral and all patients who are screened should be offered this information.</p> <p>PEPFAR Kenya will ensure that all implementing partners fully understand that index testing is always voluntary, for both sexual contacts and children, where clients are not required to give the names of their sexual partners or children if they don't want to. Clients must be directly advised that there is no obligation to participate in index testing and that it is only a service offered should the client wish to access it. All PLHIV must understand that this is voluntary. No incentives for participating in index testing may be offered or provided. Additionally, an adverse event monitoring system will be established that is capable of identifying and providing services to individuals harmed by index testing. If these demands are not or cannot be met by an implementing partner, index testing must not continue at the facility for any population.</p>	<b>Target:</b> COP20 must not contain any targets that a percentage of people newly diagnosed with HIV must come from index testing
	<b>3a. Fund an additional 6000 outreach workers to provide retention services at facilities and in the community</b>		
	"Kenya has a health workforce that is not sufficiently rationalized, right sized and with appropriate skills-mix for effective and sustained epidemic control. As a result PEPFAR investments in contracting health workers at facility and community levels are still needed. However, the county governments HRH management systems, need to be supported to a level where they can adequately meet all HRH needs by themselves, or reduce HRH for HIV services dependency ratio significantly. PEPFAR in COP 19 will invest more on health workers' rationalization and right sizing activities towards ensuring the program attains 95,95,95 cascade in a sustainable way." (COP19 SDS, pg 22)	In COP20, 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.	<b>Target:</b> Fund 6000 additional outreach workers for the general program and the KP program.

COP19 & DATA , COP 2020 PLANNING LETTER	LANGUAGE TO INCLUDE IN COP20	TARGET
<b>3b. Fund transportation for community outreach to find PLHIV who are lost to follow up and require support to remain on treatment</b>		
"Case management will be done to all new clients to ensure all New on ART are retained. Physical escorts for all newly identified clients to ensure immediate linkage to care and treatment will continue to be emphasized." (COP19 SDS, pg 39)	PEPFAR will aggressively look for PLHIV who are lost to follow up by remunerating community health workers to find individuals lost to follow up in the community and ensure immediate linkage back to the facilities.	<b>Target:</b> All implementers will fund transportation for at least four trips each month per outreach worker supporting retention at \$4 dollar per trip
<b>3c. Invest in community support groups for PLHIV at the community and facility levels</b>		
"Partnerships will be fostered with PLHIV networks to roll-out Treatment Literacy focusing on the health benefits of 'early' HIV treatment and life-long adherence. This is because the majority of PLHIV who have disengaged from care or are LTFU have been clients new on ART." (COP19 SDS, pg 39)	In COP20 the program will work with communities of people living with HIV to increase community adherence support. The community support groups are expected to increase the program's retention of people on treatment and increase treatment literacy levels among PLHIV. All support groups should be linked to PEPFAR supported sites where newly diagnosed PLHIV, PLHIV returning to care, or others struggling with adherence can be referred to for peer support.	<b>Target:</b> COP20 must support 10 PLHIV community organisations to revive support groups for community members in need of education and support linked to PEPFAR supported sites in at least five high burden regions of the country.
<b>4a. Restore the US\$18.4 million investment to the key population program</b>		
"Continued expansion of Key Populations prevention and expansion of PrEP depending on country submitted targets \$10,000,000" (COP planning level letter 2020 pg3)	To be resolved for COP 2019	<b>Target:</b> Restore full funding of US\$18.4 million to community-led organisations working with / serving KP needs
<b>4b. Increase investment in community-led service delivery, and community outreach.</b>		
<p>"In 2018, the first phase of a PEPFAR-funded size estimation activity, led by NASCOP, provided updated estimates of KP sizes based on programmatic mapping (32,580 MSM, 167,940 FSW and 16,063 PWID). ART coverage through KP-friendly services is estimated at well below 50% in all three populations. To address these gaps, PEPFAR invests in the sensitization of health workers and relevant authorities, as well as KP community engagement approaches including funding of KP led organizations to deliver services directly to community members and regular Civil Society Organization (CSO) stakeholder engagement for program guidance. Targets and resource allocation may be adjusted as we redesign the Kenya Key Populations Program with an intention of meeting the 95:95:95 goal in COP19." (COP19 SDS, pg 7)</p> <p>"In COP19, PEPFAR will continue building strong partnership with the KP Consortium, and Trans* organizations to ensure that the KP program is owned and managed by the Key Populations." (COP19 SDS, pg 7)</p> <p>"To increase service uptake, more KP led organizations will be strengthened and funded to expand community led KP service provision. KP led stand alone and integrated drop in centers (DICE) augmented will be supported, particularly to include provision of ART at all eligible DICES to increase access to comprehensive services under one roof." (COP19 SDS, pg 54)</p>	<p>The cornerstone of the key population program is communities of key populations who reach out to peers and introduce and maintain them in care. The program will be using a social network strategy that will increase the partnership with communities to find key populations who have never been tested before and increase case finding. The PEPFAR program will increase the partnership with communities of key population to reach harder to reach community members by supporting community led comprehensive centres.</p> <p>PEPFAR will maintain the key population program funding level to enable the program to provide comprehensive service delivery to communities of men having sex with men, sex workers, people who use drugs and transgender communities</p>	<p>Support upgrade/ support 12 new key population led service delivery organisations to comprehensive service delivery (3 SW, 3 MSM, 3 PWUD, 3 Trans orgs) units.</p> <p>Support three mobile outreach for MAT clients in 3 MAT counties and one program for women who use drugs to increase access.</p>



COP19 & DATA , COP 2020 PLANNING LETTER	LANGUAGE TO INCLUDE IN COP20	TARGET
<b>4c. Increase investment in data protection and data on behaviour.</b>		
No mention.	The PEPFAR program will invest in a bio-behavioural study to understand the trends in HIV transmission among key populations. The study will not use a biometric system to connect data to individual to ensure the security and safety of populations	<b>Target:</b> IBBS and data protection systems support to capture all the data required for sufficient programming for key population service delivery.
<b>5. Ensure that women of reproductive age have access to TLD to improve retention and treatment outcomes and are able to make an informed decision to start/transition to a dolutegravir based regimen, and that PLHIV on DTG are tracked for weight gain and moved back if needed.</b>		
The country is on course to meet the target of 400,000 patients on TLD by June 2018. This number is expected to rise further with the planned guideline revision to allow greater access to DTG-containing regimens for adolescent girls and young women. (COP19 SDS, pg 57)	COP20 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. COP20 will institute tracking of weight gain amongst PLHIV taking DTG and respond accordingly, including by returning people back to an efavirenz based regimen where necessary. COP20 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. COP20 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.	<b>Target:</b> All PLHIV are informed and able to access a 1st line ARV regimen suitable for their needs. All women of reproductive age will also have the choice to be initiated or transitioned to TLD.
<b>6a. Improve timely diagnosis of perinatal HIV with point of care testing and scale up optimised HIV treatment for infants</b>		
"EID coverage will be a priority in COP19, with an increased focus on early testing of HIV exposed infants within 2 months through enhanced retention, post ANC 1 retesting and referral and HEI screening at immunization. At least 95 % (57,886) of expected HEIs will be targeted for infant virologic test, of whom 90% (51,757) receiving the test at age < 2months. An estimated 1,076 positive infants will be identified and linked to treatment." (COP19 SDS, pg 80)	COP20 will support and fast track funds to implementing partners to ensure a sufficient early infant diagnosis point of care diagnostic program COP20 will cover the gap of USD 605,000 annually in EID point of care support.	<b>Target:</b> 70% of EID testing platforms situated at the point of care.
<b>6b. Make available optimised ARV for all infants and children living with HIV</b>		
Policy change on the use of DTG in children less than 14 years and below 30kgs has now begun with the Ministry of Health. This will ensure that the Kenya leaps the current viral load suppression from 90% to 95% in COP19 (COP19 SDS, pg 40)  In order to address this, PEPFAR Kenya is working with the Ministry of Health to revise policy guidelines to ensure they are aligned to the 2018 WHO recommendations for optimal pediatric recommendations by September 2019. This optimization includes starting all newly enrolled children and adolescents on LPV/r or Dolutegravir (DTG)-based ARV regimens with optimized nucleoside reverse transcriptase inhibitors (NRTI) back bone (ABC/3TC or TDF/3TC). (COP19 SDS, pg 40)	COP20 will ensure rapid transition from nevirapine based regimen to DTG based regimen for all infants and children living with HIV within dosing criteria of >20kgs. LPV/r based regimens must be made available for infants and children <20kgs using available syrup whilst making the pellets available for paediatrics who are struggling with taking the syrup. COP20 will ensure that healthcare workers will be trained on the need to support treatment literacy for mothers of children living with HIV to improve case finding, treatment adherence and retention to care.	<b>Target:</b> All children >20kg will get dolutegravir 50mg; all children >10kg can swallow whole tablets will get lopinavir/ritonavir 100/25mg tablets; all children <20kg will get lopinavir/ritonavir granules / tablets/ syrup.

COP19 & DATA , COP 2020 PLANNING LETTER	LANGUAGE TO INCLUDE IN COP20	TARGET
<b>7. Continue funding services for people living with HIV despite the proposed transition by the government to Universal Health Coverage</b>		
<p>"The National Health Insurance Fund (NHIF) and the current pilot UHC program, has integrated HIV in the benefit package, however HIV is not reimbursed given the extent of donor subsidies. Key considerations in COP19 is to ensure full integration of HIV services in the essential benefit package, incorporation of HIV costs regardless of funding sources and strategies for reimbursing providers through pre-payment schemes including NHIF" (COP19 SDS, pg 21)</p>	<p>PEPFAR will continue its commitment to people living with HIV as the Government of Kenya builds on its commitment to the Kenya people to provide universal health coverage. The program will only transition programs when they are sure that people living with HIV will have access to quality services. The program recognises that it takes a long time to transition a program as large as the HIV program and notes the country needs after the 4 county pilots that ended in December 2018 and will maintain support for the country to ensure that PLHIV have uninterrupted service delivery.</p>	<p><b>Target:</b> PEPFAR will continue to fund core services of PLHIV and to ensure PLHIV have uninterrupted access to the full range of services they need.</p>
<b>8a. Support scale up of TB preventive therapy to all people living with HIV and initiate access to 3HP for 40% of PLHIV eligible for TPT.</b>		
<p>"Kenya has made significant strides in scaling-up TB preventive therapy (TPT). According to the COP19 SDS: "TB preventive therapy (TPT) has been scaled up with over 85% of PLHIV currently on ART having received a six month course of isoniazid preventive therapy." (SDSp47)</p> <p>"We will target the remaining 20% to benefit from TPT by end of September 2020" through improved documentation, reporting, and strengthening of pharmacovigilance." (SDSp111)</p>	<p><u>TPT for adolescents and Adults:</u></p> <p>PEPFAR will support the GoK to scale-up TB preventive therapy (TPT), ensuring that all PLHIV and eligible household contacts of PLHIV with TB disease who screen negative for active TB initiate and complete a course of TPT. All people living with HIV in PEPFAR programs newly diagnosed with active TB disease will receive household contact investigations of their families and close contacts, with household contacts who screen negative for active TB offered TPT.</p> <p>COP 2020 will support use of 3HP as an alternative to IPT for 40% of PLHIV and eligible household contacts treated with TPT in COP20. Adults receiving IPT will receive the fixed-dose combination of isoniazid/cotrimoxazole/B6 (Q-TIB).</p> <p>PEPFAR KE will support GoK transition its TPT program from IPT (6H) to 3HP, pending adequate supply and drug availability. Major concerns cited in COP19 about 3HP (price/affordability and compatibility with TLD) have now been resolved.</p> <p><u>Re. price:</u> Rifapentine is now available for \$15/patient-course of 3HP from Sanofi, and a fixed-dose combination of 3HP with a lower pill burden will become available from Macleods at \$15/patient-course within COP20 implementation.</p> <p><u>Re. 3HP and TLD:</u> 1) for PLHIV already on ART: the DOLPHIN-1 study completed in 2019 demonstrated that 3HP can safely be given to PLHIV on TLD without compromising viral suppression. 2) for PLHIV starting ART: PEPFAR notes that based on SPRING-1 trial data "it seems reasonable to start 3HP and TLD simultaneously in treatment naïve patients..."</p> <p><u>TPT for children:</u> PEPFAR KE will support contact investigations for all PLHIV 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 after considering HIV status, ARV regimen, pill burden and availability of child-friendly formulations. Per the PEPFAR COP20 Guidance:</p> <p>For HIV-negative children, the preferred TPT regimen is 3HR.</p> <p>For HIV-positive children, the preferred regimen is 6H until 3HP becomes available in child-friendly dosages and formulations (expected after COP20). 3HR may be considered for any children with HIV on efavirenz-based ART.</p>	<p><b>Target:</b> 1,151,642 PLHIV initiate and complete TPT within COP20. Of these, at least 40% (460,00) should receive 3HP instead of IPT, pending adequate global supply of rifapentine.</p> <p><b>Target:</b> 100% of people living with HIV diagnosed with active TB disease (TX_TB) receive household contact investigation of family and close contacts.</p> <p><b>Target:</b> All children identified through household contact investigation (TX_TB x 2) screened for TB, and either initiate TB treatment or TPT.</p>

COP19 & DATA , COP 2020 PLANNING LETTER	LANGUAGE TO INCLUDE IN COP20	TARGET
<b>Integrated TPT within differentiated service delivery (DSD) models of HIV care. In particular, administer TPT through the multi-month scripting (MMS) and DSD models for PLHIV newly initiating ART.</b>		
<p>"Differentiated service delivery models for stable PLHIV should include all recommended TB/HIV services provided to PLHIV, including regular TB screening and TB preventive treatment (TPT). PLHIV with TB disease should be prioritized for differentiated service delivery models adapted specifically to PLHIV with advanced disease." (2020 COP Guidance, p. 287)</p> <p>"...for TPT to be delivered to all PLHIV as part of a comprehensive package of HIV care, certain programmatic adaptations must be considered to ensure PLHIV already in their differentiated service delivery models complete a course of TPT. Program managers should consider allowing completion of TPT within a differentiated service delivery model for PLHIV who have initiated but not completed TPT and are otherwise eligible for transition to a differentiated service delivery model. Stable PLHIV on ART and in a differentiated service delivery model could initiate and/or complete TPT within the model." (2020 COP Guidance, p. 287)</p>	<p><b>TPT and DSD Integration:</b> TPT will form part of the differentiated service delivery models for stable PLHIV who are eligible.</p> <p>PEPFAR KE will link the scale-up of 3HP to TLD transition in the country. In particular, 3HP and TLD should be started simultaneously in anyone newly diagnosed with HIV starting ART (based on SPRING-1 and DOLPHIN-1 trials). In PLHIV on ART switched from efavirenz to TLD, 3HP can be started 2–4 weeks after making the TLD switch. Training, adherence support, pharmacovigilance, adverse event monitoring, and reporting systems associated with TLD transition should incorporate 3HP.</p> <p><b>Human Rights and Stigma:</b> PEPFAR KE will ensure that TPT implementation respects human rights and minimizes stigma. In particular, that TPT initiation is always voluntary and introduced with full information and proper counselling on the risk/benefits. Contact investigations should be carried out in a way that minimizes the impact of stigma in the community (e.g., identifying a household as having TB or disclosing the TB or HIV status of a person without their consent).</p>	<p><b>Target:</b> TPT and, in particular 3HP, must be incorporated within DSD models of HIV service delivery and 3HP scale-up should be linked to TLD transition.</p>
<b>8b. Improve TB infection control measures and ensure TB screening and testing in 100% of PEPFAR supported sites.</b>		
<p>"Systems will be strengthened to 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" (SDSp61)</p>	<p>In COP20, PEPFAR Kenya should 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. COP20 should 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.</p>	<p><b>Target:</b> 100% of PEPFAR supported facilities will have good TB infection control measures in place, as found with spot checks, by end COP20.</p> <p><b>Target:</b> 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 COP20.</p>



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<b>8c. Improve TB testing among PLHIV by supporting better placement of GeneXpert and urine-LAM tests and training for health workers at all PEPFAR funded sites</b>		
<p>"Tuberculosis is a leading cause of morbidity, virologic failure and death among PLHIV. Kenya is a high TB, TBHIV and MDR TB burden country with a prevalence of 558/100,000 and a 50% TB and TB/HIV case detection rate[1]. Over the past 2 years Kenya has experienced a 10% annual increase in TB case notification and in 2018, 95,741 of 169,000 WHO estimated incident TB cases were notified including 25,000 (29%) HIV positive Cases [2]. In 2018, 98% of identified TB cases had a known HIV status and 97% of TB/HIV patients were on ART during TB treatment<sup>10</sup>. TB and HIV services are integrated in nearly all PEPFAR supported sites and 96% of PLHIV currently in care are screened for TB symptoms." (SDSp46-47)</p> <p>"In addition, Kenya will prioritize TB prevention and treatment through optimized TB screening, improved diagnosis using GeneXpert and TB-LAM and IPT among all eligible PLHIV." (SDSp42)</p> <p>"Despite the progress made, low TB case detection and high (10%) TB/HIV case fatality remain a major concern. In FY 2020, working with the Ministry of Health PEPFAR will strengthen integration of TB and HIV service delivery across the case identification, linkage to care and retention cascade to ensure maximum synergies." (SDSp47)</p> <p>"PEPFAR will support integrated TB and HIV case finding including TB screening among individuals undergoing HIV testing eligibility assessment in outpatient and inpatient departments, maternal and child health clinics, prisons and other Key populations' clinics and ensure HIV testing of presumptive TB cases and TB contacts. In HIV clinics high quality TB symptom screening will be done for patients in facility service delivery model. At the community level, access to a mobile phone application for TB symptom self-screening and appointment scheduling among patients in differentiated service delivery models will be facilitated." (SDSp47)</p> <p>[1] National TB prevalence survey 2016</p> <p>[2] WHO 2018 global TB report</p>	<p>In COP2020 PEPFAR will measure impact on TB-related morbidity and mortality among PLHIV by tracking progress in scaling up and implementing urine-LAM testing; the placement of GeneXpert platforms in relation to the point of care; and turn-around times for Xpert MTB/RIF Ultra results and linkage to treatment.</p> <p>In COP20, PEPFAR Kenya will use urine-LAM and Xpert MTB/RIF Ultra together to screen all people living with HIV with signs and symptoms of TB, who are seriously ill, or who have advanced HIV disease in both inpatient and outpatient settings.</p> <p>To facilitate early TB detection using urine-LAM and Xpert MTB/RIF Ultra, PEPFAR Kenya will expand and improve the quality of its TB screening efforts, including systematically conducting TB symptom screening and urine-LAM testing in high TB/HIV burden facilities, and conducting contact tracing when a PLHIV is diagnosed with TB. COP 2020 will also support training and sensitization of health care workers in the use of urine-LAM.</p> <p>In COP 2020, PEPFAR will position GeneXpert testing platforms as close as possible to the point of care (not only in laboratories), in order to ensure that rapid Xpert MTB/RIF Ultra testing is readily available in combination with urine-LAM testing in all inpatient and outpatient settings where PLHIV present for care. Where sample transport is required for Xpert MTB/RIF Ultra testing, the turn-around time for results and linkage to appropriate treatment should be less than five days.</p>	<p><b>Target:</b> 30,000 registered cases of new and relapsed TB diagnoses among PLHIV</p> <p><b>Target:</b> 100% of people presenting to care with TB symptoms, serious illness or advanced HIV receive urine-LAM and Xpert MTB/RIF Ultra testing for TB.</p> <p><b>Target:</b> 80% of Xpert MTB/RIF Ultra results turned-around in less than 5 days.</p>
<b>8d. Support TB diagnostics procurement and placement to improve detection at all PEPFAR funded sites.</b>		
<p>"Nationally 180 geneXpert® machines have been installed in laboratories spanning each county and a specimen referral network established to cover all HIV treatment sites countrywide. Majority (85%) of presumptive TB cases are tested using the Xpert MTB RIF test for TB diagnosis." (SDS pg47)</p> <p>"TB urine lateral flow lipoarabinomannan assay (TB-LAM) test will be available for severely sick hospitalized patients and chest Xray supported." (SDSp47)</p> <p>"The genexpert test will be provided for all PLHIVs presumed to have TB. TB urine lateral flow lipoarabinomannan assay (TB-LAM) test will be available for severely sick hospitalized patients and chest Xray supported. Specimen transportation for geneXpert® testing will be supported and Culture and Drug susceptibility testing (DST) services provided for PLHIV presumed to have drug resistant tuberculosis." (SDSp47)</p> <p>"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." (SDSp60)</p> <p>"The ministry of health will procure (TB-LAM) and continue to support surveillance and culture and DST." (SDSp60)</p>	<p>PEPFAR Kenya will support the procurement of commodities required for urine-LAM (e.g., TB LAM Ag urine assays, urine cups, pipettes, pipette tips, timers) and Xpert MTB/RIF Ultra testing. Urine-LAM tests and commodities will be procured in quantities that at minimum match the number of people projected to present to care in COP20 with advanced HIV disease (16% of new ART clients start treatment either in WHO stage three or four).</p> <p>PEPFAR Kenya targets for the procurement and implementation of urine-LAM will match the number of people projected to present to care with advanced HIV disease plus the number of people living with HIV projected to present to care with signs and symptoms of TB.</p> <p>PEPFAR Kenya will support rapid and accurate TB testing among PLHIV to reduce mortality, especially among people with advanced HIV disease, who are most at risk of dying of TB.</p>	<p><b>Target:</b> A portion of GeneXpert testing platforms situated at the point of care.</p> <p>Policy change to ensure that all PEPFAR funded GeneXpert cartridges are exempt from pre-export validation checks</p>

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<b>9. Support community led monitoring to increase the quality of service delivery in PEPFAR funded sites</b>		
<p>"In COP20, all PEPFAR programs are required to develop, support and fund community-led monitoring for treatment services in close collaboration with independent civil society organizations and host country governments." (COP20 Global Guidance, Section 3.3.1.2).</p> <p>"Collaboration with community groups, civil society organizations, and patients/beneficiaries can help PEPFAR programs and health institutions diagnose and pinpoint persistent problems, challenges, and barriers with service uptake at the site and facility level to effective service and client outcomes at the site." (COP20 Global Guidance, Pg 95).</p> <p>"Community-led monitoring activities, though funded by PEPFAR, should be driven by independent and local community groups and civil society organizations." (COP20 Global Guidance, Pg 71)</p>	<p>COP20 will provide funding of USD 1 million for PLHIV, TB and KP groups to engage in monitoring at high burden sites across Kenya to improve HIV and TB service delivery.</p>	<p><b>Target:</b> Provide US\$1 million for community-led monitoring by PLHIV, TB and KP groups. Issues affecting HIV and TB service delivery at site level are rapidly addressed by PEPFAR and implementing partners through an accelerated response mechanism.</p>
<b>10. Reduce viral hepatitis transmission and related mortality among people living with HIV by upscaling interventions by preventing, diagnosing, and linking people to treatment and care, and ensuring full supply of HBV birth dose, HBV preventative vaccines, and pangenotypic direct-acting antivirals (DAAs).</b>		
<p>Laboratory infrastructure, including HIV rapid testing, is donor dependent with <u>donor-funded staff</u>. Increased and sustained funding to support laboratory staff, community-based rapid diagnostic and point-of-care viral load testing is necessary to train and integrate viral hepatitis testing into the country program.</p> <p>The PEPFAR COP20 guidance states that <i>"demonstrated at least 80% ART coverage of all PLHIV and, importantly, 90% retention of clients in continuous ART services, 80% viral load coverage and 90% viral load suppression among all client, may offer, as part of OU COP strategy, funding for more comprehensive services for PLHIV, such as diagnosis and treatment of hepatitis C, diabetes or hypertension... Among these conditions, hepatitis C is particularly deleterious to PLHIV and is curable at a cost that is currently affordable across the globe. The rapid tests for diagnosis of hepatitis C are between \$0.60 and \$1. Hepatitis C viral load tests, which are required for both confirmation before treatment and documentation of cure after treatment, are the same as for an HIV VL test. Approved treatment is between \$39 and \$60 for a complete cure. These costs put the commodity cost of diagnosis, treatment, and cure below \$100 per patient. If these additional services are funded in the COP as PEPFAR programming, they must be offered without discrimination and user fees must not be charged..."</i></p>	<p><u>Primary prevention</u></p> <p>PEPFAR will support prevention services to promote health and treatment literacy about viral hepatitis transmission and prevention. The program will offer linkage to viral hepatitis testing, DAA treatment, and HBV vaccination for people at highest risk, including people who use and inject drugs. In addition, prevention services will implement a comprehensive package of harm reduction interventions and offer people who inject drugs rapid hepatitis B vaccination regimens; offer people who inject drugs incentives to increase uptake and completion of the hepatitis B vaccine schedule;; and to offer peer interventions to people who inject drugs to reduce the incidence of viral hepatitis."</p> <p><u>Testing</u></p> <p>The programs will incorporate HIV and HCV antibody self-testing into community-based testing strategies where appropriate and integrate HCV viral load testing into HIV diagnostics algorithms.</p> <p><u>Optimising Treatment and Care</u></p> <p>"Integrating viral hepatitis into the HIV diagnostics algorithm can ensure people who have a confirmed diagnosis are linked and started on DAAs or adult HBV treatment early, thereby preventing onward transmission and further liver damage. The preventative HBV vaccine can also be offered at the time of return of HIV results, depending on other health conditions, previous treatment experience, and potential drug-drug interactions... with highly effective and safe pangenotypic direct-acting antivirals, people with HCV can effectively be cured and not transmit the virus if accurate, appropriate prevention education and access to harm reduction materials are in place. Linkage to early HCV treatment for people who are HIV/HCV can prevent further liver damage and improve HIV and health outcomes."</p>	<p><b>Target:</b> 65% reduction of HBV- and HCV-related mortality</p> <p><b>Target:</b> 90% reduction of HBV and HCV incidence, with targeted interventions for key populations, particularly people who use drugs, MSM, and FSW</p> <p><b>Target:</b> Universal screening of pregnant women for HBV and HCV</p> <p><b>Target:</b> 90% childhood vaccine coverage (third dose coverage)</p> <p><b>Target:</b> 100% of pregnant women are linked to and offered HBV treatment post-birth according to national guidelines</p> <p><b>Target:</b> 100% of pregnant women are linked to and offered HCV treatment post-birth according to national guidelines</p> <p><b>Target:</b> 100% of PLHIV who are diagnosed with HBV are linked to and offered treatment according to national guidelines</p> <p><b>Target:</b> 100% of PLHIV who are diagnosed with viremic HCV are linked to and offered treatment according to national guidelines</p> <p><b>Target:</b> 100% of people who are diagnosed with viremic HCV initiate treatment</p>



