PEPFAR Technical Guidance in Context of COVID-19 Pandemic

In January 2020, a novel coronavirus, SARS-CoV-2, was identified as the causative agent of an outbreak of viral pneumonia centered in Wuhan, Hubei, China. The disease caused by this virus is called COVID-19. The disease is now widespread, and nearly every country in the world has reported cases. *https://who.sprinklr.com/*.

Widespread disturbances of international travel and shortages of medical supplies have led to challenges in the provision of medical care. In the areas hardest hit, medical facilities have been overwhelmed by large numbers of COVID-19 patients, and stay-at-home orders and staff illness provide additional challenges. During the COVID-19 pandemic, PEPFAR remains committed to continuing essential HIV prevention and treatment services, while maintaining a safe healthcare environment for clients and staff. In order to meet our commitment to uninterrupted care and treatment for PLHIV and the prevention of deaths among PLHIV due to HIV associated co-morbidities, PEPFAR is committed to adapting HIV services, so that PLHIV have the best possible outcomes within the context of stretched healthcare systems.

The evidence on the impact of COVID-19 amongst PLHIV is still scarce. There is currently no direct evidence that people with HIV are at higher risk of COVID-19, or of severe disease if affected. As more data becomes available from regions of high prevalence, we will continue to update the field on the effect of COVID-19 on PLHIV. HIV virological suppression is a critical intervention that improves the health of all PLHIV, and PEPFAR is committed to ensuring that PLHIV have uninterrupted care. Currently, there is no known effective treatment for COVID-19. We discourage the use of experimental therapies outside of registered clinical trials, as they may be dangerous. Drug-drug interactions with ART and other HIV related therapies may pose risks for our PLHIV clients.

Technical guidance is provided here for a variety of PEPFAR issues and will be updated routinely as the situation evolves.

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1. Guiding principles for the provision of services in PEPFAR-supported countries during COVID- 19 Pandemic

- ***Protect the gains in the HIV response:***
  Continuity of treatment for PLHIV is the foundation of PEPFAR programs during the COVID-19 pandemic. Several strategies are available and detailed in this document. Multi-month dispensing and decentralized delivery of medication form the basis of the PEPFAR strategy to maintain PLHIV on ART.

- ***The safety of PEPFAR-supported staff must be assured. If client services cannot be adapted to be performed safely, they should not be performed.***

- ***Reduce risk of transmission of COVID-19 among clients served by PEPFAR and PEPFAR-supported staff:***
  - All PEPFAR programs are under Chief of Mission authority; therefore, country teams and implementing partners should follow Embassy Front Office direction on all programming that requires personnel movement.
  - Minimizing patient contact with health facilities reduces risk to recipients of care and reduces the burden on these facilities. Health care facility visits should be limited to those that are medically essential.
  - Community programming should support social distancing and the use of alternative methods of communication to maintain contact and provide support to enrollees. These methods include virtual and digital platforms such as calls, SMS, social media, WhatsApp. Plans should be in place to adapt programming should service be disrupted.
  - Group-based activities should follow local guidelines for mass gatherings, and in-person group-based activities may need to be paused.

- ***In consultation with host governments, PEPFAR Operating Units (OUs) have flexibility to determine how best to continue to serve clients with HIV prevention and treatment services in areas affected by COVID-19 using the FAQs as a guide.***

2. Today's Updates

April 22, 2020

- ***Clarification MMD should include HIV-positive pregnant and breastfeeding women*** – see HIV Treatment pg.6, and Maternal Child Health pg.17
- ***Return to Care update*** – see HIV Treatment pg.7
- ***Pediatric HIV Treatment transition update*** – see Pediatric ARVs pg.10
- ***Faith and Communities Initiative update*** – see Faith and Community Organizations pg.27

3. Human Resources for Health (HRH)

PEPFAR-supported cadres should follow host government guidance on home visits and avoid unnecessary in-person interactions with clients in facilities and communities to reduce exposure to, and spread of, COVID-19.

How should PEPFAR-supported healthcare worker (HCW) staffing be modified to maintain essential HIV services?

- Reconfiguration of service delivery teams
- Task shifting/sharing
- Redeployment

PEPFAR programs should be prepared to manage staff through these challenging times, which could include quarantine, infection, increased caregiving responsibilities at home, absenteeism or social disruption. PEPFAR programs should stay abreast of health worker challenges and constraints and should track and report all changes made to HCW staffing due to COVID-19 to PEPFAR country staff.

PEPFAR-supported HCWs should be prepared to deliver the essential HIV services using service delivery teams that may be rapidly and regularly reconfigured in response to staffing shortages. Staff should be prepared for task-sharing of essential services where allowed, and work with MOH and policy makers to allow emergency task-shifting where formal task-shifting policies are not in place. PEPFAR staff whose regular services may have been temporarily paused or delayed (e.g., VMMC, roving TA) should be repurposed and redeployed to support essential HIV services (e.g., treatment services). Refresh or build capacity in the new role through rapid training as necessary. Every effort should be made to retain the health workforce that PEPFAR supports, including repurposing into new roles to support HIV services for the duration of the pandemic and redesigning how services are delivered to make it safe for PEPFAR-supported staff to continue to work.

A critical element of the PEPFAR response to COVID is decentralized services. To this end staff may be temporarily repurposed to move services out of the facility and into the community wherever possible and safe. Staff may be reallocated to community-based ARV distribution for example. Where possible, digital applications or telehealth technologies should be utilized to remotely provide services. HCWs should be supported with the tools, airtime and data required, as well as training and scripts to use the technologies effectively and protect confidentiality and privacy. PEPFAR Technical Assistance (TA) providers should provide TA through telephone or digital applications in lieu of site visits.

What training is required to prepare PEPFAR HCW to respond to HIV in the context of COVID-19?

PEPFAR-supported HCWs should receive refresher training in Infection Prevention and Control (IPC) to protect themselves and HIV patients from COVID-19. While delivering HIV services, all HCWs should be equipped to provide COVID-19 risk communications to at-risk populations and PLHIV. As appropriate to their HIV service delivery role, HCWs should be trained to screen HIV patients for COVID-19 and refer as required for testing and treatment. HCW should be provided with in-country COVID guidance and case referral information (hotlines, facilities, etc.).

All training should be provided virtually using online platforms or printed job aids. Use international and national sources whenever possible. WHO is regularly updating available COVID-19 trainings at:

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/training/online-training. Utilize digital applications such as WhatsApp, Facebook Messenger groups or the ECHO platform for regular and routine information sharing with HCW staff.

What actions should be taken to safeguard PEPFAR HCW, beyond PPE?

PEPFAR programs should follow host country and WHO guidance on minimizing HCW risk of contracting or spreading COVID-19. Identify every opportunity to support HCWs to do their jobs in a different, safer way. PEPFAR programs should report all concerns regarding HCW staff safety and movement in communities to PEPFAR country staff.

- Support HCW safety within the communities they serve by securing authorization from local authorities for continued work, and work with local governments and civil society to raise awareness in the community, in particular for lay workers such as community health workers or social workers responding to violence against children. Consider introducing a uniform, bag, or other marker to aide law enforcement/community in readily identifying CHWs on official duties and provide CHWs with documentation of their role and authorization to continue work.
- Support HCW staff to use transportation methods that reduce risk of exposure while traveling to and from work, and when delivering services in the community (i.e. refrain from public transport). Consider introducing a transport stipend or arranging transport.
- Be aware and sensitive that HCWs may have underlying conditions that may affect their outcomes if they contract COVID-19, consider offering opportunities to staff to safely and discretely transition to roles away from the front line if they are concerned.
- Provide clear guidance to HCWs on OU national policies and applicable international policies that provide for workplace rights for safety, self-quarantine, and time off for caregiving of sick family members.
- Reduce in-person contact for routine administrative tasks, such as using digital payment mechanisms to ensure continuity of salary and stipend payments.
- Support HCW staff wellness through coaching or provision of psychosocial support to manage stress and avoid burnout.
- Ensure that HCW staff are kept abreast of relevant technical updates on COVID-19.

How should PEPFAR-supported cadres work with children and families in households?

Home visits, when necessary, can still achieve important objectives. Key considerations include:

- Home visitors should help to ensure that all PLHIV have access to six months MMD, ideally through community-based distribution points, to maintain adequate supply of ARVs at home.
- To protect home visitors and beneficiaries, every effort should be made to use phone calls and/or text messages to communicate and avoid making a home visit.
- Home visitors who are at higher risk for severe COVID-19 (e.g., elderly, diabetic, or have other chronic conditions) should avoid conducting home visits. Home visitors should NOT visit beneficiaries if the visitor has any symptoms of acute illness, especially fever, cough, or shortness of

breath, even if the symptoms are mild. Home visitors should NOT visit beneficiaries known to have a recent exposure to a person who tested positive for COVID-19 or is suspected of having COVID-19.

- To ensure safety and well-being of both home visitors and families, program staff should determine whether a home visit is absolutely essential.
- Many issues can be managed through counseling by phone. If unable to communicate via phone, situations that may warrant a visit include: 1) a critically ill beneficiary that urgently needs transport assistance to the clinic or hospital, 2) a child or adult exposed to physical harm, abuse or neglect requiring urgent attention, 3) CLHIV (or adult due to disability or other limitation) who cannot access ART and is in danger of treatment interruption.
- If the visit is deemed essential, ensure appropriate measures, including personal protective equipment (PPE) if available, are in place before, during, and after the visit and that both OVC staff and the client(s) consent to a visit. Once the family is stabilized, focus should then be to assist with 6mo MMD and/or drug pick-up from a community-based distribution point to ensure adequate supply of ARVs at home.

4. HIV Treatment

What is most important for PEPFAR teams to implement at this time?

Key principles for the PEPFAR response to COVID include continuity of ART therapy and accelerated decongestion of health facilities to minimize transmission of COVID-19 and protect PLHIV. The critical intervention for all programs and individuals is to accelerate and complete scale-up of 3-6 multi-month dispensing (MMD) of ART and decentralized distribution for all PLHIV including PBFW and children. If there are any barriers to MMD (such as sufficient ARV availability) implementation, programs should alert their S/GAC Chair and PPM and USAID immediately for advice and assistance and should immediately quantify the increased ARV needs to scale up MMD. USAID is working with PSM to consider the additional quantities that may be required beyond the amount budgeted in COPs; and additional PEPFAR funding to roll out MMD at a broader scale will need to be considered by S/GAC before additional TLD is procured to support a rapid implementation of MMD

How will clinical services for PLHIV be affected?

Guidance for continuation of essential medical service may be found here https://www.who.int/publications-detail/responding-to-community-spread-of-covid-19. Ensuring and maintaining HIV viral load suppression should be considered an essential medical service for PLHIV. Please see laboratory section for suggested prioritization of viral load testing. Routine viral load monitoring in stable patients may be delayed based on local circumstances.

Can clients initiating ART receive multi-month dispensing?

PEPFAR recommends that ALL PLHIV who are starting ART receive at least 3 but preferably 6 months of drugs. Phone or electronic follow-up may be helpful to assess and support adherence and to assess and manage side effects. Evidence from cohort studies indicate that <5% of clients initiating ART will require a

change in ARV regimen in the first 6 months of treatment. Two forms of contact, as recommended in the COP 20 guidance, should be obtained in all PLHIV, especially in ART initiators.

What should I do about individuals who are on our books but have not accessed meds in in the last 3 to 6 months?

Every effort should be made **now** to trace individuals who have been lost to follow-up and provide them with the package of care and treatment that they require before COVID-19 disruptions worsen. This is a core principle of COP 20 and section 6.1.2 of the COP 20 guidance contains tools for tracking and tracing which may be adapted for use in the current environment. The HRH section of this document provides additional considerations for ensuring home visits are safe.

What about individuals who have been out of care for more than a year?

These individuals should have a CD4 performed to assess eligibility for the advanced disease package of care. If clinically unwell, these individuals should at least receive cotrimoxazole. If TB screen is negative, TPT may be provided if appropriate.

What if PEPFAR's recommendations for adapting HIV services in the context of COVID- 19 do not align with local policy?

PEPFAR operates in partnership with the host government, and under Chief of Mission authority. PEPFAR country teams are urged to work promptly and closely with national governments to effect temporary changes in policy that will allow uninterrupted essential HIV services to children, adolescents, pregnant and breastfeeding women, and adults while minimizing the recipients of care's interactions with health care facilities and health care workers during COVID-19.

Can clients still be counted as "TX_CURR" they are getting ARVs delivered but only having phone (or other virtual) contact with program staff instead of clinic visits?

Programs can continue to count clients on ART towards TX_CURR if the client is not more than 28 days from when, based on the last delivery, their ARVs would be expected to run out. Programs should continue to be available to serve clients on ART, but the interaction does not have to include in-person contact. Please see MER guide for definitions of TX_CURR and TX_ML.

We have stock of TLE in country. TLD rollout is underway, but we are having issues with supply. We also have EFV 200 in country. LPV/r pellet and granule rollout is underway but supply has been challenging. How should we prioritize treatment?

PEPFAR prioritizes continuity of therapy for recipients of care. Countries should carefully evaluate stock on hand and projected availability to determine the best options for all PLHIV, either transitioning to newer regimens or maintaining on current regimens. If an individual is stable on the current regimen and stock is available, irrespective of bottle size, it may be reasonable to continue the current regimen, with a plan to transition to optimized regimens (TLD, ped LPVr) in the future where appropriate.

How can the impact of COVID-19 be minimized for PLHIV supported by PEPFAR?

The critical intervention for all programs and individuals is to accelerate and complete scale-up of 3 to 6-month dispensing of ART and decentralized distribution.

What changes should be considered for adjusting the model of service provisions for PLHIV?

- The overarching goal is to minimize patient contact with health facilities and reduce the burden on these facilities.
- Health facilities should optimize clinic spaces in order to minimize potential exposure to COVID-19. Individuals with proven or suspected COVID-19 should be separated from where care is provided to other clients. Dedicated HIV clinic spaces where they do not already exist may be useful in accomplishing this goal.
- Through phone calls or SMS, facilities staff should proactively communicate with HIV clients using positive messaging about the need to stay healthy.
- Please see below on plans for MMD. Facilities should maximize convenient six-month refills where stock is available in the country pipeline. Supply plans should be reviewed immediately to ensure any changes to scale 6MMD rapidly are immediately placed as orders.
- Clients should preferentially receive their drug supplies outside of the health facility. These options could be used for dispensing ARV for any duration (for 1 month, 3 month or 6 month pick-ups), PrEP, HIV self-tests and other medicines already being supplied for chronic conditions (including drugs for hypertension, diabetes, etc.). Decentralized distribution approaches include:
    - Home deliveries: through peer-run groups OR private delivery mechanisms that maximize social distancing and respect client's privacy.
    - Community or private pharmacies: with scheduled pick-up times to maximize social distancing.
    - Pop-up pharmacy: that provide additional infrastructure in remote areas outside hospital or clinic settings with pick-up windows that are configured to ensure social distancing.
    - Automated lockers: provide additional infrastructure outside hospital or clinic settings for drug pick-ups.
    - Community pickup: through community structures such as schools, churches/FBOs, post offices or KP-focused sites
- Where countries are moving towards limiting movement, due to COVID-19, countries will need to work with law enforcement, national militaries, and other officials to:
    - Ensure importation and transport of health commodities isn't interrupted
    - Designate health commodity logistics, warehousing, and distribution (e.g. last mile delivery) operations - including private sector providers - as exempted activity and related personnel as essential personnel
    - Ensure that decentralized distribution approaches are permitted
- If OUs have significant movement restriction and/or high absenteeism amongst HCW, alternatives to face-to-face care provision should be considered, including the use of phone consultations.

What is the role of ARVs in the treatment of COVID-19?

There is no evidence that DTG- and EFV-based regimens which account for >90% of all ART in PEPFAR-supported program, have any activity or role in treating COVID-19 infections. Lopinavir/r has been investigated for treatment COVID-19 because of in vitro activity, but there is no evidence supporting its efficacy. A recent clinical trial failed to show a benefit[1]. Accurate messaging to prevent diversion of ARVs should be provided.

How can the most vulnerable patients be protected?

Older age and presence of uncontrolled comorbidities such as hypertension, diabetes and heart disease pose a higher risk for COVID-19 morbidity and mortality. All efforts should be made to streamline health services for older individuals living with HIV (>age 50), PLHIV with advanced disease, and those with co-morbidities. Programs should be sensitive to the medication needs of these individuals, seek methods to reduce the number of times these individuals require visiting health care facilities.

What changes in the clinic flow should be made to protect patients and HCW?

Waiting rooms can be a source of transmission for respiratory illness. Despite measures to maximally reduce the number of PLHIV coming for in-person facility visits, some visits will still be necessary.

Consider staggering clinical appointments to avoid crowding and streamlining clinic flow so PLHIV do not interact with multiple HCW (e.g. avoiding multiple points of contact between PLHIV and HCW).

Optimizing space to reduce close contact may be helpful. HIV patients should be seen in clinics that are dedicated spaces for HIV treatment services.

PLHIV with advanced HIV disease

Should evaluation of newly diagnosed clients for advanced disease continue during the COVID-19 pandemic?

Yes. Extant activities for the evaluation and management of advanced disease in clients newly diagnosed during the COVID-19 pandemic should continue.

Should individuals with advanced disease stay away from health care facilities?

Individuals with advanced disease represent a subset of PLHIV who require more intensive care, but they should still minimize health facility visits during COVID-19. All efforts should be made to maintain phone contact and to ensure that this group of individuals is seen when required.

When should individuals with advanced disease be evaluated in person?

Concerning symptoms include but are not limited to fever, persistent cough, shortness of breath, intractable headache and inability to walk unaided. For children other concerning signs and symptoms

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[1] Cao B, Wang Y, Wen D, Liu W, Wang J, Fan G et al. A Trial of Lopinavir–Ritonavir in Adults Hospitalized with Severe Covid-19. 2020. doi:10.1056/NEJMoa2001282.

include fever, lethargy, convulsions, poor oral intake, and persistent vomiting or diarrhea. Note: all CLHIV under age 5 years who are NOT taking ART are classified as having advanced disease.

Should PLHIV with advanced disease be given MMD?

Absolutely. Extra effort should be taken to ensure that these fragile patients have sufficient medications to avoid unnecessary trips to the health facility. In addition they should be provided with all of the other medicines that they may need, such as cotrimoxazole and TPT.

Pediatric ARVs

PEPFAR COP19 guidance was to phase out NVP-based ART regimens by now. What should be done with current supply of NVP-based ART regimens?

Due to high rates of resistance to NVP, PEPFAR recommends against the use of NVP-based ART regimens even during the COVID-19 response. PEPFAR funds cannot be used to procure NVP-based ART regimens. Continuity of treatment for C/ALHIV is essential. Please urgently reach out to your Chair, PPM, and HQ supply chain and ***pediatric clinical ISMEs if the only option is to provide NVP-based ART regimens.***

Our host country requires documented virological failure before optimizing a pediatric or adolescent ART regimen. What should we do if routine VL monitoring has been impacted by COVID-19 (i.e., unreliable sample transport, lengthened turnaround time due to competing needs with SARS-CoV-2 testing, etc.)?

Please see HIV Treatment FAQ "*What if PEPFAR's recommendations for adapting HIV services in the context of COVID- 19 do not align with local policy?*" In addition, WHO recommends that viral load monitoring should not be a rate limiting step to optimizing ART. CLHIV who weigh < 20 kg should be on a LPV/r regimen (or continued on an EFV-based regimen if last viral load was < 1000 copies/mL) and C/ALHIV who weigh 20+kg can be transitioned to DTG-based therapy. Transitioning C/ALHIV who weigh 20+ kg to DTG-based regimens can help spare the supply of pediatric LPV/r formulations for younger CLHIV. Please also see previous FAQ responses below.

What are the recommendations for pediatric MMD in the setting of COVID-19?

Programs should make every effort to supply children and adolescents living with HIV (CLHIV/ALHIV) initiating and refilling ART with a 3-month supply of ARVs for those who weigh < 20 kg and a 6-month supply for those who weigh 20+ kg. The caregiver should be allowed to pick up the child's medication without bringing the child, unless the child needs a clinical visit. For children requiring Cotrimoxazole, a 3-6-month supply should be provided at the same time as ARV pickup. For children starting a new medication, administration of the first dose should be demonstrated and administered in clinic, particularly LPV/r-based formulations (liquids, pellets, granules, and 100/25mg tablets). Phone or electronic follow-up for pediatric clients (within 3-4 weeks) should be emphasized and include assessment of medication dosing and administration.

HIV-exposed infants should be given the greatest quantity of infant prophylaxis, both ART and cotrimoxazole as possible to last until the next immunization or EID testing appointment.

Our stock of LPV/r 40/10 pellets and granules is inadequate for monthly dispensing; will we have enough supply to provide 3-month dispensing?

Programs should evaluate current stock (including buffer stock) to determine when replenishment stock is needed to provide MMD. This information should be communicated to interagency pediatric and supply chain ISMEs and to the OU's S/GAC Chair and PPM. PEPFAR-funded orders required for the remainder of CY 2020 should be made now.

In light of the shortage of LPVr 100/25 tablets, how can our program employ MMD for patients that require this product?

CLHIV who receive **LPVr 100/25** tablets can 1) be transitioned to a LPV/r 200/50mg formulation as soon as safely possible, or 2) receive a one month supply of LPV/r 100/25mg, or 3) depending on in-country supply, receive a 3-month supply of LPV/r 40/10mg pellets or granules. OUs are encouraged to reach out to HQ clinical and supply chain ISMEs with questions.

In the face of COVID-19 disruptions to PEPFAR-supported treatment programs, what is PEPFAR's guidance for children who are receiving EFV based regimens?

CLHIV who are already 20kg and receiving EFV should immediately transition to a DTG-based regimen. CLHIV who are <20kg and stable on EFV with virologic suppression can continue to receive EFV temporarily (during program disruption by COVID-19) but should be transitioned to DTG 50mg once they reach 20 kg.

5. HIV Testing Services

Should all people being evaluated for COVID-19 also be tested for HIV?

It is unknown whether patients with HIV are at increased risk for COVID-19. There is overlap in COVID-19 symptoms with TB (see TB-HIV FAQ guidance) and other respiratory infections, which may be more common in PLHIV.

We recommend application of the usual criteria for determining eligibility for HIV testing when patients with unknown HIV status present with symptoms consistent with COVID-19.

How will HIV testing activities be affected?

See guiding principles. All efforts should be made to support community social distancing and reduce contact of well persons with health care settings during COVID-19 period of risk. Plans should be in place to adapt programming should service be disrupted. We acknowledge that everyone who needs an HIV test may not get tested and target achievement may be impacted by COVID-19.

Potential issues/responses include:

- Adapting HTS programming to government directives or policies on social distancing.
- Maximizing use of self-testing outside of the clinic setting (including providing self-tests through decentralized distribution approaches such as: peer home delivery, private or community pharmacies, etc.)
- Prioritizing clinical-based HTS for those most in need:
    - Testing in ANC

  - Diagnostic testing for individuals presenting (or admitted) to facilities with illness suspicious for HIV infection (Diagnostictesting)
  - Individuals with TB, STIs, malnutrition
  - Early infant diagnosis (EID) detection
  - Partner/index/family testing may be offered for individuals presenting at facilities (passive testing),
  - Testing in KP programs if ongoing and not facility based.

- HRH (including lay counselors/testers) may be impacted, reducing capacity from those affected by COVID-19
- HTS should not take place where routine adequate PPE is not available, (e.g. gloves)
- For RTK implications, please see Supply Chain/Commodities section

Can community testing for HIV continue?

Programs should adapt provision of active index testing services (also referred to as provider assisted notification) and community-based HIV testing accordingly to ensure the safety and security of testing staff and other health personnel. In some settings, it may be appropriate to continue to distribute HIV self-testing kits for KP, DREAMS, OVC, and partner testing. Any changes to guidance should be reviewed with the Chair/PPM and be in accordance with Chief of Mission directives.

Can active index testing for HIV, facility or community-based, continue?

Programs should adapt provision of active index testing services (also referred to as provider assisted notification) accordingly to ensure the safety and security of testing and other health personnel. Newly diagnosed individuals should be counseled on the importance of partner testing. Client-referral should be offered as an approach for index testing. However, in the context of COVID-19, programs are encouraged to distribute HIVST kits to index clients so that partners can screen themselves prior to coming to the facility. This will ensure that only partners who are most likely to have HIV will come to the facility for confirmatory HIV testing (see FAQ about role of HIV self-testing). National policies may limit the feasibility of active index testing and country teams should review guidance with the Chair/PPM.

What is the role of HIV Self-testing in the context of COVID-19 planning?

To alleviate congestion at the facility level and reduce the need for in-person testing services, countries may consider accelerating their plans for scaling HIV self-testing distribution for those with increased risk of HIV infection. Programs may need to develop alternate workflows to ensure that patients can receive for confirmatory testing. Please discuss with your Chair/PPM to ensure there is adequate supply of HIV self-testing kits. Please see the FAQ on testing in children for additional guidance on the role of HIV self-testing in the context of COVID-19 for children.

How should partners and field staff approach HTS for children and adolescents during the COVID-19 response?

Per previous guidance, we recommend maximizing use of self-testing outside of the clinic setting and prioritizing clinical-based HTS for those children most in need

HIV Oral Screening in Children

WHO Prequalification Department approved the use of OraQuick oral HIV testing kits for use in children 2-11 years of age in November 2019. To promote HIV screening in children during the COVID-19 response, PEPFAR Programs, in collaboration with Ministries of Health, may consider providing parents with HIV **(index clients)** with oral screening kits to screen their biological children >2 years of age for HIV at home. This temporary adaptation is intended to mitigate the effects of COVID-19 on identifying children with HIV before disease progression. Children with a positive oral HIV screening require prompt confirmatory HIV testing and, if infection is confirmed, immediate ART initiation.

HIV Recency Testing

Should recency testing continue if staff and client health care setting exposure is being minimized due to COVID-19?

Due to restrictions in group gatherings and travel associated with COVID-19, trainings and site visits for activation, monitoring, and quality assurance activities for recency testing have been postponed. Recency testing adds time to the provider-client interaction and overall clinic visit, specifically for pre-test counseling to explain procedures, consent process, specimen collection, and (if applicable) return of test results. Further, recency testing does not affect the overall clinical care of patients. PEPFAR guidance recommends that "health care facilities visits should be limited to those that are medically essential." **For these reasons, it is recommended that recency testing be paused temporarily at all health facilities and laboratories, in order to reduce potential risks of COVID-19 to clients, health care workers, project staff, and clinic population**. It is further recommended that each country, in collaboration with MoH, resume recency testing and the associated public health response as soon as feasible as COVID-19 restrictions are lifted.

6. TB Services

How can we distinguish COVID-19 from tuberculosis (TB) in PLHIV?

TB and COVID-19 symptoms may overlap, and patients may be co-infected. Whether COVID-19 presents differently in HIV patients is unknown. COVID-19 typically presents more acutely. The cough for COVID- 19 is not usually productive and fever is prominent. In contrast, patients with TB usually have a persistent cough of two weeks or more. Other TB-HIV associated symptoms include weight loss or persistent night sweats.

Programs should continue to screen, test, and think TB in high prevalence areas and consider testing for both TB and COVID-19 in PLHIV, especially in people presenting with fever and cough.

COVID-19 screening is a more urgent screening and represents a higher risk to health care workers. COVID-19 screening should be performed first if indicated and available.

How will COVID-19 affect contact tracing and case-finding for TB?

Contact identification should be conducted at the first visit and patients should inform their identified contacts of their TB diagnosis and the importance of informing health care workers of their contact status should they present to a health facility for symptoms. Contact tracing may need to be deferred in the setting of COVID-19.

Community-based testing and active TB case finding strategies should follow local guidance on movement restriction and social distance measures to preserve the safety of healthcare workers and should be consistent with TB Programs' continuity of operations in setting of COVID.

How can we ensure continuity of services for TB-HIV treatment and TB Preventive Treatment (TPT) in the context of COVID-19 disruptions?

- PLHIV on TB treatment should continue their treatment and avoid potential exposures to COVID-19 at health facilities.
- TB screening algorithms should incorporate COVID-19 evaluation pathways. PLHIV screened for COVID-19 should be screened for TB. PLHIV screened for TB should be screened for COVID-19.
- Patients should be provided the full or remaining course of their drugs for TB-HIV or TPT at the next scheduled visit or sooner, if possible.
- Where possible, we recommend adhering to the usual schedule of evaluations for PLHIV with TB substituting telephonic consultations for in-person evaluations.
    - Specimen collection should adhere to national guidelines. Individuals should be provided with materials and instructions for sample self-collection in an outdoor or well-ventilated space.
    - Telephonic consultation during the intensive phase of TB treatment is critical and should focus on screening for signs of deterioration that would warrant a visit to a healthcare facility and on counseling regarding medication adherence.
    - At the end of the intensive phase of therapy a clinical visit may be warranted based on the clinical course.
- Further guidance may be found here: https://www.who.int/tb/COVID_19considerations_tuberculosis_services.pdf

How will COVID-19 epidemic affect HIV testing of individuals with presumptive TB?

All patients with suspected or confirmed TB should continue to receive HIV testing (see March 20, 2020 FAQ). Please refer to testing guidance for strategies and guidance for HIV testing in the setting of COVID-19.

How do we manage people with TB newly diagnosed with HIV in context of COVID-19 epidemic?

ART is usually started after TB therapy is underway. Consideration may be given to dispensing ART at the same time as the initial TB therapy with close telephonic consultation on when to start ART and for clinical follow-up to detect potential adverse events (e.g., IRIS-related symptoms). ART visits should be aligned with TB visits.

How will the COVID-19 epidemic affect TB testing of PLHIV with presumptive TB?

All PLHIV should be screened for both TB and COVID-19 symptoms at every visit, and if screen-positive for either or both diseases, appropriate respiratory specimen(s) collected for molecular diagnostic testing according to local policies and guidance. Note that presence of COVID-19 symptoms does not eliminate the need for TB testing, which should proceed according to current country and PEPFAR guidance. COVID-19 testing should take place according to local guidance and may be conducted concurrently with TB testing.

What about TB/HIV patients who become unwell at home?

TB-HIV patients who become unwell at home, should first contact the health facility by telephone to determine whether it is necessary to come into the facility. COVID-19 screening should be performed on the phone. Where an in-person visit is necessary, ensure understanding of procedures on arrival which should include a screen for COVID-19 and COVID-19 isolation where appropriate.

How will the COVID-19 epidemic affect people undergoing direct observed therapy (DOT)?

Individuals providing DOT should follow local guidance on social distance measures and restrictions on movement. The benefits of DOT must be balanced against the potential unintended exposure of healthcare workers. Telephone and/or video-assisted visits can help ensure adherence while abiding by social distance measures.

What infection control precautions should healthcare workers caring for TB-HIV patients take in the setting of COVID-19?

Programs should refer to WHO's Technical Guidance on Infection Control Measures in the setting of COVID-19: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance

Addressing the triple risk of stigma & discrimination for patients with TB, HIV, and COVID-19

Stigma, discrimination, and social isolation are relevant for COVID-19, TB, and HIV. Programs should use lessons learned and ongoing efforts to reduce stigma for HIV and TB to also address and reduce the potential impacts of stigma and discrimination against patients with COVID-19.

What should be done with TPT programs?

Tuberculosis preventive therapy remains a core HIV service and countries may continue their scale- up. A full course of TPT (INH or 3HP) should be dispensed. For those already on TPT, the remaining course of their TPT regimen should be given. Programs should ensure that systems are in place for adverse event monitoring whether via telephone, SMS, or electronically. Differentiated service delivery models may be helpful in this setting; adherence to infection control procedures is required.

How will TB and TPT services be affected?

For individuals already on TB or TPT regimens, please ensure they have the remaining doses needed to complete a full course of treatment. Ensure that side effect monitoring can be done via telephone, SMS, or electronically. DSD models, if in place may be utilized for community distribution and adherence support as long as they adhere to social distancing policies and guidance within the country/district.

7. Integrated Women's Health

What changes for integrated women's health services are needed for women living with HIV (WLHV) need during the COVID-19 response?

During the COVID-19 pandemic, voluntary family planning (FP) services continue to be an essential service for women of reproductive age, per country guidance. Principles of voluntarism and informed choice guide USG health service efforts.

HIV services which are integrated with contraceptive services should be optimized and streamlined to avoid unnecessary patient visits to health facilities and to efficiently use client and provider time when clinic visits are necessary. Attention should be focused on facility-based service delivery, including the following approaches:

- PEPFAR funds cannot be used to procure contraceptives, however, multi-month provision of oral contraceptive pills (OCPs) and condoms should be provided to clients who choose to use/continue use one of those methods;
- Client centered FP counseling that proactively addresses possible side effect concerns related to hormonal contraceptive use to help minimize need for revisits;
- Coordination of client FP revisits with other individual and family follow-up services to streamline and/or integrate revisit appointments;
- Voluntary long acting contraception as needed for users, develop and disseminate a schedule of service provision to ensure that clients have continued access during periods of limited facility operations/provider availability.

How will programs ensure an adequate supply of FP commodities are available for WLHIV in PEPFAR integrated programming during COVID-19?

Although PEPFAR funds cannot be used to procure contraceptives, they are made available to PEPFAR supported programs through coordination and collaboration with national FP programs and through USAID and other donor funded FP activities. Due to ongoing and newly emerging challenges with global contraceptive supply chains, it is possible that some countries may experience problems with procuring certain contraceptives. Country teams are advised to keep in close contact with their national contraceptive coordination team to get updates and report contraceptive supply problems. Contraceptives to be included in the list of essential drugs that are allowed entry into countries while shipments are restricted. Integrating FP and HIV supply chain management and distribution may also help ensure that contraceptives are available for HIV affected populations.

How will cervical cancer screening services be affected?

Cervical cancer screenings conducted outside of same-day and same-site ART clinical service visits should be limited to decrease exposure to health centers. Screening done as part of a routine ART visit may continue. Women undergoing evaluation and treatment for high grade lesions should continue with their recommended medical management. This will be reviewed in June.

8. Maternal Child Health (MCH)

How will maternal and child health (MCH) services change within the context of COVID-19?

Please defer to local government regulations for specific guidance on clinic operations. When MCH clinics are operational, please encourage or enable HIV testing for pregnant/breastfeeding women (PBFW) and treatment services for women living with HIV (WLHIV) and their HIV-exposed infants to be included within essential services, including prioritizing maternal HIV testing and treatment and early infant diagnosis. PBFW on treatment should receive MMD (see HIV Treatment FAQ). Consider options to limit or reduce time spent in clinical settings, such as providing services in community settings, bundling services, or providing them in separate mother and baby fast track areas.

Should the frequency of ANC visits be adjusted, given the current COVID-19 context?

Women should follow local and national guidelines for ANC testing.

- Regular retesting for HIV is still encouraged if feasible, especially in high burden areas, at the already-scheduled visits and at delivery;
- Women should be encouraged to leave children and other family members at home during their clinic visits. While at the clinic, all consideration should be made to allow patients to wait in uncrowded areas for their visits and to streamline visits by integration with other essential services;
- Consider operational adjustments to improve flow of patients through the clinic and to reduce amount of time spent in clinical settings;
- Consider dispersing some services to community settings when possible.

Should we continue offering PrEP to PBFW during this time?

Absolutely. PrEP is a critical HIV prevention tool. Consider multi-month dispensing of PrEP.

If safety concerns related to COVID-19 result in WLHIV giving birth outside facilities, should they be offered newborn prophylaxis to take home in case they deliver at home/in a community setting?

Yes, this can be supported through PEPFAR programming.

- Consider providing infant ARVs with dosing instructions to women who will not be able to return to the facility for delivery. Please ensure that women are offered the correct regimens and dosages pursuant to local guidelines and provide supply for as long as necessary. The weight of the unborn infant will need to be estimated by the provider in order to determine the correct dosing. It may be useful to estimate if the baby will be small, medium, or large to determine which weight band to use.
- In some countries, mother-baby packs have been used to package ARVs for mother-infant pairs together. Clinic staff can actively follow up with WLHIV by phone to check in on accurate dosing. Retention and adherence support can also be reinforced by phone through community cadres, such as M2M, Mentor Mothers and/or OVC community caseworkers.
- If a woman has been given drugs to keep at home for newborn prophylaxis and she comes to a facility for delivery, she should bring the drugs with her for her newborn.

Should EID continue during the COVID-19 pandemic?

Yes, EID is an essential service. There is high mortality associated with untreated HIV among infants. HIV-exposed infants should continue to receive an EID test and clinical assessment as close to the recommended algorithm timing as possible. Fears of COVID-19 may make women reluctant to attend postnatal visits with their infants.

Consider options for timing and location that allow for social distancing such as reducing wait times and crowded waiting rooms through scheduling and staggering appointments, streamlining clinic flow so that patients do not interact with multiple clinic providers, and providing EID and immunizations in community settings if possible.

Consider creating an area for postpartum/well-baby checkups that is near to but separated from the health care facility to reduce contact/exposure for PBFW and their infants. Every effort should be taken to minimize stigma by integrating HIV services for HIV-exposed infants and mothers with postpartum/well-child services including immunizations. If mobile testing or point of care services are available at the community level please consider expanding those options.

Women are not returning with their infants for follow up visits or HIV testing. Most mass immunization campaigns have been suspended. How can we improve services for PBFW during the COVID-19 pandemic?

Retention and adherence support to pregnant and breastfeeding women is still crucial to prevent MTCT. Consider expanding phone/SMS support to mothers and infants through existing support mechanisms (e.g. community health workers, peer navigators, M2M, mentor mothers) to align with ANC and PNC clinical touchpoints, as well as identifying transport methods to bring women or infants who are high risk or in need of clinical support to the facility.

9. HIV Prevention – General

Can implementing partners who work on HIV prevention activities continue operations during the COVID-19 pandemic?

HIV prevention activities can and should continue. The safety of staff members, volunteers and clients must be prioritized, and person-to-person interactions should be limited whenever possible – but PEPFAR is not stepping away from the life saving measures that HIV prevention services bring to people around the world. Alternate methods of communication such as phone calls, WhatsApp and text messaging services should be utilized in order to minimize individual visits, meetings or counseling sessions related to HIV prevention.

Why are we concerned about HIV acquisition rates increasing during periods of confinement/social isolation/self-quarantines?

Physical confinement measures are critical to contain the spread of COVID-19, but as these periods of confinement are extended, there is growing potential for increasing rates of sexual exposure for many people. Interpersonal violence, including sexual violence and violence against women and children may increase. Agencies need to work with IPs and Government to ensure that information about Gender Based

Violence (GBV) is provided. Please see GBV specific FAQs. Sharing local contact options of responders who can address GBV related concerns may be initial options in some PEPFAR contexts.

What are some HIV prevention services that can be kept operational within the physical distancing parameters of COVID-19?

Some examples such as the following should be considered based on populations at risk and budget availability:

- As PEPFAR teams prepare supply chain forecasts early, they should ensure that condom and lubricant supplies are also increased both to account for the increase in need, and because bulk packaging/delivery will be necessary once shipments arrive (i.e. clients will no longer be able to take 1 or 2 condoms at a time during a clinic visit or from a volunteer health care worker at a community gathering);
- Packaging of condoms and lubricants should be made in larger than normal quantities (akin to multi-month dispensing of ARVs) so that clients can obtain necessary supplies in sufficient quantities that allow them to minimize the number of collection visits they might need to make to a collection point. Distribution points or displays should be modified in order to allow clients to pick up these products without touching or handling products for other clients (e.g. avoid bowls). Clients are also encouraged to clean anything they pick up from collection points.

10. HIV Prevention - PrEP

Should PrEP be considered an essential prevention intervention during the COVID response?

PrEP is an essential component of PEPFAR HIV programming. Strong advocacy for PrEP service delivery should continue as part of comprehensive combination prevention including counseling (by phone), condoms, and lubricants, or as outlined in country guidelines.

Can multiple months of PrEP be given on the first/initiation visit? What happens to the currently standard one-month check in visit?

This should be assessed and decided by the client and provider together according to the client's needs. If a client is committed to taking several months of PrEP from initiation, then it should be allowed. Many clients express interest in taking PrEP but either don't start or don't follow-up at the one month visit. Follow-up one month after starting PrEP remains important but can be conducted through other available modalities, such as over the phone, or somewhere outside of the clinic space, in order to decrease facility congestion and adhere to social distancing guidance.

With some reductions of direct hire staff in some countries due to evacuations and/or competing priorities because of COVID-19, how can we ensure PrEP services are properly supported?

PEPFAR staff who have evacuated post continue to work from remote settings. Teams should address how IPs can make a determination how best to provide PrEP services and to provide USG agency oversight. As services are decentralized from clinics to lessen congestion, it will be important to communicate to clients where services can be accessed and provide a contact for continued communication, as needed.

Are there innovations or programmatic solutions that implementing partners (IPs) can utilize to keep PrEP services going during COVID-19?

PEPFAR recommends moving PrEP services away from and out of clinics as much as possible, using virtual options for client initiations, refills and check-ins, decentralizing dispensing of PrEP through community delivery, and moving to multi-month dispensing (MMD) as much as possible. We recommend using SMS for refill and for adherence reminders, for example. Solutions for how some IPs have shifted to decentralized and/or virtual platforms will be shared in the coming weeks through PEPFAR and the PrEP Community of Practice.

Should demand creation for PrEP continue?

Demand creation based on larger social gatherings, or social mobilization, should be paused for the duration of COVID-19 until social distancing requirements are relaxed in the specific community. However, other demand creation based on no-contact or limited-contact platforms such as radio, printed materials or virtual platforms such as videos, internet banners or podcasts should continue. With increased attention to social platforms (WhatsApp, Facebook, Instagram) to encourage community cohesion during physical isolation periods, community leaders and mentors can continue to encourage PrEP uptake safely from these settings.

How will PrEP be affected?

For individuals already on PrEP, a 3-month supply of PreP medication should be given. Any interim or follow up visits to assess side effects should be done by telephone, SMS, internet, or e-mail if possible (with agreement of clients). Teams are encouraged to immediately calculate any increase in PrEP that would be required to dispense 3 months' worth of PrEP.

Community distribution and adherence support in small groups (less than 10 people present at a time) for PrEP may help support people and would not be a burden on the health care system. Adherence group meetings over the phone and use of SMS to send reminders is suggested as well. It is suggested that decentralized drug distribution approaches be considered for PrEP that include peer home delivery, scheduled community or private pharmacy pick-ups, distribution through pop-up pharmacies (that dispense other products such as products for hypertension, diabetes, HIV self tests, etc.).

Decentralized approaches can be used whether dispensing a monthly or 3-month supply. Note that it is up to the provider and client to decide how many months to dispense according to the needs of the client, and this can be done at any visit, including the first. As multi-month dispensing of PrEP occurs, it will be important to notify supply chain colleagues to ensure adequate supply planning.

11. HIV Prevention – VMMC

How will VMMC services be affected?

New VMMCs may be delayed or paused if guidance around mass gatherings renders them impractical. Post-operative follow-up should continue for circumcisions that have already occurred with consideration given for telephonic consultation as an initial screening, before an in-person visit. We acknowledge that prevention services for men may be impacted by COVID-19.

Should country teams continue reporting VMMC Notifiable Adverse Events and conducting investigations?

Teams should continue reporting NAEs as they normally would. If guidance around travel/stay-at-home orders makes the investigation of NAEs impossible, please include that information in the initial notification email to VMMC_AE@state.gov. **Investigations of any cases involving the death of a client should continue as normal to the extent possible**. Country teams should reach out to VMMC_AE@state.gov for any further guidance as needed.

What age considerations should be followed for VMMC once services are resumed?

Due to increased risk of severe AEs in boys 10-14 years of age, PEPFAR's COP20 guidance changed the lower age limit for VMMC to 15 years. Countries were encouraged to prepare for this change in COP19 with full transition at the start of COP20. However, severe AEs have continued to occur among boys 10-14 and VMMC services are currently partially or fully paused due to the COVID-19 pandemic.

When VMMC services resume following the COVID-19 related pause, programs should:

1. Not circumcise boys age 10-14
2. For boys under 15 presenting for VMMC, provide other age-appropriate prevention services as outlined in COP20 guidance, counsel the client/parents on additional risks identified in boys 10-14 and encourage them to return for VMMC when the boy is 15 years or older.
3. Further information about use of the Shang ring will be provided when appropriate.

12. Orphans and Vulnerable Children (OVC)

Per MER 2.4 guidance, OVC "active" beneficiaries are required to have a case plan and must be monitored at least quarterly. Due to "stay at home" restrictions imposed by host country governments during COVID-19, OVC frontline workers are in many cases unable to monitor children via direct contact. Can OVC continue to be counted as "active" if contact is not made in person?

Yes. While direct contact is preferred in order to observe the status of the child and family, the MER guidance states that monitoring can occur "virtually where needed." During the COVID-19 period, it is expected that virtual contact may be the only option until operations return to normal. To be counted as "active," all OVC_SERV requirements must be met, which includes: having a case plan that has been developed (or updated) in the last 12 months; at least quarterly monitoring; and delivery of at least one of the OVC services (listed in MER Guidance Appendix E) in each of the past two quarters. Documentation of any virtual contact should be recorded in the child's case plan.

As many OVC programs shift to providing temporary virtual support to children and families via remote case management, which services may be counted under OVC_SERV?

Any OVC service included in MER Guidance (Appendix E: Illustrative eligible services for active OVC beneficiaries) that can be delivered or facilitated via remote/virtual support, in line with host country government social distancing policies and guidelines, can be counted. For example, adaptations may include providing treatment literacy and adherence support, through routine phone, SMS, and/or WhatsApp

communications and support. Remote case management can facilitate linkage to local food supplementation, hygiene supplies, social grants, and distance learning opportunities. IPs are also encouraged to incorporate COVID-19 prevention messaging per host county MOH guidelines and resources into their virtual support to households.

HIV Risk Screening in OVC

If OVC case management shifts to a phone-based virtual approach, consider including HIV risk screening of OVC with unknown HIV status in the list of phone-based services. Implementing partners can develop a list of children who warrant HIV testing to ensure children in need of testing be identified for HIV testing as soon as feasible.

OVC Enrollment in the Context of COVID-19

Should enrollment in OVC programs continue in the context of the COVID -19 epidemic?

The safety and wellbeing of OVC workers and potential beneficiaries are of the utmost importance and should be prioritized when assessing whether to continue enrollment during COVID-19. PEPFAR-supported cadres should follow host government guidance as it relates to new enrollments and avoid unnecessary interactions with potential beneficiaries in facilities and communities to reduce exposure to and spread of COVID-19. National approaches and sub-national unit operations to prevent COVID-19 transmission may vary within a given country or region.

If enrollment is not allowed nor feasible, programs should create a waiting list or tracking system to ensure that eligible beneficiaries who were not able to be enrolled due to COVID-19 can be rapidly enrolled when normal operations return.

If enrollments into OVC programs are feasible, which infants, children, and adolescents should be prioritized?

OVC programming should follow current COP guidance. Populations to be prioritized for enrollment include:

- Children and adolescents living with HIV (C/ALHIV)
- HIV-exposed infants (especially those of adolescent mothers and newly diagnosed women)
- All infants, children, or adolescents who are exposed to abuse, harm, or violence

If OVC enrollment is allowed/feasible, how should enrollments of priority sub-populations take place?

As previously discussed, OVC programs should explore the temporary use of telephone-based enrollment and referrals. In select cases (e.g. critically ill child/child failing treatment, child abuse), in-person referrals, enrollment, and immediate linkage to emergency services may be required (see PEPFAR FAQs regarding home visits and GBV/CP). Key steps for enrolling priority OVC sub-populations in the COVID-19 operating context include:

- Update program MOUs, SOPs, and/or referral protocols between OVC and accredited clinical, child protection/social service, and law enforcement service providers to include an option for routine

telephone-based referrals to the OVC program. Referrals to OVC should include accurate telephone contact information for each child's parent/primary caregiver.

- Designate relevant OVC case workers to serve as points of contact for phone-based referrals; ensure that the service providers mentioned above have case workers' current contact information; and ensure the provision of sufficient airtime for OVC case workers processing referrals via phone.
- Based on receiving a phone referral from a service provider, the OVC case worker contacts the child's parent/primary caregiver via phone; provides key information about the OVC program and the types of support provided; and offers OVC program enrollment to the family.
- If the parent/primary caregiver accepts OVC program enrollment, the OVC case worker proceeds to request additional child and family information via phone in order to complete the program enrollment form.
- The OVC case worker and parent/primary caregiver arrange an appropriate date and time for a follow-up call to conduct a broader assessment of the child and family in order to complete the OVC needs assessment form.
- The OVC case worker opens a new child and family OVC case file and initiates remote case management (including care plan development, relevant counseling, service linkage where feasible, and monitoring) via routine telephone checks-ins with the parent/primary caregiver.

Please see the FAQ on testing children under HIV Testing, and cadres working with children and families under HRH for further relevant information.

13. DREAMS

Given the inability to gather in groups, or in some cases in person, how should DREAMS IPs stay engaged with AGYW?

A major priority during this time is to maintain contact with DREAMS AGYW in the most practical and cost effective way possible. Depending on the country and local context, this might be via SMS, phone calls, or other digital platforms such as WhatsApp. Please ensure that mentors and facilitators have adequate airtime and/or data to perform these functions. Ideally, mentors would maintain contact with AGYW in their cohorts and at the same frequency they would normally meet. Digital contact should be made both individually and as a group if possible. Partners should choose the best way to stay in touch based on their context.

Contact should focus on keeping AGYW engaged with her mentor and peers, providing referrals for time sensitive services, e.g. GBV response, FP, and PrEP, and reinforcing content that was already conveyed during in-person sessions. Delivery of new sessions from DREAMS curriculum should not be delivered over SMS or digitally.

How will the key population and DREAMS activities be affected?

With respect to prevention activities for KP and DREAMS beneficiaries, planning for smaller gatherings should begin. Group-based activities should follow local guidelines for mass gatherings (e.g. community

mobilization and norms change sessions, parenting sessions, and 'safe space' sessions) and in-person group-based activities may need to be paused. If multiple groups are meeting concurrently in a shared space, teams/partners should be sure that there is enough time and space between groups so that they are still adhering to the local mass gathering guidance. For DREAMS specifically, if possible, country teams should consider temporarily moving safe spaces that are currently held in facilities into community spaces identified by AGYW and mentors. If this is not possible, teams/partners may need to consider postponing safe spaces meetings until guidance allows for them to begin again.

Additionally, where feasible and appropriate, facility-based DREAMS services should be offered in the community with appropriate social distancing.

14. Key Populations (KP) Services During the COVID-19 Pandemic

Depending on how COVID-19 impacts your country, there may be significant interruptions in access to HIV services for key populations. This may lead to economic uncertainty, increased risk-taking behavior, further experience of stigma and personal violence. Community outreach and traditional peer outreach approaches will likely be disrupted and will need to be adapted based on the client's needs.

Prioritize Uninterrupted HIV Treatment Access, Clinical Care, and Support for Key Populations

- Services should be modified and decentralized so that all KPs can continue to access treatment, PrEP and viral load testing and other care through community platforms.
- Continued coordination and collaboration among community case management teams prioritizing virtual platforms to determine appropriate and needed differentiated services for KPLHIV

Testing, Prevention and PrEP Services

- Prioritize differentiated service delivery through community initiation and refill of PrEP and delivery of HIV testing including self-testing via mobile clinics, drop-in centers (DICs), and other community platforms or alternative arrangements for pickup or delivery of services
- Ensure peer outreach workers have enough supply of commodities and/or there are also community distribution points for commodities like condoms, lubricant and self-test kits.
- **Leverage Virtual Approaches**: Use of social media, phone, SMS, and alternative methods of communication by health care and peer workers may ensure critical services are continued.

Ensure Safety of Key Populations

- Programs should track reports of barriers to service delivery
- Work with IPs and engage KP community-based organizations to provide basic communications materials including infection prevention
- Programs should ensure violence prevention mechanisms and referrals are functioning to track and link clients to needed services

Is there an update on index testing for key populations?

The evolving situation with COVID-19 may have implications for HTS implementation, monitoring and achieving HTS results, and teams are expected to operate under any COVID-19 related country guidelines as well as KP and HTS programming considerations below. However, given the progress made in recent months on ensuring HTS minimum standards through multiple processes, at this time, the previous halt on active index testing among key populations has been lifted. PEPFAR will work with country teams to ensure that either: (1) existing data confirm that current HTS provision at sites meets minimum standards or (2) sites are brought up to standards and assessed using vetted and valid tools. PEPFAR remains committed to ensuring all sites providing index testing services do so in a manner that meets established standards. Consult your S/GAC chair or PPM if needed.

15. Gender-Based Violence (GBV) & Child Protection (CP)

What should all PEPFAR teams be aware of regarding violence during the COVID-19 pandemic?

Domestic violence has sharply increased since the COVID-19 outbreak (Godin, 2020). Violence, particularly intimate partner violence (IPV), increases risk of HIV acquisition (WHO, 2013) and can negatively impact an individual's adherence, retention, and viral suppression (Hatcher, 2015), PEPFAR programs must respond to violence in order to maintain achievements in retention and viral suppression during the COVID-19 outbreak.

All PEPFAR programs (both clinical & community) can respond to GBV and CP by:

1. Advocating with host governments to designate child protection and GBV responders (and their organizations and government agencies) as essential and operational during lockdowns. This also includes child helplines and other remote services.
2. Working with local governments, community partners, local organizations, and other donors to continuously update lists/directories (e.g. contact information, opening hours) of all local GBV/CP response services and national hotlines that are functional, including both clinical and non-clinical supportive services.
3. Specific considerations for clinical and community partners are noted in the following FAQs. Additional resources can be found here: https://gbvguidelines.org/en/knowledgehub/covid-19/

If there is immediate concern for a child being exposed to physical harm, abuse or neglect that requires urgent attention, this should be reported to the appropriate accredited authorities. Please see FAQs on home visits.

How can clinical partners respond to GBV and CP issues during the COVID-19 pandemic?

1. Ensure that all staff have access to an updated list of local GBV/CP responses services and national hotlines for referrals.
2. Facilities should have printed material that provides information on functioning local GBV/CP services and national hotlines that providers can discreetly give to clients. Community partners and local organizations may already have materials available for distribution.

3. Providers should deliver age-appropriate first-line support (LIVES) to all clients who disclose violence and provide or refer clients to appropriate, functioning GBV response services.
4. Providers should help clients make a plan to stay safe at home while living in quarantine or isolation, including tips on how to safely access support. Ensuring privacy is critical (e.g., using a safety/code word if disclosing violence in proximity of the perpetrator). It is important to do no harm.
5. Providers should help clients find ways to discreetly and safely take their ARVs while in quarantine or isolation. This is important for people who have not disclosed their status or use of ART or PrEP to their partner/family.
6. Ensure PEPFAR-supported specialized GBV/CP facilities or one-stop-centers have enough phone/internet credit to provide virtual psychosocial support and safety planning services.

How can community partners respond to GBV and CP issues during the COVID-19 pandemic?

Maintain and adjust communication

- Implementing partners (IPs) should use calls, SMS, social media, and/or work with Governments to provide information about GBV/CP and COVID-19, including contact information for functioning GBV/CP response services.
- IPs with access to media such as radio, internet, or television can provide information on the risk for increased interpersonal violence during COVID-19 and resources available to those who need support.

Keep in contact with those at elevated risk for GBV or child abuse/neglect

- For participants who have disclosed experiences with violence or are potentially at higher risk for violence, staff (e.g., counselors, social workers, gender leads) may proactively reach out and discretely offer support, including developing a safety plan in the case of quarantine or social isolation and ensuring those in need know how to safely access support. Ensuring privacy is critical (e.g., using a safety/code word if disclosing violence in proximity of the perpetrator). It is important to do no harm.
- Programs that have existing relationships with individuals and families (e.g., OVC, DREAMS) should maintain communication using virtual platforms as possible. Please refer to the DREAMS FAQ on maintaining contact with AGYW.

Support frontline staff

- IPs should ensure their field staff, mentors, and community health workers have the resources (e.g., internet connection, airtime) to reach out to PEPFAR participants to provide support, safety planning, and linkage to services as necessary.
- IPs should promote self-care and prioritize safety of staff, being cognizant of potential trauma during emergency situations.

Ensure appropriate response services are in-place and known

- Ensure that all staff have access to an updated list of local GBV/CP responses services and national hotlines for referrals.

16. Faith and Community Based Organizations

How can Faith and Community leaders help with the multiplicity of challenges countries are facing due to the co-occurrence of HIV and a COVID-19 pandemic?

- Provide accurate and timely information from reliable sources about practical considerations and recommendations for religious leaders and faith communities in the context of COVID-19. Example: https://www.who.int/publications-detail/practical-considerations-and-recommendations-for-religious-leaders-and-faith-based-communities-in-the-context-of-covid-19
- Encourage PLHIV in and/or known to their congregations, to maintain an adequate supply of ART

What changes in the 'Faith and Community Initiative' activities are needed during the COVID-19 response?

In the context of COVID-19, PEPFAR-supported staff working on priority #1 of the FCI: "Engaging faith communities to reach men and children living with HIV, and to link and retain them in care", should be focused on supporting, maintaining, and extending continuity of HIV treatment for men, youth, and children, by:

- Leveraging functioning religious structures to use weekly virtual Facebook Live/YouTube® religious services for congregations and men's, women's, and youth groups, as well as congregational WhatsApp groups, to disseminate HIV Messages of Hope, prioritizing messages that use FCI message prototypes (SMS messages, video clips, etc.) to support adherence for PLHIV; leveraging these religious structures to integrate COVID-19 risk prevention communications for at-risk populations and PLHIV.
- Expanding engagement of Religious Leaders Affected by and Infected with HIV, in reducing HIV-associated stigma, to include stigma associated with TB and COVID-19
- Expanding client base of faith-engaged neighborhood Community Posts to increase convenient access to ARV pick-ups and MMD, among index clients and contacts,
- Expanding FCI models that link highly targeted HIV self-testing to treatment and retention support
- PEPFAR-supported FCI staff providing psychosocial support to boost adherence should avoid home visits and should provide such support remotely using phone, text, or WhatsApp.

17. Infection Prevention and Control

What measures should be implemented to reduce COVID-19 exposures in the healthcare setting?

- The basic principles of IPC and standard precautions should be applied in all health care facilities and are critical to containment of SARS CoV-2.
- Health care facilities visits should be limited to those that are medically essential
- All facilities should have a designated focal point to oversee and monitor infection prevention activities; this individual should be supported to provide the basic principles according to WHO guidance which include:

- Written procedures for identifying and managing clients and staff with potential COVID- 19 exposures or illness;
- Systematic triage to identify ill persons;
- Strict adherence to hand hygiene and respiratory hygiene;
- Medical masks to be used by patients with respiratory symptoms;
- Prioritization of care of symptomatic patients
- When symptomatic patients are required to wait for services; ensure they are placed in a separate waiting area.
- Appropriate supplies to allow implementation of contact and droplet precautions for all suspected COVID-19 cases;
- Strict protocols for routine cleaning and disinfection of medical equipment and environmental (especially "high touch") surfaces
- Education and training of staff regarding IC precautions for COVID-19
- Airborne precautions are recommended only for staff performing aerosol generating procedures. These procedures include tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, and bronchoscopy

Details can be found here:

https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care- when-novel-coronavirus-(ncov)-infection-is-suspected-20200125

Non-medical (or Homemade) Masks

Should IPs promote the use of non-medical (or homemade) masks as Personal protective equipment (PPE) in PEPFAR-supported health clinics/facilities?

No. Non-medical or homemade facemasks are not considered PPE because they have unknown protective capabilities. This is consistent with both CDC guidance and WHO guidance.

Should IPs promote the informal production and use of non-medical (or homemade) masks to prevent community spread of COVID-19?

- As of April 6, CDC recommends the use of cloth face coverings to lessen transmission of COVID-19 in public settings where other social distancing measures are difficult to maintain (e.g., grocery stores and pharmacies) particularly in areas impacted by COVID-19. Under no circumstances should cloth face masks replace or substitute for the approved PPE recommended for frontline workers (e.g., healthcare workers, community workers) to protect themselves from coronavirus acquisition in health facilities.
- As of April 6, WHO guidance takes a more cautious approach for non-medical masks used by the general public in community settings, citing the lack of evidence on effectiveness but also outlining a decision-making framework for policymakers.

- IPs should only consider this action if official policy, normative guidance, and/or agreement is obtained from host country governments. IPs should communicate at all times that non-medical masks are distinctly different from PPE.
- Community-based production of homemade face masks can also be integrated into current economic strengthening or income-generation activities, where such activities are already taking place and able to continue. Examples can include supplying raw materials along with training activities that are prudently adapted to ensure proper social distancing (e.g., virtual training through WhatsApp and other accessible technology).
- IP efforts should follow normative guidelines and standardized practices (such as the CDC guidance) and coordinate closely with promotional campaigns (which may or may not be implemented directly by the IP) to ensure public sensitization on proper use, re-use, and disposal as well as limitations on personal protection.

18. Laboratory Services

How has COVID-19 affected the supply chain of laboratory products and what measures should be taken to minimize its impact?

There are current delays for rapid test kits (RTKs) either manufactured in China or relying on key starting materials from China, and Asia, more broadly. Delays or pricing increases are being tracked and communicated as they arise. Current guidance is to place orders for laboratory commodities and RTKs **one month** earlier than normal, to account for potential shipping delays.

What is the overlap between viral load testing and SARS-CoV-2 testing, since they are both PCR- based?

At present, most laboratories in the Africa region are using instruments and reagents for SARS-CoV- 2 testing that are different from those used for HIV viral load and EID testing; however, SARS-CoV-2 testing options are evolving rapidly and commonly used HIV viral load and EID instruments are anticipated to be coming online for SARS-CoV-2 in the short to medium term.

How will SARS-CoV-2 testing impact HIV VL testing?

OUs should anticipate increased use of common consumables and PPE for COVID-19 and HIV-related testing in laboratories and anticipate and plan for diversion of or reductions in laboratory staff and other HRH available for HIV (VL/EID) testing due to COVID-19. Laboratories should prioritize testing based on local requirements. For HIV laboratory testing, EID and viral load services for children, PBFW, and adults with documented non-suppression on their last VL result should be prioritized.

What measures should be taken to ensure stocks of laboratory supplies?

OUs should update current stock counts at national and subnational levels and forecast for additional consumable needs to accommodate increases in COVID-19 testing. It is recommended that orders be places at least one month in advance to reduce the risk of shipping delays resulting in stock outs.

Is there a plan to use HIV VL/EID platforms for SARS-CoV-2 testing?

On Friday, March 13, the Roche SARS-CoV-2 Test received FDA emergency use authorization (EUA) and other manufacturers are developing COVID-19 tests that may be run on existing HIV VL/EID instruments.

What procedures should be carried out If testing for SARS-CoV-2 and HIV VL/EID are conducted in the same laboratories?

In PEPFAR supported laboratories running COVID-19 and HIV-related testing on the same instrument, SOPs should be developed to account for prioritization of testing (e.g., COVID-19, EID, VL).

19. Supply Chain/Commodities

Decentralized Drug Delivery

Decentralized drug delivery systems offer the opportunity to reduce risk in the health care setting and are recommended for all programs.

Supply Chain for ARVs

We don't currently have enough stock to supply each recipient with six months of therapy. What should we do?

PEPFAR advises country programs to access the current total stock on-hand in-country and develop a distribution plan to replenish all facilities and patient dispensing sites. If sufficient ARV stock is not available for 6 month dispensing for adults and adolescents and 3 month dispensing for children, countries should distribute the available drug supply with a goal that all clients have enough drug on hand to last for the next 3 months. This will require a change in procedure related to the maintenance of the minimum stock levels and buffer stock levels. Replenishment orders should be placed as soon as possible. Following this strategy will ensure that recipients of care will have sufficient ARVs in the coming months should there be additional disruptions in clinical operations or restrictions in distribution. PEPFAR is actively working to ensure supply security of HIV/AIDS commodities and will continue to provide timely updates using the USAID Supply Chain Activities Managers weekly call. USAID is also coordinating with Global Fund to ensure that ARVs are imported to prevent overstock and stock-outs. PEPFAR Country teams should work with Ministries of Health to ensure that multi-month dispensing policies are communicated to all HIV/AIDS providers, facilities, pharmacies, and supply chain to ensure continuity of services are assured. For recipients of care due for refills within the next 3 months, consideration should be given to providing additional supply early, and distributing stock to clinics rather than holding large quantities at central medical stores or provincial stores, in case local transportation and access to the clinics becomes restricted.

Should we expect delays in ARV drug orders?

A median delay of about 25 days is anticipated for adult and pediatric ARVs. Buffer stocks available in central warehouses should be sufficient to cover shortages caused by this delay. Deliveries of orders for antiretrovirals are delayed, because the majority of the US-FDA approved ARV manufacturers are based in India, which has been experiencing a lockdown in response to COVID-19. Originally planned for 21 days, the lockdown in India has now been extended until May 3, 2020.

Although pharmaceutical manufacturing is exempt from the lockdown, it is hampered by lockdown impacts on public transport and other logistics. Consequently, suppliers report operating at approximately 30 to 50 percent normal manufacturing capacity, and at least one manufacturer has completely shut down. Fortunately, in recent weeks, there has been an increase in manufacturing capacity and an improvement with in-country logistics (movement of truckers between states) as the lockdown continues. USAID, through GHSC-PSM, is actively pursuing other sources of ARVs.

Are there also delays expected for orders of non-ARV drugs?

Non-ARV medications: Most orders for essential medicines (non-ARVs) have not been significantly impacted by COVID-19 disruptions in logistics. Chinese pharmaceutical and diagnostics suppliers are operating at nearly 90% capacity. Other essential medicines, including medicines used for TPT, are mainly sourced through USAID International Wholesalers based in the Netherlands and Denmark.

What changes may be anticipated for the supply chain of drugs?

As the COVID-19 pandemic continues to evolve S/GAC, USAID, CDC and GHSC-PSM have taken steps to monitor the situation as it pertains to availability of ARVs and other drugs essential to the HIV response. Because of anticipated delays USAID has instructed the Missions to place orders one month earlier than normal lead times would suggest. As mentioned above, additional stock may be required to activate 6MMD at a wider scale and commodity needs above COP19 and COP20 plans should be discussed with USAID and PSM immediately.

What should be done to prevent country-level drug shortages?

Consider the following interventions:

- Substituting products/formulations where necessary.
- Ongoing supply plan and inventory data (PPM/R) review to identify and respond to urgent need
- Decentralized distribution approaches (as highlighted above) that include: Home deliveries, community or private pharmacies, pharmacy in a box and automated lockers.
- Order staggering to prevent delivery delays
- Prioritization exercises across Task Order and as feasible across procurers to ensure that the most urgent need is met (across products, across countries)
- Reallocation of urgently needed orders to less impacted suppliers, as warranted and feasible

Tracking Supply Chain Impact

How will supply chain for COVID-19 be tracked?

GHSC-PSM is in the process of developing a **COVID 19 Impact Dashboard**, which will allow Mission supply chain staff to track the impact of COVID-19 on their orders. Additionally, GHSC-PSM is developing a **Market Risk Map** by commodity portfolio to assess the long-term impact commodity portfolio to assess severity of the risk, probability of the risk, and timing of the potential risk to help inform our short and long-term mitigation strategies

How will USAID and GHSC-PSM Mitigate Risk?

- Early Identification of Delayed and At-Risk Orders
- Bi-weekly order status reports from all suppliers with supplemental calls as needed
- Ongoing monitoring of key raw material export data
- Ongoing market assessments to identify capacity constraints
- Ongoing updates on sampling restrictions and communications with QA labs
- Exploring alternate shipment modes to reduce delays
- Coordination meetings with WHO Access to Medicines and Health Products, and the Global Fund

Supply Chain for Personal Protective Equipment (PPE)

What about personal protective equipment?

There is currently a world-wide shortage of personal protective equipment (PPE). PEPFAR has not procured PPE in large quantities in the past and cannot currently ensure appropriate or adequate supply. We are therefore asking teams to seek alternative sources at this time. It is important that health workers providing ART services in areas impacted by COVID-19 use PPE to protect against self-exposure and transmitting to our highly vulnerable population. PEPFAR will work to gather and disseminate information about alternative sources or solutions for PPE as they become available.

Requirements for PPE can be found here:

https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE_use-2020.1- eng.pdf

20. Operations

How will operations at PEPFAR be affected and what measures should be taken to prevent disruptions?

- Social distancing measures including quarantine have resulted in disrupted operations due to evacuations, travel restrictions and fragile communications networks outside of the larger cities. PEPFAR country teams should make all efforts to stay in communication with headquarters, and with implementing partners who may be most affected.
- Requests to utilize resources that support HIV services but also respond to COVID-19 should follow budget guidance that has been provided in a separate document. Agencies at Post must, in turn, consult with the S/GAC Chair with copy to **SGAC_M&B@state.gov** ahead of granting approval for such activities.

21. Reporting and SIMS

Is the PEPFAR Quarter 2 reporting deadline still the same?

Recognizing challenges with site-level access in countries across the world, the PEPFAR Quarter 2 reporting deadline has been moved to **Friday, June 5th**. Detailed guidance is forthcoming from SGAC_SI. We will

closely monitor PEPFAR program implementation in the ensuing weeks and provide updated guidance as needed for Quarter 3 reporting.

Are we expected to continue SIMS implementation and reporting?

All PEPFAR programs are under Chief of Mission authority therefore country teams and implementing partners should follow Embassy Front Office direction on all programing that requires personnel movement. There are updated WHO guidelines and public health recommendations regarding personal safety to determine the feasibility of in-person site monitoring visits during the COVID-19 response. Please also refer to the Operational Issues and Infection Prevention and Control sub-sections of this guidance document. We recognize that SIMS implementation and reporting has, and will continue to be, affected during this time. Similar to guidance issued regarding MER, the SIMS Q2 reporting deadline has also been extended. **The SIMS FY20 Q2 import deadline is extended to May 29, 2020** (as per usual, this is one week prior to the quarterly DATIM data entry close deadline; now June 5 for FY20 Q2). Additional SIMS reporting guidance is forthcoming from SGAC_SIMS@state.gov

Budget Guidance

Please coordinate with your agency financial POCs for how to address any budget implications of implementing this guidance.

Feedback/Question Submission: As is feasible given your country situation, PEPFAR programs are requested to share new MoH guidance for HIV services in the COVID-19 context, incoming technical questions, as well as any solutions for PEPFAR programs in the context of COVID-19. Guidance that has already been issued should be shared for awareness; PEPFAR HQ would be happy to provide rapid input on guidance that is still in draft form. Please send these new MoH guidance documents directly to S/GAC by emailing them to Dr. Katy Godfrey qea0@cdc.gov, Teri Wingate gza2@cdc.gov, and Helina Meri MeriHD@state.gov, copying your Chair and PPM.

22. Information and Resources

Resources on GBV and Child Protection:

- Health care for women subjected to intimate partner violence or sexual violence: A clinical handbook – WHO, 2014
  - Job aids can be found on pages 11 (how to ask about violence) and 14-32 (LIVES, including safety planning and referrals)
- Caring for women subjected to violence: A WHO curriculum for training health-care providers - WHO, 2019
- Integrating Violence Against Children Prevention and Response into HIV Service
  - Job aids can be found in the Participants Manual on pages 48-53 (LIVES) and 72 (referrals).

Training Resources:

- The Strengthening Interprofessional Education for HIV (STRIPE) program offers trainings specific to COVID-19 for HIV care providers at: https://stripe-website-dev.globalhealthapp.net/module-material/.