PEPFAR Technical Guidance in Context of COVID-19 Pandemic

In January 2020, a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (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 coronavirus disease 2019 (COVID-19). The disease is now widespread, and every country in the world has reported cases. https://who.sprinklr.com/.

PEPFAR continues to leverage its investments in USG personnel, implementing partners, and health infrastructure, including labs, health facilities, and supply chains as well as human resources for health for HIV and, as possible, for health security needs. PEPFAR has specifically and continually strengthened more than 3,000 laboratories, 28 national reference laboratories, 70,000 health care facilities, and over 290,000 health care workers – the vast majority in Sub-Saharan Africa. Partner countries have leveraged these robust health care delivery, data, diagnostic, surveillance, and pandemic response systems and capacities to swiftly and effectively prevent, detect, and respond to various other outbreaks, such as Ebola, avian flu, cholera, and COVID-19, while advancing HIV efforts. COVID-19 is the latest challenge, but PEPFAR investments ensure that pandemic preparedness capacities are resilient, responsive, and enduring for countries to sustain epidemic control of HIV.

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. Stay-at-home orders and staff illness provide additional challenges. Throughout the COVID-19 pandemic, PEPFAR has remained 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 has been committed to adapting HIV services, so that PLHIV have the best possible outcomes within the context of stretched healthcare systems.

More than several months into this pandemic, we still have much to learn but we also have a much better understanding of how to prevent COVID-19 transmission. Many government, commercial, health and social activities have resumed. PEPFAR recognizes the dynamic and unpredictable nature of the COVID-19 pandemic; ongoing case-by-case and context-specific assessments will be essential to determine when activities should be resumed, modified or even paused again. Context-specific factors that may be used to help decision making include case rates, lockdowns, school closures and USG mission status. USG country teams and their partners must make all efforts to ensure the safety of staff and clients should be paramount in all planning. Some COVID-19 spurred innovations in HIV service delivery were client-centered, effective and resource-efficient; such innovative approaches should be incorporated into routine programming. We know that COVID-19 caused deferral of HIV testing, treatment and prevention services, and so HIV services will not only need to be resumed but accelerated in order to make up for that deferred care and get back on the robust path to epidemic control.

The evidence on the impact of COVID-19 amongst PLHIV is still scarce. We will continue to monitor the science and will communicate important advances. 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.

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 COVID-19 pandemic has highlighted the need to focus attention on site safety. COP 21 guidance emphasizes the importance of and the need for robust implementation of infection prevention and control (IPC) at PEPFAR supported health facilities. All PEPFAR programs should incorporate the implementation and monitoring of IPC interventions (i.e., administrative, environmental and personal protection) as an integral component of quality HIV care services at all PEPFAR supported facilities.

- The safety of PEPFAR-supported staff must be assured. Programs have learned how to provide client services safely and should be able to access recommended PPE more readily. If client services cannot be adapted to be performed safely, they should not be performed and the SGAC Chair/PPM should be informed.

- ***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.
  - In the setting of escalation of community transmission of COVID-19, particularly during escalations of transmission, minimizing patient contact with health facilities reduces risk to recipients of care and reduces the burden on these facilities.
  - 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. Most community programming that requires in-person contact can be safely resumed.
  - Group-based activities should follow local guidelines for large gatherings. In-person group-based activities may need to be adapted to assure safety of the participants but should be safely resumed as soon as possible.

- ***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

- Updated information about funding for staff (HRH) COVID testing. ***See pg. 5.***

- Further helpful information is updated routinely at https://pepfar.sharepoint.com/sites/covid-19 or access via pepfar.net ECTs drop down menu.
- ***Highlighting link for CSO field observations and feedback on this guidance*** – see https://www.surveymonkey.com/r/V7RJW59

3. Role of PEPFAR Coordination

What is the role of PEPFAR Coordination Offices in the larger USG COVID response?

PEPFAR Coordination Offices have stepped up to serve our broader U.S. interests during the COVID-19 disruption and we commend them for exceptional efforts under very trying circumstances. PEPFAR Coordination Offices should remain acutely focused on coordination of the PEPFAR program; this is the congressional appropriation for which PCOs are held accountable, and S/GAC depends on the oversight by the PEPFAR Coordination Office during this time. Beyond any Chief of Mission directive, involvement in the larger USG COVID response should be based on and limited to the intersection of HIV, HIV/TB and COVID-19. PEPFAR Coordination Offices should stay abreast of the ways in which PEPFAR program investments are being leveraged for the larger USG COVID-19 response and potential adaptations necessary to implement the PEPFAR program safely in an environment of COVID-19. PEPFAR Coordination Offices are not, however, responsible for coordinating the larger USG COVID-19 response.

4. Basic information about COVID-19

How is COVID-19 spread and what can people do to protect themselves and others in community and other non-healthcare settings?

The best way to prevent illness due to COVID-19 is to avoid being exposed to the virus.

The virus spreads mainly from person-to-person and especially between individuals who are in close contact (within 1-2 meters) from infected respiratory droplets produced when an infected person coughs, sneezes or talks. COVID-19 may be spread by people who are not showing symptoms.

Personal Protective Behavior refers to taking personal responsibility for one's own behavior and not endangering anyone else. Separation from other people, respiratory hygiene,(e.g., sneezing/coughing into disposable tissue or elbow, hand hygiene (see links under hand hygiene) face coverings which cover the nose and mouth, and avoiding large gatherings are all critical interventions each person can take to prevent the spread of COVID-19.

In the health care setting health care workers should wear a medical mask continuously, from the beginning of their shift to the end. This is called **continuous medical masking**. All visitors and clients of the facility should wear face coverings as described above. This is called **universal source control**.

What is known about PLHIV receiving COVID-19 vaccines?

Recommendations for COVID-19 vaccines in PLHIV may vary by the specific COVID-19 vaccine.

Evaluations of the mRNA based COVID-19 vaccines developed by Pfizer and Moderna did not exclude PLHIV. Because few PLHIV participated, there is no direct information about safety, immunogenicity and efficacy of these vaccines in PLHIV. However, they are not replicating live viral vaccines and the mRNA platform is not

expected to pose greater risk to PLHIV than people without HIV infection. **The US CDC advises that PLHIV may receive mRNA COVID-19 vaccines unless otherwise contraindicated**. It further advises that PLHIV should be counseled about: the unknown vaccine safety and efficacy profiles in immunocompromised persons, the potential for reduced efficacy due to reduced immune responses, and the need to continue to follow all current guidance to protect themselves against COVID-19.

Information and guidance for use of other COVID-19 vaccines in PLHIV is expected and we will communicate that as we are able.

When will clients and staff in programs supported by PEPFAR have access to vaccines?

There are now several vaccines that are authorized for use in more than one country. International distribution planning efforts are underway, however are not within the purview of the PEPFAR program. Guidance from the USG will be disseminated as it is available.

More information can be found here and here.

Is there a new coronavirus circulating?

Viruses commonly mutate over time, which can change some of their characteristics-for both good and bad. Since December 2020, three independent variants that appear to spread more quickly and easily than other strains (i.e., more transmissible) have been reported. These variants were originally detected in samples from the United Kingdom (B.1.1.7), South Africa (B.1.351), and Brazil (P.1), with increasing reports of detection in a number of additional countries. It does not appear that these variants cause more severe illness; data and molecular diagnostic tests seem not to be significantly affected. Vaccine efficacy for B.1.1.7 and B.1.351 appears not to be affected, however additional studies, including evaluations of in vitro diagnostics and serological tests are in progress. Attention to personal protective behaviors remains critical to mitigating the spread of SARS-CoV2, including these variants and any variants that may arise in the future. It will be important to continue monitoring for new information about these and other variants, including potential impact of variants on transmissibility, reinfection risk, virulence (i.e., greater ability to cause severe illness), performance of diagnostic tests and vaccine efficacy.

More information can be found here and here from CDC and here from WHO.

5. Human Resources for Health (HRH)

Can PEPFAR funds be used to pay for COVID testing for PEPFAR staff (HRH) to ensure continuity of HIV services?

PEPFAR IPs may use funds from their PEPFAR program management budgets to pay for COVID-19 testing, test kits and testing supplies ONLY for the purpose of providing COVID testing for PEPFAR-supported IP staff (HRH) as necessary to ensure safe, uninterrupted delivery of HIV services.

The use of PEPFAR funds for this purpose would be subject to the usual agreement conditions including, OU Agency lead and AOs/COs or project officer approval. IPs should follow local policies, guidelines, and SOPs for when such testing is indicated.

How should PEPFAR partners approach staffing for resuming services?

Over the past several months, PEPFAR programs have rapidly modified their staffing and service delivery models to maintain essential HIV treatment and prevention services and support the local COVID response as possible. PEPFAR has continued to deliver essential HIV services through reconfigured health provider teams, advanced task-sharing for essential HIV services, and repurposed or redeployed staff. PEPFAR-supported staff have been able to meet clients' needs despite challenges including health worker absenteeism due to quarantine, COVID infection and/or overall social disruption.

In the coming months, countries may move through various states of opening (some fully reopened) and potentially new shutdowns, depending on the pandemic's path. PEPFAR programs will need to remain flexible in their management of the health workforce, with the safety of health workers and clients remaining the highest priority.

As countries reopen after lock-down, PEPFAR programs should resume treatment and prevention activities if they can be performed in compliance with national government and health authority guidance, and safely, with appropriate social distancing and other modes of protection to minimize transmission of COVID-19. As services resume, PEPFAR programs should remain committed to supporting the safety of PEPFAR-supported HCWs. Programs should procure sufficient health worker supplies, including PPE, to resume HIV services delivery safely. PEPFAR-funded staff hired through the MOH will be required to follow government policies for resuming work and PEPFAR programs should support such staff to do their work safely. PEPFAR-supported cadres should continue to follow host government guidance on conducting home visits while using strategies to limit levels of in-person interactions in order to continue to minimize risk of COVID-19 transmission. To the extent possible, PEPFAR programs should continue the use of community-based services and telehealth to minimize risks to HCWs.

As the response to the COVID-19 pandemic continues, PEPFAR programs should continue to stay abreast of health worker challenges and constraints and continue to track changes made to HCW staffing. PEPFAR programs should have contingency staffing plans in place to support rapid adjustments in case of additional lockdown scenarios, staff shortages due to staff illnesses, or increases in local COVID case rates.

As services reopen, what are the recommended actions if there are any additional diagnosed cases of COVID-19 among health workers?

PEPFAR programs should make all efforts to protect community- and facility-based HCWs in the provision of services to clients. This should include implementing procedures in facilities to minimize risk to health workers in patient care areas and staff areas.

Universal source control with face coverings for all, **continuous medical masking** for health care workers, and hand hygiene (see section 19) are critical interventions to prevent the spread of COVID-19 in healthcare settings. These measures have been documented to prevent transmission of COVID-19 to health care workers[1].

[1] Wang X, Ferro EG, Zhou G, Hashimoto D, Bhatt DL. Association Between Universal Masking in a Health Care System and SARS-CoV-2 Positivity Among Health Care Workers. JAMA: the journal of the American Medical Association. 2020.

With respect to workplace exposures, the CDC defines exposure in the health care setting as a 15-minute contact with an infected individual without source control or medical masking. See here. Follow WHO or national guidelines for the management of health workers who were confirmed to be exposed to COVID-19.

What is the difference between isolation and quarantine?

Isolation refers to the practice of separating people who have disease until they are no longer infectious. Quarantine refers to separating people who have been exposed to an illness so that they do not spread the disease.

What is an exposure in the health care setting?

With respect to workplace exposures, the CDC defines exposure in the health care setting as cumulative duration of 15-minutes over a 24-hour period with an infected individual without appropriate PPE or source control (see here).

WHO or national guidelines should be followed for the management of health workers who were confirmed to be exposed to COVID-19. The CDC has updated guidance on quarantine based on modeling data which can be found here .

When should isolation end for HCW who test positive for COVID-19

Both the WHO and the CDC have recommended time-based criteria for terminating isolation in individuals who test positive for COVID-19. The updated criteria reflect recent findings that patients whose symptoms have resolved may still test positive for the SARS-CoV-2 by RT-PCR for many weeks. Despite a positive test result, these individuals are not likely to be infectious. The CDC advises that health care workers with mild to moderate illness may return to work 10 days after the appearance of symptoms, as long as they are clinically improving and are afebrile. Those with severe COVID-19 illness and those who are immunocompromised require exclusion from the workplace for longer (see here). The WHO has developed detailed guidance on management of HCW infection; updated 30 October. Of note, they recommend that asymptomatic health care workers with a positive test may return to work 10 days after their last positive test.

Clinic closures pose a risk to clients and in most cases, an isolated case of COVID-19 should not prompt clinic closure. Clinic closures may be warranted if there is a cluster of cases, especially if associated with a breach of infection prevention and control procedures may warrant clinic closure. Staff absenteeism because of illness or quarantine due to high risk exposure may also require suspending services until there are sufficient staff to provide safe and effective care. Please see FAQ (***How do we prepare for clinic closures or disruption of services related to COVID-19?)*** for suggestions on how to ensure continuity of care should clinical services be suspended. Guidance on disinfection can be found in the IPC section (here) and the associated links.

What should the role of PEPFAR programs be in ensuring testing of exposed or symptomatic PEPFAR-supported health care workers for COVID-19?

COVID-19 testing for HCWs exposed to COVID-19 or with symptoms concerning for COVID-19 can be an important tool in detecting and preventing transmission of COVID-19 in healthcare settings.

Local and national guidelines should be followed for COVID-19 testing, contact tracing and quarantine. PEPFAR programs can facilitate development and dissemination of guidelines that provide

specific policies on the use of COVID-19 testing in symptomatic and exposed health care workers that are consistent with published guidance. Where testing is limited, and where there is community transmission the WHO recommends prioritizing HCW.

If such policies exist but are not being properly implemented at PEPFAR-supported facilities country teams should discuss with host governments and inform country chairs. This is an evolving area, and the following documents may be helpful from CDC and WHO.

What training should be provided to PEPFAR HCW to continue to respond to HIV in the context of COVID-19?

PEPFAR-supported HCWs should receive regular refresher training in Infection Prevention and Control (IPC) to protect themselves and PLHIV patients from COVID-19, TB and other infections. 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 PLHIV and their household members for COVID-19 & TB and refer based on national guidelines. HCW should be provided with up-to-date in-country COVID-19 guidance and case referral information (hotlines, facilities, etc.)

During the COVID-19 pandemic, most training for HCWs and other PEPFAR providers, including prevention and OVC implementers, should be provided virtually using online platforms or printed job aids. In the rare exception that an OU would like to hold an in-person training during the pandemic, they should have a strong justification for why the training could not be done virtually. In the setting of escalating community COVID-19 spread, all in-person trainings should be paused. Country teams and implementing agencies should be fully aware of planned training events and involved in decision making on whether and how to most safely proceed. A landscape assessment is currently underway and country and activity-specific guidance, recommendations, and SOPs will be shared, as available, to assist country teams in their considerations.

WHO is regularly updating available COVID-19 training here.

What actions - beyond provision and use of PPE - should be taken to safeguard PEPFAR HCW?

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

- During continued or new lockdowns, 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. Consider introducing a uniform, badge, or other marker to aid law enforcement/community in readily identifying CHWs on official duties and provide CHWs with documentation of their role and authorization to continue work.
- In areas with higher COVID-19 transmission, 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 for staff to safely and discreetly transition to roles away from direct service delivery if they are concerned; maintaining privacy and dignity.
- 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.
- Continue to support reduced in-person contact for routine administrative tasks, such as using digital payment mechanisms to ensure continuity of salary and stipend payments.
- Ensure that HCW staff are kept abreast of relevant technical updates on COVID-19.
- The role of community health workers has expanded during the COVID-19 response and has been widely leveraged to support COVID-19 services. It is critical to safeguard and support these workers, including though adequate remuneration.

How can the wellness and mental health of the health workforce be protected in a prolonged COVID-19 environment?

- Working in a prolonged COVID-19 response environment can negatively impact the wellness and mental health of PEPFAR supported staff. PEPFAR programs should continue to focus on building PEPFAR supported health workers' resilience to reduce the risk of burnout and preempt longer term mental health effects. Ensuring a safe working environment is vital for supporting physical and mental health. Partners should conduct routine wellness checks on the health workers they support to determine their emotional and physical well-being and ability to maintain responsive services. Health workers should be taught skills to increase resilience, such as taking short breaks to calm anxiety, establishing work routines/rituals, and taking time for self-care and for grieving the loss of family members and colleagues and friends. Health workers should be given adequate time between shifts to recuperate. Partners should work to ensure that staff have access to mental health services and encourage staff to utilize the support. Further resources may be found from WHO, UNAIDS, NIMH and IASC.

Should PEPFAR-supported healthcare worker (HCW) staffing continue to be reconfigured to maintain essential HIV services?

Early in the pandemic, a number of PEPFAR HCW clinical staff were repurposed in response to staffing shortages or because PEPFAR staff's regular services were paused or delayed. As services resume, PEPFAR-supported HCWs should continue to deliver the essential HIV services using service delivery teams that may be rapidly and regularly reconfigured in response to changes in staffing requirements. Consideration should include health worker needs, the impact of service disruptions from lockdowns, patient demands for more flexible and virtual services, and community fears and concerns. PEPFAR programs should plan for additional health worker staffing needs and continued care model provider team reconfiguration, such as modified roles that may include integrated HIV and COVID-19 services (e.g., COVID-19 screening of PLHIV when warranted). Staff should continue to be prepared for task-sharing of essential services where allowed and should 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 continue to be paused or delayed (e.g., VMMC, roving technical assistance) should continue to be repurposed and redeployed to support essential HIV clinical services (e.g., treatment services). Rapid training may be required to refresh or build capacity in

new roles. 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 HCW staff to continue.

How should the use of digital applications for virtual/telehealth services continue?

PEPFAR programs have rapidly adopted use of technology to provide virtual services since the onset of the COVID-19 response. As services reopen, PEPFAR partners should continue to plan for reconfigured service delivery with use of virtual services to provide HIV services safely for the duration of the pandemic. Health workers should continue to 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 programs have also applied digital applications to provide technical assistance such as supportive supervision and clinical mentorship to providers across facilities. Continued use of these technologies in lieu of site visits, even when no longer driven by COVID-19 disruption, is encouraged where these approaches have been effective and well received by clients. Expanded use of technologies can promote better provider performance, productivity and collaboration to support client-centered care.

How can client confidentiality and privacy be safeguarded with the increasing use of digital applications for virtual/telehealth services?

As programs continue to increase their use of technology for virtual/remote patient contact, they should ensure use of standard processes to safeguard the confidentiality and privacy of clients. Key considerations for standard operating procedures include:

- Ensure virtual technology use is consistent with National Guidelines
- Develop standard operating procedures (SOPs) for the HCW's environment at the time of the conversation in order to ensure client privacy.
- Confirm with clients their individual preferences (in advance, when possible) on receiving calls, receiving voicemails, and receiving SMS messages.
- Develop SOPs for what content can be left in voicemails/sent via SMS to clients.
- Verify identity and receive client permission before discussing any health information.
- Before initiating a voice call, always confirm whether the client is in a safe in safe/comfortable environments to discuss their health care before initiating a conversation about sensitive health issues.
- Verify identity and receive client permission before discussing any health information.
- Develop guidelines for the HCW's environment at the time of the conversation in order to ensure client privacy.
- Develop guidelines regarding management of audio/video content (e.g. advising HCWs not to record/capture any content and developing safe channels for sharing client information).
- Develop guidelines for what content can be left in voicemails/sent via SMS to clients.

Is the provision of health worker hazard pay allowable?

PEPFAR's stance is that if services cannot be provided safely, they should not be provided. PEPFAR does not support providing hazard pay to PEPFAR supported health workers, unless a government mandate requires

hazard pay for all at-risk health workers, including those supported by donors, or where such pay is contractually or otherwise legally required. In such an instance, PEPFAR OUs should consult with the relevant Agency Headquarters and their Chairs to determine a way forward, considering: the current compensation of PEPFAR health workers (those whose regular compensation is higher than the sum of the government pay scale plus hazard payment will not be eligible for additional compensation), the timeline for introduction and suspension of hazard pay, and the types of health workers/roles that are eligible for payment. Under no circumstance should PEPFAR-supported workers who are not directly delivering services receive a hazard pay allowance.

6. HIV Treatment

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

Key principles for the PEPFAR response to COVID include high quality clinical care, continuity of ART therapy and accelerated decongestion of health facilities to minimize transmission of COVID-19 and protect PLHIV. Separation of clinical services and drug delivery will allow individuals to have the supplies they need for treatment and provides streamlined access care when appropriate and necessary. 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. 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.

Can ART initiation in newly HIV diagnosed be delayed in those who are also either suspected or confirmed to have COVID 19?

No. COVID-19 should not delay ART initiation.

How do we prepare for clinic closures or disruption of services related to COVID-19?

To prepare clinics for potential closure due to COVID-19 pandemic, the following steps should be taken aligning with local context and guidance:

- Develop a complete client list with contact details.
- Make the client list available to key clinic staff.
- Ensure databases are backed up and encrypted.
- Secure paper patient records, where applicable.
- Contact clients and provide instructions for medical emergencies and medication refills.
    - Post these instructions for medical emergencies and medication refills at the clinic and as an outgoing message for the clinic telephone.
    - Coordinate with MOH public address announcements providing guidance on what to do for medical emergencies, medication refills, and medical hotlines for advice and assistance during clinic closures.
- Ensure that facility and community partners are aware of clinic closure. If possible, continue to provide virtual support to OVC and other vulnerable clients.

What about clients coming to clinic who usually receive their medication elsewhere?

These clients, regardless of their citizenship or immigration status, should be provided medication. Please note that they should not be counted as TX_NEW.

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 COP20 and section 6.1.2 of the COP20 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 are returning to care after having been out of care for a year or more?

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 as well as prompt initiation of ART. If a CD4 cannot be performed, consideration should be given to providing the individual with cotrimoxazole until a CD4 count can be obtained. If TB screen is negative, TPT may be provided if appropriate. Please see updated recommendations on individuals with advanced disease.

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 changes in policy that will allow uninterrupted essential HIV services to children, adolescents, pregnant and breastfeeding women, and adults while minimizing potential exposures to 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.

The ongoing shortage of LPV/r 200/50 has been affected by COVID-19 and we expect to run out of LPV/r in mid-August. What should we do?

For adults on LPV/r, dolutegravir is the preferred alternative; either as TLD or as DTG with alternate NRTIS. ATV/r may be used for patients who are intolerant of or otherwise medically unable to use TLD or DTG. Both DTG and ATV/r are significantly less expensive than LPVr 200/50 based regimens. Due to ongoing shortages of LPV/r 100/25 mg tablets and 40/10 mg pellets/granules and lack of available alternative regimens, these pediatric LPV/r formulations should not be considered as substitutes for adults on LPV/r 200/50 mg tablets.

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 exposure to COVID-19 at healthcare 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.
- Clients should preferentially receive their drug supplies outside of the health facility. These options may 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 is not 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.

Given the priority on reducing non-essential visits to health facilities to limit COVID-2 exposure among PLHIV coupled with known adherence challenges among Adolescent and Youth living with HIV (A/YLHIV), what are the recommendations for peer support groups and mentoring for A/YLHIV?

To the extent possible, and in line with host country guidelines, please ensure that peer support groups, one-on-one peer support, and treatment literacy activities are maintained virtually and ideally at the same frequency that they would normally meet. Adherence group meetings and one-on-one peer support can convene over the phone, SMS, through WhatsApp, or through other social media platforms that adolescents find acceptable, accessible, and can protect confidentiality. One-on-one virtual check-ins should be conducted for appointments and ART/MMD pick-up scheduling.

If staff/resources are limited, the highest risk A/YLHIV should be prioritized, including those with high viral load, newly initiated on ART, that are pregnant and breastfeeding, at risk for treatment disruption (running out of ARVs at home), and those with mental health or psychosocial challenges. Adolescents without personal phones can consent for their caregivers to be engaged and are encouraged to identify an accessible phone when possible. To the extent possible, incorporate COVID-19 prevention messaging per host country MOH guidelines and resources into the adherence group meetings and one-on-one check-ins.

Please ensure that youth peer leaders and facilitators have adequate resources, including airtime and/or data, to continue performing these functions. (See here).

Children may have stressful reactions to COVID-19. How can they be supported?

Children may respond to difficult/unsettling situations in different ways: clinging to caregivers, feeling anxious, withdrawing, feeling angry or agitated, having nightmares, bedwetting, frequent mood-changes, etc. Children usually feel relieved if they are able to express and communicate their disturbing feelings in a safe and supportive environment. With assistance, children can find positive ways to express disturbing feelings. Children need adults' love and often more dedicated attention during difficult times. Children often take their emotional cues from the important adults in their lives, so how adults respond to the crisis is very important.

Techniques that can be used:

- Keep regular routines and schedules as much as possible or help create new ones in a new environment
- Provide facts about what is going on and give clear child-friendly information about how to reduce risk of infection and stay safe in words they can understand
- Demonstrate to children how they can keep themselves safe (e.g., show them effective handwashing).
- Provide information about what has happened or could happen in a reassuring, honest and age-appropriate way
- Support adults/caregivers with activities for children during home isolation/quarantine.

One-page tips for parents that cover topics like managing stress, and talking about COVID-19 can be found at "Parenting in the Time of COVID-19".

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 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.

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

There is no evidence that ARV drugs have any activity or role in treating COVID-19 infections ARVs including Lopinavir/r[2] and, more recently, tenofovir disoproxil fumarate (TDF)[3] have been studied for potential role in

[2] 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.

[3] del Amo J, Polo R, Moreno S, Díaz A, Martínez E, Arribas JR et al. Incidence and Severity of COVID-19 in HIV-Positive Persons Receiving Antiretroviral Therapy. Annals of internal medicine. 2020. doi:10.7326/M20-3689.

treatment of COVID-19 but there is no strong or *consistent evidence supporting efficacy. 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 obesity, 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.

Some of the older clients are struggling with COVID-19. How do we best help them?

Age is one of the key drivers of COVID-19 mortality and morbidity. Medical needs of older adults living with HIV need to be met and may include other comorbidities for which they require uninterrupted access to their medications.

Older adults may have more difficulty with quarantine especially if they are sheltered or alone. As with all clients, emotional support can be provided through informal networks (families) and mental health professionals. Simple facts about what is going on and clear information about how to reduce risk of infection that can be understood easily by people with and without cognitive impairment are key to improved mental health. Information in clear language with large font from multiple trusted sources (family, health care providers, media) with frequent repetition may be necessary.

Use of online platforms and messaging apps may not be the preferred method of communication for this group. Personal contact may be needed.

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. PEPFAR's recommendations for the diagnosis and treatment of individuals with advanced HIV disease can be found in the COP20 guidance. If COVID19 disrupts timely availability of CD4 testing (to assess for advanced disease), in addition to prompt initiation of ART, consideration should be given to providing cotrimoxazole to all newly diagnosed clients until CD4 testing can be performed.

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, and careful consideration should be given to whether they should be seen in person. In many instances the benefits of being seen in person outweigh the risks of COVID-19 acquisition in health care facilities. A phone consultation with a mid-level or advanced level practitioner may be helpful in monitoring this group of individuals and may lessen the need for in-person evaluations.

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 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. Medication delivery should be separated from clinical care. 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 Issues

How will the COVID-19 epidemic affect children living with HIV or HIV/TB?

Children can become infected and severely ill with COVID-19/SARS-CoV2; however, they appear to be at lower risk for severe COVID-19 disease when compared to adults. (See here). Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare condition temporally associated with current or recent infection with SARS-CoV2 among children requiring immediate intervention. (See https://www.cdc.gov/mis-c/). Most reported cases have occurred in high transmission communities. No common risk factors have yet been determined but the majority of children diagnosed with MIS-C were previously healthy.

There are few data on the impact of COVID-19 on children with HIV or TB or those co-infected with both diseases. However, children and especially children with HIV are at very high risk for mortality and morbidity from TB which can present with symptoms similar to COVID-19. Therefore, it is critical that routine programs be maintained for screening and testing for TB among children and adolescents, especially those with HIV, and among child household contacts (<5 years of age) of individuals with TB. Children assessed for SARS-CoV2 should be concurrently assessed for TB and HIV, if appropriate, with IPC precautions taken as recommended in current guidelines. If negative for TB (through screening or full diagnostic evaluation), C/ALHIV and child household contacts of individuals with TB/HIV should be initiated on TPT with MMD.

OVC programs can help support C/ALHIV and their caregivers during COVID-19 by offering community-based services. Clinical and OVC programs can work together to leverage their strengths to best support C/ALHIV's retention and adherence during COVID-19 and support their households. See the OVC Section for more information.

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.

Food Insecurity and Nutritional Status

What is the potential impact of COVID-19 on food security and nutritional status of PLHIV and OVC households?

- There is ongoing concern about food shortages and the world food program and other international organizations are monitoring impacts; as yet there are not widespread changes to food security. The situation is fluid and there is concern that a prolonged pandemic and the associated mitigation measures will profoundly increase the risks to food and economic insecurity, particularly among individuals with pre-existing vulnerabilities, including those with HIV.
- Food insecurity and poor nutritional status are recognized threats to successful ART therapy and are also associated with a range of poor outcomes for children and pregnant/breastfeeding women regardless of HIV status. ART clients previously considered stable may face rapid onset of food insecurity in the current context.
- Food insecurity is also an acknowledged driver of HIV risk behaviors, particularly among key populations selling sex, and may limit consistent condom and lubricant use, as well as uptake and adherence among PrEP and ART clients. Moreover, key populations are less likely to be eligible for food and other social protection assistance that may be available to the general population from traditional structures, government schemes, and donor-funded programs.

How should programs deal with food insecurity?

Recent SitReps all point to rapidly deteriorating food security in the Southern Africa region due to COVID-19 restrictions, including widespread unemployment, reduced cross-border remittances, and food price spikes.

- Country teams should closely monitor the evolving situation (and planned local response) through in-country food/nutrition clusters and global situation reports from WFP, FEWS NET, and FAO.
- USG country teams should coordinate closely with USG supplemental food assistance planned for the COVID-19 response, led by USAID's Bureau for Resilience and Food Security (RFS), to determine planned coverage, eligibility criteria, and resources available for priority PEPFAR beneficiaries. This supplemental assistance should be the primary mode of support, where available, for PEPFAR beneficiaries experiencing acute food insecurity related to COVID-19.
- If usual international or bilateral food assistance is unavailable in a PEPFAR supported area and given documented needs, OU's may work with their respective Chairs and PPMs to develop proposals using limited amounts of PEPFAR funding for nutrition assistance. All proposals will need to be cleared by S/GAC executive management.
- For more information about USAID's RFS programs for specific countries please contact USAID's program office in country.

What mitigation measures should be put into place for PLHIV and OVC households experiencing food insecurity as a result of the COVID-19 pandemic?

- IPs should continue food and nutritional assistance activities previously authorized under COP19.

- IPs should integrate food security and nutritional assessments into routine beneficiary follow-ups (virtual or in-person) to identify and prioritize beneficiaries requiring immediate support (highest priority are ART clients at risk of treatment disruption). IPs should clearly document any trends in deteriorating food security or nutritional status among their beneficiaries to inform country-level planning and coordination.

7. 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. 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) and where there is not adequate ventilation and appropriate waste disposal.

- 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 HIV self testing (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.

If we are expanding HIV self-testing in the setting of COVID-19, do we need to adjust our IPs' HIV self-testing targets?

Targets should not be adjusted prospectively to expand HIV self-testing in the setting of COVID-19. This should be discussed with Chairs and PPMs.

Some IPs are participating in COVID-19 contact tracing activities. Can they incorporate HIV testing/case finding into their activities as long as they are able to do so safely?

Yes, HIV and TB testing/case finding (including TB symptom screening) can be incorporated into COVID-19 contact tracing with agreement from the team. Use of HIVST through oral screening is encouraged. Please see guidance related to HIVST for adults and for children/adolescents.

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 be resumed as COVID-19 restrictions are lifted?

Recency testing continues to be an important part of PEPFAR programming which will inform targeted and effective community HIV prevention interventions. Due to restrictions in group gatherings and travel associated with COVID-19 and pauses in non-essential clinical services, trainings and site visits for activation, monitoring, and quality assurance activities for recency testing have previously been postponed, scaled-back, or transitioned to virtual formats. While recency testing may add time to the provider-client interaction and overall clinic visit and does not affect the overall clinical care of individual patients, there may be benefits to resuming the program to inform targeted and effective community HIV prevention interventions. As COVID-19 restrictions are lifted and routine HIV testing resumes, it is recommended that each country, in collaboration with MoH, consider starting or resuming recency testing as soon as infection control protocols and adequate supplies of PPE are in place to protect both clients and health care workers during the extended provider-client interactions and counselling sessions. Countries restarting recency surveillance activities after significant pause (>3 months) due to COVID-19 restrictions should consider refresher trainings and re-assessment of testing competency through QC specimen panels for staff conducting recency testing. In settings with SARS-CoV-2 transmission, trainings will need to be adapted to be consistent with local transmission prevention regulations. This will likely include appropriate personal protective equipment (PPE), smaller class size, social distancing, symptom screening, and virtual training, if appropriate.

8. 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.

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.

How will COVID-19 affect contact tracing for TB among PLHIV?

TB contact investigations are administered by the TB Programs not through PEPFAR. However, if normal TB contact investigations for PLHIV are suspended, PEPFAR programs may consider coordinating with local TB programs to identify contacts and reiterate the importance of informing health care workers of their contact status should they present to a health facility for symptoms. If PEPFAR programs are supporting TB contact investigations for TB/HIV clients, they should make every effort to maximize their use of mobile and virtual platforms for conducting contact investigations.

Community-based testing and active TB case finding strategies among PLHIV should follow local guidance on movement restriction and social distance measures to preserve the safety of healthcare workers and should be consistent with the national programs' continuity of operations in setting of COVID-19. If mobile and virtual platforms cannot be used and it is not safe for HCWs to conduct contact investigation in the community, programs may need to defer these activities.

How can we ensure continuity of services for TB-treatment in the context of COVID-19 disruptions?

- PLHIV on TB treatment, including CLHIV, should continue their TB and HIV treatment and avoid potential exposures to COVID-19 at health facilities.
    - Patients should be provided the full or remaining course of their drugs for TB 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.
    - Telephone or digital 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.
    - Provision of refills should be adapted to align with MMD for ART.
    - For PLHIV undergoing treatment for active TB, a clinical visit may be warranted based on the clinical course at the end of the intensive phase of therapy.
- 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.
- Routinely assess PLHIV for TB & COVID-19 symptoms, even if they are being seen in the community. Ensure that CHWs have a clear protocol for referring and linking PLHIV to further assessment and testing, if appropriate.
- Further guidance may be found here.

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. Please refer to testing guidance for strategies and guidance for HIV testing in the setting of COVID-19. Those who test positive for HIV, should be linked to ART.

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 clear instructions, and close follow-up 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?

Any patient presenting with suspected COVID-19, should also be tested for TB and HIV. 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 specimen(s) should be collected for molecular diagnostic testing according to local policies and guidance. Note that presence of a positive COVID-19 test 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 should be conducted concurrently with TB testing. PLHIV who screen positive for TB and/or COVID19 should be sent directly for testing, bypassing HIV outpatient clinic areas. Whenever possible, programs should facilitate the provision of safe, accessible, and free services to patients reporting TB and COVID-19 symptoms and conduct testing for PLHIV. Programs should encourage the use of innovative digital platforms to encourage PLHIV to self-report symptoms using phone, SMS, email or other digital applications.

Can we distinguish between COVID-19 and TB symptoms among PLHIV?

Although the presentation of COVID-19 among PLHIV is unknown, there is significant overlap between TB and COVID-19 symptoms. PLHIV who present with fever, cough, shortness of breath or difficulty breathing should be referred for concurrent testing for both TB and COVID-19 based on national guidelines. Countries should follow WHO guidance on laboratory testing for COVID-19 found **here**.

Appropriate specimens should be collected for both TB and COVID-19 according to specimen types found **here** and biosafety guidelines. If only sputum samples are available for collection, facilities should have clear guidelines in place for the prioritization of testing if the person is only able to produce one specimen to be tested for either TB or COVID-19. If COVID-19 testing is prioritized, then arrangements must be made to collect another specimen for TB testing. Specimens should be initially processed and transported according to national TB biosafety guidelines for TB and interim laboratory biosafety guidance related to COVID-19 found **here**. Existing TB/HIV specimen transportation mechanisms should be used to transport COVID-19 specimens for diagnosis and surveillance.

As described in the laboratory guidance, SOPs for prioritizing specimens using of the GenXpert should be followed.

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

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

How will the COVID-19 epidemic affect people undergoing directly 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?

Please see Section 17 for infection control guidance.

Addressing the triple risk of stigma, discrimination and social isolation 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 (TPT) remains a core HIV service and countries should continue their scale- up.

- TPT: Sites should have sufficient quantity of isoniazid (INH) and B6 or 3HP:
  - To dispense multi-month supplies that allow PLHIV and CLHIV already having started a TPT course to complete it without returning to the health facility
  - To cover 6 months isoniazid preventive treatment (IPT) for volumes of PLHIV and CLHIV projected to initiate TPT
  - Provision of refills should be adapted to align with MMD for ART

Programs should ensure that systems are in place for side effect and adverse event monitoring whether via telephone, SMS, or electronically. Differentiated service delivery models, if in place, may be utilized for community distribution and adherence support as long as they adhere to infection control, social distancing policies, and guidance within the country/district.

9. Integrated Women's Health

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

During the COVID-19 pandemic, voluntary family planning (FP) services and reproductive health (RH) care 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.

PEPFAR funds cannot be used to procure contraceptives except condoms; 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; where allowed by policy, emergency contraceptive pills (ECPs) can also be provided to women in need of this method

- Through coordination with other programs that procure contraceptives, voluntary long-acting and reversible contraceptives (LARCs) and permanent methods (PMs)should be offered and available to clients; Sites should develop and disseminate a schedule of service provision to ensure that clients have continued access during periods of limited facility operations/provider availability; for women

who wish to discontinue implants or IUDs, removal services should be offered when possible or referred for removal to an appropriate facility that can provide the service;

- Fertility awareness methods of contraception may be helpful because they do not require commodities, resupply, or continued contact with health care, but women must be informed of expected efficacy of all methods to allow informed choice;
- Client-centered FP education and counseling should proactively address possible side effect concerns related to hormonal contraceptive use to help minimize need for revisits;
- Client FP revisits should be coordinated with other individual and family follow-up services to streamline and/or integrate revisit appointments.

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 are 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.

ANC attendance is down during COVID-19 due to social distancing guidelines and fear. Are there other ways we can make sure pregnant and breastfeeding women (PBFW) are reached for testing and treatment services?

HIV self-testing may be used as a testing strategy for PBFW. HVST can be utilized for initial or retesting points depending on the country-context. Women who screen positive should be fast-tracked for confirmatory testing and care and treatment services. Tests can be delivered by community health workers, mentor-mother groups, or other appropriate ways of reaching women at risk. Self-testing can be used by everyone except for those receiving PrEP. Virtual follow-up after self-test distribution should be used with all precautions followed if home visits are needed. Other guidance on HVST can be found within that section of the FAQs as well as COP guidance documents.

1. How will cervical cancer screening services be affected?

Cervical cancer screening for WLHIV should be considered an essential service and every effort should be made to conduct these screenings within routine same-day and same-site ART clinical service visits. Cervical cancer screenings conducted outside of same-day and same-site ART clinical service visits should be limited to decrease exposure to health centers. Planned cervical cancer screenings may also be held in community spaces in countries who have reduced routine ART clinic visits through the use of MMD, with appropriate use of PPE and social distancing measures in place. Women undergoing evaluation and treatment for high grade lesions should continue with their recommended medical management with scheduling considerations to decrease exposures described above. Where HPV testing is available,

consideration should be given to offer HPV testing (either patient or provider collected) as the first level of screening with VIA reserved for those with a positive HPV test. Lastly, effective and timely treatment of precancerous lesions is essential to prevent progression to cervical cancer; as a result, where feasible, country teams should explore options for treatment catch-up strategies, such as LEEP camps and similar service delivery models in accordance with national safety protocols for COVID-19.

10. 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) with refill tracked to a scheduled ANC visit. 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. Consider home delivery of ARV prophylaxis for HIV exposed-infants when MCH and PMTCT clinics are not operational.

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.

Are you tracking ANC attendance to protect against increases in MTCT rates?

Country teams are following local Ministry of Health guidance as it pertains to ANC service delivery and monitoring mechanisms. Although not a global policy, some teams and countries are trying to proactively reach women who have missed ANC visits to offer HIV testing and infant prophylaxis as needed or requested.

Should we continue offering PrEP to PBFW during this time?

Absolutely. PrEP is a critical HIV prevention tool. Consider multi-month dispensing of PrEP. Additional discussion of PrEP in PBFW considerations below in section 11, HIV Prevention- 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. Routine immunizations are also an essential life-saving health service for infants, and EID testing and EPI schedules are commonly aligned. Fears of COVID-19 may make women reluctant to attend postnatal visits with their infants, threatening scheduled EID testing and immunizations.

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 during the same health facility visit or 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, PNC, and FP 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.

11. 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); Please see the supply chain section on condoms.
- 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.

12. 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, including outside of the clinic space or by phone. This decreases facility congestion and allows better adherence to social distancing and mask guidance, but also increases accessibility of services for clients. Success with multi-month dispensing of PrEP during COVID-19 should encourage its continuation and scale-up even as COVID-19 disruptions and restrictions ease. HIV testing is required every 3 months for PrEP users with a blood sample using the approved national algorithm.

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, and/or are returning to post. Teams should address how IPs can make a determination how best to provide PrEP services and to provide USG agency oversight. Differentiated service delivery for PrEP should be supported. 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 facilities, 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. PrEP will be rapidly expanded in COP20 to maximize impact on reducing potential new infections. We recommend using SMS for refills and pill taking reminders, for example. While these innovations are important to COVID mitigation, they should also be continued even when mitigation for COVID is no longer needed as an ongoing effective way to increase clients' access to PrEP.

Should demand creation for PrEP continue?

Demand creation based on larger social gatherings, or social mobilization, may be paused 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.

Programs should actively and regularly evaluate the ability to safely resume the full spectrum of demand creation activities.

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. Even when/where social distancing requirements are relaxed in the specific community, these follow up methods can be continued where effective to increase clients' access to PrEP.

Community distribution and adherence support in small groups 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, or 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.

13. HIV Prevention – VMMC

VMMC services were heavily impacted by the COVID pandemic with a significant decrease in productivity seen in Q3 during which many programs were partially or completely suspended.

As of September 2020, most PEPFAR priority countries have resumed VMMC services. However, resumption has not been uniform due to varying local COVID-19 situations, and most programs continue to operate at a decreased volume due to COVID-19-related restrictions. Innovative approaches to demand generation, client scheduling, and remote follow up are just a few of the ways programs have adapted to continue service provision in the context of COVID-19. We acknowledge that the COVID-19 pandemic continues to affect VMMC performance and want to emphasize the continued need to assess the local context and prioritize the safety of healthcare workers, clients, and communities when making decisions about VMMC program implementation.

What should VMMC programs consider in restarting services in the context of COVID-19?

Programs should actively and regularly evaluate the ability to safely resume VMMC services. When restarting VMMC services, programs should conduct a readiness and risk assessment, and adapt services as required to mitigate risk in the context of COVID-19. This will require careful consideration of how programs and services will be modified to align with the "new normal." Although VMMC is an important component of the overall strategy to address the HIV epidemic, it is an elective, preventive intervention. Thus, the risks and benefits of reopening a site/program must be weighed. Each program will need to adapt their approach and activities to their context and unique transmission scenario, considering both the epidemic and compliance with national standards and guidelines.

Using a phased approach in reopening (for example, initially limiting the number of locations and procedure volume at those locations) allows programs to quickly address inevitable challenges. If essential risk mitigation interventions needed to comply with national standards are not possible at a particular site(s), programs should not resume services at that site until these interventions are either available. The safety of participants and practitioners must be assured in PEPFAR supported programs. See guidance on infection protection and control and PPE.

Please see here for further considerations, and resources for programs to use in planning for restarting services.

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. Interviews can be conducted virtually if in-person is not possible. **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.

Should possible or confirmed cases of COVID-19 among VMMC clients or staff be reported to PEPFAR by the site as a notifiable adverse event (AE)?

On resumption of service delivery IPs should have written procedures for identifying and triaging clients and staff with potential COVID-19 exposures or illness. Possible and confirmed cases of COVID-19 identified through VMMC site activities should be tracked and reported in accordance with national standards but should not be reported as VMMC-associated AEs to PEPFAR. Site-level information about possible and/or confirmed cases of COVID-19 among VMMC clients or staff is vital for decision making for the program (e.g. weighing the risks/benefits of resuming or re-suspending services). Because a timely and appropriate response can reduce transmission, IPs should develop plans consistent with national guidance for how to respond to potential or confirmed COVID-19 cases. Please see section 4 for further details about HCW with COVID-19.

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

It is now FY21 and COP20 guidance on age for VMMC eligibility is in effect including:

1. No circumcision in boys under age 15
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.

The only exception to this age guidance is use of the ShangRing device to circumcise boys aged 10-14 years if the program has received approval to do so. This must be accompanied by enhanced safety monitoring as detailed in the OGAC communication (email) sent to programs on 1 October 2020. Guidance may be found here:
https://pepfar.sharepoint.com/:f:/r/sites/ProgramQuality/Shared%20Documents/VMMC%20Guidance/Enhanced%20ShangRing%20Monitoring?csf=1&web=1&e=7Oy899

14. DREAMS

How are DREAMS activities being affected?

In most countries, in-person DREAMS activities have been limited or paused, especially those that involve group in-person meetings. This involves interventions across multiple DREAMS core components and target populations, such as AGYW (including AGYW who belong to key populations), parents/caregivers, and community members. Because DREAMS aims to build social connections between AGYW and behavioral

skills through hands-on practice, in-person delivery is a critical feature of DREAMS programming and should be prioritized for resumption as soon as safe and allowable by local guidelines.

How can we continue in-person, group-based DREAMS activities in the era of COVID-19?

All DREAMS activities that involve group gatherings (e.g., community mobilization and norms change sessions, parenting sessions, and 'safe space' sessions) should follow local guidelines for COVID-19 prevention, including those on mass/group gatherings. During escalations of community COVID-19 spread, partners may need to pause in-person group activities based on local guidelines on lockdowns, gatherings, etc. If this is the case, partners should stay engaged with AGYW based on the Continuum of Virtual DREAMS Content Delivery outlined below until the surge has subsided. See page 7 in HRH Section on maintaining safety of health workforce in the evolving context of COVID.

While adhering to proper COVID-19 safety measures for staff, mentors, and beneficiaries, we encourage teams to be creative in providing interventions and services to AGYW. For instance, if allowed, and whenever possible, DREAMS interventions should be delivered outdoors with smaller groups of AGYW using proper COVID-19 precautions (e.g. cloth face coverings for facilitators and beneficiaries, social distancing, hand sanitizer). Please refer to the Infection Control and Prevention section of this document for additional detail. If DREAMS groups are delivered indoors, teams/partners should ensure that the room is well-ventilated and can accommodate social distancing requirements and that all staff and participants follow face-covering recommendations. If multiple groups are meeting concurrently in a shared space, whether indoors or outdoors, teams/partners should ensure enough physical space is allowed between groups to adhere to local mass gathering guidance. Larger cohorts of AGYW can be split into smaller groups.

If groups cannot gather or individuals cannot meet in person, how should DREAMS IPs stay engaged with AGYW?

Since COVID-19 restrictions are being eased in many communities, paused in-person DREAMS activities should be re-assessed on a frequent, regular basis to ensure they are resumed *as soon as* safe and allowable by local guidelines. However, where in-person group-based activities still need to be paused based on local regulations, a major priority is to maintain contact with DREAMS beneficiaries 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. Digital contact should be made both individually and as a group if possible. As possible, partners should report on the number and proportion of AGYW with whom they are able to maintain contact.

Contact should focus on keeping beneficiaries engaged with mentors and peers and providing referrals for time-sensitive clinical services (e.g. GBV response, FP, and PrEP). AGYW should continue to access clinical services as needed. In addition, IPs should deliver information ranging from basic check-ins to delivering some content from curriculum-based interventions (see Figure below). However, most DREAMS curricula have an evidence base dependent on in-person interactions; therefore, **DREAMS IPs should NOT deliver full curriculum-based interventions in a virtual format.** In addition, challenges with internet and technology access are widespread and prevent equitable virtual delivery. A discussion around virtual training of trainers is ongoing and will be included in this guidance soon. While this discussion is ongoing, IPs should hold off on conducting virtual Training of Trainers sessions. For additional detail on content that can be delivered at each point in this continuum, see the Virtual Delivery of DREAMS content during COVID-19 document on the DREAMS SharePoint site.

At this time, some AGYW who need to complete one or more curriculum-based intervention(s) in order to complete the DREAMS program may NOT be able to complete the intervention or the DREAMS primary package. They should stay enrolled in DREAMS and complete other interventions as possible until able to resume the in-person interventions. The definition of an active DREAMS beneficiary remains as stated in the AGYW_PREV MER 2.4 reference sheet (i.e. at Q4 they must be enrolled in DREAMS and have started or completed at least one DREAMS service/intervention within the past 12 months). Inactive DREAMS beneficiaries should not be counted under AGYW_PREV. If a large number of beneficiaries are inactive due to COVID-19 complications, please make note of this in the narrative as directed in the indicator reference sheet. Country teams should identify ongoing challenges and solutions to share with AGYW ISMEs.

Figure: Continuum of Virtual DREAMS Content Delivery

How should DREAMS mentors and facilitators be supported during this period?

Mentors and facilitators should have adequate phone airtime and/or data to perform the functions described above (e.g. checking in with beneficiaries, providing referrals to services). Continued support and supervision must be provided to mentors as they carry out their duties in this new implementing environment. Mentors should attempt to maintain contact with beneficiaries in their cohorts with the same frequency with which they would have met before COVID. The IP staff responsible for supervising mentors should continue to routinely engage with mentors and ensure that they have the relevant information and resources to actively link DREAMS beneficiaries to services.

15. Orphans and Vulnerable Children (OVC)

Per MER 2.4 guidance, OVC "active" beneficiaries in the OVC Comprehensive program are required to have a case plan and must receive and eligible service and 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. Since COVID-19 restrictions are being eased in many communities, paused in-person OVC activities should be re-assessed on a frequent, regular basis to ensure they are resumed *as soon as* safe and allowable by local guidelines. While direct contact is preferred to observe the status of the child(ren) and family, the MER guidance states that monitoring can occur "virtually where needed." In settings of significant COVID-19 transmission virtual contact may be the only option. This can be through phone calls, SMS, WhatsApp, or group chats. To be counted as "active" under the OVC Comprehensive program, all OVC_SERV requirements must be met, including: 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 eligible OVC service (listed in MER Guidance Appendix E) in each of the previous two quarters. Documentation of any virtual contact should be recorded in the child's case plan. If beneficiaries do not meet this definition of "active" for FY20Q4, they should be counted as "exited without graduation" and an explanation provided within the

OVC_SERV MER narrative. Per MER 2.4 guidance, beneficiaries counted under OVC_SERV due to their participation in an approved primary prevention of HIV and sexual violence intervention or an eligible OVC service through DREAMS should always be reported as "active."

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 country MOH guidelines and resources into their virtual support to households.

HIV Risk Screening in OVC

If OVC case management shifts to a phone-based or 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 need HIV testing to ensure these children are linked to services as soon as possible. OVC staff should work with nearby facilities to facilitate completion of testing referrals. IPs and OVC staff should be aware of potential confidentiality issues due to a virtual case management approach and should mitigate these issues as possible.

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, communities, and homes 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 or 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)
- Children of parents living with HIV at risk of poor retention
- Children of female sex workers (especially children of HIV+ FSW in order to support index testing)

- 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 adequate airtime for OVC case workers processing referrals via phone. Provide case workers with forms, paper records to document calls.
- 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.

16. 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.

What should be prioritized for Key Populations?

- Uninterrupted HIV treatment access, clinical care, and support are critical to maintaining access 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

What can be done to support people who inject drugs to maintain access to medication assisted treatment (MAT) given COVID-related restrictions?

- Country teams should work with IPs, partner governments, civil society and others to explore and implement take away dosing of MAT, where stable MAT clients are provided with extra doses of medication to reduce the need to attend the clinic for daily dispensing. Policy changes may be required.

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. PEPFAR funding cannot support the provision of housing for at-risk clients, but instead recommends referring to existing resources

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.

17. 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.

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.

18. Civil Society Engagement

How can community and civil society organizations provide input to PEPFAR about its response to COVID-19?

PEPFAR values the perspective of community and civil society organizations at both the global and local level. Community and CSO engagement with and observations of PEPFAR programming and response to COVID 19 can help us further refine our activities. If CSOs and communities have questions, comments, or observations about how PEPFAR is adjusting in the context of COVID 19, feedback can be provided here. PEPFAR teams are encouraged to share this opportunity with local CSOs.

In addition, PEPFAR encourages OUs to engage in virtual consultations with local civil society and community organizations as teams make decisions about and adaptations to programming in the context of the COVID 19

pandemic. While it is understood that varying degrees of physical distancing measures may preclude in-person meetings in many countries, country teams are encouraged to make use of virtual technologies to convene or otherwise seek critical input from the communities and constituencies that they serve.

What does PEPFAR do with the feedback from stakeholders?

As of July 10, 2020, PEPFAR has received 58 submissions to its online COVID-19 stakeholder feedback mechanism (here). Responses were submitted by a range of civil society organizations and community-based implementing partners. Diverse topics were covered, including comments, questions, and concerns about the purchase of PPE, availability of nutritional support, HIV commodities availability, virtual program adaptations, MER target achievement, and others. Each submission is reviewed by a PEPFAR U.S. government interagency task team, drawing in additional subject matter experts as necessary, to determine which refinements are needed to PEPFAR's COVID-19 FAQ and guidance, which is updated weekly. PEPFAR continues to find these questions and feedback extremely important for understanding "on the ground" realities and will continue to review incoming submissions and make adjustments or clarifications to the guidance accordingly.

19. 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. See example here.
- Encourage PLHIV in and/or known to their congregations, to maintain an adequate supply of ART and to request multi-month distribution 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 the continuity of HIV testing and decentralized treatment services 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 ART adherence and continuity of treatment; 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 living with HIV, in reducing HIV-associated stigma/discrimination, to also address the harms of stigma/discrimination associated with TB and COVID-19

- Expanding client base of faith-engaged decentralized neighborhood Community Posts to increase convenient access to MMD, among index clients and contacts,
- Expanding evidence-based FCI models that promptly link highly targeted HIV self-testing to either prevention or treatment services
- PEPFAR-supported FCI staff providing psychosocial support to boost adherence should conduct home visits and in-person support in accordance with national and local COVID-19 mitigation regulations.

PEPFAR-supported staff working on priority #2 of the FCI: "Strengthening Justice for Children" will need to adjust the 4 required activities to align with local "stay at home" orders and guidance regarding mass gatherings.

- Since COVID-19 restrictions are being eased in many communities, paused in-person JfC activities should be re-assessed on a frequent, regular basis to ensure they are resumed *as soon as* safe and allowable by local guidelines. Please see the DREAMS and OVC sections of this document (Sections 13 and 14) for guidance on how to resume in-person, group-based JfC activities in the era of COVID-19. For countries in which restrictions prohibiting these activities still exist, OUs should continue to follow the guidance below:
- Country teams and IPs should continue planning for future trainings and education modules as well as who the target audience(s) will be and appropriate venues for when restrictions are lifted.
- If already part of implementation plans, efforts focused on Justice Sector systems change should continue and be finalized, with government entities using conference calls and video platforms, if available.
- Justice for Children implementing partners should review the technical guidance on Child Protection and GBV (see section 15) to ensure that they can provide appropriate assistance regarding post-violence care for survivors of violence.
- Investigation is underway to determine whether evidence-based interventions and curricula can be delivered remotely or virtually and further guidance will be issued if and when these approaches are deemed safe and appropriate.

20. 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 facility visits should be minimized when possible.
- **Universal source control measures** should be used. This refers to the use of face coverings over the mouth and nose to prevent spread of respiratory secretions when talking, sneezing, or coughing. Because of the potential for asymptomatic and pre-symptomatic transmission, source control measures are recommended for everyone in a healthcare facility, even if they do not have symptoms

of COVID-19. The WHO has recommendations about the composition of these face coverings and how to use them appropriately.

- Patients with respiratory symptoms should be provided medical masks, as opposed to face coverings, upon entry to the health care facility
- HCW should practice **continuous medical masking.** As of June 5, WHO recommends that facility-based health care workers should continuously wear a medical mask throughout their shift in order to prevent transmission of COVID-19 in settings where widespread COVID-19 is suspected or documented. See here. This includes wearing masks in breakrooms or other spaces where they may encounter co-workers. More information on medical masks from the FDA can be found here. Eye protection (goggles or face shields) worn with medical masks provide additional protection for individuals exposed to people with respiratory symptoms or known COVID-19. More information can be found here.
- 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;
    - 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. Any healthcare worker or caregiver providing care to a known or suspected COVID-19 patient either in a facility or home should wear a medical mask. Both the CDC and the WHO recommend the use of eye protection: either a face shield or goggles.
    - Strict protocols for routine cleaning and disinfection of medical equipment and environmental (especially "high touch") surfaces such as table surfaces and door handles;
    - Education and training of staff regarding IC precautions for COVID-19;
    - Ensure adequate ventilation in waiting areas and procedure/testing areas, using an "open window policy
    - Assurance of appropriate and safe waste disposal of PPE and other items that might have been exposed to COVID-19
    - Contact and droplet precautions are recommended for COVID-19 protection. 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.
    - Guidance on cleaning and disinfection of environmental surfaces in the context of COVID-19 can be found here. With appropriate cleaning, environmental contamination should not be a reason to close clinics.

- Similarly, home care or community healthcare workers should consider using a medical mask when in direct contact with a patient (e.g. when obtaining blood for an HIV test) and social distancing measures cannot be maintained. Updated guidance that including information about disposal of potentially contaminated medical waste has been provided by the WHO in this document on page 3.

What measures should be implemented to ensure safety in non-clinical workplaces?

The safety of all PEPFAR supported staff including implementing partner staff, must be assured. Activities must be in compliance with national government and health authority guidance and include appropriate social distance, hand hygiene and face coverings for source control. Remote work options should be considered where feasible and appropriate (see here).

How can we perform hand hygiene during visits to clients without running water?

Alcohol based hand rubs are an effective method of hand hygiene and are an important part of the WHO "clean hands" campaign, which has been active since 2009 (see here). WHO and UNICEF are now sponsoring "Hand Hygiene for All Global Initiative" cosponsored by UNICEF (see here).

Hand hygiene is a critical intervention for the prevention of COVID-19 infection. It is also important for prevention of healthcare associated infections and combatting spread of multidrug resistant bacteria – for this reason, hand hygiene remains essential to quality healthcare delivery.

A method for local production of hand hygiene products is here.

More information on personal protective equipment can be found in that section.

Cloth face coverings (or Homemade Masks)

Should IPs promote the use of non-medical (or homemade) masks as personal protective equipment (PPE) for health care personnel 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 from the wearer of the mask of COVID-19 to others 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. Cloth face coverings also may prevent spread of COVID from persons who are infected, but do not have symptoms. Cloth face coverings should not replace or substitute for the approved PPE recommended for frontline workers (e.g., healthcare workers, community workers) as protection from coronavirus acquisition in health facilities.
- Updated guidance on face covering and best from WHO can be found here. The WHO suggests that cloth face coverings can be considered in several circumstances including in areas with known or suspected widespread transmission and areas of high population density, especially where there is limited or no capacity to implement other containment measures such as physical distancing, contact

tracing, appropriate testing, and isolation and care for suspected and confirmed cases. The WHO recommends 3 layer face coverings and has suggestions for the composition of those coverings.

- Decisions regarding the use, promotion and informal production of cloth face coverings should align with local customs and guidance issued by national authorities in the context of COVID-19. If cloth face coverings are used, best practices should be followed about how to wear, remove, and dispose of them, and for hand hygiene after removal. IPs should always communicate that cloth face coverings used in community settings are distinctly different from PPE used in healthcare settings for the provision of clinical services.
- Community-based production of cloth face coverings 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 recommended 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 of cloth face coverings as well.

21. Laboratory Services

Can PEPFAR funds be used to pay for COVID-19 testing, test kits and testing supplies for the purpose of providing COVID testing for PEPFAR-supported HRH staff?

No. Although in country PEPFAR programs are encouraged to work closely with MOH officials and other stakeholders to continue to leverage existing PEPFAR supported health care workers, lab technicians and infrastructure, including instrumentation. This support is as it has been throughout the pandemic, will ensure concomitant testing for HIV (VL, EID), TB and COVID-19. Clear protocols and procedures for prioritization that allow for uninterrupted testing for priority HIV viral loads and early infant diagnosis should be in place as has been described previously. PEPFAR funds should not be used for COVID specific test kits, sample transport, reagents and supplies that are to be used solely for COVID-19 testing. These commodities and services should be supported through other cost sharing processes that allow for the use of COVID-19 funds from other sources to support COVID-19 related lab testing.

COP21 Guidance (page 382) states that 'COVID-19 mitigation options within the facilities that allow for social distancing such as: reduction in waiting times for sample collection, avoiding crowded waiting rooms, scheduling and staggering appointments, streamline clinic flow so that patients for sample collection do not interact with multiple clinic providers, and reactivating safe sample transport systems should be implemented to ensure improved sample collection and testing. More use of DBS [dried blood spot] for sample collection outside of the facility to avoid many patients coming to the facility for sample collection should be encouraged'. All PEPFAR programs should adhere to these and other workplace safety guidelines to prevent COVID-19 infection of both healthcare workers and patients.

How should PEPFAR supported laboratories ensure uninterrupted HIV (VL/EID) and TB testing in the midst of COVID-19?

The goal of antiretroviral therapy is virological suppression that should be determined by testing for viral load at six months after initiating ART and then yearly thereafter. Though many PEPFAR supported programs have made significant progress in achieving between 85% and 95% viral load suppression, some of these countries are below 80% viral load testing coverage. Similarly, though significant progress has been made in improving infant diagnosis, many countries have not yet reached the 90% target for EID coverage by 2 months of age and have lengthy turnaround time and poor linkage to ART (<95%). Recent efforts to bridge these gaps have been impacted by COVID-19 at the country level. Many patients did not come to the clinic for sample collection and laboratories were unable to transport samples from rural communities to the central laboratory for testing.

Supply chain challenges associated with border closures and global flight restrictions, further led to reagent stock outs and sample backlogs. The use of instruments originally procured for HIV (VL/EID) and TB testing and repurposing of some HIV molecular staff to support COVID-19 has also impacted some programs. As such, previous guidance recommended prioritization of COVID-19, EID, TB, and VL for children, PBFW, and virally non-suppressed clients. As the COVID-19 situation improves, PEPFAR teams should work with country MOH and other stakeholders to routine and uninterrupted VL, EID and TB testing. In doing this, COVID-19 mitigation options should be deployed within the facilities that allow for social distancing. These include reduction in waiting times for sample collection, avoiding crowded waiting rooms, scheduling and staggering appointments, streamlining clinic flow so that patients for sample collection do not interact with multiple clinic providers, and reactivating safe sample transport systems. These should be implemented to ensure improved sample collection and testing. More use of DBS for sample collection outside of the facilities to avoid many patients coming to the facility for sample collection should be encouraged. The use of point of care platforms in the interim to test and deliver quick results to avoid patient or sample movement should be considered as well.

As noted, programs faced huge supply chain issues at the beginning of COVID-19 due to manufacturing gaps or delays in shipment due to air traffic and border closures; which have improved significantly in many countries. To avoid this, programs should place orders for laboratory test kits and consumables at least one month earlier than baseline to account for potential shipping delays. OUs should routinely review and update current stock counts at national and subnational levels and forecast for additional consumable needs. In PEPFAR supported laboratories running COVID-19 and HIV-related tests on the same instrument, standard operating procedures (SOPs) should be developed in collaboration with the MOH and other stakeholders to document how concomitant testing will occur. Issues to be considered and agreed upon include consumable use, sample transport, data systems, space and time allocation, and HRH.

22. Supply Chain/Commodities

Supply Chain for ARVs

The supply chain has been substantially impacted by COVID. The supply chain continues to operate at a reduced capacity and delays are anticipated for the foreseeable future.

Are there delays in pediatric drug supplies? Will there be delays in rollout of more optimal pediatric formulations?

DTG 10 mg dispersible tablets is anticipated to be available in country beginning April to June, with widespread availability in July to September 2021.

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 and manufacturers in India.

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. OUs were instructed to submit updated supply plans for the following commodities (ARVs, PrEP, TPT, HIV RTK, VL, and EID) to determine the feasibility of implementation of acceleration of 6MMD (and 3MMD); to facilitate coordination with the Global Fund; and to communicate anticipated orders to the ARV manufacturers.

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
- Reallocation of urgently needed orders to less impacted suppliers, as warranted and feasible

Supply Chain for Condoms

My country is concerned about potential condom and/or lubricant stock-outs due to COVID-19. What are our options to access PEPFAR assistance for these commodities?

While some PEPFAR programs are accustomed to using central funds to procure condoms and/or lubricants, many countries currently obtain male and female condoms and lubricants from non-PEPFAR sources for distribution within PEPFAR-supported services. At this time, PEPFAR's GHSC-PSM mechanism has experienced minimal delays with condom and lubricant commodities, but we are aware that other donor sources are experiencing more significant delays in production and/or shipments due to COVID-19. Early modeling on the global potential impact of COVID-19 on HIV indicates that disruptions in condom supply may lead to an increased incidence of HIV. Condom availability is an essential component of many PEPFAR prevention, testing, and treatment services and national programs should strive to make sure that in-country supplies are sufficiently available.

Based on coordination with other country actors (donors, private suppliers, etc.), country teams are highly encouraged to discuss their condom and lubricant supply status with their supply chain POCs, tabulate any anticipated gaps in condom and/or lubricant availability within PEPFAR programs, and estimate their potential budget needs. PEPFAR's GHSC-PSM program has some ability to rapidly source additional condoms and/or lubricants communicating earliest product availability dates as a stop-gap measure. If usual condom and lubricant support is unavailable in a PEPFAR supported area, OUs may work with their respective Chairs and PPMs to develop proposals for reprogramming limited amounts of PEPFAR funding for condoms and lubricants. These proposals should follow previously provided reprogramming guidance and will require approval by S/GAC.

Tracking Supply Chain Impact

How will supply chain risks for COVID-19 be tracked?

GHSC-PSM in conjunction with USAID has developed 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 short-term and long-term sourcing risks and develop mitigation strategies as appropriate.

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

Personal Protective Equipment (PPE)

What about personal protective equipment?

There has been 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.

However, implementing partners may use PEPFAR funding to procure restricted PPE items without further approvals in either of the following two situations:

1) For the protection of, and use by, PEPFAR supported staff. In this situation, implementing partners may procure “restricted PPE items” from any source (including from US sources);

OR

2) For the safe and effective continuity of PEPFAR-funded programs. In this situation, implementing partners may procure “restricted PPE items” manufactured locally or regionally or outside the

United States provided that those "restricted PPE items" are not, and could not reasonably be, intended for the U.S. market.

"Restricted PPE" refers to N95 and similar filtering respirators, medical masks, and gloves[4].

Cloth masks and other face coverings that do not protect the wearer are not PPE. The procurement of these items is not subject to the limitations set forth in this guidance.

Implementing partners should ensure that facility and community-based staff providing HIV services are equipped with PPE appropriate to their job duties (e.g., HIV testing, handling of drugs, etc.), in accordance with available local guidelines for use of PPE. Partners should consider PPE requirements and needs for community health workers, home visit staff and other community staff according to national and WHO guidelines for community-based care during COVID-19.

Note: HIV testing (or other direct HCW-patient interaction for HIV services) should not take place where routine adequate PPE is not available, (e.g. gloves, masks for phlebotomy).

Requirements for PPE can be found here. Information about the use of PPE for infection prevention may be found in the IPC section 19.

See additional information on respirators, surgical masks, and face masks from the US Food and Drug Administration here and here, plus further resources from the CDC here.

23. 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.

24. Reporting and SIMS

We are having challenges collecting data. Is there a process for relaxing some of the data requirements?

PEPFAR does want to acknowledge the need for flexibility due to the impact of COVID-19, but in order to best understand the services PEPFAR needs to provide clients who are also impacted by COVID-19, reporting must be as complete and timely as possible. Thus, the original MER 2.0 v 2.5 reporting

[4] https://www.federalregister.gov/d/2020-07659

requirements should be followed for all FY2021 reporting, as much as feasible. We do recognize that the COVID-19 situation is constantly evolving and want to keep all PEPFAR and PEPFAR-supported staff as safe as possible, and in compliance with Chief of Mission directives and Host Country Government policies. Teams that are having challenges should inform their S/GAC chair and PPM of these difficulties ASAP and note these challenges and impact on reporting within the OU-level and technical area narratives. Programmatic and reporting challenges may also be noted in the COVID-19 Implementation Tracking Templates.

We are missing some quarter four data. Can we use modeled data?

No. Only actual results can be submitted as verified data into DATIM, along with standard approval processes, which provide Agency and Interagency sign off on the validity of those results.

The team should try to provide background on what data has not been able to be reported and compare to what was able to be reported at Q3, during their Q4 POART. There are dossiers in Panorama that look at site level reporting over time that should help with this.

Are we expected to continue SIMS implementation and reporting?

SIMS implementation and reporting has been limited by the pandemic and expect it will continue to be affected during this time. Teams are requested to keep their S/GAC chair and PPM updated on changes in SIMS implementation status. In general SIMS assessments should not be performed in where COVID-19 spread is prevalent in the community.

Budget Guidance

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

25. Information and Resources

Resources and Information on Implementing PEPFAR During COVID-19 Pandemic:

- https://pepfar.sharepoint.com/:b:/r/Shared%20Documents/01.06.21%20PEPFAR%20Technical%20Guidance%20During%20COVID.pdf?csf=1&web=1&e=VABGla

World Health Organization's Mobile Learning App:

- With content in six languages, the app delivers mobile access to a wealth of COVID-19 knowledge resources developed by WHO, including up-to-the-minute guidance, tools, training, and virtual workshops to support health workers in caring for patients infected by COVID-19 and protect themselves as they do their critical work. It is available in the Apple App Store https://apps.apple.com/us/app/who-academy/id1506019873?ls=1 and the Google Play Store https://play.google.com/store/apps/details?id=org.who.WHOA

Specimen Handling, Testing and Laboratory-related Resources

- CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

- WHO Guidance on Laboratory Testing of 2019-nCoV in Humans: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance
- WHO Laboratory Biosafety Guidance Related to COVID-19: https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19)

Information for Pediatric Healthcare Providers:

- https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html

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/.

Food Security references:

- Food and Agricultural Organization, Q&A: COVID-19 pandemic – impact on food and agriculture, http://www.fao.org/2019-ncov/q-and-a/impact-on-food-and-agriculture/en/?fbclid=IwAR0LkDhDLGABJx6kgwXJs9R4f0CjocQVnIMEpMGFmBnV4Fo57yCAqXhnRss
- International Food Policy Research Institute, Poverty and food insecurity could grow dramatically as COVID-19 spreads, 4/16/20. https://www.ifpri.org/blog/poverty-and-food-insecurity-could-grow-dramatically-covid-19-spreads

Hand hygiene resources

- CDC hand hygiene https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html
- WHO info graphic https://www.who.int/infection-prevention/campaigns/clean-hands/WHO_HH-Community-Campaign_finalv3.pdf