PEPFAR Technical Guidance in Context of COVID-19 Pandemic

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

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

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

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

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

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

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

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

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

2. Today's Updates

June 10, 2020

- ***Updates to WHO guidance on non-medical masks*** – see pg. 34
- ***Brief update on pediatric ARVs in Supply Chain*** – see pg. 38
- ***Highlighting PEPFAR COVID-related online resources*** – see https://www.pepfar.net/sites/COVID-19/default.aspx 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. Human Resources for Health (HRH)

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

My country is starting to lift lockdown restrictions. Can PEPFAR partners and USG staff begin resuming activities that have been previously suspended or modified?

Resumption of activities may occur if they can be performed safely and in compliance with national government and health authority guidance with appropriate social distancing and other modes of protection to minimize transmission of COVID-19. PEPFAR staff hired through the MOH will be required to follow government mandates for resuming work. PEPFAR programs should support such staff to do their job safely. Also, please note the section below:" ***What actions should be taken to safeguard PEPFAR HCW, beyond PPE?"*** still applies. As noted in our guiding principles, PEPFAR programs are under chief of mission authority.

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

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

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

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

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

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

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

All training should be provided virtually using online platforms or printed job aids. Use international and national sources whenever possible. WHO is regularly updating available COVID-19 trainings at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/training/online-training. Utilize digital applications such as WhatsApp, Facebook Messenger groups or the ECHO platform for regular and routine information sharing with HCW staff.

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

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

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

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

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

- Home visitors should help to ensure that all PLHIV have access to six months MMD, ideally through community-based distribution points, to maintain adequate supply of ARVs at home.
- To protect home visitors and beneficiaries, every effort should be made to use phone calls and/or text messages to communicate and avoid making a home visit.
- Home visitors who are at higher risk for severe COVID-19 (e.g., elderly, diabetic, or have other chronic conditions) should avoid conducting home visits. Home visitors should NOT visit beneficiaries if the visitor has any symptoms of acute illness, especially fever, cough, or shortness of breath, even if the symptoms are mild. Home visitors should NOT visit beneficiaries known to have a recent exposure to a person who tested positive for COVID-19 or is suspected of having COVID-19.
- To ensure safety and well-being of both home visitors and families, program staff should determine whether a home visit is absolutely essential.
- Many issues can be managed through counseling by phone. If unable to communicate via phone, situations that may warrant a visit include: 1) a critically ill beneficiary that urgently needs transport assistance to the clinic or hospital, 2) a child or adult exposed to physical harm, abuse or neglect requiring urgent attention, 3) CLHIV (or adult due to disability or other limitation) who cannot access ART and is in danger of treatment interruption.
- If the visit is deemed essential, ensure appropriate measures, including personal protective equipment (PPE) if available, are in place before, during, and after the visit and that both OVC staff and the client(s) consent to a visit. Once the family is stabilized, focus should then be to assist with 6mo MMD and/or drug pick-up from a community-based distribution point to ensure adequate supply of ARVs at home.

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.

Telehealth

How should PEPFAR-supported cadres protect client confidentiality and privacy when using digital applications or telehealth technologies?

PEPFAR programs are encouraged to use digital applications or telehealth technologies to enable HCWs to continue providing support to clients while minimizing in-person contact during the COVID-19 pandemic. As programs increase their use of technology for virtual/remote patient contact, they are encouraged to develop standard processes to safeguard the confidentiality and privacy of clients. Key considerations for standard operating procedures include:

- Use of virtual technology is consistent with National Guidelines
- Develop guidelines for the HCW's environment at the time of the conversation in order to ensure client privacy.
- Confirm clients their individual preferences (in advance, when possible) on receiving calls, receiving voicemails, and receiving SMS messages.
- Before initiating a voice call, always confirm whether the client is in safe/comfortable environments to discuss their health care before initiating conversations 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.

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

Can clients initiating ART receive multi-month dispensing?

PEPFAR recommends that ALL PLHIV who are starting ART receive at least 3 but preferably 6 months of drugs. Phone or electronic follow-up may be helpful to assess and support adherence and to assess and manage side effects. Evidence from cohort studies indicate that <5% of clients initiating ART will require a change in ARV regimen in the first 6 months of treatment. Two forms of contact, as recommended in the COP 20 guidance, should be obtained in all PLHIV, especially in ART initiators.

How do we prepare for clinic closures?

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 COP 20 and section 6.1.2 of the COP 20 guidance contains tools for tracking and tracing which may be adapted for use in the current environment. The HRH section of this document provides additional considerations for ensuring home visits are safe.

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

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

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

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

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

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

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

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

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 patient contact with health facilities and reduce the burden on these facilities.
- Health facilities should optimize clinic spaces in order to minimize potential exposure to COVID-19. Individuals with proven or suspected COVID-19 should be separated from where care is

provided to other clients. Dedicated HIV clinic spaces where they do not already exist may be useful in accomplishing this goal.

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

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.

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

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

How can the most vulnerable patients be protected?

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

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

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

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

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

PLHIV with advanced HIV disease

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

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

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

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

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

When should individuals with advanced disease be evaluated in person?

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

Children can become infected and severely ill with COVID-19/SARS-CoV2, however they do appear to be at lower risk for severe COVID-19 disease when compared to adults. https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html.

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.

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.
- 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.

5. HIV Testing Services

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

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

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

How will HIV testing activities be affected?

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

Potential issues/responses include:

- Adapting HTS programming to government directives or policies on social distancing.
- Maximizing use of self-testing outside of the clinic setting (including providing self-tests through decentralized distribution approaches such as: peer home delivery, private or community pharmacies, etc.)
- Prioritizing clinical-based HTS for those most in need:
    - Testing in ANC
    - Diagnostic testing for individuals presenting (or admitted) to facilities with illness suspicious for HIV infection (Diagnostictesting)
    - Individuals with TB, STIs, malnutrition
    - Early infant diagnosis (EID) detection
    - Partner/index/family testing may be offered for individuals presenting at facilities (passive testing),
    - Testing in KP programs if ongoing and not facility based.
- HRH (including lay counselors/testers) may be impacted, reducing capacity from those affected by COVID-19
- HTS should not take place where routine adequate PPE is not available, (e.g. gloves)
- For RTK implications, please see Supply Chain/Commodities section

Can community testing for HIV continue?

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

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

Programs should adapt provision of active index testing services (also referred to as provider assisted notification) accordingly to ensure the safety and security of testing and other health personnel. Newly diagnosed individuals should be counseled on the importance of partner testing. Client-referral should be offered as an approach for index testing. However, in the context of COVID-19, programs are encouraged to distribute 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 continue if staff and client health care setting exposure is being minimized due to COVID-19?

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

population. It is further recommended that each country, in collaboration with MoH, resume recency testing and the associated public health response as soon as feasible as COVID-19 restrictions are lifted.

6. TB Services

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

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

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

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: https://www.who.int/tb/COVID_19considerations_tuberculosis_services.pdf

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

All patients with suspected or confirmed TB should continue to receive HIV testing. 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.

7. Integrated Women's Health

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

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

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

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

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

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

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.

How will cervical cancer screening services be affected?

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

8. Maternal Child Health (MCH)

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

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

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

Women should follow local and national guidelines for ANC testing.

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

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.

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

Yes, this can be supported through PEPFAR programming.

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

Should EID continue during the COVID-19 pandemic?

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

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

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

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

Retention and adherence support to pregnant and breastfeeding women is still crucial to prevent MTCT. Consider expanding phone/SMS support to mothers and infants through existing support mechanisms (e.g. community health workers, peer navigators, M2M, mentor mothers) to align with ANC and PNC clinical

touchpoints, as well as identifying transport methods to bring women or infants who are high risk or in need of clinical support to the facility.

9. HIV Prevention – General

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

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

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

Physical confinement measures are critical to contain the spread of COVID-19, but as these periods of confinement are extended, there is growing potential for increasing rates of sexual exposure for many people. Interpersonal violence, including sexual violence and violence against women and children may increase. Agencies need to work with IPs and Government to ensure that information about Gender Based Violence (GBV) is provided. Please see GBV specific FAQs. Sharing local contact options of responders who can address GBV related concerns may be initial options in some PEPFAR contexts.

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

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

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

10. HIV Prevention - PrEP

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

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

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

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

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

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

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

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

Should demand creation for PrEP continue?

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

How will PrEP be affected?

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

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

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

11. HIV Prevention – VMMC

How will VMMC services be affected?

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

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

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

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

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

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

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

12. Orphans and Vulnerable Children (OVC)

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

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

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

Any OVC service included in MER Guidance (Appendix E: Illustrative eligible services for active OVC beneficiaries) that can be delivered or facilitated via remote/virtual support, in line with host country government social distancing policies and guidelines, can be counted. For example, adaptations may include providing treatment literacy and adherence support, through routine phone, SMS, and/or WhatsApp communications and support. Remote case management can facilitate linkage to local food supplementation, hygiene supplies, social grants, and distance learning opportunities. IPs are also encouraged to incorporate COVID-19 prevention messaging per host county MOH guidelines and resources into their virtual support to households.

HIV Risk Screening in OVC

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

OVC Enrollment in the Context of COVID-19

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

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

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

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

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

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

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

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

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

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

13. DREAMS

How will the key population and DREAMS activities be affected?

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

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

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

A major priority during this time is to maintain contact with DREAMS AGYW in the most practical and cost-effective way possible. Depending on the country and local context, this might be via SMS, phone calls, or other digital platforms such as WhatsApp. Please ensure that mentors and facilitators have adequate airtime and/or data to perform these functions. Mentors must be provided with sufficient supervision and support while carrying out their duties in this new implementing environment. Mentors should attempt to maintain contact with AGYW in their cohorts and at the same frequency with which they would normally meet. 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. Digital contact should be made both individually and as a group if possible. Partners should choose the best way to stay in touch based on their context. As possible, partners should report on the proportion of AGYW with whom they are able to maintain contact. Country teams should identify ongoing challenges and solutions to share with AGYW ISMEs.

Contact should focus on keeping AGYW engaged with her mentor and peers, providing referrals for time sensitive services, e.g. GBV response, FP, and PrEP. In addition, IPs should deliver information ranging from basic check-ins to delivering some material from curriculum-based interventions (see Figure below). At this time, DREAMS IPs should NOT be delivering full curriculum-based interventions in a virtual format. This means that AGYW who need to complete one or more curriculum-based intervention(s) in order to complete the DREAMS program will not be able to complete the intervention of the DREAMS primary package at this time. For additional detail on content that can be delivered at each point in this continuum, see new Virtual Delivery of DREAMS Content During COVID-19 document on the DREAMS SharePoint site.

Figure: Continuum of Virtual DREAMS Content Delivery

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

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

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

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

Testing, Prevention and PrEP Services

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

Ensure Safety of Key Populations

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

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

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

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

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

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

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

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

1. Ensure that all staff have access to an updated list of local GBV/CP responses services and national hotlines for referrals.
2. Facilities should have printed material that provides information on functioning local GBV/CP services and national hotlines that providers can discreetly give to clients. Community partners and local organizations may already have materials available for distribution.
3. Providers should deliver age-appropriate first-line support (LIVES) to all clients who disclose violence and provide or refer clients to appropriate, functioning GBV response services.
4. Providers should help clients make a plan to stay safe at home while living in quarantine or isolation, including tips on how to safely access support. Ensuring privacy is critical (e.g., using

a safety/code word if disclosing violence in proximity of the perpetrator). It is important to do no harm.

5. Providers should help clients find ways to discreetly and safely take their ARVs while in quarantine or isolation. This is important for people who have not disclosed their status or use of ART or PrEP to their partner/family.
6. Ensure PEPFAR-supported specialized GBV/CP facilities or one-stop-centers have enough phone/internet credit to provide virtual psychosocial support and safety planning services.

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

Maintain and adjust communication

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

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

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

Support frontline staff

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

Ensure appropriate response services are in-place and known

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

16. 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.

17. Faith and Community Based Organizations

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

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

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

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

- Leveraging functioning religious structures to use weekly virtual Facebook Live/YouTube® religious services for congregations and men's, women's, and youth groups, as well as congregational WhatsApp groups, to disseminate HIV Messages of Hope, prioritizing messages that use FCI message prototypes (SMS messages, video clips, etc.) to support adherence for PLHIV; leveraging these religious structures to integrate COVID-19 risk prevention communications for at-risk populations and PLHIV.
- Expanding engagement of Religious Leaders Affected by and Infected with HIV, in reducing HIV-associated stigma, to include stigma associated with TB and COVID-19

- Expanding client base of faith-engaged neighborhood Community Posts to increase convenient access to ARV pick-ups and MMD, among index clients and contacts,
- Expanding FCI models that link highly targeted HIV self-testing to treatment and retention support
- PEPFAR-supported FCI staff providing psychosocial support to boost adherence should avoid home visits and should provide such support remotely using phone, text, or WhatsApp.

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.

- Educational sessions and trainings for implementing partners, community leaders, and community members will need to be delayed or paused if restrictions on mass gatherings are in place. This includes: delivery of the Sexual Violence 101 module to community leaders; training of implementing partners on and delivery of evidence-based interventions such as Coaching Boys into Men and No Means No; training of implementing partners (primes and subs) on child safeguarding policies; and, trainings on justice sector responses to sexual violence against children.
- 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.

18. Infection Prevention and Control

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

- The basic principles of IPC and standard precautions should be applied in all health care facilities and are critical to containment of SARS CoV-2.
- Health care facilities visits should be limited to those that are medically essential
- All facilities should have a designated focal point to oversee and monitor infection prevention activities; this individual should be supported to provide the basic principles according to WHO guidance which include:
    - Written procedures for identifying and managing clients and staff with potential COVID- 19 exposures or illness;

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

Details can be found here:

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

Non-medical (or Homemade) Masks

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

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

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

- As of April 6, CDC recommends the use of cloth face coverings to lessen transmission 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. Under no circumstances should cloth face coverings 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 from WHO can be found here: https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak. 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.

- 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.

19. Laboratory Services

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

There are current delays for HIV test kits and consumables in some countries either due to manufacturing gaps or delays in shipment due to air traffic and border closures. Current guidance is to 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 for COVID-19 testing.

What is the overlap between viral load (VL)/early infant diagnosis (EID), TB, and SARS-CoV-2 testing?

Because of the recent WHO emergency use listing (EUL) and FDA emergency use authorization (EUA) for the use of HIV viral load (VL), early infant diagnosis (EID), and TB-related instruments for SARS-CoV-2 testing, there is potential for increased demand on HIV (VL/EID) and TB laboratory diagnostic networks. OUs should anticipate increased use of common (multiplex) instruments, facilities, consumables, and PPE for COVID-19 HIV, and TB-related testing in laboratories and anticipate and plan for diversion of or reductions in laboratory staff and other HRH available for HIV (VL/EID) and TB testing due to COVID-19. Laboratories should prioritize testing based on local policies and needs. For HIV laboratory testing, EID and VL services should be prioritized for children, PBFW, and adults with documented non-suppression on their last VL. OUs should strongly consider collecting simultaneous specimens for both TB and COVID-19 testing (see TB section for further guidance).

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

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 prioritization of testing (e.g., COVID-19, EID, TB, VL), consumable use, sample transport, data systems, space and time allocation, and HRH.

How will additional laboratory systems-related costs due to COVID-19 testing be handled?

For efficiency, use of existing national laboratory capacity, systems and networks for COVID-related testing is strongly encouraged. Funding dedicated for HIV and TB testing should not be reallocated for COVID-19. Any additional costs (e.g., lab, HRH, sample transport) for COVID-19 testing should be paid (cost sharing) using country specific COVID-19 supplemental funds from other sources to the greatest degree possible.

20. Supply Chain/Commodities

Decentralized Drug Delivery

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

Supply Chain for ARVs

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

PEPFAR advises country programs to access the current total stock on-hand in-country and develop a distribution plan to replenish all facilities and patient dispensing sites. If sufficient ARV stock is not available for 6-month dispensing for adults and adolescents, and 3 month dispensing for children, countries should distribute the available drug supply. This will require a change in procedure related to the maintenance of the minimum stock levels and buffer stock levels. Central warehouses should maintain stock that is below the typical minimum stock levels. Replenishment orders should be placed as soon as possible. This strategy will help ensure that recipients of care will have sufficient ARVs in the coming months should there be additional disruptions in clinical operations or restrictions in distribution. PEPFAR is actively working to ensure supply security of HIV commodities and will continue to provide timely updates using through the network of USAID Supply Chain Activity Managers. USAID, on behalf of PEPFAR, is also coordinating with the Global Fund to ensure that ARVs are imported to prevent stock-outs. PEPFAR country teams should work with Ministries of Health to ensure that multi-month dispensing policies are communicated to all HIV providers, facilities, pharmacies, and individuals involved in the supply chain to ensure continuity of services. Products should be distributed to clinics rather than holding large quantities at central medical stores or provincial stores, in case local transportation and access to the clinics becomes restricted.

What is the median delay and what percentage of orders are impacted by COVID related delays?

	Total Lines	Delayed Lines	Median Delay
Adult ARV	345	68	35
Pediatric ARV		52	28
Condom	104	14	30
Lab	1304	132	42
EM	151	6	36
TB HIV		7	25
VMMC	44	1	42
TOTAL	1948	280	40

Table 1. GHSC-PSM Risk Report as of June 1, 2020. Delays are measured in days.

Should we expect delays in ARV drug orders?

A median delay of about 35 and 29 days is anticipated for adult and pediatric ARVs, respectively. Buffer stocks available in central warehouses should be sufficient to cover shortages caused by this delay. USAID is reviewing the updated supply plans that have been submitted in order to assess the situation in each country. Deliveries of orders for antiretrovirals are delayed because the majority of the USFDA approved ARV manufacturers are based in India, which has been experiencing a lockdown in response to COVID-19. India has extended its lockdown through May 31st with states having autonomy to ease restrictions as they deem fit. Several ARV suppliers are located in areas where restrictions are more stringent ("red zones").

Throughout the lockdown, pharmaceutical manufacturing was deemed an essential activity. However, manufacturing capacity and exportation of final pharmaceutical products was impaired due to restrictions of movement of people, and significant shortage of logistical capability. With restrictions lifted in several parts of India, several ARV manufacturers have reported that operations are at 60 to 70%, compared to 30 to 40% approximately six weeks ago. They have, however, reported that incoming raw materials from China have been impacted due to logistical constraints.

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

Prior to COVID-19 we were aware of a shortage of LPV/r 100/25 mg tablets and issued contingency plan guidance to help mitigate this shortage. Manufacturers are continuing to increase production capacity of LPV/r 40/10 mg pellets/granules, which should meet demand by the end of this calendar year.

We are also working with ARV manufacturers to accelerate the introduction of pediatric DTG formulations. The anticipated timeline for introduction is CY21Q1. This plan has not experienced any delays in light of COVID.

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. We are seeing significant delays in the range of 8-12 weeks for certain products such as Vitamin B6. Please refer to the Table for specific median delays related to these products.

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. The updated supply plan was due to USAID by May 21st. A review of the supply plans will enable USAID to determine if commodity needs above COP19 and COP20 plans are required.

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

Consider the following interventions:

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

Tracking Supply Chain Impact

How will supply chain 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 is currently a world-wide shortage of personal protective equipment (PPE). PEPFAR has not procured PPE in large quantities in the past and cannot currently ensure appropriate or adequate supply.

Essential PPE may be procured by implementing partners for HIV clinical services under the following conditions:

1. For the protection of, and use by, PEPFAR-supported health care providers, and;
2. Locally or regionally, provided that such items are not, and could not reasonably be expected to be, meant for the United States market, including but not limited to, instances where such procurements are needed to ensure continuity of safe and effective implementation of foreign assistance programs.

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). Further guidance will be forthcoming.

Requirements for PPE can be found here:

https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC_PPE_use-2020.3-eng.pdf

21. 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.

22. Reporting and SIMS

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

No, the original MER 2.0 v 2.4 reporting requirements should be followed for all FY2020 Q2 reporting. The reporting deadline for FY20 Q2 has been extended as previously indicated to June 5. S/GAC will not be sending out any supplemental guidance to relax quarter two data reporting requirements. 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.

Are we expected to continue SIMS implementation and reporting?

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

Budget Guidance

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

Feedback/Question Submission: As is feasible given your country situation, PEPFAR programs are requested to share new MoH guidance for HIV services in the COVID-19 context, incoming technical questions, as well as any solutions for PEPFAR programs in the context of COVID-19. Guidance that has already been issued should be shared for awareness; PEPFAR HQ would be happy to provide rapid input on guidance that is still in draft form. Please send these new MoH guidance documents directly to S/GAC by

emailing them to Dr. Katy Godfrey qea0@cdc.gov, Teri Wingate gza2@cdc.gov, and Helina Meri MeriHD@state.gov, copying your Chair and PPM.

23. Information and Resources

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

- https://www.pepfar.net/sites/COVID-19/default.aspx

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:

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