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PEPFAR Technical Guidance in Context of COVID-19 Pandemic

March 25, 2020 Updates

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

Key principles for the PEPFAR response to the novel coronavirus (COVID-19) include continuity of ART therapy and accelerated decongestion of health facilities to minimize transmission of COVID-19 and protect PLHIV. The critical intervention for all programs and individuals is to accelerate and complete scale-up of 6-month dispensing of ART. If there are any barriers to 6-month MMD implementation, programs should alert their S/GAC Chair and PPM immediately for advice and assistance.

Is the PEPFAR Quarter 2 reporting deadline still the same?

Recognizing challenges with site-level access in countries across the world, the PEPFAR Quarter 2 reporting deadline has been moved to Friday, June 5th. Detailed guidance is forthcoming from SGAC_SI. We will closely monitor PEPFAR program implementation in the ensuing weeks and provide updated guidance as needed for Quarter 3 reporting.

What should be done with TPT programs?

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

What treatments are available for COVID-19?

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 particular risks for our PLHIV clients.

What about personal protective equipment?

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

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

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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.

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 gea0@cdc.gov, Teri Wingate gza2@cdc.gov, and Helina Meri MeriHD@state.gov, copying your Chair and PPM.

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March 20th Guidance

In January 2020 a novel coronavirus, SARS-CoV-2, was identified as the causative agent of an outbreak of viral pneumonia centered around Wuhan, Hubei, China. The disease caused by this virus is called COVID-19. The WHO is reporting that there are now over 400,000 cases in 196 countries or territories.¹ There has been widespread disturbance of international travel and shortages of medical supplies. In the areas hardest hit, medical facilities are overwhelmed in handling the large numbers of COVID-19 patients. During the COVID-19 pandemic, PEPFAR remains committed to supporting the provision of care and treatment of individuals with HIV while maintaining a safe healthcare environment for clients and staff. Deaths due to HIV and other co-morbidities must continue to be prevented during this time. In order to meet our commitment to continued care and treatment for PLHIV and the prevention of deaths among PLHIV due to HIV associated co-morbidities, PEPFAR is committed to supporting the host government response to the COVID-19 pandemic by leveraging existing PEPFAR resources, such that PLHIV have the best possible outcomes within the context of stretched healthcare systems. Overarching principles as well as specific technical guidance is provided for PEPFAR operational issues; prevention, testing, clinical services, supply chain, and laboratory activities; infection prevention and control; and budget guidance. This document will be updated routinely as the situation evolves.

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

- ***Protect the gains in the HIV response:***
 - *Ensure continuous antiretroviral therapy (ART) provision to current recipients of care so that they have at least a three- and ideally a six-month supply of ART in order to maintain virologic suppression.*
- ***Leverage PEPFAR-supported systems and infrastructure:***
 - *Utilize lab and surveillance systems and capacity to test for COVID-19.*
- ***Reduce transmission of COVID-19:***
 - *Protect front line health care workers.*
 - *Reduce non-essential exposure of staff and clients to health care settings which may be both overburdened and potential sources of risk.*
 - *Note: this may require modification and/or temporary suspension of non-essential services.*
- ***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:***
 - *It is understood that scale-up of HIV prevention and treatment services may be delayed, given the COVID-19 pandemic; but we must innovate and adapt to local needs to try to maintain services, continue operations and reporting.*

OPERATIONAL ISSUES

¹ <https://experience.arcgis.com/experience/685d0ace521648f8a5beeee1b9125cd>

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

- *Social distancing measures including quarantine may result in disrupted operations due to travel restrictions and fragile communications networks outside of the larger cities. PEPFAR country teams should develop plans to stay in communication with headquarters, and with implementing partners who may be most affected.*
- *Implementing partners should evaluate staff and supply resources that normally support PEPFAR/HIV services but that may be necessary to support COVID-19 control and treatment activities, after discussion with the PEPFAR team. Any requests to utilize resources that support HIV services but also respond to COVID-19 cannot be undertaken by an implementing partner without first consulting Agency grants management officers and receiving written authorization to do so. 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.*

PREVENTION ACTIVITIES

How will VMMC services be affected?

New voluntary medical male circumcisions may be delayed or paused if guidance about mass gatherings cannot be followed. 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.

How will cervical cancers 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.

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). 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. Social media may be a useful alternative platform to maintain connections between AGYW and mentors (but should not be used for delivery of curriculum-based interventions). Additionally, where feasible and appropriate, facility-based DREAMS services should be offered in the community with appropriate social distancing.

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How will PrEP be affected?

For individuals already on PrEP, a 3-month prescription 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. 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.

HIV TESTING

How will HIV testing activities be affected?

HTS Programming Considerations

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
- 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 (Diagnostic testing)
 - 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 adequate PPE is not available, which is routine guidance (e.g. gloves)
- For RTK implications, please see below Supply Chain section

PROVISION OF CLINICAL CARE

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.

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

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

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.*
- *Facilities should maximize convenient six-month refills.*
- *Clients should preferentially receive their drug supplies outside of the health facility**
- *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.*

**See Decentralized Drug Distribution strategic guide*

What is known about how COVID-19 affects PLHIV?

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.

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 being in health care facilities.

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 is being investigated for use in the setting of COVID-19; there is no conclusive evidence at present supporting its efficacy. A recent clinical trial failed to show a benefit². Accurate messaging to prevent diversion of ARVs should be provided.

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

² Cao B, Wang Y, Wen D, Liu W, Wang J, Fan G et al. A Trial of Lopinavir–Ritonavir in Adults Hospitalized with Severe Covid-19. 2020. doi:10.1056/NEJMoa2001282.

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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.

How will TB and TPT services be affected?

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

SUPPLY CHAIN FOR ARVs

Will the drug supply chain be affected?

The ARV manufacturers (largely based in India) are reporting having sufficient active pharmaceutical ingredients (API) to continue production of formulations, specifically TLD and other ARVs. GHSC-PSM is exploring all modes of transportation to reduce the transit time and prepone the delivery of orders. S/GAC recommends that programs continue to scale up six-month MMD in order to ensure patients have a sufficient supply of ARVs in the event that patients are unable to visit the clinic.

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

*As the COVID-19 pandemic continues to evolve S/GAC, USAID, CDC and GHSC-PSM have taken steps to monitor the situation as it pertains to availability of ARVs and other drugs essential to the HIV response. Because of anticipated delays USAID has instructed the Missions to place orders **one month earlier than normal lead times would suggest***

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*
- *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*

LABORATORY OPERATIONS AND SUPPLY CHAIN FOR LABORATORY

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

There are current delays for rapid test kits (RTKs) either manufactured in China or relying on key starting materials from China, and Asia, more broadly. Delays or pricing increases are being tracked

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*and communicated as they arise. Current guidance is to place orders for laboratory commodities and RTKs **one month** earlier than normal, to account for potential shipping delays.*

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

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

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

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

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

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

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

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

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

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

TRACKING SUPPLY CHAIN IMPACT

How will supply chain for COVID-19 be tracked?

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

How will USAID and GHSC-PSM Mitigate Risk?

- *Early Identification of Delayed and At-Risk Orders*

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- 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

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

SUPPLY CHAIN FOR PERSONAL PROTECTIVE EQUIPMENT (PPE)

Requirements for PPE can be found here:

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

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The Chinese government has taken control of medical PPE supply for priority use in Wuhan and has disallowed export of these products. We will continue to monitor China's export restrictions for changes in this policy.

Alternative PPE products are available from Europe, but these products may be more expensive to procure. GHSC-PSM is pursuing alternative products from Europe and delays of 6 weeks are expected. PSM is currently reviewing country PPE orders and budgets to mitigate these delays. Minimum delays of 6 weeks are expected but may change as the situation evolves.

Alternative products may be available from Europe but are more expensive. GHSC-PSM is reviewing country urgency and budget to mitigate these delays.

BUDGET GUIDANCE

Adaptation of PEPFAR programs to ensure HIV patients receive the services they need in the context of COVID-19 is expected to occur within the confines of existing, approved COP19 budgets and mechanisms, such that operational plan updates are not required.

Should a programmatic adaptation arise that would necessitate an operational plan update or otherwise require special consideration, please reach out to the S/GAC Chair and PPM and SGAC_Budget@state.gov with a description of the situation you are seeking clarity on. SGAC M&B will coordinate with the Chair/PPM and the SGAC FO to resolve the issue. Please do not initiate an OPU before receiving feedback on issue.