Meeting Targets and Maintaining Epidemic Control (EPIC) Project

COOPERATIVE AGREEMENT NO.
72OOAA19CAOOOO2

Modifying Models for Decentralized Distribution of ART through the Private Sector to Address Disruptions Related to COVID-19

May 2020

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

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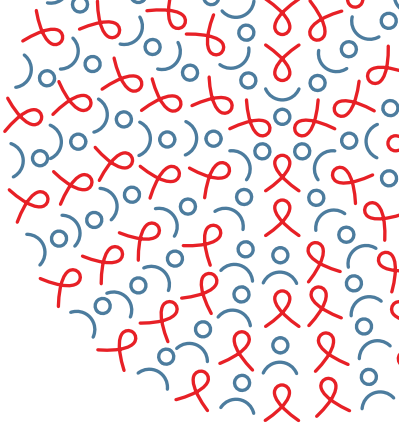
Meeting Targets and Maintaining Epidemic Control

This work was made possible by the generous support of the American people through the United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The contents are the responsibility of the EpiC project and do not necessarily reflect the views of USAID, PEPFAR, or the United States Government. EpiC is a global cooperative agreement (7200AA19CA00002) led by FHI 360 with core partners Right to Care, Palladium International, Population Services International (PSI), and Gobee Group.



INTRODUCTION

A recent report, *Decentralized Distribution of Antiretroviral Therapy through the Private Sector: A Strategic Guide for Scale-up*, reviewed three decentralized distribution models—community pharmacy (CP), automated dispensing models, and private hospital models—that can make services more convenient for patients while reducing the burden on health systems. With increased pressure on the public health sector in the context of the COVID-19 pandemic, it is likely that all routine PEPFAR-funded services will be affected, including initiation and continuation of antiretroviral therapy (ART). Many health workers will be reassigned to the COVID-19 response, and many patients will not be able to travel to health facilities because of social distancing and lockdowns. Thus, decentralized distribution models may have an even greater role to play in ensuring safe access to ART. This document provides guidance on how these models can be modified during the COVID-19 pandemic in order to increase their accessibility, capacity, and safety.

Why the Time for Decentralized Distribution Is NOW

Even though there is no evidence yet that people living with HIV (PLHIV) have a higher risk of contracting COVID-19 or, if infected, that they are more severely affected, as with other respiratory illnesses, COVID-19 poses a higher risk to people with underlying co-morbidities such as cardiovascular disease, diabetes mellitus, chronic lung disease, cancer, chronic kidney disease, and those with severe immunosuppression. Additionally, PLHIV require regular access to services at a time when (1) a visit to crowded public health facilities carries a risk of acquiring or transmitting COVID-19, and (2) routine treatment sites may be harder to reach because of stay-at-home orders, curfews, and a partial or complete shutdown of public transportation. In addition, some differentiated service delivery (DSD) models, such as community ART refill groups (CARGs), are discouraged during the COVID-19 pandemic unless measures are taken to ensure that requirements for social distancing are met. Gathering together in groups (especially larger than five people) carries increased risk of person–person COVID-19 transmission.

To continue providing essential services to PLHIV, achieve virologic suppression, and maintain gains in HIV epidemic control, we must ensure that patients in need of ART continue to receive their medication uninterrupted. During the COVID-19 pandemic there are three priority areas for ART services:

- Ensuring access to services for new ART clients
- Ensuring continued care and retention of existing ART clients
- Minimizing potential exposure to COVID-19 for both patients and clinic/program staff

The key technical approaches to ensure uninterrupted and safe provision of ART services include:

- Using remote communication methods (e.g., phone calls, text messages, social media) for information, consultations, counseling, and adherence support while ensuring safety and providing a positive client experience.
- Using mass media and other digital communication platforms to support demand creation and enrollment of new ART clients.
- Advancing decentralized distribution of ART.
- Scaling up the CP model and any other interventions (e.g., home delivery, alternative pick-up points) that ensure access to ARVs with minimal risk to clients and staff.
- Continuing multimonth dispensing (MMD) for ARVs and for TB preventive treatment with the understanding that this strategy will require ongoing reassessment and, possibly adjustment, based on available supplies.
- Ensuring flexibility and innovation of HIV programs serving clients in areas affected by COVID-19 so that they can continuously assess the rapidly changing situation and adjust their procedures accordingly.
- Ensuring strict adherence to appropriate social distancing protocols everywhere that service delivery continues.

Modifying Private-Sector Decentralized Distribution Models in the COVID-19 Context

In order to support ART refills in the context of the COVID-19 pandemic, decentralized distribution models can be modified or adapted to increase their accessibility, affordability, capacity, and safety. Many private facilities (e.g., pharmacies, clinics, and hospitals) are likely to remain open even during countrywide lockdowns, because governments deem health care to be an essential service. In collaboration with ministries of health, some decentralized distribution models can be implemented without delay, whereas others (e.g., automated dispensing units) may require time to establish and should be considered medium- to long-term options. Possible adaptations are summarized in the Table 1.

EXAMPLES OF DECENTRALIZED DISTRIBUTION (DD) OF ART

- Home delivery by program staff in Nigeria, Kenya, and Nepal
- Delivery from private pharmacies to patients' homes in Uganda and Kenya
- Provision at KP-led community-based drop-in centers in Malawi, Kenya, DRC, and Haiti
- Mobile-based clinical teams in Eswatini, South Africa, and Haiti
- Apps and online appointments in Kenya and Nigeria
- Use of the Online Reservation App in multiple countries

Table 1. Adaptations of existing decentralized distribution models during COVID-19

PRIVATE HOSPITAL	AUTOMATED DISPENSING	COMMUNITY PHARMACY	ADDITIONAL APPROACHES

• Expand model to include private clinics/surgeries
• Allow in-house pharmacies to dispense to patients from public sites
• Waive fees to help with uptake
• Offer patients an option to receive free government ARVs in case they temporarily lose ability to pay
• Schedule pick-up times and maintain physical distancing in all waiting areas to minimize contact and maintain safety
	• Increase capacity of existing dispensing sites
	• Maintain safety:
	  • Adhere to social distancing guidelines
	  • Deploy strict sanitation protocols
	• For new installation (when feasible), consider lockers as the most cost-effective option that can work even without internet access
		• Expedite deployment through electronic assessment, web-based training
		• Expand services to include both clinically stable and non-stable patients
		• Waive fees to help with uptake
		• Map patients to limited number of CPs (based on distance and client traffic)
		• Ensure adequate support and monitoring through electronic and telecommunication platforms
		• Offer home delivery of ARVs
		• Schedule pick-up times to minimize interactions and maintain safety
			Home delivery
			• Helps most vulnerable avoid exposure to clinics
			• Uses a variety of channels (CHWs, pharmacy, support staff, program staff, expert clients, postal service)
			• Obtain consent before home delivery and use discrete ARV packaging to reduce reisk of stigma and violence
			• Provide PPE to staff delivering
			Alternative pick-up points
			• Drop-in centers (DICs)
			• Other places that remain open during lockdowns
			• Develop guidance on safety

Community Pharmacies

The CP model is based on a partnership between a public health facility (the hub) and a standalone private retail pharmacy (commonly referred to as a *community pharmacy*) within its catchment area. CPs will remain open even in shelter-in-place/lockdown situations because they are considered essential services. Under a lockdown scenario—when public transportation is limited or, if used, creates additional risks for COVID-19 transmission—CPs will be convenient points for ARV pick-up because many are located within walking distance of patients' homes. Home delivery of ARVs by CP staff is another option that should be considered where possible. This service is already offered by a few pharmacies in Kenya, Uganda, Nigeria, and other countries.

Key changes to the CP model in the COVID-19 context may include:

1. Expediting selection of CPs for ARV pick-up through use of online assessments, and web-based training for pharmacy staff.
2. Expanding from serving clinically stable ART clients (as most national DSD guidelines recommend), to also including ART clients who are not yet clinically stable. This change should be supported by clearly defined guidance for the hub facility to monitor and follow-up (both through remote communication and in person when absolutely needed) with non-stable clients.
3. Carefully mapping clients to CPs; a health facility may offer clients a number of CPs from which to choose based on proximity and patient traffic (to minimize distance and to avoid overcrowding in any given CP).
4. Eliminating any patients' fees during the COVID-19 emergency. Where possible, these fees should be supported by government/donors/implementing partners (IPs).

5. Adjusting MMD based on the ARV stock status and supply projections, which may require dispensing less than a 3-month supply. Where stocks are adequate, a 6-month supply should be the goal.
6. Where possible, offering home delivery of ARVs (and other medications) as part of essential services offered by the CP.
7. Using various electronic and telecommunication platforms to ensure two-way communication between the health facility and patients to help provide adequate support and monitoring for those using CPs. This may require having a simple online portal or app, and/or using SMS, WhatsApp, social media, or scheduled phone calls.
8. Making arrangements to avoid having too many clients attend any one CP at the same time. This may involve scheduling ARV pick-up times individually, having patients wait outside, and ensuring that patients maintain adequate physical distance while waiting.
9. Sharing COVID-19 prevention information with PLHIV. Where possible, use informational posters to limit time spent face-to-face with the pharmacist and minimize waiting time for other clients. Pharmacists can still answer individual questions as needed before or after ART pick-up by phone.

Private Hospitals and Private Clinics

During the COVID-19 pandemic, private clinics and hospitals that are not specifically dedicated to management of COVID-19 patients could play a role as refill points. While these facilities vary widely in quality and capacity, many are well-placed to extend ART services, either as medicine pick-up sites or clinical care sites. However, programs must carefully balance the benefit of easing access to ART during a pandemic with the risk of potential exposure to coronavirus among patients seeking care at private facilities.

Key considerations for the private facility model include:

1. Making ARV pick-ups safer by scheduling in advance to minimize waiting time and maintaining physical distancing guidelines among patients in all waiting areas.
2. Ensuring that private facilities meet basic quality standards as well as data collection/reporting requirements. One of the ways to achieve this is by leveraging existing clinic franchises typically supported by nongovernmental organizations (e.g., Population Services International), where providers are already trained and data management systems are in place.
3. Government/donors/IPs covering consultation or service fees at private facilities through direct reimbursements, service level agreements, or other mechanisms (at least for the duration of pandemic) in order to reduce barriers and ensure that private providers are adequately paid for their time.

Automated Dispensing Models

Because these models do not require interface between health care workers and clients, they may be the safest model in the context of COVID-19. However, automated dispensing models can be relatively expensive and take time to set up, and the COVID-19 emergency requires immediate solutions. In countries where automated models are currently operational (South Africa and Zambia), it would be important to consider increasing their capacity (the number of clients who can receive refills through the automated model) while maintaining safety—adhering to safe distance guidelines, scheduling pick-up times in advance where possible, and maintaining strict sanitation protocols. Among different automated dispensing options, lockers may be the most cost-effective and, where possible, setting those up should be considered a longer-term solution.

Additional Approaches

Home delivery of ARVs

CPs or project-supported hospital teams can deliver ARVs to clients' homes, or where feasible, this service can be run from a central dispensing unit (CDU) directly to a client home or alternative pick-up location. There are several ways in which home delivery of ARVs can be optimized.

1. CP to patient homes through:
    - Pharmacy courier (could be any pharmacy support staff other than the pharmacist)
    - Designated person from the community (could be a community health worker, peer navigator, an expert client, or person living with HIV who leads one of the community support/refill groups, etc.)
2. Health facility or pharmacy to patients' homes through:
    - Community health workers
    - A third party (could be a formal delivery service or designated person from the community)
    - Postal service
    - Program staff

When implementing home delivery at a time of lockdown, care should be taken to minimize risk of stigma and violence (because it is possible that others in the home do not know the clients' status). Each client should be contacted before a home delivery, so program staff can assess for any indication of possible domestic violence or stigmatization and also to obtain clients' verbal informed consent. Additionally, the medicines should be packed discreetly, so others cannot tell what medicines are being delivered. Confidentiality is critical to make sure that home deliveries do not lead to inadvertent disclosure of a client's status.

» *A community pharmacist boards at the jetty with supplies for clients along remote creeks in Akwa Ibom State, Nigeria.*

Innovation in home delivery of ARVs

A good example of home delivery is from Mbo LGA in Akwa Ibom State, Nigeria; by March this year **40% of the more than 5,489 clients** on ART at Enwang primary health center receive ART through home delivery. This innovative project to address persistent retention challenges designed by Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) (funded by USAID and implemented by FHI 360) now holds promise to ensure that patients can continue to receive their ART safely during the COVID-19 pandemic.

Other pick-up or delivery locations

In some programs, churches, mosques, and health facilities have been used for support group meetings and for ARV pick-up prior to the COVID-19 pandemic. However, during the COVID-19 emergency, many places of worship may be closed or allowed to conduct only very limited activities, and other public gatherings have been banned. Programs should be creative in identifying locations in the community (those that remain operational at a time of social distancing/lockdown) where refills can be picked up or delivered to. For example, drug shops (both licensed and informal) in rural areas can serve as ARV pick-up points. For any identified pick-up points, clear guidance should be developed to limit interactions and ensure safety.

Making Decentralized Distribution Safer for Providers and Clients

When possible, remote screening for COVID-19 symptoms should be done before clients pick up their medications and before staff deliver them. If COVID-19 symptoms are found during remote screening, programs should make special arrangements to minimize/prevent direct contact with clients. For example, staff making home deliveries could leave packages on doorsteps and alert clients to ensure immediate pick-up; clients should be provided with personal protective equipment (PPE) before entering the CP or other facility; or clients could be asked to designate another person to complete the pick-up. All clients with suspected infection should be referred to a site designated to provide COVID-19 testing following national protocols.

People dispensing ART at private facilities or making home deliveries should wear PPE and follow other preventive measures, such as physical distancing and hand washing.

» *A staff member leaves a package of ARVs on a client's doorstep to adhere to social distancing guidelines.*

Expediting the Scale-up of Decentralized Distribution Models

Conducting in-country discussions on which models to implement and on the feasibility of providing refills for several months at a time based on stock status is a critical first step. Teams should use site-level data to help prioritize which clients to direct to which decentralized pick-up locations, including ad-hoc delivery or pick-up points—like retail shops, closed schools, or churches. This should be followed by establishing an appointment system at decentralized pick-up points, and spacing clients' appointments over the course of the day using phone calls, apps and online appointments to support social distancing and reduce COVID-19 transmission. Country teams should consider quickly scaling up the CP model and any other interventions that ensure access to ARVs with minimal risk to the clients and staff. Because CPs are already common and operational in the majority of settings, programs can rapidly identify interested registered CPs to become decentralized distribution points for ARVs. Considering the time-sensitive nature of services during this pandemic, the programs should:

- Where possible, start with pharmacy chains to maximize coverage quickly.
- Identify community pharmacies that already have experience in dispensing ARVs in order to reduce the training time.
- Use electronic/online systems for quick assessment and training of private pharmacy staff.
- Set up virtual support systems (e.g., through telephone, WhatsApp, or web-based consultation) for CP staff who may face challenges dispensing ARVs.
- Use web-based dispensing software where feasible to ensure that refills are documented. Web-based platforms, or apps used by private pharmacies for home delivery of medicines, may be quickly adapted to support decentralized distribution of ARVs during this emergency response.

Plans for deployment of automated decentralized distribution models like pharmacy dispensing units, e-lockers, and CDUs may be finalized and, if funding is available, installation started once the emergency situation improves.

Managing Stocks of ARVs

The COVID-19 pandemic is affecting every country in the world, which has implications for the global supply chain of HIV medicines. India, where most of the ARVs for sub-Saharan Africa are manufactured, is currently under lockdown. While it is recommended that programs continue to scale up six-month MMD, careful monitoring of ARV stock and coordination with government/donors are essential. As the COVID-19 pandemic continues to evolve, it is possible that countries may experience disruptions in the supply chain and programs will have to ration existing stocks of ARVs and other essential medicines. This may necessitate adjusting MMD plans by, for example, providing refills for fewer than 6 months at a time, which will result in clients needing more frequent refills than before. In these circumstances, the convenience of ARV pick-up points for clients is critical to their ability to maintain an uninterrupted supply.

Programs may also consider using decentralized distribution to deliver medications for tuberculosis and/or other opportunistic infections, PrEP, condoms, and HIV self-test kits.

Conclusion

In light of this pandemic, which has the potential to overwhelm public sector health facilities, divert health care resources, limit travel, and increase the risk of COVID-19 infection to both clients and providers, we recommend that governments and donors/programs support rapid scale-up of decentralized distribution models to ensure that PLHIV can be retained on life-saving HIV treatment during these extraordinary times.