Decentralized Drug Distribution in Malawi: Final Report

Background

The HIV prevalence in Malawi is among the highest in the world with 8.1% of people aged 15–49 living with HIV. Despite an estimated 990,000 people living with HIV (PLHIV) in Malawi, the country has made important progress in controlling the HIV epidemic. In 2021, 91% of all PLHIV in Malawi know their HIV status, 87% are on antiretroviral therapy (ART) and, of those, 94% are virally suppressed, according to Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates.[1] However, as the number of PLHIV on ART increases, the national HIV program is struggling to retain those clients on treatment. The COVID-19 pandemic and related restrictions have exacerbated this challenge. Moreover, the time and cost to travel to public facilities for treatment services remains a substantial barrier to retention. Addressing these enduring challenges requires new solutions, such as decentralizing ART distribution outside of public sector facilities and into new and underutilized access points including the private sector.

Decentralized drug distribution (DDD) moves ART services out of public ART sites into convenient community locations. To support Malawi government efforts to achieve the 95-95-95 UNAIDS goals, Population Services International (PSI) Malawi, a consortium partner of the Meeting Targets and Maintaining Epidemic Control (EpiC) project funded by the United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), provided technical assistance to introduce DDD through private clinics in Malawi. This DDD model aimed to increase the number and convenience of ARV dispensation sites, both to improve treatment access and to help decongest public sector clinics overwhelmed with ART provision to an increasing number of PLHIV. This report summarizes the achievements and lessons learned from this initiative, which took place from September 2020 through August 2021.

[1] UNAIDS. Malawi country factsheet 2020 [Internet]. Geneva: UNAIDS; 2021 [accessed 2021 Sep 23]. Available from: https://www.unaids.org/en/regionscountries/countries/malawi.

EpiC is a global cooperative agreement dedicated to achieving and maintaining HIV epidemic control. It is led by FHI 360 with core partners Right to Care, Palladium International, Population Services International (PSI), and Gobee Group.

Accomplishments

STAKEHOLDER ENGAGEMENT

Introducing the DDD model in Malawi required engagement and collaboration with a wide range of stakeholders including Baylor Foundation Malawi and Partners in Health (PEPFAR implementing partners), Ministry of Health Department of HIV and AIDS (DHA), District Health Offices (DHOs), and the leadership of all public health facilities in the project districts: Mulanje, Machinga, Kasungu, and Mangochi.

BASELINE ASSESSMENTS

In the initial phase of the activity, all private clinics (20) in the four project districts were assessed to ascertain availability and willingness to participate in DDD. A formal clinic accreditation assessment was conducted in October 2020 led by representatives of Malawi's health system regulatory bodies including Medical Council of Malawi (MCM), Pharmacy Medicines Regulatory Authority (PMRA), the DHA, and the Malawi Business Coalition Against HIV and AIDS (MBCA), the umbrella organization that primarily coordinates and enhances the private sector response to HIV in Malawi. A landscape assessment was conducted soon after to understand stakeholder perceptions regarding ART provision in private clinics. Stakeholders included clients on ART, ART focal persons in public facilities (typically the ART nurse or clinician), and private clinic providers.

Clinic accreditation for antiretroviral (ARV) drug dispensation

The objectives of the accreditation assessment were to evaluate the private clinics against the set eligibility criteria (Table 1), determine the capacity and readiness of private clinics to dispense ARVs, and provide recommendations to ineligible clinics to help them improve and be accredited. The final accreditation report, completed in December, included a list of private clinics that met the criteria and were accredited by the government to provide HIV services (Table 2).

Table 1. Key ART site assessment and accreditation criteria

1	Availability of the adequate number of clinical or nursing staff
2	Availability and willingness of staff to participate in DDD
3	Clinic staff trained or willing to be trained on ART
4	Appropriateness and readiness of infrastructure
5	Appropriateness of both internal and external security
6	Compliance with regulatory body authority requirements

Table 2. Accredited private clinics by district

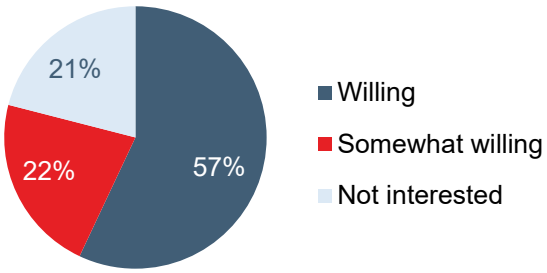
District	Private Clinics (Accredited)
Kasungu	Yankho Private Clinic
	Kalikeni Private Clinic
	Kasungu FPAM
	Emmanuel Private Clinic
Mangochi	Medicare Private Clinic
	Mangochi FPAM
Machinga	Umoyo Private Clinic
	Liwonde Hospital
Mulanje	Chikuli Private Clinic
	Banja Care Private Clinic

Stakeholder landscape assessment results

The landscape assessment conducted in November 2020 consisted of structured interviews with 82 ART clients, 17 ART coordinators, and 28 private clinic providers. All providers (100%) and the majority of ART clients (72%) who participated showed interest in the the model. Slighly over half (57%) of the clients were willing to pay a nominal fee to receive HIV services in private clinics (Figure 1). Among those willing to pay, MK500 (~US$0.62) was most commonly reported as an acceptable consultation fee. Other key insights from qualitative components of the assessment included:

- Clients thought the model would offer convenience for those who are busy
- Clients noted no long queues at private clinics would be time saving
- Clients alluded to cost savings as they would no longer have to travel long distances to clinics as frequently, especially as bus fares increased during COVID-19 restrictions
- ART coordinators at public facilities thought the quality of care for PLHIV who remained in the clinics would improve because of reduced workload

Figure 1. Willingness to pay for services at private clinics among ART clients



CAPACITY BUILDING

Private clinic providers training

With support from MOH and MBCA, all selected private clinic providers received the National Certification on HIV/AIDS Management training to equip them with skills needed to offer the standard package of care per the national treatment guidelines and protocols. The trained private providers were a cadre of nurses and clinicians registered by Nurses and Midwives Council of Malawi (NMCM). The training was conducted by certified trainers from the MOH and MBCA; topics listed in Table 3. National monitoring and evaluation (M&E) tools for HIV care were also provided to private clinic providers (Box 1).

Table 3. Content covered during ART training	
1	Summary of new policies in HIV/ART
2	Integrating clinical HIV services
3	Prevention of mother-to-child transmission (PMTCT) strategy
4	Diagnosing HIV infection and exposure
5	HIV-related diseases
6	Standard monitoring of HIV patients
7	Preventive services for HIV patients
8	Understanding ART regimens and formulations
9	Prescribing and dispensing ARVs
10	Starting ART
11	Combining ART and tuberculosis (TB) treatment
12	Continuing ART
13	Differentiated ART services
14	Management of labor and delivery, newborn, and postnatal follow-up
15	Transition to new ART regimens (2018/2019)
16	Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)
17	Pharmacovigilance
18	Monitoring and evaluation
19	Supply management

Box 1. M&E tools provided to private clinics

1. ART registers
2. HIV care clinic registers
3. High viral load registers
4. DNA PCR test registers
5. Adult formulation ART cards
6. Pediatric formulation ART cards
7. Exposed child cards
8. Requisition books stock cards
9. Viral load facility monthly reporting tool
10. Exposed child under 24 months follow-up reporting form
11. Integrated TB/HIV clinic quarterly reporting form

Additionally, providers were trained on viral load (VL) management and procedures to ensure clients devolved to private clinics still accessed VL testing. As part of the training, private providers were paired with public facility ART coordinators during ART days for VL sample collection. After a week of observation, private providers practiced collecting blood samples under the supervision of the ART coordinators to ascertain they could collect blood on their own at their clinics and follow the relevant standard operating procedures (SOPs) for sample collection, processing, and transfer to collection points.

Photo credit: Gift Kambandanga, EpiC Project Manager

Private clinic provider observes public health facility provider collect viral load samples during the training session.

TECHNICAL ASSISTANCE AND DEMAND CREATION

Quality assurance

In collaboration with the MOH, EpiC reviewed and adopted the MOH quality assurance (QA) system for DDD and rolled it out to the private clinics. DHO ART coordinators supported the QA activities, specifically supervision and mentorship, as part of routine activities. By August 2021, all 10 DDD private clinics received supportive supervision visits from DHO teams to ensure compliance to QA standards. The public health facilities from which clients were devolved were also included in two national ART supervision teams' quarterly visits. Both DHO and national ART supervision teams provided positive feedback. No critical issues were identified in the supervised private clinics.

Demand creation strategy

The demand creation strategy was developed for targeted, coordinated, and results-oriented communication activities to help increase uptake of ART at private clinics. In developing this strategy, individual factors (e.g., knowledge, attitudes, and behaviors), interpersonal factors (e.g., peers, social networks), institutional factors (e.g., workplace or business environment, access to services), community factors (e.g., social capital), and public policies were considered.

The landscape assessment identified factors that ART clients felt were most important for ARV pickup locations, which included convenience, privacy, and proximity to where clients live. Key messages focused on how DDD addresses these factors and other benefits.

- Don't be hard on yourself 'osamaukhwimitsa moyo'— you can access ART services from private clinics in your area.
- Be in charge of the time and day to get your ART refills.
- Enjoy the convenience of accessing ART at a private clinic in your area.
- You can now access ART at your nearest private clinic.
- At the private clinic you can access ART at any time, any day.
- Accessing ART at the private clinic is safe and discreet.
- Save time, get your refill at your nearest private clinic.
- A viable option that works for you; now you can get your ART refills at your nearest private clinic.
- Beat the queue; refill at your nearest private clinic.
- You will get the same help you get at a public hospital at the private hospital

Expert clients (ECs) are PLHIV established on treatment who have a good understanding of HIV care and treatment services and help other PLHIV access and navigate HIV services. They, as well as PLHIV support groups, were identified as ideal for providing DDD information. A one-day

training was held with 42 ECs and 22 support group leaders to strengthen their knowledge about DDD and how to encourage peers to enroll (Table 4).

Table 4. Number of trained expert clients and ART group leaders

District	Expert Clients	ART Support Group Leaders
Kasungu	15	4
Mangochi	6	2
Machinga	12	6
Mulanje	9	10

The training session focused on the following areas:

- Raising awareness about the DDD model
- Promoting the benefits of the DDD model
- Assessing willingness of PLHIV to pay for services
- Addressing the key norms, both perceived social and subjective norms (e.g., private clinics are for the rich and services are expensive)
- Addressing general ART adherence issues and roles of ECs and support group leaders in DDD

The DDD messages, mode of delivery, and outreach were customized for clients' needs and circumstances as shown in Table 5.

Table 5. Demand creation strategy approach

	Male: age 25–35	**Male: age 15–24**	**Female: age 15–24**	**Female: age 25–35**
Segment	Married and has a small business. He relies on daily sales for survival. He thinks spending more time at the hospital for his refill interferes with his business.	Still in high school and finds it difficult to refill ART during the day. He also hates being in a queue together with adults to have his ART refilled.	Loves fun and trendy things. Whenever she is not feeling well, she goes to the nearest private clinic because she wants to appear to have money, though, of course the 'blesser' will settle the bill.	She wants to care for her family by doing 'seasonal business' from mango in the rainy season to sugar cane in the dry season. She thinks reducing the travel distance and time spent on ART refills will allow her to focus her time more on her business.

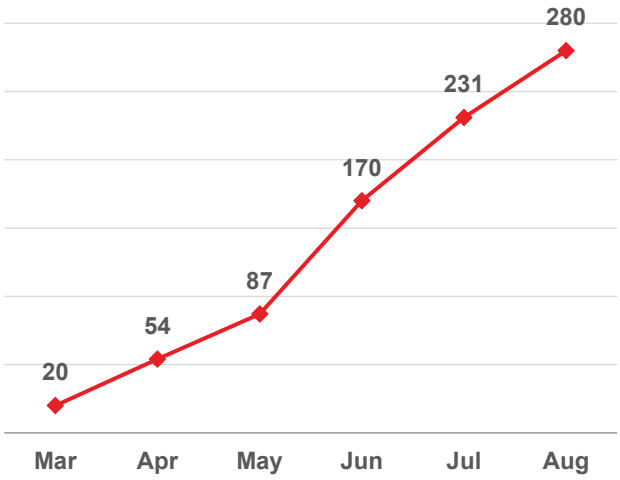
Message	• Save time, get your refill at your nearest private clinic at your own time and day • Be in charge of the time and day to get your ART refills, migrate to private clinics.	• It's safe and discreet to have your refill at a private clinic • Chill, access ART where you are comfortable at a private clinic near you.	• Life is good when I can access ART anytime and at the place of my choice. • Beat the queue, refill at the private clinic.	• Have your refill at a private clinic and quickly get back to your business. • A viable option that works for you, now you can get your ART refills at your nearest private clinic.
Delivery channels	• Expert clients • Road signage • Posters	• Mass media-community radio • Posters	• Road signage • Mass media-community radio • Posters	• Expert client • Mass media-community radio
Outreach	• One on one • Group sessions. • Clinic talks	• Youth friendly day outreaches • Peer-driven approaches • One on one • Group sessions	• One on one • Peer driven • Group sessions	• One on one • Group sessions • FBOs • CBOs

ART service provision rollout and key results

In March 2021, ART service provision was rolled out in all the accredited DDD private clinics coupled with the full scale-up of demand creation activities including mobilizing ECs, organizing mass communications through community radio and local television, conducting targeted outreach sessions at markets, workplaces, and schools, and distributing fliers and posters. By August 2021, 280 clients were receiving ARVs and ongoing HIV care from 10 private clinics.

The uptake of DDD during the initial months of implementation was slow due to a dispensation fee of MK1,000 per one-

Figure 2. Cumulative number of clients accessing ART via DDD by month



month supply of ARVs based on the regulatory advice of the MBCA, which was found to be higher than what most clients could afford. Discussions were immediately initiated with MBCA and by early June 2021, the project successfully negotiated a flat consultation fee of MK300 per visit, regardless of the number of months of dispensation, with which all concerned parties (clients, providers, and ECs) were comfortable to proceed. The newly renegotiated fee was communicated to PLHIV through ECs and to providers through EpiC staff, which eventually led to an improved enrollment rate (Figure 2).

Client feedback group discussions

Unstructured group discusions facilitated by ECs and the EpiC team were conducted in July 2021 in each district with clients who picked up ARVs at private clinics. The aim was to collect feedback from clients to inform programming and contribute to the continuous learning process. Discussions were conducted to assess the following areas:

- Factors that prompted the clients to enroll in DDD
- Reasons why some private clinics were attracting more clients while others were not
- Areas needing improvement and suggestions for future interventions

Key feedback included:

- “Our dignity is now maintained”— Clients highlighted that while the queues for ARV refills are outside the private clinic’s consultation room, no one knows what each client is at the clinic for except the clinician or nurse in the consultation room.
- “We are treated as kings and queens.”— Clients noted the lack of congestion at DDD clinics as an ideal setup amid the COVID-19 pandemic.
- Clients indicated that the preference for certain clinics over others is an issue of the clinic location. Some clinics are close to main streets and busy locations, like the market, where clients feel a lack of visual privacy from people who may suspect them as ART clients. Clinics located on less busy streets are preferred.
- Some clients suggested an expansion of DDD, especially in areas where clients walk long distances to access ARVs at public facilities.

Achievements by indicator

From March to August 2021, EpiC supported 280 clients on ART from 13 public health facilities in four districts to pick up their refills at 10 DDD private clinics. These public health facilities were chosen based on their proximity to the private clinics within the four districts.

Indicators		Achievements to date
DDD_HF: Number of health facilities/stand-alone sites from which clients are devolved to DDD pickup points (PUPs) or other DDD modalities for ARVs for treatment and/or PrEP		13
Number of DDD PUPs and other DDD modalities providing ARVs and PrEP to clients devolved from health facilities		10
TX_CURR_DDD: Number of adults and children currently accessing ARVs through DDD PUPs or other DDD modalities	Private clinics	280
Number of people trained/retrained in DDD		14

Lessons learned

The implementation of DDD in Malawi offered valuable lessons critical for successful scale-up. The strong buy-in of stakeholders and the willingness of clients to enroll in DDD demonstrated the potential of the model to successfully complement government efforts for reducing barriers to treatment continuity and decongesting public facilities, especially in the context of COVID-19. Stakeholder inputs and guidance on how to scale up and improve the intervention was critical for the success of DDD in Malawi. Establishing a good working relationship with government structures (MOH, DHO, DHA, and other regulatory councils) also helped position the project as a supportive arm to government initiatives and promoted buy-in from other stakeholders. This was vital for the smooth implementation of project activities. The strong engagement of clients on ART was also crucial for the development of vigorous demand creation strategies necessary to reach a wider population of people who can benefit from DDD.

Next steps

EpiC Malawi will continue to engage stakeholders for collaboration and to ensure a smooth transition when the clinics are stable and self-sufficient in implementing DDD. Demand creation strategies, including mobilizing ECs, broadcasting radio messages, and disseminating posters and flyers, will be continued for project visibility. In FY22, under Malawi Country Operational Plan (COP) funding, EpiC will focus on advancing DDD scale-up through the following activities:

- Support accreditation of private clinics not accredited in FY21 and those newly established in the four districts to expand the opportunity to a larger number of clients
- Broaden service provision at private clinics to include PrEP to support the National HIV Prevention Strategy
- Migrate data management to an electronic M&E system (i.e., DHIS2 tracker) for easy and streamlined data access and use

- Conduct a cost analysis of DDD to estimate resources required to establish and sustain the DDD intervention in Malawi and the financial benefits to patients and the public health system to inform MOH policy and scale-up decisions
- Evaluate the viability and sustainability of the private clinic model to improve continuity of treatment to inform decisions for scale-up
- Advocate with the MOH for scale-up of DDD into additional districts to increase coverage and support for public health facilities

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