

Decentralized Drug Distribution in Mozambique: Final Report

Background

Mozambique has an estimated HIV prevalence of 13.2 percent with significant variation across provinces (from 5.2 percent in Tete Province to 22.9 percent in Maputo Province), sex, and age groups. The country has made important progress toward meeting the Joint United Nations Programme on HIV/AIDS (UNAIDS) 95-95-95 targets, with 82 percent of people living with HIV (PLHIV) aware of their status, 68 percent on antiretroviral therapy (ART), and 56 percent virally suppressed.¹ Gaps and challenges related to initiation and continuity of treatment persist among PLHIV, jeopardizing the country's progress toward achieving epidemic control.

The increased uptake of HIV treatment services has resulted in challenges to the health system and clients. Due to limited financial and human resources, as well as limited space for service delivery, the public health system and health providers have been overwhelmed by client volume. At the same time, ART clients experience long waiting times and, sometimes, multiple unnecessary visits to health facilities for antiretroviral drug (ARV) pick-ups. These challenges compromise clients' adherence to care and continuity of treatment.

To address this, several differentiated service delivery (DSD) models have been introduced. These include fast-track, multimonth dispensing (MMD), community ART groups, family group model, and adherence clubs. Additionally, in April 2020, Mozambique initiated public-private pharmacy (FARMAC) ART distribution for a limited number of clients in four FARMAC pharmacies in Maputo City. With these models, PLHIV who are established on treatment have the option of receiving a three- or six-month MMD (3- or 6-MMD) of ARVs at health facilities or locations outside of the health facility, which reduces the frequency of clinic and ARV pick-up visits. This allows the limited human resources staff to focus care on people who are ill or in need of more intensive clinical follow-up.

Although the existing DSD models have improved service delivery and utilization by addressing some of the challenges faced by providers and clients, other challenges persist, especially in the context of

¹MISAU/Serviços Nacional de Saude (2020). Relatório Anual 2020; Relatório Anual das Actividades Relacionadas ao HIV/SIDA.

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 Gobe Group.



the COVID-19 pandemic. Most ART clients continue to visit the health facilities for their ARV pick-ups and other nonclinical services, which congests facilities and increases health providers' and clients' risk of COVID-19 transmission. Additionally, these services are generally available during limited periods of the day, which are often times when clients may not be available due to work, school, family, transportation challenges, or other engagements. Scale-up of DSD models and additional innovative approaches are needed for ART delivery to make services safer and more convenient for clients and health providers while reducing the burden on the health system.

The Decentralized Drug Distribution (DDD) model in Mozambique

From January 2020 to September 2021, the Meeting Targets and Maintaining Epidemic Control (EpiC) project's DDD program in Mozambique, funded by the United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), supported the development and rollout of a national model for decentralized delivery of ART through private pharmacies. Since June 2020, the program has successfully worked with the Ministry of Health (MOH), PEPFAR implementing partners, and other stakeholders to design and implement the DDD pharmacy model, incorporating learnings from the existing small-scale FARMAC pharmacy model and creating networks of health facilities and private pharmacies across the country. In this initial phase, the MOH approved model is being implemented in 33 health facilities and 77 private pharmacies across the country's 11 provinces.

Clients who meet the eligibility criteria (Box 1) are offered an opportunity to enroll in the private pharmacy model at the health facility where they access HIV care. Participating health facilities may be linked to up to seven private pharmacies depending on geographic location. Clients who decide to enroll can select one of those private pharmacies based on convenience or preference.

After enrollment, the client is expected to receive all subsequent 3-MMD ARV refills at the designated private pharmacy and to continue to receive clinical and laboratory care at the health facility. At the private pharmacy, the client receives a package of services, including:

- Weight and blood pressure monitoring
- Adherence support and monitoring
- Tuberculosis screening
- ARV dispensing

Box 1. Client eligibility criteria for DDD

- Express interest in the DDD model
- Clinically stable: virally suppressed (undetectable or <1000 copies/ml)
- Demonstrate good adherence during the previous six months
- Do not have clinical conditions associated with World Health Organization HIV clinical stages III and IV
- Not on prophylaxis (Co-trimoxazole or tuberculosis prophylaxis)
- Not pregnant or lactating
- On first-line regimen with tenofovir, lamivudine, and dolutegravir (TLD) or tenofovir, lamivudine, and efavirenz (TLE)
- For children: 10 years and older with weight above 30 kilograms and on TLD

Accomplishments

STAKEHOLDER ENGAGEMENT

From June 2020, EpiC engaged several stakeholders in the process of developing and implementing the DDD model. These included:

- Ministry of Health (MOH) entities:
 - National Directorate of Pharmacy/Direção Nacional de Farmácia (DNF)
 - The Central Medical Stores/Central de Medicamentos e Artigos Médicos (CMAM)
 - National HIV Program/Programa Nacional de ITS – HIV/SIDA (PNC ITS-HIV/SIDA),
 - Provincial Directorates of Health Services of the 11 provinces
- United States Government (USG) agencies (USAID, CDC)
- PEPFAR implementing partners (Collaborating Centre for Health, Friends in Global Health, ICAP, Abt Associates, Ariel Glaser Foundation, Elizabeth Glaser Pediatric AIDS Foundation)
- National Association of Private Pharmacies
- FARMAC pharmacies, a state-linked chain of community pharmacies
- Other FHI 360 projects (COVida, an orphans and vulnerable children project, and PASSOS, which provides treatment for key populations) to explore adaptation of the private pharmacy model for their target populations
- All stakeholders were continuously engaged, and this was instrumental in ensuring their buy-in, contextualizing the DDD model to the country context, and receiving support through implementation and rollout.

ASSESSMENT OF PRIVATE PHARMACIES

In June and July 2020, EpiC conducted a survey with private and FARMAC pharmacies to assess their willingness and readiness to distribute ARVs. In this survey, 347 pharmacies across the country were contacted, and 197 (56.8 percent) responded. Data for 176 (50.7 percent) were analyzed; the remaining 21 were excluded from analysis due to incomplete data.

Key findings:

- Among private pharmacies, 77 percent (135) met the minimum criteria (Box 2) to dispense ARVs to clients.
- Ninety-one percent (160) of private pharmacies showed interest in providing ARV dispensing services.
- Most private pharmacies have longer operating hours than public health facilities (including 95 percent open after 5 p.m. and 97 percent on Saturdays and occasionally during public holidays).
- Sixty-one percent (107) of pharmacy personnel had previous training in ART.
- Documentation and management of client data would be a new activity for the private pharmacies and would require some training on data management with an easy-to-use electronic data management system.

Box 2. Criteria for pharmacies to dispense ARVs as part of DDD

- Licensed by the Directorate of Pharmacy
- Interest in participating in DDD
- Appropriate and adequate space for privacy and safe storage of ARVs
- Registered (licensed) and adequate pharmaceutical personnel
- Willingness to provide ARV pick-up services whenever open
- Willingness to enter a memorandum of understanding with the MOH and implementing partner

From this assessment, 83 of the 176 private pharmacies were deemed ready to start DDD. The findings of the assessment were presented to stakeholders and informed the design of the DDD pharmacy model for the country.

Interviews with clients about ART and DDD

To understand client perspectives regarding ARV drug decentralization, EpiC conducted 15 telephone interviews with PLHIV support and savings group members in Maputo City, Zambézia, and Manica provinces.

In general, clients were open to the idea of picking up ARVs at private pharmacies. The most important considerations for respondents were pharmacy staff attitudes and competence, privacy, and convenience.

“It would be close, and that would be easier for me because now I have to ask my boss for time off from work to go to the hospital, and it takes all day to be seen, and my boss doesn’t like it. When somebody asks the boss, sometimes it takes two days to authorize, and I might be without any medicine left. To pick up at the private pharmacy would be good because it’s close, and I wouldn’t have to ask my boss anymore because service isn’t delayed there.”

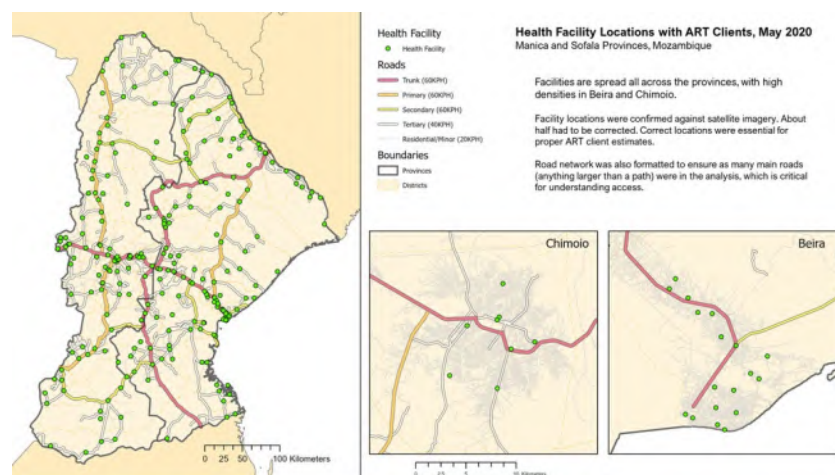
– Individual living with HIV,
Maputo City

The findings, together with similar acceptability studies conducted earlier in 2017–18 by FHI 360 in Manica, Sofala, Tete, and Niassa provinces and the CCS in Maputo City, informed the model design.

MAPPING

A mapping exercise (Figure 1) was conducted in Sofala and Manica provinces to understand client, health facility, and private pharmacy geographical distribution and to inform prioritization of health facilities in the first phase of DDD. Population point data and PLHIV density were mapped, and travel time from any given location to the closest sites and pharmacies was modeled. This analysis was used to select pharmacies for the initial phase of implementation and other ARV pick-up points.

Figure 1. Map of health facility locations



DEVELOPMENT OF THE DDD PHARMACY MODEL AND MOH APPROVAL

Based on the findings of the pharmacy assessment, client interviews, and the mapping exercise, EpiC developed the implementation plan for the DDD private pharmacy model. The draft of the DDD pharmacy model and the findings of the pharmacy assessment, client interviews, and mapping exercise were presented to the MOH in July 2020, and a DDD technical working group (TWG) was subsequently created. This TWG comprised representatives from MOH entities (DNF, CMAM, PNC ITS-HIV/SIDA), EpiC, USG agencies, and several PEPFAR implementing partners. The task of the TWG was to review the model presented by EpiC and use the experience of implementing the small-scale FARMAC pharmacy model in Maputo City and learnings from other country experiences to develop a DDD model applicable to FARMAC and other private pharmacies throughout the country. The adapted model was presented to the MOH and approved in September 2020.

DEVELOPMENT OF OPERATIONAL TOOLS AND MATERIALS

To operationalize the DDD pharmacy model, EpiC worked with the MOH and implementing partners to develop several documents and tools, including:

- **Training materials for DDD service delivery staff (private pharmacists and health facility staff)** were adapted from existing MOH training materials and the generic DDD training materials developed by FHI 360. The content included modules to equip public and private providers with ART-related counseling skills and knowledge and guidance on DDD-related services and systems.
- **Standard operating procedures (SOPs)** were written to guide implementation of the model. This included the selection of health facilities and private pharmacies, demand creation for DDD, client eligibility review and enrollment at the health facilities, pharmaceutical care and the provision of the service package at the private pharmacy, and drug supply and management.
- **Demand creation posters** were developed to provide basic information on DDD to the clients and facilitate demand generation at the health facility and in the community.
- **A technical assistance (TA) and supervision guide** was created to standardize provision of routine TA to the health facilities and private pharmacies across provincial teams and ensure adequate implementation and continuous quality of DDD services.
- **Health and logistics electronic information management systems (iDART mobile and SIGFAP)** were adapted from existing information systems (iDART and SIGLUS) used in health facilities by PEPFAR health information systems and supply chain partners FGH and Global Health Supply Chain-Procurement and Supply Management (GHSC-PSM). iDART mobile allows for paperless and real-time referral of clients, guides provision of the service package, including dispensing, and enables real-time updates of the clients' electronic medical records at the health facility by pharmacies. SIGFAP supports medication management and allows tracks stock at the private pharmacy.

SELECTION OF HEALTH FACILITIES AND PRIVATE PHARMACIES

The criteria for selection of the initial group of health facilities and private pharmacies were developed by the DDD TWG. Three high-volume health facilities were selected from each province using the following criteria:

- Have at least 2,000 clients currently on ART
- Have been providing 3-MMD for at least one year
- Have a functional electronic client information management system (iDART/Electronic Patient Tracking System [EPTS])

Seven private pharmacies were selected per province, and each was linked to the three selected health facilities in the same province. All selected pharmacies met the criteria in Box 2.

TRAINING AND CAPACITY BUILDING: TRAINING OF TRAINERS (TOT) AND PROVINCIAL LEVEL TRAINING

EpiC worked with the MOH to train health providers and program managers on DDD. The training was conducted in two phases. The national level training of trainers (TOT) was held in March 2021 and included 96 technical personnel and program managers (from the MOH and implementing partners) from the national and provincial levels. Subsequent provincial level trainings were held between April and May 2020 with 374 participants, including pharmacy personnel from the selected private pharmacies, health providers from participating health facilities, and provincial program managers from the provincial directorates of health and implementing partners.

Table 1. Number of personnel trained on DDD pharmacy model across 11 provinces

Cadre/Category	No. trained
National/provincial trainers (technical personnel and program managers)	96
Private pharmacy personnel	137
Health facility staff	153
Provincial/district program managers (MOH, IPs)	84
Total	470

BUSINESS CASE DEVELOPMENT

EpiC provided continuous technical support to the implementing partners and provincial health directorates in operationalizing DDD. EpiC technical staff supported the development of MOUs to guide the relationship between the provincial MOH, the private pharmacies, and the implementing partners. Additionally, EpiC worked with the DNF to finalize the accreditation process for the selected pharmacies to provide ARV dispensing services.

EpiC led the negotiation process for determining the dispensing fees for the private pharmacies with the MOH, and based on MOH guidance that no client should pay for ARV pick-up at private pharmacies, the TWG agreed all pharmacies would receive a fixed monthly fee of 15,000 Mozambican meticals (US\$235) from implementing partners regardless of client volume. This agreement was included in the signed MOU.

TECHNICAL ASSISTANCE AND DEMAND CREATION

To support demand creation, EpiC assisted the provincial teams in disseminating information regarding the DDD model to clinicians and ART clients in participating health facilities. To ensure clients were aware of DDD and its potential benefits, EpiC worked with the MOH to design a poster (Figure 2) that was placed in the health facility and worked with health providers to integrate DDD messages into health talks in the facilities.

Results

Challenges with accreditation of private pharmacies by the MOH caused delays in the initiation of client referrals. Client identification and referral began at the end of July 2021 with provinces starting at different times. The achievements below (Table 2) are of the three provinces (Zambezia, Maputo, and Cabo Delgado) to first initiate rollout, between July 19 and August 20, 2021. Four DDD indicators were tracked upon initiation, and the achievements against targets are below.

Figure 2. Demand creation poster for DDD



Table 2. DDD indicators for Zambezia, Maputo, and Cabo Delgado provinces

Indicator	Target	Achievement to date	% Achievement to date	
DDD_HF: Number of health facilities/stand-alone sites from which clients are devolved to DDD pick-up points (PUPs) or other DDD modalities for ARVs for treatment and/or PrEP	33	42*	127%	
Number of DDD PUPs and other DDD modalities providing ARVs and PrEP to clients devolved from health facilities	77	74**	97%	
TX_CURR_DDD: Number of adults and children currently accessing ARVs through DDD PUPs or other DDD modalities	Pharmacy	7,510	451	2%
Number of people trained/retrained in DDD	427	437	102%	

*33 health facilities, three per province, were approved for this initial phase. An exception was added for Maputo City, where the FARMAC model was already being implemented. This figure includes the three health facilities previously implementing the FARMAC model and an additional six new health facilities.

**77 pharmacies, seven per province, were approved for this initial phase. An exception was added for Maputo City to include nine pharmacies (six FARMAC and three private). Niassa Province decided to select only three pharmacies after considering the client volumes in the participating health facilities. One private pharmacy in Sofala Province withdrew due to the delays in initiation of activities and was no longer willing to participate in DDD.

Lessons learned

The continuous engagement of all stakeholders, including the MOH, DNF, and USG agencies, through the DDD TWG was crucial for introducing, obtaining strong buy-in for, and implementing DDD, especially in the context of COVID-19 and the multiple competing priorities of the MOH departments and implementing partners. While EpiC faced delays due to MOH processes and slow communication, the DDD TWG facilitated steady progress toward successful implementation. Other lessons included:

- New approaches with policy change implications, such as DDD, encounter hesitancy and resistance from the MOH and health facility staff. It is important to identify and address all concerns from stakeholders.
- MOH leadership is crucial, especially for DDD and other interventions that are linked to the national public health system and have wide geographical coverage. This facilitates collaboration with the lower levels of the health system that are responsible for implementation.

- A robust TA and supportive supervision plan for FARMAC and private pharmacies involving the provincial MOH and clinical partners is crucial, especially in the initial phase of implementation, to ensure early identification of gaps and challenges.
- Because DDD is a new initiative, has wide geographical coverage, and involves multiple partners in implementation, it is necessary to have a central coordination mechanism that provides technical support and monitoring of the model (including health facilities, pharmacies, supply chain system, reporting, etc.) to ensure clients continuously receive quality care.

Next steps and transition plan

In fiscal year 2021 (FY21), the EpiC team has provided central coordinating to ensure the successful rollout of DDD. At the end of FY21, EpiC will transition this role to PEPFAR clinical partners. Before the end of FY21, EpiC will do the following:

- Support IPs and provincial DDD teams with demand creation activities, client identification and referral, and tracking of referred clients. This will allow for the identification of model design gaps and appropriate action.
- Work with the national DDD TWG to carry out initial TA and supportive supervision visits and assist the provincial teams to develop TA and supportive supervision plans for each of the provinces. More intensive supportive supervision is crucial in the first six to nine months to monitor client referral, provision of the package of services, and supply management and logistics systems.
- Work with USG agencies and the DDD TWG to share developed tools and materials and transition EpiC DDD activities to PEPFAR clinical partners. EpiC will engage partners individually and collectively.
- Starting FY22, EpiC will work with PEPFAR and the MOH to plan for:
 - a. A survey to assess satisfaction among clients picking up ARVs through the DDD model and health provider perspectives and experiences of DDD, with a focus on the DDD pharmacy model
 - b. A geo-mapping exercise in the provinces not involved in the first phase, which is expected to provide crucial information on client and health facility distribution and inform decisions on expansion of the DDD pharmacy model and potential for other DDD options

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