

**Meeting Targets and Maintaining
Epidemic Control (EPIC) Project**

COOPERATIVE AGREEMENT NO.
7200AA19CA00002

Decentralized Distribution of Antiretroviral Therapy through the Private Sector

**A STRATEGIC GUIDE FOR SCALE-UP
DECEMBER 2019**



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Acknowledgments

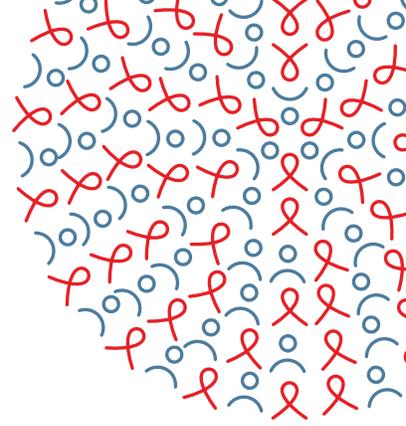
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The authors would also like to thank everyone who provided review and/or feedback, including Hannah Margusee, Susanna Baker, Judy Chen, Kelly Badiane, Tom Minior, and Josef Tayag.

This report is 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 FHI 360 and do not necessarily reflect the views of USAID, PEPFAR, or the United States Government.

Abbreviations

| | |
|----------------|--|
| AIDS | acquired immunodeficiency syndrome |
| AIM | AIDS impact model |
| ART | antiretroviral therapy |
| ARV | antiretroviral |
| ATP | ability to pay |
| CCMDD | central chronic medication dispensing and distribution |
| CDU | central dispensing unit |
| CIDRZ | Center for Infectious Disease Research in Zambia |
| CP | community pharmacy |
| CPM | community pharmacy model |
| DD | decentralized distribution |
| DDM | decentralized distribution model |
| ELMIS | electronic Logistics Management Information System |
| EMR | electronic medical record |
| HIV | human immunodeficiency virus |
| HRH | human resources for health |
| IDI | Infectious Diseases Institute |
| IHVN | Institute of Human Virology in Nigeria |
| KHFSA | Kenya Health Financing Systems Assessment |
| LTFU | loss to follow-up |
| MMD | multi-month dispensing |
| MMS | multi-month scripting |
| MOH | Ministry of Health |
| MOU | memorandum of understanding |
| NASA | National AIDS Spending Assessment |
| PCU | prescription collection unit |
| PDU | pharmacy dispensing unit |
| PEPFAR | U.S. President's Emergency Plan for AIDS Relief |
| PLHIV | people living with HIV |
| SFI | Sustainable Financing Initiative |
| SOP | standard operating procedure |
| TB | tuberculosis |
| TX_CURR | number of people currently receiving ART |
| WHO | World Health Organization |
| WTP | willingness to pay |



EXECUTIVE SUMMARY

The purpose of this document is to provide information and guidance to countries considering introduction and/or scale-up of the decentralized distribution models (DDMs) for providing antiretroviral therapy (ART) through the private sector. The guide includes (1) a summary of existing DDMs, (2) information to help donors, governments, and program managers make decisions about what model may suit their country/setting best, and (3) action steps to follow in planning for introduction and scale-up of these models at national and subnational levels.

Effective and sustainable delivery of ART to a growing number of people living with HIV (PLHIV) accessing treatment requires innovative approaches that will make services more convenient for patients while reducing the burden on health systems. One such innovative approach to ART provision includes transitioning clinically stable clients currently receiving ART in public facilities to obtain their refills from private sector providers. Three DDMs for providing ART through the private sector are being tried in several countries with promising results. The following DDMs of ART were identified through a desk review and interviews with key informants in several countries in sub-Saharan Africa:

- **Community pharmacy.** Patients on ART in public facilities who are clinically stable are devolved to a private community pharmacy for antiretroviral (ARV) medication refills. The service is either free or available for a small dispensing fee. Pharmacies receive ARVs from the government/public facility. The version of this model where patients contribute is more sustainable because it encourages domestic resource mobilization.
- **Automated dispensing models.** These include pharmacy dispensing units (PDUs), prescription collection units (PCUs)/lockers, and central dispensing units (CDUs). The automated models require fewer human resources for health (HRH) and improve access to ART. Patients receive ARV refills through unmanned systems but can reach a pharmacist electronically or over the phone if support is needed. Patients are not charged for either ARVs or services.
- **Private hospitals.** Under this model, the private health facility may receive government-/donor-funded ARVs that are provided to PLHIV for free, but the client pays for consultations and other services. Unlike the previous two models, in this model, clients can receive comprehensive HIV services in addition to ARVs. Some hospitals purchase their own supply of ARVs and charge the patients for both medications and services. The degree to which unsubsidized HIV services are used is unknown.

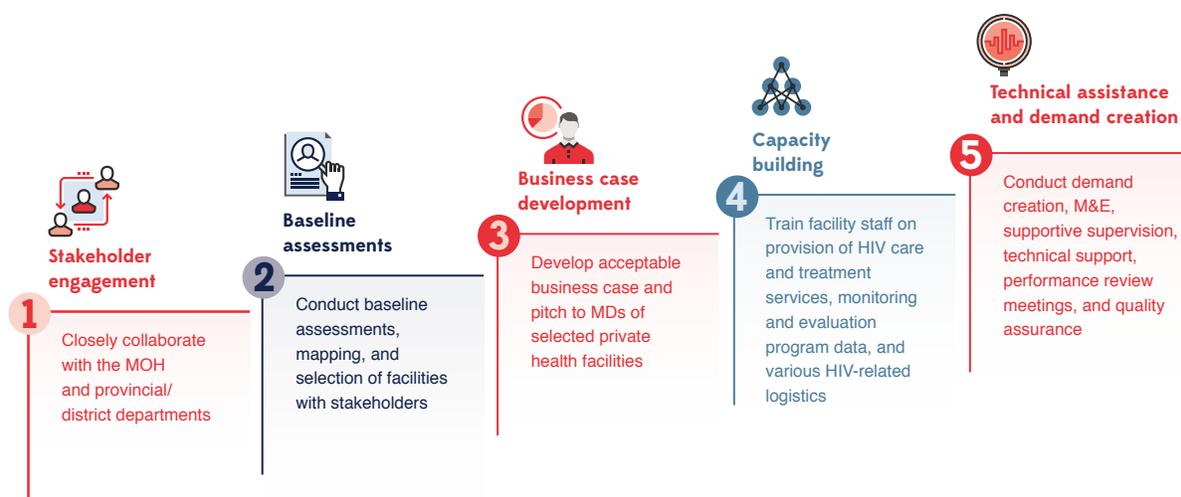
Governments or implementing partners wishing to introduce or scale up one or more of the DDMs for ART must take into consideration a wide variety of country-specific factors, including:

- Context of the regions in which the DDMs are to be implemented or scaled up (e.g., regions with the highest number of patients on ART, densely populated urban areas with crowded clinics and limited human resources, etc.)
- The size of the patient population on ART (TX_CURR) and the approximate proportion of those who are clinically stable and eligible to be transitioned to the private sector (for the purposes of this guide, defined as being 18 years or older, on the first-line ART regimen, and virally suppressed)
- The benefits to patients of the DDM(s) through the private sector compared to other differentiated service delivery (DSD) models
- For models where patients are charged a service fee, the approximate proportion of PLHIV with ability and willingness to pay for the specific DDM

Other strategic considerations for successful implementation of DDMs for ART include:

- An enabling environment, including supportive policies and legal/regulatory requirements being in place, stakeholder engagement, good coordination between public and private sector providers, and mechanisms for data management (collecting the data, sharing the data between public and private partners, and merging private sector data with government databases)
- Private sector readiness, such as adequate infrastructure, trained providers, systems for quality assurance/quality improvement, and mechanisms for ensuring availability of ARVs through a robust supply chain and effective coordination among government, public health facilities, and private sector health providers/outlets
- Clear selection criteria for public and private facilities to participate in decentralized distribution (DD) of ART, as well as eligibility criteria for patients who can be transitioned to the private sector

THE PROCESS of introducing and scaling up one or more DDMs for ART is made up of the following steps:



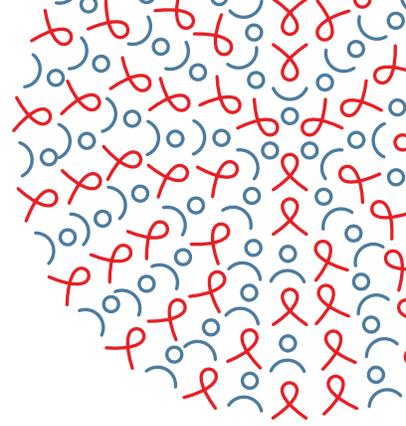
The anticipated impact includes:

- Reduction in the number of patients lost to follow-up and potentially fewer new infections and AIDS-related deaths
- Cost savings for funders (e.g., governments, U.S. President's Emergency Plan for AIDS Relief [PEPFAR]). Some of those savings would arise from reduced expenses of human resources, facility overhead, and ARV commodities (if a proportion of patients transitions to a fully private DDM).
- Cost savings for patients from reduced transportation costs and opportunity costs

As an example, this guide provides estimates of the potential impact of the scale-up of the community pharmacy model in Zimbabwe for 2020–2024 using an estimation model developed by Palladium.

Zimbabwe: Under the DD scale-up scenario, the model predicts that 130,875 ART patients would be under a community pharmacy model (CPM) by the year 2024, representing 10 percent of all people on ART ages 18 and older. The model predicts some improvements in retention in care under the DDM scenario, and fewer new infections and AIDS-related deaths. Based on the model, the Government of Zimbabwe and PEPFAR would save US\$0.4 million and US\$0.8 million, respectively, while cost savings to patients will exceed US\$12 million.

For Zimbabwe, and potentially other countries considering scaling up DDMs, the savings to governments and donors may be increased through further engagement and innovations in the private sector, resulting in more patients choosing to use DDM.



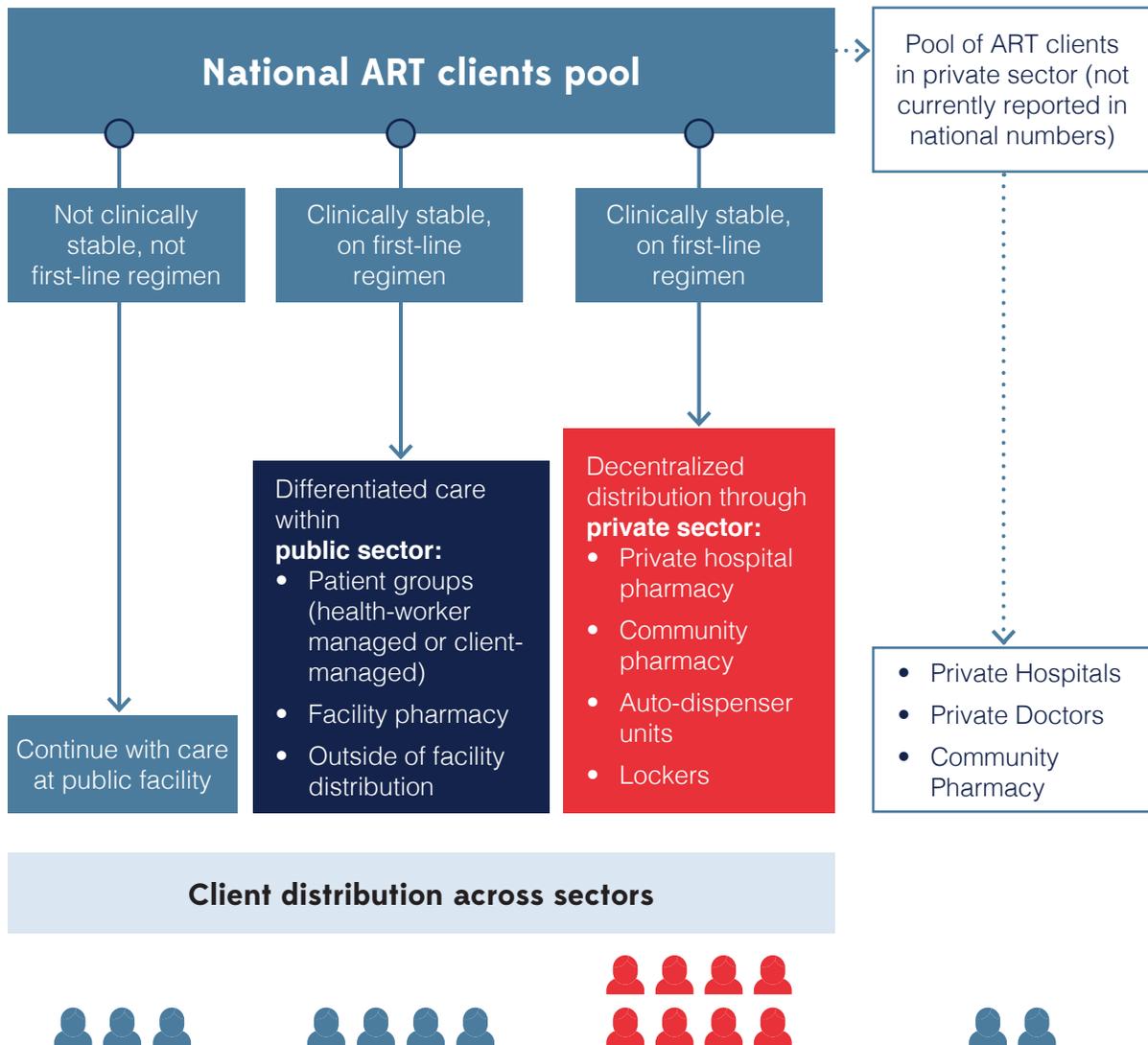
1 Why consider decentralized distribution through the private sector and what are its potential benefits?

By mid-2019, 24.5 million PLHIV worldwide were accessing ART, up from 7.7 million in 2010 (UNAIDS, 2019). While the number of new infections has decreased by 40 percent since the epidemic's peak in 1997, nonetheless approximately 1.7 million people were diagnosed with HIV in 2018. Currently, it is estimated that Africa has 25.8 million PLHIV, of whom 16.5 million are reported to be on ART (UNAIDS, 2019); the majority have been on treatment for longer than one year and are clinically stable. While the test-and-treat approach can improve HIV outcomes and reduce the number of new infections, the approach has resulted in a quickly growing number of patients on ART. This has increased the burden on public health systems, causing long queues at the clinics and prolonged client waiting times. The high volume of patients at the clinics allows less time per patient, leading to reduced quality of client-provider interactions and fueling loss to follow-up (LTFU).

Additionally, the HIV response continues to be heavily funded through external resources, mainly PEPFAR and the Global Fund, although funding levels are decreasing. At the end of 2018, US\$19 billion was available for the HIV response in low- and middle-income countries, almost 1 billion less than in 2017 (UNAIDS, 2019). UNAIDS estimates that US\$26.2 billion will be required for the HIV response in 2020. This deficit may negatively affect the availability of HIV commodities and the necessary human resources for providing HIV care and treatment. Countries must put in place systems to ensure that gains made in controlling the HIV epidemic are not reversed and that HIV treatment services become more efficient and sustainable amidst declining donor funding.

To ensure the sustainability of HIV treatment services, the private sector should play a bigger role by increasing access to ART (Figure 1). DD presents an opportunity to take a “total market approach” to achieving epidemic control.

FIGURE 1. Vision for future distribution of ART through the private sector



While differentiated care within public facilities, including the introduction of multi-month dispensing (MMD) of ARVs, has offered opportunities to simplify care for patients, it does not sufficiently reduce the burden on health care systems and remains unsustainable without donor support. Thus, countries are exploring how the private sector can complement public sector differentiated care efforts and increase service delivery coverage, quality, and convenience (Figure 2). Private sector outlets are a promising additional avenue for the provision of HIV services. These outlets may offer clients increased privacy, greater trust, more convenient locations and scheduling, more consistent stock availability, shorter wait times, and greater client-centered care. They can offer specific client populations, such as men, added value to ensure they are retained in care.

The majority of PLHIV are currently accessing care from public facilities where HIV treatment is largely available and free of charge. However, a number of countries with a growing middle class may be well positioned to take advantage of the private sector, where services are more convenient (e.g., faster service, closer to home) while still affordable. For example, one study in Kenya found that 24 percent of PLHIV on ART who were surveyed were willing to pay a dispensing fee for ARV refill services in private pharmacies (McKinsey, 2017), as were 29 percent of PLHIV on ART who were surveyed as part of the Sustainable Financing Initiative (SFI) baseline assessment conducted by the Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) in Nigeria. Nevertheless, patients' needs and preferences should be taken into consideration when deciding on fully subsidized DD models vs. those involving a service fee.

Various challenges need to be addressed to successfully increase private sector participation in the provision of HIV treatment services and commodities. These include (1) a lack of private sector health workers and support staff trained in the provision of HIV services—most of the HIV training has been focused on public sector providers, and (2) a lack of understanding of how to make private sector ART provision attractive to both clients and providers (e.g., balancing convenience and affordability for clients with some kind of profit for private providers).

Countries' scale-up of HIV service delivery through the private sector could contribute to their journey to self-reliance by easing the burden on the public sector, making services more accessible to clients while maintaining quality, and contributing to greater financial sustainability of HIV care and treatment programs.

1.1 Complementarity between DD through the private sector and MMD in public sector

DD of ART through the private sector adds another option to existing DSD models, such as MMD. Although the frequency of pick-ups (e.g., every three or six months) may impact the business case for private pharmacies and other dispensing points, patient convenience should be the overarching reason for scale-up of the models. An optimal mix of differentiated models should be planned according to patient-defined needs. Regardless of the frequency of the refills, DD of ART through the private sector has benefits, including convenience (e.g., locations near home or workplace, being open late and on weekends, avoiding long queues at busy

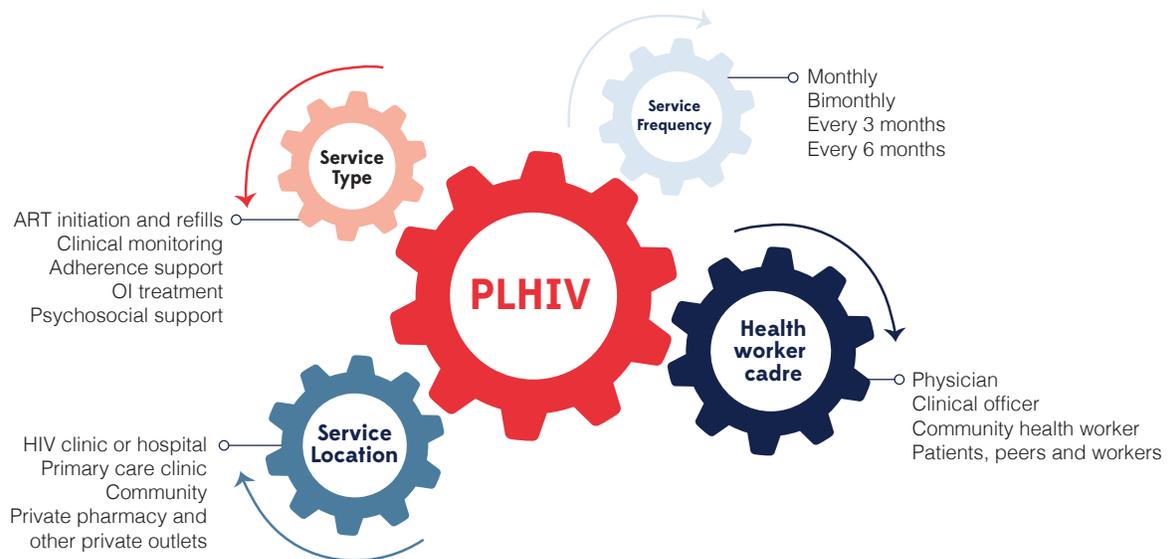


BENEFITS OF DD OF ART THROUGH THE PRIVATE SECTOR

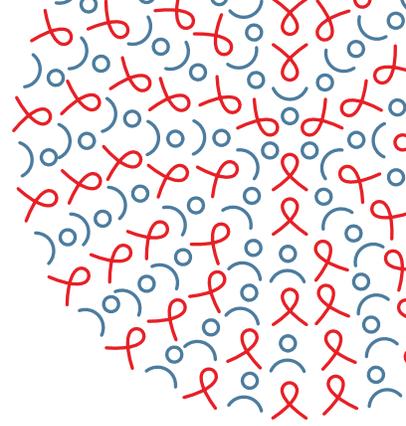
- Provides more choices to accommodate client preferences; offers convenience and confidentiality while maintaining quality
- Reduced case load at the public health facilities, which allows for better client-provider interaction
- Reduction in the average patient waiting time at the public health facilities
- Improved adherence to clinic appointments among PLHIV
- Strengthening of the private sector through CP staff capacity building and quality assurance
- Increased client satisfaction with services
- Potential cost savings for clients because of proximity of services
- Improved access to care for clients who must work during regular clinic hours
- Reduced stigma associated with hospital visits
- Strengthened referral system between public and private sector
- Cost savings to the public sector from reduced client load

public facilities), confidentiality, and perception of higher quality of services. Alternative pick-up points that integrate other medicine and are more discrete/private than traditional ARV refill points can also reduce stigma. Additionally, depending on clinical guidelines/policies in the country and available DD models, some patients who may not be eligible for MMD, such as those who are not stable, could benefit from the convenience offered by DD for refills while continuing to get clinical care at the health facility. The proximity of the services gives the patients the flexibility to choose how often to come for the refills. For instance, a patient who may not want to store a six-month supply of ARVs at home may choose to collect ARVs every two or three months instead of every six months. Therefore, countries planning for a rapid expansion of six-month dispensing should take into consideration patients' preferences and offer more choices.

FIGURE 2. Differentiated approach to HIV care—how DD of ART through the private sector fits¹



¹Adapted from World Health Organization, 2016



2 Country context and policy landscape

2.1 World Health Organization and UNAIDS

Both the World Health Organization (WHO) and UNAIDS support differentiated models of care in general (regardless of health sector), which are defined as client-centered approaches organized around the health needs, preferences, and expectations of PLHIV and communities.

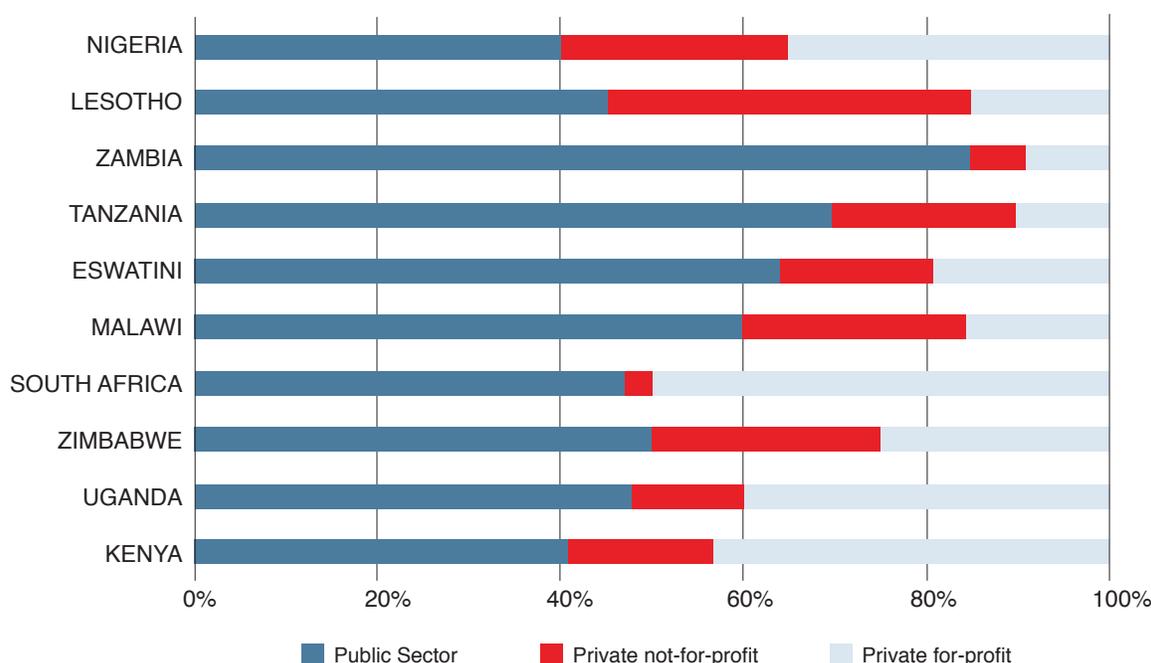
Differentiated models of care emphasize upholding individual dignity and respect, especially for vulnerable populations, and engaging and supporting people and families to play an active role in their own care by informed decision-making. Differentiated care includes multi-month scripting (MMS) and dispensing (MMD) of ARVs for clinically stable clients with refills being received in facilities or the community. There are a number of models, including health care worker-managed, client-managed, facility-based individual, and community individual. DD of ART through the private sector provides an additional opportunity for stable clients to receive ART.

2.2 PEPFAR and the Global Fund

Both the Global Fund and PEPFAR (PEPFAR, 2019a) support the differentiated care approach and MMS/MMD for clinically stable clients. Moreover, they encourage private sector involvement; most of the currently implemented DDMs of ART through the private sector have been supported by either the Global Fund or PEPFAR. Partnership with the private sector and other nongovernmental stakeholders to increase the impact and support sustainability of HIV service delivery is one of PEPFAR's priorities for accelerating progress toward HIV epidemic control. PEPFAR continues to use data and collaborate with partners to look for the best possible solutions to reach more people while maximizing limited financial resources. The PEPFAR strategy includes leveraging private sector market-driven approaches, distribution networks, marketing expertise, innovation, and technology to help achieve epidemic control (PEPFAR, 2019b).

Health services in different PEPFAR-supported countries are delivered through the public sector, private not-for-profit sector, and private for-profit sector, although the respective contributions of different sectors are difficult to accurately establish due to limited data on private for-profit and private not-for-profit sectors. The relative contributions of the different sectors based on available information are shown in Figure 3.

FIGURE 3. Estimates of the relative contribution of public and private health care delivery in 10 sub-Saharan Africa countries (multiple years)²



2.3 Selected countries

South Africa

Approximately half of the national health expenditure in South Africa is dedicated to the private health care sector, an indication that as an industry, private health care has gained both political and economic importance over the past few decades. The private health sector plays a pivotal role in assisting the government in fulfilling its constitutional mandate of providing quality health services to South African citizens (Econex, 2013). The National Department of Health developed differentiated care strategies to reduce the burden on health facilities by “rewarding” adherence of stable chronic patients, including patients on ART (NDOH, 2015). This approach offered faster service and more flexibility for patients by allowing them to choose their preferred medication collection service (client-centered focus) from three options: a spaced, fast-lane appointment system (in a facility), adherence clubs (in a facility or the community, where ART is provided), and DD through a central chronic medication dispensing and distribution (CCMDD) system. There are also other factors that facilitate ARV provision through the private sector. These include pre-packaging of ARVs (and the policies that allow non-pharmacists to dispense products that were packaged by pharmacists in an approved packaging process) and the availability of a wide variety of pick-up points where pre-packaged ARVs are



In South Africa, **7.7 million** people are living with HIV.

Adult HIV prevalence is **20.4%** and ART coverage is **62%** for adults and **63%** for children.

²Based on expenditure on health and the number of facilities where available (NDHS, 2013; Econex, 2013; Swaziland NHP, 2014; Ferrinho, 2011; Uganda’s private Health Sector opportunities for growth, Report, 2017; Malawi Private Health Sector Mapping Report, 2013; Tanzania Private Sector Assessment, 2013; Lesotho NCDS, 2014).

shipped. The design of DD approaches in South Africa was informed by efforts to analyze the root causes of low adherence to ART, reasons for low enrollment, and the accessibility of existing ART sites for the most-affected populations. Other innovative dispensing options are also supported by the South African government and PEPFAR, and the Department of Health works in collaboration with the private sector to improve access.

Nigeria

According to the National AIDS Spending Assessment (NASA), in 2014, 27.2 percent of the financing of HIV interventions in Nigeria was provided by the government and 2.1 percent by the private sector, while the remainder was provided by international development partners. Only 8.3 percent of states fund up to 30 percent of their own HIV response.

The *Nigerian National Guidelines for HIV Prevention Treatment and Care* (2016) adopted WHO recommendations for differentiated care, allowing less frequent clinic visits and MMS/MMD for clinically stable clients with HIV (FMOH, 2016). The guidelines also introduced decentralization, which involves the devolution of some HIV services from tertiary- and secondary-level ART centers to primary health centers. Under this arrangement, primary health centers can initiate ART and provide routine ARV refills. Implementation of decentralized ART services involved shifting some HIV management tasks from physicians to non-physician providers, from nurses to community health extension workers, and subsequently to trained peer educators, expert patients, and community-based caregivers. While devolution of clients with HIV to the private sector is not specifically addressed in national guidelines or policies, the government supports decentralization approaches currently implemented with donor funding (e.g., private community pharmacies).



In Nigeria,
1.9 million people are
living with HIV.

HIV prevalence is **1.4%**
and ART coverage is
55% for adults and
35% for children.

Uganda

The private health sector in Uganda consists of private not-for-profit and private for-profit providers; private for-profit facilities, including private health practitioners, private hospitals, pharmacies, and drug shops; and traditional and complementary medicine practitioners.

The private sector as a whole delivers roughly 45 percent of health services and covers about 50 percent of the reported outputs (Dambisya et al., 2014). The Uganda differentiated care guidelines provide for client-centered models, acknowledging specific barriers identified by clients and empowering them to manage their disease with support of the health system (Uganda Ministry of Health [MOH], 2017). The guidelines also recommend moving away from a “one-size-fits-all” approach and responding to subpopulation needs, hence allowing for innovative methods of service delivery. Uganda has quality standards for private sector engagement in the delivery of HIV services, and the MOH-developed standards for accreditation of private providers include requirements for trained personnel, drug dispensing, storage facilities, laboratory capacity, record and data management, and links to social support in the community. Through collaboration with the public sector, private providers are trained in HIV service delivery and receive mentorship from PEPFAR implementing partners. Private providers are required to distribute ARVs at no cost to HIV patients but can charge a consultation fee and bill for other services.



In Uganda,
1.4 million people are
living with HIV.

Adult HIV prevalence is
5.7% and ART coverage
is **73%** for adults and
66% for children.

Kenya

While Kenya ART guidelines recommend a differentiated approach to care and allow provision of ARVs for three months at a time, there is currently no clearly defined policy for private sector engagement in HIV service delivery. At the same time, a number of private sector facilities receive ARVs from the government and subsequently dispense to PLHIV. The private sector is also engaged in providing services related to family planning and tuberculosis (TB) as part of the public–private sector initiative. According to the *Kenya Health Financing Systems Assessment (KHFS)* (Dutta et al., 2018), the public and private sectors manage and operate comparable levels of Kenya’s health infrastructure, at 41 percent and 43 percent, respectively. Use of private health services is high — approximately 52 percent of the urban and 32 percent of the rural population visit private providers for their health care needs. KHFS also confirmed that the private sector provides many health services that match those offered in the public sector. However, when it comes to HIV, the private sector lacks key commodities, a specialized workforce, and/or incentives, all of which result in HIV services less likely to be available in the private sector. Nevertheless, MOH data show that during 2015, 90,117 patients (7 percent) received HIV testing and counseling services in private sector facilities, and 1,665 children and 10,251 adults received ART, representing 1.5 percent of all patients on ART in Kenya. Because the Kenya private sector is one of the most developed and dynamic in sub-Saharan Africa (Barnes et al., 2010), DD of ART through private sector outlets is a promising possibility.

Kenya has many legal and regulatory components in place to facilitate growth of the private health sector. For example, the government has made universal health coverage one its four key priorities, and there is already an ongoing pilot in four of the 47 counties. However, HIV services are not currently included in the service package because they are well funded by donors.

Zimbabwe

Health care in Zimbabwe is provided by public facilities, nonprofit groups, church organizations, company-operated clinics (such as those of mining companies), and for-profit clinics (Osika et al., 2010). According to the Zimbabwe Service Availability and Readiness Assessment of 2015, only about 101 of 1,848 health facilities were private. However, the 32 private hospitals constitute 15 percent of all hospitals in country. Zimbabwe’s once vibrant health system continues to suffer from the effects of the country’s economic crisis, which left the extensive network of hospitals, clinics, and other health facilities severely incapacitated in terms of personnel, equipment, and drug supplies. In the face of mounting challenges in health care delivery, the government sees the private sector as an important partner in increasing access to health care for the country’s population. In 2015, Zimbabwe launched the *Strategic Framework for Public–Private Partnerships for TB and HIV Prevention, Treatment, Care, and Support, 2014–2016*, which outlines how the private sector can be engaged in the HIV response. The document is intended to serve as a guide to actors from the public and private sectors in formulating policies, strategies, and agreements



In Kenya,
1.6 million people are
living with HIV.

Adult HIV prevalence is
4.7% and ART coverage
is **69%** for adults and
61% for children.



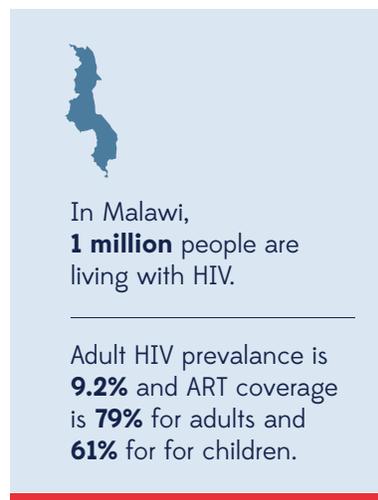
In Zimbabwe,
1.3 million people are
living with HIV.

Adult HIV prevalence is
12.7% and ART coverage
is **83%** for men, and
93% for women
76% for children.

for collaborating to achieve universal access. It also provides a broad monitoring and evaluation framework to assess progress toward that goal (Strategic framework, Zimbabwe, 2014). Zimbabwe is one of the first countries to introduce a national AIDS levy set at a 3 percent income tax for individuals and a 3 percent tax on the profit of employers and trusts. The levy has enabled the government to successfully raise over US\$30 million per year since 2012, a visible sign of the commitment of the government and people of Zimbabwe to fund their own HIV response (Bhat et al., 2016). Zimbabwe practices a differentiated care approach and allows for three-month refills of ARVs to clinically stable patients (Zimbabwe Ministry of Health and Child Care, 2017) but offers no guidance specific to private sector distribution of ARVs.

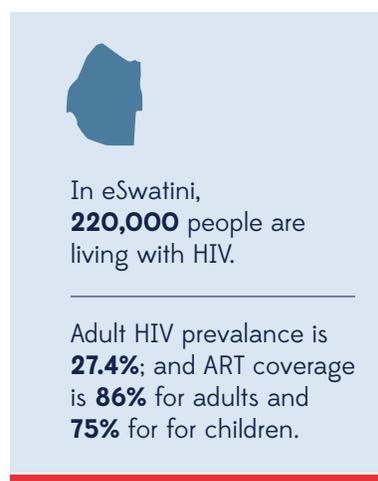
Malawi

While the public sector is the largest provider of health services in Malawi, approximately 40 percent of services are provided by non-state actors, including the Christian Health Association of Malawi (CHAM), commercial providers, and other nonprofit actors (SHOPS Project, 2012). Private for-profit facilities constitute about one-quarter of all health facilities, but their contribution to the health sector in Malawi is still small, and there has been minimal engagement of the private sector in the delivery of HIV services. As of 2010, 59 private facilities were providing ART, treating 3.9 percent of the total number of patients on ART in Malawi (Montagu et al., 2011). The Malawi Business Coalition against HIV/AIDS bears primary responsibility for coordinating the scale-up of the private sector ART program, including facilitating training with the MOH and supervising accredited private sector clinics. Malawi's 2016 *Guidelines on the Clinical Management of HIV* (3rd edition) include differentiated ART delivery for adults and children. However, there are no specific guidelines or policies in place for decentralized ART provision through the private sector.



eSwatini

According to 2013 service mapping data, there are 287 facilities across four regions of eSwatini. Six categories of health facility ownership were identified: government, mission, industry, privately owned by nurses, privately owned by doctors, and those owned by nongovernmental organizations. As the majority owner of health facilities in the country, the government is the main provider of health services (Magagula, 2017). Although access to health care is adequate, limited health care personnel and resources make it virtually impossible to efficiently administer quality services. eSwatini policies support decentralization of HIV treatment services to the community level. The 2016 *National Policy Guidelines For Community-Centred Models of ART Service Delivery (CommART) in Swaziland* recognize the need for differentiation throughout the treatment pathway and specifically provide guidance for stable client management (SNAP, 2016). They are accompanied by a set of standard operating procedures. The guidelines support less frequent clinic visits for stable clients (every six months), as well as less frequent prescription pick-up (every three months). However, they do not address decentralization through the private sector.



Tanzania

The public and private health sectors are present at all levels of the health system in Tanzania. In total, there are an estimated 6,342 health facilities across the mainland. The public sector currently operates close to 70 percent of them. The vast majority of government facilities are lower-level health centers and dispensaries. At the higher levels of the health system, the private health sector is more prevalent, with the for-profit, nonprofit, and parastatal organizations operating 60 percent of all hospitals. The public–private mix varies from region to region throughout mainland Tanzania (SHOPS Project, 2013). In 2017, the Tanzanian Ministry of Health, Community Development, Gender, Elderly, and Children outlined differentiated care approaches in the document titled, *HIV Service Delivery Models: Mapping HIV Service Delivery Strategies in Tanzania*. The recommendations for clinically stable clients include less frequent clinic visits (once or twice a year) and medication refills once every three months (or every six months based on stock availability). Out-of-facility individual models are also encouraged and include fixed community distribution points, mobile outreach ART delivery, home delivery, and adherence clubs. Currently, there are no policies in place for the provision of ART through the private sector. The SHOPS Plus project (Abt Associates) in Njombe revealed that there is a need for provision of ART away from the overcrowded facilities to reduce patient treatment access costs. However, the idea of introducing a fee for ART distribution services was not acceptable to the public sector stakeholders and to many PLHIV. The main reason was the fear of interruption of patient treatment plans in case of inability to pay. The other key finding of the SHOPS Plus project was that many patients prefer family-centered care and will not seek out decentralized ARV pick-up if only certain members of a family, but not all, are eligible. The USAID-funded SHOPS demonstration also supported the increase of private sector health insurance coverage among PLHIV as a means of increasing access to HIV services in the private health sector in a sustainable way.

Zambia

According to the Zambia National Human Resources for Health Strategic Plan 2011–2015, the main providers of health care services in the formal health sector of Zambia include public health facilities under the MOH, the Ministry of Defense, and the Ministry of Home Affairs. Other providers in the formal system include private for-profit clinics, drug stores, diagnostic centers, and hospitals. In 2018, the Zambian MOH updated its *Consolidated Guidelines for Treatment and Prevention of HIV Infection* to include guidance for differentiated service delivery for clinically stable clients and for people living with advanced HIV disease. The guidelines state that “the MOH supports the promotion and provision of various differentiated service delivery models in order to lessen the burden of care for both patients and providers and to allow the health system to refocus resources on those patients in most need.” The guidelines allow for MMS/MMD and decentralization to the community level, but there are no policies outlining private sector involvement. There are a few employer or private health insurance schemes in Zambia, but the majority of the population is required to pay for health care out of pocket. The government recently introduced a social health insurance scheme to replace the out-of-pocket system; subscriptions started in October 2019 and benefits will start in February 2020, and it is hoped that this will close the financing gap.



In Tanzania,
1.6 million people are
living with HIV.

Adult HIV prevalence is
4.6%; and ART coverage
is **52%** for men, **78%** for
women and **46%** for
for children.



In Zambia,
1.2 million people are
living with HIV.

Adult HIV prevalence is
11.3%; and ART coverage
is **78%** for adults and
79% for for children.

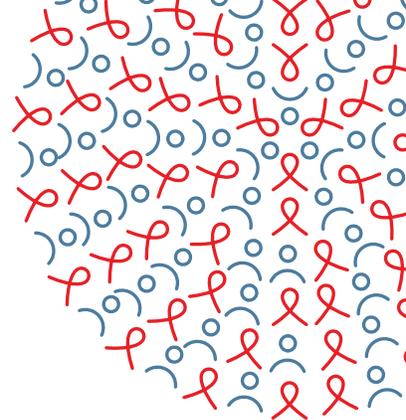
Lesotho

According to the *National Health Strategic Plan, 2017–2022*, there are 372 health facilities in Lesotho. Forty-two percent of the health centers and 58 percent of the hospitals are owned by the MOH, while 38 percent of the health centers and the same proportion of the hospitals are owned by the Christian Health Association. The remaining facilities are privately owned. About 90 percent of the private for-profit health facilities are situated in the four largest districts (Maseru, Berea, Mafeteng, and Leribe). Lesotho's *National Guidelines on the Use of Antiretroviral Therapy for HIV Prevention and Treatment, 5th edition* (Lesotho MOH, 2016) endorsed differentiated care and recommended that stable patients be given ARV refills lasting three to six months and encouraged the establishment of community adherence groups for stable patients in order to decongest health facilities. The guidelines also allowed appropriately trained lower-level cadres of health workers to initiate and re-prescribe ART and stated that ART initiation and refills should be decentralized as close to the community as possible, including at health outreaches and health posts. No guidance or policies outlining the role of the private sector in HIV service delivery were included.



In Lesotho,
340,000 people are
living with HIV.

Adult HIV prevalence
is **23.6%**; and ART
coverage is **60%** for
adults, and **70%** for
for children.



3 Decentralized distribution models for ART through the private sector

A number of different private sector models for DD of ART are currently being implemented (for a summary, see Tables 1 and 2). In some countries, there is more than one model. At the heart of all DDMs is the differentiated service delivery approach, which simplifies and adapts HIV services to better serve the needs of PLHIV and reduce the burden on health systems (WHO, 2016). Figure 4 shows how DD fits into the differentiated care framework. Patients receiving ART through the DD models would need to be screened for TB and also receive TB preventive therapy through the model.

FIGURE 4. The building blocks of DD³

| | | |
|--------------|--|------------------------------------|
| WHEN | Every 3–6 months | Every 12 months |
| WHERE | Community pharmacy or automated dispenser closer to patient’s home or work | Facility where patient is enrolled |
| WHO | Pharmacist, pharmacy technician | Nurse or doctor |
| WHAT | ART, adherence counseling, TB screening, TB preventive therapy | Clinical consultation, viral load |

³Adapted from www.differentiatedcare.org

The models below offer additional opportunities for clinically stable patients.

3.1 Community pharmacy (CP)

This model is based on a partnership between a public health facility (hub) and a standalone private retail pharmacy (referred to in this guide as a community pharmacy or CP) within its catchment area. One hub facility can partner with more than one CP. Clinically stable clients from the facility can choose to receive their ARV refills through the CP while still coming back to the public facility for routine review every 6 to 12 months. The client consents to join the program and is asked to choose a CP from the list of participating pharmacies; however, the client is free to change the CP or return to the facility any time for any reason (e.g., inability to pay or dissatisfaction with the services at the CP). Figure 5 lists the roles and responsibilities of the public facility, CP, and patients.

CPs are selected based on the following criteria:

- Willingness to participate in the program
- Having a valid trading license
- Having a registered pharmacist who is trained (or willing to be trained) in HIV-related aspects of service provision (e.g., country ART guidelines, essential knowledge of ARVs, adherence counseling)
- Meeting necessary infrastructure requirements

The pharmacist must agree to perform all associated drug dispensing, patient counseling, and documentation tasks. The pharmacy must have adequate space and facilities for privacy to allow confidential counseling. The community pharmacy signs a memorandum of understanding (MOU) with the implementing partner and/or hub public facility that clearly states the roles and responsibilities of each party. ART commodities are provided to the pharmacy through coordination with the facility or national/regional supply chain team.

FIGURE 5. Roles and responsibilities in decentralized distribution of ART through community pharmacies

| PUBLIC FACILITY | COMMUNITY PHARMACY | PATIENT |
|---|---|--|
| <ul style="list-style-type: none"> • Identifies devolved eligible patients • Links devolved patients to community pharmacy • Transfers required patient records, prescriptions, and ARVs to community pharmacy • Reviews patients' health status every 6 months or more frequently if indicated | <ul style="list-style-type: none"> • Dispenses ARV drugs to devolved patients • Provides pharmaceutical care (answering questions, counseling about ARVs) • Schedules refill appointments, makes reminder calls • Tracks defaulters • Refers patients with medical needs back to public facility • Maintains records, shares records/information with health facilities | <ul style="list-style-type: none"> • Chooses the community pharmacy where will receive ARVs • Goes to community pharmacy on schedule for refills • Pays for pharmaceutical services (e.g., dispensing fee) • Receives free ARVs • Returns to public facility every 6 months for check-up (more frequently if indicated) • May switch to a different community pharmacy for any reason or return to public sector |

There are at least two variations of the CP model — one where clients receive free ARVs but pay a dispensing fee, and one with no fees charged to the patient. DD of ART through CPs is currently being implemented in Nigeria, Zambia, South Africa, and Uganda, and is at the planning stage in Kenya.

Community pharmacy model that includes a dispensing fee

The key characteristics of this model are:

- Participating CPs receive no direct funding but are presented with a business case to support HIV services.
- The implementing partner staff provide orientation and training to participating CPs as well as continuous technical support.
- Clients pay a dispensing fee, but ARVs remain free. For example, in Nigeria, it is a set fee of ₦1,000 (US\$2.74) per visit irrespective of the quantity of ARVs dispensed, and the PEPFAR/implementing partner provides no funds to the CP. This amount was negotiated with the professional association for CPs and may vary based on the socioeconomic variables in each community.
- Clients are allowed to switch among pharmacies, which could promote competition and lead to better quality services.
- CPs send collected data back to the public facility. In some cases, client data are collected and sent to the facility by the implementing partner.

A baseline assessment in Nigeria found that 92 percent of CPs were willing to provide the services, more than 30 percent of clients were willing to access services at a CP, and up to 20 percent of clients were willing to pay the dispensing fee for ART refills. In addition, public sector health workers were, for the most part, comfortable with devolving clients to community pharmacies for their drug refills.

“I like the new initiative because it is convenient, I get to discuss with the pharmacist, and I don’t have to spend my whole day anymore at the hospital. I have been attending a General Hospital since 2013 and I never spent less than four hours, unlike this new initiative. Now I spend twenty to thirty minutes with the pharmacist.”

Community pharmacy model with no fees

This model is similar to the one above, with the main difference being that patients do not pay a dispensing fee. The donor (through implementing partner) or government pays the CP for the services rendered to the patients.

An example of this model is in Uganda. Funded by PEPFAR and implemented by the Infectious Diseases Institute (IDI), it links four high-volume health facilities (more than 5,500 clients total) to six CPs. Each patient’s medicine is sourced from his or her respective primary facility and delivered by the IDI logistics teams. A program-supported nurse is placed in each pharmacy to assist with ART dispensing (a two-month supply is provided at each client visit), provide health education, screen for danger signs, track follow-up visits, and conduct stock and record management. The CPs are typically located along easy-to-access routes and are spacious enough to accommodate patient traffic. They are open daily until 8 p.m. and over the weekend and public holidays for ART dispensing. Regular supervision is provided by the MOH, Kampala Capital City Authority, and IDI.

An analysis of this ARV refill model in Uganda found that over a period of 21 months, a total of 8,820 PLHIV (2,558 of whom were male) enrolled. More than 99 percent of all patients enrolled were able to refill their medicines successfully, and 12-month retention in care was 98 percent. More than 99 percent of clients on this model are still virally suppressed.

“I can’t believe it,” he says. “I can call the nurse and schedule an appointment. I can jog here and back. I can come after work...My boss even thinks I’m now healed because I no longer ask to go to the clinic.”

Other examples are models implemented by the Institute of Human Virology in Nigeria (IHVN) and the Center for Infectious Disease Research in Zambia (CIDRZ).

Under these models, the community pharmacy is paid a flat monthly stipend irrespective of the number of patients who come for refills. In the IHVN program, the CP is paid about US\$245 per month (approximately US\$138 for the supervising chief pharmacist, US\$83 for the assistant pharmacist, and the rest for Internet/communication and transportation). In Zambia, the CP is engaged on the principle of corporate social responsibility; however, the pharmacist receives a stipend of approximately US\$75 per month, which is equivalent to the amount paid to a lay volunteer at the facility level. Sustainability of the monthly payments to the CP is an issue. For instance, in Nigeria, the IHVN model had to be stopped in one region when there was a change of implementing partner from one supported by CDC to one supported by USAID. The USAID partner used a model that charged patients a dispensing fee and had to re-enroll CPs who were willing to participate in this model. The patients had to return to the public health facility for refills during the transition and had to be sensitized about the new model that required them to pay for the dispensing services.

Analysis of the pilot implementation of the IHVN model in Nigeria found that almost 10 percent of the stable patients on ART were successfully devolved from eight health facilities to 10 CPs. Prescription refills were at 100 percent, and almost all the participants (99.3 percent) were retained in care after they were devolved. Only one participant was lost to follow-up (Avong et al., 2018).

In South Africa, patients from high-volume sites are contracted to a patient-selected private general practitioner whom they visit for routine checkups and annual blood work. The patients then receive their ART refill at a CP allowing for quarterly collection. The clients can also choose the community pharmacy as a pick-up point under the CCMDD program.

In a number of the reviewed countries, community pharmacies currently offer home delivery of prescription medicines through use of motorbike riders. There is the possibility that the home delivery of ARVs could be included in the services offered under the CP model.

3.2 Automated dispensing models

Several dispensing models have been developed by Right to Care and implemented in South Africa and Zambia. These include pharmacy dispensing units, prescription collection units/lockers, and central dispensing units. These models offer an alternative, innovative approach to DD of ART that can ease pressure on public sector facilities, particularly in highly populated and rapidly growing urban areas.

Pharmacy dispensing unit (PDU)

A PDU (Figure 6) uses electronic and robotic cloud-based technology to dispense prescribed medication to patients. It has an interactive touchscreen and a user-friendly interface that allows for two-way Skype-like audio-visual interaction with the pharmacist. Therefore, when needed, patients can be counseled before the medication is dispensed on how to take their medication and what side effects they may encounter. Patients also receive SMS notifications and reminders to ensure timely collection and adherence. It is currently used in South Africa, where 18 PDU sites are operational. Figure 7 shows the key features of a PDU.

“The PDUs are game changers,” says Shabir Banoo. “The excitement on the faces of patients when they get their medicines in minutes – rather than hours – is truly something to behold.”

The PDU costs about US\$200,000 to set up. It is the most expensive of the technology-based innovations and requires both reliable Internet and electricity. The PDU also dispenses medication for other chronic health conditions, which de-links the PDUs from HIV and prevents stigmatization.

FIGURE 6. PDU, Right ePharmacy, Right to Care



CREDIT: ePharmacy, Right to Care, SA.

FIGURE 7. PDU features

| AN AUTOMATED TELLER MACHINE (ATM)-TYPE INTERFACE | BACK-END TECHNOLOGY, CONSISTING OF A COMPACT MEDICINE STORAGE UNIT | ELECTRONIC CLOUD DISPENSING RECORD AND TELEPHARMACY REPORTING CAPABILITIES |
|--|--|--|
| <ul style="list-style-type: none"> • Interactive visual and verbal communication • Touch screen, handset, and earphone jack • PIN-authenticated access • Medicine collection bin • Dispensing receipt printer | <ul style="list-style-type: none"> • Cloud-based dispensing software • Customized shelving and storage • Automated stock rotation • Real-time stock monitoring and reporting • Electronic temperature control • Barcode scanning product ID • High-speed robotic arm • Integrated conveyer system • Automated printer and labeler | <ul style="list-style-type: none"> • Patient demographic data, ID, and contact details • Gender distribution and age bands • Automated/on-hand stock monitoring and ordering • Drug class (ATC classes) and pharmaceutical supplier (overall and on patient level) • High-volume/popular collection times and days • Eleven official language capabilities |

Prescription collection unit (lockers)

Prescription collection units (PCUs) use an electronic locker system to improve patient access to pre-dispensed medication parcels (Figure 8). The lockers are temperature controlled, set in a secure location, and, as with PDUs, use cloud-based technology that enables remote dispensing and live patient counseling. The lockers use smartphone technology to inform clients about their next collection date and send out reminders. When it is time to pick up their medicine, clients receive a one-time code, which is used to open the locker and access the medicine. Once the client gets to the locker location and enters the necessary details, they are informed which locker has their medication. As soon as the locker is emptied, the central system is notified so that medicines for another client can be dispatched.

The cost of setting up a locker unit is about US\$8,000 per site. Lockers have been rolled out to 67 sites in South Africa and Zambia so far. The smart locker allows patients to collect chronic medication, including ART, in as little as 36 seconds, without entering the clinic or receiving assistance from a health care worker. Use of the lockers has drastically reduced the waiting times to collect lifesaving medication, while reducing foot traffic in overcrowded clinics and making ART more accessible to the millions who need it.

Central dispensing unit (CDU)

The CDU model is currently implemented in Zambia and South Africa. In this model, dispensing activities are centralized and generally automated, but delivery/pick-up of medication by clients occurs at alternative pick-up points, which may include lockers, informal retail outlets, churches, supermarkets, health facilities, or CPs. Once the patient is enrolled, they choose a convenient pick-up point where the medicine will be sent. The public health facility provides a one-month supply of medicines and subsequently sends a script for the

FIGURE 8. Prescription collection unit (lockers)



CREDIT: ePharmacy, Right to Care, SA
<https://rightpharmacy.co.za/prescription-collection-lockers/>

next five-month supply to the CDU. The CDU unit dispenses a prescribed supply of medicines, dispatches the patient's medicine package to the selected pick-up point, and notifies the patient through an SMS. MMD is one of the threats to this model, because the vendors charge per pack and a reduction in the number of packs will mean a reduction in profit for the vendor. With the introduction of the packs that provide a three-month or six-month supply of ARVs, changes may be considered to the pay structure (e.g., charging greater fees for multi-month packs). The CDU is responsible for reporting to the facility the number of packs dispatched, the number collected by the patients, and the number of uncollected packs. The CDU will promptly inform the facilities about uncollected packs to facilitate timely defaulter tracing and arrange for the return of uncollected packs 14 days from the expected date of pick-up.

The CDU performs the following prescription filling functions:

- Bulk pre-packing and stock reference allocation (automated)
- Electronic capturing of patient demographics and prescription
- Automated scheduling of next refill and delivery
- Picking and dispensing of items (manual or automated —volume dependent)
- Labeling, packing, and distribution of medicine
- Telephonic support to ensure adherence
- Clinical quality assurance and integration with other supported programs

The current cost of providing a refill through the CDU in Zambia is about US\$15 per patient; however, this can be reduced to as low as US\$2 per patient per refill with an increased number of patients enrolled in the system. The Zambia CDU has had a challenge with delayed enrollment of patients into the program. In South Africa, the CDU is serving over 2.5 million clients under the chronic medicines program. In 2017, the use of the central chronic medicines dispensing and delivery model resulted in a 43 percent reduction in patient costs, a 48 percent decrease in National Department of Health costs to serve patients, a 12 percent to 16 percent increase in PHC facility capacity, and a 22 percent increase in adherence (NDoH Actuals, 2017).

3.3 Private hospital models

Private hospital model with free ARVs

All HIV care-and-treatment services are provided under this model. PLHIV who are willing to pay out of pocket or through third-party payers (such as prepaid health insurance) are linked to a network of selected private facilities to access care and treatment services at an affordable rate. The private hospitals provide care to all categories of patients, including both clinically stable and unstable patients. In several countries where this model is implemented, private hospitals have signed an MOU with the government that allows them to receive free government ARVs or donor ARVs. The patients are charged for consultation and other services (e.g., lab tests, sample transportation, etc.) but receive free ARVs. The consultation fees vary depending on country and location of the private hospitals, ranging from about US\$2 to US\$20. Some of the private sector hospitals receive support from donors and provide HIV services free of charge just like public facilities.

Providers undergo training to ensure that they have the technical expertise needed to offer the standard package of care for PLHIV as per the national treatment guidelines and protocols. The hospitals provide regular reports to the government using existing reporting tools with restocking based on reporting. The hospitals involved in HIV service delivery are often part of a franchise, association, or chain. However, the investment in providing full HIV services in the private sector has been low because of the low demand for fee-based HIV services.

Fully private hospital model

These are hospitals that charge for consultation and other services as well as for ARVs and cater mostly to patients who have private health insurance or have ability to pay (ATP). The number of HIV patients enrolled in these hospitals is thought to be very low. However, because these hospitals do not normally provide reports to the public sector about the number of ART patients, it is hard to know the actual number of people accessing the services. For now, the use of this model is not expected to grow significantly because of the higher cost of ARVs and lack of a pooled procurement mechanism to enable the facilities to get favorable prices. The patients who use this category of hospitals normally prefer brand name ARVs (e.g., Atripla) to the generic fixed-dose combinations readily available in the public sector.

Private wings of public hospitals

There are a few public facilities in Nigeria under the SFI project that have started providing expedited care to patients on a fee-for-service basis in a private wing. The services are mainly paid for out of pocket. The revenue raised from the private wing is used to support the provision of free HIV services to other clients and to supplement staff salaries. There were about 1,502 patients enrolled in the Nigerian states of Akwa Ibom, Cross River, Rivers, and Lagos, paying between US\$5 and US\$30 per visit. This model is not common because most countries in Africa have policies that prohibit charging for HIV services in public facilities, but it is available for general and specialist services for other conditions.

The characteristics of the different models are summarized in Table 1. These models have many successes as well as challenges. Table 2 lists DD models by country.

TABLE 1. Summary of decentralized distribution models (by model)

| MODEL | GEOGRAPHIC LOCATION/SIZE | FUNDER/ IMPLEMENTING PARTNER(S) | FEATURES | SUCCESSES | CHALLENGES |
|---|--|---|--|---|--|
| Community pharmacy (charges a dispensing fee) | <p>Nigeria Implemented in 320 CPs (Lagos, Abuja Rivers, Cross River, and Akwa Ibom)</p> | <ul style="list-style-type: none"> Funder: PEPFAR/ USAID Implementing partners: FHI 360 (prime) and Howard University-SFI (sub) | <ul style="list-style-type: none"> Client pays dispensing fee of ~US\$3.00 ARVs provided free PEPFAR implementing partners provide orientation and training to participating community pharmacies | <ul style="list-style-type: none"> More than 15,266 patients devolved to community pharmacies since 2017 98% retention and 83% viral suppression rate Overall strengthening of the private sector New source of income for private sector facilities Decongestion of public sector facilities leading to better quality care Increased collaboration between public facilities and private pharmacies Improved data management at the facility level and introduction of technology in data management Stakeholder engagement from the beginning of the process | <ul style="list-style-type: none"> Patients willing to pay a fee for services but not for ARVs Patient perception of fees being too high Some patients returned to public facilities because of inability to pay Out-of-pocket payment increases patient risk for defaulting Low health insurance coverage for HIV services Attrition of trained health workers Logistical challenges in ensuring availability of commodities Increased documentation burden for the pharmacies Reluctance to transfer eligible patients from public to private sector facilities |

TABLE 1. Summary of decentralized distribution models (by model)

| MODEL | GEOGRAPHIC LOCATION/SIZE | FUNDER/ IMPLEMENTING PARTNER(S) | FEATURES | SUCCESSES | CHALLENGES |
|-----------------------------|---|--|--|---|---|
| Community pharmacy (no fee) | <p>Nigeria</p> <p>68 CPs linked to 35 public hospitals in four states (Abuja, Nasarawa, Katsina, and Kano)</p> | <ul style="list-style-type: none"> Funder: PEPFAR/CDC Implementing partner: IHVN | <ul style="list-style-type: none"> No client fees Cost to program ~US\$3,000 per pharmacy per year CPs receive free government ARVs and stipend to cover services | <ul style="list-style-type: none"> More than 5,500 clients devolved to community pharmacies for refills 98% retention and 100% viral suppression Resulted in gradual decongestion of health facilities Reduction in stigma Flexible refill times Reduced cost to patients since can refill closer to home | <ul style="list-style-type: none"> Fixed fee (~US\$245 per pharmacy per month irrespective of number of patients served) provides no incentive to community pharmacy to try to grow the number of patients Sustainability is problematic because it is based on availability of donor funding |

TABLE 1. Summary of decentralized distribution models (by model)

| MODEL | GEOGRAPHIC LOCATION/SIZE | FUNDER/ IMPLEMENTING PARTNER(S) | FEATURES | SUCCESSES | CHALLENGES |
|-----------------------------|---|---|--|---|--|
| Community pharmacy (no fee) | <p>Uganda</p> <ul style="list-style-type: none"> Four high-volume public facilities are linked to 6 CPs | <ul style="list-style-type: none"> Funder: PEPFAR/CDC Implementing partner: IDI | <ul style="list-style-type: none"> No client fees Each patient's medicine is sourced from his or her primary facility and delivered by IDI logistics teams IDI-supported nurse is placed in each pharmacy to assist with ART dispensing and other tasks CPs are open daily until late, including weekends and holidays | <ul style="list-style-type: none"> About 9,000 clients enrolled over a period of 21 months Retention rate of 98% More than 99% of clients in the model are still virally suppressed Waiting time at public clinics was reduced from >3 to <1.5 hours Incentivizes treatment adherence and health-seeking behaviors for clients | <ul style="list-style-type: none"> Patients wanted refills of longer than 2 months Patients want to send relatives or other people to collect ARVs on their behalf Want pharmacy working hours extended beyond 8 p.m. even though dispensing nurses already work longer hours HIV patients in other programs also want to be transferred to IDI sites so they can access this service The program depends on the availability of the program's dispensing nurse at the pharmacy |

TABLE 1. Summary of decentralized distribution models (by model)

| MODEL | GEOGRAPHIC LOCATION/SIZE | FUNDER/ IMPLEMENTING PARTNER(S) | FEATURES | SUCCESSSES | CHALLENGES |
|-----------------------------|--------------------------|--|--|---|---|
| Community pharmacy (no fee) | Zambia | <ul style="list-style-type: none"> Funder: PEPFAR/ CDC Implementing partner: CIDRZ | <ul style="list-style-type: none"> Started in October 2018 Flexible work hours No client fees (CPs are engaged on principle of corporate social responsibility) Pharmacists are paid a monthly stipend of ~ US\$75.00 Long operating hours, including weekends (open until 10:00 PM) Data are collected by CIDRZ staff on a weekly/monthly basis | <ul style="list-style-type: none"> 237 clients by February 2019 (the program is new, so data on retention, viral suppression, etc. are not yet available) Patients save time and money Flexible pick-up times Patients do not have to pay for the service Reduced stigma Pharmacists are kept up to date about HIV services Increased clientele for the pharmacy Reduced burden on public health facilities | <ul style="list-style-type: none"> Public facilities hesitant to transition patients to private sector Need for strong referral system between public facilities and private facilities/community pharmacies Prepayment schemes/health insurance is critical for sustainability Need for continuous supervision |

TABLE 1. Summary of decentralized distribution models (by model)

| MODEL | GEOGRAPHIC LOCATION/SIZE | FUNDER/IMPLEMENTING PARTNER(S) | FEATURES | SUCCESSES | CHALLENGES |
|-----------------------------|--------------------------|---|--|--|--|
| Community pharmacy (no fee) | South Africa | <ul style="list-style-type: none"> • Funder: PEPFAR/USAID/CDC and Government of SA • Implementing partner: Right to Care e-pharmacy | <ul style="list-style-type: none"> • Works like an ATM and has an ATM-type interface, including: <ul style="list-style-type: none"> » Touch screen, handset, and earphone jack » PIN-authenticated access » Interactive visual and verbal communication » Medicine collection bin » Dispensing receipt printer • Patients receive SMS notifications and reminders to ensure timely refill collection and adherence • The patient does not pay for the service • High-volume and popular collection times and days • 11 official languages | <ul style="list-style-type: none"> • 18 PDUs have been involved in more than 160,000 dispensing episodes • Flexible ARV pick time and easy consultation • 96% collection compliance since inception • 78% of dispensed items have been first-line ART • More than 260,000 items dispensed • Maintained an average of 98% collection compliance in the past 3 months • Units also contain other chronic medications, which prevents HIV stigmatization | <ul style="list-style-type: none"> • Need for stable electricity supply and high-speed Internet required • High start-up capital required • Need for robust last mile logistics |

TABLE 1. Summary of decentralized distribution models (by model)

| MODEL | GEOGRAPHIC LOCATION/SIZE | FUNDER/ IMPLEMENTING PARTNER(S) | FEATURES | SUCCESSES | CHALLENGES |
|-------------------------------------|--------------------------------|---|--|--|--|
| Prescription collection units (PCU) | South Africa and Zambia | <ul style="list-style-type: none"> • Funder: PEPFAR/ USAID • Implementing partner: Right to Care e-pharmacy | <ul style="list-style-type: none"> • Air-conditioned • Automated; has system to send out reminders to patients and able to track when client picks up medicine • Very fast access to medicines, patient can get refill in under a minute • Unmanned (so frees up HRH) and installed in secure locations • Uses smart phone technology • Affordable and easy to set-up • Patient does not pay and can pick up medicine at any time | <ul style="list-style-type: none"> • Reduced stigma • Pharmacists keep abreast of knowledge about current HIV services • Increased clientele for the pharmacy • Reduced burden on public health facilities | <ul style="list-style-type: none"> • Needs very good last mile logistics • Temperature control requires a stable source of electricity |

TABLE 1. Summary of decentralized distribution models (by model)

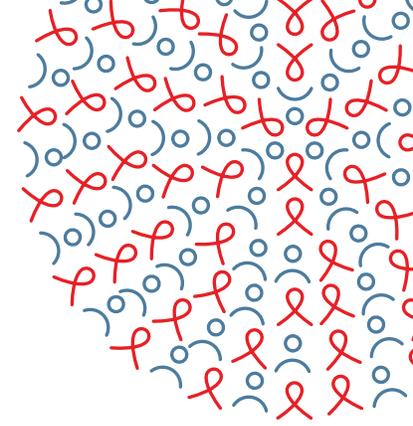
| MODEL | GEOGRAPHIC LOCATION/SIZE | FUNDER/ IMPLEMENTING PARTNER(S) | FEATURES | SUCCESSSES | CHALLENGES |
|-------------------------|--------------------------------|---|---|---|---|
| Central dispensing unit | South Africa and Zambia | <ul style="list-style-type: none"> Funder: PEPFAR/ USAID Implementing partner: Right to Care e-pharmacy (USAID) | <ul style="list-style-type: none"> Automated systems, therefore reduced need for HRH Flexible pick-up points, including CPs, supermarkets, churches, lockers, retailers Patient chooses pick-up point Monthly (or multi-month) medicine packs are sent to the selected pick-up point Patient does not have to pay for service Sends SMS reminders to patients | <ul style="list-style-type: none"> Reduced stigma because dispenses other chronic diseases medicines Improved experience for patients (reduced waiting time, reduced travel distance) Easy to monitor from a central point | <ul style="list-style-type: none"> Public facilities hesitant to refer patients to private sector (leads to slow enrollment in DD) High costs because of the limited number of patients Missed appointments increase costs Missed appointments distort monthly statistics Reverse logistics when patients do not pick up the drugs |

TABLE 1. Summary of decentralized distribution models (by model)

| MODEL | GEOGRAPHIC LOCATION/SIZE | FUNDER/ IMPLEMENTING PARTNER(S) | FEATURES | SUCCESSES | CHALLENGES |
|---------------------------------------|--|--|--|--|---|
| Private hospital model with free ARVs | Uganda, Nigeria, Kenya, Tanzania, Zambia, Eswatini, Lesotho | <ul style="list-style-type: none"> • Funder: PEPFAR/ USAID/CDC and national governments • Implementing partners: various | <ul style="list-style-type: none"> • Provide comprehensive HIV services • Must be licensed with required number of trained staff • Receive free ARV drugs from government • PEPFAR implementing partner provides technical assistance • Provide monthly reports to the government • Clients pay for services but not for ARV drugs | <ul style="list-style-type: none"> • Reduces stigma • Convenience • Reduced waiting time • Patients contribute toward their care | <ul style="list-style-type: none"> • Need for continuous monitoring • Increase data management demands • In some cases, no proper documentation and reporting by the private sector • Demand on the government supply chain for ARVs • Financial sustainability is problematic since model relies on receiving medicines and mentorship from government/donors • Fear of stigmatizing other patients who come to the hospital if seen as an HIV hospital • Limited health insurance coverage |

TABLE 2. Summary of DD of ART models (by country)

| COUNTRY | TYPE OF MODEL(S) IMPLEMENTED |
|----------------|--|
| Nigeria | CPs, private hospital |
| South Africa | PDU, CCMDD, lockers, CPs, private hospital |
| Zimbabwe | Private hospital |
| Zambia | CPs, CDU lockers, private hospital |
| Malawi | Private hospital |
| Eswatini | Private hospital |
| Lesotho | Private hospital |
| Tanzania | Private hospital |
| Uganda | CPs, private hospital |
| Kenya | Private hospital |



4 Guidance for implementation and scale-up of DD of ART through the private sector

DD of ART complements DSD models in the public sector and should be added to the menu of available options. Decisions by governments or implementing partners to introduce or scale up one or more of the DDMs should take into consideration a wide variety of country-specific factors. Some of those factors can be analyzed, assessed, and tracked over time. However, it is essential to understand that those factors are mostly interrelated and thus affect each other. For example, income distribution for the PLHIV population, patients' ATP for specific drugs or health services, and the presence and strength of private sector facilities can all be closely linked. Thus, any informed decision regarding the scale-up of DDMs must consider these multiple factors in a comprehensive manner, not in isolation.

4.1 Factors to consider when deciding on a private sector DD model

4.1.1 How big is your country/program's population of clinically stable clients who can potentially be transitioned into a private sector distribution system?

- The majority of patients in ART programs are clinically stable: According to the 2019 PEPFAR report to the U.S. Congress, about 80 percent of all PLHIV who receive ART are clinically stable, which means that a large cohort of patients can be enrolled into differentiated models of care, including those implemented through the private sector.
- Consider how this population is distributed across different regions or provinces, so that scale-up of DD models can prioritize those with the highest HIV prevalence and large numbers of PLHIV on ART.

4.1.2 What would be a potential impact from the scale-up of DDM?

- You may use a mathematical model to assess the potential impact from implementing or scaling up one or more of the DDMs.

An Excel-based model such as the one developed by Palladium under the PEPFAR- and USAID-funded Meeting Targets and Maintaining Epidemic Control (EpiC) project can be used by policymakers, program implementers, researchers, and any other stakeholders interested in exploring DDMs in a country or within subnational units in a country. The Palladium model provides users (and consumers of the results) the opportunity to capture the different types of inputs and data that are necessary and consider the evidence-based assumptions that must be made in order to produce reliable estimates.

The main features of this model, including its multiple steps, the type of data and parameters needed, assumptions, and the type of results it produces, are described in **Appendix 1**. An illustrative example of estimating impact of scaling up DDM in Zimbabwe is included in **Appendix 2**.

The model produces four key outcomes.

- i. Estimated maximum market potential for DDMs, measured by the number of PLHIV receiving ART services through the public sector who would be eligible to switch to one of the DDMs within the private sector, would have geographical access to at least one of the DDMs, would have the financial means to do so (referred to as ATP), and would switch if the final price to pay under one or more DDMs fell below a certain threshold.
- ii. Estimated reduction in the number of patients lost to follow-up (and potentially new infections and AIDS-related deaths) due to an increased proportion of ART patients choosing one of the DDMs. This, along with improved treatment adherence, may improve viral load suppression rates.
- iii. Estimated cost savings for funders (e.g., governments, PEPFAR), measured as the amount of financial resources that funders will save through the scale-up of DDMs if a certain proportion of that potential market of PLHIV switches to a DDM. Savings would arise from reduced expenses on human resources, facility overhead, ARV commodities, laboratory diagnostics, patient tracking, etc. While the model does not include savings associated with fewer patients switching to more expensive second-line regimens or needing treatment for opportunistic infections under DDMs, these costs would add to the overall estimated savings to the program.
- iv. Estimated cost savings for patients receiving HIV care, measured as the amount of financial resources to be aggregately saved after patients opt to receive their ARV medication (and potentially other HIV services) through DDMs and not solely through public facilities. These cost savings would comprise savings from reduced indirect costs, which include transportation costs and opportunity costs (travel time, time spent waiting in the health care facility, and informal caretakers' time for those with children), and fewer visits per year. These cost savings will be partially or completely offset if the DDMs are not fully subsidized or require some payment from patients in order to receive their ARV commodities or HIV services.

4.2 Steps to follow when planning for implementing/scaling-up DD of ART

4.2.1 Ensure supportive policies and legal/regulatory requirements are in place

Government policies and regulations for private sector engagement in the delivery of ART are crucial for the success of the strategy. The leadership and guidance of national government officials is also critical to the successful implementation and scale-up of DDMs. Policies need to address the following, allowing:

- MMD of ARVs
- Private sector participation in HIV service delivery (with clear guidance on who can provide ART and frequency of refills/follow-up)
- Dispensing at alternative locations such as through automated models
- Sharing of government drugs with private sector facilities. The policy should also address necessary changes to the supply chain to accommodate moving the commodities from the public sector to the private sector
- Sharing of patients' information between public and private facilities and reporting requirements to ensure there is no double reporting or underreporting

Additionally, policies should define the mechanism/procedures for ensuring quality of services in the private sector (e.g., inclusion of private sector providers in national training events, technical working groups, accreditation, QA/QI cycles).

From a legal/regulatory perspective, it is important to ensure that private outlets, such as pharmacies involved in DD of ART, are registered and operating legally and that pharmacists have a current license. Governments and programs can work with drug regulatory authorities and pharmacists' associations to ensure efficient and clear processes for licensing CPs (if needed) that express a desire to participate in DD of ART.

4.2.2 Engage key stakeholders from the very beginning

Experiences from countries that implemented DD models showed that one of the most important factors for successful introduction and implementation of community-based differentiated treatment models, including DD in the private sector, was buy-in from multiple stakeholders (for examples of key stakeholders, see Figure 9).

This will help to generate awareness and ownership of the intervention. The engagement should address and align the interests of each of the various stakeholders with the interest of the patients.

The final decisions about what DD models to use should be made after stakeholder engagement. For example:

- Engaging MOH at all levels ensures that necessary supportive policies and guidelines are in place and necessary changes to the supply chain and monitoring/evaluation systems are made
- Engaging PLHIV and civil society ensures that the model selected is acceptable to them and that their concerns (e.g., service fee) are addressed
- Engaging private sector providers helps to address their motivation, incentives, and offer justification for their involvement in the provision of care
- Engaging with public sector health care providers when planning for DD of ART is equally important since they must accept and actively participate in the referral of their patients to the private sector. The engagement should address their concerns about patients' ability for self-care and need for adherence support and follow-up. The engagement of public sector stakeholders also helps to develop a rapport with the community pharmacy staff (or other private sector providers) for seamless implementation of the program.
- Holding regular meetings with all stakeholders to sensitize them about DDMs, solicit their feedback, and provide continuous updates on the implementation/scale-up process

FIGURE 9. Examples of key stakeholders



4.2.3 Identify and agree on the DD model(s) to implement/scale up nationally or in different subnational areas

- Decision about which model (or models) to implement should take into consideration the size of the population of clinically stable patients on ART and potential impact of different models (as described above). Additional factors include:
 - » Stakeholder buy-in
 - » Feasibility of implementing a particular model (for example, in settings where electricity and Internet access are not reliable, automated dispensing models cannot be sustained)
 - » Accessibility and geographical distribution of private provider outlets
 - » Acceptability of the different models to patients (do they meet their needs in terms of convenience, privacy, etc.)
 - » Unmet needs/gaps not addressed by existing DSD models
 - » Populations not served by existing models, such as men
- Select one or more models that are appropriate for your setting (community pharmacy, one of the automated dispensing models, or private hospital model)
- For selected models, decide if and how much patients can contribute to their care; patients' contributions would make a model more sustainable than fully subsidized models.
 - » Patients' ability and willingness to pay (WTP) may be different in different geographical areas (e.g., urban vs. rural). To estimate WTP and ATP, consider conducting a rapid assessment or extrapolate estimates from data on use of other health services in the private sector (if such data are available), or even data for some HIV services from countries with a similar context. Associations of PLHIV can also provide valuable input.
 - » In cases when the DD model involves any charges to patients, changes to patients' ATP over time should be anticipated and a mechanism put in place for an easy and timely transition in and out of the private sector and between the models, as needed. Even if some patients can initially afford paying the service fee on their own, ART is a lifelong commitment, and the cost may become unaffordable at some point in the future (e.g., if an individual's economic situation changes).
 - » Depending on WTP and ATP, decide if patients can be expected to pay any fee. Possible choices include the models where services and medications are:
 - Fully paid by donors/governments
 - Subsidized by donors/government with patients paying part of the cost (e.g., dispensing fee, adherence counseling fee, etc.)
 - Covered partially or fully by health insurance, or fully paid for by patients (these options are currently uncommon, but may be applicable in a limited number of settings)

4.2.4 Define selection criteria for participation in DD of ART through the private sector

When planning to introduce DD through the private sector, it is important to clearly define criteria used for (1) selecting public facilities that can benefit best from transitioning a proportion of their patients to the private sector, (2) selecting private facilities/outlets to partner with, and (3) selecting patients eligible to receive their ARVs from a private facility. The criteria are outlined below.

For public facilities

The key objectives of the DD of ART are to improve patient experience and decongest public health facilities. Thus, the main considerations in selecting facilities from which stable patients (who consent) will be transitioned to the private sector to continue with ART include:

- Large population of clinically stable patients on ART
- High daily patient volume
- Long waiting times
- HRH shortages
- Inability of current DSD models to meet the needs of facility's patient population (e.g., reflected in high LTFU)

Busy facilities are commonly located in urban or peri-urban areas, in which a high number of private sector facilities are also available to facilitate the transition. A baseline assessment of public facilities, including discussions with providers and clients, will help to agree upon/define a numerical value for each of these criteria.

For private facilities/outlets

Engagement with vendors (for automated models) or pharmacy professional, regulatory, and licensing bodies will facilitate the selection of appropriate private outlets. The criteria for selection include:

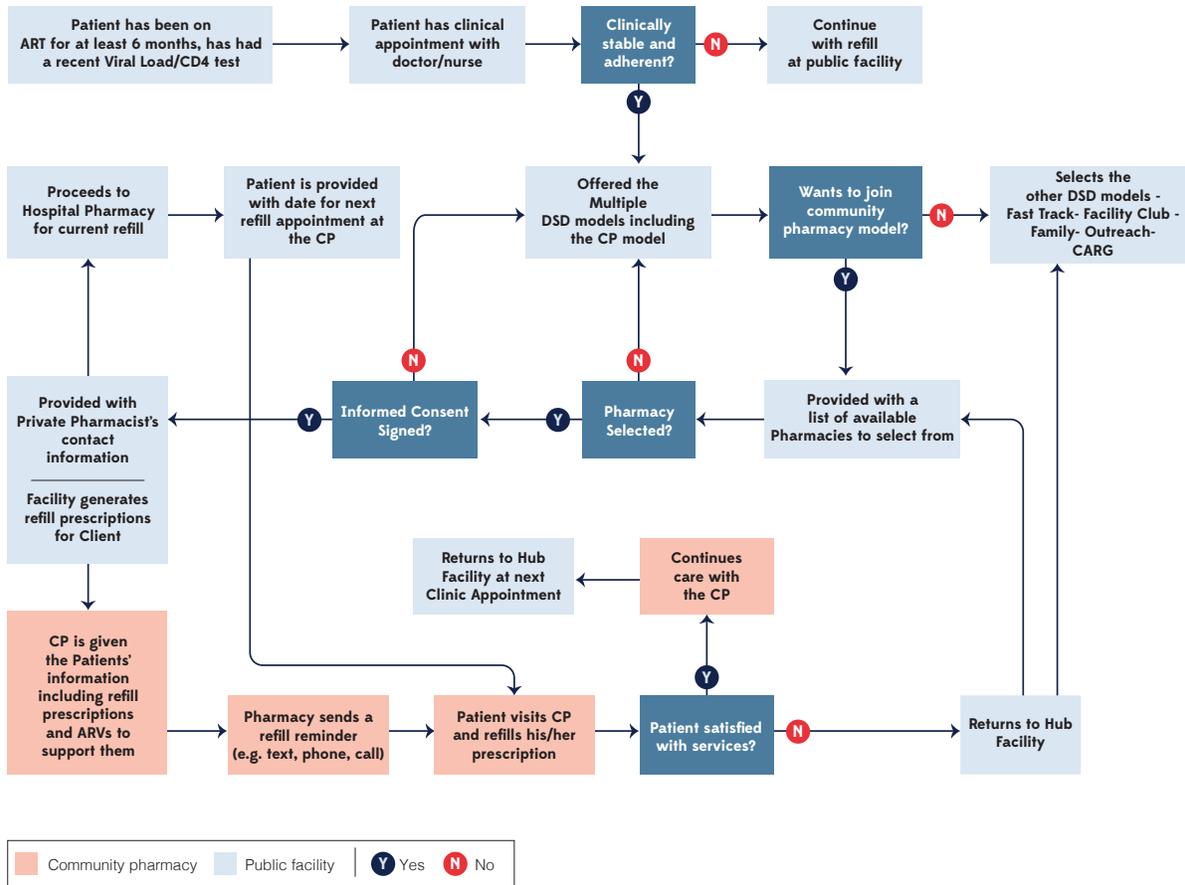
- Being registered and licensed
- Convenient location and adequate infrastructure
- Trained staff (or willing to be trained, in which case training needs should be assessed). For automated dispensing models, staff should also have knowledge and experience with operating the selected automated model.
- Willingness to participate in DD of ART
- Willingness to sign an MOU with a public health facility/government/donor, which defines the terms of engagement and roles and responsibilities of each party involved in the process

For clients

Criteria for selection of clinically stable clients may vary somewhat from country to country and evolve with time as new, easier to take ARVs are introduced. WHO defines clinically stable clients as:

- On ART for at least one year (note that some country programs shorten this period to six months)
- No adverse drug reactions that require regular monitoring
- No current illnesses or pregnancy, and not currently breastfeeding
- A good understanding of lifelong adherence
- Evidence of treatment success, such as two consecutive undetectable viral load measures or, in the absence of viral load monitoring, rising CD4 counts or CD4 counts above 200 cells/mm³ (note that scaling up viral load testing is critical to ensure successful enrollment of patients into both DSD models and DDMS, and should go hand in hand).

FIGURE 10. Pathway for enrolling clinically stable patients to a community pharmacy (or other DD model)



The example of the pathway for devolving stable patients from a facility to a DD model of choice (in this case, a community pharmacy) is shown in Figure 10. DD of ART models should be offered along with existing DSD models and patients should be allowed to make an informed choice.

All patients who are eligible for DSD based on national guidelines are also eligible for DD of ART. Additional criteria include:

- Willing to enroll in DD of ART
- Provide written informed consent

4.2.5 Conduct an assessment of private sector facilities

The assessment should include the criteria for private facility listed in section 3.2.4 (also see Figure 11). When assessing community pharmacies for adequate infrastructure, ensure the following minimum requirements are in place:

- Sufficient space to accommodate increase in patient traffic
- Space that ensures audio and visual privacy in order to provide counseling/address patient concerns
- Drug storage space that meets requirements (with temperature not exceeding 30° C, not exposed to direct heat and high humidity, adequate shelving, availability of locking cabinets)
- Adequate space and/or electronic infrastructure for managing and storing patient records and registers
- Reliable electricity/or backup system, GSM network, and Internet access, which are essential if electronic systems are used for reporting and timely sharing of information
- Security measures to guard against break-ins/burglary (secure windows, doors, locked storage spaces).

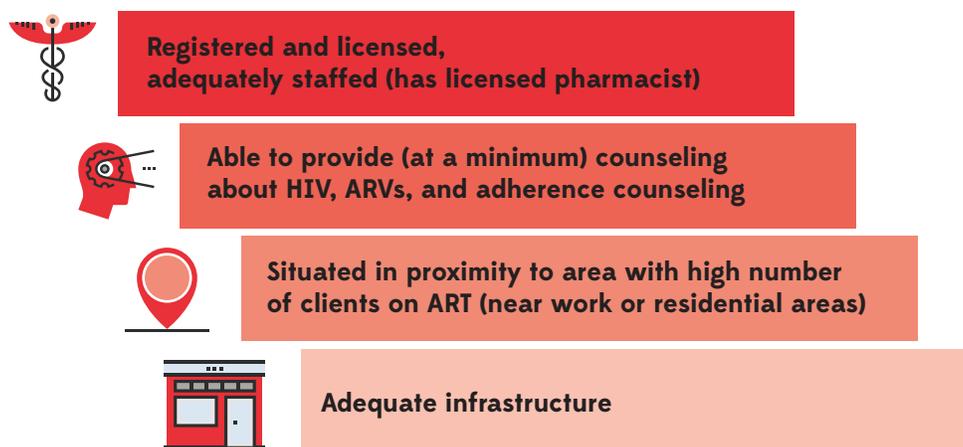
For the automated dispensing models assess for these infrastructural requirements:

- Reliable electronic medical record system that will be able to link with the facility records to allow for automated dispensing
- Reliable last-mile system to ensure timely replenishment of inventories
- Systems for client notification, reminders, and for provision of information in case of queries on medicine use
- Reliable electricity/or backup system, GSM network, and Internet access, which are essential for automated dispensing models and any models where electronic data collection is introduced
- Where applicable, a call center to respond to patient concerns during automated dispensing

Additionally, while dispensing chronic disease medications other than ARVs is not a requirement, it is considered a plus as it helps to reduce stigma.

Once the community pharmacies are assessed, they should be mapped around the public health facilities. The process of selection and mapping of community pharmacies should also involve the key stakeholders.

FIGURE 11. Identifying community pharmacies



4.2.6 Develop a business case to present to community pharmacy or other private facility

Following the assessment and mapping of the community pharmacies, hold a business case discussion with the owners of the qualified CPs. The business case should highlight the following benefits to the pharmacy:

- Direct revenue from fee-for-service and indirect revenue from ancillary drug needs
- Increased visibility for the pharmacist due to involvement in public health interventions
- Special appreciation/recognition during national conferences of Pharmaceutical Society/ professional association
- Increased foot-fall
- Robust capacity building which can be applicable to other disease areas and contributes to professional development
- Corporate social responsibility

After the discussion, the owners should decide if they are interested in participating in the provision of ARV refills and pharmaceutical care to the patients. Those who accept will then be required to sign an MOU with the government and/or any other relevant organization.

4.2.7 Build provider capacity to offer quality services

Private providers may have different levels of readiness to offer ARV refills and associated HIV services.

- Based on the gaps identified during facility assessment and before DD of ART is launched at the facility, train the pharmacists and the staff of the selected community pharmacies to ensure that they:
 - » Have a clear understanding of relevant national policies, guidelines, and protocols
 - » Have required knowledge of ARV drugs and are able to counsel patients about correct use, side effects, reasons to contact their health care provider, etc.
 - » Understand and can uphold quality-of-care standards
 - » Are able to offer quality adherence counseling
 - » Know when and where to refer patients
 - » Understand importance of preventing stigma and discrimination while offering services to PLHIV
 - » Understand information management requirements and have necessary skills to meet these requirements
- As part of building a rapport between the public health and private facility staff, the community pharmacy staff should visit the public facility as part of the initial orientation to understand site-level procedures and processes during ART refills. This will enable better future consultations and communication.
- Plan for continuous capacity building. Because management of HIV evolves with time as new medicines are rolled out, private sector providers will need refresher trainings and updates to ensure that they are providing a high quality of care. Governments and programs should:
 - » Involve private sector providers in national training programs as much as possible
 - » Explore using electronic or web-based learning, which may be more practical for the private health sector since they are often less willing or able to let their staff leave the facilities to attend trainings/workshops
- Coordinate with pharmacy associations, private sector networks, and other professional societies responsible for continuous medical education as part of accreditation and licensing requirements. Involving these associations/networks in conducting baseline assessment and any subsequent training activities can strengthen their ability to provide quality assurance and future HRH training, thus contributing to sustainability of DDM of ART.
- Establish a mechanism for regular monitoring (with defined indicators), supportive supervision, and performance review at the very beginning. This will ensure adherence to best practices and continuous quality improvement.

4.2.8 Create demand for DD of ART while respecting informed choice

There are a number of different DSD models currently being implemented in the public sector of various countries. DD of ART through private sector is an additional option that has its own benefits. In order to create demand for the DD of ART models:

- Sensitize staff in public health facilities about the availability of the DD models and provide them with all the relevant information and tools.
- Add the private sector DD option to the list of public DSD options that are discussed with patients at the facility level.
- Provide information about the DD of ART models to patients during adherence discussions and support group meetings. Educate clients about what is required for them to participate in the model and how to maintain eligibility to stay enrolled.
- Develop information, education, and communication materials and make those available to patients to help them get a better understanding of the DD models and their attributes to allow them to make an informed choice of the option that suits them best.
- Engage associations of PLHIV so that they can inform their members about the availability of DD in the private sector in addition to other DSD models.
- Where resources are available, mass communication should be used to educate clients about the DD models.
- Encourage clients who are using DD of ART model to share their experiences with other clients.
- Reassure patients that they are free to return to the health facility at any time for any reason and switch to another pharmacy or back to receiving their ARVs in public sector if they are not satisfied with private sector model.

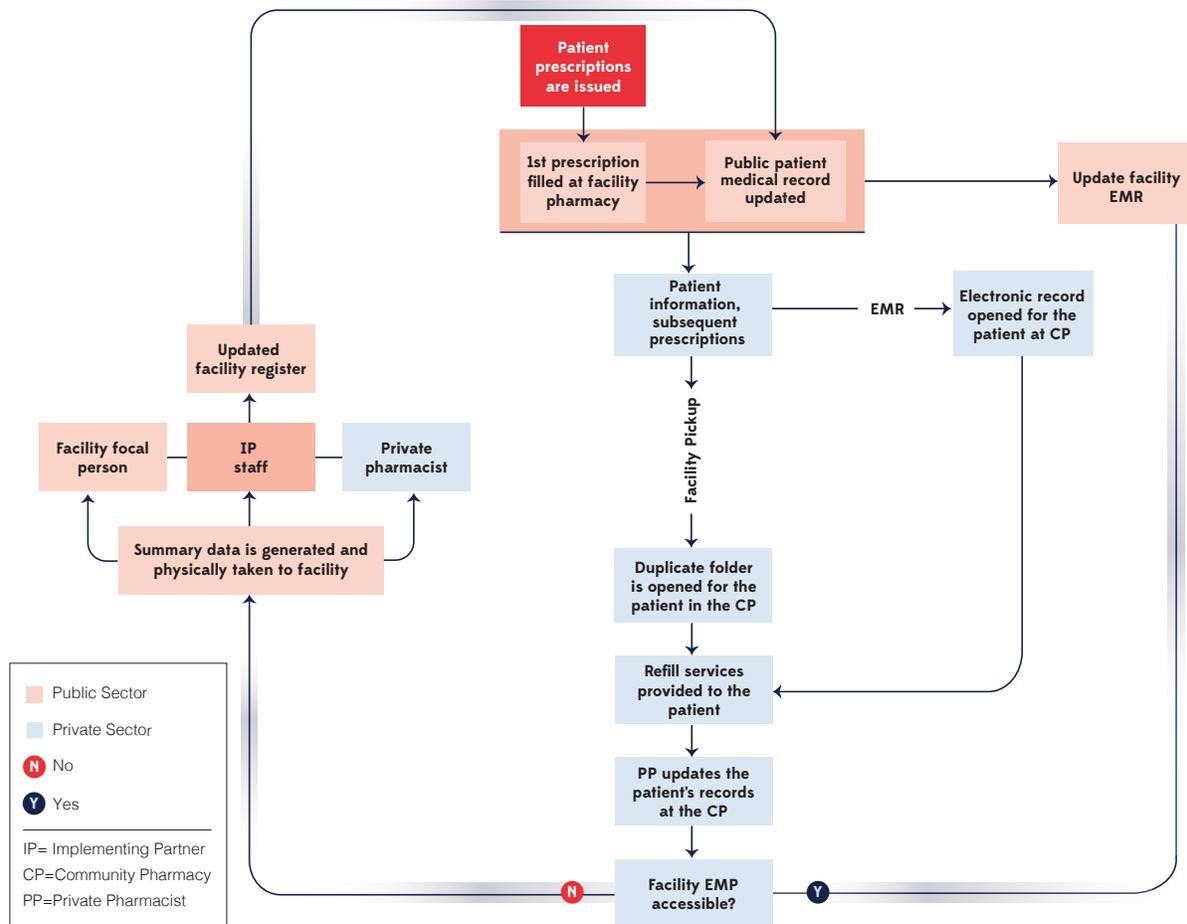
4.2.9 Ensure tools and systems for data management, monitoring, and evaluation are in place

At the program level, donors and government should routinely collect and analyze data such as retention rates, viral load suppression, and costs associated with clients picking up their ARVs through DD models. Pick-up sites may or may not be tracked in existing national HMIS systems or in PEPFAR's DATIM tracking system. For purposes of reporting to the MOH and PEPFAR, patients enrolled in the community pharmacy or automated DD models are still counted under the public facility where they receive their prescriptions. Therefore, the routine patients' service data, including ART refills using DDM, should be collated with the hub facility's report and submitted to the MOH and PEPFAR as part of routine reporting requirements. Figure 12 shows an illustrative data flow between a public facility and a private facility that provides refills. Under a purely private hospital DD model, the private facility that issues the prescription to the patients should be the reporting unit for those patients served by it.

The DD models should be listed on the patient care and treatment book as available options from which patients may choose. Specific codes as per national system should be assigned to the models. These codes/models should also be included in the automated appointment list.

At the facility level, there is a need for an effective and efficient system for data collection and two-way exchange between the public health facilities and the private sector providers. The data collection tools should be simple with clear guidance about what indicators to record and what mechanism private providers will use to share these data with the public facility:

FIGURE 12. Illustrative data flow between public and private facilities



- Establish a system for the exchange of data between the public facility and private sector provider. An electronic system that allows for real-time data sharing will be preferable. However, if not available, a paper-based system should be used for non-automated models (e.g., CP, private hospital) while effort is made to move towards an electronic system.
- In case of the automated dispensing models, ensure that electronic/real-time sharing of patients' data between the public health facility and the automated dispensing model is supported.
- Adapt data management approaches as needed. As the number of clients using DDM increase in scale, there is need to reduce the data burden on the private sector provider, which may require a more efficient electronic data management system (see sidebar).
- Develop data collection tools and train private sector providers on their use. The data collection tool to be used by the community pharmacy should be similar to that being used at the facility dispensing point. This will allow for easy transfer of information between the public and private facility.
- Develop standard operating procedures (SOPs) for filling out data collection tools and share SOPs with the private sector providers.

- When defining data-sharing pathways for merging data from the private and public sectors, take precautions to avoid duplication (e.g., when patients are transferred back and forth between sectors).
- Ensure that private sector providers know:
 - » When to report back to the public sector facility where the patient receives the refill prescriptions
 - » How to send information to the facility about the patients who have picked up their refills
 - » To notify the facility immediately or as soon as possible about the patient who has defaulted or referred back to the facility for review. The defaulter tracing mechanism at the facility should be triggered immediately after information is received from the private provider.
- Where the public sector has functional electronic medical record (EMR) system, make effort to create interoperability with the private sector EMRs.
- Hold regular review meetings between the private sector providers and public health facility providers
- Conduct regular supportive supervision for the private sector providers by MOH and/or local technical experts, members of professional associations, and other relevant bodies
- Develop facility, district, regional and national dashboards to monitor the acceptance of the DD of ART and the patients' outcomes under the DDM.

Periodically, programs should conduct a comparative analysis to ensure DD models are responding to patient needs. Routine monitoring data on viral suppression and adherence should be reviewed and where possible, compared against similar cohorts of other stable patients that are not enrolled in a DD model. Comparisons would need to rely on longitudinal data extracted from EMR or EDT systems kept for patients receiving medicines through DD models versus those not enrolled in DD models.



ELECTRONIC DATA MANAGEMENT SYSTEMS

An electronic data management system enables real-time transfer between private sector pick-up sites and the national reporting system. Third-party cloud applications that allow controlled access by both the public and private sector could be used. A cloud-based system will allow private sector pick-up sites to sign into the system and enter the necessary information; the public facility will be able to see the information in real time and take an appropriate action. Some countries already use cloud-based ART Dispensing Tools (ADT) that allow real-time information sharing and reporting. Some of the ADTs are open access, and therefore may be adapted for use in other countries. If the private sector has no access to the national reporting system, hiring programmers to build an application programming interface (API) between the pick-up point electronic system and referring clinic EMR should be considered. The API should allow for real-time data exchange to ensure continued patient management and monitoring. One of the key requirements for the data sharing between the private and public facilities is privacy and confidentiality; therefore the system should allow for de-identification and exchange of only relevant data for the purposes of providing patient refills and adherence monitoring in the private sector. Both the private and public sector systems should be properly protected with the relevant firewalls to prevent unauthorized access to information. At the very minimum, sharing information on who came and did not come to pick up ARVs on a specific day should be communicated to the health facility to allow for timely tracking.

4.2.10 Ensure ARV availability in private sector through necessary adjustments to the supply chain and/or efficient ways to transfer of ARVs from public to private facility

Depending on the supply model, ARVs may be supplied by government central/regional distributor, or by the public health facility from which patients were referred, or they may be purchased directly by the private sector provider. The key objective of the supply chain is to ensure that commodities are available at the dispensing point when the patient appears at the refill point. The supply chain process that includes private sector providers should be clearly defined, including the basis for resupply.

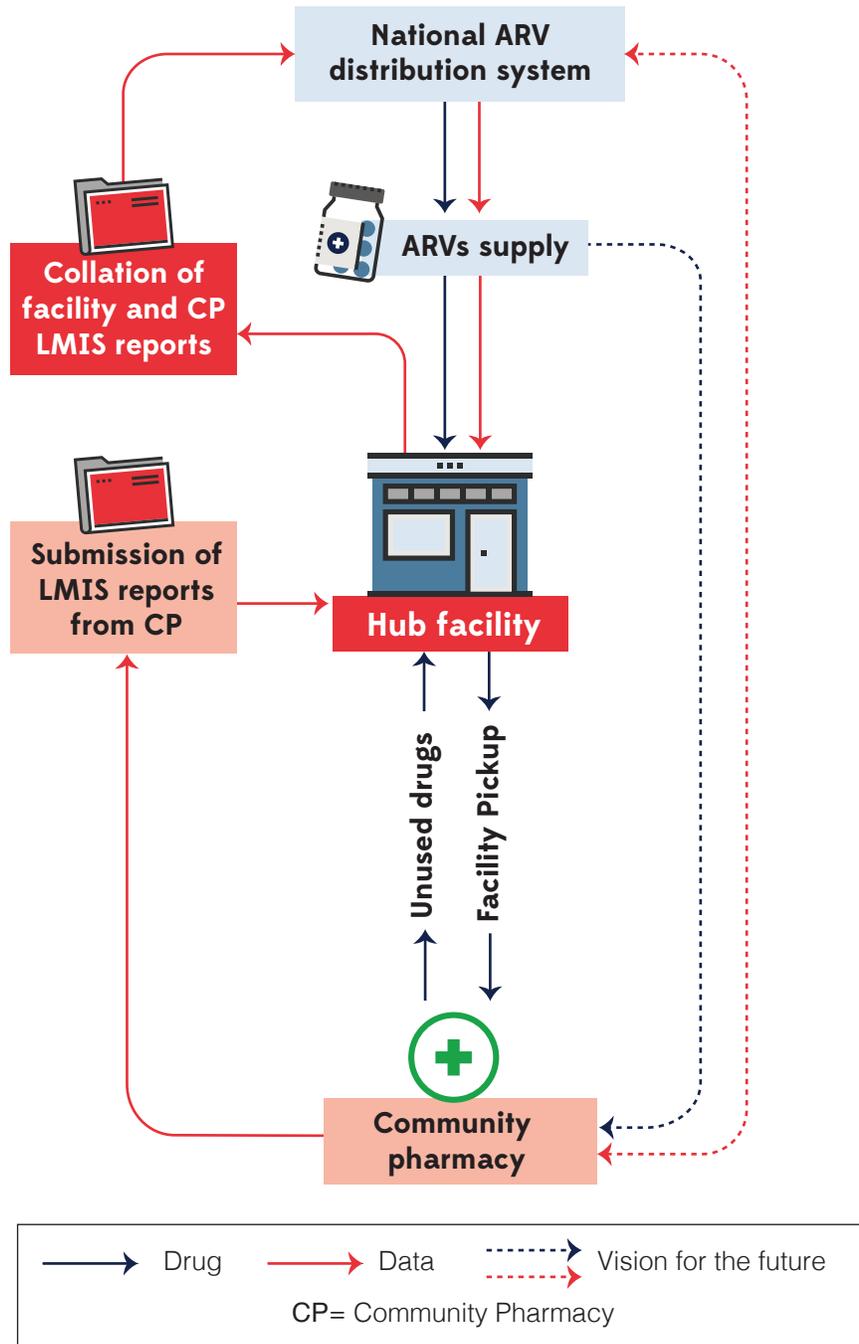
There are three methods of supplying the ARVs to the private sector:

- Supplied by the national/regional distributor
 - » Include the selected private pharmacies on the supply list of national/regional distributors
 - » Clearly outline the processes for requisition, allocation, receipt and reporting procedures
 - » If the community pharmacies are many, they may be grouped together and a receiving hub for a group of pharmacies can be used to minimize the distribution costs
 - » Train the private sector providers on the government supply chain system so that they are able to complete the necessary documentation in time.
- Supplied by the public health facility (hub) to its affiliated pharmacies (spokes)
 - » Outline the pathways: Determine who is responsible, how the drugs are transported to the private facility, what documentation is required, how frequent are the ARV transfers (to accommodate the refills), and what are the reporting requirements.
 - » The community pharmacy staff may collect from the public facility or the ARVs can be delivered by the facility or implementing partner staff
 - » Design/adapt the relevant logistics tools to be used for requisition, dispatch, receipt and reporting
 - » Train the private sector providers on the government supply chain system so that they are able to complete the necessary documentation in time. The community pharmacy should send the logistic reports to the public health in time for national reporting.
- Purchased directly
 - » If ARVs are purchased directly by private sector providers, explore what kind of support they may need to manage stock effectively and provide capacity building based on their needs.
 - » Design/adapt the relevant national tools to be used for requisition, dispatch, receipt and reporting.
 - » In case of reimbursement, the requirement documentation should be agreed upon.

Since a number of community pharmacies may already be stocking ARVs, it is advisable to consider marking the government/donor-funded drugs “Government/PEPFAR funded, not for resale” to allow for easy differentiation. This will also assist in ensuring that free government/donor-funded commodities are not sold to patients. The use of a primary pack bar code reader where feasible would go a long way in ensuring that the ARVs for a named client are tracked. Before these systems are set up, a system that delivers ARV packs only for patients referred to the particular private pharmacy and a consumption report for them to the facility for those will ensure accountability.

Including other medicines, such as isoniazid for TB preventive therapy, drugs for TB treatment, and PrEP, will not only improve patient experience but also make the models more efficient.

FIGURE 13. Proposed logistics system

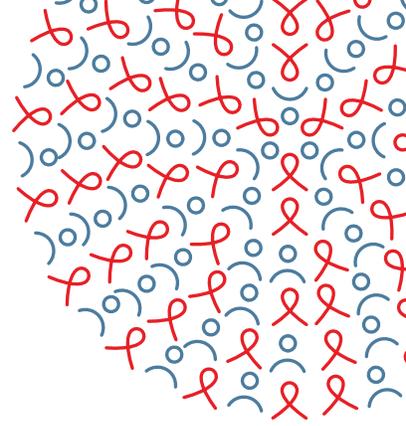


An electronic Logistics Management Information System (eLMIS) is preferable and where not available effort should be made to design or acquire such system to be used by both the private and public sector. Figure 13 shows the flow of ARVs supply and consumption data between national ARV distribution system, public facility, and private facility. Potential changes to this flow may involve direct supply of ARVs from the national distribution system to the private facility.

4.2.11 Plan for sustainability of DDD approaches

Sustainability of DD models relies on countries finding alternative ways to pay for them. Consider these as the first steps toward sustainability:

- Advocate for and facilitate increase in health insurance coverage for PLHIV. Many countries do not have policies requiring private health insurers to cover HIV services. In order to enhance participation of the health insurance sector, national governments should develop blueprints for policies that ensure that HIV services are gradually being covered by both universal health insurance and private health insurance providers. These blueprints should factor in results from proper costing studies on the provision of HIV care and comprehensive treatment packages. Itemizing different components and making clear how much each component would cost (rather than providing a lump sum estimate) can make it easier to build a business case and negotiate required coverage with health insurance providers.
- Explore ways to make ARVs in the private sector more affordable. This can mean:
 - » Supporting pooled procurement of ARVs by either allowing private providers to access the government pool so they can benefit from government-negotiated competitive rates, or by supporting private providers to pool together to negotiate better rates.
 - » Setting a price point for ARVs distributed through the private sector if clients are expected to start paying for ARVs in addition to services. Careful consideration should be given to what would be affordable for clients, while still maintaining some profit margin for private provider.



Summary and Recommendations

Private sector models can bring services closer to home and make them more accessible and convenient for PLHIV who are clinically stable. DDMs will help to reduce burden on congested public health facilities and improve the quality of care for patients on ART.

Programs and governments can decide what model may work best in their country/program context. Different models of decentralized ART distribution being implemented include:

- **Community pharmacy models.** Patients receive ARVs for free (paid for by government/donors), but are charged for services (dispensing, counseling), or receive both ARVs and services free of charge.
- **Automated dispensing models.** Include PDUs, PCUs/lockers, and CDUs. Patients are not charged for either ARVs or associated services.
- **Private hospital models.** Include hospitals where ARVs are provided for free, but patients are charged for other services, and hospitals where patients are charged for services as well as ARVs (uncommon).

Most countries have a relatively high number of licensed private (community) pharmacies, particularly in urban and peri-urban areas, and WHO recently recommended increasing the role of the community pharmacists in HIV care. In countries where the community pharmacy model of DD is being implemented, data demonstrate a high rate of prescription refills, high retention in care, and very low LFTU.

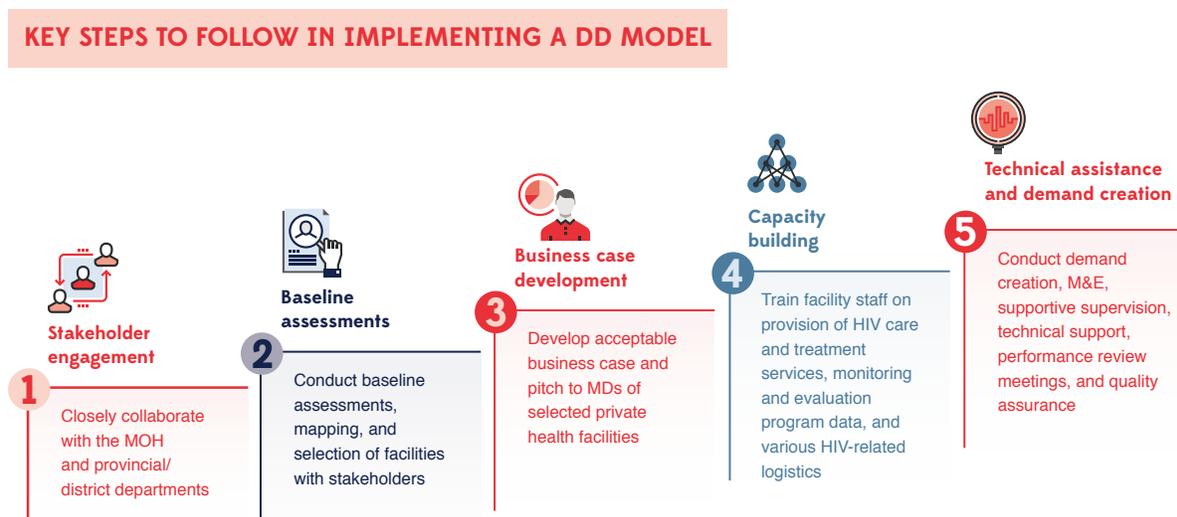
Desk review and key informant interviews that informed the development of this guide revealed that while there are policies in place for differentiated HIV care in public sector facilities, policies specific to decentralization through the private sector are missing. It would be important to address this gap and have policies in place that define private sector involvement in HIV treatment and care, necessary changes to the supply chain, and ways to ensure that private sector providers have access to affordable ARVs.

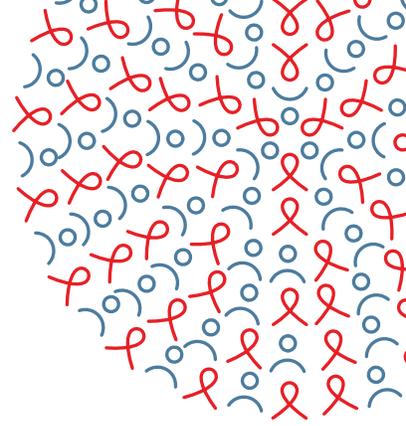
Key considerations for scale-up include:

- **Conducting a market analysis**, which should take into consideration the size of the population of clinically stable patients, their WTP for services in private sector, potential cost savings for public sector, and benefits for private providers and patients.
- **Creating an enabling environment**, which will require advocating for and developing supportive policies, engaging stakeholders early and continuously, improving coordination between public and private sectors, and having a system for managing the data.
- **Ensuring service readiness**, including adequate infrastructure, trained providers, a mechanism for quality assurance/quality improvement, and availability of ARVs.
- **Having clear criteria** for selecting public and private facilities to participate in DD as well as criteria for identifying clinically stable clients eligible for transitioning to the private sector.

Key steps to follow in implementing a DD model

Once a market analysis has been completed follow these steps to can be implement a DD model:





Appendices

Appendix 1: Description of the estimation model to assess the potential impact of introduction/scale-up of DDMs

Palladium designed this estimation model to provide estimates on the potential impact of the introduction or scale-up of one or more DDMs. The model focuses on estimating epidemiological impact, market size, and cost savings for funders and HIV patients with the introduction or scale-up of three DDMs: CPM, private hospital model, and centralized lockers model.

The estimation model does not provide cost-effectiveness estimates for each DDM, define thresholds to recommend/not recommend the implementation or scale-up of DDMs, or suggestions about what type of DDMs should be implemented, if any at all. This model provides policymakers and program implementers (the final users of the model) with a better understanding of the different factors that play a role in DDM implementation/scale-up, and with illustrative estimates on the magnitude of cost savings from the scale-up of one or more DDMs in a specific country or region.

Assumptions, scenarios, and parameters to estimate the main three outcomes

The model requires the identification of two scenarios. First, a baseline scenario (also considered the comparison scenario, or the counterfactual scenario), which assumes that the coverage of people on ART (including under any of the DDMs currently in place) remains constant over a specific time period. Thus, if a country has not implemented any DDMs yet, the baseline scenario will consider no patients under DDMs over the same time period. The second scenario is the DDM scale-up scenario, which must be defined by the user by providing key inputs, including the magnitude of the potential scale-up of one or more DDMs, mainly in terms of geographical areas, and the estimated final price to HIV patients if they switch to any of those DDMs.

Potential access to DDMs is determined through three steps. First, the population of interest is defined as all HIV patients on ART who fulfill the following eligibility criteria: they must be 18 years or older, they must be on a first-line regimen, and they must be virally suppressed. Second, the model requires users to identify potential geographical access for the **DDM scale-up scenario** (regions within a country where one or more DDMs would be implemented or scaled up) over the time period (the model currently does not allow for different levels of penetration for each model within regions, only whether a model is present in a specific region or not). Third, only PLHIV with ATP will switch to a DDM (this does not imply that, in practice all of those with ATP would switch; other factors, financial or not, will also play a role). See below for an explanation on how ATP can be estimated.

This model relies on a few key **assumptions**. First, it assumes that, on average, private providers working under the DDMs do a better job at following up with patients, so LTFU rates are smaller under DDMs. Second, it assumes that if a DDM has some presence in a specific region, all DDM-eligible PLHIV can potentially access it. Third, it assumes that if more than one DDM is available in a geographical area and a patient can afford more than one, he/she will have the same likelihood of switching to either model.

Ability to pay and potential market size

Estimating the ATP is a key step in the estimation process of the potential market size. In order to estimate the ATP, the model needs the following key parameters:

- Final price to patients for ART under each of the relevant DDMs over the modelling period (if full subsidization is being considered, the final price to the patients would be set to zero)
- Average household income across quintiles in the country (or region)
- Proportion of PLHIV in the country distributed across income quintiles
- An estimate of what proportion of their income PLHIV would be willing to spend in order to switch to a DDM

Using these four parameters, the model estimates the maximum potential market size (number of all eligible PLHIV with ATP) for the DDMs. The model also predicts epidemiological impact based on indicators such as the number of PLHIV on ART, ART patients lost to follow-up, number of new HIV infections, and number of AIDS-related deaths.

Cost savings for funders and patients

The estimation model calculates the amount of financial resources to be saved by the funders once a certain number of PLHIV switch from a public model to a DDM. Savings for funders like governments and PEPFAR may come in the form of reduced expenditures on the direct provision of HIV services to patients (as more patients will be accessing HIV services in the private sector); fewer expenses dedicated to human resources, facility overhead, ARV commodities, and laboratory diagnostics; and less effort required to track patients who are LTFU, among others. Yet, this would also depend on whether, and by how much, funders or donors would keep funding/subsidizing the provision of some HIV services. These cost savings will be offset by investments to be made on start-up or scale-up capital costs.

The model also estimates cost savings for patients by subtracting how much patients would pay for HIV services if they transition to a DDM from how much they would save in indirect costs, mainly through reduced transportation costs (since they may visit points of care less frequently and maybe closer to their homes) and reduced opportunity costs and time investment (in the form of lost wages as a result of having fewer visits, and each visit taking less time than in public facilities).

Comparing the baseline with the scale-up DDM scenario, the estimation model merges all cost and benefit streams over a specified period of time and provides the user with the estimated net potential impact on savings for both funders and patients for a specific country given the parameters provided by the user.

Data requirements

In addition to the key parameters indicated above, the model requires the following variables over the time period to be specified by the user:

- Final price to be paid by patients for HIV services if they switch to either of the DDMs available (this can include price for ARV dispensing, counseling, CD4 and viral load testing, among others, as defined by the user under the scale-up DDM scenario)
- Geographical regions where DDMs would be available
- Number of eligible PLHIV already under one of the DDMs
- Predicted viral load suppression rate and LTFU rate under each DDM
- Epidemiological data from country's official AIDS Impact Model (AIM) file in Spectrum, including estimates of the number of PLHIV 18 years and older and PLHIV on ART
- Programmatic data on the number of new patients each year, rate of LTFU; percentage of patients on first-line ART regimen; and viral load suppression rate
- Annual cost per patient on ART (broken down by human resources, overhead, ARVs, and lab diagnostics at public sector facilities and under all the DDMs)
- Indirect costs for HIV patients: estimated transport costs and lost wages (productivity loss) under all relevant DDMs

Data for the first two variables must be provided by the user of the model; the other data can be obtained from national AIM files and PEPFAR databases for epidemiological information, programmatic and administrative data from partners implementing similar DDMs in other countries in the region, and DHS and other secondary data sources. If not available, they must be discussed and explored with key stakeholders and local partners. Alternatively, they can be extrapolated from data from previous years, especially parameters predicting future trends for the modelling period.

Appendix 2. Illustrative example: introducing and scaling up DDMs in Zimbabwe

We applied the estimation model to the Zimbabwean context in order to estimate the potential market size, epidemiological impacts, and cost savings to funders and patients if DDMs are scaled up or introduced in the country for the period of 2020-2024.

Context

Currently, no DDMs have been consistently implemented in Zimbabwe. As the government of Zimbabwe and donors consider the possibility of introducing and then scaling up a community pharmacy model, it is important to know the potential market size, epidemiological impacts, and potential cost savings to funders and patients under different scale-up scenarios.

Assumptions

Two scenarios have been defined: a baseline scenario, under which no DDMs are in place, and a community pharmacy scale-up scenario, which assumes community pharmacies providing ARV dispensing services would gradually increase over the next five years and that ART patients in Bulawayo, Harare, Kwekwe, Gweru, and Mangwe would have access to community pharmacies by 2024.

The overall estimation relied on data inputs from the 2019 Zimbabwe AIM file, Zimbabwe COP19 and PEPFAR program data, costing studies from similar countries, 2015 Demographic and Health Survey, and other sources. Preliminary assumptions were made regarding potential final prices to the clients for HIV care or commodities

per year under each model,⁴ and also regarding what proportion of their household income patients would be able to allocate in order to pay for switching to a DDM. Table 3 displays some of the HIV epidemiological impact estimates produced by the model from 2020 to 2024 under both scenarios. Finally, the modelling also assumes that 50% of those patients eligible to switch to a DDM, and with the ability to pay to do so, would switch to a DDM.

Findings

Potential market size

Under the community pharmacy scale-up scenario, the model predicts that 130,875 ART patients would be enrolled in the community pharmacy model by the year 2024 based on eligibility criteria, geographical access, ability to pay, and an uptake rate of 50%. This represents about 10% of all people on ART ages 18 and older in 2024. See Table 4 and Figure 14 for anticipated enrollment for 2020-2024.

Epidemiological impact

Table 3 displays the epidemiological estimates for both scenarios for the five-year period. Since Zimbabwe has already achieved a high rate for retention of patients in HIV care, currently estimated at 93% in 2019, scaling up the community pharmacy model will have minimal impact on improving LTFU rates and ART coverage. Still, the model predicts minor improvements in retention in care under the DDM scenario, resulting in slightly fewer new infections and AIDS-related deaths from 2020 to 2024.

Cost savings

Scaling up the community pharmacy model reduces the public sector resource requirements for HIV and allows for some cost-sharing with ART patients. Through the reduction in the number of patients receiving ARVs in the public sector, the Government of Zimbabwe and PEPFAR would save an estimated \$0.4 million and \$0.8 million, respectively, in costs associated with public facility health worker time and facility overhead from 2020 to 2024 (Table 5). Cost savings are relatively modest because the government and donors are still expected to pay for ARVs and public facility clinical visits, which are the biggest ART cost drivers

Although cost savings to the government and donors are modest, the model predicts that ART patients will experience significant cost savings through the reduction of lost wages by switching to the community pharmacy model (Table 6). From 2020 to 2024, ART patients are expected to save \$11.7 million in lost wages and \$1.9 million in transportation costs under DDM scenario. However, the model predicts that these cost savings would be partially offset by the introduction of dispensing fees to partially cover the cost to the private provider. Net cost savings to patients therefore are estimated to be \$12.4 million. If final prices to the patients at point of care were higher, cost savings to the government and PEPFAR would be higher as well, but cost savings to ART patients would be lower.

In sum, the model predicts that introducing and scaling up a community pharmacy model in Zimbabwe would have minimal impacts on epidemiological outcomes and cost savings to the government and PEPFAR. However, from a client-centered care and cost perspective, there are significant benefits. Patient cost savings from 2020 to 2024 will be more than ten times the size of estimated cost savings from the government or PEPFAR. Greater levels of price subsidization and increased patient WTP can positively impact enrollment levels which, in turn, would increase the overall net savings for the government and PEPFAR, when more patients enroll this new model. In addition, if the model is implemented in areas where retention is low, or targeted at some populations with low retention, the cost savings could be substantial at a subnational level.

⁴The modeling assumes that patients would pay a \$1 dispensing fee for each pick-up and that patients will make three pick-up visits at a private pharmacy in a year and one pickup will remain at the public facility. By 2024, the model assumes that half of ART patients would make two pick-up visits per year and half would make four pick-up visits per year, with one pick-up always at a public facility

FIGURE 14. Number of ART patients enrolled in the community pharmacy model annually

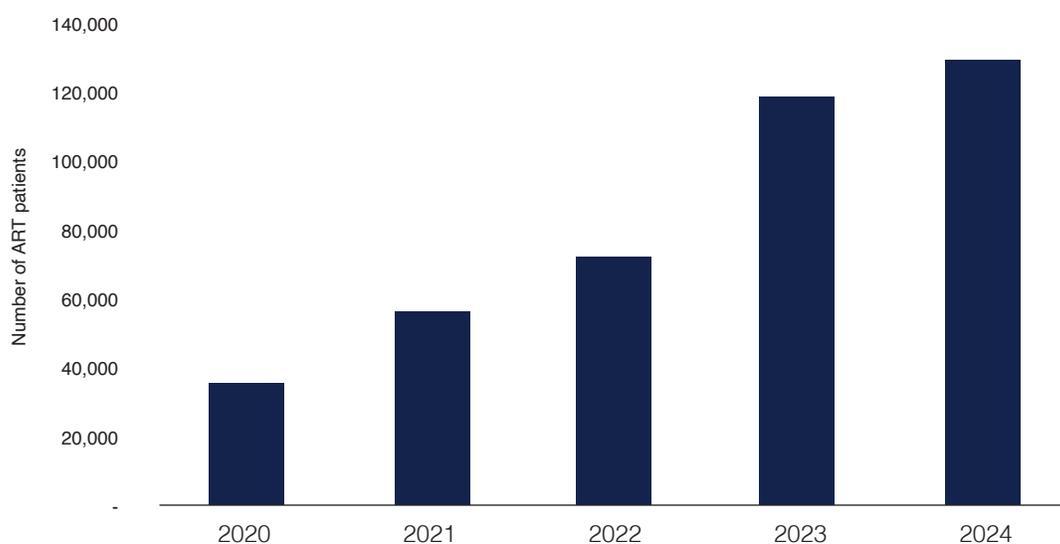


TABLE 3. HIV-related estimates; baseline and DD scale-up scenarios

| BASELINE SCENARIO | 2020 | 2021 | 2022 | 2023 | 2024 |
|-----------------------------|-------------|-------------|-------------|-------------|-------------|
| Adult HIV patients on ART | 987,802 | 990,156 | 1,016,873 | 1,039,404 | 1,068,551 |
| ART coverage (%) | 81.3% | 80.8% | 82.2% | 83.3% | 84.8% |
| ART patients LTFU | 69,146 | 69,311 | 71,181 | 72,758 | 74,799 |
| New HIV infections | 38,474 | 37,750 | 37,533 | 37,292 | 37,004 |
| AIDS-related deaths | 23,149 | 23,971 | 23,584 | 22,920 | 22,446 |
| DD SCALE-UP SCENARIO | 2020 | 2021 | 2022 | 2023 | 2024 |
| Adult HIV patients on ART | 989,575 | 992,972 | 1,020,517 | 1,045,393 | 1,075,095 |
| ART coverage (%) | 81.5% | 81.0% | 82.5% | 83.8% | 85.3% |
| ART patients LTFU | 67,498 | 66,692 | 67,792 | 67,189 | 68,713 |
| New HIV infections | 38,465 | 37,738 | 37,525 | 37,287 | 36,998 |
| AIDS-related deaths | 22,705 | 23,240 | 22,803 | 22,220 | 21,777 |

TABLE 4. Estimated DD-eligible patients and enrollment, by scenario

| BASELINE SCENARIO | | 2020 | 2021 | 2022 | 2023 | 2024 |
|---------------------------------------|--------------------------|-------------|-------------|-------------|-------------|-------------|
| DD model-eligible patients | | 929,122 | 937,293 | 945,898 | 954,754 | 964,333 |
| Anticipated enrollment into the model | Public | 1,214,539 | 1,225,220 | 1,236,468 | 1,248,045 | 1,260,566 |
| | Community pharmacy model | 0 | 0 | 0 | 0 | 0 |
| DD SCALE-UP SCENARIO | | 2020 | 2021 | 2022 | 2023 | 2024 |
| DD model-eligible patients | | 929,122 | 937,293 | 945,898 | 954,754 | 964,333 |
| Anticipated enrollment per model | Public | 954,121 | 936,651 | 947,627 | 925,628 | 944,220 |
| | Community pharmacy model | 35,454 | 56,321 | 72,890 | 119,764 | 130,875 |

TABLE 5. Total costs and savings to funders (US\$ millions)

| MODEL | TOTAL COSTS | COSTS TO GOVERNMENT | COSTS TO PEPFAR |
|-------------------|--------------------|----------------------------|------------------------|
| Baseline costs | \$580.6 | \$117.8 | \$139.3 |
| DD scale-up costs | \$580.3 | \$117.4 | \$138.5 |
| Savings | \$0.3 | \$0.4 | \$0.8 |

TABLE 6. Cost savings to patients (US\$ millions)

| MODEL | DISPENSING FEE | TRANSPORTATION COSTS | LOST WAGES |
|-------------------|-----------------------|-----------------------------|-------------------|
| Baseline costs | \$0 | \$63.3 | \$270.3 |
| DD scale-up costs | \$1.1 | \$61.4 | \$258.6 |
| Savings | -\$1.1 | \$1.9* | \$11.7 |

* There are anticipated reductions in transportation costs to patients if they pick up drugs closer to home or close to the work place.

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