

Differentiated Care in Ethiopia

The way forward



ETHIOPIANS AND AMERICANS
IN PARTNERSHIP TO FIGHT HIV/AIDS

PEPFAR

March 2017

Table of contents

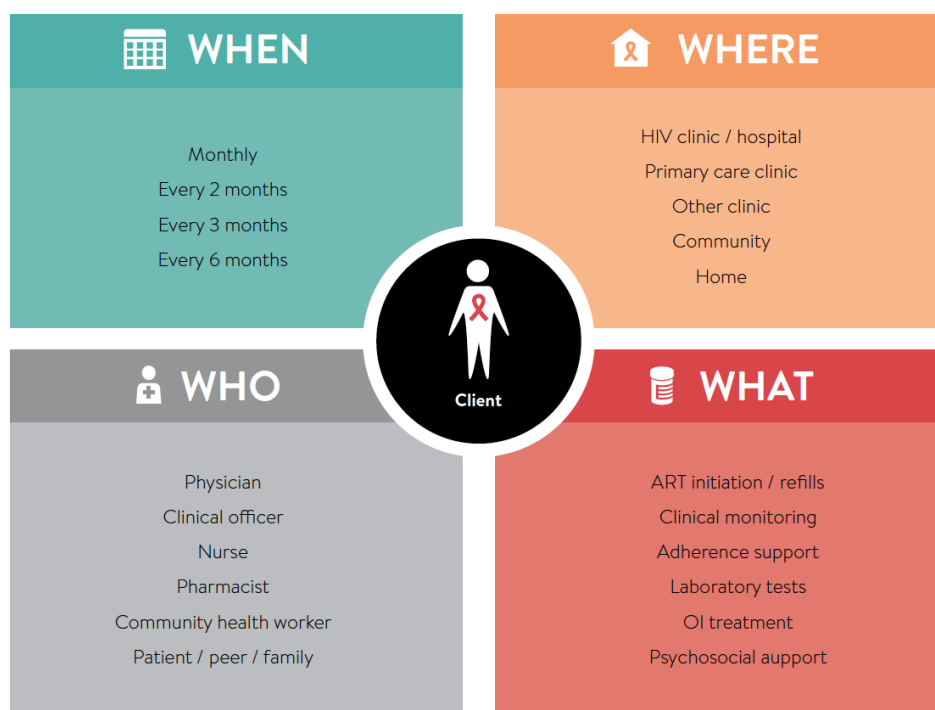
I. What is differentiated care?	2
WHO guidelines	2
Why do we need differentiated ART delivery?	3
Community engagement in differentiated ART delivery.....	4
II. Ethiopian context	5
National-level policies with WHO recommendations & current ART delivery	7
Current challenges in delivering ART in Ethiopia.....	8
III. Differentiated service delivery models	9
Key enablers	10
IV. Roadmap for Ethiopia	10
Engagement of national stakeholders	10
Phased scale up.....	11
Criteria for inclusion of clients in service delivery models in Ethiopia	12
Monitoring and evaluation	13
Next steps for developing differentiated models of care	13
Annex 1. Evidence base for facility-based individual models.....	16
Annex 2. Evidence base for out-of-facility individual models	18
Annex 3. Evidence base for healthcare worker-managed group models	20
Annex 4. Evidence base for client-managed group models.....	22
Annex 5. Template for assessing relevant policies related to differentiated ART delivery	24
Annex 6. Template for mapping common examples of differentiated ART delivery at a national level	25
REFERENCES	26

I. What is differentiated care?

Globally, 36.7 million people are living with HIV and 18.2 million people are receiving antiretroviral therapy (ART)¹. With the release of the World Health Organization (WHO) 2016 guidelines, the era of “treat all” HIV-positive individuals with ART is upon us². The recommendation is based on evidence that immediate ART reduces morbidity and mortality of people living with HIV (PLHIV); however, the expanded eligibility for treatment puts strain on health systems in challenging environments that lack human and financial resources. For this reason, we must re-examine how ART is traditionally delivered. Differentiated care provides a framework for this re-examination of service delivery models and how treatment is delivered to PLHIV. Differentiated care is a client-centred approach that simplifies and adapts HIV services across the cascade, in ways that both serve the needs of PLHIV better and reduce unnecessary burdens on the health system³.

The building blocks of differentiated service delivery centre on four questions: when, where, who and what. The building blocks are the key components of building a differentiated model of service delivery (Figure 1)⁴. How these components are combined into a service delivery framework will vary across countries and populations, but the common intention should be to improve acceptability and care outcomes.

Figure 1: The building blocks



WHO guidelines

It is understood that much of HIV service delivery is currently facility based and, in nearly all countries, the delivery of HIV care in the initial phase of rapid scale up has been based on a “one-size-fits-all”, clinic-based model, largely undifferentiated for individual needs^{5,6}. There is a growing cohort of clients who have been on treatment for several years. At the same time,

there is a need to expand timely access to ART for those who have yet to start treatment. During a consultation on care packages for PLHIV, WHO reviewed the growing diversity of client needs and assessed how programmes can treat and care for people differentially⁶. Broadly, four groups of clients with specific needs can be identified, as shown in Table 1.

Table 1: Diversity of care needs for people living with HIV²

People living with HIV	Care package elements
People presenting when well	Adherence and retention support
People with advanced disease	Clinical package to reduce mortality and morbidity
Stable individuals	Reduced frequency of clinic visits and community ART delivery models
Unstable individuals	Adherence support, viral load testing, switch to second- or third-line ART if indicated, monitoring for HIV drug resistance

Why do we need differentiated ART delivery?

ART has transformed HIV infection from a progressive, typically fatal infection to a chronic disease that persists for many decades. To accommodate the growing number of stable individuals on ART and improve health outcomes, differentiated models of ARV delivery have been developed. Most include engagement or increased involvement of the community.

Generally, the benefits of differentiated ART service delivery can be summarized as:

1. Improving clients' lives

Differentiated ART delivery can improve the quality of care and access to treatment for PLHIV. It can serve to better reach underserved populations and to address issues surrounding stigma and discrimination that many PLHIV face when accessing HIV services. Differentiated ART delivery is responsive to the individual needs of PLHIV and often results in better adherence, client satisfaction and client empowerment².

2. Improving health system efficiencies and outcomes

Supporting clients in initiating ART is critical, but retention in care and adherence to effective treatments is required to achieve viral suppression. Retention data from many countries demonstrate that ART programmes globally face substantial challenges in maintaining clients on ART with viral suppression^{7,8}.

Data from sites where differentiated ART delivery has been adopted highlight that such interventions can be part of improving retention and adherence, and of achieving the second and third 90 outlined in the Joint United Nations Programme on HIV/AIDS (UNAIDS) global 90-90-90 targets^{9,10}. When ART was first provided in resource-limited settings, the majority of clients were treatment naïve and presented with advanced disease, and treatment was delivered in the same way for all clients, regardless of existing co-morbidities or other medical needs.

3. Supporting “treat all”

Worldwide, 36.7 million people are living with HIV and 18.2 million people are receiving ART. With the implementation of the WHO 2016 recommendation to “treat all” HIV-positive individuals with ART, health systems, often already under extreme pressure due to lack of human and financial resources should re-examine how ART care is delivered.

4. Reaching 90-90-90

Although there are 18.2 million people on treatment, treatment coverage is still below 50%⁹. Clients who are not currently on treatment need to access ART within a service delivery model that meets their needs and expectations.

Further, the healthcare system must rapidly scale up the number of clients on ART. As highlighted within the most recent WHO guidelines, different packages of care are essential to address these diverse needs – it’s time to deliver differently.

Community engagement in differentiated ART delivery

An estimated 95% of HIV service delivery is currently facility based. Much greater emphasis on community engagement will be needed to ensure equitable access to HIV services in this climate of declining resources. In order to optimize efficiencies, UNAIDS projects that community-based service delivery will have to be ramped up to cover at least 30% of total service delivery. Not only will community-based service delivery reduce costs, but bringing services closer to the people who need them will also improve service uptake.

Effective differentiated HIV treatment delivery relieves the burden on health systems and providers by making people full partners in their own care and management, and has increased rates of service retention and treatment adherence¹¹. Table 2 shows a summary of strategies for differentiated service delivery models.

Table 2: Summary of strategies for differentiated delivery of ART*

Key objective	Appointment spacing and fast-track ARV refill	At enrolment into care		Community ART distribution points	Community ART groups
		Facility-based clubs	Community-based clubs		
Patient perspective					
Reduce costs (time and transport)	Yes	Yes	Yes	Yes	Yes
Increase peer support	No	Yes	Yes	Yes	Yes
Enhance community participation	No	Potentially	Potentially	Potentially	Yes
Health-care perspective					
Reduce workload					
Nurse	Yes	Yes	Yes	Yes	Yes
Pharmacist	Yes	Yes	No	Yes	Yes
Counsellor/health-care worker/peer supporter	N/A	No	No	No	No
Maintain and improve health care					
Retention	Yes	Yes	Yes	Yes	Yes
Improve self-management of patients	Yes	Yes	Yes	Yes	Yes

*Adapted from 2016 WHO consolidated guidelines

II. Ethiopian context

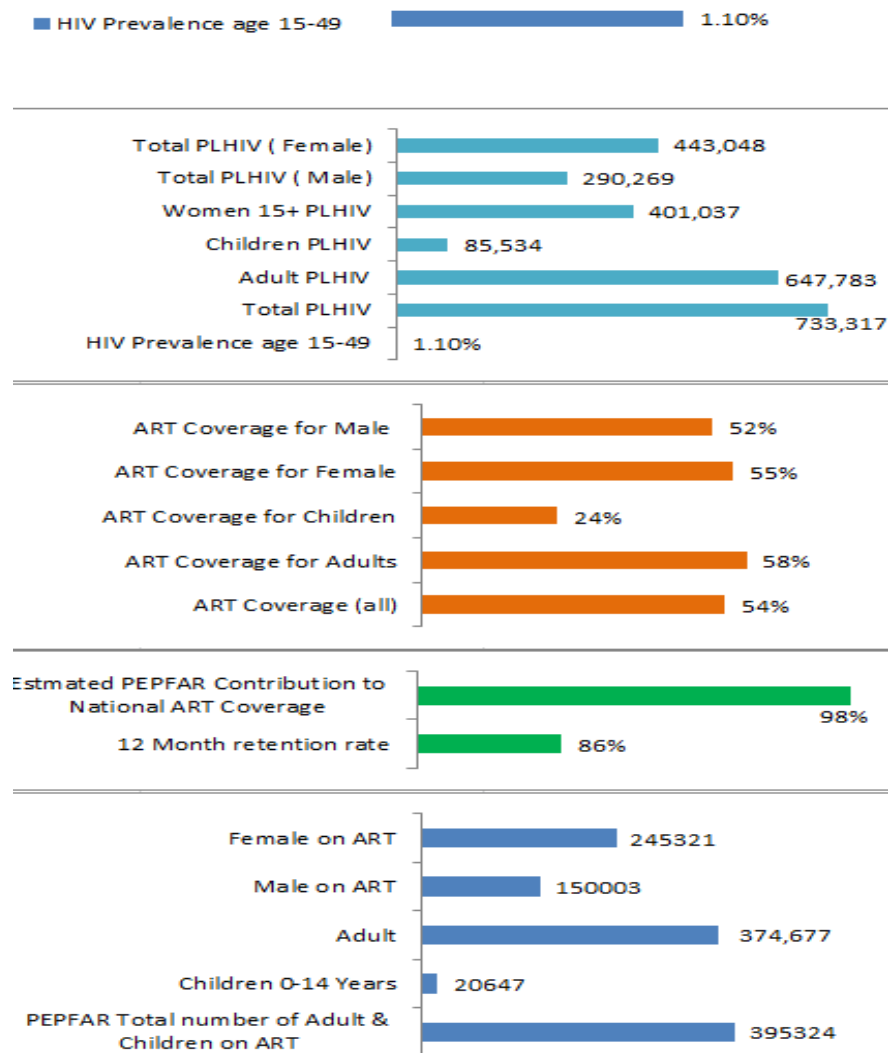
Ethiopia has implemented decentralization of services and task shifting of ART delivery consistent with the WHO 2013 recommendations. In the current ART service delivery model in Ethiopia, ART service provision has been decentralized from hospitals to health facilities, and physicians, health officers and nurses provide ART initiation and refill. ART refill and clinical assessment is done in a health facility every month until at least seven months after initiation of ART. Thereafter, the healthcare provider assesses the general health and adherence status of the patient and may prescribe ARVs for up to three months. However, the average ARV refill is every one to 1.5 months. This makes the current Ethiopia HIV ARV treatment model entirely facility based. There is no differentiated care, as defined by the WHO 2016 recommendation.

The Federal Ministry of Health (FMOH) recently established a subgroup composed of in-country stakeholders and partners tasked to develop the scope of work for piloting appointment spacing for ART refill and clinical follow up in three selected high-burden hospitals. As part of the monitoring and evaluation of this pilot, the cost of implementing such a model will also be assessed. The FMOH decided that piloting other differentiated service models (e.g., CAG, CAC and community ART distribution point) should be put on hold. In the meantime, the FMOH accepted that stakeholders engage in the development of a discussion paper, which will serve as a basis for further discussion, engagement and subsequent consultative meeting among multiple stakeholders before considering piloting additional models.

There is a need to gain an understanding of the cost for implementing differentiated service delivery models in this context. With the ART Delivery Optimized Tool (A DOT) prepared by the US President's Emergency Plan for AIDS Relief (PEPFAR) interagency team, we compare the cost of implementing Test and Start in the current facility-based service delivery (with appointment spacing for ARV refill and clinical services every 1-2 months) versus optimized service delivery (with appointment spacing of six months). Applying this tool shows that implementing the latter provides an overall cost saving of about 20%.

There are some limitations to the A DOT. The cost of service delivery at the health facility does not include host government service delivery costs, such as salaries for healthcare providers. Furthermore, additional costs that are expected to be incurred during the operationalization/implementation of the new differentiated service delivery model are not included. A DOT has not included the differentiated community service delivery model components.

Figure 2: PEPFAR 2016 annual programme review for Ethiopia



*PLHIV burden is based on SPECTRUM 2015

*ART coverage is from APR 2016 data

Based on SPECTRUM 2015, an estimated 733,317 people were living with HIV in Ethiopia in 2016. The Federal HIV/AIDS Prevention and Control Office also reported (at its Joint Review Meeting in Hawassa in November 2016) that about 60% (439,990) of PLHIV know their status. This means that 293,327 PLHIV do not know their status. According to data from PEPFAR Annual Program Review (APR) for 2016, a total of 395,324 PLHIV are currently on ART, which is 54% of the total number of PLHIV (395,324/733,317).

To meet the second 90 target in 90-90-90 (getting 90% of PLHIV onto treatment), 659,995 people would have to be on treatment. Currently, 395,324 PLHIV are on ART, which is about 59.9% of the target (395,324/659,995). It could be said that Ethiopia, in its current situation, is 60% of the way towards meeting the first 90 target and 59.9% towards meeting the second by 2020.

National-level policies with WHO recommendations & current ART delivery

In 2008, WHO, in collaboration with PEPFAR and UNAIDS, published global recommendations and guidelines for task shifting in the context of HIV service delivery, drawing on extensive evidence, including specially commissioned research¹². At the International Conference on Task Shifting in Addis Ababa, Ethiopia, in January 2008, participants adopted a declaration that calls for using task shifting to promote the reorganization and decentralization of health service delivery¹³.

Task shifting of ART services allows health officers and nurses to prescribe and refill ART drugs. Lay counsellors also provide HIV testing and counselling. The government of Ethiopia also recognized the importance of a formalized community health worker cadre as a source of primary healthcare for the population. This led to the introduction of government-employed cadres developed under the Health Extension Program (HEP) and later the Urban Health Extension Program. The Health Extension Worker (HEW) and Health Diagnostics Assistant (HDA), working in collaboration with PLHIV volunteers, conduct community outreach to identify and link PLHIV and their families to community resources and services. These services complement clinical HIV care and treatment interventions and support retention in care and ART adherence, and improve quality of life.

Ethiopia has already adopted major strategies of WHO guidance for ART treatment and scale up. ART delivery has been decentralized from high-burden hospitals to health centres. Currently, there are about 1,117 health facilities, hospitals and health centres providing ART services¹⁴. Both ART drug refill and clinical follow up, including laboratory investigation, take place at the ART health facilities and are carried out by healthcare providers. Case managers, who are trained lay workers and most of whom are PLHIV, provide adherence and psychosocial services at these ART health facilities. However, there are still many hospitals and health centres found in major towns that have high client load, overburdening the health facilities and healthcare providers. In addition, these obligations often overburden the HEW and HDA, whose main role is to serve as a source of primary healthcare for the population.

Ethiopia has adopted the new 2016 WHO guidelines, and developed a supplemental guide to implement Test and Start as of October 2017. This means that all HIV clients will start ART at the time of diagnosis, irrespective of their CD4 count status. This is likely to have immediate impact on the second and third 90s as a result of the planned “catch-up” campaign this has been launched and the intention is to test about 2.5 million people and identify 80,230 new PLHIV in 11 months.

In order to maximize the individual- and population-level benefits of HIV treatment, it is essential that people on ART are retained in care and properly adhere to the treatment. It will therefore be essential to engage PLHIV in determining the optimal model of care to meet their needs. Furthermore, in order to overcome challenges of continued scale up, community-based strategies that reduce the burden on health systems and PLHIV and that improve quality of care and retention for those on ART are needed. Strategies with models that take services outside of the health facility and closer to the home, especially for stable clients, should be considered.

To assess the policy barriers and enablers to supporting the implementation of differentiated ART delivery, a series of policy questions related to the *when, where, who* and *what* of service delivery should be assessed (see Annex 5).

Current challenges in delivering ART in Ethiopia

There is an acute shortage of healthcare workers in low- and middle-income countries. According to WHO and the Global Health Workforce Alliance, 83 countries (including Ethiopia) fall below the minimum density threshold of 22.8 skilled health professionals for every 10,000 people¹⁵. The persistent shortage of healthcare workers represents one of the greatest obstacles to achieving the 90-90-90 targets. The Test and Start strategy will render all newly diagnosed and pre-ART HIV clients eligible for treatment right away. Many health facilities are already overburdened, and service delivery models must respond to the ever-increasing number of people on ART.

Ethiopia has recently started community-based health insurance schemes that will allow the poor to have access to health services at public health facilities. This will further contribute to overburdening of health facilities and healthcare providers for other (non-ART) services, and will ultimately impact the quality of ART and other chronic care services¹⁶.

According to the country's new strategic plan, which covers the period, 2015-2020, the country has set targets to be reached through targeted HIV strategies and interventions, envisioned to end AIDS by 2030. Furthermore, the FMOH devised the "catch-up" campaign to expedite the implementation of an investment case, ensure reaching the three UNAIDS 90 targets, and then sustain the momentum and gains of the campaign afterwards. Ethiopia aims to increase the cumulative number of people currently on ART.

Following the campaign, the country intends to provide HIV testing and counselling to an additional 2,432,196 clients and find an additional 60,135 new HIV-positive clients within a six-month period. Overall, through the nine months of the "catch-up" campaign and through the post-campaign phases (7 August 2016 to 12 June 2017), a total of 130,560 new HIV-positive clients are expected to be enrolled on ART. Consistent with the Test and Treat All approach, which the country adopted as of 30 September 2016, the total number of clients currently on ART will increase from the current figure of 391,844 to 522,408 (an increase of 33%). As a result of this effort, it is anticipated that health facilities and healthcare providers will be overburdened by this rapid influx of clients, potentially compromising ART outcomes, such as adherence and retention. Thus, it is a critical time to promptly pilot and scale up the appropriate mix of the new ART service delivery models.

Viral load measurement was used to identify suspected treatment failure cases. Subsequently, Ethiopia has established a task force and developed a routine viral load scale up and implementation plan. Accordingly in 2016, the plan was that 65% of clients on ART will have their viral load measured. The expectation was that this percentage will progressively increase in subsequent years. However, implementation is lagging far behind the target and must be expedited in order to reach the desired target of the routine viral load implementation plan.

III. Differentiated service delivery models

As HIV programmes in resource-limited settings have grown, the number of facilities providing care has increased dramatically. In addition to this decentralization, ART delivery has increasingly utilized task shifting. Several implementing organizations – notably Médecins Sans Frontières (MSF) and health ministries – have been pioneers in developing these models. More recent innovations in ART delivery, or differentiated models of ART delivery for stable clients, can be categorized into four models:

1. In **facility-based individual models**, ART refill visits have been separated from clinical consultations. When clients have an ART refill visit, they bypass any clinical staff or adherence support and proceed directly to receive their medication (e.g., appointment spacing and “fast-track” ART refill model from Malawi).
2. **Out-of-facility individual models** describe those where ART refills and, in some cases, clinical consultations are provided to individuals outside of healthcare facilities (e.g., PODI model in DRC, CDDPs in Uganda). These models are inclusive of community pharmacies, outreach models and home delivery.
3. In **healthcare worker-managed group models**, clients receive their ART refills in a group, and either a professional or a lay healthcare staff member manages this group (e.g., adherence clubs in South Africa, teen clubs in Swaziland, MACs in Kenya). Healthcare worker-managed groups meet within and/or outside of healthcare facilities.
4. In **client-managed group models**, clients receive their ART refills in a group, and the clients themselves manage and run the group (e.g., CARGs in Zimbabwe and CAGs in Mozambique). Generally, client-managed groups meet outside of healthcare facilities.

Within these models, all clients continue to have clinical consultations as part of their package of care. Multiple models can work in parallel so that a client can move between them during the course of their lifetime. Further, the models are flexible to accommodate clients who may want to or require up referral. By being up referred, the intensity of care is increased to reflect the clinical needs of the client.

Outcomes have been reported for four countries in sub-Saharan Africa and the impact assessed through routine programme data¹⁷. These models have been introduced and implemented in other countries; all these approaches were found to reduce the burden for clients (reduced time and cost of travel to clinic and less income loss) and the health system (reduced clinic attendance), while maintaining high retention in care (more than 90% retained in care across multiple time points). A summary of the evidence base for each model is provided in Annexes 1-4.

Most differentiated ART delivery models, however, demonstrate:

- Reduced burdens for clients and the health system
- Increased retention in care
- Lower service provider costs.

More importantly, models of care must be relevant, appropriate and responsive to the needs of people living with HIV.

No single approach exists for differentiated ART delivery, and different approaches have been developed in sub-Saharan Africa. Models must be adapted to their contexts in recognition of several factors, such as barriers to access and retention in care, the extent of service decentralization and task shifting, the availability of safe and simple ART regimens, health service capacity, and regulatory or logistical constraints on ART delivery.

Following evidence from implementers, differentiated models of ART delivery have been incorporated into national guidelines in Zimbabwe, Swaziland, South Africa and Kenya.

Key enablers

The success of differentiated care models in delivering ART is dependent on sufficient, reliable support and resources, including a cadre of trained lay workers, a flexible and reliable medication supply access to quality clinical management and a reliable monitoring system for comprehensive client care. The models also require ongoing evaluation and further adaptation in order to address gaps, such as reaching clients who are at high risk of loss to follow up. Improving access to health services, including ART, and support for retention in care is enhanced by decongestion of high-volume clinics. This takes place through decentralization of services to, for example, community service outlets, and through task shifting beyond nurse-initiated management of ART (NIMART) by deploying community cadres such as community health workers, peer educators and PLHIV. Adherence is also improved by decreasing client time, cost and visits, and this takes place by expanding access to health services through community outlets and through use of community cadres and resources. Peer support through peer and/or PLHIV networks that invest in management of their own care reduces stigma. A social fabric is created through community mobilization, which is not the case with individual care.

IV. Roadmap for Ethiopia

Engagement of national stakeholders

Adopting these models and taking them to scale requires strong commitment and leadership from national ministries of health and other stakeholders, including the donor community and implementing partners; it also needs the engagement of the community, including PLHIV, to ensure accountability and local adaptation.

Prior to implementation of any of these models, a formal consultation process should occur at the national and district levels with healthcare providers, networks of people living with HIV and community representatives. This will help determine which refill strategy is the best fit for the given context. Ensuring adequate training and ongoing monitoring and supervision from district health teams will also be essential for a successful scale up.

Community stakeholders should be consulted in the planning and implementation of community-based models. Early experience shows that collaboration with local networks of people living with HIV has the potential to stimulate increased demand for accountability from the health system through a so-called watchdog role that monitors medication stock-outs or other breakdowns in the quality of client care. This is one reason why the current trend of reduced funding from international partners for these networks is a concern; with adequate funding for civil society, including networks of PLHIV, community-based models can potentially enable community engagement and participation in accountability within the scale up of the HIV response. It is essential to engage PLHIV in determining optimal models of care¹⁸.

In each of these models, community members are involved in key tasks that support the establishment, training, monitoring and facilitation of peer groups. They also perform some basic clinical responsibilities (such as providing symptom-based general health assessments).

A critical challenge in many countries is the lack of a framework to support lay or basic trained workers as part of the overall health service; remuneration, retention packages and adequate supervision are often lacking^{19,20}. A major stumbling block for ministries of health is the unwillingness to include a new group in their budgets while existing ones are facing difficulties with remuneration and retention. Given the precedent for such lay support in other areas of healthcare, such restrictions should be lifted²¹. These areas include the model of community case management of malaria and WHO's recent recommendation that trained and supervised community healthcare workers dispense ART between regular clinic visits.

Phased scale up

In each of the sub-Saharan countries where different models have been explored, relevant stakeholders discussed the epidemiology and context (such as the level of decentralization and task-shifting policies and the prevalence and nature of the epidemic) through consultative meetings. The appropriate model was identified and piloted before scaled-up implementation of the suitable mix of models.

There is no "one size fits all" strategy to reduce the burden for both healthcare workers and clients when providing HIV care for an increasing number of people. Choosing the most appropriate mix of models (facility and community) will be context specific and depend on a range of factors (Figure 3).

Figure 3: Factors to consider in adopting service delivery models



Table 3: Criteria for inclusion of clients in service delivery models in Ethiopia*

Service Delivery Approach	Current Status	COP17 Proposed Approach
Eligibility for ART	Test & Start	Test & Start
ART initiation	Test and Start with initiation of ART as soon as the patient is ready	Same day ART initiation for those who are ready
Service delivery approach: PEPFAR Ethiopia is planning to start the implementation of new service delivery models for stable patients in high volume ART sites (defined as those sites with high client volume)	Clinic visit with drug pick for stable patients: every 01 to 03 months Appointment spacing every 6 months for stable patients is being piloted in 6 high case-load health facilities	Roll-out appointment spacing (every 6 months) for stable patients to other high case load facilities in 20 towns and other scale-up SNU. Pilot other community ART models
Definition of Stable Patients	<p><u>Inclusion criteria</u></p> <ol style="list-style-type: none"> 1. On ART for at least 12 months 2. Most recent VL < 1,000 or 3. In the absence of VL, CD4 count should be > 200 <p><u>Exclusion criteria</u></p> <ol style="list-style-type: none"> 1. Second line treatment 2. HIV positive pregnant and breastfeeding women 3. Children < 15 years of age. 4. Presence of current illness (including OI, severe malnutrition and comorbidities) 	<p><u>Inclusion criteria</u></p> <ol style="list-style-type: none"> 1. On ART for at least 12 months 2. Most recent VL < 1,000 or 3. In the absence of VL, CD4 count should be > 200 <p><u>Exclusion criteria</u></p> <ol style="list-style-type: none"> 1. Second line treatment 2. HIV positive pregnant and breastfeeding women 3. Presence of current illness (including OI, severe malnutrition and comorbidities)
Laboratory testing	<p>CD4 count: baseline (If possible) and to make decision on CPT discontinuation and initiation of NVP based regimen</p> <p>VL: at 6 months following initiation of ART, 12 months and then yearly</p> <p>Other laboratory services: need based (including pregnancy testing and RFT)</p>	<p>CD4 count: baseline (If possible) and to make decision on CPT discontinuation and initiation of NVP based regimen</p> <p>VL: at 6 months following initiation of ART, 12 months and then yearly</p> <p>Other laboratory services: need based (including pregnancy testing and RFT)</p>

*PEPFAR COP 17 Strategic Direction Summary

Monitoring and evaluation

Reliable monitoring system: Monitoring and evaluation (M&E) are essential parts of the implementation of any community model. Accountability for client clinical management, antiretroviral therapy management and adherence support must be preserved while maintaining the capacity to provide troubleshooting for inevitable problems.

Key indicators: To ensure programme accountability, a number of indicators should be followed at the clinic level. These include client attendance at the medication distribution points and the receipt of medications. Routine electronic simplified monitoring systems can help track these key indicators, potentially supported by mHealth.

VL monitoring: Proper and timely evaluation of the adherence status of clients using viral load (VL) is important in the context of implementing a differentiated service delivery model, where the frequency of clinical consultations by facility-based healthcare providers is reduced by allowing the acquisition of medication for longer periods. The level of client adherence to treatment is evaluated reliably through viral load measurement. Clients accessing ART through community-based services will need to be referred to the facility for routine monitoring, including CD4 or VL services.

Next steps for developing differentiated models of care²²

There are five steps to consider in developing differentiated models of care.

Step 1: Assess ART data, delivery and policies

- Assess the data for understanding what is currently happening in terms of client outcomes and how ART services are currently being provided for healthcare worker and client perspectives.
- Undertake an initial broad mapping of differentiated ART delivery to determine what is being implemented in country and the coverage of the intervention – what proportion of health facilities are providing that intervention.
- The mapping may be carried out through a desk review of published literature, local country and partner activity reports, and a survey of district ART coordinators and implementing partners.
- Assess the policies by comparing national level policies with current WHO recommendations.
Policies should be reviewed in alignment with the building blocks, as well as for integration.
 - When – frequency of clinical and refill visits
 - Where – decentralization
 - Who – task shifting and sharing, who can collect ART (client vs. buddy)
 - What – services provided
 - How – integration of HIV and TB services, etc.

Step 2: Define challenges

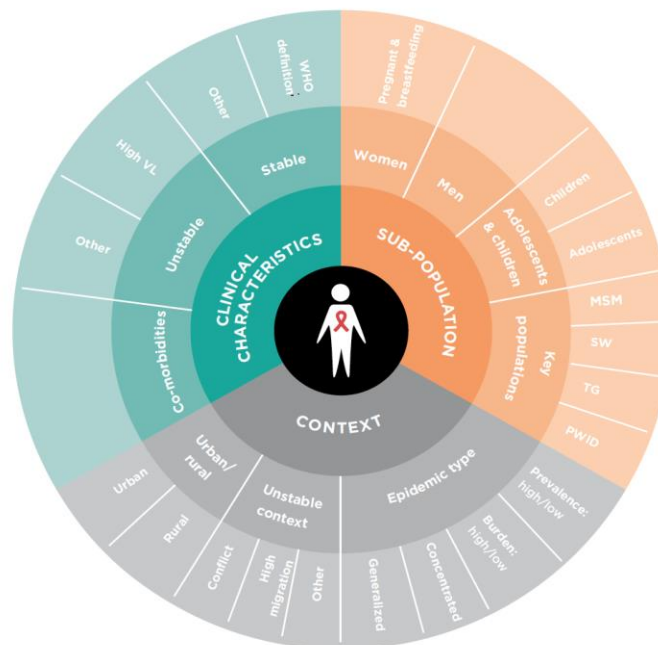
Host a workshop and engage key stakeholders from both the health system and civil society to sensitize ART coordinators and implementing partners on the background and core principles of differentiated ART delivery. Present the outcomes of the national level desk review while providing an opportunity for stakeholders to present existing examples of differentiated care

implemented in their settings. The stakeholders should also be engaged in a plan for local/district situation analysis.

Step 3: Define for whom ART delivery will be differentiated

With a clear understanding of the data, current delivery programme and policies in place, proceed with prioritizing differentiated ART delivery, the challenges of clients and the health system. Based on the challenges, prioritize who ART delivery should be differentiated for. Utilize the three elements in Figure 4 to define who the differentiated model will be for, considering the clinical characteristics, subpopulation and context (Figure 4).

Figure 4: The three elements



Step 4: Build a model of differentiated ART delivery

Once it is defined who is eligible, one can proceed with defining a model of differentiated ART delivery. It is recommended to first define differentiated ART refills, and thereafter, determine the model for clinical consultations and location.

Step 5: Consider additional adaptations that can be made to further differentiate ART delivery

Repeat the same steps for additional populations. While doing so, discuss at a district and/or facility level the specific model mechanics (i.e., criteria for up referral, relevant adaptations to M&E materials, etc).

Step 6: Implementation of model of differentiated ART delivery

Implement developed model/s through pilot programmes or phased approach in selected regions and selected sites. Scale up will be based on experiences and lessons from pilot programmes.

It is important to plan for evaluation of models to learn lessons for quality improvement and to guide scale up. A similar consultative approach as in selecting models can be used to plan and develop questions for the evaluation.

Way forward: It is vital that key stakeholders, most importantly PLHIV, are involved in the decision-making process in choosing the right approach for differentiated care in Ethiopia. The PEPFAR team will host a workshop in March 2017 to present on current differentiated service delivery models that are working in Ethiopia, engage stakeholders on a local/district situational analysis, review the current body of evidence, and have consensus on a way forward for a community-based approach to differentiated care (see Annex 5 and 6).

Acknowledgments: The PEPFAR Ethiopia team acknowledges stakeholders, including the Federal Ministry of Health (FMoH), HIV/AIDS Prevention and Control Office (HAPCO), and Network of Networks of HIV Positives in Ethiopia (NEP+), for their support in development of this concept note. Support for editing and distribution was provided by the International AIDS Society (IAS). Special recognition to Anna Grimsrud (IAS), Dr Meena Srivastava (USAID), Dr Afework Negash (USAID), Dr Ilana Lapidus-Salaiz (USAID), Dr Tekelu Weldegebreal (USAID), Sophia Brewer (USAID), Dr Abubakar Bedri (CDC), Dr Ishani Pathmanathan (CDC) and Dr Isaac Zulu (CDC) for providing significant technical review and input.

Annex 1. Evidence base for facility-based individual models

Also known as “fast track”, appointment spacing, multi-month prescription, quick pick up, pharmacy refill only and fast track wing.

OVERVIEW

Individuals who are stable ART clients are assessed and enrolled in the facility fast-track system. In this model, clinical assessments are carried out once or twice a year. In the interim, clients collect medication directly from the facility pharmacy or dispensing room, using a repeat script prescribed during their clinical visits. The limited evidence for facility-based individual models suggests increased cost effectiveness for the health system, improved quality of care and client outcomes, and reduction in client time spent accessing healthcare.

Table 4: Summary of evidence for facility-based individual models

Location	Model	Description	Outcomes
Uganda N=829 ²³	Pharmacy-only refill programme (PRP)	6-monthly clinical review, 2 month ART refills	<ul style="list-style-type: none"> More cost effective compared with standard of care (US\$520 vs. \$655 annually)
Uganda N=262 ²⁴	Fast-track system	6-monthly clinical visits, 2-monthly ART refills after seeing triage nurse	<ul style="list-style-type: none"> Median waiting time reduced from 102 to 20 min Increased patient/provider satisfaction
Uganda N=1,481 ²⁵	Refill pick-up system	6-monthly clinical review and ART refill 30-90 days at clinical discretion	<ul style="list-style-type: none"> Significant reductions in missed appointments (24.4% to 20.3%) Medication gaps ≥ 3 days reduced (20.2% to 18.4%)
Uganda and Kenya N=4,562 ²⁶	Nurse-driven triage for patient evaluation	3-month ART refills for stable patients with consolidation of services at encounter	<ul style="list-style-type: none"> Significant reductions in time spent at the health facility and away from work Out-of-pocket expenses reduced in Uganda but not in Kenya
Malawi N=3,819 ^{27,28}	Fast-track clinic system	6-monthly clinical review and 3-monthly ART refill from lay health workers. Known as 6-monthly appointment (SMA) strategy	<ul style="list-style-type: none"> 12-month retention 97%
Malawi N= 5,308 ²⁹	Fast-track clinic system	SMA strategy	<ul style="list-style-type: none"> 80.8% enrolled Median time from eligibility to enrolment = 6 months Probability of death or LTFU 5 years after SMA eligibility: <ul style="list-style-type: none"> 56.3% never enrolled in SMA 13.9% early SMA enrollees 8.1% late SMA enrollees Higher rate of death and LTFU during non-SMA vs. SMA periods
South Africa ³⁰	Separate clinic for stable patients	6-monthly clinical visits and 2-monthly ART refills	<ul style="list-style-type: none"> Reduced waiting times and missed appointments from 13.3% to 2.2%
Kenya and Uganda N=83 ³¹	Appointment spacing for children 2-14 years	3-monthly visits	<ul style="list-style-type: none"> 88% retention in care 92% VL suppression at 48 weeks

Evidence of the effectiveness of facility-based individual models has been reported from three studies in Uganda.

The first was a cost-effectiveness study conducted after implementing a pharmacy-only refill programme (PRP) (6-monthly clinical reviews and 2-monthly ART refills from the pharmacy). The PRP was less costly (US\$520 vs. \$655 annually) and more cost effective compared with the standard of care²³.

The second study assessed clinic efficiencies after implementation of a fast-track system (6-monthly clinical visits with 2-monthly ART refills after seeing a triage nurse). Median waiting time was reduced from 102 to 20 minutes, with increased client and provider satisfaction in the intervention group compared with the standard of care²⁴.

The third was a descriptive study after implementation of a refill pick-up system (6-monthly clinical review and ART refill 30-90 days at clinician discretion). There were significant reductions in missed appointments from 24.4% to 20.3% (AOR: 0.67; CI: 0.59-0.77) and medication gaps of three days or more from 20.2% to 18.4% (AOR: 0.69; CI: 0.60-0.79) in the intervention group compared with the standard of care²⁵.

Recent data from the SEARCH trial undertaken in Uganda and Kenya also show that streamlined care (nurse-driven triage for client evaluation, 3-month ART refills for stable clients, and consolidation of services at encounter) meant significant reductions in time spent at the health facility and away from work or other usual activities. Out-of-pocket expenses for clients from baseline to one year later were reduced in Uganda but not in Kenya²⁶.

There is increasing data reported from Malawi relating to an increasing cohort of stable clients enrolled in a fast-track clinic system (6-monthly clinical review and 3-monthly ART refills from lay healthcare workers) known as the six-monthly appointment (SMA) strategy. Initial 12-month retention outcomes reported among the 5,800 clients in the SMA model was 97% (95% CI: 96-97%)^{27,28}.

A more recent retrospective study that assessed all stable clients eligible for the SMA model between 2008 and 2015 (n=18,957) found 80.8% enrolled with median time from eligibility to enrolment of six months (IQR: 0-17 months). Cumulative probability of death or loss to follow up five years after first SMA eligibility was 56.3% (95% CI: 52.4-60.2%) among those never SMA enrolled; it was 13.9% (95% CI: 12.5-15.6%) among early SMA enrollees (within 6 months of eligibility) and 8.1% (95% CI: 7.2-9.0%) among late SMA enrollees (more than 6 months after eligibility). In addition, a significantly higher rate of death or loss to follow up (LTFU) was observed among clients during non-SMA periods compared with those during SMA periods (adjusted rate ratio: 1.87; 95% CI: 1.68-2.08, p<0.001)²⁹.

In South Africa, a study reported outcomes after implementing a separate clinic for stable clients (6-monthly clinical visit and 2-monthly ART refills from a pharmacy) to increase client throughput. It reported reducing waiting times and missed appointments from 13% to 2.2%³⁰.

Appointment spacing has been proven to have optimal outcomes in children, too. A study in 2016 reported on the feasibility and outcomes for Test and Start in children and adolescents aged 2-14 years in Kenya and Uganda with CD4 of 500³¹. The routine visit schedule was weeks 0, 4 and 12, and then every 12 weeks; stable adherent children were seen every 3 months thereafter. Outcomes showed 88% retention in care, and 92% of those tested had viral load suppression at 48 weeks.

Annex 2. Evidence base for out-of-facility individual models

Also known as mobile outreach, fixed community ART distribution points, community pharmacy, home delivery.

OVERVIEW

In these models, 1-3-monthly ART refills are distributed to stable clients outside of the health facility environment. ART refills are provided to clients either directly at their home by community health workers or collected by the client from a community pharmacy or at specific community locations operated either by community health workers or through a mobile outreach service operated from the facility or subdistrict health service. ART refills are usually separated from clinical follow up, which takes place 1-2 times annually at the facility.

Out-of-facility individual models vary according to where in the community the services are provided, as well as what services are delivered and by whom. They can be divided into three categories: fixed community points, mobile outreach ART delivery, and home delivery.

Table 5: Summary of evidence for out-of-facility individual models

Location	Model	Description	Outcomes
Uganda N=3,457 ^{32,33}	Community drug distribution point (CDDP)		<ul style="list-style-type: none"> ○ Cross-sectional outcomes, 2004-2009 ○ 69% retention, 17% mortality, 6% transferred out, 9% LTFU ○ LTFU 16.5% in facility and 4.28% in CDDP arm ○ VL suppression 93%
Malawi N=8,528 DRC N=1,935 South Africa N=2,829 Mozambique N=(multiple studies referenced) ³⁴	Community ART distribution points (PODI)	Different scaled-up ART delivery approaches for stable patients	<ul style="list-style-type: none"> ○ 94% retention at 36 months in Malawi ○ 89% retention at 12 months in DRC ○ 97% retention at 40 months in South Africa ○ 92% retention at 48 months in Mozambique
Swaziland N=471 ³⁵	Combination community ART care	Comprehensive care outreach (COC) – deployed	<ul style="list-style-type: none"> ○ COC retention 78.4% at 6 months
South Africa N=269 ³⁶	Mobile ART delivery	Comprehensive ART services (including ART refills) for HIV/TB+ workers provided by mobile outreach	<ul style="list-style-type: none"> ○ VL suppression 91.2% ○ Retention 93% at 6 months, 90% at 12 months
Uganda N=1,448 ³⁷	Home ART delivery	Assessment on whether home-based HIV care is as effective as facility-based care	<ul style="list-style-type: none"> ○ No difference in virological failure rates for home vs. facility care ○ Mortality rates similar ○ Health services and patient cost per year less for home delivery vs. facility (US\$793 vs. \$838 for health series and \$18 vs. \$54 for patient)
Kenya N=208 ³⁸	Home ART delivery	Assessing whether community-based care delivered by PLHIV could replace clinic-based HIV care	<ul style="list-style-type: none"> ○ No significant intervention-control differences found for detectable VL, mean CD4 count, change in ART regimen, new opportunistic infections or pregnancy rates ○ Intervention clients made half as many clinic visits as did controls

Fixed community points

Promising results have been found regarding fixed community points with evidence from the community drug distribution point (CDDP) model in Uganda and the community ART distribution points (PODI) in the Democratic Republic of the Congo (DRC). In Uganda, cross-sectional outcomes at study endpoint for clients initiating ART from 2004 to 2009 (median time on ART: 5.7 years; IQR: 4.1-7.2) in the CDDP model were 69% retention, 17% dead, 6% transferred out and 9% LTFU. In CDDP clients, viral load suppression (<1,000 copies/mL) was 93% (median time on ART: 7.0 years; IQR: 5.0-8.0). In a subsequent conference abstract, LTFU was reported as 16.5% in the facility arm and 4.28% in the CDDP arm ($p < 0.0001$)^{32,33}.

In the DRC, retention at 12 and 24 months post transfer to the PODI was 89.3% and 82.4%, respectively³⁴.

Mobile outreach ART delivery

There is limited published evidence of utilizing mobile outreach services to distribute ART refills outside of the health facility. Two conference abstracts report on outcomes. In Swaziland, health facilities were offered a choice of three ART delivery models for implementation. One health centre and one clinic implemented an outreach service to support remote communities; one health centre chose to implement ART adherence clubs (ACs) and 12 clinics implemented CAGs. Twelve-month retention was 77% for the outreach service model (n=102), 96% in ACs (n=289) and 81% in CAGs (n=336)³⁵.

In South Africa, comprehensive ART services (including ART refills) were provided by mobile outreach on South African-Zimbabwean border farms to vulnerable, highly mobile Zimbabwean migrant farm workers and their families³⁶. The intervention piloted a travel package, including a three-month ART refill. Viral suppression was 91.2%, and of those clients who indicated planned travel to Zimbabwe, only 2% did not return within three months of their planned return date.

Home delivery

There are two cluster randomized controlled trials from Kenya and Uganda reporting outcomes from home ART delivery models.

In Uganda, there was no difference between the virological failure rates for home versus for facility care (rate ratio, RR: 1.04, 0.78-1.40; equivalence shown)³⁷. Mortality rates were also similar between the groups (0.95, 0.71-1.28). Health services and client cost year were less for home delivery compared with facility refill (US\$793 vs. \$838 for health services and \$18 vs. \$54 for client).

In Kenya, no significant intervention-control differences were found with regard to detectable viral load, mean CD4 count, change in ART regimen, new opportunistic infections or pregnancy rates. Intervention clients made half as many clinic visits as did controls³⁸.

Annex 3. Evidence base for healthcare worker-managed group models

Also known as ART adherence clubs, family clubs, youth clubs, client adherence groups.

OVERVIEW

Healthcare workers are responsible for the management of the provision of ART drug supply, care and support to groups of stable clients. 25-30 stable clients meet for 30-60 minutes and are facilitated by a lay healthcare worker who provides a brief symptom screen, referral where necessary, peer support and distribution of pre-packed ART to all the members present every 2-3 months (4-6 times a year). No client folders are pulled; nor is individual adherence counselling provided. Group members have their viral load taken at one of their annual group visits and are seen individually for clinical review at their next group visit. They also have access to clinicians through the model referral mechanisms if they become unwell.

Group members are allowed to send a friend or family member to collect their ART drug supply in the group. Group attendance is recorded as a client visit in the paper-based registers, which are then captured in the facility's electronic monitoring system. Evidence on healthcare worker-managed groups highlights improved client outcomes, both at individual sites and at scale, and suggests benefits for other client groups, including children, their caregivers and adolescents.

Table 6: Summary of evidence for healthcare worker-managed group models

Location	Model	Description	Outcomes
Western Cape, South Africa N=32,425 ^{39,40}	Adherence club (AC)	55 facilities offering 1,308 ACs 2-monthly ART refills (6x/year)	At 12 months: <ul style="list-style-type: none"> ○ Retention 94.9%, LTFU 2.1% ○ Transfer out 3.9% ○ VL suppression 96.8%
Khayelitsha, Cape Town N=502 ^{41,42}	Adult AC	Testing effectiveness of AC in adults who had been on ART for at least 18 months, CD4 >200 and virologically suppressed.	<ul style="list-style-type: none"> ○ Retention for stable clients enrolled in AC 97% vs. not enrolled in AC = 85% ○ LTFU reduced by 57% ○ Viral rebound reduced by 67% ○ US\$300 for AC model vs. \$374 for standard of care
Gugulethu, Cape Town N=8,150 ^{43,44}	Community-based AC	Examined outcomes for ART patients decentralized to community-based adherence clubs compared with patients managed in the community health centre	<ul style="list-style-type: none"> ○ 12-month retention 94% post AC enrolment ○ 3% VL rebound by study end ○ 67% reduction in risk of LTFU for AC compared with standard of care
Khayelitsha, Cape Town N=337 ⁴⁵	Youth-specific AC	Adapted adult ART AC model for youth-only participation Enrolled ART ineligible and newly initiated on ART youth	Retention at 12 months: <ul style="list-style-type: none"> ○ Clients stable on ART 94.3% ○ Newly initiated on ART 86.4% ○ Youth ineligible for ART 52.9%
Khayelitsha, Cape Town N=139 ⁴⁶	Family ACs	Evaluated retention and virological outcomes of children enrolled in the family ART adherence clubs (FCs)	<ul style="list-style-type: none"> ○ Cross-sectional retention of children in family AC was 93% ○ 91% of children retained in care achieved VL suppression

The majority of evidence for healthcare worker-managed group models comes from implementation of the ART adherence club (AC) model in the Western Cape, South Africa. Details of the model expansion highlight that from January 2011 to March 2015, 32,425 clients were in an AC (25.2% of the total ART cohort)³⁹. Fifty-five facilities were offering a total of 1,308 ACs. Outcomes of clients in ACs were much better than those from previous studies. In a cluster random sample of 10% of ACs from sites not supported by research, retention, LTFU and transferred-out rates were 94.9% (CI: 92.9-94.8), 2.1% (CI: 1.6-2.8) and 3.9% (CI: 3.2-4.7) at 12 months, respectively, and viral suppression was 96.8% (CI: 96-97.4)⁴⁰.

Two comparison cohort studies report client outcomes from ACs. In the pilot study in Khayelitsha, Cape Town, retention at study end was 97% for those stable clients who enrolled in an AC versus 85% for those who did not. LTFU was reduced by 57% (hazard ratio, HR: 0.43; 95% CI: 0.21-0.91) and viral rebound by 67% (HR: 0.33; 95% CI: 0.16-0.67)⁴¹. A costing study found the piloted AC model cost effective with a cost per client year of US\$300 versus \$374 for standard of care⁴². In Gugulethu, Cape Town, 94% were retained at 12 months post AC enrolment, with 3% experiencing viral rebound by study end^{43,44}. After adjustment, AC participation was associated with a 67% reduction in the risk of LTFU (aHR: 0.33; 95% CI: 0.27-0.40) compared with clients in the standard of care.

Three small studies reported outcomes of youth-specific ACs, family ACs and clients enrolled in adult ACs who had recently re-suppressed after a viral rebound episode. For youth ACs, ART client outcomes were good. Retention at 12 months for youth stable on ART was 94.3% (CI: 85.4-96.8); for youth newly initiated on ART, it was 86.4% (CI: 78.7-91.4); and for youth ineligible for ART, it was 52.9% (CI: 40.0-64.2)⁴⁵.

For family ACs, cross-sectional retention of children who had enrolled in the family AC was 93%⁴⁶. For clients who had re-suppressed after a nurse-led intervention and were immediately referred into an adult AC, 12-month retention and viral suppression after AC enrolment was 94.8% (CI: 89.8-97.4) and 85.2% (CI: 78.0-90.1), respectively **Error! Bookmark not defined.**

Three studies have described various aspects of the AC model. The first describes the AC model and the strategy used by local health authorities to scale out the model⁴⁷. The second describes the quality improvement approach embedded in the scale-out strategy⁴⁸. The third describes the adjusted AC model implemented in Gugulethu, where ACs were run at a community venue instead of the clinic.

The Western Cape AC model changed from providing 2-monthly ART refills (six times a year) to providing a 4-monthly ART refills at year end (five total visits per year) to accommodate year-end holiday migration. A comparison study found no difference in short-term retention or viral rebound risk comparing clients who receive two months versus four months of ART over the holiday period⁴⁹.

Annex 4. Evidence base for client-managed group models

Also known as community ART group (CAG), community client-led ART delivery (CCLAD), community ART refill group (CARG), community adherence group, peer support group.

OVERVIEW

Clients stable on ART form groups of 4-10 each. They meet at a group member's home or venue convenient to all the members. Each member reports on adherence, and undergoes a pill count and brief symptom screen, which is completed on a group monitoring form. The group may use the opportunity to provide each other with peer support. Each member takes a rotating turn to attend the healthcare facility for monitoring tests and clinical review while collecting ART refills for all members of the group. All members' ART cards/clinical folders are drawn at the facility, and the attending group member reports on the health and adherence of each member listed on the group monitoring form to the clinician who completes the client ART card/clinical folder. The collecting member thereafter travels home, meets the group at the same venue and distributes collected ART refills. Any group member who is unwell or reports symptoms can attend the facility with the group representative or seek clinical support at any other time.

Table 7: Summary of evidence for client-managed group models

Location	Model	Description	Outcomes
Mozambique N=5,729 ⁵⁰	Community adherence groups	Measured impact of CAG on long-term retention by estimating mortality and LTFU rates and assessed predictors for attrition	<ul style="list-style-type: none"> ○ Retention at 12, 24, 36 and 48 months: 97.7%, 96.0%, 93.4% and 91.8% ○ Mortality and LTFU rate of 2.1 and 0.1/100 per patient year ○ 37.6% of patients enrolled in a CAG with higher retention (97.5%) vs. never enrolled (82.3%) ○ Cost and time savings with improved certainty of ART access and mutual peer support; facilitated better adherence
Mozambique N=1,306 ⁵¹	Community adherence groups	Lay counsellors provide information at clinic appointments, screen patients for CAG and follow up	<ul style="list-style-type: none"> ○ 13.8% joined a CAG ○ Reduced mortality by 55.1% and LTFU 84.3%
Mozambique N=4,925 total of which 312 were children >15 years (1,164 CAGs) ⁵²	Community adherence groups	Family CAGs with inclusion of children	<p>Median follow up of children was 13 months:</p> <ul style="list-style-type: none"> ○ 277 (89%) alive on treatment ○ 7 (2%) transferred out ○ 10 (3%) went back to individual care ○ 18 (6%) died, equal to 4 deaths per 100 person-years of children in CAG ○ Retention 94% and attrition 6% with no child lost to follow up
Lesotho N=199 in CAG N=397 not in CAG ⁵³	Community adherence groups	Stable CAG patients take turns collecting ART for fellow group members	<ul style="list-style-type: none"> ○ 12-month retention 98.7% of stable clients in CAG vs. 90.2% who did not join ○ In CAG: median time on ART 54 months ○ Not in CAG: median time on ART 21 months
Haiti N=80 ⁵⁴	Community adherence groups	Stable patients receiving ART from community groups and facilitate monthly ART distribution	<ul style="list-style-type: none"> ○ Cross-sectional retention 88.4%

Data from client-managed group models shows improved client outcomes with qualitative evidence supporting reduced costs and increased time savings. The majority of the evidence for client-managed groups comes from the large cohort of clients enrolled in Tete community ART groups (CAGs) in Mozambique.

In a 2014 descriptive cohort study, retention outcomes at 12, 24, 36 and 48 months were 97.7%, 96.0%, 93.4% and 91.8%, respectively, with a mortality and loss to follow up (LTFU) rate of 2.1 and 0.1/100 per client year, respectively⁵⁰. A recent retrospective cohort study also assessed retention in care for all clients on ART for more than six months and who were 15-60 years old between 2008 and 2012. A total of 37.6% of such clients enrolled in a CAG and such clients had higher overall retention (97.5%) than those who never enrolled (82.3%)⁵⁰.

Data from two qualitative studies found cost and time savings for clients and improved certainty of ART access and mutual peer support, which facilitated better adherence^{55,56}. A descriptive editorial explains the step-wise scale-up approach that was taken from the pilot site, to the district, and eventually nationally in Mozambique⁵⁷.

A recent retrospective study undertaken in eastern Mozambique assessed all ART clients over 15 years of age who were eligible to join a CAG (n=1,306) from 2010 to 2015 for associations between baseline characteristics and total days late for appointments in the first six months on ART (prior to CAG eligibility) and CAG participation. It found no associations other than female sex. Only 13.8% joined a CAG, with CAG participation reducing mortality by 55.1% (adjusted hazard ratio, aHR: 0.449; 95% CI: 0.264-0.762) and the risk of LTFU by 84.3% (aHR: 0.157; 95% CI: 0.086-0.288)⁵¹.

CAGs have also shown promising outcomes for children as “family CAGs”. Between 27 February 2008 and 31 March 2012, CAGs were implemented in 20 health facilities in seven districts in Tete province of Mozambique. A total of 4,925 people formed 1,164 CAGs, and of these people, 312 (6%) were children below 15 years, with median age of seven years (IQR: 5-10). Median follow-up time of children in CAGs was 13 months with the following outcomes as of March 2012⁵²:

- 277 (89%) alive on treatment
- 7 (2%) transferred out
- 10 (3%) went back to individual care
- 18 (6%) died, equal to 4 deaths per 100 persons-years of children in CAGs
- No child lost to follow up

Retention among children in CAGs was 94%, and attrition was 6%. Access to and improved retention on treatment for children is feasible in a resource-poor setting through adult client involvement in service delivery.

Subsequently, data from three smaller cohorts in Lesotho, Swaziland and Haiti also report positive outcomes.^{53,54} In Lesotho, a mixed-method comparison cohort study found 12-month retention of 98.7% (95% CI: 94.9-99.7) of stable clients who joined a Lesotho CAG (n=199 with median time on ART of 54 months) versus 90.2% (95% CI: 86.6-92.9) among those who did not join the CAG (n=397 with median time on ART of 21 months)⁵³.

Annex 5. Template for assessing relevant policies related to differentiated ART delivery

 <p>WHEN</p>	<p>What is the minimum frequency of clinical consultations/visits?*</p> <p>What is the maximum ART refill allowed?*</p> <p><i>*Do these recommendations apply to all adults, adolescents, children and key populations living with HIV?</i></p>
 <p>WHERE</p>	<p>Can ART be distributed at peripheral health facilities?*</p> <p>Can ART be distributed at the community level?*</p> <p><i>*Do these recommendations apply to all adults, adolescents, children and key populations living with HIV?</i></p>
 <p>WHO</p>	<p>Can non-physician clinicians, midwives and nurses maintain clients on ART?*</p> <p>Can trained and supervised community health workers dispense ART between regular clinical visits?*</p> <p>Can trained and supervised community health workers dispense ART between regular clinical visits?*</p> <p>Is there a policy that enables clients to send a “treatment buddy” or representative to collect their ART refills on their behalf?</p> <p><i>*Do these recommendations apply to all adults, adolescents, children and key populations living with HIV?</i></p>
 <p>WHAT</p>	<p>Are there any policies related to community-based care?*</p> <p>Are there any policies defining the criteria for a “stable” client?*</p> <p>Is there a policy supporting the cessation of CD4 count monitoring if viral load testing is available?</p> <p><i>*Do these recommendations apply to all adults, adolescents, children and key populations living with HIV?</i></p>

REFERENCES

- ¹ UNAIDS. Get on the Fast Track. Geneva, 2016.
- ² World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed., 2016.
- ³ Grimsrud A, Bygrave H, Doherty M, Ehrenkranz P, Ellman F, Ferris R et al. Reimagining HIV service delivery: the role of differentiated care from prevention to suppression. *JIAS*. 2016, 19:21484.
- ⁴ International AIDS Society. Differentiated Care for HIV: A Decision Framework for ART Delivery, 2016.
- ⁵ Fast-Track – ending the AIDS epidemic by 2030. Geneva: UNAIDS; 2014 (http://www.unaids.org/en/resources/documents/2014/JC2686_WAD2014report, accessed 1 November 2015).
- ⁶ Scoping consultation on care packages for people living with HIV. Meeting report, 24-26 September 2014. Geneva: World Health Organization (<http://www.who.int/hiv/pub/arv/consultation-carepackages-phiv/en/>, accessed 1 November 2015).
- ⁷ Fox MP, Rosen S. Retention of Adult Patient on Antiretroviral Therapy in Low- and Middle-Income Countries: Systematic Review and Meta-analysis 2008- 2013. *J Acquir Immune Defic Syndr*. 2015; 69(1):98-108.
- ⁸ Boender TS, Sigaloff KC, McMahon JH, Kiertiburanakul S, Jordan MR, Barcarolo J, et al. Long-term Virological Outcomes of First-Line Antiretroviral Therapy for HIV-1 in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis. *Clin Infect Dis*. 2015;61(9):1453-61.
- ⁹ UNAIDS. Community-based antiretroviral therapy delivery: experiences from MSF. Geneva: UNAIDS, 2015.
- ¹⁰ Bemelmans M, Baert S, Goemaere E, Wilkinson L, Vandendyck M, van Cutsem G, et al. Community supported models of care for people on HIV treatment in sub-Saharan Africa. *Trop Med Int Health*. 2014;19(8):968–77.
- ¹¹ UNAIDS; 90-90-90: Partnering for sustainable health and development, background paper to frame the political context for the Addis Ababa consultation.
- ¹² WHO, PEPFAR, UNAIDS. Task shifting: rational redistribution of tasks among health workforce teams: global recommendations and guidelines. Geneva: 2008, World Health Organization; 2008, <http://apps.who.int/iris/handle/10665/43821>.
- ¹³ 90-90-90 and one million community health workers: Partnering for sustainable development (Non-Paper).
- ¹⁴ Joint Review Meeting, HAPCO Report June 2016.
- ¹⁵ Global Health Workforce Alliance, WHO. A universal truth: no health without a work force. Geneva: World Health Organization; 2013 (<http://www.who.int/workforcealliance/knowledge/resources/hrhreport2013/en>)
- ¹⁶ Scaling Up Strategy of CBHI in Ethiopia_2015_Draft.doc.
- ¹⁷ Bemelmans M, Baert A, Goemaere E, Wilkinson L, Vanendyck M, van Cutsem G et al. Community-supported models of care for people on HIV treatment in sub-Saharan Africa. *Trop Med Int Health*. 2014;19 (8):968–77.
- ¹⁸ CIVICUS, 2013. State of civil society: creating an enabling environment. World Alliance for Citizen Participation (CIVICUS), Johannesburg, South Africa.
- ¹⁹ Mwai GM, Mburu G, Torpey K, Frost P, Ford N, Seeley J. Role and outcomes of community health workers in HIV care in sub-Saharan Africa: a systematic review. *Journal of the International AIDS Society* 2013; 16: 18586.
- ²⁰ Ledikwe JH, Kejelepula M, Maupo K, Sebetso S, Thekiso M, Smith M et al. Evaluation of a well-established task-shifting initiative: the lay counsellor cadre in Botswana. *PLoS One* 8, e61601.
- ²¹ Chanda P, Hamainza M, Moonga HB, Chalwe V, Pagnoni F. Community case management of malaria using ACT and RDT in two districts in Zambia: achieving high adherence to test results using community health workers. *Malar J*. 2011; 10,158.
- ²² Differentiated Care for HIV: A Decision Framework for ART Delivery ; International AIDS Society, 2016.
- ²³ Babigumira JB, Castelnuovo B, Stergachis A, Kiragga A, Shaefer P, Lamorde M, et al. Cost effectiveness of a pharmacy-only refill program in a large urban HIV/AIDS clinic in Uganda. *PLoS One*. 2011;6(3):e18193.
- ²⁴ Alamo ST, Wagner GJ, Ouma J, Sunday P, Marie L, Colebunders R, et al. Strategies for optimizing clinic efficiency in a community-based antiretroviral treatment programme in Uganda. *AIDS and Behavior*. 2013;17(1):274-83.
- ²⁵ Obua C, Kayiwa J, Waako P, Tomson G, Balidawa H, Chalker J, et al. Improving adherence to antiretroviral treatment in Uganda with a low-resource facility-based intervention. *Global Health Action*. 2014;7.

-
- ²⁶ Jakubowski A, Kabami J, Mwai D, Snyman K, Clark T, Ayieko J, et al. Provision of streamlined HIV care associated with reduced economic burden of care-seeking among HIV-infected adults. 21st International AIDS Conference, Durban, 18-22 July 2016.
- ²⁷ McGuire M, Pedrono G, Mukhua B, Huckabee M, Heinzelmann A, Szumilin E. Optimizing client monitoring after the first year of ART: three years of implementing 6-monthly clinical appointments in rural Malawi. Abstract for IAS, 2011.
- ²⁸ Bemelmans M, Baert S, Goemaere E, Wilkinson L, Vandendyck M, Cutsem G, et al. Community-supported models of care for people on HIV treatment in sub-Saharan Africa. *Tropical Medicine & International Health*. 2014;19(8):968-77.
- ²⁹ Cawley C, Nicholas S, Szumilin E, Perry S, Amoros Quiles I, Masiku C, et al. Six-monthly appointments as a strategy for stable antiretroviral therapy patients: evidence of its effectiveness from seven years of experience in a Medecins Sans Frontieres supported programme in Chiradzulu district, Malawi. 21st International AIDS Conference, Durban, 18-22 July 2016.
- ³⁰ Maharaj T, editor. Strategies to address clinic waiting time and retention in care; lessons from a large ART center in South Africa. 17th International Conference on AIDS and STIs in Africa, Cape Town, 2013.
- ³¹ Mwangwa et al. 48-week outcomes of African children starting ART at CD4>500 with streamlined care. CROI, 2016.
- ³² Okoboi S, Namwanje L, Oceng R. P6. 052 Integrating Family Planning Services into HIV Comprehensive Care and Treatment Clinics: A Case of the AIDS Support Organization (TASO) Tororo. Sexually transmitted infections. 2013;89(Suppl 1):A385-A.
- ³³ Mpima D, Birungi J, Makabayi R, Kanters S, Luzze C. Community Antiretroviral Therapy (ART) delivery models for high client retention and sustaining good adherence: The AIDS Support Organisation (TASO) operational research findings, CDC/PEPFAR funded project in Uganda. 7th IAS Conference on HIV pathogenesis, treatment and Prevention, Kuala Lumpur, 30 June-3 July 2013.
- ³⁴ Bemelmans M, Baert S, Goemaere E, Wilkinson L, Vandendyck M, Cutsem G, et al. Community-supported models of care for people on HIV treatment in sub-Saharan Africa. *Tropical Medicine & International Health*. 2014;19(8):968-77.
- ³⁵ Pasipamire L, Kerschberger B, I. Zabsonre I, Ndlovu S, Sibanda G, Mamba S, et al. Implementation of combination ART refills models in rural Swaziland. 21st International AIDS Conference, Durban, 18-22 July 2016.
- ³⁶ Matambo T, Hildebrand K, C M, Wilkinson L, Van Cutsem G, Bauernfeind A, et al. Targeted adherence strategies for provision of cross border antiretroviral therapy (ART) to migrant farm workers in Musina, South Africa. 19th International AIDS Conference, Washington, 22-27 July 2012.
- ³⁷ Jaffar S, Amuron B, Foster S, Birungi J, Levin J, Namara G, et al. Rates of virological failure in patients treated in a home-based versus a facility-based HIV-care model in Jinja, southeast Uganda: a cluster-randomised equivalence trial. *The Lancet*. 2010;374(9707):2080-9.
- ³⁸ Selke HM, Kimaiyo S, Sidle JE, Vedanthan R, Tierney WM, Shen C, et al. Task-shifting of antiretroviral delivery from health care workers to persons living with HIV/AIDS: clinical outcomes of a community-based program in Kenya. *Journal of Acquired Immune Deficiency Syndromes*. 2010;55(4):483-90.
- ³⁹ Wilkinson L, Harley B, Sharp J, Solomon S, Jacobs S, Cragg C, et al. Expansion of the Adherence Club model for stable antiretroviral therapy clients in the Cape Metro, South Africa 2011-2015. *Tropical Medicine & International Health*. 2016.
- ⁴⁰ Tsondai P, Wilkinson L, Grimsrud A, Mdlalo P, Trivino A, Boulle A. High rates of retention and viral suppression in the Scale-up of Antiretroviral Therapy Adherence Clubs in Cape Town, South Africa. 21st International AIDS Conference, Durban, 18-22 July 2016.
- ⁴¹ Luque-Fernandez MAVC, G.; Goemaere, E.; Hilderbrand, K.; Schomaker, M.; Mantangana, N.; Mathee, S.; Dubula, V.; Ford, N.; Hernan, M. A.; Boulle, A. Effectiveness of client adherence groups as a model of care for stable clients on antiretroviral therapy in Khayelitsha, Cape Town, South Africa. *PLoS One*. 2013;8(2):e56088.
- ⁴² Bango F, Ashmore J, Wilkinson L, Cutsem G, Cleary S. Adherence clubs for long-term provision of anti-retroviral therapy: Cost-effectiveness and access analysis from Khayelitsha, South Africa. *Tropical Medicine & International Health*. 2016.

-
- ⁴³ Grimsrud A, Lesosky M, Kalombo C, Bekker L-G, Myer L. Implementation and Operational Research: Community-Based Adherence Clubs for the Management of Stable Antiretroviral Therapy Clients in Cape Town, South Africa: A Cohort Study. *Journal of Acquired Immune Deficiency Syndromes*. 2016;71(1):e16-e23.
- ⁴⁴ Grimsrud A, Sharp J, Kalombo C, Bekker L-G, Myer L. Implementation of community-based adherence clubs for stable antiretroviral therapy patients in Cape Town, South Africa. *Journal of the International AIDS Society*. 2015;18(1).
- ⁴⁵ Wilkinson L, Moyo F, Henwood R, Runeyi P, Patel S, de Azevedo V, et al. Youth ART adherence clubs: Outcomes from an innovative model for HIV positive youth in Khayelitsha, South Africa. 21st International AIDS Conference, Durban, 18-22 July 2016.
- ⁴⁶ Wilkinson L, Henwood R, Kilani C, Dumile N, Jack N, Gwashu F, et al. Promoting paediatric antiretroviral treatment (ART) adherence and retention: outcomes of children receiving ART in family ART adherence clubs in Khayelitsha, South Africa, 8th International AIDS Conference, Vancouver, 19-22 July 2015.
- ⁴⁷ Wilkinson LS. ART adherence clubs: A long-term retention strategy for clinically stable clients receiving antiretroviral therapy. *Southern African Journal of HIV Medicine*. 2013;14(2):48-50.
- ⁴⁸ Horwood CM, Youngleson MS, Moses E, Stern AF, Barker PM. Using adapted quality-improvement approaches to strengthen community-based health systems and improve care in high HIV-burden sub-Saharan African countries. *AIDS*. 2015;29:S155-S64.
- ⁴⁹ Grimsrud AP, G.; Sharp, J.; Myer, L.; Wilkinson, L.; Bekker, L. G. Extending dispensing intervals for stable patients on ART. *Journal of acquired immune deficiency syndromes (1999)*. 2013.
- ⁵⁰ Decroo T, Koole O, Remartinez D, dos Santos N, Dezembro S, Jofrisse M, et al. Four-year retention and risk factors for attrition among members of community ART groups in Tete, Mozambique. *Tropical Medicine & International Health*. 2014;19(5):514-21
- ⁵¹ Jefferys L, Hector J, Hobbins M, Ehmer J, Anderegg N. Improved survival and retention in HIV treatment and care: the value of community ART groups for HIV clients on ART in rural northern Mozambique AIDS, Durban, 2016.
- ⁵² Decroo et al. Early experience of inclusion of children on ART in Community ART groups in Tete, Mozambique.
- ⁵³ Vandendyck M, Motsamai M, Mubanga M. Community-based ART resulted in excellent retention and can leverage community em-powerment in rural Lesotho, a mixed method study. *HIV/AIDS Res Treat Open J*. 2015;2(2):44-50.
- ⁵⁴ Naslund JA, Dionne-Odom J, Junior Destin e C, Jogerst KM, Renold S en echarles R, Jean Louis M, et al. Adapting and Implementing a Community Program to Improve Retention in Care among patients with HIV in Southern Haiti: "Group of 6". *AIDS Research and Treatment*. 2014.
- ⁵⁵ Rasschaert F, Telfer B, Lessitala F, Decroo T, Remartinez D, Biot M, et al. A qualitative assessment of a community antiretroviral therapy group model in Tete, Mozambique. *PloS one*. 2014;9(3):e91544..
- ⁵⁶ Rasschaert F, Decroo T, Remartinez D, Telfer B, Lessitala F, Biot M, et al. Adapting a community-based ART delivery model to the patients' needs: a mixed methods research in Tete, Mozambique. *BMC Public Health*. 2014;14(1):364.
- ⁵⁷ Decroo T, Lara J, Rasschaert F, Bermudez-Aza E, Couto A, Candrinho B, et al. Scaling up community ART groups in Mozambique. *Int STD Res Rev*. 2013;1(2):49-59.