



# DIFFERENTIATED SERVICE DELIVERY FOR HIV TREATMENT: **SUMMARY OF PUBLISHED EVIDENCE**

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# OVERVIEW

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The evidence for differentiated service delivery (DSD) for HIV treatment is summarized and presented by model type:

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This summary of evidence includes published data up until October 2020, including from peer-reviewed publications and conference abstracts. To read more, download the original research through the hyperlinks in the References (pages 18-21) and visit [www.differentiatedservicedelivery.org](http://www.differentiatedservicedelivery.org)

## ACRONYMS

AC - adherence club	LTFU - loss to followup
aHR - adjusted hazard ratio	MACs - medication adherence clubs
AIDS - Acquired immunodeficiency syndrome	MMD - multi-month ART refills
aOR - adjusted odds ratio	MMPs - multi-month prescriptions
aRD - adjusted risk difference	PODI - community ART distribution points
ART - antiretroviral therapy	PRP - pharmacy-only refill programme
C-BART - community-based ART	R6M - Rendez-vous de Six Mois
CAGs - community ART groups	RD - risk difference
CARGs - community ART refill groups	RR - risk ratio
CCLAD - client-led ART delivery model	SEARCH - Sustainable East Africa Research in Community Health study
CDDP - community drug distribution point	SMA - six-monthly appointments
CI - confidence interval	SOC - standard of care
DSD - differentiated service delivery	TASO - The AIDS Support Organization
DRC - Democratic Republic of the Congo	TB - tuberculosis
HBD - home-based delivery	UAGs - urban adherence groups
HIV - human immunodeficiency virus	VL - viral loads
HR - hazard ratio	WHO - World Health Organization
IQR - interquartile range	





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Evidence on healthcare worker-managed groups highlights improved client outcomes, both at individual sites and at scale, and suggests benefits to specific client populations, including children, their caregivers and adolescents and increasingly to breastfeeding women and their infants, key populations and clients who have struggled with adherence previously.

### Quantitative

The majority of evidence for healthcare worker-managed group models comes from implementation of the

antiretroviral therapy (ART) adherence club (AC) model in Cape Town, South Africa. Details of the model expansion show that from January 2011 to March 2015, 32,425 clients were in an AC (25.2% of the total ART cohort). Fifty-five facilities were offering a total of 1,308 ACs (1). In a cluster random sample of 10% of the Cape Town ACs (3,216 adults)

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from non-research-supported ART sites, retention was 95.2% (CI 94-96.4) at 12 months and 89.3% (CI 87.1-91.4) at 24 months. In the 13 months prior to database closure, 88.1% of clients had viral loads (VL) taken, with VL  $\leq$ 400 copies/ml in 97.2% (CI 96.5-97.8) (2). An evaluation of disengagement from care in Khayelitsha, Western Cape, reported AC participation as highly protective against disengagement (hazard ratio 0.27 (CI 0.24-0.30) (3). A 2019 evaluation of long-term virologic outcomes of 8,058 clients ever enrolled in AC care in Khayelitsha showed high annual VL completion over 40 months (82-85%), with 6% experiencing an elevated VL at a median of 363 days from AC enrolment (IQR 170-728) (4).

With ACs recognized since 2015 as one of three endorsed differentiated ART delivery models in South Africa, national retention and viral load suppression outcomes were evaluated in a 2019 study comparing 24 randomly allocated intervention and control facilities. AC clients had higher 12-month retention (89.5% versus 81.6%, aRD 8.3%; CI 1.1% to 15.6%) and comparable sustained viral suppression ( $<400$  copies/mL any time  $\leq$  18 months) (80.0% versus 79.6%, aRD 3.8%, CI -6.9% to 14.4%). Retention associations were stronger for men than women (men RD 13.1%, CI 0.3% to 23.5%; women RD 6.0%, CI -0.9% to 12.9%) (5).

Four comparison cohort studies report client outcomes from ACs (6, 7). 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. Loss to followup (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) (6). In Gugulethu, Cape Town, 94% were retained at 12 months post AC enrolment, with 3% experiencing viral rebound by study end (7). 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. In the rural Cape Winelands, a 2019 retrospective cohort study of all adult clients starting ART in 2014-2015 found lower loss to followup in those attending an AC (aHR 0.25, CI 0.11 to 0.56). This finding was confirmed on analysis restricted to those eligible for AC referral (aHR 0.28, CI 0.12 to 0.65) (8). A costing study found the Khayelitsha piloted AC model cost effective, with a cost per client year of \$300 versus \$374 for standard of care (9).

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Four additional studies described various aspects of the AC model in the Western Cape. The first describes the AC model and the strategy used by local health authorities to scale the model (10). The second outlines the quality improvement approach embedded in the scale-up strategy (11). The third describes the adjusted AC model implemented in Gugulethu, where ACs were run at a community venue instead of the clinic (12). The Western Cape AC model changed from providing two-monthly ART refills (six times a year) to providing a four-monthly ART refill 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 period (13). A non-inferiority cluster randomized trial comparing retention, VL completion and VL suppression outcomes of experienced AC clients receiving six-monthly ART refill in their ACs compared with those in the aforementioned Western Cape AC model found similar 24-month retention (intervention 93.1% (CI 91.2-94.7); SOC 94.0% (CI 92.4-95.2)), higher VL completion (94.5% vs. 89.3%) and similar VL suppression (96.3% vs. 97.5%) (14).

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In Zambia, urban adherence groups (UAGs) are also part of national DSD policy. A study using a matched-pair cluster randomized study design, only enrolling DSD eligible clients willing to join a UAG at intervention and control clinics,

found the rate of late drug pick-up was lower in UAG participants compared to clinic-based care participants (aHR 0.26, 95% CI 0.15-0.45) (15). Median medication possession ratio was 100% in intervention participants compared with 96% in control participants. Although 18% of the UAG group meeting visits were missed, on-time drug pick-up (within seven days) still occurred in 51% of these missed visits through alternate means (use of buddy pick-up or early return to the facility).

## Qualitative

Six qualitative studies looked at healthcare worker and/or client perceptions around ACs. The first explored the acceptability of community-based ACs from a health worker perspective, including enablers and barriers to roll out (16). The second explored the perceptions of AC members and non-members at two sites in Khayelitsha and Gugulethu, Cape Town (17). The third explored the perceptions of clients who were enrolled in either community or facility-based ACs in Witkoppen, Johannesburg (18). The fourth took place in Lusaka, Zambia, where client and provider perceptions of UAGs were explored (19). In Cape Town, two recent qualitative studies were undertaken. One nested within a non-inferiority cluster randomized trial explored client, healthcare worker and key informant experiences and perceptions of receiving six-month ART refills in ACs (20). The second explored how participation in postnatal ACs affected knowledge transmission, peer support, health-seeking behaviour and satisfaction with the care provided (21).

Two studies in Zambia and one in South Africa compared outcomes after providing clients with a choice of differentiated ART delivery model. Within the PopART study in Lusaka, Zambia, clients in two study arms were offered a choice for collecting a three-month ART refill in: i) clinic-based care or home delivery (HBD); or ii) clinic-based care or community-based AC (22). Twelve-month viral suppression was non-inferior in the community DSD models (above 98% in all three arms). More clients were lost to care in the clinic-based care arm (52/781; HBD 18/825; AC 20/808) with more deaths in the HBD arm (17; clinic-based 2; AC 7). In a retrospective outcomes analysis of clients who enrolled in DSD models in Zambia from 2015-2017, 12-month retention was 81% in clinic-based care compared

with 83% in CAGs, 95% in UAGs, 79% in home delivery and 69% in mobile outreach. Provider costs per person retained was higher in DSD models than in clinic-based care (23). In KwaZulu-Natal, South Africa, clients were offered a choice between community ART groups (CAGs), community ACs, in-facility individual fast-lane pick-up or out-of-facility individual pick-up. Overall DSD model retention was high at 12, 24 and 36 months when compared with those who qualified for a DSD model but remained in clinic-based care, but viral suppression was significantly lower for those who had participated in the group models by 36 months (24).

## Specific populations

Four studies from Cape Town and one from Uganda, reported outcomes for specific populations: adolescents, children and their caregivers, postnatal women and men who have sex with men receiving their care from youth-specific ACs, family ACs or adults ACs, respectively. 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) (25). For family ACs, child and caregiver retention was 93.7% (CI 88.7-96.6) and 93.9% (CI 85.9-97.4) at 12 months and 86.1 (CI 79.5-90.8) and 89.7 (CI 80.4-94.8) at 36 months (26). For women initiated on ART during pregnancy and who chose to join an existing community-based adult AC immediately post-delivery (84/129; 65%) compared with ART at their clinic, viral loads above 1,000 copies/ml were lower at 12 (AC 16% and clinic 23%) and 24 months (AC 29% and clinic 37%) (27). In a further study, postnatal women and their infants were offered enrolment into postnatal clubs. These included both stable and high-risk mother-infant pairs until the infant reached 18 months.

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Eighteen-month retention was 79.2% (28), with 76% of mothers with a VL taken between 12 and 18 months and viral suppression of 94%. Eighty-one percent of infants completed nine-month HIV testing and 64% 18-month HIV testing compared with 51% and 32% of historical controls (29). In Uganda, ACs were implemented for men who have sex with men with 100% viral suppression maintained after 11 months of follow up (30).

### Among previously clinically unstable

Two studies reported on client outcomes for clients who had previously struggled with adherence. In Cape Town, 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 (31). In Mozambique, ACs were implemented for clients with a history of HIV treatment failure. Retention at 12 and 24 months was (95% CI 98.2-99.7) and 96.4% (95% CI 94.6-98.2), respectively. Concurrently, 85.8% (95% CI 83.1-88.2) and 80.9% (95% CI 77.8-84.1) of clients maintained VL suppression. Among 90 clients attending AC and simultaneously having VL rebound, 64 (71.1%) achieved VL re-suppression, 10 (11.1%) did not re-suppress and 14 (15.6%) had no subsequent VL result (32).

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In 2020, a study in Cape Town compared retention and viral suppression outcomes of 503 AC clients who had experienced viraemia and had either been referred back to clinic-based care or erroneously remained in ACs. Those who remained in ACs had the same 12-month retention (93%), slightly lower VL completion (77% versus 84%) and higher VL re-suppression (62% versus 53%) (33).

### Among those with hypertension or diabetes

Two early studies have evaluated medication adherence clubs (MACs), which adjusted the AC model to incorporate stable hypertension or diabetic clients. A retrospective descriptive study of 1,432 clients in MACs reported 3.5% LTFU in the first year after enrolment (34). A qualitative study found the model acceptable to both clients and healthcare workers, saving clients time and reducing queues at the clinic (35).



# CLIENT-MANAGED GROUPS

*Photo credit: Peter Casaer/MSF*

The most common example of a client-managed group is a self-forming group of people living with HIV who meet at an agreed community location and nominate a member to collect ART for the group from the facility on a rotational basis. That member then distributes ART to the group at the agreed community location. Data from client-managed group models have shown improved client outcomes, with qualitative evidence supporting reduced costs and increased time savings.

The earliest evidence for client-managed groups came from a large cohort of clients enrolled in community ART groups (CAGs) in Tete, Mozambique. In a 2014 descriptive cohort study (36), retention outcomes at 12, 24, 36 and 48 months

were 97.7%, 96.0%, 93.4% and 91.8%, respectively, with a mortality rate of 2.1 and LTFU rate of 0.1/100 per client year. Data from three qualitative studies found cost and time savings for clients and improved certainty of ART access and mutual peer support, including health educational benefits,

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which facilitated better adherence (37, 38, 39). A descriptive editorial explains the step-wise scale-up approach that was taken from the pilot site, to the district, and eventually nationally in Mozambique (40).

## Quantitative

Scaled-up CAG model outcomes were published in late 2016 in an evaluation of trends observed after a decade of ART scale up in Mozambique (41). From 2004 to 2013, 455,600 people over 15 years of age had initiated ART, with 6,766 enrolling in a CAG at 69 facilities from 2011 to 2013. CAG participation was associated with a 35% lower LTFU but similar mortality. Incidence of LTFU and mortality after ART initiation for CAG and non-CAG participants was 2.9% and 0.3% at two years and 10.1% and 1.4% at four years. In a further study (42) reporting outcomes for the same cohort of CAG clients matched with eligible non-CAG clients (37% of cohort) at facilities offering the CAG model, eligible non-CAG clients had a significantly higher LTFU rate (hazard ratio, HR 2.36; 95% CI 1.54-3.17) but also similar mortality. Interestingly, the study also compared outcomes of clients in CAGs who were eligible for CAGs with those in CAGs who were ineligible (19% of cohort). One-year retention was 92.5% and 86.4%, respectively (LTFU 6.7% and 9.6%; mortality 0.8% and 4%).

A recent retrospective study undertaken in northern 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 reducing the risk of LTFU by 84.3% (aHR 0.157; 95% CI 0.086-0.288) (43). A 2019 conference abstract compared viral suppression rates after the introduction of routine VL monitoring among persons receiving ART for more than six months at 83 health facilities, including those in CAGs (12% of the sample, n=1,823). The overall viral suppression rate was 76%, with significantly higher suppression rates among people in CAGs than those not in CAGs (OR 1.16 95% CI 1.03-1.30) (44).

In Lesotho, a small mixed-method comparison cohort study found 12-month retention of 98.7% (95% CI 94.9-99.7) among stable clients who joined a CAG (n=199, median time on ART 54 months) versus 90.2% (95% CI 86.6-92.9) for those who did not join the CAG (n=397, median time on ART 21 months) (45). More recently, a cluster randomized trial in 30 facilities in Lesotho compared three-monthly clinical consultations and ART refill collection from a health facility (n=1,898), three-monthly ART refills from CAGs as per the national CAG model (n=1,558) and six-monthly individual ART refill collection from community pick-up points (n=1,880). Both latter community DSD models required annual clinical consultations at the health facility. Twelve-month retention was similar across arms (94.9% vs. 95.4 vs. 93.3%) and achieved the pre-specified non-inferiority limit (-3.25%) with viral suppression above 98% across arms (46). The associated costing study found that the two community DSD models reduced provider costs per client by approximately 7% and, importantly, client costs by approximately 60% (47).

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In Zimbabwe, community ART refill groups (CARGs) have been endorsed in the National Operational and Service Delivery Manual. Clients collect ART refills every three months; members attend once a year as a group for clinical review and viral load. Qualitative work has explored patient and provider perspectives of CARGs (48), male engagement in CARGs (49), and client and provider preferences for TB preventative treatment integration into the CARG model (50). Combined with a discrete choice experiment, it was found that clients in urban areas preferred facility-based individual models to community-based group models (51). A three-arm, cluster randomized non-inferiority trial across 30 health facilities compared three-monthly clinical consultations and ART refill collections from the facility, three-monthly ART refills from CARGs as per the national CARG model and six-monthly ART refills from CARGs. Twelve-month retention was similar across arms (clinic-based 91%; three-monthly CARG 93.3%; six-monthly

CARG 93.6%) and met the pre-specified noninferiority limit (-3.25%, risk difference (RD)). VL completion at 12 months was poor across all arms (below 50%) but particularly in the six-monthly CARG arm (8%). Intention-to-treat VL suppression was above 99% for clinic-based and three-monthly CARGs and marginally reduced in six-monthly CARGs, mostly driven by poor VL completion (92.9%) (52).

In Uganda, The AIDS Support Organization (TASO), a non-governmental organization supporting more than 100,000 people living with HIV, has reported encouraging adherence outcomes (89%) among a sample of clients (n=2,799) in its community client-led ART delivery model (CCLAD) (53). In Eswatini, health facilities offered three different models (CAGs, mobile outreach and facility ACs). Among those enrolled, 12-month retention was high at 93.7%, but retention by model varied substantially (CAG 70.4%; mobile outreach 86.3%; facility AC 90.4% ( $p < 0.001$ )) (54). In a small study in Haiti, cross-sectional retention for a cohort of 80 CAG clients was 88.4% (55).

## Qualitative

Qualitative studies in Malawi and Zambia also explored client and provider perceptions of CAGs. In Malawi, positive experiences regarding peer support were reported, but CAG uptake was hindered by limited awareness of the existence of CAGs or how they functioned (56). In Zambia, qualitative work demonstrated that both healthcare workers and clients favoured CAGs due to their ability to decongest the clinics and reduce workload. Several health system issues were, however, cited as problematic. Challenges included inadequate supplies of ARVs and the inability to have monitoring tests performed according to the CAG schedule due to stock-outs of specimen bottles (57).

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## Specific populations and contexts

Three studies reported outcomes for specific populations and contexts. A small study, which offered clients with elevated VLs enrolment in a CAG alongside attendance at a dedicated VL clinic, reported high CAG uptake (89.6%), but limited re-suppression (27.8%) among those with a documented follow-up VL (58). In the Central African Republic and the Democratic Republic of the Congo, CAGs, combined with extended refills, enabled continuity of care throughout several outbreaks of violence (59). In Uganda, CCLADs were introduced for clinically stable female sex workers. Two CCLADs of seven members each were formed. Retention rates of 100% were achieved in each group and all female sex workers remained virologically suppressed. ART adherence improved from 75% to 95% (60).

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*Photo credit: Paul Odongo/MSF*





# FACILITY-BASED INDIVIDUAL MODELS

*Photo credit: Albert Masias/MSF*

The principle of differentiating between the need for a clinical visit versus an ART refill visit, combined with extended ART refills, has been used in a number of facility-based individual models of ART delivery. These models go beyond only extending ART refills to reducing time spent at the facility setting up fast-track or quick pick-up services.

## Quantitative, including cost data

Evidence of the effectiveness of facility-based individual models has been reported from four studies in Uganda (61-64). The first was a cost-effectiveness study conducted after implementing a pharmacy-only refill programme (PRP)

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(six-monthly clinical reviews and two-monthly ART refills from the pharmacy) (61). The PRP was less costly (US\$520/year versus \$655/year) and more cost effective than the standard of care (62). The second study assessed clinic efficiencies after implementation of a fast-track system (six-monthly clinical visits with two-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 care. The third was a descriptive study after implementation of a refill pick-up system (six-monthly clinical review and ART refill of 30-90 days at clinician discretion) (63). There were significant reductions in missed appointments from 24.4% to 20.3% (adjusted odds ratio, aOR 0.67; 95% CI 0.59-0.77) and medication gaps of three days or more from 20.2% to 18.4% (aOR 0.69; 95% CI 0.60-0.79) in the intervention group compared with the standard of care. The fourth evaluated PRP revised to six-monthly clinical reviews and three-monthly refills directly from the pharmacy (64). Overall retention was 99.3% and among those who completed 12 months in the PRP, viral suppression was maintained at 98.8%.

Data reported from Malawi describes a growing cohort of clinically stable clients receiving multi-month ART refills (MMD) or enrolled in a fast-track clinic system (six-monthly clinical review and three-monthly ART refills from lay healthcare workers) known as the six-monthly appointment (SMA) strategy. In a 2017 mixed-methods process evaluation, 100% of 730 Malawian ART sites offered multi-month ART refills with 72.9% of eligible clients accessing MMD (65). Only 11 (1.5%) facilities offered SMA, with 77.7% of eligible clients at these facilities enrolled in SMA. A 2018 retrospective study assessed all clinically stable clients eligible for the SMA model between 2008 and 2015 (n=22,633) at these 11 facilities (66). It found that 81% enrolled in SMA with median time from eligibility to enrolment of 12 months (interquartile range 3-27 months) and median cumulative time on SMA was 14.5 months. The cumulative probability of retention in care one year after first SMA eligibility was 86.8% (CI 85.6-87.8%) among those who never enrolled, 97.3% (CI 96.8-97.6%) among early SMA enrollees and 99.8% (CI 99.7-99.9%) among late SMA enrollees. The corresponding figures at five years were 47.4% (CI 45.0-49.7%), 85.5% (CI 84.0-86.9%) and 93.4% (CI 92.8-94.0%). Among eligible clients enrolling for SMA, the adjusted hazard of attrition was 2.4 (95% CI 2.0-2.8) times higher during periods of SMA discontinuation than during periods on SMA. Male gender, younger age, more recent SMA eligibility and WHO Stage 3/4 conditions in the past year were also independently associated with attrition from SMA. Approximately 26,000 consultations were “saved” during 2014 alone.

The Sustainable East Africa Research in Community Health (SEARCH) study, a test-and-treat trial in Kenya and Uganda, streamlined HIV care for adults ( $\geq 15$  years; CD4  $\geq 350$  cells/ $\mu$ l) and children (2-14 years; CD4  $\geq 500$  cells/ $\mu$ l), including nurse-driven triage and referral for visits with physician for complex cases; three-month combined clinical and ART refill visits for stable clients; consolidation of multiple chronic disease services at encounter; client appointment flexibility; and missed appointment tracing from ART start at first visit. This resulted in 48-week retention and viral suppression among adults of 92% (897/972) and 93% (778/838) and retention and viral suppression among children of 89% (74/83) and 92% (65/71) in Uganda and Kenya, respectively (67). There were also 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 Kenya (68). Costing of streamlined HIV care was similar or lower to standard of care cost estimates after accounting for VL testing and VL result counselling session costs (69). In the Western Cape, South Africa, a “quick pick-up” model for clinically stable clients documented that 12 months after joining the model, 96% of clients were still in care, with 85% of them remaining in the model (70).

### **Those in the fast-track model were more likely to be retained at 12 months (RR 1.52) and maintain viral suppression (RR 1.07).**

Two studies in Zambia evaluated fast-track facility DSD models. In 2020, a study compared all clients in routine facility-based care (n=83,764) with those in the fast-track model (n=3,671) where clients went directly to a dedicated room where they received an expedited clinical visit and ART refill every three months. Those in the fast-track model were more likely to be retained at 12 months (RR 1.52) and maintain viral suppression (RR 1.07) (71). An analysis of 62,084 clinically stable clients (on treatment for >6 months with CD4 >200 cells/ $\mu$ l and not on TB treatment or unwell) showed that the longer the appointment interval and ART refill (up to six months), the less likely the client was to have missed appointments, have a gap in medication or become lost to follow up (72). Associated qualitative work to explore healthcare workers and client experiences of a fast-track

model demonstrated that healthcare workers and clients viewed the model as being able to decongest the clinic and reduce waiting times (73). Overall, the model was highly applicable and acceptable. There were requests to carry out additional activities, such as taking weight and blood pressure, that were continued in the dedicated fast-track service room.

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One study in KwaZulu-Natal, South Africa, compared outcomes after providing clients with a choice of differentiated ART delivery model (24). Clients were offered a choice between in-facility individual fast-lane pick-up (also known as spaced fast-lane appointment), out-of-facility individual pick-up, community adherence groups (CAGs) and community adherence clubs (ACs). Retention was high at 12, 24 and 36 months across all DSD models when compared with those who qualified for a DSD model but remained in clinic-based care, but was highest at 90.6% at 36 months for facility individual pick-up. Viral suppression was high in both individual DSD models at 36 months (facility individual pick-up at 92.6%, community individual pick-up at 93.8% compared with routine clinic care at 88.6%) and significantly lower for those who had participated in the group models.

## Implementation

Importantly, an increasing number of studies are evaluating DSD implementation. In Zimbabwe, a mixed-method DSD model implementation evaluation in a rural district with 26 health facilities found that only 31% has implemented a fast-track individual facility refill model, but that clients spent 40% less time at the facility than those in routine care (74).

To date, the majority of differentiated ART delivery models have provided two or three months of ART. In Ethiopia, six-monthly refills were introduced at health facilities with biannual clinical visits. In total, 51% of clients were assessed to be eligible for this model, of whom 49% enrolled (75).

## Qualitative

Three qualitative studies explored six-monthly ART refills. In Malawi, a study assessed provider and client perceptions of six versus three monthly refills. Both clients and providers reported larger supply had more benefits. Providers' concerns regarding medication storage challenges and the risk of sharing ART were not supported by clients (76). A second study, in Zambia, determined provider perceptions only and established that providers perceived multi-month dispensing to hold significant benefits with advantages of six- over three-monthly dispensing (77). In Ethiopia, focus groups were held with clients eligible for six-monthly refills, some of whom had enrolled and other who had not. It showed high model satisfaction for those who enrolled, but importantly, that this model did not suit everyone. Decreased facility visits, lack of private space for medication storage and mistrust of the healthcare systems were reasons for not enrolling (78).

## Specific contexts

Appointment spacing has also been shown to have benefits in low-prevalence settings. In Guinea in West Africa, the SMA model was piloted in 2013 and expanded in 2014 following the outbreak of the Ebola virus disease (79). The six-monthly spacing approach, *Rendez-vous de Six Mois* (R6M), was scaled up to 60% of the cohort (n=1,166). Clients outside of the capital city of Conakry received six-monthly clinical visits and ART refills, and those in Conakry received three-monthly ART refills and six-monthly appointments. The R6M group had a 60% reduction in the risk of attrition compared with the standard of care after adjusting for duration on ART and TB co-infection.

Outside of sub-Saharan Africa, a facility-based individual differentiated ART delivery model implemented in Yangon, Myanmar, has reported good early outcomes (80). Clients were differentiated between unstable, short-term stable (29.2% of cohort) and long-term stable (51.2% of cohort). Short-term stable clients received three-monthly combined clinical review and ART refills visits, alternating between a physician and nurse. Long-term stable clients received six-monthly clinical reviews from a nurse and three-monthly fast-tracked ART refills from a pharmacist or dispenser.



**In politically unstable settings, such as the Central African Republic, South Sudan and the Democratic Republic of the Congo, the ability to provide extended refills of three to six months has also enabled continuity of ART delivery during periods of acute conflict.**

The number of clients that a team, made up of a physician, nurse and counsellor, could manage increased from 745 in 2011 to 1,627 in 2014, averting 41,116 physician visits. Aggregated 12-month retention for both clinically stable groups was 98.7%, with clinical treatment failure of 0.8% and immunological treatment failure of 5.8%.

In politically unstable settings, such as the Central African Republic, South Sudan and the Democratic Republic of the Congo, the ability to provide extended refills of three to six months has also enabled continuity of ART delivery during periods of acute conflict (81).

## Specific populations

Extended ART refills and fast-track service delivery models have also shown benefits for children. In a study assessing

the implementation of multi-month prescriptions (MMPs) for children across six sub-Saharan African countries, clients aged 0-19 years were transitioned to MMPs when they were defined as clinically stable (82). The study analysed outcomes from more than 22,000 children, 66% of whom were transitioned to MMPs. Of those transitioned, 2.6% were lost to follow up and 2% died. Virological suppression remained high over the first five years in MMPs, ranging by year from 79% to 85%. These results provide reassuring evidence that children and adolescents who are clinically stable can have good outcomes with reduced visit frequencies and extended ART refills.

A children-focused DSD model implemented in Tanzania utilized MMPs and also introduced a fast-track component where children could go directly to the pharmacy to collect their ART refills after an initial triage (83). Clients in this model received ART refills every two months and had a clinical visit every four months. A total of 51.3% of the paediatric, adolescent and young adult ART clients were able to be enrolled in this model, with 98.8% remaining in care. Reduced clinical visits and extended ART refills for clinically stable adults, children and adolescents should be a priority model of differentiated service delivery that can yield benefits in both high- and low-prevalence settings.



# OUT-OF-FACILITY INDIVIDUAL MODELS

*Photo credit: Peter Casaer/MSF*

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; (including private pharmacies) mobile outreach ART delivery; and home delivery.

## Fixed community points

Promising results have been found in models using fixed community points. Evidence has come from the community drug distribution point (CDDP) model in Uganda, the community ART distribution points (PODI) in the

Democratic Republic of the Congo (DRC), external pick-up points in South Africa, community pick-up points in Zambia and community private pharmacy collection in Nigeria and Uganda.

In Uganda, cross-sectional outcomes for clients initiating ART from 2004 to 2009 (median time on ART 5.7 years; interquartile range, IQR 4.1-7.2 years) in the CDDP model were that 69% were retained in care, 17% had died, 6% were transferred out and 9% were lost to follow up (LTFU). Among CDDP clients, viral load suppression (<1,000 copies/mL) was 93% (median time on ART 7.0 years; IQR 5.0-8.0) (84). In a subsequent conference abstract, LTFU was reported as 16.5% in the facility arm and 4.28% in the

CDDP arm (85). A costing comparison study in Uganda put the model from TASO, including TASO-run clinics for new initiations and the CDDP model for stable clients, at US\$74/visit and \$332/client/year compared with a mobile ART delivery model utilizing expert clients to dispense ART (US\$45/visit; \$404/client/year) and a facility-based nurse-led model (US\$38/visit; \$257/client/year) (86).

In the DRC, a retrospective cohort analysis found LTFU and death among PODI clients to be at 2.2% and 0.1% at six months, 4.8% and 0.2% at 12 months and 9% and 0.3% at 24 months, respectively, with overall crude attrition of 5.66/100 person years with little variation over time (87). Two 2018 conference abstracts also reported on PODI outcomes. The first on 576 clients enrolled in a PODI from October 2016 to December 2017 reported 12-month retention of 98% (88). The second on 1,484 ART clients enrolled at the four PODI houses resulted in decanting of linked facilities by 44-47%. The four PODI houses show high retention rates of 92-100% at three, six and nine months and VL suppression above 90% (89).

In South Africa, external pick-up points were endorsed as one of the country's three differentiated ART delivery models. This model allows clients to choose a non-facility based venue for ART refill collection. These include fixed community points, private pharmacies and, more recently, lockers. National retention and viral load suppression outcomes were evaluated in a 2019 study comparing 24 intervention and control facilities. External pick-up point clients had lower 12-month retention (81.5% versus 87.2%, aRD -5.9%; CI -12.5% to 0.8%) and comparable sustained viral suppression (<400 copies/mL any time ≤18 months) (77.2% versus 74.3%, aRD -1.0%; CI -12.2% to 10.1%).

**In Zambia, clinically stable clients were able to select community pick-up points for ART refill collection. ART refills were pre-packed by a central dispensing unit. Six participating clinics enrolled 6,303 clients to collect from 19 community pick-up points (rural markets, shopping malls and some at clinics), with a 96% retention rate, 94% ART refill pick-up compliance rate and 93% viral suppression rate (<50 copies/ml).**

Interestingly, the study reported increased viral suppression among men (RD 11.1%; 95% CI -3.4% to 25.5%) (5). A qualitative study of external pick-up points reported quicker and more convenient ART collection in the community, seen as a reward for taking ART well and reduced disruption in client life activities. At private pharmacies, some clients reported receiving inferior care compared with paying customers, and some worried about inadvertently revealing their HIV status. Clients and healthcare workers had to negotiate problems with Central Chronic Medication Dispensing and Distribution implementation, such as delayed SMS reminders, ART not being available at the external pick-up point and a few private pharmacies placing restrictions on ART pick-up times (90).

**Nigeria is expanding an out-of-facility model where community private pharmacies are linked with public health facilities and clients can elect to collect two-month ART refills from these pharmacies.**

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Nigeria is expanding an out-of-facility model where community private pharmacies are linked with public health facilities and clients can elect to collect two-month ART refills from these pharmacies. An early evaluation reported a 100% prescription refill rate and 99.7% retention in care (92). Uganda has also started utilizing private pharmacies, with six serving as community ART refill points for stable clients from four high-volume health facilities (>8,000 ART clients) (93). A nurse-dispenser distributes ART refills with six-monthly clinical reviews at the health facility. Over a 30-month period (January 2017 to June 19), 9,921 (29% men) clients enrolled, representing 30% of clients at the four facilities. Of these, 96% had received ART refills as scheduled, and the average waiting time at the pharmacy was <10 minutes. The 12-month retention rate was 98%, and >99% of enrolled clients remained virally suppressed.



In northern Namibia, two high HIV-burden districts with far distances to clinics implemented C-BART sites (94). Community members constructed basic structures close to their homes where healthcare workers visited quarterly to provide HIV clinical assessment, ART refills and VLs. Clients did not need to attend health facilities. In a retrospective cohort analysis of 909 adults ( $\geq 15$  years) and 122 children enrolled from 2007-2017, 12-, 24-, 36-, 48- and 60-month retention remained at 97% for adults and 81.5% for children.

## Mobile outreach ART delivery

There is limited published evidence of utilizing mobile outreach services to distribute ART refills outside of the health facility. In Eswatini, health facilities were offered a choice of three ART delivery models for implementation (mobile outreach, CAGs and facility-based ACs). One health centre and one clinic implemented mobile outreach to support remote communities. Among those enrolled in DSD models, 12-month retention was high at 93.7% but retention within models varied substantially (mobile outreach 86.3%; CAGs 70.4%; ACs 90.4%) (95).

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 families (96). The intervention piloted a travel package, including a 3-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. In a retrospective outcomes analysis of clients who enrolled in DSD models in Zambia from 2015 to 2017, 12-month retention was 81% in clinic-based care compared with 69% in two-monthly mobile outreach to rural health centres with both cohorts including non-stable clients. Provider costs per person retained was unsurprisingly much higher in the mobile outreach model (US\$291 versus US\$124) (23).

## Home delivery

There are four 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 1.04, 95% CI 0.78-1.40; equivalence shown) (97). Mortality rates were also similar between the groups (rate ratio 0.85, 95% CI 0.71-1.28). Health services and client cost per 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 controls (98).

In Tanzania, a non-inferiority cluster trial randomized 24 health facilities to: i) clinic-based ART delivery for all clients or: ii) the offer of home-based delivery (HBD) by lay healthcare workers for stable adult clients with an annual clinical review visit at the facility (99). In the intervention arm, 516 (44.4%) of the clients took up an offer to receive ART refills in or close to their homes (87.4% of stable clients). At the end of the study period (mean follow-up time was 326 days), loss to follow up was 18.9% in the intervention clinics and 13.6% in the control clinics, with 9.7% (91/943) of intervention clients and 10.9% (95/872) of control clients failing virologically.

In Lusaka, Zambia, within the PopART study, clients in two study arms were offered a choice for collecting a three-month ART refill within: i) clinic-based care or home delivery, or ii) clinic-based care or community-based AC (22). Twelve-month viral suppression was non-inferior in the community DSD models (above 98% in all three arms). More clients were lost to care in the clinic-based care arm (52/781; HBD 18/825; AC 20/808) with more deaths in the HBD arm (17; clinic-based 2; AC 7).

Two South African studies report on home ART refill delivery. A retrospective cohort study of clients utilizing private healthcare through a private health management scheme compared outcomes between clients receiving their ART refills through a courier service at home ( $n=14,620$ ) and those who collected their ART refills at a private pharmacy ( $n=19,202$ ) (100). The likelihood of viral suppression was higher for the home refill group (81% vs. 71%).

In a marginal structure model addressing time-varying aspects and causality, home refill was associated with



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an even higher benefit (aHR 0.66, 95% CI 0.55-0.78). A descriptive study reports on eligibility and uptake of home delivery of ART and other chronic disease refills (including hypertension, diabetes, mental health conditions, dyslipidaemia, osteoarthritis, asthma and epilepsy) during

the COVID-19 pandemic at a single clinic in the Tshwane health district (101). Thirty-two percent of 1,727 clients evaluated were eligible for home delivery, of whom 432 (79%) accepted.



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