Tropical Medicine and International Health doi:10.1111/tmi.12699

VOLUME 21 NO 6 PP 743–749 JUNE 2016

Expansion of the Adherence Club model for stable antiretroviral therapy patients in the Cape Metro, South Africa 2011–2015

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Abstract

OBJECTIVE The ambitious '90-90-90' treatment targets require innovative models of care to support quality antiretroviral therapy (ART) delivery. While evidence for differentiated models of ART delivery is growing, there are few data on the feasibility of scale-up. We describe the implementation of the Adherence Club (AC) model across the Cape Metro health district in Cape Town, South Africa, between January 2011 and March 2015.

METHODS Using data from monthly aggregate AC monitoring reports and electronic monitoring systems for the district cohort, we report on the number of facilities offering ACs and the number of patients receiving ART care in the AC model.

RESULTS Between January 2011 and March 2015, the AC programme expanded to reach 32 425 patients in 1308 ACs at 55 facilities. The proportion of the total ART cohort retained in an AC increased from 7.3% at the end of 2011 to 25.2% by March 2015. The number of facilities offering ACs also increased and by the end of the study period, 92.3% of patients were receiving ART at a facility that offered ACs. During this time, the overall ART cohort doubled from 66 616 to 128 697 patients. The implementation of the AC programme offset this increase by 51%.

CONCLUSIONS ACs now provide ART care to more than 30 000 patients. Further expansion of the model will require additional resources and support. More research is necessary to determine the outcomes and quality of care provided in ACs and other differentiated models of ART delivery, especially when implemented at scale.

keywords antiretroviral, drug delivery systems, community-based distribution, medication adherence, loss to follow-up

Introduction

In June 2015, UNAIDS announced that Millennium Development Goal 6 was achieved ahead of schedule and that 15 million people worldwide were receiving antiretroviral therapy (ART) [1]. New and ambitious targets were promptly set – to have 90% of people living with HIV know their status, 90% of those diagnosed HIV positive accessing ART, and 90% of those virally suppressed, or '90-90-90', by 2030 [2]. These goals become even more important as we officially enter the test-and-treat era. WHO now recommends ART initiation immediately after HIV diagnosis [3], reflecting evidence from the START and TEMPRANO trials [4, 5]. The question is no longer when to start ART, but rather how to effectively deliver ART and support life-long retention and adherence for all HIV diagnosed patients in ART care.

Models of care that increase ART management efficiencies for patients by reducing visit frequency and decentralising services closer to patients' homes have demonstrated improved retention and viral suppression

outcomes [6–10]. A differentiated care approach argues that the health system responds as patient needs change, and so once a patient is stable on ART, simplifying drug collection mechanisms and reducing unnecessary clinical follow-up visits should be prioritised to support ongoing retention and adherence. The evidence for differentiated models of ART delivery is expanding [11–18]. However, there is limited evidence available on the feasibility of taking these models to scale.

The Adherence Club (AC) model is one such differentiated model of ART delivery designed for stable patients. Originally, a pilot project of Médecins Sans Frontières (MSF) in Khayelitsha Cape Town [11], it was adopted by the Western Cape and City of Cape Town Health Departments in 2011. We describe the scale-up of ACs across the Cape Metro health district between January 2011 and March 2015.

Methods

Setting

Cape Metro health district serves a largely urban population of approximately 3.75 million people in and around Cape Town in the Western Cape province of South Africa [19]. The antenatal HIV prevalence in the district was 19.7% in 2013, ranging between sub-districts from 8.2% to 34.4% [20]. ART has been provided free of charge in the public health system since the national roll-out in 2004. The ART programme has evolved over time to reflect updated national guidelines around when to initiate ART and the number of facilities providing ART has increased. At the end of March 2015, Cape Metro health district delivered ART care to 128 697 patients at 70 urban and peri-urban based facilities. The ART cohorts in these 70 facilities ranged from 26 to 8884 patients.

The Adherence Club model of ART delivery

The Western Cape Government Department of Health (WCG DoH) adopted the AC model for the Cape Metro district in January 2011. Details of the AC model have been published previously [12]. Briefly, it provides ART distribution, care and support to groups of stable patients. While variation exists, all ACs have certain core components. Each is composed of 25–30 patients who meet for 30–60 min five times a year to receive their pre-packed ART (every 2 months except over year-end when a 4-month supply is standardly provided) [13]. At each AC meeting, there is a brief symptom screening and a short facilitator-led group discussion. Blood is drawn for viral load monitoring at the fourth month and a clinical consultation occurs at the sixth month with this schedule repeating annually. If symptomatic, AC patients have priority access to an allocated facility nurse. AC visits are recorded in paper-based AC registers which are then captured in the facility's electronic monitoring system (EMR).

Most ACs under study were facilitated by lay healthcare workers (LHCWs), such as lay facility counsellors or community health workers, with management support from nurses and/or clinicians. The AC model gives patients the flexibility to ask a third-party 'buddy' to attend the AC meeting and pick up their medication at every alternate standard AC meeting.

Patients were eligible to join an AC if they were stable, initially defined as being on ART for 18 months or longer with two consecutive suppressed viral loads (<400 copies/ml), a CD4 cell count above 200 copies/ml, no other chronic conditions requiring more frequent clinical consultations and a referral from a clinician. In 2013, the CD4 cell count criterion was dropped and time on treatment was reduced to 12 months, and from January 2015 the minimum time on ART was reduced to 6 months and only one suppressed viral load was required to meet the eligibility criteria. Eligible patients were not obliged to join but offered the choice to join an AC or stay within clinician-led clinic-based care.

Phased expansion approach to implementation scale-up

Beginning in the first half of 2011, the AC model was scaled-up through three waves of implementation. The first wave identified 15 willing ART facilities struggling with congestion, with ART cohorts of more than 1000 patients. The majority of these facilities' cohorts exceeded 2000 patients. The second wave dropped the clinic size criteria, and the last wave allowed all remaining willing facilities to implement the AC model. As previously described [12, 21], a collaborative quality improvement approach to implementation was taken. Briefly, the approach included setting up a provincial steering committee, nominating and training AC model mentors who supported a number of facilities during implementation and met bi-monthly to resolve issues arising from implementation, and providing two or three learning sessions 6 months apart for facility teams in each implementation wave.

Non-governmental organization (NGO) support was limited to providing technical support in the provincial steering committee and learning sessions with scale-up driven by the Western Cape and City Health Departments. No additional funding was provided to the

Western Cape Health Department to support scale-up of ACs. LHCWs were already employed as adherence counsellors or community health workers by various NGOs who are in turn funded by the Western Cape Health Department. AC implementation was driven by the provincial steering committee members and AC model mentors, mostly sub-district HIV managers and clinic doctors with an additional 1–3 part-time mentors from supporting NGOs [12].

Data collection and analysis

Data on patient visits were collected from two routine sources. The first was the monthly AC data aggregated for each club and reported monthly by sites, the second source was the routine EMR in the health district that was used to derive the total ART cohort over the study period.

We report the number of patients receiving ART in an AC *vs.* the total number of patients in the ART programme. AC data are derived from the aggregate AC database and the total ART cohort numbers are from the EMR. Retention in AC care (obtained from the AC database) was defined as the number of people who attended an AC visit in either the month reported or the previous month. The total retention in the ART cohort (obtained from the EMR) was defined as ART patients who had a clinic or AC visit in the last 3 months. Implementation was described over time and the proportion of patients in AC care is presented as a proportion of the total ART cohort.

We also investigated the extent to which patients transitioned into the AC model offsets the increase in the total ART cohort. This was derived from the total number of patients retained in ACs as a proportion of the total increase retained in the ART cohort over the period of study.

Results

The AC programme grew from providing ART treatment, care and support to 7.3% of the ART cohort at the end of 2011 to 25.2% by March 2015 (Table 1, Figure 1). The number of patients in an AC increased from 5683 to >32 000 over the same time period. The number of facilities offering ACs also increased from 16 to 55 between 2011–March 2015. In December 2011, 54% of the ART cohort were receiving treatment in a facility offering ACs but by March 2015 that percentage had grown to more than 90% (92.3%). The average number of patients in each AC remained relatively constant over time ranging from 24 to 27 patients per club.

The overall ART programme also grew during the AC implementation period from 53 facilities providing ART to 66 626 patients at the beginning of 2011 to 70 facilities and 128 697 patients in March 2015 (Table 1, Figure 2). Therefore, over the 4-year period of AC scale-up, the overall ART cohort nearly doubled in size. With the addition of 62 071 patients to the ART cohort, the scale-up of the AC programme to 32 425 stable patients offset the growth of the overall ART cohort by 51%. In 2011, the equivalent of just over a third of the increase in the number of patients retained in the ART cohort enrolled into this differentiated model of ART delivery for stable patients. From 2012 onwards, this grew to half of the total increase.

Discussion

Over a 4-year period, ACs were scaled-up rapidly, shifting 25% of the Cape Metro health district's ART cohort to this differentiated model of ART delivery for stable patients. By March 2015, more than 90% of ART patients were receiving care at a facility that offered ACs. Over the same period, the overall ART cohort size nearly doubled to

Table 1 Overview of Adherence Club model implementation by year, 2011–March 2015

	December 2011	December 2012	December 2013	December 2014	March 2015
# of ACs	239	606	898	1139	1308
# of patients in an AC, *n* (% of total cohort)	5683 (7.3)	14 458 (15.2)	21 358 (19.6)	30 549 (24.0)	32 425 (25.2)
# of ART facilities with ACs	16	36	43	52	55
Total # of ART facilities	53	56	62	70	70
Average # of patients/AC	23.8	23.9	23.8	26.8	24.8
Total # of ART facilities	53	56	62	70	70
# of patients in ART facilities with ACs, *n* (% of total cohort)	42 315 (54.1)	77 748 (81.8)	100 012 (91.6)	111 716 (87.8)	118 807 (92.3)
Total # of patients on ART	78 161	95 069	109 162	127 310	128 697

AC, Adherence Clubs; #, number; ART, antiretroviral therapy.

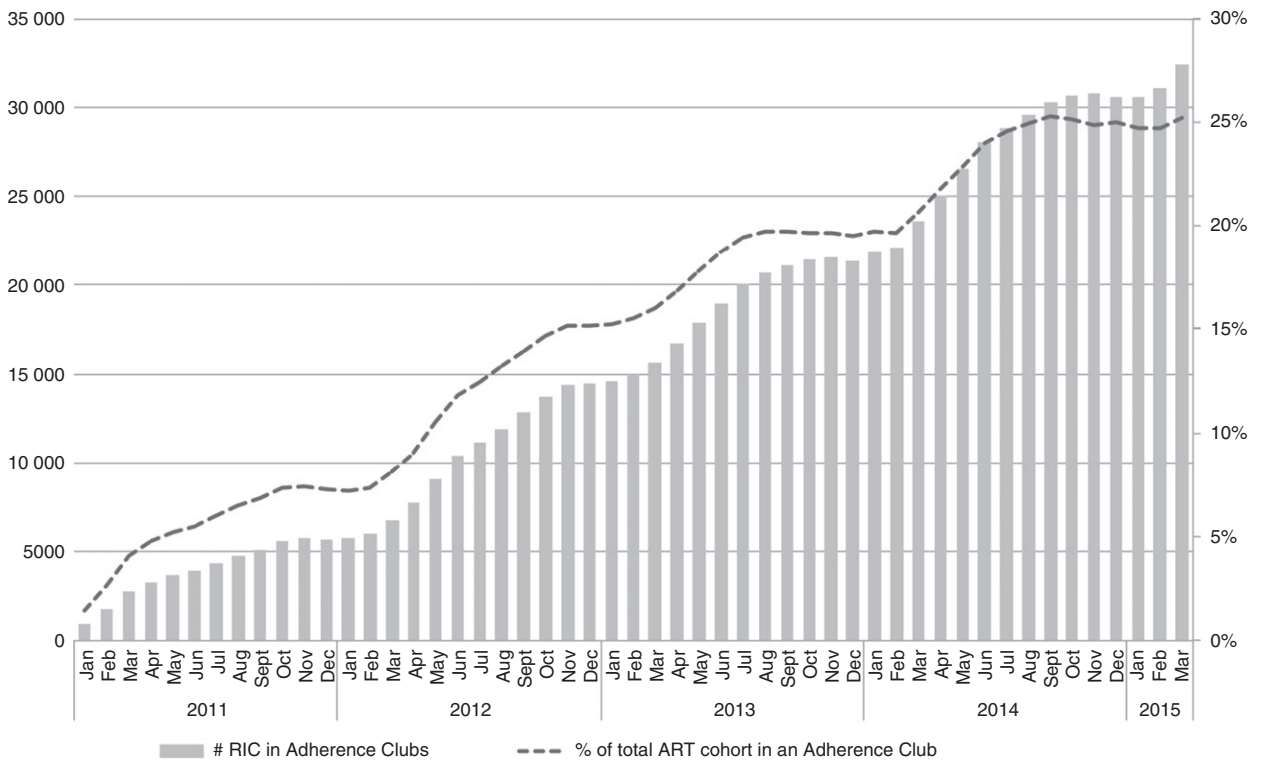

Figure 1 Number of patients retained in an Adherence Club and percentage of total ART cohort in an Adherence Club, January 2011–March 2015. Acronyms: ART, antiretroviral therapy; RIC, retained in care.

120 000 patients with AC scale-up offsetting half of the cohort growth.

This is the first study describing the implementation of a model of differentiated ART delivery at scale. While other pilot and demonstration projects have shown promising outcomes [14–16], little evidence on their scalability post adoption into government standard of care is available.

The acceptability and feasibility of AC implementation is reflected in the pace of scale-up, the proportion of patients accessing ART in an AC and the total size of the AC programme after 4-years.

The approach of the Clubs Steering Committee was to provide guidance on AC eligibility and structure while supporting individual sites to adapt the model components to better suit their context and resources. This flexibility was used by sites to adapt eligibility criteria, roles and responsibilities of the different cadres of staff involved, the location of AC meetings, the patient population served, the ART dispensing strategy utilised and the integration of other services into the model. These model adaptations are summarised in Table 2.

Facilities adjusted a number of eligibility criteria: the minimum duration of time on ART (from 12 to 6 months on ART), regimen (inclusion or exclusion of second-line patients), co-morbidities (inclusion or exclusion) and stability duration (one *vs.* two consecutive suppressed viral load measurements). The location of AC meetings also varied; most facilities offered Acs within the health facilities but some moved them elsewhere within the primary healthcare facilities or into communities. Examples of community-based ACs are those offered outside the health facility but close by [17], those outside the health facility and close to patients' homes and those offered in patients' homes. The staff who facilitated ACs also varied – while the model was piloted with LHCWs leading ACs, some sites utilised more highly trained staff such as nurses, while other sites capacitated 'expert patients' within ACs to lead the sessions.

Two types of medication pre-packing and dispensing were used in Cape Metro: a centralised Chronic Dispensing Unit (CDU) and the individual facility pharmacy. The Western Cape Government Department of Health partnered with a private company to deliver named packets of medication for each patient that were then dispensed offsite. While CDU dispensing greatly lightens the burden on the pharmacy, the AC model can be implemented with or

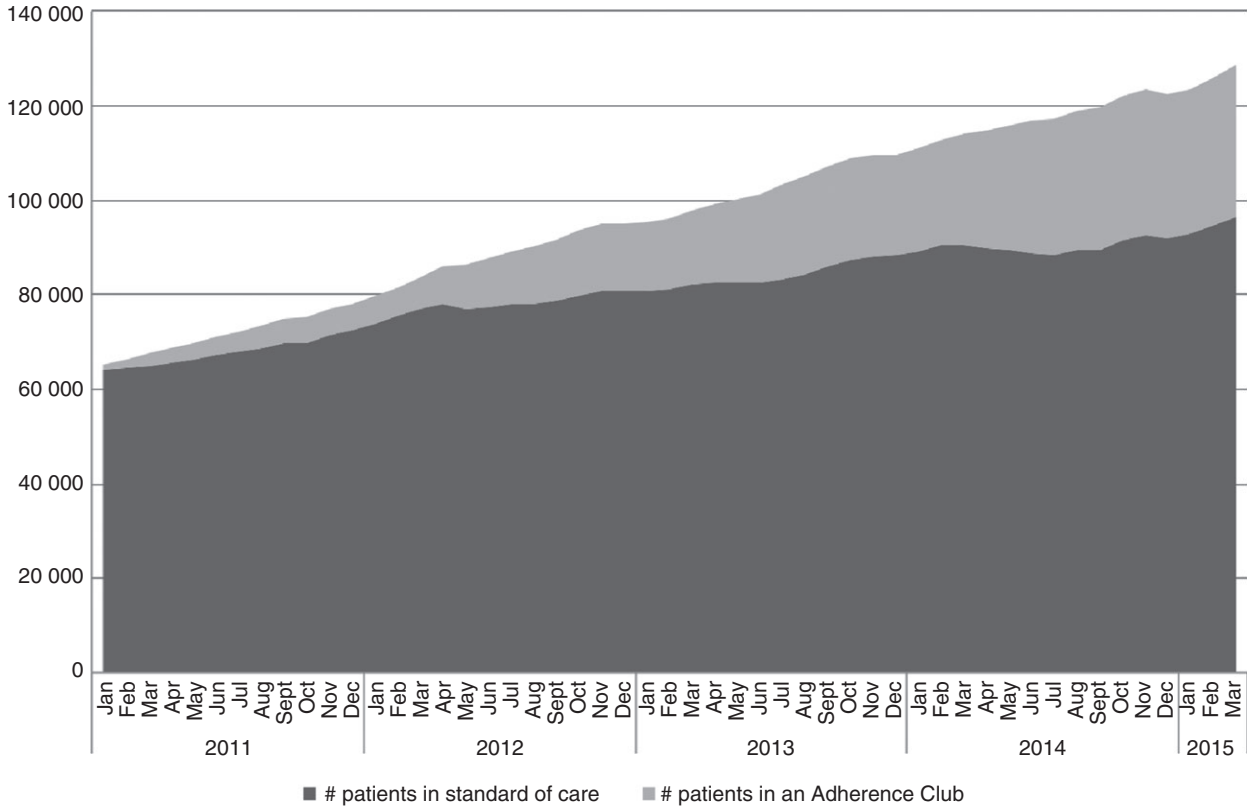

Figure 2 Number of patients in the antiretroviral therapy programme by model of care, 2011–March 2015.

without the CDU service. The first wave of model implementation did not have the option of the CDU service, which was only accessible from mid-2012.

While the scale-up of ACs to more than 30 000 patients represents a paradigm shift in how ART can be delivered, further adaptations and additional resources will be needed to transition a greater proportion of the cohort into ACs or similar models of ART delivery. AC implementation to date largely relied on leveraging existing Department of Health HIV resources. To fully realise the potential of such differentiated models of care for ART delivery and ensure quality of care within both this model and the clinician-led clinic-based model, sufficient numbers of stable patients need to be removed from routine clinician-led care to yield effective decongestion of primary healthcare facilities. This cannot be achieved with existing resources as patient numbers continue to grow. It will require funding of the AC model's costs, not only the appointment of additional lay LHCWs and increased pharmacy, clinical and data capturing time, but funded capacity to manage the model. Without such funding, the expansion seen to date is likely to cease and/or the quality of care provided to patients through this simplified model put at risk with negative consequences for long-term retention and adherence, the key objectives of the AC model.

Our findings should be considered in light of two key limitations. First, we report only on the number of patients in ACs as a proportion of the total ART cohort. The source of AC data is aggregated; no individual patient level data from ACs were available. From 2011 to 2013, AC data were collected from paper tally sheets, which were compiled at facility level from paper registers. During 2013, AC monitoring was phased into the EMR, which does track individual level data and patient outcomes. However, for this study, we are unable to report on the patient characteristics or outcomes of patients in ACs. Secondly, we did not conduct a detailed survey on the adaptations to the AC model made by each of the 55 facilities throughout 4 years of implementation and cannot therefore quantify the adaptions made by facility.

The present study highlights useful directions for future research. Most importantly, while this study provides a

Table 2 Adherence Club model components that can be adapted and adaptations that were made by implementing sites

Components of the AC model that can be adapted	Types of adaptations made by sites when implementing the AC model
Eligibility criteria	Duration of time of ART required
	Inclusion of patients on second line ART
	Number of suppressed viral loads required
	Inclusion of patients with co-morbidities
Location of AC meetings	Within ART facility
	Community venue close to facility
	Community venue close to club member's home
	Home of Club member
Cadre of staff facilitating the AC	Lay counsellor
	Community health worker
	Nurse (professional or auxiliary)
	Pharmacy assistant
	Club member
ART dispensing strategy	Pre-packed at central dispensing unit
	Pre-packed at health facility
Integrated services provided	Condom distribution
	Family planning
	Hypertension/diabetic drug supply
Patient population	General adult population
	Families
	Youth
	Men
	High risk (experienced viral rebound in the past)

AC, Adherence Clubs; ART, antiretroviral therapy.

basic overview of AC expansion, investigating patient outcomes in this model at scale is needed. Such an analysis would benefit from reporting on the impact of time on ART when enrolled into the model, time in the model, retention in both AC and facility care and viral rebound since enrolment. While the AC model aims to decongest health facilities, its principal objective is to improve the patient experience of long-term ART care. Studies using qualitative methods to examine patient perspectives on this model of care would be extremely valuable, including patients who enrolled in the AC model, patients who chose not to enrol and those who exited the model either voluntarily or after becoming ineligible in terms of model guidelines. Thirdly, future policy makers and implementers would benefit from a health system analysis describing the enablers and barriers to scale-up within government health services. Lastly, similar studies reporting on the expansion outcomes of other community-based models of care for ART delivery [22] adopted by government health authorities, such as the Community ART Group model in Mozambique, should be funded and undertaken.

Our experience of implementing a differentiated model of ART delivery across a health district has also yielded important policy lessons. We were limited to dispensing ART in 2-month refills according to provincial guidelines. Other policies were more supportive, including the ability of LHCWs to distribute ART and the ability to reduce the frequency of clinical visits for stable patients to an annual consultation. Further advocacy is needed to extend ART dispensing refills between clinical visits, reduce the frequency of ART rescripting requirements from 6-monthly to annually to align with clinical visits and ensure implementation of policies that support task-shifting and decentralization of ART delivery.

In conclusion, ACs were implemented across the Cape Metro health district over a 4-year period providing ART care and support to more than 30 000 patients. Further expansion of the model to more than 25% of the ART cohort and quality of care maintenance will require additional resources and support. More research is necessary to determine the outcomes and quality of care provided in ACs and other differentiated models of ART delivery, especially when implemented at scale.

Acknowledgements

We thank all staff involved in the Western Cape Department of Health AC programme, in particular, the past and present members of the AC Steering Committee with specific mention of Jannie Mouton, Lindsay Wilson (Western Cape Provincial Department of Health), Michéle

Youngleson and Farzaneh Behroozi (Institute for Healthcare Improvement). We are grateful to Morna Cornell for her feedback on early drafts of this manuscript. Finally, thanks to the patients of the AC programme.

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