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“Only twice a year”: A qualitative exploration of six-month antiretroviral treatment refills in adherence clubs for people living with HIV in Khayelitsha, South Africa

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“Only twice a year”: A qualitative exploration of six-month antiretroviral treatment refills in adherence clubs for people living with HIV in Khayelitsha, South Africa

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Short running title: Exploration of six-month ART refills for people living with HIV

Key words: multi-month refill, multi-month dispensing, differentiated service delivery, differentiated models of care, health system, HIV, adherence clubs, patient-centred, patient-centered, ART retention in care, healthcare worker-led group model, chronic care.

Abstract

Objective: Longer intervals between routine clinic visits and medication refills are part of patient-centred, differentiated service delivery (DSD), and have been shown to improve patient outcomes as well as optimise health services – vital as ‘universal test-and-treat’ targets increase numbers of HIV patients on antiretroviral treatment (ART). We performed a qualitative study to explore the experience and acceptability of six-month refills in adherence clubs in Khayelitsha, South Africa.

Design and setting: In-depth interviews were conducted in isiXhosa with purposively selected patients and in English with healthcare workers and key informants. All transcripts were audio-recorded, transcribed and translated to English, manually coded and thematically analysed. The participants had been involved in a randomised controlled trial evaluating multi-month ART dispensing in adherence clubs in Khayelitsha, comparing six-month and two-month refills.

Participants: Twenty-three patients, seven healthcare workers and six key informants were interviewed.

Results: Patients found six-month refills increased convenience and reduced unintended disclosure. Contrary to key informant concerns about patients’ responsibility to manage larger quantities of ART, patients receiving six-month refills were highly motivated and did not face challenges transporting, storing or adhering to their treatment. All participant groups suggested that strict eligibility criteria were necessary for patients to realise the benefits of extended dispensing intervals. Six-month refills were felt to increase the health system’s efficiency, but there were concerns about whether the existing drug supply system could adapt to six-month refills at scale.

Conclusions: Patients, healthcare workers and key informants found six-month refills within adherence clubs acceptable and beneficial, but concerns were raised about the reliability of the supply chain to manage extended multi-month dispensing. Stepwise, slow expansion could avoid overstressing supply and allow time for the health system to adapt, permitting six-month ART refills to enhance current DSD options to be more efficient and patient-centred within current health system constraints.

Strengths and limitations of this study

- This study aims to add to the literature on the experience of six-month ART refills in order to comprehensively evaluate the value of extended refills
- The experiences of patients in both the standard of care two-month refill clubs and the six-month refill clubs are represented, as well as those of staff and key informants
- Interviewer positionality was reviewed throughout the study by holding regular debriefings with the study team to clarify findings and how the researcher's background may have affected them
- Recruitment of particular patient groups was challenging, therefore men, patients under 30 years old and those not retained in care might have been under-represented
- Some misunderstandings about randomisation for the quantitative study might have influenced patient perceptions of eligibility for six-month refills

Summary

What is already known?

- Differentiated service delivery (DSD) models and longer antiretroviral (ART) refill intervals benefit both patients and the health system
- Six-month ART refills are safe in terms of patient outcomes, with non-inferior viral load suppression and retention in care compared to standard of care

What are the new findings?

- Six-month refills are convenient for patients, help prevent unintended disclosure, and motivate patients to be adherent.
- Patients manage the increased ART supply responsibly, taking measures to store their medication appropriately and prevent theft. They do not commonly share medication and are committed to taking their treatment regularly.
- Six-month refills support creating time for healthcare workers to spend on other tasks and manage a larger number of patients.
- There are significant concerns that the current pharmacy and supply chain systems will not be able to support the implementation of six-month ART refills

What do the new findings imply?

- Patients and healthcare workers find six-month refills acceptable within the adherence club model and key informants are cautiously optimistic about the benefits
- Six-month ART refills could represent an evolution of current DSD options to be more efficient and patient-centred, and allow for the health system to maintain good quality of care for the increasing numbers of patients on ART.
- Concerns regarding the supply chain necessitate a gradual expansion of longer refills to allow the health system to absorb the change

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Introduction

Improved and simplified antiretroviral therapy (ART) means that HIV can be managed as a chronic disease, but requires the health system to adapt to respond to the changing needs of patients on lifelong treatment. Service delivery of HIV care has evolved from a 'one-size fits all' approach to respond to the diverse need of people living with HIV in resource limited settings. Patient-centred, differentiated service delivery (DSD) models for clinically stable ART patients, such as adherence clubs, have proven successful in both improving patient outcomes and optimising health services to provide quality care to the increasing numbers of patients on ART (1,2). Multi-month ART dispensing has been endorsed by the World Health Organization to further reduce the burden of care on both patients and the health system (3) and scale-up of six-month refills has been accelerated as part of PEPFAR's 2019 country operational plan (12).

Evidence from multiple studies and a 2016 systematic review suggest that extending refill and visit intervals is safe for patients, with equivalent or better outcomes (retention in care, viral load (VL) suppression, morbidity and mortality) (4–8). In addition, longer intervals have been shown to improve clinic efficiency, reduce waiting time and improve satisfaction with services (9). They also increase the number of patients that healthcare workers (HCW) can manage (10), essential in the era of 'universal test and treat' as larger numbers of patients are initiated on ART. However, there is limited qualitative evidence on the impact of extended dispensing intervals to six months, particularly patient and HCW perspectives (1).

In Khayelitsha, South Africa, *Médecins Sans Frontières* (MSF) successfully piloted the adherence club model for clinically stable patients, where a group of patients receive their ART refills together through a lay facilitator, who also provides education (13–15). The model has now been endorsed in policy and scaled up throughout the country (14). MSF implemented a randomised controlled trial to compare extending ART refill intervals from two to six months among existing adherence club patients (16). Preliminary results show non-inferiority in terms of 12-month retention (97% compared to 98%) and VL suppression (98% compared to 97%) (8).

This qualitative study explored patient, HCW and key informant experiences and perceptions of extending ART refills to six-months within the adherence club model.

Methods

Study design

This is a descriptive qualitative study including in-depth interviews (IDIs) with patients, HCWs and key informants.

Setting

Khayelitsha, South Africa

Khayelitsha is a large, peri-urban informal settlement outside of Cape Town, South Africa, home to a population of at least 500 000 people. It has the highest HIV prevalence in the Western Cape province (17) with approximately 47 000 adults on ART in 2019, of which 30% of are men and 42% receive ART in adherence clubs. It has one of the longest standing and largest treatment programmes in South Africa (17).

The population is extremely mobile, with many people moving between the informal settlement and a neighbouring province. Additionally, high rates of unemployment, violence, mental health issues and substance abuse contribute to poor engagement with health services (17–20).

Randomised controlled trial of extended ART refills within adherence clubs

A cluster-randomised controlled non-inferiority trial extending ART refills from two to six-months within existing adherence clubs was conducted from 2017 to 2019 at Site B Community Health Centre, a large provincial, primary care clinic in Khayelitsha (16). The study was conducted within routine adherence club conditions. The intervention has been described in detail elsewhere (16) and is summarised in Table 1 below.

Table 1. Procedures and comparison of the standard of care and intervention arms in the randomised controlled trial of extended ART refills (13–16)

	Standard of care: Two-month refill adherence clubs	Intervention: Six-month refill adherence clubs
Eligibility	Eligibility for adherence club care <ul style="list-style-type: none"> • Adults over 18 years • On the same ART regimen for at least six months • Undetectable VL • No current tuberculosis or pregnancy or condition requiring regular clinical follow-up <i>All participants were previously enrolled in an adherence club care at Site B Community Health Centre</i>	
Adherence club visits	Frequency: Two monthly (four visits receiving two months ART refills and one visit receiving four month ART refill over the December holiday period) (five per year)	Frequency: Six-monthly (two per year)
	Provider: Led by club facilitator (lay counsellor) Location: In the community (such as a library or community hall) or the facility	
Routine bloods (VL and for clinical review, depending on the regimen)	Frequency: 12-monthly Provider: Managed by a nurse	Location: At the facility, an additional individual visit, scheduled 1 month before the adherence club visit
	Location: At the facility, part of the adherence club visit	
Clinical consultations	Frequency: 12-monthly Provider: Managed by a nurse	Location: At the facility (part of the adherence club visit)
	Location: At the facility (part of the adherence club visit)	
Grace period	Patients can collect medication up to five days after their scheduled appointment	
Treatment “buddies”	Allowed to collect on a patient’s behalf at every other visit	Not permitted

This qualitative study was conducted to explore perceptions, concerns, benefits and burdens related to extending the ART refill length within this trial.

Study population, sampling and recruitment

Patients in the trial database were categorised by, age, gender, type of adherence club (community- or facility-based) and club status at the time of enrolment into the qualitative study: retained in club care (therefore also VL suppressed [<400 copies/mL] at last blood draw) or not retained in club (removed from their adherence club due to VL failure, missing a club appointment or another condition making them ineligible for club care, such as tuberculosis or pregnancy). Eligible patients for the qualitative study were purposively sampled and recruited telephonically by an MSF counsellor.

HCWs (Department of Health clinicians and pharmacists, not-for-profit (NPO) club facilitators, MSF nurse and pharmacy assistant) were individually invited to participate after introductions from the clinic's operational manager and direct managers for MSF staff. Follow up to organise the logistics and discuss participation was conducted over email or text message. All HCWs involved with the care of patients in the trial were invited to participate.

Key informants included individuals with influence over the adoption of extending ART refill duration for clinically stable ART patients in the Western Cape and an understanding of the policy process. Key informants were selected using snowball sampling, beginning with those identified by the research team, and were contacted by email.

Data collection

IDI guides were piloted with MSF staff not involved with the trial and revised. Patients were interviewed in isiXhosa by a research assistant, using guides developed in English. Interviews were conducted either at the patient's home or MSF office (based on patient preference).

HCW and key informants were interviewed in English by the Principal Investigator (PI). Interviews were conducted in a private office, a clinician's room or a boardroom.

All IDIs were conducted between June and November 2019 and were audio-recorded. Data collection continued until saturation was reached. The PI and research assistant both work for MSF and held fortnightly debriefings to reflect on the impact of their position on the data collection and analysis, and discuss emerging themes from the interviews (including differences and similarities between the participant groups), to allow continued exploration of emerging themes.

Data analysis

Interviews were transcribed and all isiXhosa interviews were translated into English. Transcripts were reviewed by the original interviewer and compared to handwritten field notes to check the quality and validate the data.

All transcripts were manually coded and thematically analysed by the PI, using a network approach to develop primary themes then group them into organising and overarching themes, as described by Attride-Stirling (21). Selected transcripts were coded by the research assistant and a co-investigator, and were then discussed among the research team to agree on the coding and analysis framework.

Patient and Public Involvement

We did not directly include patient and public involvement in this study, but the research question was developed by a team who work closely with patients and the community involved. Patients have been invited to be part of the dissemination of results and the advocacy efforts that stem from this study and the parent RCT.

Ethics and informed consent

This study was approved by the MSF Ethics Review Board (reference 1910), the University of Cape Town's Human Research Ethics Committee (HREC 191/2019) and the Western Cape Provincial Department of Health. All participants gave written consent in English or isiXhosa. The specific roles of key informants and HCW's organisations are anonymised to protect their identity. Patients were reimbursed for their time and transport costs.

Results

Demographics

A total of 36 IDIs were conducted (ranging in length from 19 minutes to one hour), including 23 patients (16 in six-month and seven in two month ART refill clubs), seven HCWs, and six key informants. Table 2 summaries the demographics and roles of the interviewees.

Table 2. Summary of interviewee demographics and categories

Study number	Age	Sex	Category
Patients (P)			
6 months (6M)			
P6M_1	42	F	Retained in original club
P6M_2	45	F	Retained in original club
P6M_3	38	F	Retained in original club
P6M_4	40	F	Retained in original club
P6M_5	42	M	Retained in original club
P6M_6	36	F	Retained in original club
P6M_7	59	F	Retained in original club
P6M_8	66	F	Retained in original club
P6M_9	39	F	Returned to clinic for pregnancy management
P6M_10	46	F	Retained in original club
P6M_11	52	F	Not retained in club care due to missed visits
P6M_12	41	F	Returned to clinic for high viral load >1000 copies/mL
P6M_13	40	F	Returned to clinic for high viral load >1000 copies/mL
P6M_14	39	F	Retained in original club
P6M_15	30	F	Retained in original club
P6M_16	47	F	Retained in original club
Two months (2M)			
P2M_1	38	F	Retained in original club

P2M_2	58	F	Not retained in club care due to missed visits
P2M_3	52	M	Returned to clinic for tuberculosis management
P2M_4	49	F	Not retained in club care due to missed visits
P2M_5	36	F	Not retained in club care due to missed visits
P2M_6	35	F	Retained in original club
P2M_7	54	F	Retained in original club
Healthcare worker (HCW)			
HCW_1	59	F	Lay counsellor facilitator
HCW_2	59	F	Lay counsellor facilitator
HCW_3	31	F	Nurse
HCW_4	41	F	Doctor
HCW_5	38	F	Nurse
HCW_6	36	M	Pharmacy assistant
HCW_7	53	F	Lay counsellor facilitator
Key informants (KI)			
KI_1	Not collected	M	Pharmacy
KI_2		F	Pharmacy
KI_3		M	Programmatic management (urban)
KI_4		F	Programmatic management (urban)
KI_5		M	Pharmacy
KI_6		F	Programmatic management (rural)

Themes

Patient, HCW and key informant perspectives were combined in six overarching themes that emerged from the data: three relating to the impact of extending ART refills to six-months on the patients, two relating to the impact on the health system and one overlapping theme exploring eligibility (see figure 1).

Figure 1. Overarching themes related to the impact of the model on patients and the health system

<figure 1>

1. Impact on patients

Extending ART refills to six months within the club model influenced patients and their care in several ways, including 1) the convenience of ART engagement, 2) unintended disclosure and 3) their responsibility and motivation.

1.1. Convenience

Patients, HCWs and key informants agreed that extending ART refills to six months decreased obstacles to accessing facilities, reducing the burden of frequent clinic visits and reducing travel costs for patients

It made a big difference. I am now saving all the R20s [transport money] (P6M_8)

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3 Patients described time as very valuable and a major benefit of six-month refills is that “it saves a lot of
4 time” (P6M_10). The time saved by not attending the club visit is used to go to work, look for
5 employment, child care, household chores, shopping and addressing challenges that arise in their lives.

6 *It helps them a lot because these patients now have got the time to look after themselves*
7 *(HCW_2)*

8
9
10 Patients noted that increasing the time between visits allows for extended travel: for work or to address
11 issues where family live outside of the province.

12 *It changed my life so much because I know that I have my pills for six months. For example, we*
13 *go out, we attend funerals, we have problems in our homes [rural areas] so now I can stay the*
14 *whole month or three months at home. I couldn't do that when I was in two-months because I*
15 *had to rush and come back for my appointment and if you missed it you must start afresh. So*
16 *now it saves time and it saves everything (P6M_10)*

17
18
19 Six-month ART refills were described by HCWs as “a huge help for patients who are working”
20 (HCW_4) as “it’s not easy to get jobs so if they found a job they don’t want to lose it” (HCW_7).
21 Employment was noted by patients as a significant barrier to accessing the health system, either
22 because going to work prevented them from attending their appointment or travel took them out of the
23 area. Attending an ART appointment rather than work was described as stressful by patients due to the
24 loss of income and the risk of loss of employment if work was missed:

25 *I did not like two-months as I was going to the clinic all the time. I could see that I would lose my*
26 *job because some bosses don't like you telling them that you are HIV positive. Even when I go to*
27 *the clinic I don't want the paper [sick note]. [Six-month clubs] are not difficult like the two-*
28 *months. In the two-month club you have to go to the clinic, and that can lead you to be fired by*
29 *your bosses because they will ask 'what's wrong with this person who goes to the clinic every*
30 *two months?' (P6M_5)*

31
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33 The fear of annoying their employer by asking for frequent days off and the fear of disclosure to
34 employers that they did not trust meant that patients felt they “had to lie in the two-month [club]...and
35 come up with new excuses” (P6M_10)

36
37
38 Longer ART refills allowed patients more time to organise and plan their lives, and reduced the stress of
39 trying to balance their life and ART commitments. It also provided patients with a sense of security to
40 manage stock-outs or uncertain medication supply.

41 *Six months was good for me, because when you have to do something you are always anxious.*
42 *Six months is a lot, you have peace of mind, and you know you have your pills in front of you.*
43 *Even if something happens and you are told the pills are finished, I will know I have mine: only*
44 *those that gets two months supply will be affected (P6M_2)*

45 46 47 **1.2. Unintended disclosure**

48 HCWs and key informants were concerned that larger numbers of ART bottles would result in
49 unintended disclosure when transporting the medication and storing it at home. Patients were more
50 concerned about the noise that the large number of bottles made

51 *My only problem is the noise that they make. They are in these containers and there is a lot of*
52 *them...so they make noise and I cannot go everywhere with them. I was worried when a friend*
53 *of mine called me to come to her place. I was in a taxi, so I had to get off and go to her. That did*
54 *not make me feel good because I was carrying my pills. I am refusing to let go of my bag,*

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3 because I am like 'leave my bag alone dude!' That stressed me. I knew that even if I wanted to
4 stay longer, I had to quickly go because now I can't even go outside and leave my bag, and when
5 I am touching my bag, it is making a noise and you can see that its pills. She was asking what
6 was in my bag, what are these pills for? But I can't tell her. (P6M_5)
7

8
9 Patients felt less frequent visits reduced the risk of disclosure at work, because "the day you mention the
10 word HIV, is the day you lose your job" (P2M_4). Patients in both six and two-month clubs were not
11 greatly concerned about disclosure at home as most had disclosed to their immediate family and asked
12 them for support with adherence. Some patients described being "afraid to be seen in the clinic"
13 (P6M_1). Patients, HCWs and key informants felt that six-month refills provided patients with more
14 privacy and could help to reduce unintended disclosure as community members were less likely to
15 assume infrequent visits were for ART.

16
17 *I would say there is a change because the frequent visits to the library to get medication meant*
18 *that even people who didn't know your status could tell you were part of the people who went*
19 *there, which would raise questions. Now they won't be able to see that because you won't be*
20 *going as frequently (P6M_9)*
21

22 **1.3. Responsibility and motivation**

23
24 Key informants were concerned that if patients were provided with larger quantities of medication they
25 would use it irresponsibly, adherence would worsen and seeking care when ill would be delayed until a
26 scheduled appointment. They were also concerned about suboptimal storage of medication, that
27 patients might share or sell medication or that it would be stolen.

28
29 *There were cases where they told us it was stolen. We know for a fact that the drugs do get used*
30 *for other purposes as well and we know of instances where people were collecting ARV's and*
31 *selling them. But who knows, most of them had lost them, or they were stolen, or they don't*
32 *know why they're finished (KI_5)*
33

34 Patient experiences did not support these concerns, and they reported many mechanisms to remind
35 them to take their treatment daily and attend appointments, including setting phone reminders, using
36 calendars, timing their pills with popular TV shows and asking family members to remind them.
37 Irrespective of the trial arm, patients in clubs valued their health and their treatment and reported being
38 highly self-motivated.

39
40 *I am taking my treatment well, this is my health and my life, and I don't have another life. My life*
41 *depends on me (P6M_10)*
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43
44 *What is important in my life is my life (P2M_7)*

45 Patients reported making use of the grace period or would rebook if they missed an appointment, and
46 reported that they either had, or would, visit health services if they became sick in between visits or lost
47 their medication

48
49 *You don't have to wait the whole six month until your date for you to come to the clinic... I would*
50 *go to the clinic like everyone else and tell the doctor I am in the club but I am sick at that time*
51 *(P6M_9)*
52

53 Patients reported having a specific place to store their medication that was cool, dark and safe from
54 theft and children's access. Most said that they do not share their medication, because staff have
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3 instructed them not to, other people are not using the same regimens, they worry about running out of
4 pills and they value the treatment for their own use.

5 *The pills are calculated for me not her, she must go to the clinic to take hers... I can't give*
6 *anyone my pills. Even my siblings know these are mine not for everyone (P6M_2)*
7

8 Theft of medication (in the facility, in transit or at home) had not affected any of the participants directly
9 and was not a major to concern. Patients had “heard about those who smoke and sell them” (P6M_10)
10 but this was unsubstantiated by specific examples. It was felt pills were lost as collateral in the theft of a
11 bag rather than being the target of theft, thus patients took action to mitigate theft of their belongings.

12 *I take a taxi, because there are pickpockets, and come straight home (P6M_15)*
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14

15 In addition, patients and HCWs felt that the benefits of six-month ART refills actually increased patient
16 adherence further.

17 *We are very trusted with the six months... we are given enough time to look after ourselves, that*
18 *is where our confidence is built (P6M_3)*
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23 **2. Impact on the health system**

24 From the HCW and key stakeholder perspective, the main benefit for the system was increased
25 efficiency and the main concern was the impact on the medication supply system. There was a feeling
26 that despite the benefits of longer refills, there were still significant challenges and for some the non-
27 inferior trial outcomes were not enough to justify the risks and additional investment required to
28 implement longer duration ART dispensing. Ultimately, there was cautious optimism about six-month
29 refills, with key informants acknowledging the benefits while warning of the legitimate concerns and
30 practical challenges described below.
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34 **2.1. Efficiency**

35 From the perspectives of the HCWs and key informants, one of the main benefits of six-month ART
36 refills for the health system was the “efficiency gains” and the ability to “service more people with the
37 same number of staff” (KI_5). It was reported that the need to do this was driven by pressure from the
38 ‘universal test and treat’ guidelines:
39

40 *They are coming every two months or every six months: that's a third that you have*
41 *cut... That's huge... Now that we are trying to start everyone who gets tested on ARVs,*
42 *the numbers we are looking at are going to be immense. (HCW_4)*
43
44

45 The HCW workload for each club visit was described as remaining the same or slightly increasing
46 (particularly for pharmacists) but increasing the refill interval within the adherence club model resulted
47 in reduced workload overall, particularly for club facilitators and data clerks:

48 *Personally it has helped me a lot because it reduces the workload... So that gives me a little*
49 *relief. It's not that I am relieved from them, but I'm relieved from the workload... So you prepare*
50 *your registers, you prepare the medication and you must be earlier than usual when you are*
51 *going to do the club. It's more preparation if the patient is going to be...doing a clinical visit and*
52 *taking bloods. But now I don't have that big preparation. They are giving me a gap. (HCW_2)*
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The additional time created by seeing patients less frequently was used to manage other activities that were previously neglected or more stressful due to high patient volumes, including administration and management of ad hoc problems in the clinic.

Patients in the six-month clubs perceived there to be an increase in peer and club facilitator support, despite concerns from key informants that the reduced visit frequency would diminish support. Paradoxically the decreased visit frequency in the six-month model increased the quality of the support because patients could take an entire day off work instead of rushing through the session in order to attend to other competing tasks for the day, as they had been doing when in two-month clubs. Patients and HCW also described patients enjoying the reunion with peers when they returned for the club visit.

When they come back, they come back with that excitement. "We have been away from the clinic, how are you?" They are happy! They are now enjoying the club. (HCW_2)

2.2. Medication supply system

A major concern raised by key informants and HCWs was the current medication supply system's capacity to adapt to six-month refills. They expressed concern regarding the smaller facilities with limited storage space that would require more frequent deliveries from the depot. Key informants felt that the supply system was already *"on a knives edge"* (KI_1) and planning was dependent on factors outside local control, including manufacturers, national contracts and demand from other provinces.

You need good stocks to be able to hand that out... But with what happens at national level, sometimes our systems are not good enough and that could create a real disaster. (KI_4)

While acknowledging that for the *"ART program itself, it's been very rare to have stock outs"* (KI_4) compared to other chronic disease treatment, the impact of stock-outs for patients receiving six-month ART refills could detrimentally impact supply by creating peaks in the demand for medication. There was concern over the *"industrial amounts of medicine"* that would be in the community rather than within the health system's control.

It's a lot of medicine to be sitting in people's homes ... So it's a lot of money tied up in people's homes where you don't have access to it as you would in the health system... I mean that's a lot of medicine that's going to be sitting out in communities. (KI_2)

"Ultimately the drugs are for the community" (KI_3) and slow and careful expansion of longer refills was suggested as a way to avoid *"absolute disaster"* (KI_4), allowing time for planning and problem solving. This would reduce stress on the supply chain and the risk of overwhelming the system.

3. Eligibility

There was consensus across key informants, HCWs and patients that if the existing club model were adapted to provide six-month refills, it would not be appropriate for everyone and would benefit a *"select small group of patients"* (KI_2). There was consistency across interviewees in suggesting strict criteria with evidence of long-term adherence, such as multiple suppressed VL results. It was felt that newly initiated patients need experience on ART to develop maturity, build up understanding and knowledge and learn to solve challenges. Both HCWs and patients suggested that all ART patients should start in two-month clubs and 'graduate' to six-month refills when they had proved themselves .

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You cannot skip to the six-months if no one knows how you took the two-months. They have to see that you are taking the two-month supply first to show that you are taking it well. If you are not taking the two-month well, don't even bother going to the six-months. If you are someone who puts their health before anything, you can take the six-months supply. I would advise them to go to the clinic and start with the two-months and see if you manage and if you do, you can get on the six-months. (P2M_4)

It was also felt that patients should 'earn' the reward of six-month refills, as one patient described:

We also started there [two-month refills]. We were standing in those queues. It was not easy for us: we worked for that six-months. They must also work for it so that they can get to where we are. They must start with the two-months: we started from the bottom and we climbed our way up until we were alright. (P6M_8)

Six-month ART refills were viewed by HCWs and patients as a reward for good adherence, with patients viewed as 'VIPs' who "feel like champions" (HCW_1). Six-month refills motivated and empowered patients to be adherent and take control of their treatment, with the possibility of losing the benefits ensuring adherence.

They took their treatment more seriously because they loved being in the six-month [club] and you tell them if the viral load increases unfortunately, I won't be able to keep you in the six-month club. They took their medication because they wanted to be in the six-month arm. They continue to be quite motivated, to take treatment and take control. (HCW_5)

Discussion

This study is the first to qualitatively evaluate perceptions of ART refills longer than three months (22), and explore patient, HCW and key informant experiences of six-month refills for clinically stable HIV patients in adherence clubs. Six-month refills were recently trialled by MSF and the Western Cape Department of Health in South Africa, with non-inferior patient outcomes to the standard of care clubs receiving two-month ART refills (8).

All participants agreed that six-month refills were a motivation for adherence and that the main benefit was the increase in free time and convenience, even in addition to the time-saving benefits described previously for the club model itself (2). Longer refills also gave patients 'peace of mind' and a sense of control in managing their treatment, despite the uncertainties in their lives and the health system, such as stock outs.

Our data suggest that patients did not struggle with adherence, storage or safety of their medication, contrary to key informant concerns. Patients valued their health and their treatment, but also valued their life responsibilities, such as work and family. The frequency of ART visits was a significant stress and in their experience of two-month refills, patients reported finding ways around their visits that did not jeopardise other obligations. Patients live in complicated worlds that require navigation of competing priorities (23), and if a choice has to be made, life commitments may be prioritised at the expense of ART. Six-month refills helped to overcome this tension by reducing the impact of many previously described barriers to engagement with the health system, such as travel, stigma, inconvenience of appointments, changes to routine and being busy preventing attendance (24). As focus shifts to mechanisms of retaining patients in lifelong care, it is increasingly necessary for DSD to put

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3 patient's preferences at the centre of service design (1,2,23). Longer refill intervals support patients to
4 incorporate ART into their daily life and can enhance the convenience of current DSD models.
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7 In addition to patient benefits, six-month refills were felt to increase the health system's efficiency, a
8 well-documented benefit of DSD (2) and ascribed to reduced visit frequency in previous studies (10).
9 This is an important consideration in the era of 'test and treat', where growing numbers of people
10 starting ART has not been met with an increase in the number of HCWs to support this expansion. A
11 majority of patients on ART are expected to be eligible for DSD models and this is likely to have a
12 significant impact on DSD infrastructure (25). Current DSD options need further evolution to make even
13 more efficient use of resources, in order to cope with the growing ART cohort.
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16 A significant concern for HCWs and key informants was whether the existing drug supply system could
17 adapt to provide six-month ART refills at scale. The precariousness of the supply chain would both limit
18 the feasibility of implementation and be worsened by the additional stress longer ART refills would place
19 on the system. These concerns highlight the critical importance of DSD optimisation, health system
20 planning and close monitoring of phased implementation at national and provincial levels to ensure
21 feasibility and long-term sustainability.
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24 Interestingly, patients (including those receiving two-month refills), HCWs and key informants alike felt
25 that extended refills were only suitable for a select group of patients, who needed to both prove
26 themselves (with evidence of long term adherence such as multiple suppressed VL results) and earn the
27 benefits by 'doing their time' with shorter refill intervals. While eligibility criteria are important to
28 ensure that DSDs are implemented appropriately, meeting these criteria does not necessarily result in
29 successful outcomes (25). The need for strict eligibility criteria to ensure successful outcomes needs to
30 be balanced with the patient-centred benefits six-month refills could offer to clinically stable patients.
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33 There are several limitations to this study that bring into question the transferability of the findings to
34 other settings. It was challenging to recruit men, patients under 30 years old, and those not retained in
35 care at the time of recruitment for this qualitative study. The participants in the randomised controlled
36 trial from which the participants for this qualitative study were drawn, were recruited from existing
37 adherence clubs (eligibility for which demonstrates long term adherence) questioning the transferability
38 of the findings to settings that do not offer group DSD models or to patients not yet clinically stable on
39 ART. However, participants in the two-month refill clubs were also included to explore whether six-
40 month refills impacted the experience of those who were already shown to be stable patients.
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43 Some of the benefits described by patients and HCW, such as the 'reward' of being chosen for the six-
44 month refill clubs, or the special 'VIP' treatment, came from a misunderstanding of the randomisation
45 process (despite multiple rounds of consent) as 'being chosen'. Clubs are already seen as a reward for
46 'taking treatment well', and pre-existing confusion about 'qualifications' for club eligibility has been
47 previously described in this population, which may have contributed to misunderstandings about the
48 further differentiation to six-month refills (2).
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51 Interviewers were MSF employees and supported the original trial, which could have potentially
52 influenced how open the participants felt they could be in their interviews. This positionality was
53 reviewed and discussed in regular debriefings to reduce the impact on the collection and analysis of
54 data. Patients may also have been reluctant to share challenges in case this jeopardised the
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continuation of the model, however this could also be perceived as their belief in the benefits of the model and their desire to continue in it.

Conclusion

Six-month refills have previously been demonstrated to be safe in terms of patient outcomes, and this qualitative study established that extending ART refill length within the adherence club model was also highly acceptable and valued amongst patients and HCWs. Key informants were cautiously optimistic about the benefits for selected long-term clinically stable patients, but remained concerned about feasibility of implementation with supply chain posing the biggest challenge.

The evolution of current models is necessitated by the continuing need to increase the number of patients on ART under 'universal test and treat' and also successfully retain them on lifelong treatment. Six-month refills have potential to augment current DSD options to be more efficient and patient-centred, regardless of the model through which ART is provided. Gradual expansion of six-month ART refills could avoid overstressing supply and allow time for the health system to adapt, potentially facilitating sustainable adherence for large numbers of patients within current resource constraints.

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Conflicts of interest

This research was conducted through the Structured Operational Research and Training Initiative (SORT IT), a global partnership led by the Special Programme for Research and Training in Tropical Diseases at WHO (WHO/TDR). The model is based on a course developed jointly by the International Union Against Tuberculosis and Lung Disease (The Union) and Médecins Sans Frontières (MSF/Doctors Without Borders). The specific SORT IT programme that resulted in this publication was managed by MSF and the research was undertaken as part of routine MSF activities with MSF Khayelitsha contributing from staff salaries and operational budget.

Patient and Public Involvement

We did not directly include patient and public involvement in this study, but the research question was developed by a team who work closely with patients and the community involved. Patients have been invited to be part of the dissemination of results and the advocacy efforts that stem from this study and the parent RCT.

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Formal analysis: Claire Keene, Petros Isaakidis.

Funding acquisition: MSF SORT IT course

Methodology: Claire Keene, Petros Isaakidis.

Project administration: Claire Keene, Nompumelelo Zokufa

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Writing – review & editing: Leigh Snyman, Jacqueline Voget, Lynne Wilkinson, Tali Cassidy, Risa Hoffman, Erin von der Heyden, Vinayak Bhardwaj, Siphokazi Zide-Ndzungu, Anna Grimsrud

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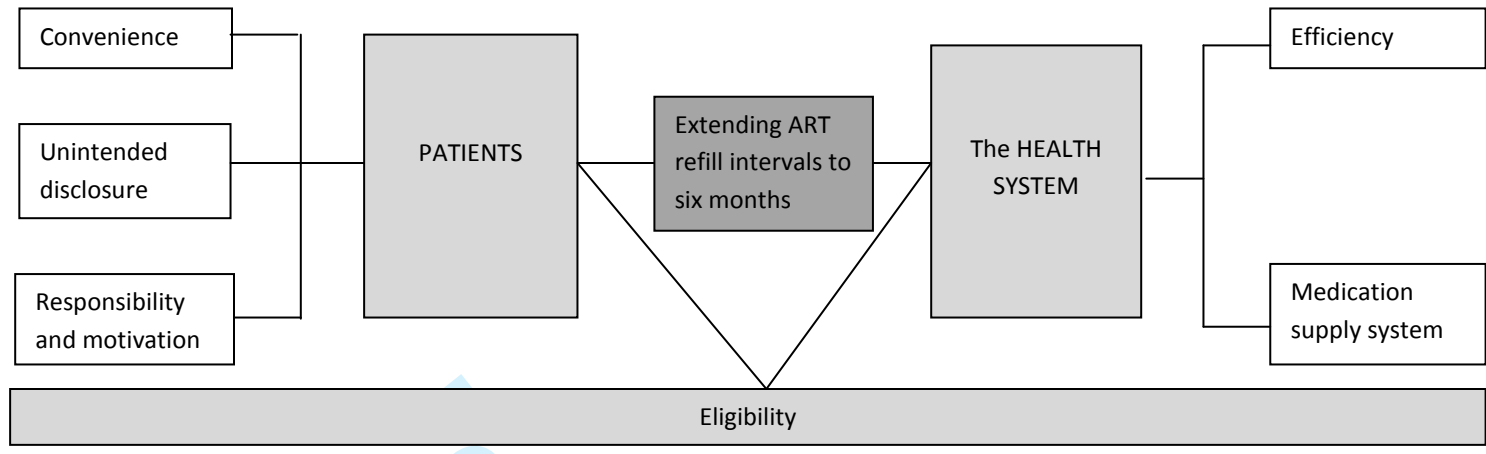
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Standards for Reporting Qualitative Research (SRQR)*

<http://www.equator-network.org/reporting-guidelines/srqr/>

“Only twice a year”: A qualitative exploration of six-month antiretroviral treatment refills in adherence clubs for people living with HIV in Khayelitsha, South Africa

Page/line no(s).

Title and abstract

<p>Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	<p>✓ 1</p>
<p>Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	<p>✓ 2</p>

Introduction

<p>Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	<p>✓ 4</p>
<p>Purpose or research question - Purpose of the study and specific objectives or questions</p>	<p>✓ 4</p>

Methods

<p>Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	<p>✓ 5</p>
<p>Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	<p>✓ 7</p>
<p>Context - Setting/site and salient contextual factors; rationale**</p>	<p>✓ 5</p>
<p>Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	<p>✓ 6</p>

1 2 3	Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	✓ 7
4 5 6 7 8	Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	✓ 7
9 10 11 12 13	Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	✓ 7
14 15 16 17	Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	✓ 8
18 19 20 21	Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	✓ 7
22 23 24 25	Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	✓ 7
26 27 28 29	Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	✓ 6, 7

Results/findings

31 32 33 34 35	Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	✓ 9
36 37 38	Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	✓ 8-15

Discussion

39 40 41 42 43 44 45 46	Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	✓ 15
47 48	Limitations - Trustworthiness and limitations of findings	✓ 16

Other

49 50 51 52 53	Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	✓ 18
54 55 56	Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	✓ 18

1 *The authors created the SRQR by searching the literature to identify guidelines, reporting
2 standards, and critical appraisal criteria for qualitative research; reviewing the reference
3 lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to
4 improve the transparency of all aspects of qualitative research by providing clear standards
5 for reporting qualitative research.
6
7

8 **The rationale should briefly discuss the justification for choosing that theory, approach,
9 method, or technique rather than other options available, the assumptions and limitations
10 implicit in those choices, and how those choices influence study conclusions and
11 transferability. As appropriate, the rationale for several items might be discussed together.
12

13
14 **Reference:**

15 O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative**
16 **research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
17 DOI: [10.1097/ACM.0000000000000388](https://doi.org/10.1097/ACM.0000000000000388)
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BMJ Open

“Only twice a year”: A qualitative exploration of six-month antiretroviral treatment refills in adherence clubs for people living with HIV in Khayelitsha, South Africa

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“Only twice a year”: A qualitative exploration of six-month antiretroviral treatment refills in adherence clubs for people living with HIV in Khayelitsha, South Africa

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Abstract

Objective: Longer intervals between routine clinic visits and medication refills are part of patient-centred, differentiated service delivery (DSD). They have been shown to improve patient outcomes as well as optimise health services – vital as ‘universal test-and-treat’ targets increase numbers of HIV patients on antiretroviral treatment (ART). This qualitative study explored patient, healthcare worker and key informant experiences and perceptions of extending ART refills to six-months in adherence clubs in Khayelitsha, South Africa.

Design and setting: In-depth interviews were conducted in isiXhosa with purposively selected patients and in English with healthcare workers and key informants. All transcripts were audio-recorded, transcribed and translated to English, manually coded and thematically analysed. The participants had been involved in a randomised controlled trial evaluating multi-month ART dispensing in adherence clubs, comparing six-month and two-month refills.

Participants: Twenty-three patients, seven healthcare workers and six key informants.

Results: Patients found that six-month refills increased convenience and reduced unintended disclosure. Contrary to key informant concerns about patients’ responsibility to manage larger quantities of ART, patients receiving six-month refills were highly motivated and did not face challenges transporting, storing or adhering to treatment. All participant groups suggested that strict eligibility criteria were necessary for patients to realise the benefits of extended dispensing intervals. Six-month refills were felt to increase health system efficiency, but there were concerns about whether the existing drug supply system could adapt to six-month refills on a larger scale.

Conclusions: Patients, healthcare workers and key informants found six-month refills within adherence clubs acceptable and beneficial, but concerns were raised about the reliability of the supply chain to manage extended multi-month dispensing. Stepwise, slow expansion could avoid overstressing supply and allow time for the health system to adapt, permitting six-month ART refills to enhance current DSD options to be more efficient and patient-centred within current health system constraints.

Strengths and limitations of this study

- This study is one of the first to qualitatively evaluate perceptions of ART refills longer than three months
- The experiences of patients in both the standard of care two-month refill clubs and the six-month refill clubs are reported, as well as those of staff and key informants
- Interviewer positionality was reviewed throughout the study by holding regular debriefings with the study team to clarify findings and how the researcher's background may have affected them
- Interviewers were Médecins Sans Frontières employees and supported the parent trial, which may have influenced how open the participants felt they could be in their interviews.
- Recruitment of particular patient groups was challenging, therefore men, patients under 30 years old and those not retained in care might have been under-represented

Introduction

Improved and simplified antiretroviral therapy (ART) means that HIV can be managed as a chronic disease, but requires the health system to adapt to respond to the changing needs of patients on lifelong treatment. Service delivery of HIV care has evolved from a 'one-size fits all' approach to respond to the diverse need of people living with HIV in resource limited settings. Patient-centred, differentiated service delivery (DSD) models for clinically stable ART patients, such as adherence clubs, have proven successful in both improving patient outcomes and optimising health services to provide quality care to the increasing numbers of patients on ART (1,2). Multi-month ART dispensing has been endorsed by the World Health Organization to further reduce the burden of care on both patients and the health system (3) and scale-up of six-month refills has been accelerated as part of PEPFAR's 2019 country operational plan (4).

Evidence from multiple studies and a 2016 systematic review suggest that extending refill and visit intervals is safe for patients, with equivalent or better outcomes (retention in care, viral load (VL) suppression, morbidity and mortality) (5-9). In addition, longer intervals have been shown to improve clinic efficiency, reduce waiting time and improve satisfaction with services (10). They also increase the number of patients that healthcare workers (HCW) can manage (11), essential in the era of 'universal test and treat' as larger numbers of patients are initiated on ART. However, there is limited qualitative evidence on the impact of extended dispensing intervals to six months, particularly patient and HCW perspectives (1).

In Khayelitsha, South Africa, *Médecins Sans Frontières* (MSF) successfully piloted the adherence club model for clinically stable patients, where a group of patients receive their ART refills together through a lay facilitator, who also provides education (12-14). The model has now been endorsed in policy and scaled up throughout the country (13). MSF implemented a randomised controlled trial to compare extending ART refill intervals from two to six months among existing adherence club patients (15). Preliminary results show non-inferiority in terms of 12-month retention (97% compared to 98%) and VL suppression (98% compared to 97%) (9).

This qualitative study explored patient, HCW and key informant experiences and perceptions of extending ART refills to six-months within the adherence club model.

Methods

Study design

This is a descriptive qualitative study including in-depth interviews (IDIs) with patients, HCWs and key informants.

Setting

Khayelitsha, South Africa

Khayelitsha is a large, peri-urban informal settlement outside of Cape Town, South Africa, home to a population of at least 500 000 people. It has the highest HIV prevalence in the Western Cape province (16) with approximately 47 000 adults on ART in 2019, of which 30% of are men and 42% receive ART in adherence clubs. It has one of the longest standing and largest treatment programmes in South Africa (16).

The population is extremely mobile, with many people moving between the informal settlement and a neighbouring province. Additionally, high rates of unemployment, violence, mental health issues and substance abuse contribute to poor engagement with health services (16–19).

Randomised controlled trial of extended ART refills within adherence clubs

A cluster-randomised controlled non-inferiority trial extending ART refills from two to six-months within existing adherence clubs was conducted from 2017 to 2019 at Site B Community Health Centre, a large provincial, primary care clinic in Khayelitsha (15). The study was conducted within routine adherence club conditions. The intervention has been described in detail elsewhere (15) and is summarised in Table 1 below.

Table 1. Procedures and comparison of the standard of care and intervention arms in the parent randomised controlled trial of extended ART refills (12–15)

	Standard of care: Two-month refill adherence clubs	Intervention: Six-month refill adherence clubs
Eligibility	Eligibility for adherence club care <ul style="list-style-type: none"> • Adults over 18 years • On the same ART regimen for at least six months • Undetectable VL • No current tuberculosis or pregnancy or condition requiring regular clinical follow-up <i>All participants were previously enrolled in an adherence club care at Site B Community Health Centre</i>	
Adherence club visits	Frequency: Two monthly (four visits receiving two months ART refills and one visit receiving	Frequency: Six-monthly (two per year)

	four month ART refill over the December holiday period) (five per year)	
	Provider: Led by club facilitator (lay counsellor)	
	Location: In the community (such as a library or community hall) or the facility	
Routine bloods (VL and for clinical review, depending on the regimen)	Frequency: 12-monthly	
	Provider: Managed by a nurse	
	Location: At the facility, part of the adherence club visit	Location: At the facility, an additional individual visit, scheduled 1 month before the adherence club visit
Clinical consultations	Frequency: 12-monthly	
	Provider: Managed by a nurse	
	Location: At the facility (part of the adherence club visit)	
Grace period	Patients can collect medication up to five days after their scheduled appointment	
Treatment "buddies"	Allowed to collect on a patient's behalf at every other visit	Not permitted

This qualitative study was conducted to explore perceptions, concerns, benefits and burdens related to extending the ART refill length within this trial.

Study population, sampling and recruitment

Patients in the trial database were categorised by, age, gender and whether they were retained in their club at the time of enrolment into the qualitative study. This was done to ensure that a balance of perspectives was obtained and that we recorded the views of participants for whom the model of care was successful at facilitating adherence (those who were retained in club care and therefore also virologically suppressed [<400 copies/mL] at last blood draw), and those who were removed from the adherence club as it was no longer the appropriate model of care for them (removed due to VL failure, missing a club appointment or another condition making them ineligible for club care, such as tuberculosis or pregnancy).

Patients from the six-month arm were interviewed to understand their experiences, and a small sample of patients from the two-month arm was recruited to differentiate between experiences of the club model itself and the longer refill interval. Eligible patients for the qualitative study were purposively sampled and recruited telephonically by an MSF counsellor.

All HCWs involved with the care of patients in the trial were invited to participate, and included Department of Health doctors, nurses and pharmacists, not-for-profit (NPO) club facilitators (lay counsellors), an MSF nurse and an MSF pharmacy assistant. HCWs were individually invited to participate after introductions from the clinic's operational manager and direct managers for MSF staff. Follow up to organise the logistics and discuss participation was conducted over email or text message.

Key informants included individuals from the Department of Health involved in the management of ART programmes and pharmacy processes, and who had influence over the adoption of extending ART refill

1
2
3 duration for clinically stable ART patients in the Western Cape. Key informants were selected using
4 snowball sampling, beginning with those identified by the research team, and were contacted by email.
5

6 ***Data collection***

7
8 IDI guides were piloted with MSF staff not involved with the trial and revised. Patients were interviewed
9 in isiXhosa by a bilingual research assistant, using guides developed in English. Interviews were
10 conducted either at the patient's home or MSF office (based on patient preference).
11

12 HCW and key informants were interviewed in English by the Principal Investigator (PI). Interviews were
13 conducted in a private office, a clinician's room or a boardroom.
14

15 All IDIs were conducted between June and November 2019 and were audio-recorded. Data collection
16 continued until saturation was reached. The PI and research assistant both work for MSF and held
17 fortnightly debriefings to reflect on the impact of their position on the data collection and analysis, and
18 discuss emerging themes from the interviews (including differences and similarities between the
19 participant groups), to allow continued exploration of emerging themes.
20

21 ***Data analysis***

22
23 Interviews were each transcribed once and all isiXhosa interviews were translated into English.
24 Transcripts, including the translation of the data, were reviewed by the original interviewer and
25 compared to handwritten field notes to check the quality and validate the data.
26

27
28 All transcripts were manually coded and thematically analysed by the PI, using a network approach to
29 develop primary themes then group them into organising and overarching themes, as described by
30 Attride-Stirling (20). Selected transcripts were coded by the research assistant and a co-investigator, and
31 were then discussed among the research team to agree on the coding and analysis framework.
32

33 ***Patient and Public Involvement***

34
35 We did not directly include patient and public involvement in this study, but the research question was
36 developed by a team who work closely with patients and the community involved. Patients have been
37 invited to be part of the dissemination of results and the advocacy efforts that stem from this study and
38 the parent RCT.
39

40 ***Ethics and informed consent***

41
42 This study was approved by the MSF Ethics Review Board (reference 1910), the University of Cape
43 Town's Human Research Ethics Committee (HREC 191/2019) and the Western Cape Provincial
44 Department of Health. All participants gave written consent in English or isiXhosa. The specific roles of
45 key informants and HCW's organisations are anonymised to protect their identity. Patients were
46 reimbursed in cash for their time and transport costs and the amount was clarified during the
47 recruitment and consent process.
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Results

Demographics

A total of 36 IDIs were conducted (ranging in length from 19 minutes to one hour), including 23 patients (16 in six-month and seven in two month ART refill clubs), seven HCWs, and six key informants. Table 2 summarises the demographics and roles of the interviewees.

Table 2. Summary of interviewee demographics

Study number	Age	Sex	Study number	Age	Sex
Patients (P)					
Six month refill (6M)			Two month refill (2M)		
P6M_1	42	F	P2M_1	38	F
P6M_2	45	F	P2M_2	58	F
P6M_3	38	F	P2M_3	52	M
P6M_4	40	F	P2M_4	49	F
P6M_5	42	M	P2M_5	36	F
P6M_6	36	F	P2M_6	35	F
P6M_7	59	F	P2M_7	54	F
P6M_8	66	F			
P6M_9	39	F			
P6M_10	46	F			
P6M_11	52	F			
P6M_12	41	F			
P6M_13	40	F			
P6M_14	39	F			
P6M_15	30	F			
P6M_16	47	F			
Healthcare worker (HCW)			Key informants (KI)		
HCW_1	59	F	KI_1	Not	M
HCW_2	59	F	KI_2	collected	F
HCW_3	31	F	KI_3		M
HCW_4	41	F	KI_4		F
HCW_5	38	F	KI_5		M
HCW_6	36	M	KI_6		F
HCW_7	53	F			

Themes

Patient, HCW and key informant perspectives were combine in six overarching themes that emerged from the data: three relating to the impact of extending ART refills to six-months on the patients, two relating to the impact on the health system and one overlapping theme exploring eligibility (see figure 1).

Figure 1. Overarching themes related to the impact of the model on patients and the health system

<figure 1>

1. Impact on patients

Extending ART refills to six months within the club model influenced patients and their care in several ways, including 1) the convenience of ART engagement, 2) unintended disclosure and 3) their responsibility and motivation.

1.1. Convenience

Patients, HCWs and key informants agreed that extending ART refills to six months decreased obstacles to accessing facilities, reducing the burden of frequent clinic visits and reducing travel costs for patients *It made a big difference. I am now saving all the R20s [transport money] (P6M_8)*

Patients described time as very valuable and a major benefit of six-month refills is that *“it saves a lot of time” (P6M_10)*. The time saved by not attending the club visit is used to go to work, look for employment, child care, household chores, shopping and addressing challenges that arise in their lives.

It helps them a lot because these patients now have got the time to look after themselves (HCW_2)

Patients noted that increasing the time between visits allows for extended travel: for work or to address issues where family live outside of the province.

It changed my life so much because I know that I have my pills for six months. For example, we go out, we attend funerals, we have problems in our homes [rural areas] so now I can stay the whole month or three months at home. I couldn't do that when I was in two-months because I had to rush and come back for my appointment and if you missed it you must start afresh. So now it saves time and it saves everything (P6M_10)

Six-month ART refills were described by HCWs as *“a huge help for patients who are working” (HCW_4)* as *“it's not easy to get jobs so if they found a job they don't want to lose it” (HCW_7)*. Employment was noted by patients as a significant barrier to accessing the health system, either because going to work prevented them from attending their appointment or travel took them out of the area. Attending an ART appointment rather than work was described as stressful by patients due to the loss of income and the risk of loss of employment if work was missed:

I did not like two-months as I was going to the clinic all the time. I could see that I would lose my job because some bosses don't like you telling them that you are HIV positive. Even when I go to the clinic I don't want the paper [sick note]. [Six-month clubs] are not difficult like the two-months. In the two-month club you have to go to the clinic, and that can lead you to be fired by your bosses because they will ask 'what's wrong with this person who goes to the clinic every two months?' (P6M_5)

Patients felt they *“had to lie in the two-month [club]...and come up with new excuses” (P6M_10)* because they feared annoying their employer by asking for frequent days off and were worried about disclosing their HIV status to employers that they did not trust.

Longer ART refills allowed patients more time to organise and plan their lives, and reduced the stress of trying to balance their life and ART commitments. It also provided patients with a sense of security to manage stock-outs or uncertain medication supply.

Six months was good for me, because when you have to do something you are always anxious. Six months is a lot, you have peace of mind, and you know you have your pills in front of you.

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2
3 *Even if something happens and you are told the pills are finished, I will know I have mine: only*
4 *those that gets two months supply will be affected (P6M_2)*
5
6

7 **1.2. Unintended disclosure**

8 HCWs and key informants were concerned that larger numbers of ART bottles would result in
9 unintended disclosure when transporting the medication and storing it at home. Patients were more
10 concerned about the noise that the large number of bottles made

11 *My only problem is the noise that they make. They are in these containers and there is a lot of*
12 *them...so they make noise and I cannot go everywhere with them. I was worried when a friend*
13 *of mine called me to come to her place. I was in a taxi, so I had to get off and go to her. That did*
14 *not make me feel good because I was carrying my pills. I am refusing to let go of my bag,*
15 *because I am like 'leave my bag alone dude!' That stressed me. I knew that even if I wanted to*
16 *stay longer, I had to quickly go because now I can't even go outside and leave my bag, and when*
17 *I am touching my bag, it is making a noise and you can see that its pills. She was asking what*
18 *was in my bag, what are these pills for? But I can't tell her. (P6M_5)*
19
20

21 Patients noted that less frequent visits reduced the risk of disclosure at work, because *"the day you*
22 *mention the word HIV, is the day you lose your job"* (P2M_4). Patients in both six and two-month clubs
23 were not greatly concerned about disclosure at home as most had disclosed to their immediate family
24 and asked them for support with adherence. Some patients described being *"afraid to be seen in the*
25 *clinic"* (P6M_1). Patients, HCWs and key informants felt that six-month refills provided patients with
26 more privacy and could help to reduce unintended disclosure as community members were less likely to
27 assume infrequent visits were for ART.

28
29 *I would say there is a change because the frequent visits to the library to get medication meant*
30 *that even people who didn't know your status could tell you were part of the people who went*
31 *there, which would raise questions. Now they won't be able to see that because you won't be*
32 *going as frequently (P6M_9)*
33
34

35 **1.3. Responsibility and motivation**

36 Key informants were concerned that if patients were provided with larger quantities of medication they
37 would use it irresponsibly, adherence would worsen and seeking care when ill would be delayed until a
38 scheduled appointment. They were also concerned about suboptimal storage of medication, that
39 patients might share or sell medication or that it would be stolen.

40
41 *There were cases where they told us it was stolen. We know for a fact that the drugs do get used*
42 *for other purposes as well and we know of instances where people were collecting ARV's and*
43 *selling them. But who knows, most of them had lost them, or they were stolen, or they don't*
44 *know why they're finished (KI_5)*
45
46

47 The experiences reported by patients did not support these concerns; patients reported many
48 mechanisms to remind them to take their treatment daily and attend appointments, including setting
49 phone reminders, using calendars, timing their pills with popular TV shows and asking family members
50 to remind them. Patients in clubs valued their health and their treatment and reported being highly self-
51 motivated in both the six and two-month clubs.

52 *I am taking my treatment well, this is my health and my life, and I don't have another life. My life*
53 *depends on me (P6M_10)*
54
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3 *What is important in my life is my life (P2M_7)*
4

5 Patients reported making use of the grace period or would rebook if they missed an appointment, and
6 reported that they either had, or would, visit health services if they became sick in between visits or lost
7 their medication
8

9 *You don't have to wait the whole six month until your date for you to come to the clinic... I would*
10 *go to the clinic like everyone else and tell the doctor I am in the club but I am sick at that time*
11 *(P6M_9)*
12

13 Patients reported having a specific place to store their medication that was cool, dark and safe from
14 theft and children's access. Most said that they do not share their medication, because staff have
15 instructed them not to, other people are not using the same regimens, they worry about running out of
16 pills and they value the treatment for their own use.

17 *The pills are calculated for me not her, she must go to the clinic to take hers... I can't give*
18 *anyone my pills. Even my siblings know these are mine not for everyone (P6M_2)*
19

20 Two participants (P6M_5 and P6M_13) reported that they had shared medication, but only with their
21 spouses under exceptional circumstances and only if they were on the same regimen. They also had
22 plans to mitigate the impact on their adherence: sharing a limited amount, requiring the medication to
23 be returned or accompanying the recipient to the clinic for their refill.
24
25

26 Theft of medication (in the facility, in transit or at home) was not reported by any of the participants and
27 was not a major concern. Patients had *"heard about those who smoke and sell them"* (P6M_10) but this
28 was unsubstantiated by specific examples. Participants felt pills were lost as collateral in the theft of a
29 bag rather than being the target of theft, thus patients took action to mitigate theft of their belongings.
30

31 *I take a taxi, because there are pickpockets, and come straight home (P6M_15)*
32

33 In addition, patients and HCWs reported that the benefits of six-month ART refills actually increased
34 patient adherence further.

35 *We are very trusted with the six months... we are given enough time to look after ourselves, that*
36 *is where our confidence is built (P6M_3)*
37
38
39

40 **2. Impact on the health system**

41 From the HCW and key informant perspective, the main benefit for the system was increased efficiency
42 and the main concern was the impact on the medication supply system. Some participants noted that
43 despite the benefits of longer refills, there were still significant challenges and for some the non-inferior
44 trial outcomes were not enough to justify the risks and additional investment required to implement
45 longer duration ART dispensing. Ultimately, there was cautious optimism about six-month refills, with
46 key informants acknowledging the benefits while warning of the concerns and practical challenges
47 described below.
48
49

50 **2.1. Efficiency**

51 From the perspectives of the HCWs and key informants, one of the main benefits of six-month ART
52 refills for the health system was the *"efficiency gains"* and the ability to *"service more people with the*
53
54
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1
2
3 *same number of staff” (KI_5). It was reported that the need to do this was driven by pressure from the*
4 *‘universal test and treat’ guidelines:*

5 *They are coming every two months or every six months: that’s a third that you have*
6 *cut... That’s huge... Now that we are trying to start everyone who gets tested on ARVs,*
7 *the numbers we are looking at are going to be immense. (HCW_4)*
8
9

10 The HCW workload for each club visit was described as remaining the same or slightly increasing
11 (particularly for pharmacists) but increasing the refill interval within the adherence club model resulted
12 in reduced workload overall, particularly for club facilitators and data clerks:

13 *Personally it has helped me a lot because it reduces the workload... So that gives me a little*
14 *relief. It’s not that I am relieved from them, but I’m relieved from the workload... So you prepare*
15 *your registers, you prepare the medication and you must be earlier than usual when you are*
16 *going to do the club. It’s more preparation if the patient is going to be...doing a clinical visit and*
17 *taking bloods. But now I don’t have that big preparation. They are giving me a gap. (HCW_2)*
18
19

20 HCWs reported that the additional time created by seeing patients less frequently was used to manage
21 other activities that were previously neglected or more stressful due to high patient volumes, including
22 administration and management of ad hoc problems in the clinic.
23

24 Patients in the six-month clubs perceived there to be an increase in peer and club facilitator support,
25 despite concerns from key informants that the reduced visit frequency would diminish support.
26 Paradoxically the decreased visit frequency in the six-month model increased the quality of the support
27 because patients could take an entire day off work instead of rushing through the session in order to
28 attend to other competing tasks for the day, as they had been doing when in two-month clubs. Patients
29 and HCW also described patients enjoying the reunion with peers when they returned for the club visit.

30 *When they come back, they come back with that excitement. “We have been away from the*
31 *clinic, how are you?” They are happy! They are now enjoying the club. (HCW_2)*
32
33

34 **2.2. Medication supply system**

35
36 A major concern raised by key informants and HCWs was the current medication supply system’s
37 capacity to adapt to six-month refills. They expressed concern regarding the smaller facilities with
38 limited storage space that would require more frequent deliveries from the depot. Key informants felt
39 that the supply system was already “on a knives edge” (KI_1) and planning was dependent on factors
40 outside local control, including manufacturers, national contracts and demand from other provinces.

41 *You need good stocks to be able to hand that out... But with what happens at national level,*
42 *sometimes our systems are not good enough and that could create a real disaster. (KI_4)*
43
44

45 While acknowledging that for the “ART program itself, it’s been very rare to have stock outs” (KI_4)
46 compared to other chronic disease treatment, it was suggested that the impact of stock-outs for
47 patients receiving six-month ART refills could detrimentally impact supply by creating peaks in the
48 demand for medication. There was concern over the “industrial amounts of medicine” that would be in
49 the community rather than within the health system’s control.

50 *It’s a lot of medicine to be sitting in people’s homes ... So it’s a lot of money tied up in people’s*
51 *homes where you don’t have access to it as you would in the health system... I mean that’s a lot*
52 *of medicine that’s going to be sitting out in communities. (KI_2)*
53
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55

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3 “Ultimately the drugs are for the community” (KI_3) and slow and careful expansion of longer refills was
4 suggested as a way to avoid “absolute disaster” (KI_4), allowing time for planning and problem solving.
5 This would reduce stress on the supply chain and the risk of overwhelming the system.
6
7

8 9 **3. Eligibility**

10 There was consensus across key informants, HCWs and patients from the six and two-month clubs, that
11 if the existing club model were adapted to provide six-month refills, it would not be appropriate for
12 everyone and would benefit a “select small group of patients (KI_2). There was consistency across
13 interviewees in suggesting strict criteria with evidence of long-term adherence, such as multiple
14 suppressed VL results. It was proposed that newly initiated patients need experience on ART to develop
15 maturity, build up understanding and knowledge and learn to solve challenges. Both HCWs and patients
16 suggested that stable ART patients eligible for the adherence club model should start in two-month
17 clubs and ‘graduate’ to six-month refills when they had proved themselves.
18

19 *You cannot skip to the six-months if no one knows how you took the two-months. They have to*
20 *see that you are taking the two-month supply first to show that you are taking it well. If you are*
21 *not taking the two-month well, don't even bother going to the six-months. If you are someone*
22 *who puts their health before anything, you can take the six-months supply. I would advise them*
23 *to go to the clinic and start with the two-months and see if you manage and if you do, you can*
24 *get on the six-months. (P2M_4)*
25

26
27 It was also recommended that patients should ‘earn’ the reward of six-month refills, as one patient
28 described:

29 *We also started there [two-month refills]. We were standing in those queues. It was not easy for*
30 *us: we worked for that six-months. They must also work for it so that they can get to where we*
31 *are. They must start with the two-months: we started from the bottom and we climbed our way*
32 *up until we were alright. (P6M_8)*
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35 Six-month ART refills were viewed by HCWs and patients as a reward for good adherence, with patients
36 viewed as ‘VIPs’ who “feel like champions” (HCW_1). Six-month refills motivated and empowered
37 patients to be adherent and take control of their treatment, with the possibility of losing the benefits
38 ensuring adherence.

39 *They took their treatment more seriously because they loved being in the six-month [club] and*
40 *you tell them if the viral load increases unfortunately, I won't be able to keep you in the six-*
41 *month club. They took their medication because they wanted to be in the six-month arm. They*
42 *continue to be quite motivated, to take treatment and take control. (HCW_5)*
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46 **Discussion**

47 This study is one of the first to qualitatively evaluate perceptions of ART refills longer than three months
48 (22), and explore patient, HCW and key informant experiences of six-month refills for clinically stable
49 HIV patients in adherence clubs. Six-month refills were recently trialled by MSF and the Western Cape
50 Department of Health in South Africa, with non-inferior patient outcomes to the standard of care clubs
51 receiving two-month ART refills (9).
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3 All participants agreed that six-month refills were a motivation for adherence and that the main benefit
4 was the increase in free time and convenience, even in addition to the time-saving benefits described
5 previously for the club model itself (2). Longer refills also gave patients 'peace of mind' and a sense of
6 control in managing their treatment, despite the uncertainties in their lives and the health system, such
7 as stock outs.
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10 Our data suggest that patients did not struggle with adherence, storage or safety of their medication,
11 contrary to key informant concerns. Patients valued their health and their treatment, but also valued
12 their life responsibilities, such as work and family. The frequency of ART visits was a significant stress
13 and in their experience of two-month refills, patients reported finding ways around their visits that did
14 not jeopardise other obligations. Patients live in complicated worlds that require navigation of
15 competing priorities (22), and if a choice has to be made, life commitments may be prioritised at the
16 expense of ART. Six-month refills helped to overcome this tension by reducing the impact of many
17 previously described barriers to engagement with the health system, such as travel, stigma,
18 inconvenience of appointments, changes to routine and being busy preventing attendance (23). As the
19 health system's focus shifts to mechanisms of retaining patients in lifelong care, it is increasingly
20 necessary for DSD to put patient's preferences at the centre of service design (1,2,22). Longer refill
21 intervals support patients to incorporate ART into their daily life and can enhance the convenience of
22 current DSD models.
23

24
25 In addition to patient benefits, six-month refills were felt to increase the health system's efficiency, a
26 well-documented benefit of DSD (2) and ascribed to reduced visit frequency in previous studies (11).
27 This is an important consideration in the era of 'test and treat', where growing numbers of people
28 starting ART has not been met with an increase in the number of HCWs to support this expansion. A
29 majority of patients on ART are expected to be eligible for DSD models and this is likely to have a
30 significant impact on DSD infrastructure (24). Current DSD options need further evolution to make even
31 more efficient use of resources, in order to cope with the growing ART cohort.
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34 A significant concern for HCWs and key informants was whether the existing drug supply system could
35 adapt to provide six-month ART refills at scale. The precariousness of the supply chain would both limit
36 the feasibility of implementation and be worsened by the additional stress longer ART refills would place
37 on the system. These concerns highlight the critical importance of DSD optimisation, health system
38 planning and close monitoring of phased implementation at national and provincial levels to ensure
39 feasibility and long-term sustainability.
40
41

42 Patients (including those receiving two-month refills), HCWs and key informants alike felt that extended
43 refills were only suitable for a select group of patients, who needed to both prove themselves (with
44 evidence of long term adherence such as multiple suppressed VL results) and earn the benefits by 'doing
45 their time' with shorter refill intervals. While eligibility criteria are important to ensure that DSDs are
46 implemented appropriately, meeting these criteria does not necessarily result in successful outcomes
47 (24). The need for strict eligibility criteria needs to be balanced with the patient-centred benefits six-
48 month refills could offer to clinically stable patients.
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50
51 There are several limitations to this study that bring into question the transferability of the findings to
52 other settings. It was challenging to recruit men, patients under 30 years old, and those lost from clinic
53 care at the time of recruitment for this qualitative study. These groups accounted for a small proportion
54 of the original study population (23%, 4.5% and 5% respectively) and were also particularly difficult to
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3 contact during the recruitment process. The participants in the randomised controlled trial from which
4 the participants for this qualitative study were drawn, were recruited from existing adherence clubs
5 (eligibility for which demonstrates long term adherence) questioning the transferability of the findings
6 to settings that do not offer group DSD models or to patients not yet virologically suppressed on ART.
7 However, participants in the two-month refill clubs were also included to explore whether six-month
8 refills impacted the experience of those who were already shown to be stable patients.
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10
11 Some of the benefits described by patients and HCW, such as the 'reward' of being chosen for the six-
12 month refill clubs, or the special 'VIP' treatment, came from a misunderstanding of the randomisation
13 process (despite multiple rounds of consent) as 'being chosen'. Clubs are already seen as a reward for
14 'taking treatment well', and pre-existing confusion about 'qualifications' for club eligibility has been
15 previously described in this population, which may have contributed to misunderstandings about the
16 further differentiation to six-month refills (2).
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19 Interviewers were MSF employees and supported the parent trial, which could have potentially
20 influenced how open the participants felt they could be in their interviews. This positionality was
21 reviewed and discussed in regular debriefings to reduce the impact on the collection and analysis of
22 data. Patients may also have been reluctant to share challenges in case this jeopardised the
23 continuation of the model, however this could also be perceived as their belief in the benefits of the
24 model and their desire to continue in it.
25

26 **Conclusion**

27
28 Six-month refills have previously been demonstrated to be safe in terms of patient outcomes, and this
29 qualitative study established that extending ART refill length within the adherence club model was also
30 highly acceptable and valued amongst patients and HCWs. Key informants were cautiously optimistic
31 about the benefits for selected long-term clinically stable patients, but remained concerned about
32 feasibility of implementation with supply chain posing the biggest challenge.
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35 The evolution of current models is necessitated by the continuing need to increase the number of
36 patients on ART under 'universal test and treat' and also successfully retain them on lifelong treatment.
37 Six-month refills have potential to augment current DSD options to be more efficient and patient-
38 centred, regardless of the model through which ART is provided. Gradual expansion of six-month ART
39 refills could avoid overstressing supply and allow time for the health system to adapt, potentially
40 facilitating sustainable adherence for large numbers of patients within current resource constraints.
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Conflicts of interest

This research was conducted through the Structured Operational Research and Training Initiative (SORT IT), a global partnership led by the Special Programme for Research and Training in Tropical Diseases at WHO (WHO/TDR). The model is based on a course developed jointly by the International Union Against Tuberculosis and Lung Disease (The Union) and Médecins Sans Frontières (MSF/Doctors Without Borders). The specific SORT IT programme that resulted in this publication was managed by MSF and the research was undertaken as part of routine MSF activities with MSF Khayelitsha contributing from staff salaries and operational budget.

Patient and Public Involvement

We did not directly include patient and public involvement in this study, but the research question was developed by a team who work closely with patients and the community involved. Patients have been invited to be part of the dissemination of results and the advocacy efforts that stem from this study and the parent RCT.

Funding

This research received no specific grant from any funding agency in the public, commercial and not-for-profit sectors. MSF staff carried out the research as part of their routine roles.

Data sharing

Data are available on request in accordance with MSF's data sharing policy. Requests for access to data should be made to data.sharing@msf.org.

Author Contributions

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Formal analysis: Claire Keene, Petros Isaakidis, Nompumelelo Zokufa, Emilie Venables.

Funding acquisition: MSF SORT IT course

Methodology: Claire Keene, Petros Isaakidis.

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Writing – review & editing: Leigh Snyman, Jacqueline Voget, Lynne Wilkinson, Tali Cassidy, Risa Hoffman, Erin von der Heyden, Vinayak Bhardwaj, Siphokazi Zide-Ndzungu, Anna Grimsrud

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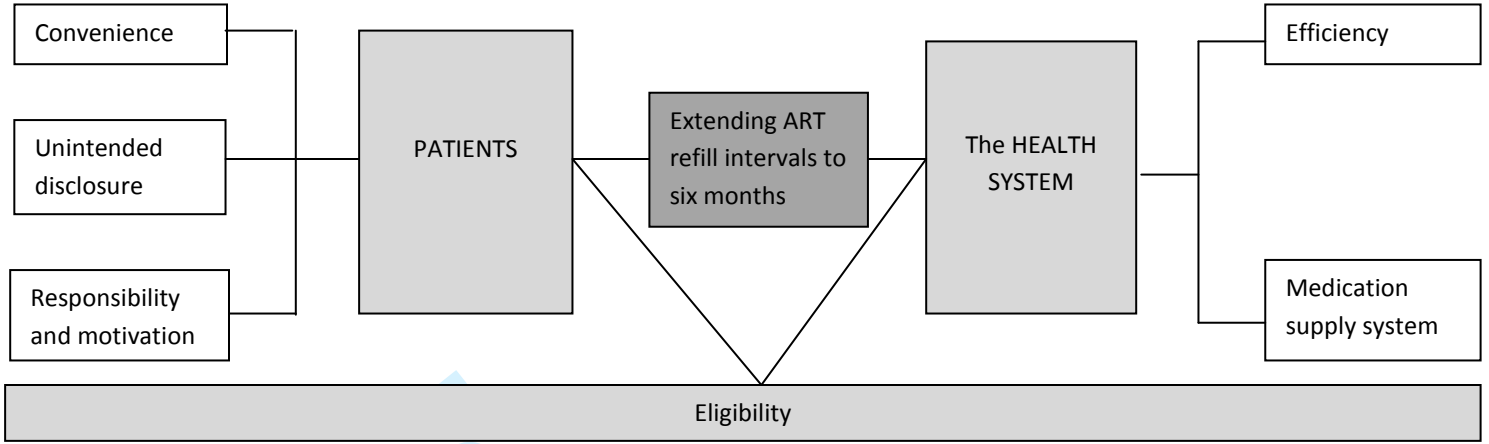
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Standards for Reporting Qualitative Research (SRQR)*

<http://www.equator-network.org/reporting-guidelines/srqr/>

“Only twice a year”: A qualitative exploration of six-month antiretroviral treatment refills in adherence clubs for people living with HIV in Khayelitsha, South Africa

Page/line no(s).

Title and abstract

<p>Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	<p>✓ 1</p>
<p>Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	<p>✓ 2</p>

Introduction

<p>Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	<p>✓ 4</p>
<p>Purpose or research question - Purpose of the study and specific objectives or questions</p>	<p>✓ 4</p>

Methods

<p>Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	<p>✓ 5</p>
<p>Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	<p>✓ 7</p>
<p>Context - Setting/site and salient contextual factors; rationale**</p>	<p>✓ 5</p>
<p>Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	<p>✓ 6</p>

Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	✓ 7
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	✓ 7
Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	✓ 7
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	✓ 8
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	✓ 7
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	✓ 7
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	✓ 6, 7

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	✓ 9
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	✓ 8-15

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	✓ 15
Limitations - Trustworthiness and limitations of findings	✓ 16

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	✓ 18
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	✓ 18

1 *The authors created the SRQR by searching the literature to identify guidelines, reporting
2 standards, and critical appraisal criteria for qualitative research; reviewing the reference
3 lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to
4 improve the transparency of all aspects of qualitative research by providing clear standards
5 for reporting qualitative research.
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8 **The rationale should briefly discuss the justification for choosing that theory, approach,
9 method, or technique rather than other options available, the assumptions and limitations
10 implicit in those choices, and how those choices influence study conclusions and
11 transferability. As appropriate, the rationale for several items might be discussed together.
12

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14 **Reference:**

15 O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative**
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