A Comparative Evaluation of the Successes and Challenges of the Antiretroviral Therapy Adherence Clubs in the Helderberg District of the Western Cape Province, South Africa

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Declaration

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the authorship owner thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or part submitted it for obtaining any qualification.

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Date: ………14/ 03 /2014………………………..

Abstract

Aims and objectives: To perform a comparative evaluation of the successes and challenges of the anti-retroviral therapy (ART) adherence clubs in the Helderberg District of the Western Cape Province.

Methods: Phase 1: A retrospective review of patient records, comparing a group of patients enrolled in the ART adherence clubs with a pre-enrollment group. Outcome measures were CD4, viral load (VL), opportunistic infections and HIV-related hospital admissions. Statistical analysis with Statistica Version 11. Phase 2: A qualitative exploration of the views and experiences of patients and health care providers on the efficiency and patient-friendliness of the adherence club system.

Results: Phase 1: The files of 281 patients were compared for measurable outcomes of ART. Despite the median baseline CD4 being higher and the median time on treatment being lower in the pre-enrollment group, opportunistic infections were more common in the pre-enrollment group, and there were more detectable VLs ($p < 0.05$; Pearson Chi- square; Mann- Whitney U- test). Phase 2: Focus group discussions and interviews were conducted with 93 patients and 6 staff members. ART clubs were generally felt to be efficient, accessible, convenient, patient-friendly, supportive, accommodating of the needs of working people, as well as decreasing the workload of the ART clinic and hospital pharmacy. Participants identified several problems, namely inadequate medical- and counseling support, poor documentation, logistical issues with the chronic dispensing unit (CDU), fragmentation of clinical services, and the high administrative load on clinicians. Recommendations made by participants on how problems in the system can be addressed include the appointment of more non-clinical staff, providing opportunities for staff training, scheduling regular doctor visits, providing ongoing adherence support, performing regular audits, digitalizing scripts, addressing logistical- and flow management issues, and the integration of ART with other clinical services.

Conclusion: ART adherence clubs benefit both the patients enrolled and the greater health system. Their ability to improve HIV treatment outcomes in the study setting supports the expansion of the club programme, as well as its exploration as a model for the management of other chronic diseases.

Acknowledgements

Introduction

Without a doubt, the HIV/ AIDS pandemic is the greatest healthcare challenge of our time. Worldwide an estimated 36.3 million people are living with HIV/ AIDS. The greatest burden of disease (67%) is borne by Sub- Saharan Africa, where 22.5 million people are living with HIV/ AIDS.[1,2] Since the announcement of the roll-out of free anti- retroviral therapy (ART) in 2003, 1.8 million South African adults and children (reflecting 50% of those eligible for treatment) have been started on ART. The South African National Strategic Plan aims to have 80% of people eligible for ART on treatment by 2016.[1-4]

The roll-out of highly active ART has had a dramatic effect on those afflicted with HIV/ AIDS. Viral suppression allows immune reconstitution, which delays progression of disease, improves overall quality of life and decreases mortality.[2] Vertical transmission along with infant mortality rates has decreased substantially.[1,3-9]

Successful treatment with ART is dependent on excellent adherence (>95% adherence), which is only maintained by 70% of patients.[5] Poor adherence results in viral replication and mutation, treatment failure, progression of disease and eventually death. Cross-resistance limits treatment options, and the risk of transmission of resistant viruses to drug-naïve individuals is a major public health issue.[5,6] The importance of excellent adherence can hence not be over-emphasized. Programmes aimed at improving adherence result in major healthcare savings long term.[10,11] Effective, patient-orientated interventions are required to optimise adherence.[9-17]

Methods used in both resource-rich and resource-poor settings to monitor adherence to ART and predict ongoing success or future treatment failure include: laboratory markers such as CD4 and viral load (VL) (considered the gold standard of monitoring treatment efficacy), plasma drug levels (limited to research settings)[4], medication event monitoring systems (MEMS Caps), pill counts, pharmacy refill data and patient self- report.[4-6, 8, 11, 18-21]

Predictors of good adherence and barriers to adherence have been identified [1]in order to develop the following interventions aimed at improving adherence, namely patient education, adherence case management (intensive support of 'at risk' patients) [15], Direct Observed Therapy/ DOTS, simplified drug regimens, adherence devices (pill boxes and reminder devices), buddy systems, incentives (e.g. transport and food vouchers), and adherence clubs.[5, 6, 9, 11, 15, 17, 19, 22-27]

Increasing patient volumes and limited human resources have resulted in the evaluation of patient group-based models of care as alternatives to main-stream ART care. Adherence clubs are patient-friendly group clinics, run by health care workers. Patients older than 18 years who have been on ART > 18 months and have had two consecutive undetectable VLs, are eligible to join. Each club

consists of a group of about 30 people that meets every second month at a community venue. Files are prepared ahead of time, laboratory results checked and medication packed. Members are weighed and asked about symptoms of opportunistic infections and side-effects, blood tests are taken if due and medication dispensed. On occasion a speaker may speak to the group about relevant health topics. The clinic is concluded within two hours.[3] Adherence clubs are thought to be more convenient and efficient, decrease congestion at the base clinic and result in less loss to follow- up.[3,28- 30]

Medicins Sans Frontière (MSF) Khayelitsha piloted the first ART adherence clubs at their Ubuntu Clinic in 2007. Similar group-based community models of care were launched at their treatment sites in Lesotho, Mozambique and Malawi. Buy-in from the Western Cape Department of Health with rapid roll-out resulted in the formation of 600 ART clubs, accommodating 16 000 patients, between January 2011 and December 2012.[30]

At Helderberg Hospital there are currently 2000 patients enrolled in the ART programme. The first adherence club was launched in February 2011. At the time data was collected for this study, 470 patients were enrolled in 22 clubs, which meet on different days at one of three venues (Helderberg Hospital, Somerset West Clinic and Sir Lowrie's Pass Clinic) , either early in the morning (before the regular clinic starts), or mid-morning on a Friday (considered an off-peak time). An estimated further 200 patients qualified for club membership, but were not yet enrolled.

The MSF team has recently published two articles on their pilot project in Khayelitsha. Adherence clubs there have been shown to decrease loss to follow-up by 57% and virological rebound by 67%, proving that they are effective in improving retention and virological suppression in stable patients.[29] No study has been published on the impact the adherence clubs have had since their inception in the Helderberg area. The author hoped to explore whether the programme has been successful, whether there are problems, and how any problems identified may be overcome.

If it is established that attendance of the ART adherence clubs in this district results in a higher degree of success (as measured by sustained viral suppression and a lower incidence of opportunistic infections and HIV-related hospital admissions), when compared with patients not yet enrolled in the program, the basis will be formed on which the ongoing support and expansion of the programme beyond the boundaries of this province may be motivated for. The identification of barriers to the success of the programme will allow the implementation of remedial actions to enhance its overall effectiveness.

Aims and Objectives

The aim of this study was to perform a comparative evaluation of the successes and challenges of the ART adherence club programme in the Helderberg District.

The objectives of this study were:

- To compare treatment and other outcomes between patients enrolled in the adherence clubs and those not yet enrolled.
- To explore the views of patients and healthcare workers on the efficiency, accessibility, convenience and patient-friendliness of the adherence clubs.
- To describe challenges experienced by participants and the recommendations proposed to overcome them.

Methods

The study was approved by both the Human Research Ethics Committee at Stellenbosch University (Re. Protocol no. 512/06/148) and the Western Cape Department of Health (Re. 2013 RP O77).

The project consisted of two phases, the first part being a quantitative study, and the second being a qualitative study. During Phase 1 of the study, which entailed a retrospective review of records, the files of all patients qualifying for enrollment in the adherence clubs (selected for participation, but pre-intervention), as well as the files of a similarly-sized group of patients from the existing adherence clubs (post-intervention), were drawn and checked for the following information: baseline CD4 and clinical stage at the start of treatment, length of time on treatment, the two most recent CD4s and VLs (recorded as '12 months ago' and '6 months ago'), and presentation to the ARV-clinic or district hospital with opportunistic infections and HIV-related hospital admissions in the 24 months preceding the study (June 2011- June 2013).

A statistician was consulted to discuss the size and sampling of the groups. For a comparative study, the groups would ideally have to be of a similar or same size and consist of at least 100 people each to be statistically significant. An attempt was made to identify all patients who qualify for club enrollment, but are not yet enrolled. A total of 146 patients were identified. In order to select the intervention (enrolled) group, the files of all patients attending Club 1 and every third club thereafter were drawn. These included Clubs 1, 4, 7 and 10; Club 13's register was missing at the time of the study, therefore Club 14, which was the next chronologically listed club, was included. A total of 137 patients from those clubs fit the inclusion criteria, which were:

1. Age greater than 18 years

2. Must be on treatment for more than 18 months and

3. Must have viral suppression, defined as VL< 500 RNA cps/ ml.

Data was collected by checking patient folders for the required information (baseline CD4 and clinical stage, time on treatment, two most recent CD4s and VLs, and opportunistic infection) and recording it on the attached data collection sheet, designed for this study (see Appendix 1).

During the second phase, the investigator conducted in depth interviews with 6 of the health care providers involved with the clubs (the other 2 nurses were on leave at the time), and interviews and focus group discussions with voluntary participants from conveniently selected clubs attended by the investigator over a 6-week period (93 patients in total). The investigator attended all clubs which did not impact on her own clinical duties, namely Clubs 1-3 and 5-10. The investigator introduced herself and the study at the beginning of each club and invited voluntary participants to stay on for an interview or focus group discussion at the conclusion of the clinic. Participants signed a voluntary consent form, which was available in English, isiXhosa and Afrikaans. Refreshments (juice and muffins) were offered to participants after the interviews/ discussions.

Interviews and focus group discussions were conducted by the investigator herself and responses noted in short-hand for later transcription and reflection. The interview and discussion guides used have been included (see Appendix 2). The data collected was searched for commonly coded responses or themes, which were grouped together and summarized.

The complete set of quantitative and qualitative data has been confidentially stored and is available for audit on request.

Analysis

Phase 1

Phase 1 of the study was a retrospective review of patient records, comparing similarly-sized sample groups of patients- one group qualified for and had been selected for enrollment into an adherence club (n= 146), but were still 'pre- club'; the other group consisted of patients who were already attending an adherence club (n= 137). The groups were compared in terms of CD4- count, viral load, incidence of opportunistic infections and hospital admissions. Although loss- to- follow- up rates and mortality rates are other measures of success of ART, they were not included, as they were not applicable to the pre-enrollment group.

Quantitative data from the pre-enrollment and enrollment groups was collected in Excel for analysis by a statistician, using Statistica Version 11 of 2013. Means and standard deviations were used to analyse numeric variables with normal distributions. Medians and interquartile ranges were used to analyse data which was not normally distributed. Categorical variables were presented as frequency distributions. Data was presented graphically using histograms (continuous variables) and bar charts (categorical variables). A 95% confidence interval for the mean was produced in the estimation of population parameters. When comparing the two groups, continuous variables were compared using the Mann- Whitney U test and box and whisker plots, and categorical variables were compared using the Pearson's chi test for association, as well as the Fishers exact two tailed test in the cases where expected frequencies were less than five. A significance level of 5% was applied throughout.

Phase 2

Phase 2 of the study was of a qualitative nature and involved the conduction of semi-structured interviews with the healthcare providers involved with the adherence clubs, as well as semi-structured interviews and focus group discussions held with club attendees. Participation in the study was voluntary. The fieldwork was conducted by the researcher, who noted, transcribed and analysed responses, looking for commonly coded themes and summarizing these in a coherent whole.

Results of Phase 1

1. **Participants' characteristics**

   Participants were all virally suppressed adults who had been on treatment for more than 18 months and were attending Helderberg Hospital's ART Clinic. The pre-enrollment group had been selected to join the adherence clubs, but had not yet enrolled; the post-enrollment group consisted of individuals already attending adherence clubs (mean time in clubs= 15.7 months).

2. Statistical comparison of the Pre-club and Club- groups

Table 2.1- Descriptive statistical comparison of the Pre-club and Club- groups in terms of means (CI 95.00 %)

	Pre-club (n= 145)	CI 95.00%	Club (n= 136)	CI 95.00%
Baseline CD4 (x 10^6/ l)	166.27	151.69- 180.85	131.85	118.91- 144.78
Time on treatment (months)	38.29	34.74- 41.83	58.48	54.67- 62.29
CD4 1 year ago (x 10^6/ l)	389.94	358.59- 421.3	420.68	385.95- 455.42
VL 1 year ago (RNA cps/ ml)	14.27	6.87- 21.66	9.38	1.21- 17.53
CD4 6 months ago (x10^6/ l)	462.35	427.91- 496.79	482.64	446.45- 518.83
VL 6 months ago (RNA cps/ ml)	5.85	2.72- 8.99	9.99	5.53- 25.51
Incidence of opportunistic infections	0.51	0.39- 0.63	0.23	0.15- 0.31
HIV- related admissions to hospital	0.11	0.06- 0.16	0.07	0.03- 0.12

Table 2.1 illustrates the differences between the two groups. The mean baseline CD4-count was higher in the pre-club group than in the club group, although the club group's mean CD4's at 6 months ago and 12 months ago were consistently higher than in the pre-intervention group, while the mean length of time on treatment was higher in the club group, than in the pre-intervention group. The club group's viral loads remained stable, where as those of the pre-club group improved from 12 months until 6 months prior to the study. There was a higher incidence of opportunistic infections in the pre-club group, when compared with the club group.

3. Baseline clinical stages

Table 3.1- Frequency table describing baseline clinical stages

	All groups	Pre-club group	Club group
Stage I	28%	33.79%	21.32%
Stage II	22%	22.76%	22.06%
Stage III	40%	35.86%	43.38%
Stage IV	10%	7.59%	13.23%

Looking at Table 3.1, more patients in the Pre-club group started ART as Stage 1 patients, where as more patients in the club group started at Stage II or III.

4. Baseline CD4 counts

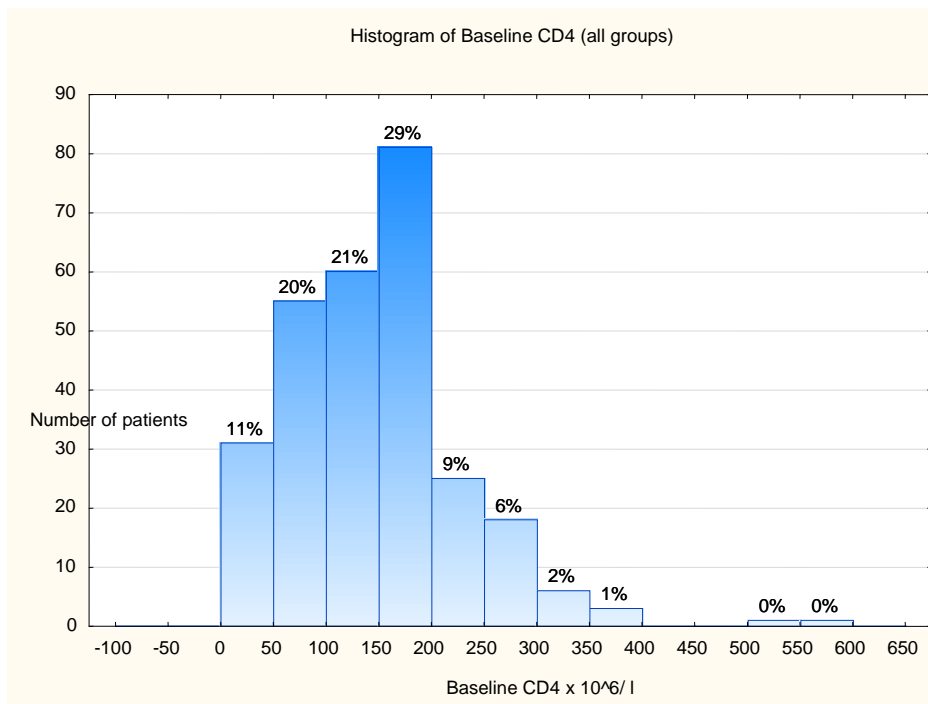*Figure 4.1- Graphic description of distribution of baseline CD4 (all)*

Figure 4.1 shows that the majority (81%) of patients started ART at absolute CD4 counts < 200 (reflecting previous ART guidelines); 70% had baseline CD4 counts of 50- 200.

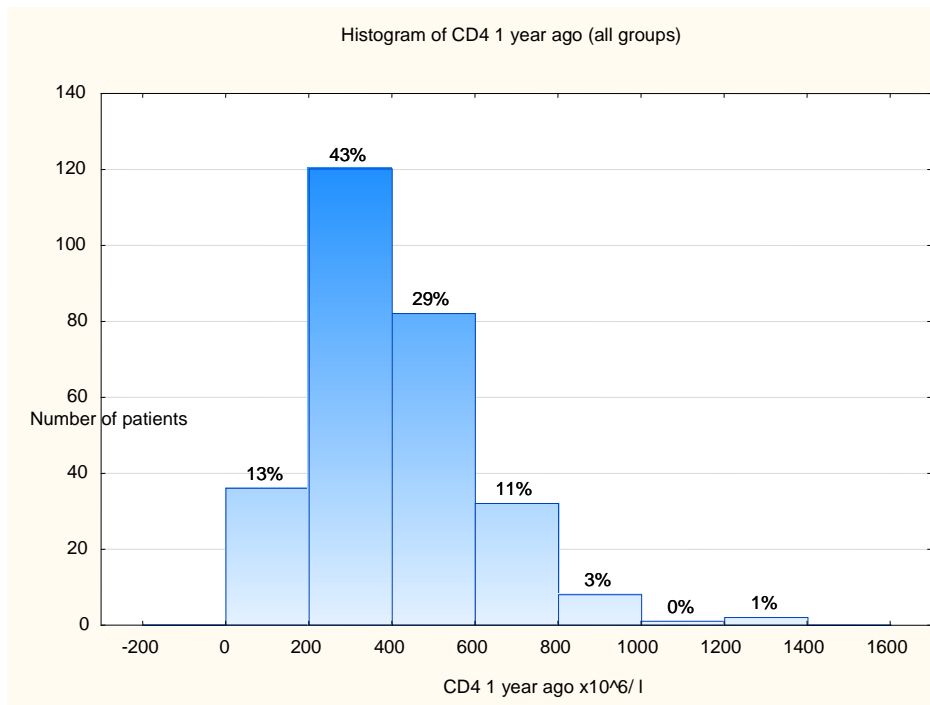*Figure 4.2- Graphic description of distribution of CD4 1 year ago (all)*

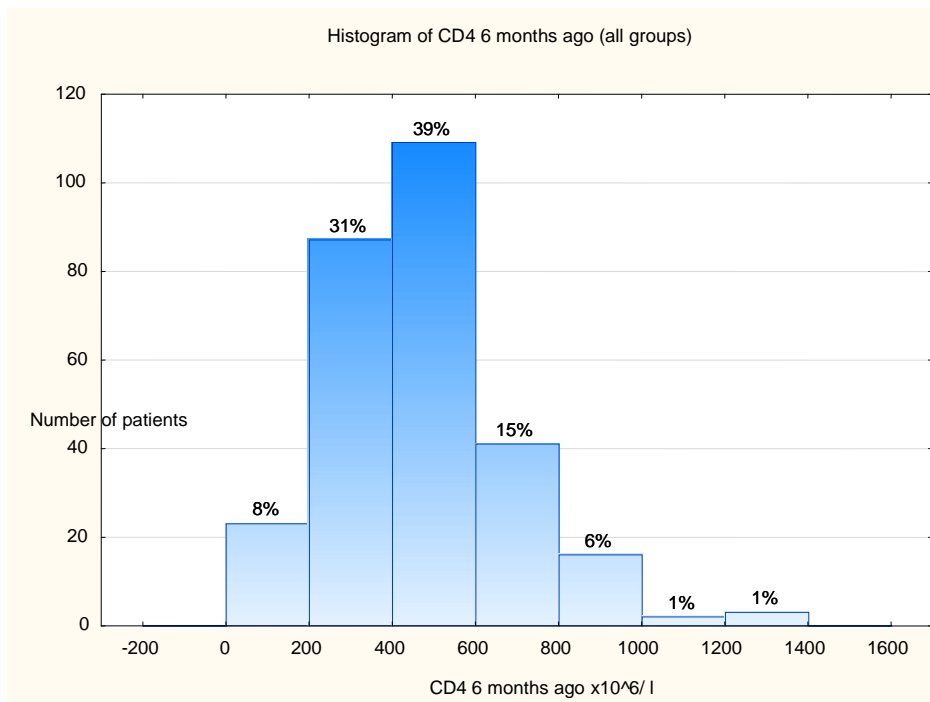Figure 4.2 shows that by 12 months prior to the study (which reflects a mean time on treatment of 28.29 months in the pre- group and 48.48 months in the post- group), only 13% of patients remained at absolute CD4 counts< 200.

Figure 4.3- Graphic description of distribution of CD4 6 months ago (all)

Figures 4.3 shows that by 6 months prior to the study commencing (reflecting a mean time on

treatment of 32.29 months in the pre- group and 52.48 months in the post- group), only 8% of patients remained at CD4 counts < 200.

5. **Comparison between the Pre-club and Club groups in terms of viral load 1 year ago and 6 months ago**

Table 5.1- Comparison between the pre- club and club groups in terms of viral load 1 year ago and 6 months ago

	Pre-club (1 year ago)	Club (1 year ago)	Pre-club (6 months ago)	Club (6 months ago)
Undetectable	86.9%	91.91%	88.97%	95.59%
Detectable	13.1%	8.09%	11.03%	4.41%

Table 5.1 is a frequency table, comparing the frequency of non- detectable and detectable VL's. There were more detectable VL's at 1-year than at 6 months ago (all), with a statistically significant difference between the two groups at 6 months (p= 0.04).

6. **Comparison of incidence of opportunistic infections**

Table 6.1- Comparison of incidence of opportunistic infections (all)

Number of presenting opportunistic infections	All groups	Pre-club	Club
None	69.4%	60.00%	79.41%
1	24.21%	29.66%	18.38%
2	4.98%	7.89%	2.21%
>2	1.41%	2.76%	0.00%

Table 6.1 compares the incidence of opportunistic infections between the pre- and post- groups. There was a statistically significant difference between the two groups in terms of having had no opportunistic infection or 1 opportunistic infection (p= 0.002). More patients in the club group had no opportunistic infections over the two- year period considered for the study, when compared with the pre- club group, and more patients in the pre- club group had 1 opportunistic infection during the study period, when compared with the club group.

7. Hospital admissions with opportunistic infections

Table 7.1- Comparison of admissions with HIV- related illnesses (all)

Number of admissions	Pre- club	Club
Nil	88.97%	92.65%
>1	11.03%	7.35%

Table 7.1 suggests a marginal difference between the two groups in terms of the number of hospital admissions, although this was not of statistical significance (p= 0.29).

There was a statistically significant difference between the two groups in baseline CD4 and length of time on treatment on performance of the Mann- Whitney U- test (p= 0.00). The median baseline CD4 was higher in the pre-group than in the post-group, and the median time on treatment was lower in the pre-group, when compared to the post-group. More people appear to have started ART at lower baseline clinical stages in the pre-group than in the post-group, although the observed difference is not of statistical significance (p= 0.068). Opportunistic infections were more likely to occur in the pre-club group than the post-group (p= 0.002). There was an increased frequency in the number of detectable viral loads in the pre-intervention group, but the difference was only of statistical significance at 6 months (p= 0.043).

Results of Phase 2

1. Participants' characteristics

A total of 93 patients agreed to participate, and 6 health care workers involved with the unit were interviewed. Patients had been on ART between 2 and 10 years. Some had only joined a club recently, whereas others had been in their respective club since the system was introduced in February 2011.

All 6 healthcare providers involved with Helderberg Hospital's ARV clinic were interviewed (two members were on leave). The time the staff members interviewed had been involved with HIV-care and/ or ART ranged from 1.5 – 9 years.

2. Themes identified

Without exception, all patients believed that they had been doing well since joining the clubs and were satisfied with the club system, citing the following reasons:

- *Time efficiency* ('before there were long queues', 'I have to get up early, but I leave early'[C2], 'staff arrive prepared, so the club is run efficiently'[C5])

- *Suitability to the lives of working adults* ('I am a student and don't need to miss classes anymore'[C2], 'suits my working life- I am always punctual and don't have to make up excuses'[C9])

- *Convenience* ('it is easy now', 'before it was difficult; now it is more convenient'[C3])

- *Accessibility* ('the club site is accessible'[C3])

- *Trust in clinic staff* ('we have an open, trusting relationship with the nurses', 'we are treated as equals and not judged', 'I feel I can say anything to the nurses here'[C10])

- *Health education* ('the staff often talk to us about health topics'[C1])

- *Peer support* ('there is support from the other patients- they are like my brothers and sisters'[C2])

- *Privacy* ('less chance of being recognised'[C7], 'more privacy and confidentiality'[C9])

The majority of patients interviewed did not think there were any problems with the club system and could not think of ways the system could be improved, although the following issues were raised by some:

- *Timing of the clubs meeting at Somerset West Clinic* (Fridays at 11h30)- a number of working patients attending the clubs at Somerset West clinic felt that although the venue was easily accessible, the timing of the session was not convenient ('the timing of the club interferes with my working day', 'an earlier time slot would be good'[C5]). The other clubs all meet at 07h00.

- *Need for more medical support* ('If you have a health issue, you must see the doctor or sister at a different time', 'because I don't see the doctor anymore, I don't know my CD4 or viral load', 'I want to see a doctor every 6 months'[C6]).

- *Need for ongoing counselling* - some patients were concerned about their own forgetfulness ('I have sometimes forgotten the club date', 'our pills aren't counted anymore; some people may begin to neglect their health'[C5]).

- One group interviewed said they would enjoy *social events* at the club, with one member suggesting a Christmas party [C3].

Staff members identified the following benefits of the club system to patients:

- *Time efficiency* ('quicker- patients don't have to wait a long time', 'patients don't have to miss work or use up leave to attend the clinic'[P1,4])

- *Convenience* ('patients can see we have tried to accommodate them', 'patient- friendly system'[P1])

- *Motivation/ encouragement* ('patients have a goal in mind', 'motivation helps with compliance'[P2], 'motivation for health care workers who see the fruits of their labour'[P6])

- *Peer support* ('stable patients form friendships and bonds'[P4], 'patients collect medication for group members who can't attend', 'boundaries have shifted- bloods are drawn in front of the other patients, and they encourage each other'[P5])

The clubs were felt to be benefitting the health system in the following ways:

- *Pressure taken off the hospital pharmacy* ('less pressure on the pharmacy because pills are pre- packed by the Chronic Dispensing Unit/ CDU'[P1])

- *Improved flow of the ART clinic* ('de-cluttering of the regular clinic'[P2,3,6], 'less one on one time is required with patients', 'large group of patients is managed in a short period'[P5])

- *Improved health outcomes* ('stable patients are admitted to hospital less often', 'less sick patients')

- *Health promotion* ('group education opportunities', 'ART is promoted to the outside by satisfied patients')[P4]

- *Infection control* ('waiting areas at the clinic are less crowded, which is good for infection control'[P4])

- *Health management* ('it has made us re- look chronic disease management as a whole'[P6], 'ART clubs can serve as a model for the management of all chronic diseases'[P4])

The clubs at the various sites were all felt to be running well. Most staff members commented on the fact that the club meeting in Sir Lowrie's Pass Village was a tightly-knit group in a small community. Members knew each other well and knew when there were problems with other group members. They took ownership of the club and helped staff set up. It was also believed that club members attending the venue at Somerset West clinic easily felt at home, as this was also the venue for the Wellness Club many had previously attended.

The following issues were identified by staff as problems with the club system:

- *Poor documentation* ('patients missed are incorrectly labeled as defaulters'[P1])

- *Problems with the CDU* ('incorrect packaging', 'medication not collected within 5 days is sent back via the CDU and the patient has to transfer out of the club system again- this involves a lot of administrative work and costs more'[P1])

- *Flow management* ('lag effect of late-comers on the regular clinic', 'patients who don't stick to their time slots impact on the running of the regular clinic'[P1])

- *Increased administrative workload on clinicians* ('huge admin. load', 'other studies have shown staff feel despondent about the amount of admin. work they have'[P6])

- *Lack of medical input* ('no doctor visits', 'when the doctors were involved, they did a lot of counseling- now that's gone')

- *Lack of integration of ART and other chronic care* ('inconvenient for patients to get ART from one site and other chronic care from another site'[P4], 'staff has been trained to focus on HIV and other issues are missed')

- *Introduction of INH- prophylaxis* (patients will have to be brought back to the hospital for TB- screening [P1])

- *Tracing of patients* ('patients often don't answer their phones or their numbers don't work', 'patients always seem to have excuses', 'difficult to trace defaulters'[P4])

- *Lack of health promotion* ('patient education is neglected when there is less face- time')

- *Lack of patient involvement* ('patients are still spoon fed- they don't take responsibility or any initiative themselves')

Some suggestions were made as to how the club system could be improved:

- *Staff training* ('so much changes in HIV-staff would like to attend more courses, but find it difficult to attend more than a day at a time because the team staying behind is under pressure'[P1,4], 'nurses need more training in recognizing alerts')

- *Addressing the administrative load* ('involving more non-clinical staff- clinicians should be doing clinical work'[P6], 'do intermittent audits of the registers and folders and get staff members who enjoy admin.to get the registers and folders up to date'[P5])

- *Reporting of all CDU- related problems* to the pharmacy [P1]

- *Computerisation of the system* ('electronic scripts are neat and missing scripts can easily be re- printed'[P1])

- *Checking patients' details* at each visit [P2]

- *Addressing patient behaviour* ('re-education of latecomers'[P1], 'involving the counselors with the clubs', 'involving home-based care workers to visit patients'[P4])

- *Introducing doctor visits* ('implementing at least once yearly medical check- ups'[P1])

- *Convenience* for patients ('scheduling early evening clinics to accommodate working people', ' using more community- based venues')

- *Employment of more staff* ('another certified nurse practitioner would be great'[P1], 'rotation of hospital doctors through the ARV clinic helps')

- *Flow management* ('addressing time management issues with nurses'[P1])

- *Integration of clinical services* ('integration of ART and family planning is going to happen with the support of the Desmond Tutu Foundation'[P1], 'integration of provincial and City of Cape Town services'[P4,5])

Verbatim responses by participants of the qualitative phase have been coded for future reference/ audit.

Discussion

Looking at the quantitative data obtained during Phase 1, there was a statistically significant difference between the two groups in baseline CD4 and length of time on treatment on performance of the Mann- Whitney U- test. The median baseline CD4 was bigger in the pre- group than in the post- group, and the median time on treatment was smaller in the pre- group, when compared to the post- group. More people appear to have started ART at lower baseline clinical stages in the pre- group than in the post- group, although the difference was not statistically significant. The observed differences probably reflect changing national policies in terms of patients now starting ART at higher CD4- counts and earlier stages of disease (e.g. pregnant women).

Opportunistic infections were more likely to occur in the pre-club group (which is why the mean increase in CD4 is expected to be lower in the pre-group than the post-group), and there was an increased frequency in the number of detectable viral loads in the pre-intervention group, but the difference was only of statistical significance at 6 months. These findings reflect the expectation that patients attending the adherence clubs should be doing well, firstly because they have already proven themselves to be reliable and responsible (by qualifying for the clubs), and secondly because the club system makes adherence to their treatments easier.

Research conducted at the MSF pilot site in Khayelitsha has shown that attendance of the ART adherence clubs results in a reduction of both loss to care and virological rebound. 97% of patients attending clubs remained in care, in comparison with 85% of patients attending routine care. These figures compare well with their site in Tete, Mozambique, where 97.5% of those attending clubs remained in care.

Patients attending the adherence clubs were generally enthusiastic about the system, saying that the adherence clubs were efficient, better- suited to working patients, accessible, convenient and more private. They liked the clinic staff and felt that their relationships with clinic staff were open and based on trust. They had formed supportive relationships with other group members. Healthcare providers also thought that the clubs were a form of motivation for adherence.

The club system was felt to be positively impacting on the healthcare system by taking workload off the hospital and its pharmacy (less sick patients were admitted, and treatment orders were taken over by the CDU), taking a load off the regular ART clinic and allowing clinical staff to focus on new and ill patients, improving infection control at the clinic and providing opportunities for health promotion.

Many of the patients attending the mid-morning clubs at Somerset West clinic said they would prefer an earlier time slot, as they felt the current slot impacted on their working day too much. At the MSF site in Khayelitsha evening clubs have been introduced to accommodate the needs of working people.

A large group of patients expressed the need for regular medical check-ups, despite them doing well physically- this is likely to be due to emotional reasons. Some patients requested reminders of their club dates, as they often forgot their dates. One small group said they would like social events being arranged for the clubs.

Staff experienced the increase in the administrative workload as the major problem with the clubs. There were ongoing problems with the CDU, and healthcare was still fragmented, with ART treated as a separate entity. The club system was mainly a doctor-driven system, and clinical staff spent a lot of time doing non-clinical work, with little time for health promotion. There was agreement on the need for more medical input.

It was difficult to trace patients who had defaulted because contact details on the registers were often outdated.

As a lot of the work of running the adherence clubs is administrative in nature, staff members were in agreement that ways had to be found to streamline work and involve non-clinical staff, so that clinicians could be freed up to schedule regular check- ups and attend to sick patients. Issues with the CDU had to be reported to the responsible pharmacist. Patient's contact details had to be updated at each visit. The counsellors had to be involved more to provide ongoing support to patients, along with home-based care workers and patient champions. Staff required training and development in the form of courses and exchanges with staff from other sites. The system could be made more patient-friendly by launching early- evening clinics to accommodate more working people. It would be vital for services to become more integrated in the future, with patients receiving primary care, ART and other chronic care at the same facility.

The results of the qualitative study are encouraging- both health care providers and users feel that the club system has been beneficial to patients and healthcare delivery. The issues raised by participants namely the inconvenience of mid- morning club sessions, the need for more medical input and health promotion, as well as the administrative problems raised, are issues that can be overcome with the buy- in from clinic staff members and district management.

Patients attending ART adherence clubs are less likely to be lost to follow-up, experience virological rebound or become ill with opportunistic infections. Group- based models of chronic care are patient-friendly, budget- friendly and efficient ways of delivering ART in areas with a high burden of disease.

Conclusion

The formation of ART adherence clubs is a strategy aimed at both increasing retention to care, as well as efficiency of service delivery. Quantitative data from other studies have shown that patients attending adherence clubs are less likely to be lost to follow-up or have virological rebound. The data collected in this study suggests that club patients are doing well in terms of their CD4, VL and presentation with opportunistic infections, when compared with a pre-enrollment group.

The majority of patients interviewed at the Helderberg ART clubs are satisfied with the system, and staff members involved with the clubs believe the system benefits both the patients enrolled and the greater health system. Study participants highlighted several administrative issues which limit the effectiveness and efficiency of adherence clubs. Participants recommended the employment of more non-clinical staff, creating opportunities for learning and exchanges of staff, providing more medical support and counseling, addressing CDU orders and flow management issues, and addressing administrative hurdles.

The ability of adherence clubs to improve HIV outcomes in this study setting and others suggests that the programme should be explored as a model for both national ART roll-out in South Africa, as well as the management of other chronic diseases.

Afterword

By the end of October 2013, 29 adherence clubs had been formed, with 967 patients enrolled. Since the inception of the adherence club system at Helderberg Hospital in February 2011, only one patient had defaulted, and there had been no mortalities.

Appendix 1: Quantitative Data Collection Sheet

Patient no.	Baseline clinical stage	Baseline CD4	Time on Rx	CD4 1 year ago	VL 1 year ago	CD4 6/12 ago	VL 6/12 ago	OIs	Admissions

Data Capturing Sheet - a Comparative Evaluation of the Successes and Challenges of the ART Adherence Clubs in the Helderberg Dist

Appendix 2:Questionnaires

Questionnaire 1 (to be used in interviews with health care providers)

A Comparative Evaluation of the Successes and Challenges of the ART Adherence Clubs in the Helderberg District

Study leader: Dr VMB Klocke, Division of Family Medicine and Primary Care, Stellenbosch University

Question 1

How long have you been involved with the ART programme at Helderberg Hospital?

Question 2

In which ways do you think ART adherence clubs are benefitting patients?

Question 3

In which ways do you think the clubs are benefitting the health system?

Question 4

Do you think there are problems in the club system? Please describe the problems.

Question 5

Have you noticed a difference between the various clubs at the different sites you are managing?

Question 6

How do you think problems in the club system can be addressed?

Questionnaire 2 (to guide focus group discussions)

A Comparative Evaluation of the Successes and Challenges of the ART Adherence Clubs in the Helderberg District

Study leader: Dr VMB Klocke, Division of Family Medicine and Primary Care, Stellenbosch University

Question 1

Which ART Club are you attending?

Question 2

How long have you been attending this Club?

Question 3

How long have you been on ART?

Question 4

How have you been doing on your treatment since joining the Club?

Question 5

Describe the ways in which attending the Club has helped you with your treatment.

Question 6

Describe any problems you have noticed at your ART Club.

Question 7

Describe the ways in which you think your ART Club could be improved.

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