Guidelines for ARV Adherence clubs

1. Objectives

- a. This guideline is intended to be used as a tool to support sites in establishing Adherence Clubs (AC) for patients stable on ART
- b. The broad objective of the AC is to:
 - reduce the load on clinical services whilst not compromising the quality of patient care
 - ii. maintain (achieve) good long-term adherence in patients on ART through shorter clinic visits and appropriate adherence support

2. Broad Overview

- a. <u>Membership</u>: An adherence Club consists of a group of no more than 30 clients who are judged to be adherent to and stable on HAART (see 3).
- b. <u>Timing</u>: Club members meet every second month as a group. The Club visit lasts approximately 1-1.5 hours. Each clinic should consider appropriate time for adherence club considering accessibility for working patients (early morning or extended hours) and off peak low patient load periods with less pressure on space and human resources.
- c. <u>Process</u>: At each club visit, Club members are clinically assessed (by weight and symptom screen see 7), participate in a group support/education activity and are issued with 2 months' pre-dispensed medication in the club venue.

d. Team:

- a. Each clinic should have a designated Clubs Manager who takes overall responsibility for the activities required to run successful ACs. (S)he may delegate to other members in the team, but the ultimate responsibility rests with her/him. This manager should be a nurse.
- b. Each club has assigned to it a team of a Club facilitator (a counsellor, peer educator or equivalent) and a professional nurse (the Club PN). Other possible team members could include a data capturer/clerk, a pharmacy assistant.
- c. The Club facilitator is responsible for running the club session including registering members, conducting the AC support/education group conducting

symptom screening, referring patients to Club PN if appropriate, issuing predispensed/Centralised dispensing Unit (CDU) ARVs, and completing club registers.

d. The Club PN is responsible for clinical oversight of a Club on the day of the club visit.

e. Clinical Care and Counselling:

- a. Club members with symptoms/weight loss/other clinical problems are referred by Club facilitator and receive an individual consultation with the Club PN on the same day (see 7).
- b. Annually, monitoring and safety bloods are taken in the Club. At the following visit, all club members have an individual consultation with a clinician.
- c. Club members may be seen by a counsellor on an individual basis if they request this.
- d. Club members are re-scripted for ARV drug supply purposes every six months (see 11).
- f. <u>Club Records</u>: Each Club has a Club file which contains the scripts of the Club members and a Club register (see sec 12) which records attendance, weight, results of symptom screen and blood results. Client Folders are only drawn at rescripting visits, at annual clinical consultation or when a Club member receives a consultation during a routine Club visit.
- g. Club members may be excluded from the Club based on a number of clinical and adherence criteria (see 8) but may return to club at discretion of clinician (see 9).

3. Eligibility Criteria for Club membership

- a. A Client may qualify to join an Adherence Club if (s)he meets the following criteria:
 - i. Adult
 - ii. On the same HAART regimen for at least 12 months (regimen 1 or 2). However, in the case of a single drug substitution, clinician to determine when eligible.
 - iii. Most recent 2 consecutive viral loads undetectable; the most recent of these taken in past 6 months (thus minimum of 12 months on HAART).
 - iv. No current TB
 - v. No medical condition requiring regular clinical consultations.

- b. Clinicians confirm the clients's eligibility for Club membership.
- c. Membership of a Club is voluntary

4. Annual visit schedule (See timeline below)

Visit no.	Type of club visit	Activities	CDU visit no.
Month -1		Recruitment	Attend pharmacy
Month 0	Enrolment visit	Scripting	Attend pharmacy (2 m supply)
Month 2	Routine visit		1
Month 4	Blood visit	Bloods taken	2
Month 6	Clinical visit	Clinical consultation + re-scripting	3
Month 8	Routine visit		1
Month 10	Routine visit		2
Month 12	Re-scripting visit	Re-scripting	3

a. Cycle repeats from M2

5. Tasks in Organisation and Running of Clubs.

a. Preparation for Club (Day before the Club):

- i. Collect the Club file from where it is safely stored
- ii. Deliver Club file to pharmacy for dispensing medication/pre-dispensing of medication received from CDU. (See 11)
- iii. Before 'blood taking' day:
 - complete lab forms for CD4, VL (and any other safety bloods that needs to be taken.). Patient stickers should be in the Club file. Lab forms should have Club number entered into 'Ward' field
 - collect stock of necessary blood tubes, needles, syringes, webcols etc.
- iv. Before 'clinical visit' day:
 - draw folders, ensure that results filed in Club members' files (or call NHLS if necessary)
 - enter the results into the register for that Club.

ensure CDU script book available for re-scripting Club members.

b. Club Day

- i. Club register to be completed at all visits.
- ii. All Club members to be weighed, and weights entered into register. On clinical visit days, weights also to be entered into Club member's file. If buddy attends, 'buddy' is entered into the 'weight' block. See 12).
- iii. Symptom screen to be done, either individually, or in the group, or both. Results of symptom screen to be entered in Club register and Club members with significant weight loss or symptoms, or who request to see a clinician, should be seen by the Club PN on the same day (see 7).
- iv. On 'blood' days, to ensure bloods are taken, appropriately marked and packaged.
- v. If 'clinical visit day', direct patients to the allocated clinician, and deliver the patient folders to the clinician. Ensure that Club member is re-scripted preferably on clinical visit day otherwise no later than 5 working days thereafter (see 12).
- vi. Fetch and issue patient meds.
- vii. If a patient sends a buddy on a blood-taking/clinical visit day, or for the second time in succession, the buddy is told to inform the client that they should visit the Clubs manager at the facility within 5 working days (see 6).

c. After Club has ended (on same day as Club)

- i. Deliver bloods to the place where they are collected by the NHLS courier.
- ii. Return unissued meds to the pharmacy, formally handing these over to one of the pharmacy staff.
- iii. Check register for names of those
 - a. who did not either attend the AC personally or send a buddy to collect ARVs , or
 - b. who have sent a buddy on a Blood day, or on a clinical consultation day
 - c. who have sent a buddy twice in succession.

The folders of these patients should be drawn, and kept aside in a designated space e.g. with Clubs Manager. Should the patient not arrive within a week (5 working days), the patient should be classified as a defaulter (see 6) and recalled.

d. Between Clubs

i. <u>During week post Club</u>: manage the case where a Club member or buddy arrives after the day of the club to fetch ARVs, seek consultation or have bloods taken. Situation reviewed; if appropriate, Club member referred to pharmacy for issue of ARVs. The Club register is updated to show that the Club member / buddy attended.

ii. One week post Club:

- a. Review Club register and client folders kept aside to determine who has not either attended or sent buddy. Recall those patients and update the register to indicate that the patient defaulted.
- b. Deliver the Club register to the data capturers so they can capture the visit, the weight and any results entered. Ensure that the Club register are thereafter returned to a designated storage site.
- iii. Week 1 to week 4: Ensure that a system is in place for review of all Club blood results, and recall of those patients the clinician decides should be recalled.
- iv. Week 1 to week 8: Ensure all results are filed into Club member folder in preparation for clinical visit. Results should also be entered into the Club register. (see 10).

6. Club attendance requirements and definition of defaulter

- a. Club members may send a buddy to collect medication for them on their Club visit day except:
 - i. on date of first attendance at the club
 - ii. on a Blood day
 - iii. on a clinical consultation day
 - iv. If s/he did not attend personally on the previous club day i.e. buddy attends twice in succession
- b. Where the Club member sends a buddy on the blood day or the clinical consultation day, the buddy will be asked to inform the Club member that they need to come to the clinic to see the Clubs Manager within 5 working days of the club visit date. Should the client not present during this time, (s)he would be classified as a defaulter.

- c. If a Club member sends a buddy to collect medication, 'buddy' is recorded in the register in the place of the weight. The buddy is informed that the Club member must attend the next visit.
- d. Should the Club member present within 1 week (5 working days), the Clubs manager reviews the case, and where appropriate refers to pharmacy for the issuing the ARVs. This will be recorded in the Club register as a visit. If a blood, clinical or scripting visit the Clubs Manager will ensure that appropriate action taken for the specific visit.
- e. However, should a Club member not attend personally or send a buddy to collect meds within 1 week (5 working days) of the club day, the Club member will be regarded as a defaulter, and recorded as such in the Club register.
- f. Defaulting Club members will be recalled through the contact details recorded in the register and the client will be required to return to mainstream care once they attend the clinic again.

7. Clinical management of Clubs

At each visit, Club Facilitator is responsible for ensuring that:

- a. The Club member is weighed, and weight recorded in register
- b. The Club member is asked individually / in group / both re the following, and results of the screening are entered into register:
 - i. TB symptoms (cough, weight loss, night sweats, fatigue)
 - ii. Late onset ARV side effects (lipodystrophy)
 - iii. Pregnancy
 - iv. Any other symptoms of concern
- c. Where the Club member is identified with any of the above symptoms, the Club member is referred to the Club PN for an individual consultation with their folder .
- d. The Club facilitator should also review the weights in the register to determine whether a client has lost weight. If this is the case, this client should be referred to the Club PN.
- e. The Club PN consults these identified Club members..
- f. The clinician(s) decide whether Club members referred from Club should remain in the Club or return to mainstream care

8. Criteria for return to Mainstream Care

- a. Club member is classified as defaulter (see 6e)
- b. Viral load > 400
- c. Other safety blood results significantly abnormal
- d. Club member develops TB
- e. Other indications assessed in individual clinical consultation.
- f. Criteria b to e will be picked up soon after receipt of annual blood test results, but at the latest during the annual clinical consultation.

9. Criteria for return to Club

a. Clubs Manager, in consultation with Club PN / Club doctor, will use his/her discretion to assess clients for possible return to a club after returning to mainstream care (sec 7). The client is not required to meet the initial criteria for club membership (sec 4).

10. Results and recalls

- a. Clubs Manager is responsible for ensuring that:
 - i. All Club results (VL, CD4s and safety bloods) are reviewed by a clinician.
 - ii. Patients are recalled as indicated by the clinician who reviews results.

Results are to be entered into the register, between club dates, or failing that, soon before or on the clinical visit club day.

Results should be filed in the client's folders before the Clinical visit club day.

b. Where a Club facilitator becomes aware of a detectable viral load or decreasing CD4 count entered in the Club register, the Club facilitator should immediately refer the Club member to the Clubs Manager if the Club member has not already been seen by a clinician.

11. Pharmacy

- At enrolment visit ARVs will not either be pre-packed by clinic pharmacy or each newly enrolled Club Member will attend the pharmacy after enrolment club visit for collection of ARVs.
- b. At the enrolment club visit (first club session after recruitment by clinician), an authorised clinician will complete a 6 month CDU script (or where the clinic is not

utilising CDU services, a clinic script) for the new Club member in triplicate. One copy will remain in the Club member's folder. The remaining 2 copies will be placed in the Club file.

- c. Where CDU Scripts, the Club file containing 1 original and 1 copy will be delivered within5 working days of Club enrolment visit to the clinic pharmacy.
- d. The clinic pharmacy will ensure the following is clearly reflected on each CDU script before submitting original script to CDU:
 - I. The number of the club
 - II. 2 month dispensing period
 - III. Next 3 club visit dates
- e. The clinic pharmacy will submit the original CDU scripts to the CDU within 5 working days from receiving the Club file to ensure ARVs prepacked for next club visit.
- f. The Club file will then be returned by the clinic pharmacy to the Clubs Manager.
- g. The Clubs Manager will submit the Club file to the clinic pharmacy two days before each club visit so ARVs can be pre-dispensed for the first 2 months.
- h. Once the first script is delivered to the CDU, provided new scripts are received by the CDU from the clinic pharmacy every 6 months, the CDU will continue to provide the clinic pharmacy with pre-packed ARVs for the club.
- i. Pre-dispensed ARVs to be issued at Club visit. Patient / buddy to sign CDU form as proof that ARVs collected.
- j. The Clubs Manager must ensure that Club members are re-scripted 6 monthly at M6 by clinician at clinical consultation visit and at M12 and every 6 months thereafter.
- k. The Clubs Manager must submit the Club file to the clinic pharmacy within 5 working days of re-scripting in order that new CDU scripts can be submitted to CDU timeously for supply fo ARVs for next club visit date.

12. Monitoring and evaluation

- a. Each club has a Club file which contains a copy of the Club member's script (standard/CDU script). The file should also contain patient stickers.
- b. The Club File should be kept with the Club register (including the Club Tally sheet)

- c. Club register to be used every visit (See ARV chronic club register and associated guidelines for its use). The club tally sheet at the back of the register should also be completed at every visit.
- d. The Club register should be regularly reviewed by Clubs Manager.
- e. 5 days after the club visit, relevant information in the Club register must be transferred to the facility ARV register (paper or electronic) by the clinic data clerk.
- f. Once monthly the Clubs Manager will transfer the data in the club tally sheet into the clinic clubs tally sheet and submit to sub-structure HAST co-ordinator/MO or CoCT HIV/TB co-ordinator.

Annual timeline

