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**SOP 2.1: CAG Intervention Participant Recruitment-Informed Consent-Enrolment**

### **PURPOSE**

This standard operating procedure (SOP) describes the procedures for the recruitment, and enrolment of study participants into the CAG model of differentiated service delivery.

### **SCOPE**

This SOP applies to all personnel involved in the CAG model.

**MATERIALS**

Enrollment Form

CAG Assembly Form

CAG Group Membership Register

CAG Appointment Diary

CAG Model Infographic

**RESPONSIBILITIES**

 **Lay Health Care Worker Supervisor (HCW supervisor)** is rresponsible for:

* Conducting enrollment procedures
* CAG assembly
* Generating CAG group membership register, clinic visit schedule, and CAG appointment diary

**Lay Health Care Worker (“CAG Supervisor”)** is responsible for:

* Assisting the HCW supervisor with enrollment procedures, CAG assembly
* Entering data into the central database or filing forms into patient files

**PROCEDURES (See CAG Intervention Enrolment Flowchart)**

**1. Identification of Individuals to Approach for Recruitment**

Patients at clinics with the CAG model will be identified and invited by clinic staff. The original invitees will be given the opportunity to return to clinic with their friends

Recruitment will occur at clinics participating in the CAG model delivery of care, the amount of CAGs created should be determined by the ART manager. The original invitees will also be given the opportunity to return to the clinic with their friends the subsequent week (week 2).

For every patient that vocalizes they are interested in joining CAG or whose file has been identified as a potential eligible patient, the lay HCW will ask the clinician to review the patient’s chart to determine if they meet eligibility criteria for joining a CAG.

Inclusion criteria:

* HIV-positive adolescents and adults (> 14 years of age)
* Last CD4 count (obtained within the last six months) > 200 cells/mm3
* Not acutely ill
* On ART for at least 6 months

Exclusion criteria:

* Inability to participate in the group activities due to cognition deficits or mental illness.
* Pregnancy

If eligibility criteria are met, the clinician will direct the patient to the lay HCW at the end of the clinical visit. The lay HCW will briefly inform the patient that they have been invited to learn about a program that could make getting ARV’s easier for the patient and if interested will bring them to the HCW supervisor who will discuss the CAG model in full detail with them*.*

For patients that answer that they are unsure of their pregnancy status they will be offered the opportunity to take a pregnancy test by the clinician in order to further determine eligibility or if a pregnancy is unavailable the clinician will probe with questions

**2. Describing the CAG Model**

The HCW supervisor will briefly describe the CAG model using the *CAG Model Infographic* The patient will be asked if they are interested in joining a CAG. If they are not interested, then the HCW supervisor should thank the patient and escort them out of the room. If they are interested, then the HCW supervisor will initiate a discussion about enrolment into the CAG model of care.

**3. Completing the Enrolment Form**

Once a patient agrees to join a CAG, the HCW supervisor will complete the Enrolment Form. Answer each question on page 1 (General) and then answer the questions on page 2 (CAG model). Where indicated, provide a written description and a map for how to get to the patient’s house from clinic. This information will be used both for grouping patients into CAGs as well as to trace the patient if they are lost to follow-up.

**4. Assembling CAGs**

After initial enrolment, enrolled patients should be asked to return the following week with any friends with whom they would like to join a CAG. Those who cannot identify any friends do not need to return to clinic at this time. Based on the home location of enrolled patients, the HCW supervisor may suggest that the enrolled patient return with his friends on a specific day so that others from the same neighbourhood might meet each other to form a group together. The friends of the already enrolled patients will have their ART charts drawn from storage and will be assessed by a clinic nurse or clinician for eligibility. If the friend is found to be eligible, they will go through steps 2 through 4 above to become enrolled in the CAG.

TheHCW supervisor (with the assistance of the Lay HCW) will then use the CAG assembly sheet to assist with placement of all enrolled patients into groups of 3-8 based on their home location. This includes those patients who enrolled initially who did not identify any friends. Each group should be assigned a CAG group number (see CAG assembly sheet).

If a patient lives in a community where there are only 1 or 2 people in the same area, then a CAG group cannot be performed and these individuals can be considered for enrolment at a later day if more individuals from their community are identified. If there are 3,5, 7, or 8 people in the same area then the HCW supervisor can offer the group the option to form a CAG with the understanding that frequency of visits to the clinic for drug pick-up would be more frequent since there are fewer than 6 CAG members, or for groups with more and 6 members 2 patients may be due for their clinical at the same time.

After CAG formation is complete, each CAG group should be assigned and distributed between the lay HCWs at the site such that each lay HCW is responsible for an equal number of CAGs.

**5. Generating the CAG group membership register**

Once the groups of 6 have been assembled on the paper worksheet, the CAG group membership register needs to be filled out for each group.

1. Fill out the information about the CAG at the top of the form including the Clinic Name, the CAG Group Number, and the Staff ID Number. Each CAG supervisor should have received a Staff ID Number at the time of training. Leave the CAG leader and the CAG leader mobile number blank for now.
2. List the ART ID and First Name, Sur Name for each CAG Group member.
3. Use the enrolment forms to complete the next several columns: Sex, Date of Birth, Mobile phone 1, Mobile phone 2.
4. For “Date joined CAG”, write the date of CAG enrolment for that patient.
5. Develop a schedule of all CAG member clinic visits to the facility: Select one of the CAG group members. This person should be assigned a Clinic Visit 1 date two months from their date of CAG enrollment. Add each additional CAG member and assign them a Clinic Visit 1 date one month after the Clinic Visit 1 for the person listed above them. The CAG members do not have to be ordered in any special way. Continue through the list until all six CAG members have been assigned a Clinic Visit 1. Then for each patient assign Clinic Visit 2 to be six months after their Clinic Visit 1. (\*Note: It is important that the first clinic visit occurs two months after the earliest member in the CAG group enrolled. This is so that no CAG member is without medication for any duration of time). (\*Additionally, if CAG groups have fewer than 6 members or more than 6 members, this will alter the way that clinic visits are distributed).
6. Update the next appointment date in the clinical form in the patient’s ART file using the Clinic Visit 1 date for that patient. Ensure that all CAG member ART files are then given to the data associate for entry into the central database.

**6. CAG Assembly Meeting**

Next, the HCW supervisor and the lay HCW will contact each individual in a group (via mobile) and ask them to come to the facility for an introductory CAG assembly meeting.

The lay HCW will lead the CAG assembly meeting. The lay HCW will explain the CAG model again and describe the responsibilities of all CAG members and the CAG leader (see SOP 2.11: “Roles and Responsibilities of CAG Personnel”). The group will elect a CAG leader. The CAG code of conduct will be reviewed and the opportunity to adapt or modify the code will be given. The lay HCW will answer any questions that the group has. The group members will be told of their clinic appointment dates and their ART cards will be updated. The first clinic appointment date in the group (this will be the first rotating CAG member) will correspond approximately with the date of the first CAG meeting.

**7. Completion and uploading of the group membership register**

After the CAG meeting is over, the CAG supervisor should complete the CAG group membership register by adding the information about the elected CAG leader’s name and mobile number. The CAG group membership register should now be complete and should be entered into the the data collection tool and uploaded to the central database within 72 hours. If this is not being captured electronically, appropriate arrangements should be made to organize CAG meeting group registers in a binder at the facility.

### **ABBREVIATIONS AND ACRONYMS**

SOP *Standard Operating Procedure*

CAG *Community Adherence Group*

HCW *Health Care Worker*

**HCW supervisor** *Health Care Worker supervisor*

**SOP 2.11: Roles and Responsibilities of CAG Personnel**

### **PURPOSE**

This standard operating procedure (SOP) describes the key roles and responsibilities for all personnel involved in implementation of the Community Adherence Groups (CAG) model.

### **SCOPE**

This SOP applies to all personnel involved in the CAG model of care.

**MATERIALS**

CAG Group Membership Register Form

CAG Monthly Attendance Register Form

CAG Event Form

CAG Appointment Diary

Data collection tool for electronic data collection

**RESPONSIBILITIES**

**Health Care Worker Supervisor (HCW supervisor)** is rresponsible for:

* Conducting enrollment procedures
* CAG Assembly
* Retrieving and storing CAG members’ files
* Facilitating clinic visits for CAG members
* Coordinating with clinic tracing staff to ensure patient tracing as outlined in this protocol
* Supporting and supervising the lay HCW in all their duties

**Lay Health Care Worker (“CAG Supervisor”)** is responsible for:

* Assisting the HCW supervisor with enrollment and CAG assembly
* Maintaining the group CAG membership register and updating this information in the central database using the data collection tool as specified in this protocol
* Providing orientation to CAG members
* Providing supervision of CAG meetings
* Completing and entering the data from the CAG monthly attendance register into the the central database after a CAG meeting
* Facilitating the up-referral of any CAG members who need a clinic visit
* Responding to disputes that cannot be self-resolved by CAG members
* Alerting the HCW supervisor in the event of a hospitalization or death of a CAG member
* Completing the event form in the event of a qualifying event and entering this data into the central database

**CAG Leader** is responsible for:

* Facilitating the selection of location and time of CAG meetings on a monthly basis
* Leading the monthly CAG meetings including moderating the adherence discussion and ensuring completion of the monthly attendance register
* Ensuring the monthly attendance register is returned to the Lay HCW within 48 hours of meeting
* Contacting a CAG member who misses a monthly meeting as specified in this protocol
* Notifying the lay HCW if a CAG member misses a monthly CAG meeting
* Notifying the lay HCW if a CAG member needs assistance with up-referral

**\*Note:** some of the CAG leader responsibilities may rotate or be shared amongst other group members based on the group’s preference, but the CAG leader will remain as the point of contact

**All CAG members** involved in the CAG model are responsible for attending clinic visits and CAG meetings as specified in this SOP and for abiding by a code of conduct (as specified in the SOP 2.12: Ethics and Confidentiality – CAG Members.

**Pharmacy Technologist** is responsible for:

* Pre-packing and labeling all CAG members drugs in their CAG group drug collection bag
* Dispensing drugs for all CAG members to the rotating CAG member attending the clinical visit
* Completing the pharmacy form at the time of group drug dispensation
* Providing the CAG member with the pre-filled monthly attendance register at the time of drug pick-up
* Communicating on a daily basis (or as needed) to coordinate with HCW supervisor, lay HCW, and clinic staff about CAG operations

**Data Associate** is responsible for:

* Entering completed clinical visit and pharmacy forms into the central database

**PROCEDURES (See Appendix 1: CAG Flowchart)**

**HCW Supervisor:**

1. Procedures during the enrolment period
	1. Please refer to SOP 2.1 Recruitment/ Enrolment of CAG Participants) for the following activities: recruitment, enrolment, and CAG assembly.
	2. The HCW supervisor should write the anticipated clinical visits for each CAG member into the CAG Appointment Diary using the CAG Group Membership Register. The CAG group number should be written next to the appointment date.
	3. **Label** each CAG members ART patient file with a sticker on the upper right corner of the cover.
	4. Work with clinic staff to identify an appropriate separate location for CAG member file storage if possible/feasible
	5. Work with clinic staff to ensure they are aware of the CAG filing system
2. Procedures for routine monthly visit of a CAG member
	1. The HCW supervisor should communicate the upcoming clinic visits using the **CAG** **Appointment Diary** to the lay HCW on a weekly basis.
	2. The HCW supervisor should pull CAG members’ ART files from storage location at least one day prior to the monthly visit of a CAG member and give them to the pharmacy technologist for pre-packing and labeling of drugs.
	3. After the pharmacy technologist has prepared the medications for all the CAG members, the HCW supervisor should retrieve the members’ files and provide them to the triage nurse on the day of the CAG member visit.
	4. After the monthly visit of a CAG member, the HCW supervisor should bring CAG member ART files (with completed pharmacy forms) to the data clerks’ office for data entry.
	5. The HCW supervisor should place CAG members’ files back into designated storage space after forms entered into central database by data associate.
3. Procedures for managing up-referrals and down-referrals
	1. Work with clinic staff to facilitate a clinic visit for any CAG member needing up-referral to the facility (either temporarily or permanently). A patient may be temporarily up-referred to the clinic because they are ill. A patient may be permanently up-referred if they no longer want to be in a CAG, are pregnant, or it was determined that they must leave a CAG due to misconduct.
	2. After the clinic visit, consult with the clinician and other clinic staff to determine whether an up-referred patient will need additional clinic visits or whether they can continue the clinic visit schedule assigned to them in their CAG. Determine if they will continue receiving medications through the CAG or through the clinic. Notify the lay HCW of this information so that the lay HCW can inform the CAG group.
	3. If a CAG member requires additional special clinical visits due to illness, the HCW supervisor should communicate with the clinician and other clinic staff after every visit to determine the status of the patient. The HCW supervisor will communicate with the lay HCW regularly to adjust the clinic visit schedule and medication pick-up for the entire CAG accordingly.
	4. For patients who are up-referred because they are pregnant, the HCW supervisor should facilitate a visit to the MCH department.
	5. If a CAG member is being permanently up-referred after a CAG meeting they should be given a 1-month supply of medications until they are linked back into routine care
4. Procedures for managing a CAG member who missed a group meeting or clinic visit
	1. If the HCW supervisor is notified of a patient who missed a CAG meeting or clinic visit (and could not be located by the CAG leader or other group members), the HCW supervisor should communicate with the clinic tracing staff in order to ensure that the patient is traced according to current clinic standards.

If the missing patient returns to clinic:

* + 1. determine if he feels ill or is due for a clinical visit
		2. determine whether the CAG member wants to remain in a CAG or not
		3. determine the date of the last attended CAG meeting
	1. If the patient feels ill or is due for a clinical visit, the HCW supervisor should facilitate a visit with the clinician by communicating with clinic staff
	2. If the patient no longer wants to be in a CAG, arrange for a clinic visit. This patient should be considered a departing CAG member and the group medication pick-up for the group should be adjusted accordingly. See the section below on “Procedures for managing the departure of a CAG member” for additional instructions.
	3. If the patient feels well, is not due for a clinical visit, wants to remain in a CAG, and the date of the last attended CAG meeting was less than 30 days ago, the HCW supervisor should facilitate medication pick-up at the pharmacy until the next scheduled CAG meeting and arrange for an enhanced adherence counseling visit with the CAG supervisor.
	4. If greater than 30 days has elapsed since the last attended CAG meeting, management should be decided on a case-by-case basis. These cases should be discussed with the ART manager at the facility.
1. Events requiring notifications to the ART manager
	1. Notify the ART manager immediately in the event of a hospitalization or death of a CAG member
	2. Notify the ART manager of a CAG dispute that cannot be resolved by the CAG, the lay HCW, or the HCW supervisor.

**Lay Health Care Worker “CAG Supervisor”:**

1. Procedures for supervising CAG meetings
	1. Conduct a CAG orientation meeting after a CAG has been assembled to discuss the code of conduct (see SOP 2.12: Ethics and Confidentiality - CAG) and to provide guidance on group adherence counselling.
	2. Attend and provide supervision at CAG meetings during months 1, 2, 6, and 9. During these supervision visits the CAG supervisor should
		1. Provide the opportunity for CAG members to ask any questions they might have about how a CAG is supposed to function, the roles and responsibilities of CAG members, and the code of conduct (see SOP 2.12: Ethics and Confidentiality - CAG).
		2. Observe the adherence discussion at the CAG meeting
		3. Identify if there are any specific issues or problems in this CAG and discuss these issues with the HCW supervisor.
2. Procedures before and after a monthly CAG meeting
	1. At least one day before a CAG member clinic visit, use the CAG group register to pre-fill the following fields on the **monthly attendance register**: Clinic Name, CAG Group Number, ART ID, and First Name & Surname for each of the CAG members.
	2. Provide the pre-filled register to the pharmacy technologist at least one day prior to anticipated CAG member clinic visit.
	3. After a monthly CAG meeting, meet in-person with the CAG leader within 48 hours after the meeting to obtain the CAG monthly attendance register.
	4. After receiving the monthly attendance register from the CAG leader, review the form to make sure that the CAG members have completed all questions for each CAG member.

Examples:

* + *For a missing CAG member, “Attended? should be ‘no’.*
	+ *If a CAG member reported being ill, then the specific symptom questions for that member should be completed.*
	+ *If a member missed the meeting but later obtained his medications from the CAG leader, “Attended” should be ‘no’ but “Received Meds?” should be ‘yes’.*
	1. Assess whether any patients need to be referred to the clinic. A patient should be referred to the clinic if they are ill, are pregnant, or no longer want to be in a CAG. Review the questions on the monthly attendance register to determine if any one reported being ill or pregnant. Complete the last column of the CAG monthly attendance register titled “Referred to Clinic?” by indicating yes (‘Y’) or no (‘N’). If a CAG member is being referred to clinic, then complete the **event form** to describe why.
		1. If a CAG member reported being ill, the CAG supervisor should urgently notify the HCW supervisor to arrange a clinic visit either that day or the next day.
		2. If a CAG member is found to be pregnant, the CAG supervisor should notify the HCW supervisor so that the patient can be seen in the MCH department. The patient can continue in the CAG as a social member but will not continue to receive medications through the CAG. They should be considered a departing CAG member and the medication pick-up for the group should be adjusted accordingly. See the section below on “Procedures for managing the departure of a CAG member” for additional instructions.
		3. If a CAG member no longer wants to be in a CAG, the CAG supervisor should notify the HCW supervisor to arrange a clinic visit. In addition, the lay HCW should work with the CAG to adjust the medication pick-up for the CAG group accordingly. See the section below on “Procedures for managing the departure of a CAG member” for additional instructions.
	2. Assess whether any patients missed the CAG meeting. See “Procedures for managing a missing CAG member” section below for additional instructions.
	3. Enter the data from the CAG monthly attendance register into the central database within 72 hours of receipt of the register
	4. Bring the completed CAG monthly attendance register to the clinic and store in a designated secured storage area
1. Procedures for managing a CAG member who misses a group meeting
2. If a CAG member misses a CAG meeting and has not collected their medicine from the CAG leader within 48 hours of the meeting:
	1. Verify whether the CAG leader attempted to contact them at least two separate times.
	2. Collect the medicines and bring any unused medications back to the clinic pharmacy
	3. Inform the HCW supervisor so that this patient can be traced according to current clinic practices
	4. Complete an **event form** for the missing CAG member.
3. If a missing CAG member later returns to care (either by contacting other CAG members, the CAG supervisor, or by visiting the clinic):
4. Determine if he feels ill or not. If he feels ill, the HCW supervisor should be notified immediately so that a clinic visit can be arranged.
5. Determine the reason the patient missed his CAG meeting and try to address any barriers. If the patient no longer wants to be in a CAG, the CAG supervisor will work via the HCW supervisor to arrange for a clinic visit. They should be considered a departing CAG member and the group medication pick-up for the group should be adjusted accordingly. See the section below on “Procedures for managing the departure of a CAG member” for additional instructions.
6. If the patient feels well, wants to remain in a CAG, and the date of the last attended CAG meeting was less than 30 days ago, communicate with the HCW supervisor to facilitate medication pick-up at the pharmacy until the next scheduled CAG meeting. If greater than 30 days has elapsed since the last attended CAG meeting, management should be discussed with the HCW supervisor and the ART manager and assessed on a case by case basis.
7. Complete an **event form** for the missing CAG member who has now returned to care.
8. If a CAG member misses more than one meeting:
9. The CAG member is still potentially eligible to remain in the CAG. However, the decision should be made on a case-by-case basis in conjunction with the other CAG members and the HCW supervisor.
10. Complete an **event** **form** to document the management of the CAG member who has missed multiple meetings.
11. Procedures for managing a rotating CAG member who missed a clinic visit or failed to deliver medications to the rest of the group

If the rotating CAG member designated to come to clinic for clinical visit and to pick up medications for the CAG does not show up to clinic or does not deliver the medications to the group, then the lay HCW should contact the CAG leader to (1) arrange for alternate means for medication pick-up and (2) to contact the missing rotating CAG member to come to clinic.

Additionally, because ART files will be with the nurse at triage the day of a CAG member visit, if the rotating member has not arrived to the triage nurse then the triage nurse should alert the HCW supervisor and Lay HCW so that the CAG Leader can be contacted.

In addition, if the rotating CAG member does not collect the bag of drugs from the Pharm Tech, then the Pharm Tech should also alert the HCW supervisor and Lay HCW so that the CAG Leader can be contacted.

1. Managing other issues in a CAG
	1. If the CAG leader raises any concerns to the Lay HCW apart from the situations described above (e.g. disputes within the CAG or CAG members not respecting the rules of conduct) the Lay HCW will attempt to address the issue directly with the involved CAG member(s). If necessary, the Lay HCW may assemble an ad-hoc CAG meeting to resolve a group issue. The Lay HCW will fill out an **event form** detailing the event and the measures taken to address the issue. If the Lay HCW is unable to resolve the issue themselves, they will notify the HCW supervisor who will provide additional assistance in resolving the issue at hand.
	2. In the event that a CAG member has given prior notice that they will not be able to attend their clinical visit on their assigned day, the Lay HCW will arrange (via the CAG leader) for another member of the CAG to collect the drugs from the facility and will facilitate (via the HCW supervisor) rescheduling of the members’ clinic visit. The new clinic visit should be recorded in the CAG Appointment Diary.
2. Completion of the Event Form
	1. The purpose of the event form is to document all events that require CAG supervisor supervision. This may include assisting an ill CAG member, identifying CAG members who missed CAG meetings or clinic visits, assisting missing CAG members who seek to re-engage in care, assisting CAG members who no longer want to be in a CAG, and helping to resolve CAG disputes.
	2. The CAG supervisor should first indicate the date that the form was started under Today’s Date (ideally this should be the date that the CAG supervisor first learned of the event).
	3. A separate event form should be completed for each event. The same form should not be used to document multiple events.
	4. After a supervision form is completed entirely, it should be entered into the central database within one week.
3. Procedures for managing the departure of a CAG member
	1. There are several reasons why a CAG member may permanently leave a CAG. These include: patient no longer wants to be in a CAG, patient asked to leave because of CAG misconduct, transfer to another CAG or another clinic, pregnancy, death, or lost to follow-up. Lost to follow-up is defined as when a patient cannot be located > 30 days after missing a CAG meeting.
	2. On the date(s) that the departing CAG member was scheduled to pick up drugs for the group, another member will need to be identified to pick-up medications on that day. The **CAG Appointment Diary** should be updated to note that a clinic visit has been replaced with a pharmacy only visit for group drug pick-up.
	3. An **event form** should be completed to document that the CAG member is permanently departing.
	4. The last column of the **group membership register** should be completed to record the date that the CAG member departed from the group.

**CAG Leader:**

### Facilitate monthly CAG meetings within the community including facilitating agreement on time and location of the meeting and contacting CAG members as necessary

* Ensure monthly meetings occur either on the day of drug collection or the following day depending on what the group has decided upon
* Ensure completion of the CAG monthly attendance register form at each CAG meeting
* Meet with the lay HCW within 48 hours of the CAG meeting to provide them with the register form and notify the lay HCW of any ill CAG members, any CAG members who no longer wish to be in a CAG, and any CAG members who missed the meeting.
* In the event that a CAG member did not attend the CAG meeting, the CAG leader will attempt to contact the missing CAG member (either via mobile or in-person) within 48 hours of the CAG meeting. A minimum of two attempts to contact the missing CAG member should be made. If they are not able to contact the missing CAG member, they will notify the lay HCW at the time of transfer of the CAG monthly attendance register and will provide the lay HCW with any unused medications to return to the facility.
* In the event that a CAG member is identified as being ill (either at the CAG meeting or any time between monthly CAG meetings), the CAG leader will notify the lay HCW to facilitate a clinic visit (if the ill CAG member has not already contacted the lay HCW themselves). Note: All CAG members should be encouraged to contact the lay HCW directly if they are ill and need a facility visit.
* The CAG leader will attempt to help the group self-resolve any group disputes including CAG members not following the rules of conduct or disagreements between CAG members. If the CAG is unable to resolve the dispute, the CAG leader will contact the lay HCW to assist.
* Note: some of the CAG leader responsibilities may rotate or be shared amongst other group members based on the group’s preference, but the CAG leader will remain as the point of contact

**CAG Member:**

* Attendance of 2 clinical visits (roughly 6 months apart). During these clinic visits, collecting medication for all CAG members and bringing this medication back to the community for dispensation at the monthly CAG meeting.
* Attendance at all monthly CAG meetings in the community at a place/time of the CAGs’ choice for a duration of 12 months
* Familiarize themselves and abide by the CAG Code of Conduct which includes being responsible for:
	+ The safety and proper storage/transport of medications from retrieval at the facility until the CAG meeting occurs
	+ Maintaining the confidentiality of any discussions that occur within the CAG meetings as well as other members’ HIV status
	+ Actively participating in adherence discussions during monthly CAG meetings
	+ In the event that they are unable to attend the CAG meeting, informing the CAG leader so that arrangements for picking up their medications from another CAG member can be made
	+ In the event that they are unable to attend a scheduled clinic visit, informing the CAG leader so that arrangements for picking up the groups’ medications can be made
	+ In the event that they become ill, contacting the lay HCW to arrange for a clinic visit

**Pharmacy Technologist:**

* Work with HCW supervisor to understand the schedule of CAG attendance and medication needs and establish a system for medication preparation and dispensation for CAG members that aligns with clinic operations
* At least one day prior to the CAG member clinic visit, the pharmacy technologist receives the CAG group member files from the HCW supervisor and should prepare a one-month supply of ARV medications for each CAG group member.
* Write each CAG members name on the medication box so that medicine can easily be identified by each CAG member at the CAG meeting.
* Uses the pre-filled monthly attendance register (given to him/her by the CAG supervisor) to ensure that medications have been prepared for the appropriate people and place the medications and the register in the supplied bag until the arrival of the CAG member.
* Completes a pharmacy form for each CAG member and gives the supplied bag (containing the groups’ medications and the monthly attendance register) to the CAG member who is picking up medications for the group
* In the event that a CAG member did not collect medications on behalf of the CAG group on the assigned day, they should alert the HCW supervisor and/or Lay HCW so that the CAG Leader can be notified to contact the missing member and alternative medication distribution arranged

**Data Associate:**

* Enters clinic and pharmacy forms for all CAG members into the central database
* Communicates with HCW supervisor s regarding missing data and/or forms

### **ABBREVIATIONS AND ACRONYMS**

SOP *Standard Operating Procedure*

CAG *Community Adherence Group*

HCW *Health Care Worker*

HCW supervisor *Health Care Worker Supervisor*

**SOP 2.12: Ethics and Confidentiality of CAG Members**

### **PURPOSE**

This standard operating procedure (SOP) is to describe the procedure for establishing a code of ethics and confidentiality for CAG members.

**SCOPE**

This SOP applies to all CAG members at facilities where the CAG model of care is being implemented.

**MATERIALS**

Basic Code of Conduct information sheet

**RESPONSIBILITIES**

**CAG members** are responsible for understanding and abiding by the CAG code of conduct

**CAG supervisor (Lay HCW)** is responsible for explaining the CAG code of conduct and providing support in maintenance of the CAG code of conduct

**Basic CAG Code of Conduct**

The basic tenets of the CAG Code of Conduct are the following:

* I will treat all other CAG members with respect at all times
* I will maintain the confidentiality of all other CAG members’ HIV status at all times
* I will not share personal information or what has been discussed within CAG meetings to anyone outside the group
* I will carry and store drugs for other CAG members safely and I will protect the identity of other CAG members during this process
* I will try to resolve any disagreements with other CAG members with care and respect

**Procedures for Establishing a CAG Code of Conduct**

* The lay HCW will distribute the CAG Code of Conduct information sheet at the initial CAG assembly meeting
* The lay HCW will explain the basic elements of the CAG Code of Conduct and will answer any questions posed by CAG members.
* The lay HCW will then invite CAG members to suggest any additional codes of conduct that they wish to add to the basic Code of Conduct. The lay HCW will provide sufficient time for discussion and for consensus to be built among CAG members.
* The lay HCW will document any additional codes agreed upon by this particular CAG group on a copy of the information sheet. This information sheet will be retained by the HCW.
* Each CAG member will provide verbal agreement to abide by the modified CAG code of conduct.
* The lay HCW will then suggest that the code of conduct can be revisited and revised as necessary at the next two CAG meetings based on the group’s experience in the first two months. The lay HCW will bring the information sheet to these future meetings for possible revision.

**Procedures for Handling Breaches in the Code of Conduct**

In the event of a reported breach, the lay HCW will, in the first instance, call an ad-hoc meeting of all CAG members to air the complaint, establish the facts, and come to a mutual agreement on the way forward. Possible outcomes include: the event was determined to be the result of a misinterpretation or misinformation, the responsible CAG member apologizes, the responsible CAG member chooses or is requested to leave, etc.

After resolution of the event, the Lay HCW will be responsible for filling out a Supervision Form to document the event for study/program evaluation.

### **ABBREVIATIONS AND ACRONYMS**

CAG *Community Adherence Group*

HCW *Health Care Worker*

**CAG GROUP MEMBERSHIP REGISTER**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinic Name:** |  | **CAG Group Number:** |  | **CAG Supervisor Staff ID Number:** |  | **CAG Leader****Name:** |  |
| **CAG Leader****Mobile Number:** |  |
|  |
| **ART ID** | **First Name** | **Surname** | **Sex****(M/F)** | **DOB****(DD/MM/YY)** | **Mobile Number 1** | **Mobile Number 2** | **Date joined CAG****(DD/MM/YY)** | **Scheduled clinic visit 1****(DD/MM/YY)** | **Scheduled clinic visit 2****(DD/MM/YY)** | **Date permanently left CAG1****(DD/MM/YY)** |
|  |  |  |  | \_ \_ / \_ \_ /\_ \_ |  |  | \_ \_ / \_ \_ /\_ \_ | \_ \_ / \_ \_ /\_ \_ | \_ \_ / \_ \_ /\_ \_ | \_ \_ / \_ \_ /\_ \_ |
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1If patient permanently leaves CAG, fill out Event Form

**CAG MEETING ATTENDANCE REGISTER**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Clinic Name:** |  | **CAG Group Number:** |  | **Date of CAG Meeting****(DD/MM/YY):** | **\_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_**  |
| **CAG Meeting Place:** |  |
|  | **TO BE COMPLETED BY CAG SUPERVISOR** |
| **ART ID** | **First Name** | **Surname** | **Attended (Y/N)** | **Signature (Initials)** | **Pregnant (Y/N)** | **Feel ill?****(Y/N)** | ***IF YOU FEEL ILL, have you been experiencing any of the following in the last two weeks?*** | **Received meds (Y/N)** | **Signature****(Initials)** | **Referred to clinic (Y/N)****(If yes, complete event form)** |
| **Fever (Y/N)** | **Night****sweats (Y/N)** | **Weight loss (Y/N)** | **Cough (Y/N)** | **Severe headache****(Y/N)** | **Other (describe)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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CAG EVENT FORM

|  |  |
| --- | --- |
| 1. Today’s Date (D­D/MM/YY) | \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_  |
| 2. Clinic Name  |  |
| 3. CAG Supervisor Staff Name | ­­ |
| 4. CAG Group Number |  |
| 5. Date Event Reported to Lay HCW (D­D/MM/YY) | \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ |
| 6. Does this event involve only one member of the group? | ☐ Yes, Involves only one member. List ART ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_☐ No, Involves more than one member. *Go to “CAG Group Dispute” option below*  |
| 7. Indicate the EVENT of concern and the ACTION(s) taken below (REMEMBER: Only **one** event per form) |

***EVENT ACTION(s) TAKEN***

|  |  |
| --- | --- |
| ☐ CAG member ill but not hospitalized 🡪  | * Did you notify the HCW supervisor so patient can be seen in clinic? 🞏 Yes 🞏 No
 |
| ☐ CAG member hospitalized 🡪  | * Did you notify the HCW supervisor so clinic staff can be informed? 🞏 Yes 🞏 No
 |
| ☐ Rotating CAG member scheduled to pick up medicines for group did not show up for clinic visit 🡪  | * Was alternative medication pick-up for CAG group members arranged? 🞏 Yes 🞏 No
* Was the missing CAG member located? 🞏 Yes 🞏 No
* If missing CAG member was not located, did you notify the HCW supervisor so that their name can be given to clinic tracers? 🞏 Yes 🞏 No 🞏 Not applicable
 |
| ☐ Rotating CAG member picked up medicines but did not deliver medicines to the rest of the CAG group 🡪  | * Was alternative medication pick-up for CAG group members arranged? 🞏 Yes 🞏 No
* Was the missing CAG member located? 🞏 Yes 🞏 No
* If missing CAG member was not located, did you notify the HCW supervisor so that their name can be given to clinic tracers? 🞏 Yes 🞏 No 🞏 Not applicable
 |
| ☐ CAG member did not attend scheduled CAG meeting 🡪 \*Note: If multiple members did not show up to a meeting, fill out an event form for each missing member | * Did the CAG leader attempt to contact the missing CAG member? 🞏 Yes 🞏 No
* Was alternative medication pick-up for CAG member arranged? 🞏 Yes 🞏 No
* Was the missing CAG member located? 🞏 Yes 🞏 No
* If the missing CAG member was NOT located, did you notify the HCW Supervisor so that their name can be given to clinic tracers? 🞏 Yes 🞏 No 🞏 Not applicable
 |
| ☐ CAG member departing from CAG 🡪 | What is the reason for departure?🞏 No longer wants to be in a CAG (return to care at clinic)🞏 Asked to leave CAG because not following CAG rules 🞏 Transfer to another CAG🞏 Transfer to another clinic🞏 Pregnant🞏 Died 🞏 Lost to follow-up (patient cannot be located > 30 days after a missed CAG meeting or clinic visit)🞏 Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| ☐ CAG group dispute 🡪 | How was (or will) the dispute be resolved?🞏 I have/will resolve issue with individual CAG members(s) in person🞏 I have/will arrange emergency CAG meeting with entire CAG🞏 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| ☐ Other 🡪  | Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

PLEASE WRITE ANY ADDITIONAL NOTES/COMMENTS REGARDING THE EVENT ON THE BACK OF THIS FORM

***PAGE 2- BACK OF FORM***

INSTRUCTIONS FOR FILLING OUT THE CAG EVENT FORM:

1. A separate CAG event form should be filled for *each* event that has occurred
2. Begin by filling fields 1-5 with general details
3. Question 6 should only be marked “Involves more than one member” if the event was a CAG group dispute. All other events will be in relation to an individual member
4. When indicating the “Event” that took place tic only one “Event” box and answer ***ALL*** the questions relating to that Event in the “Action(s) Taken” box
5. If there are additional notes/comments write them below

NOTES/ COMMENTS:

|  |  |  |
| --- | --- | --- |
| **CAG Group 1****Neighborhood: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 | **CAG Group 2****Neighborhood: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 | **CAG Group 3****Neighborhood: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| **CAG Group 4****Neighborhood: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 | **CAG Group 5****Neighborhood: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 | **CAG Group 6****Neighborhood: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |

**CAG ASSEMBLY WORKSHEET**

 **CAG Model of Care Enrollment Form**

**Part 1: General**

|  |  |
| --- | --- |
|  |  |
|  |  |
| 3. | Date of enrollment (DD/MM/YY): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ |
| 4. | Enrolled by:  |
| 5. | Clinic Name:  |
| 6. | Patient First Name:  |
| 7. | Patient Surname: |
| 8. | ART ID:  |
| 9. | Sex (M/F):  |
| 10. | Date of Birth (DD/MM/YY): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ |
| 11. | Patient Mobile Number 1:  |
| 12. | Patient Mobile Number 2:  |

**Part 2: CAG Model**

|  |  |
| --- | --- |
| 1. | What type of enrollment is this?🞏 Patient was invited to participate by clinic staff (Go to Question 2)🞏 Patient was invited to participate by someone who is already enrolled in a CAG (Do not answer Question 2. SKIP to Question 3) |
| 2. | a. | If patient was invited by clinic staff, ask the patient*:* ***To enter this program, people with HIV need to be on ARVs for at least 6 months AND feel healthy. Do you have any friends in your community that you think meet these requirements AND whom you would like to invite to be in a CAG with you?*** 🞏 Yes 🞏 No  |
|  |  | ii. | If yes, then ask the patient: ***Can you tell me how many people you think you might invite?*** \_\_\_\_\_\_\_\_\_\_ Number of people |
| 3. | Ask the patient: ***Can you describe how to get to your house from clinic?***Please provide very detailed directions on how to reach the patient's house from the clinic **DESCRIPTION:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**MAP:** |
| 4 | Based on the patient’s description, what is the name of the neighborhood this patient lives in? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 5. | Ask the patient: ***What name do you go by in your neighborhood? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** |

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