Community-Based Antiretroviral Therapy Delivery

Implementation Guide

KHANA

July 6th, 2020

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Acknowledgements

We would like to express our sincere appreciation and gratitude to the technical team of the National Center for HIV/AIDS, Dermatology and STD, implementing partners, for their excellent technical support and guidance in the development of this implementation guide for this project.

List of Tables and Figures

Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CAD	Community-based Antiretroviral Therapy Delivery
CAW	Community Action Workers
HIV	Human Immunodeficiency Virus
IP	Implementing Partners
MMD	Multi-Month Dispensing
NCHADS	National Center for HIV/AIDS, Dermatology and STD
OI	Opportunistic Infection
PLHIV	People living with HIV
RH	Referral Hospital
SOP	Standard Operating Procedure
WHO	World Health Organization

1- Background

In Cambodia, antiretroviral therapy (ART) has been provided only at the government ART clinics. Nationally, there were 68 ART Clinics across all 25 provinces in 2019 [1]. Making a trip to an ART clinic on a monthly or bimonthly basis to receive repeated prescription poses a heavy burden on the clients in terms of both time and money. In addition, under the current scheme, the necessity for the ART clinics to meet with the demand of all of the ART clients, including the stable clients who visit bi-monthly, is a huge burden on the facilities and the service providers. Reduction in number of client visits per given timeframe is expected to help the health providers spend more time for unstable and complicated cases and improve the overall service quality. By end of 2019, 60,835 people have been diagosed with HIV and put on treatment [1] . At the facility level, multi-month dispensing (MMD) has been introduced to 20 selected populated ART clinics. This inititative aims to increase service efficiency and decrease congestion through a reduction in clinical visits and pickup appointments for stable HIV patients on ART [2].

Community-based service delivery has been an integral part of the response to HIV in other parts of the world, and Cambodia's national HIV programme acknowledges the major contribution of such approach including the proposed community-based ART delivery (CAD) model. In 2016, the World Health Organization (WHO) recommended that stable ART clients can safely reduce the frequency of clinic visits, potentially receiving ART in community setting [3]. Researches from other contexts have also suggested that communities can be engaged to provide ART with good outcomes [4]. Most CAD model have been demonstrated to reduce burdens for patients and the health systems, increase retention in care and lower service provider costs [3]. KHANA and its partners, including the National Center for HIV/AIDS, Dermatology and STD (NCHADS), believe that an adaptation of a CAD model that meaningfully includes community-based services will be essential, particularly as the national program intensifies case-finding and "Treat All" approach, to meet the national targets.

2- Objectives

This document will help operationalize and guide the implementation of the interventions. The Community Action Framework already introduced several models of differentiated care to be provided to stable people living with HIV in Cambodia, and CAD is one of the models to reduce the burden of the patients and healthcare providers. Specific objectives of this project are:

1. To develop a CAD model for Cambodia.
2. To evaluate the feasibility and effectiveness of the model and its impact on the continuum of care and treatment outcomes for people living with HIV in Cambodia.
3. To determine the cost-effectiveness of the CAD model as compared to the MMD model.
4. To document and disseminate lessons learnt to national and international stakeholders.
5. To advocate for the development of a standard operating procedure (SOP) for national scale-up.

3- Intervention Sites

Approximately 2,000 stable people living with HIV will be selected from nine ART clinics located in the capital city and four provinces selected to participate to this project. The selection of the ART sites was based on the following:

- Funding coverage under the Global Fund
- Availability of implementing partners
- Availability of data on stable people living with HIV under MMD coverage

Table 1: ART clinics in the selected project sites with names of NGOs working in the areas

Provinces/Municipality	**IP***	**ART Clinic**	**# of Estimated Stable Patients (IP database)**
Phnom Penh	AUA	Pochintong RH	226
	AUA	Meanchey RH	378

Koh Kong	CPN+	Smach Meanchey PH	586
	CPN+	Sre Ambil RH	243
Kampong Thom	CPN+	Kampong Thom PH	503
Takeo	PC	Daunkeo RH	591
	PC	Kirivong RH	336
Kampot	PC	Kampot RH	550
	PC	Kampong Trach RH	609
Total:			5,316

*Implementing partner: KHANA's sub-grantee to implement CAD model at field level

4- Process to develop the CAD Model

KHANA will coordinate with NCHADS to form a joint project team consisting of key technical staff to agree on implementation guide, monitoring tools, quality assurance checklist and lists of people living with HIV in selected ART clinics for the CAD model. All clients' data are managed by NCHADS, and the first step will be extracting the data disaggregated by gender, age and type of sub-populations including adolescents[1], trangender women and men who have sex with men from NCHADS database using the definitions introduced by WHO [5]. Once the list is completed with patient ART codes, a consultative meeting combined with the project orientation will be convened by NCHADS and KHANA with key providers from the selected ART clinics and implmenting parters at each site to divide stable patients into their groups based on the ART sites. Key partners (Catholic Relief Service, Reproductive Health Association of Cambodia, Men's Health Cambodia, and Cambodian Women for Peace and Development) of the Global Fund Funding Request for both prevention and care will be invited to the orientation and consultative meeting. Key populations[2] and adolescents living with HIV will be classified in separate groups. ART counselors at each ART site will be requested to ask people living with HIV who are pre-identified in the list whether they are willing to join the CAD model implementation study.

[1] Adolescents are defined by the stage of their physical and psychological transition from puberty to adulthood, which mostly happens when they reach their 15th birthday. CAD will ensure that the adolescents aged 15-17 years old will be provided with specific interventions to address their adolescence transition and development stage besides ART.

[2] Key Populations in this project only include Men who have Sex with Men and Transgender Women.

The frontline workers to deliver the CAD services will be PLHIV recruited from the community and they will be named Community Action Worker (CAW)[3]. The CAWs will receive intensive trainings, coaching and mentoring from the attached ART clinic and IP field staff on ARV dispensing, drug storage, and patient's vital sign assessment and recording from the corresponding ART physicians and pharmacists. Their roles and responsibilties will be closely linked with the teams supported by the Global Fund.

To closely monitor the work of the CAWs, a respective ART clinic team consisting of an ART counselor and a physian will be tasked to conduct regular supervisions with porgram team of the implementing partners to the community groups at least once a month in the first six months. The supervisions will be extended to once every two months later after the CAWs becoming familiar and performing well.

5- Definition of Stable People Living with HIV on ART

According to the definition by the WHO [6], and the SOP for Appointment-spacing and Multi-Month Dispensing (MMD) in Cambodia by NCHADS [2] , the following criteria define stable patients on ART:

1. Receiving ART for at least 1 year AND
2. No adverse drug reactions or ARV drug-drug interaction (DDI) requiring regular monitoring AND
3. No suspected or confirmed TB, no other opportunistic infection (OI), and not on any prophylaxis AND
4. Not pregnant/breastfeeding (for women)
5. Having good understanding of lifelong treatment and adherence AND
6. Presenting with evidence of treatment success: two consecutive undetectable viral load measures (or, in the absence of viral load monitoring, rising CD4 counts or CD4 counts above 200 cells/mm^3 and objective adherence measure).

[3] Community Actions Framework

6- Identification of Stable People Living with HIV and Registration

CAD project team will sit together with Database Management Unit (DMU) of NCHADS and its implementers to agree on the list of ART clinics and appoint a small team to generate patients' data based on the WHO's criteria. A list of eligible patients will be developed using a collective list of active and stable patients from IPs in each selected site by checking to confirm with the eligibility criteria of the project. The list will be returned back to IPs to discussed with physician at the ART clinic to confirm if they are eligible for including in the project. After confirmation, the list will be finalized as confirmed eligible to CAD list by keeping eligible patients who meet the inclusion criteria by definition and recommendation from their physician. The confirmed eligible to CAD list should allow the CAW to see ART code, ART site, patient's address by health center and village, their next appointment and contact information (annex 1).

The confirmed eligible to CAD list will be used as sampling frame to health center, villages and participants. Health centers with at least 25 eligible patients in catchment area of selected ART site will be purposively selected. Villages in the selected health center with the number of patients at least 10 patients will be purposively selected. Additional village will be randomly selected to add up to a total member of 25 with 30% as an alternative mount in each group. All eligible patients in the selected villages will be contacted to inform about the project and asked for their interest to join the project. A list of those patients who confirm to join the project will be consolidated as eligible to register list and further used to get inform consent (annex 2), then register into CAD project. If there is any possible rejection to join the project, the alternative villages will be used. The detail of sampling procedure is attached in annex 3.

In total, 2,000 stable people living with HIV receiving services at nine ART clinics in the selected five project sites will be registered in the project to test the model, and their participation will be consented. Each participant will be in touch by CAW to inform about the CAD project and reasons for the selection, and written informed consent will be requested from them to participate in the intervention. They will be clearly informed that they could decline the participation at anytime without any consequences on the services they receive at the clinic. Upon the agreement with a consent form signed or thumb-printed, the CAW will register them into a list of the intervention group using registration form.

6.1 Eligibility Criteria for Participants to CAD Project

An individual will be considered eligible for participating in the CAD project if they meet the following criteria:

- Clinically stable defined by the above-mentioned criteria
- Age ≥15 years
- On first line ARV regimen

6.2 Assigning and Transferring Stable Participants to Community ART Groups

The process of assigning the groups will take around one month. If the appointments of the participants do not fall within one or two months, they will be called to come earlier than the date of the appoitment. Members of each group will be assigned based on their residential villages. A group should combine members from 2-3 nearby villages. After assigning the groups, program staff of the respective implementing partners will select CAWs. CAWs should be recruited from former self-health group of people living with HIV if possible. One CAW may manage only one group. The number of each group members may vary depending on the actual number of the stable people living with HIV in the ART sites. A total of 82 community ART groups will be established.

On average, each ART clinic will have 25 community ART groups. If, for example, group 1 starts its first dispensing on May 4, 2020, the next group should start on the following day (May 05, 2020) to avoid the congestion at the attached ART clinic. All the 25 groups should run across the whole month.

To minimize the unprecedented risks, such as ARV drug losses, the dispensing within the group consisting of 25 members or more would be divided into two schedules. CAWs responsible for the groups will pick up the ARV pre-packaged drugs from the pharmacy twice a month.

6.3 Mapping the Existing Community Saving Groups

As part of the sustainability of the model, the project will also explore other existing community activities which have been up to running to intergrate with the community ART groups. One of these activities could be the saving groups owned and run by the members of the community.Each implementing partner will map out its active saving groups with a list of current members. There should be two scenarios as following:

1. Active saving groups do not exist in the villages where the CAD is implemented. If this is the case, the implementing partner field staff will provide support to initiate a saving group within the community ART groups and take the opportunity to include other community members. Regular meetings of the saving groups could be conducted on the same day when CAWs despense ARV to the members.
2. Active saving groups exist in the villages where the CAD is implemented. The implementing partners will facilitate with the saving committee to combine or add on the CAD group members who are willing to participate. In this case, the ARV dispensing would be done separately if PLHIV members have not yet disclosed their status to the whole group. However, the dislosure would also be facilitated by CAW and IP field staff if PLHIV members consent.

7- Implementing Procedure for CAWs

CAWs in the CAD model will play important roles in task shifting and contribute to the reduction of burden at the facility levels. CAWs will be recruited from different groups including women, key populations and adolescents living with HIV.

7.1 Inclusion Criteria for CAWs

1. Being a stable people living with HIV on ART for more than 2 years
2. Having good adherence with medical appointments and ART (to be evaluated by his/her ART physician or IP field staff)
3. Having completed at least primary school of formal education
4. Being a member of the community where they live
5. Showing interest and commitment to support the project
6. Having passion to work with other people living with HIV

To make sure that CAWs will be doing best of their work, the steps described in Figure 1 will be established for them to strictly follow for each dispensing:

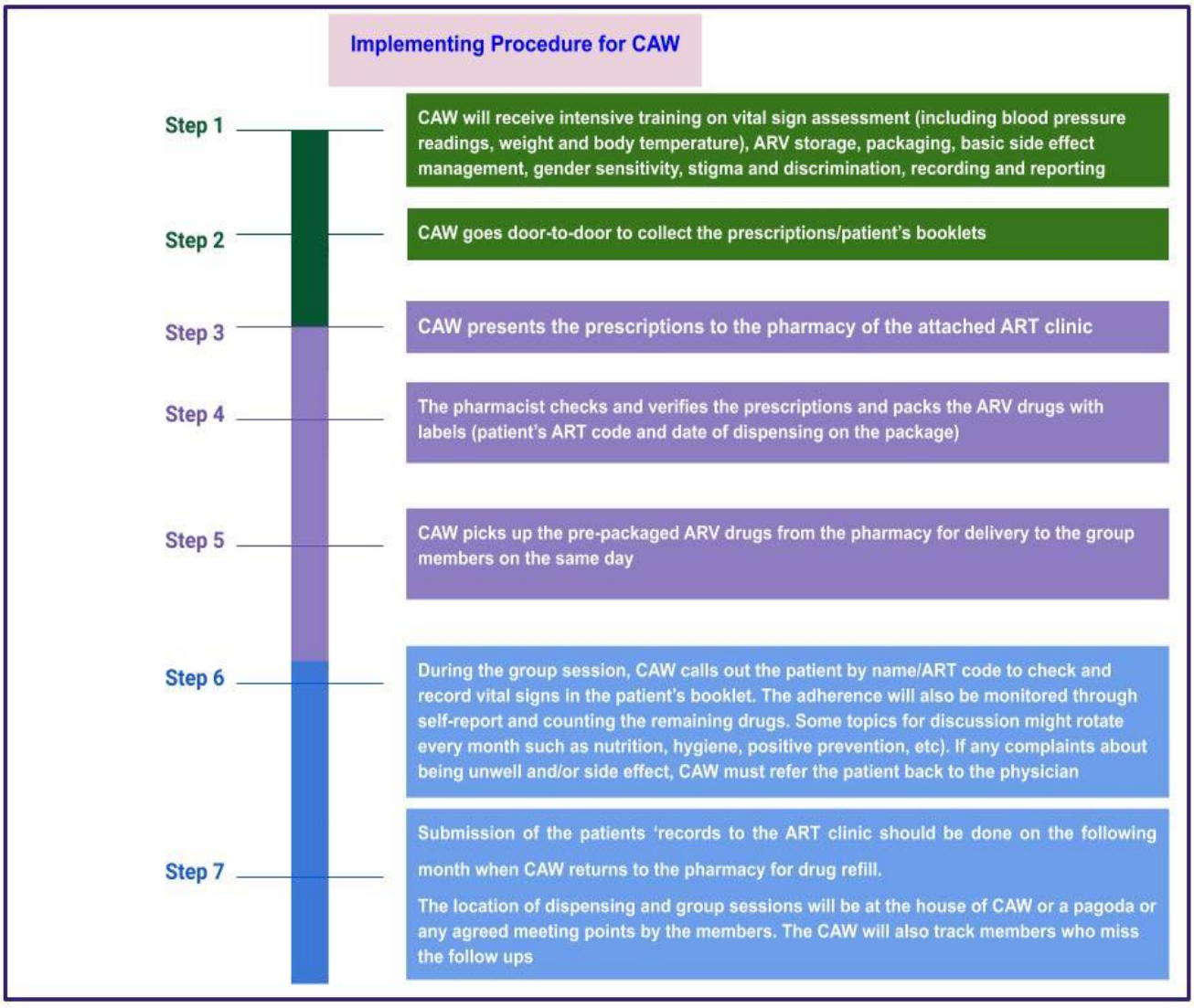


Figure 1: Implementing Procedures for Community Action Workers

The project will explore possibility of using a phone application for CAWs to alert and monitor the appointment and remind the members about the viral load testing date and adherence to ART. For the first three months of dispensing, CAWs will be accompanied by field staff of the implementing partners or a nurse from the attached ART clinic for mentoring purposes.

8- ARV Dispensing Flow and Reporting

CAWs will be the frontline people to pick up the ARV drugs from the attached ART pharmacy. They will be working closely with the ART clinic physicians to report any issues or complaints from the members and the pharmacy staff to bring the patient's ART booklet for drug monthly refill. All the pre-packaged ARV drugs from the pharmacy collected by CAWs will be dispensed on the same day to the members to mitigate all the risks related with losses, drug leakage and storage conditions. CAWs will produce monthly report of the dispensing and submit it to the pharmacy on the following month.

Figure 2: Communication Flow for CAW with service providers and patients

9- Roles and Responsibilities of NCHADS, KHANA and Implementing Partners

Table 2: Summary of roles and responsibilities of key personnel in the project

Designation	In-Charge	Functions
Joint Project Management Team	NCHADS AIDS Care Unit, KHANA Project Lead and Management of IP	• Introduce the project to the ART clinics and relevant partners • Develop trainings for CAWs • Develop monitoring tools/checklist • Conduct supervision/monitoring to sites • Check the quality of CAWs' work
KHANA	Senior Program Officer	• Monitor the project activities • Coordinate necessary support between the project management team and CAWs • Report any challenges and discuss resolutions with IP and CAWs
Attached ART Clinics	ART physicians	• Approve the lists of the stable patients • Train CAWs on how to check for vital signs and what to record in the patient's booklet, possible side effects and how to manage minor side effects, and when to refer the patients • Write prescriptions for 3 - 6 months (plus buffer)

	Pharmacy staff	• Train CAWs on how to read the pre-packaged ARV drugs and drug storage during delivery, what information to be recorded after dispensing • Prepare monthly pre-packaged ARV drugs to be collected by CAWs
Implementing Partners	Field Staff/Project Assistant	• Support CAWs to integrate saving • Check and verify reports/records from CAWs before submitting to the ART clinic • Monitor the work of CAWs • Create a list of viral load test dates to support CAWs
	Community Action Workers (CAWs)	• Check for patient's vital signs (blood pressure reading, body temperature, BMI etc) • Dispense monthly pre-packaged ARV drugs • Follow up missed appointments • Organize monthly meeting among community ART group member • Refer patients to the nearby health facility or designated ART clinic if they report not well. • Follow up the missed appointments at home. • Complete patient's registers to be submiited to the ART clinic on a monthly basis.

		• Remind the group members of their next medical appointment and viral load testing.

10- Quality Assurance

KHANA and implementing partners will put in place the monitoring activities to ensure that quality assurance associated with this pilot is consistent with recognized best practices. The following actions will be taken:

1. Prior to the start of the dispensing activities, CAWs will be trained by ART clinic physicians and pharmacy team on the storage of the ARV drugs during delivery, the dispensing process, the vital sign checking and reporting.
2. Field staff of the implementing partners will be present at the community ART group meetings to ensure compliance with the established standard implementing procedure.
3. The ART pharmacy staff and/or counselors will join with the field staff of the implementing partners at least once per six months to supervise and provide corrective measures to the CAWs at the selected dispensing sites.
4. KHANA staff will perform regular spot checks on the work of CAWs and field staff of the implementing partners to ensure that the delivery approach will be performed correctly, in collaboration with NCHADS and the attached ART clinics. The corrective measures will be provided onsite after each monitoring visit.

11- Monitoring and Reporting

- Develop health registers and dispensing recording forms for CAW
- Supply health tracking materials (scale, height tap, thermometer) for CAW
- Create a quality assurance checklist to monitor the performance of the CAWs
- Conduct regular joint monitoring visits to the sites by NCHADS, KHANA and implementing partners every 2 months

Implementation Timeline

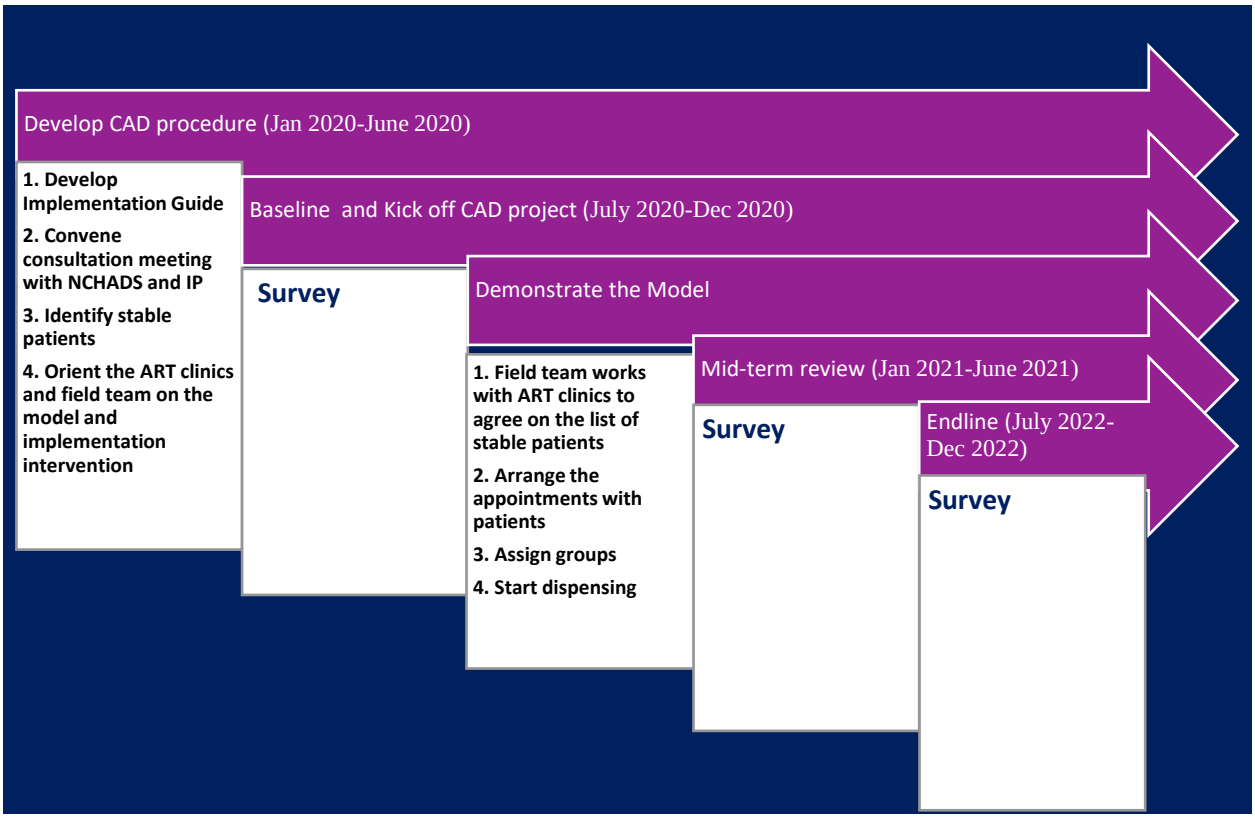


Figure 3: Summary Timeline for project overall project implementation

Reference:

[1] NCHADS, “Summary Quarterly report on HIV-AIDS and HCV-HIV Co-infection.pdf.” Phnom Penh, 2019.

[2] NCHADS, “Standard Operating Procedure on Appointment-spacing and Multi-Month Dispensing (MMD) in Cambodia.” Phnom Penh, 2020.

[3] Medecins sans Frontieres and UNAIDS, “Community-Based Anti Retroviral Therapy Delivery,” pp. 1–17, 2015.

[4] M. Bemelmans *et al.*, “Community-supported models of care for people on HIV treatment in sub-Saharan Africa,” *Trop. Med. Int. Heal.*, vol. 19, no. 8, pp. 968–977, Aug. 2014, doi: 10.1111/tmi.12332.

[5] World Health Organization, “The use of anti retro-viral drugs for treatment and prevention of HIV infection,” no. June, pp. 176–180, 2013, [Online]. Available: https://www.who.int/hiv/pub/guidelines/arv2013/intro/keyterms/en/.

[6] M. V. and N. F. Greer Waldrop, Meg Doherty, “Stable patients and patients with advanced disease: consensus definitions to support sustained scale up of antiretroviral therapy,” *Trop. Med. Int. Heal.*, 2016.

Annexes

Annex 1. Patient's Data Template to be generated from the database

ART Clinic	Health Center	Village	ART Code	Gender	Appointment Type	Next Appointment	Phone Contact

Annex 2. Informed Consent Form

Hello, my name: …… I am ……. Let me brief you about the project and the reasons for selecting you to join this project. KHANA and its implementing partners (IPs) namely AUA, PC and CPN+ in collaboration with NCHADS and ART clinics agreed to demonstrate a pilot project in your community focusing on improving treatment adherence, retention in care and engaging more with stable people living with HIV on ART. If you agree to participate to this project, you will receive your monthly ARV drugs from your group leader called CAW at a nearby community pick-up point. By doing this, we aim to cut down your cost and time to travel to an ART clinic and reduce the workload of health providers at the clinic. This model will also maximize the adherence to and retention in ART and keep engaging you with other community members.

With your agreement, our team will register you into our project, and your medical appointments will be rescheduled to six months, but still you can visit the ART clinic anytime you need. You will receive your monthly ARV drugs and additional education/basic health check-ups from your group leader at a pick-up point close to your home.

Participation in this pilot project is completely voluntary. It is your choice to not participate in any or all parts of this project. Choosing not to participate in this project will not affect your eligibility to access any public health services or future programs. If you chose to participate, you consent to your personal information, including test results, being shared with the government health system and KHANA. Aggregated, non-identifying data from this pilot may be published or shared in the form of public reports, scholarly publications or any other media.

If you have any questions about any aspect of this project, please ask any representative of KHANA and an implementing partner before giving your consent for participation. Any complaints or issues you encounter during your participation; you are strongly encouraged to report to this contact at….

Signature or Thumbprint
Name:

Annex 3: Sampling Procedure for CAD

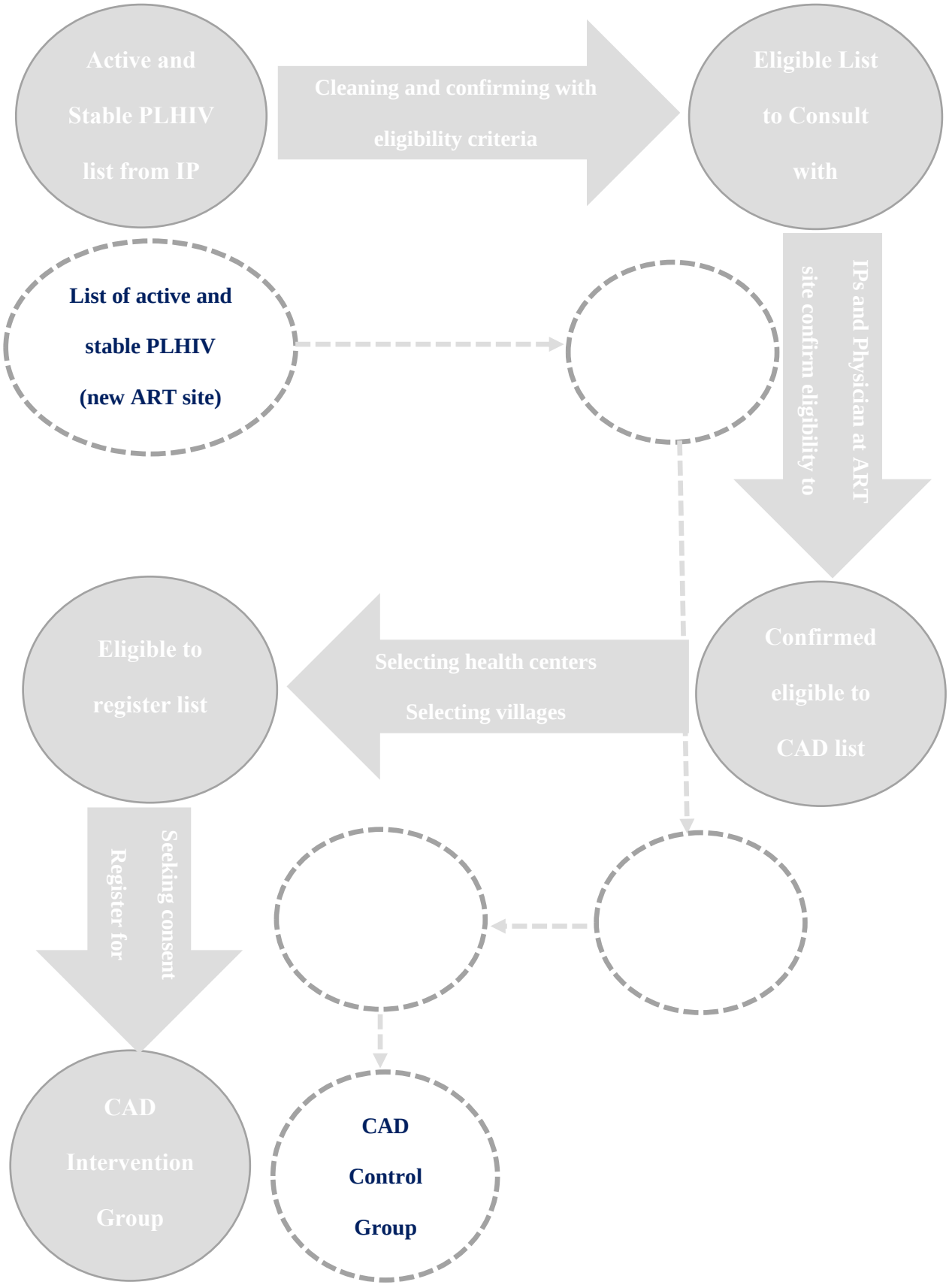
CAD project team will sit together with Database Management Unit (DMU) of NCHADS and its implementers to agree on the list of ART clinics and appoint a small team to generate patients' data based on the WHO's criteria. A list of eligible patients will be developed using a collective list of active and stable patients from IPs in each selected site by checking to confirm with the eligibility criteria of the project. The list will be returned back to IPs to discussed with physician at the ART clinic to confirm if they are eligible for including in the project. After confirmation, the list will be finalized as confirmed eligible to CAD list by keeping eligible patients who meet the inclusion criteria by definition and recommendation from their physician. The confirmed eligible to CAD list should allow the CAW to see ART code, ART site, patient's address by health center and village, their next appointment and contact information (annex 1).

The confirmed eligible to CAD list will be used as sampling frame to recruit CAD study participant as following procedure:

1- Selecting health center: health centers with at least 25 eligible patients in catchment area of selected ART site will be purposively selected. The health center with number of patients less than 25 will be drop from the list.

2- Selecting village of patient's residence: villages in the selected health center with at least 10 patients will be purposively selected. One or two more villages with number of patients less than 10 in the selected health center will randomly selected using simple random sampling approach (random number in android app) to add up to a total number of patients to 25 in each group from. The remaining number in the selected village will be calculated as at least 30% of total required number for an alternative.

3- Selecting study participant: all eligible patients in the selected villages will be contacted to inform about the project and asked for their interest to join the project. A list of those patients who confirm to join the project will be consolidated as eligible to register list and further used to get inform consent, then register into CAD project. If there is any possible rejection to join the project, the alternative villages will be used. All registered patients will be listed as CAD intervention group. Recruitment of control group will be following the same procedure after agreed on identifying ART site with NCHADS.


Active and Stable PLHIV list from IP
Cleaning and confirming with eligibility criteria
Eligible List to Consult with
List of active and stable PLHIV (new ART site)
IPs and Physician at ART site confirm eligibility to
Eligible to register list
Selecting health centers
Selecting villages
Confirmed eligible to CAD list
Seeking consent Register for
CAD Intervention Group
CAD Control Group