Implementation Guide for Community Based Differentiated ART Service Delivery Models in Ethiopia

List of Abbreviations

AARHB   Addis Ababa Regional Health Bureau

AIDS   Acquired Immunodeficiency Syndrome

ARV   Antiretroviral drugs

ART   Antiretroviral therapy

CAGs   Community ART Refill Groups

CEF   Community Engagement Facilitator

DSD   Differentiated Service Delivery

DSDM   Differentiated service delivery model

FMOH   Federal Ministry of Health

HEP   Health Extension Professionals

HIV   Human Immunodeficiency Virus

HSTP   Ethiopian Heath Sector Transformation Plan

PLHIV   People living with HIV

RHB   Regional health bureau

U/HEP   Urban/health extension program

UHEP   Urban health extension professional

UHEP-CAG   Urban health extension-managed community ART refill group

UNAIDS   United Nations Program on HIV/AIDS

VSLA   Village saving and loan associations

WHO   World Health Organization

Table of Contents

1. Introduction

World Health Organization (WHO) is promoting the use of community based ART in a global strategy to end HIV by 2030. The community based ART approach is overwhelmingly supported because it seems to be the only viable strategy for delivering HIV treatment services closer to the people and improving ART uptake, retention in care and decongesting overburdened public health facilities. In sub-Saharan Africa, the community based ART is being promoted as the key for treating the over 20 million people living with HIV (PLWHA). The last decade particularly witnessed a progressive shift from hospital-based ART to primary health centers and more recently to the community. In effect, the community-based approach to treating HIV has always been in the background but was not well publicized. Especially in the current situation of COVID 19 pandemic, the frequency of health facility visits need to be minimized and it is advisable to maintain most of the services at community level.

COVID-19 poses a significant risk to countries with fragile health systems and disease surveillance capabilities. Individuals living with HIV, especially those with co-morbid conditions and/or advanced HIV disease may be at greater risk for COVID-19 related complications. Prevention and rapid containment of COVID-19 is a priority in order to reduce the impact on the provision of needed services to people living with HIV. It is important to have plans and guidance to ensure the continuity of care of individuals living with HIV in the face of additional demands arising from COVID-19 screening and treatment. To contain and mitigate the spread of COVID-19 in communities affected by HIV, Programs should promote policies and procedures that properly triage, and isolate patients seeking care for acute respiratory illness and minimize exposure of both ART clients and staff to patients with COVID-19.

Strengthening community-based services for HIV treatment to deliver ART at community sites is among the recommended strategies to ensure continuity of care and containment of COVID 19. In the upcoming months, the risk and burden of COVID 19 is supposed to increase. This will have a greater impact on retention of all PLHIVs in care. Hence, considering implementation of community based refill models will have a paramount importance.

Benefits of Community Based HIV Care and Treatment Models:

- It provides an opportunity to offer ART to clients who prefer to receive their care and treatment in the community for various reasons
- Fewer and focused visits to the health facility for clinical evaluation and laboratory monitoring in between the community based services
- Minimizes transportation costs and the time spent at health facilities
- Increased client satisfaction and empowerment

- Reduce the risk of COVID 19 infection

2. Purpose of the guideline

The purpose of this document is to guide the implementation of Community Based Differentiated ART Service Delivery Models.

3. Objectives of the guideline

1. Improve quality of HIV care and treatment services
2. Improve health system efficiencies and outcomes
3. Enhance the achievement of the 95-95-95 targets
4. Minimize the impact of COVID 19 on PLHIV

4. Target Audiences of the Implementation guide

This implementation guide targets all stakeholders who participate in the implementation of the health extension professional-managed community ART refill (HEP-CAG) and peer lead community ART distribution (PCAD) models of HIV service delivery. Particularly, its target audiences are the following:

- Health care professionals providing care to people infected and affected with HIV.
- HIV program managers at the various levels.
- Health extension supervisors and program managers.
- Health extension professionals.
- Organizations involved in HIV care/ART service delivery.
- Community based organizations working on the provision of HIV services in the regions.
- Associations of people living with HIV.
- National and regional networks of associations of people living with HIV.
- Partner organizations.

5. Overview of Differentiated Service Delivery (DSD)

5.1 The Core Principles and Building Blocks of DSD

5.1.1 The Core Principles

a) Client-centered care

The core principle for differentiating care is to provide ART delivery in a way that acknowledges specific barriers identified by clients and empowers them to manage their disease with the support of the health system. WHO highlights the need for client-centered care to improve the quality of HIV care services.

b) Health system efficiency

With the population of PLHIV having increasingly diverse needs, it is acknowledged that health systems will have to adapt away from a "one-size-fits-all" approach. DSD supports shifting resources to clients who are the most in need by supporting stable clients to have fewer and less intense interactions with the health system.

5.1.2 The Building Blocks

The building blocks of DSD center on four questions: (1) When, (2) Where, (3) Who and (4) What. The building blocks are the key components of building a differentiated model of service delivery (Figure 1). In all models of service delivery, the client is at the center. It is up to the Ministry of Health (MoH) and stakeholders to work with health care workers and clients to determine which of the **WHEN** (service frequency), **WHERE** (service location), **WHO** (Service provider) and **WHAT** (Type of service) blocks to consider in the model that they select to implement. The stakeholders must balance the goal of improving client outcomes with their ability to utilize the available health system resources.
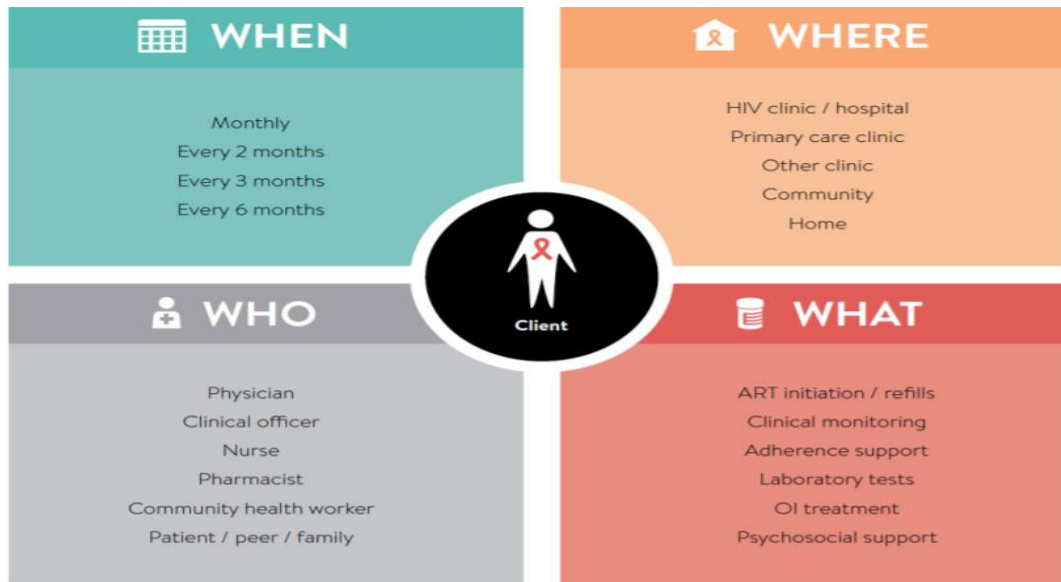
Figure 1: The DSDM building blocks

5.2 The Elements to Consider in Differentiated Care

In order to provide client-centered care, there is a need to consider the following:

- The clinical characteristics of the client (stable, unstable or complex)
- The specific populations (e.g., adults, children and adolescents, pregnant and breastfeeding women, key populations, men)
- The context (e.g., urban/rural, unstable context, epidemic type.)

This will allow building appropriate models of HIV Testing and Screening and HIV Care and Treatment using the building blocks described in the previous section. The elements are presented in figure below.
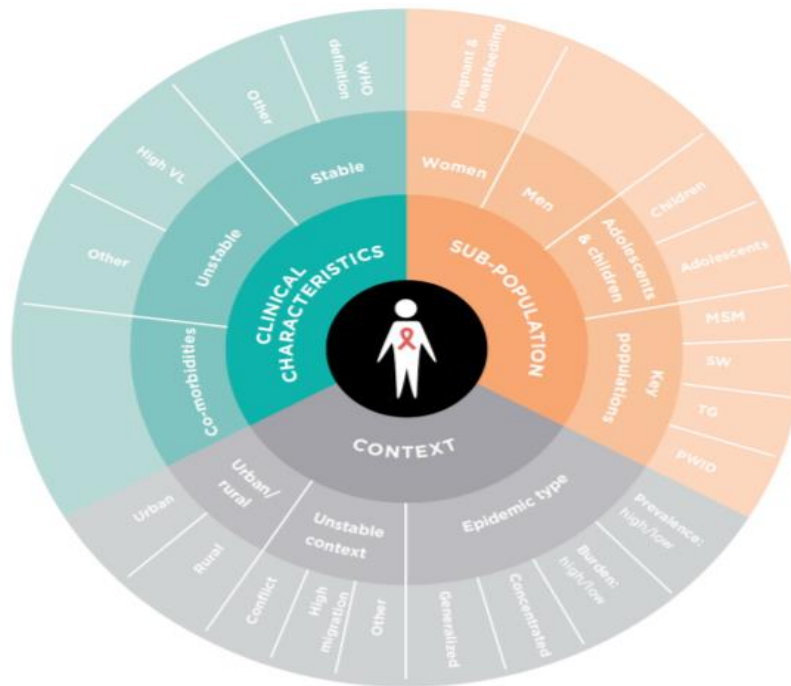
Figure 2: The three elements

6. Differentiated HIV Care and Treatment

6.1 Definition

Differentiated HIV Care and Treatment refers to a strategic mix of approaches to address the specific requirements of a subgroup of clients living with HIV. It includes approaches aimed at modifications of client flow, schedules and location of HIV Care and Treatment services for improved access, coverage, and quality of care.

6.2 Rationale for Differentiated HIV Care and Treatment

The current service delivery models in most health facilities in Ethiopia are characterized by:

- Overcrowding of clients during week days
- Delays in service delivery
- Heavy work load due to monthly refills, poor appointment management, etc.
- Repetitive and unnecessary clinic visits (to stable clients)
- Unnecessary mixing of clients and services e.g. adolescents and adults; unstable and stable patients
- Untailored health education due to the mix of clients
- Poor quality of care (documentation gaps, low client satisfaction, low commitment and motivation of HCWs, etc.)

Majority of the clients are stable and now need HIV care and treatment services tailored to their needs. This will result the following client-focused and health system benefits:

- Reduce pressure for medication refills at the health facility.
- Optimize staff workload hence increase service delivery cost-efficiency.
- Reduce the frequency/burden of travels to facilities hence provide clients more opportunities to engage in other activities (e.g. house hold activities, Income generating activities, etc.).
- Provide opportunities for tailored counselling and health education.
- Improve client care and treatment outcomes.
- Minimize the risk of exposure to COVID 19 through:
    - Empowering patients to take more responsibility to manage their own health.
    - Encouraging peer-to-peer support.

Table 1: Unique needs and potential solutions through DSD based on clinical characteristics

System focus	Benefit
Client focused benefits	- Reduced number of visits for stable clients leading to reduced costs - Empowerment and involvement/rights – clients will be able to better manage their own care - Reduced waiting time leading to client satisfaction - Increased access and adherence (for community delivery) - Increased/improved linkage to supportive services (e.g. gender based violence (GBV), nutrition support, psychosocial support e.g. peer support groups - PSGs) - Promotes GIPA (greater involvement of people living with HIV) e.g. expert clients or peer leaders
Systems benefits	**Human Resource** - Anticipated to improve health workers' attitudes through training, reduced workload through task-shifting/sharing hence spreading the burden to many health workers. - Targets skill to those that are in more need **Governance/leadership** - There will be an opportunity to engage leadership at the Region/Zone/woreda/Sub city and health facility levels to lead and coordinate; advocate for; and conduct social mobilization for DSD implementation **Service Delivery** - Increased coverage - Improved quality of services - Facilitate the 95-95-95 target achievement **Medicines/logistics systems** - Improved supply chain management **Financial management** - Improved efficiency – achieving program goals at lower costs **HMIS** - Less data for a clinic per day/encounter - Improved quality of data

7. Adopted Community-Based Differentiated HIV Care and Treatment Models in Ethiopia

The 2016 WHO consolidated guidelines identified four group of PLHIVs: people who present when well, people presenting to care with advanced disease, unstable patients who are on ART but need careful monitoring to ensure timely action as required, and people who are on ART and stable. The last group is likely to represent most people on ART and they can safely reduce the frequency of clinic visits, potentially receiving ART in community settings. Differentiating between the service needs of these groups of patients and determining where and how to deliver those needs are key to maximizing treatment outcomes and efficiencies. Cognizant of this fact, community-based models of ART were suggested and piloted in several settings.

Ethiopia has adopted various differentiated service delivery models since end of 2016. Appointment spacing is being implemented in full scale, healthcare worker managed (UHEP) community-based ART refill model has been piloted in Addis Ababa and Gambella since end of 2018 and Fast track ART refill model is being introduced. This guidance will address the scale up implementation of two community based ART refill models, the health extension professional managed community ART refill model (UHEP/HEP_CAG) and the peer lead community based ART distribution model (PCAD).
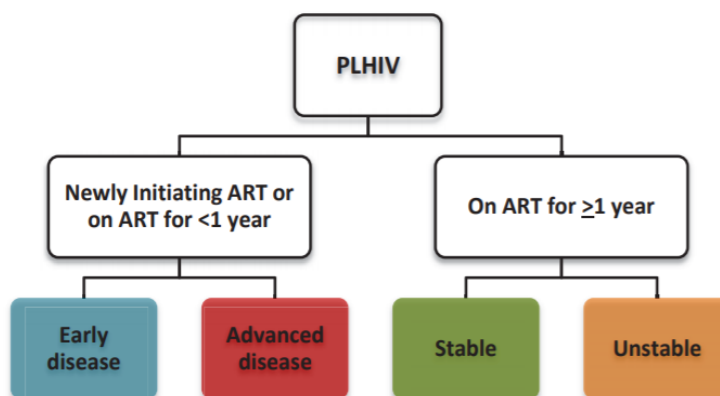
Fig. 3. Patient Classification for Differentiated Care

Eligibility criteria for community based differentiated ART refill or distributions

The eligibility criteria are developed based on WHO's definition of stable individuals. WHO defines stable patients as "as those who have received ART for at least one year and have no adverse drug reactions that require regular monitoring, no current illnesses or pregnancy, are not currently breastfeeding, have good understanding of lifelong adherence and evidence of treatment success (i.e. two consecutive viral load

measurements below 1000 copies/mL). In the absence of viral load monitoring, rising CD4 cell counts or CD4 counts above 200 cells/mm3, an objective adherence measure, can be used to indicate treatment success."

Thus, the following group of PLHIV are eligible for inclusion to the community ART refill or distribution models:

- Is greater than 18 years of age;

- Provided consent to participate in the UHEP-CAG or PCAD;

- Have received ART for at least one year and have no adverse drug reactions that require regular monitoring;

- Is still on first line regimen;

- Have no current illnesses or pregnancy and are not currently breastfeeding;

- Have good understanding of lifelong adherence; and

- Have evidence of treatment success (Current viral load measurement (with in the last 12 months) below 1000 copies/mL). ALTERNATIVELY, rising CD4 cell counts or CD4 counts above 200 cells/mm3 (in the absence of viral load determination).

The following groups of patients are excluded from participating in this model of care:

- Pregnant and lactating mothers;

- Adolescents and children below 18years;

- Clients that are not yet stable; or

Note: The above criteria does not consider the current COVID 19 pandemic. In the context of COVID 19, it is recommended to be more flexible and the criteria need to be inclusive enough to accommodate unstable clients. See the details below in the CVID 19 context implementation sections.
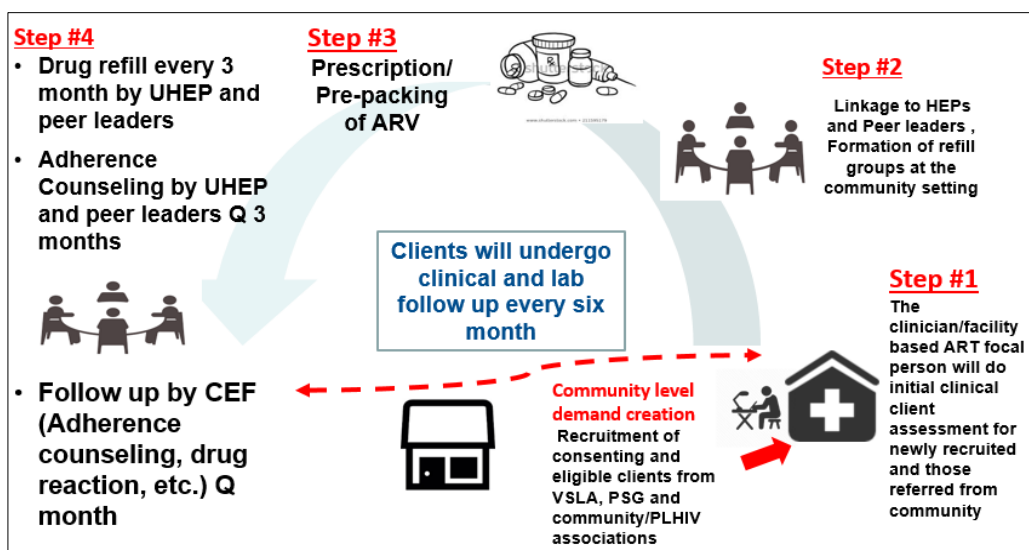
Fig.4. Community Based differentiated HIV Care and Treatment Service Cascade

7.1 Health Extension Professional Managed Community ART refill group (HEP_CAG)

HEP_CAG was piloted in Addis Ababa (at selected 32 high load facilities and in Gamballa (at seven health facilities) using urban health extension professionals (UHEP). This model utilizes health extension professionals (HEPs) who already have roles in HIV testing and other HIV service provision as one of their packages. Community ART refill groups (CAGs) are self-forming groups comprising of stable clients on ART living in the same community/locality that have a shared understanding. Each group will comprise six to ten individual members. The CAG members share experiences about living positively with HIV, and are empowered to offer and receive peer psychosocial support and follow-up. The group members, in collaboration with healthcare workers, select a Team Leader to coordinate communication between group members and the health extension professional. The ART refill is for three months and each CAG will have one community refill in between the heath facility visits that will happen every six months. Clients can return or referred to the facility at any point in the cycle for any issues that may arise between scheduled health facility visits.

Table. 2. Building Blocks of the HEP_CAG Model

Building block	ART refill	Clinical consultation
When	3 months	6 months
Where	Community	ART facility
who	UHEP/HEP	Clinician
what	ART refill and adherence support	Clinical and laborartory follow up
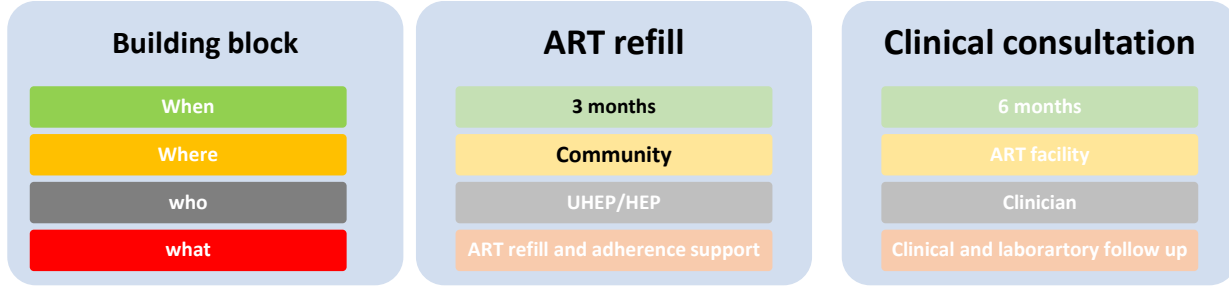
7.1.1 Summary of the HEP_CAG service delivery Cascade

7.1.1.1 HEP_CAG Group Size

It is recommended that the HEP_CAG groups will comprise of 6 – 10 individual members. This is just for mapping of clients living in same localities but the service provision will be individually or through home-to-home delivery depending on the individual client preferences until the COVID 19 pandemic ends. The refill will be changed to group based refill after the COVID 19 pandemic ends.

7.1.1.2 *Organizing for HEP_CAG service delivery*

Health facilities:

- HF based ART service providers will educate and counsel all clients on ART during the clients' regular follow-up visits or telephone consultation & obtain consent from clients for community based refilling at residential areas or home.
- Mapping and recruitment of clients for the community-based refill will base on their location or residential areas.
- HF based service providers will support those clients who gave consent to be included in the community based refill service and prepare a list of clients that are living in the same locality or register to the community based ART refill register.
- Adjust their appointment date by considering the available stock of ARVs at each client's hands and making same day refilling arrangements at their preferred community site.
- The members will select their team leader who is responsible for leading and representing the team and identifying and addressing challenges in consultation with the HEP.
- Communicate the list to the designated service provider to conduct the community-based refill (HEPs or CEFs).

ART pharmacy:

- Receive the list of identified clients for community based refill from the ART clinic.
- Pre packing of ARV and other OI drugs (if any) by ART pharmacy prior to the refill appointment date.
- Provide the pre-packed or pre labeled medication for HEPs or pears representing the groups.
- Updating of pharmacy based refill registers.

Community level:

- HEP/CEF will remind clients prior to the ART refill date.
- The service provider who is responsible to do the community-based refill will appoint clients with in a few minutes interval and refill individually or distribute their medication to their home depending on their preferences.
- Conduct brief assessment of adherence and screen for common OIs.
- Refer or advise clients with identified clinical conditions or significant adherence barriers.
- Follow and arrange a refill time and date for those who will not be reached at the appointment date or who missed the refill for various reasons.
- Document the refill status of each clients on the refill register.

7.2   Peer lead community based ART distribution (PCAD)

The peer lead Community based ART distribution (PCAD) groups are self-forming groups of PLHIV comprising of stable clients living in the same community/locality. In PCAD, group members will take turns to pick up ARVs at the health facility and distribute among the other group members in the community. Each client will get clinical evaluation and lab monitoring service as per the national guideline. They will manage their own health and take action with the support of community and facility based healthcare workers. The PCAD group members share experiences about living positive with HIV, and are empowered to offer and receive peer psychosocial support and follow-up. The group members, in collaboration with healthcare workers, will select a team leader to coordinate communication between group members and the healthcare workers and to provide ongoing adherence assessment and support at community level. The peer leader will be oriented to enable them conduct adherence assessment and monitoring of other events among group members. Clients will be also well informed and can return or be referred to the health facility at any point in the cycle for any issues that may arise between scheduled

health facility visits. The healthcare providers at each health facility will identify clients living in same locality and will link to the peer leaders or other community based service providers that are supporting the model. Each PCAD will have six individual members on average. This will help to align with the clinical consultation visits at health facilities as the recommended clinical consultation visit in our set up is every six months. The mapping and enrollment of individual clients into PCAD model will be, as groups of PLHIVs living in the same locality but the refill will be done individually and all the necessary precaution need to be taken until the risk of COVID 19 pandemic ends in the country. The group members will select a date and will meet every three months to discuss and share their experiences. While conducting the discussion, all the necessary precaution need to be taken to prevent COVID 19. However, after the COVID 19 pandemic ends, the service will continue as community based peer lead group refill or distribution model.

Table. 3. Building Blocks of the PCAD Model

Building block	ART refill	Clinical consultation
When	3 months	6 months
Where	Community	ART facility
who	Peer/PLHIV	Clinician
what	ART refill and adherence support	Clinical and laborartory follow up
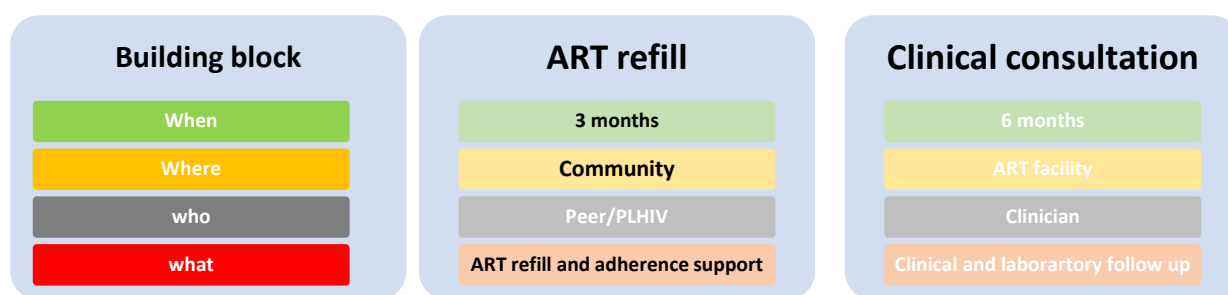
7.2.1 Summary of the PCAD service delivery Cascade
7.2.1.1 *PCAD Group Size*

It is recommended that the PCAD groups comprise of 6 individual members on average but it is possible to include more members depending of specific contexts. However, the group size better not exceed 12, if in case there is a need to include more than six members.

7.2.1.2 *Organizing for PCAD*

Health Facility:

1. Orientation of healthcare workers on the PCAD approach
2. Healthcare workers will conduct the following activities:

   - Identify and map clients by their locations
   - Educate, counsel and sensitize clients about PCAD
   - Register consented clients for PCAD on the community based DSD register
   - Oversee completeness of tools

- Train, monitor, supervise and follow up with PCAD Group Leaders
- Ensure implementation and quality assurance of the groups' functionality and operations
- Coordinate the preparation for clinic visits for patients in PCAD e.g. retrieval of files, prepacking medicines, ensure availability of PCAD monitoring forms etc.

3. Stable clients will be listed in accordance to their locations, preferably villages.

4. Sensitize all stable clients, one-on-one or as a group, explaining the implications and benefits of joining a PCAD group.

5. Encourage stable clients to form groups on their own to foster ownership and belonging. These groups should be formed guided by;
   - Locality of proposed group members
   - Ability to read and write for at least one of the proposed group members
   - Group size i.e. 6 members on average per group

6. Assess each client's readiness to join a group. In this assessment process, the following questions can be asked:
   a. Have you disclosed to anyone? If yes, to who? If not, why not?
   b. Would you like to know other clients who would like to form a group in your community?
   c. Are you willing to be known by them?
   d. Would you like to consent to join a group? If all answers are "Yes" then the client will be included in the group. If "No" to any question, the health worker should support the client accordingly.

7. Orient the newly formed groups on the approach about their roles and responsibilities (the do's and don'ts of the group).

8. Support the group to develop a visit plan that ensures all members attend health facility visits at six months' intervals for comprehensive clinical evaluations and every twelve months for VL monitoring.

9. Support the group to develop a drug refill schedule and appoint individual members to pick the drugs from the health facility every three months on rotation bases.

10. At three months' intervals, drug refills will be given to each individual during group drug refill meetings or individual distribution at a chosen community site of clients home.

11. Communicate the group appointment dates to the members and record in the facility PCAD register.

12. VL monitoring will be done for all group members during the comprehensive clinical evaluation visits. The group members' VL monitoring visits should be harmonized to ensure that it is aligned with the health facility visits for comprehensive clinical evaluation.

13. Support the PCAD group members to select a peer leader to undergo additional training (e.g. TB screening, other OI identification and referral, nutritional and adherence assessment, etc.). The leader must have basic reading/writing skills.

14. Assign each group a unique identifier (PCAD Group ID).

15. Record all patients joining PCAD in the appropriate registers and update registers to track the events for each client over time.

16. Document the clinical evaluation visits for each individual on the appointment card.

ART pharmacy:

- Receive the list of identified clients for community-based refill from the ART clinic.
- Pre packing or labeling of ARV and other OI drugs (If any) by ART pharmacy prior to the refill appointment date.
- Provide the pre-packed or pre labeled medication for HEPs or pears representing the groups.
- Updating of pharmacy based refill registers.

Community Level

1. Peer leaders will conduct an introductory meeting at community level with all the necessary precaution to prevent COVID 19.

2. Group members will agree on the location and method (individual, home-to-home or as small group) of the refill service. The group members will agree on the method of refill (individual, ho-t0home or small COVID 19 risk free size). Health posts, PLHIV association offices, youth centers, Idir offices, individual member's home etc. can be considered as a refill site.

3. Agree and develop a drug refill schedule and appoint individual members to pick the drugs from the health facility every three months on rotation bases.

4. Develop a visit plan that ensures all members attend health facility visits at six months' intervals for comprehensive clinical evaluations and every twelve months for VL monitoring.

5. The refill will happen individually at a specific location or can be distributed to individual home by the individual member who picked the medications from the HF or by the peer leader depending on their consensus or preference.

6. Group members will agree on the mode of facilitation for the group members that will be selected to pick drugs on behalf of the group in a given month, e.g. group contributions or from their savings (if any).

7. Group members will be encouraged to meet monthly to promote bonding, provide psychosocial support to each other and also conduct their other group activities e.g. Income generating activities, loans and saving activities.

8. The community level adherence assessment will be conducted during the drug pick-up meeting or individual refill or home delivery and the findings will be documented on the PCAD monitoring form.

8. The Health Extension Program, Health Extension Professionals, and the Family Health Team

With the goal of making basic primary health care services accessible to the rural community, the Ethiopian government launched the health extension program (HEP) in the agrarian areas beginning in 2003. Based on lessons from the successful implementation of the agrarian health extension program, the HEP has expanded to urban and pastoral areas. The HEP is intended to transfer ownership and responsibility of maintaining health to individual households so that communities are empowered to produce their own health. The focus of HEP is disease prevention and health promotion, with limited curative care. It is the healthcare service delivery mechanism of the people, by the people, and for the people by involving the community in the whole process of healthcare delivery and by encouraging them to maintain their own health. The program involves women in decision-making processes and promotes community ownership, empowerment, autonomy and self-reliance.

The Government of Ethiopia has initiated the Urban Health Extension Program (HEP) in 2009 to expand the coverage of community-level health services to the Urban population. The Health Extension Program is expected to provide different service packages. These services are grouped into four main themes: hygiene and environmental sanitation, family health care, prevention and control of communicable and non-communicable diseases, and injury prevention, first aid, referral and linkages. The entire modality of Health Extension Program will focus on preventive, promotive, and rehabilitative services targeting households, youth centers and the schools.

The Health Extension Professionals (HEPs) are trained female nurses who have undertaken extensive training on the principles of the health extension program and the related packages. They already have roles in HIV testing and service provision. The revised health extension implementation guidelines clearly outline the roles and responsibilities of HEPs in HIV. Providing general education on HIV, HIV testing and counseling for targeted population groups, providing appropriate referral and linkage to ART services, adherence counseling and support, referral and linkage to different psychosocial support services, and STI

screening are some of the roles that outlined in the implementation guideline. They are already trained in those areas and, thus, HEPs can manage the CAGs with minimal training.

The family health team (FHT) is a model designed to address the complex health needs in urban settings. Each team have two sub-teams: one that goes to the community and another one that stays at the health center to provide service to the community members referred to the health center by the other team. A family health team is composed of both clinical and public health professionals. Each team is supposed to be composed of two physicians/health officers/BSc nurses, two diploma nurses, four to five urban health extension professionals and a team of other professionals (mental health nurses, environmental health specialists, and social professionals) which are supposed to be utilized by the respective teams in the center. The family health team participate in the prevention and control of common communicable diseases, including HIV, sexually transmitted diseases, tuberculosis, and hepatitis both at the health facility level and the community.

9. Rationale of Community ART Refill/ Distribution in the Context of COVID-19

As per the FMOH COVID-19 management guide, the following major points were stated;

➢ Health service Providers should use the necessary Personal Protective Equipment (PPE) e.g. gloves and facemasks. If a Client is suspected of having COVID-19, a gown and goggle should be used in addition to gloves and medical facemask (where feasible).

➢ Maintain infection prevention standards in the ART by sanitizing all surfaces e.g. with hypochlorite per MOH guidelines.

➢ Inform MOH, relevant authorities and IPs in case of any suspected COVID-19 case in ART patients. Documenting the clinical course of COVID-19 for PLWHIVs is important to inform optimal care.

➢ Adhere to FMOH guidance on ART prescribing

1. Provide 6 Months' Multi-month Dispensing (6MMD) for patients eligible for Appointment spacing model.
2. Provide 3 Months Multi-month Dispensing (3MMD) for
   - PMTCT,
   - Pediatrics,

- Newly identified clients,

- Clients on second line ART and

- Those unstable clients with HVL and on EAC that doesn't seek admission

3. Provide fast track ART refill model (FTAR) for eligible patients

4. Where feasible, clients can have their ART delivered to them through community implementing partners at home to increase continuity of ART and decrease the need for health facility visits.

5. Considering family based refill (if there are more than one family member on ART, one of them can collect for all the other family members on treatment) but the index case should contact ART provider through phone call).

6. PLHIVs, especially those with other co-morbidities and age above 60 years can delegate someone else who is younger and well oriented on prevention measures to collect the ARV on their behalves.

7. Flexible service delivery model and client centered services should be encouraged.

8. At high load ART sites with multiple ART clinics, interventions like spacing of waiting seats and clinics should be implemented.

10. Scale up implementation of the community ART DSD models in the context of COVID 19

In case of any of these models (HEP_CAG and PCAD), the ART refill will be either individually or home-to-home ART distribution. The assumption is to serve at least a quarter (20% - 25%) of stable clients currently on treatment through either individual or group based community ART refill models. Guidance and follow up support from FMOH and commitment of the RHBs is the critical step to materialize the scale up implementation. There is a need to be more flexible to address the needs of different categories of clients in the current context. The community based refill group formation need to be inclusive enough to accommodate a variety of clients as recommended by FMOH, PEPFAR and WHO. Besides, recruiting stable clients for community based ART refill services, other marginally eligible clients (those who may not fulfil all the WHO stable client definition or criteria but do not have a condition that may require a more frequent clinical visit) can be included. This may include for example:

o Those clients on ART for at least 6 months and stable.

- Adolescents (Wt. > 20 kg as recommended by PEPFAR) or age > 10 years who are stable and fully disclosed

All the DSD models should be client centered (i.e. all clients need to be fully aware, verbal consent should be obtained for inclusion, and all the necessary actions should be taken to fully maintain the privacy and confidentiality of clients).

International implementing organizations and local implementing partners will provide technical support on the cascading of the implementation of the community based models.

11. Community Based ART delivery in the context of COVID-19 lock down

In case of semi or total lock down of areas for COVID-19 pandemic retention and holding, maintaining the delivery of ARVs for PLHIV in the area during the lock down period will be required. PLHIVs in a defined community will be delivered with refill of their ARVs by designated HEP or other HCWs including community based service providers. This approach is helpful for community or PLHIV living under total or semi restricted lock down areas for covid-19 prevention. To make the approach effective health facilities shall identify clients coming from the lock down/ restricted area and communicate to the community ARV distribution agent, be HEP, community based workers or HCW designated for this service. The assigned providers will collect the ARVs for clients under lock down from respective health facilities and deliver to individual clients at their appointment date. For the facilitation, a vehicle can be arranged for ARV pick up from the facilities and during home delivery to clients.

In this approach, the collaboration and information exchange between the HFs and community level ARV distributors is crucial. The ARV refill performed at community/ house-to- house shall be documented at the facility level ART registers. The health facilities make the initial communication with clients on community level delivery (including home-to-home) during the lock down period. The community refill will be performed periodically as per the agreed up on frequency and this approach is expected to decrease LTFUs and improve retention.

12. Important precaution during the refill to minimize the risk of COVID 19 infection until it ends

- In case of any of these models, the ART refill will be either individually or as a small COVID 19 risk free groups size (group size ≤ 4 members) until the pandemic risk ends.

- Both the clients and service providers need to follow all the recommended COVID 19 prevention modalities:
    - Avoid any physical contact
    - Keeping the recommended physical distance (two meters)
    - Hand washing or using alcohol/sanitizer before providing or receiving the drugs
    - Using face mask at the time of drug refill (both clients and service providers)
    - Avoided touching mouth, nose, eye with hands
- Shorten the group discussion (if that is in-group as per the state of emergency law recommendation group size) duration by making a very brief discussion on adherence status, encountered challenges and any arising concern of clients.
- As the recommended group size is greater than the state of emergency recommendation, (most have ≥ 6 members), the refill should be individually or the group should be reduced into smaller group size (≤ 4 members per group) at the time of the refill. While doing group refill, it should be in line with the state of emergency guidance (a group size of 4 or less) all the time.
- Supporting and motivating service providers (provide PPE).
- If possible, arrange transportation on the group refill dates and provide PPE for service providers who will do the community based refill until the risk of COVID 19 infection ends.

13.   Roles and Responsibilities

The scale up of health extension professional-managed community ART refill (HEP_CAG) or peer lead community ART distribution (PCAD) models of differentiated care will be managed and coordinated at different levels: Federal, Regional, woreda/sub-city, health facility, and community levels. The Federal ministry of health and the regional health bureaus will lead the overall implementation. The health extension and the HIV programs will jointly implement it. Associations of people living with HIV and PLHIVs have a significant role to play.

13.1 Federal Ministry of Health (FMOH)
- Guide the implementation of community based ART refill services in the context of COVID 19 pandemic.
- Communicate or provide guidance for all the relevant bodies on the importance of community based ART refill services to minimize the frequency of HF visit by PLHIVs.

- Organize and support national level orientation trainings

- Support RHBs on the implementation of community based DSD models.

- Lead the national DSDM TWG.

- Provide all the necessary guidance.

- Monitor the implementation progress.

13.2 Regional Health Bureaus

- Establish and lead regional level DSDM TWG or taskforce.

- Cascade orientation trainings for service providers and peer leaders

- Guide the community based ART refill or distribution.

- Communicate or circulate the guidance to all the relevant bodies in the region.

- Communicate and support health facilities and community-based implementers on the implementation of community based DSD models.

- Monitor the implementation progress

- Ensure quality service delivery.

13.3 Health facilities

- Implement the interim guidance on COVID 19 and HIV service delivery.

- Identify eligible and willing clients and recruit for community based ART refill and distribution.

- Arrange and facilitate onsite orientation sessions for service providers.

- Assign HEPs to undertake the ART refill.

- Identify those who missed their follow up visit or LTFU cases and provide the list to community based service providers for early tracking and re-engagement.

- Identify those with unsuppressed viral load result and link them to community based targeted adherence interventions after initiating EAC service.

13.4 HEP Supervisor

- Manage health extension professionals and coordinate with other health facility staff to implement health extension professional-managed community ART refill groups.

- Facilitate the identification and mapping of clients for HEP_CAG and PCAD together with the HEPs and PLHIV associations.

- Monitor the performance of health extension professionals on community based refill model.
- Provide supportive supervision to the health extension professional-managed community ART refill or distribution.
- Convene and facilitate monthly catchment area meetings of health extension professionals and CAG leaders to review the performance.
- Participate in the quarterly supportive supervision visits and regional review meetings.
- Ensure timeliness and accuracy of data entry and conduct review of forms.

13.5 Health Facility Focal Person for the community based ART delivery

Each health facility is expected to assign a focal person for the community based ART refill or distribution and the focal person will be responsible for the following activities.

- Facilitate the orientation of new and existing staff members on community based ART service delivery models.
- Liaise with the community based ART refill or distribution service providers (HEP, Pear leaders), especially at hospitals as there are no HEP baseding at hospitals.
- Support the establishment or mapping of community based ART refill or distribution groups.
- Analyze and report the outcomes back to health facility staff.
- Ensure monitoring, supervision, training, and quality improvement of the community based DSD models.
- Consult with and report to Zone/sub-city/woreda health office.
- Work with the health extension professionals.

13.6 Health Extension Professionals

- Involve in analyzing and mapping of PLHIVs in collaboration with the health facilities and associations of people living with HIV.
- Coordinate and manage the community ART refill groups.
- Work closely with the CAG leaders.
- Pick drugs from the pharmacy and sign for them.
- Screen PLHIV for common opportunistic infections and side effects of ARVs.
- Refill antiretroviral drugs and other OI medication as needed.
- Assess adherence status of individual clients.
- Ensure that the PLHIVs are attending the HIV care and treatment clinic as per their appointments.

- Offer psychosocial support, health education, monitoring, and referrals provision.
- Identify & refill drugs for those clients not coming during refilling schedule

13.7 Pear leaders

- Facilitate group meetings.
- Lead discussions during meetings.
- Record the pill count on the group register during the meeting before drug refilling.
- Check on the adherence of group members.
- Facilitate the assignment of individual members to collect the medications form health facilities on behalf of the other members at their turn.
- Ensure communication between the health worker and the group members in case any problems occur in the group.

13.8 PCAD members

- Support the establishment and promotion of HEP_CAG and PCAD in the community.
- Support health education and adherence messaging within membership.
- Report any adverse drug effects, OIs or other issues to the group leader.
- Facilitate pill counts within membership for their medicines and report pill counts to the group representative or group leader.
- Attend health facility on behalf of the whole membership when their turn is due.
- Attend health facility at any time they feel unwell even if they are not due
- Pick up the medication for themselves and for other group members.
- Distribute medicines correctly to other group members.
- Advise other members to seek medical care at health facilities when needed

13.9 PLHIV associations and PLHIVs
- Advocate on the importance of community based refill in order to minimize exposure to COVID 19 for PLHIVs.
- Arrange community based ART refill sites.
- PLHIV will have a demand creation, facilitation and LTFU tracing role.
- Identify clients living in the same area, provide information on community based ART refill and facilitate recruitment for community-based refill through linkage of identified and willing clients to their respective ART follow up health facilities.

13.10 Implementing Partner/Project HOPE

- Provide guidance for LIPs on community based service delivery.

- Support provision of orientation sessions for service providers.

- Assign technical staffs who will follow and support the service delivery

- Identify and communicate all the encountered challenges to RHBs or MOH.

- Develop community based DSDM SOPs and formats in collaboration with other stakeholders.

- Provide monitoring formats and job aids.

- Analyze the performance and lessons learned through the pilot implementation.

13.11 Local Implementing Partners

- Support provision of orientation sessions for service providers.

- Support and facilitate the recruitment of clients for community based service delivery by HFs.

- Facilitate the community-based refill through allocation and supply of the required logistics.

- Assign responsible CEFs to assist HFs in the prior identification of the refill dates of the already recruited clients and remind HFs to avoid missed appointment dates.

- Assign CEFs to all the DSDM facilities in their catchment to support its implementation.

- Arrange refill sites at community level in their catchment.

- Receive the lists of LTFU cases and conduct community or home based tracking and re-engage to care and treatment services.

- Provide targeted adherence interventions for those with unsuppressed viral load by receiving their list from health facilities.

- Identify encountered challenges and communicate to the respective sub cities, RHB or project HOPE.

- Provide guidance and technical support for new sites in their catchment.

- Distribute the revised guidance and formats to all implementation sites.

14.   Critical Enablers

14.1 Budget:

When working in a very demanding situation, an eminent additional budget requirement will be there. In order to ensure the continuity of quality service delivery and to maximally protect both the service providers and users from acquiring COVID 19 infection, the following additional consideration need to be there at least until the pandemic ends:

- Provision of PPE and hand hygiene materials for service providers and users.

- Communication and transportation allowance for service providers

- Provide need based and targeted financial and food support. This can be done either through linkage of those with identified nutrition support need to community based supports. There are different stakeholders that are mobilizing different resources to support those in need during the pandemic.

14.2 Developing a more flexible guidance:

In a situation of preventing a more contagious pandemic, the priority is containment of the infection through minimizing exposure of every one. This requires immediate and adaptive solutions that can help assuring the continuity of essential services. Therefore, developing a more flexible guidance focusing on client needs and preferences is highly needed. As mentioned in the FMOH guidance (summarized above), even marginally eligible clients can be included or their follow up will be less frequent than the usual. This guidance will progressively updated considering current conditions of the pandemic.

14.3 Establishing Regional Level DSDM Taskforce

- The accelerated implementation of community based ART refill needs the engagement of various stakeholders.
- Establishing a regional level taskforce involving the following stakeholders is advisable in order to closely monitor and strengthen its accelerated implementation:
  - o RHB (both HIV and health extension program representation)
  - o Local implementing partners
  - o Implementing partner staffs (international organizations)
  - o PLHIV associations

15. Orientation/training

FMOH and implementing partners (Project HOPE) will provide TOT orientation for health extension and HIV program managers at the regional health bureau, Zone and woreda level and including staffs of responsible local implementing partners (LIPs) on the implementation of community based ARV refill or distribution models. These program managers will cascade the orientation in collaboration with responsible local implementing partners at the targeted health facilities.

Health extension professionals and peer leaders will be trained on screening for common opportunistic infections and side effects of ARVs, first line ARVs, adherence to ART, community ARV refill or distribution service delivery in the context of COVID-19. LIPs at the respective regions will support and facilitate the training of community based ART refill or distribution service providers (UHEP, HEP, peer leaders).

16. Materials /tools

The following resources are essential for the smooth running of the implementation of the community based ARV refill and distribution models:

- Carrier bags (for the health extension professionals)
- Zip-lock bags or other packing materials
- Masking tape
- Markers
- Stickers
- Pick list
- Monitoring and evaluation tools, and

17. Supply chain

Pre-packaged drugs are required to implement this model. Pharmacy staff in the hospitals and health centers generate a drug pick list, which is used to request drugs that are then availed for pre-packing. Pharmacy staff at the facility (hospital/health center) using the pick lists as a guide do pre-packing of drugs for clients in these models. These drugs can be prepacked using different methods (tied using a masking tape or packed in Zip-lock bags and clearly labeled with the client's name and unique ART number for easy identification and distribution). Where a client has more than one packet of drugs, the packets of drugs are tied/held (fixed) together with a masking tape or in Zip lock bag and labeled. This is to ensure that drugs of clients are not mixed up. These pre-packaged drugs will again be grouped. The responsible service providers for the community refill or distribution will pick the pre-packaged drugs (ARVs and other drugs) and then distribute it to the community ART refill & distribution members.

18.   Monitoring and Evaluation
18.1 M and E tools

The monitoring and evaluation of the implementation of Community ART Refilling and Distribution models will take into consideration requirements of the monitoring and evaluation of the national HIV program. However, as this is a COVID19 Pandemic period, the following joint monitoring activities will be carried out by the respective public health system structures in collaboration with partners.

- Support the preparation of joint HF implementation plan.

- Joint monitoring sites visits.

- Regular performance progress review meetings.

- Facilitate generation and exchange of electronic performance reports from each facility.

- Integrate the community based ART refill or distribution service delivery in to the existing electronic monitoring system.

18.2 Supportive supervision

Systematic supportive supervision of the implementation and outcomes of the community based ART refill or distribution models is one of the critical enabler, especially during the current pandemic period. The national DSDM technical working group, the regional health bureau focal person, the woreda/sub-city focal persons, the HEP supervisors and the implementing partners will conduct biannual supervisory visits at the selected sites. Responsible LIPs and Wereda, Zone/Sub city health offices will conduct quarterly supervisory site visits.

18.3 Quality Monitoring
o A very brief quality-monitoring tool will be used and the tool will focus on monitoring the continuity of care, stock status at hand, adherence to treatment and satisfaction of service users.
o HFs need to conduct a quick quality assessment and monitoring on quarterly bases.
o There should be client centered care and service providers need to focus on addressing client needs and priorities.

18.4 Recording and reporting tool
- Client eligibility assessment tool
- Client assessment tally sheet
- ART register
- Pharmacy register
- Client follow-up Card
- UART ID
- ART refill form managed by peer leader (PCARD registration)
- Electronic data entry
- Quarter/ monthly reporting format

18.5 Recording and Reporting timeline
- Daily recording- screening and identification [ART clinic clinicians or ART focal]
- Daily refill recording- [HWs, Peers]
- Daily pharmacy pick up recording- [Pharmacist]

- Daily chart update- [ART provider]

- Daily CommCare entry [LIPs]

- Monthly/ quarterly reporting (ART focal person)

18.6 Reporting hierarchy of PACD
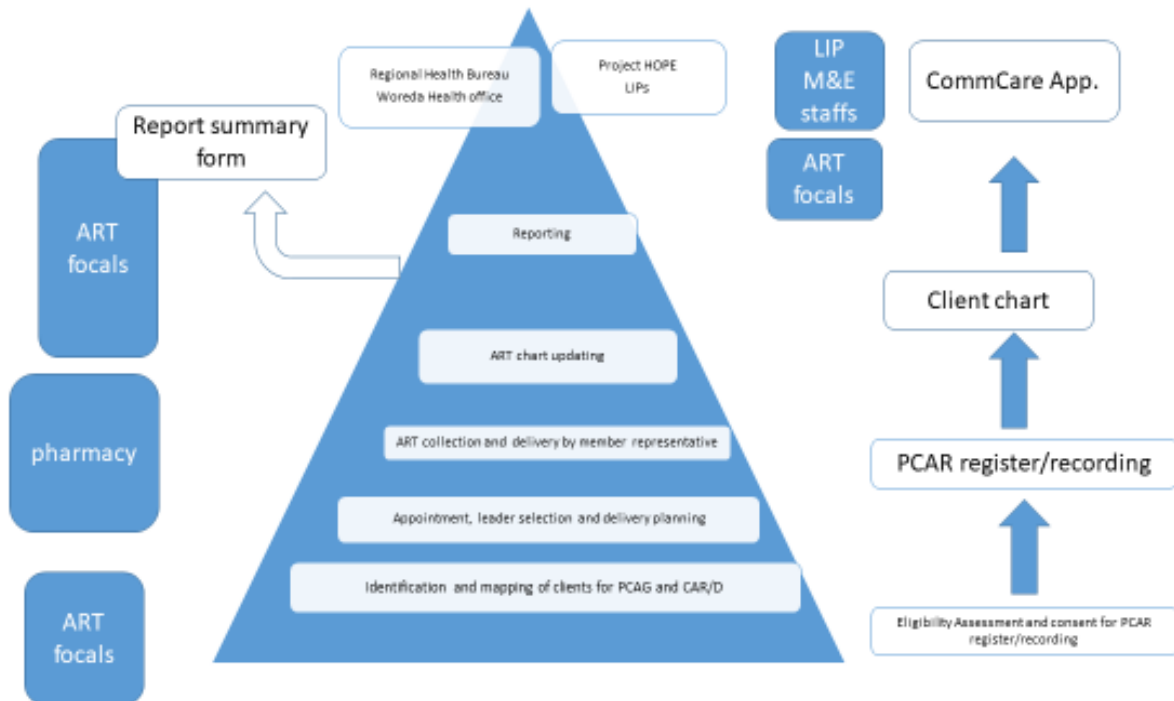
Fig. 5. Reporting hierarchy for the PCAD model

1. M & E Tools

1.1.UHEP or Peer Lead Community ART Refill or Distribution

Initial Patient Assessment Form

(To be filled by the ART Provider)

1.	Name of Health Facility: _____ Name of patient: _____Age_____Sex___ MRN_____ Unique ART no. _____	Date of Assessment: _____

2.	[Ask patient]: When did you start ART? (select one)
	    a. Less than 1 year ago
	    b. More than 1 year ago
		Confirm from record
		DD/MM/YYYY
		___/___/_____

3.	[Ask patient]: In the past year, have you ever experienced adverse drug reactions (side effects) related to taking your ARV medicines that required regular monitoring? ☐ Yes ☐ No Please, list the side-effects you have experienced: _____ _____ _____ _____	Confirm from record and list side-effects _____ _____ _____ _____ _____ _____
4.	What type of ART regimen is the patient currently on? (Check patient chart and Choose One from the list)	
	Based on the above is the patient on first line regimen?	☐ Yes ☐ No
	Has the patient been on this regimen for at least 03 months?	☐ Yes ☐ No
5.	Is the patient currently on TB treatment?	☐ Yes ☐ No
6.	Is the patient on treatment for any other OI?	☐ Yes ☐ No
7.	If a **female client,** is she either pregnant or breastfeeding or both?	☐ Yes ☐ No
8.	If you sometimes miss a dose, ask the client to tell you the reasons. (*Allow the patient time to think of all possible reasons for forgetting.*) _____ _____ _____ _____ _____	Check the record for level of adherence for the last 12 months: Always Good ☐ Mostly Good ☐ Always Fair ☐ Mostly Fair ☐
9.	Has the patient ever stopped ART or has previously been Lost-to-follow up in the past 12 months? [Check medical record] If *Yes*, what was the reason:	☐ Yes ☐ No

	_____ _____	
10.	Check last 2 viral load measures from the patient's medical record/ chart.	
	Date and value of most recent VL done _____copies/ml	DD/MM/YYYY ___/___/_____
	Date and value of 2nd most recent VL done _____copies/ml	DD/MM/YYYY ___/___/_____
11.	If VL record is not available, check if recent CD4 count is > 200 cells/mm3. Date and value of recent CD4 Count. _____ cells/mm^3	DD/MM/YYYY ___/___/_____
12.	Client was told about UHEP-PCARD and give consent	☐ Yes ☐ No
13.	If yes to the above question, has the client given consent?	☐ Yes ☐ No

Summary of Eligibility

Eligibility criteria – Client is eligible for UHEP- Community ART Refill or Distribution as below:

- Stable clients Provided consent to participate in the community refilling;

  - Have received ART for at least six months and have no adverse drug reactions that require regular monitoring;
  - Is still on first line regimen;
  - Is on the current regimen at least for three months;
  - Have no current illnesses or pregnancy and are not currently breastfeeding;
  - Have evidence of treatment success (at least one viral load measurements below 1000 copies/mL or CD4 count > 200 cells/ml and evidence of clinical improvement through clinical evaluation).

During the COVID 19 epidemic, other marginally eligible clients can alos be included in community based ART refill services, like for example:
- Adolescents (Wt. > 20 kg as recommended by PEPFAR) who are virally suppressed, fully disclosed and without any clinical condition that may require more frequent clinical visits.

NB.
- Other unstable clients can get a community based ART refill to minimize the risk of COVID 19 until it ends. After the pandemic ends, the unstable clients will be changed to the conventional care model but the community-based refill will continue for stable clients depending on their preference.

Client Eligible to UHEP-PCARD:

       Yes_____   No_____

Linked to PCARD
       Yes_____   No_____

1.2. **Urban Health Extension Professional or Peer- Lead Community ART Refill or Distribution (UHEP_PCARD)**

Eligibility Assessment Tally Sheet

Region :_____ **Zone/Sub City:** _____ **Woreda:**
_____ **Ketena**_____

Name of Health Facility: _____ **Name of service provider:**_____

Ser. No.	Name of Client	Age	Sex	Unique ART #	Assessment Date dd/mm/yyyy	Eligibility Assessment: 1. Eligible 2. Not Eligible	Consent: 1. Accepted 2. Declined	Enrolled in PCARD (Y/N)	Remark
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									
11.									
12.									
13.									
14.									
15.									
16.									
17.									

1.3. **Urban Health Extension Professional or Peer Managed Community ART refill or Distribution (UHEP_PCARD)**

Community Based Refill Register

Region :_____   Zone/Sub City: _____   Woreda: _____ Ketena_____

Name of Health Facility: _____   Name of Health Post:_____   Name of PCARD service provider: _____

PCARD ID:_____   Name of PCARD: _____

Appointment date of *1st Refill:* ____/____/_____   *2nd Refill:* ____/____/_____   *3rd refill:*____/_____/_____
*4th Refill:*____/_____/_____

S. N o.	Name of community PCARD Member	Unique ART #	Age	Sex (M/F)	Address (Tele.)	Dispensed ART pill count				Remark
						1st refill	*2nd refill*	*3rd refill*	*4th refill*	
						pill count[3]	*pill count[3]*	*pill count[3]*	*pill count[3]*	
1.										
2.										
3.										
4.										
5.										
6.										
7.										
8.										
9.										
10										
11										
12										
13										
14										
15										

1.4. **CHCT- UHEP-PCARD Line List Receiving Form from HF**

Name Of HF:-_____	Region:_____ Sub city _____ Zone/ Woreda _____		Ketena/Gote:_____

ART Provider Name & Signature: _____UHEP/ Peer Leader Name & Signature :_____
Health Post Name:_____

S.No.	Full name of client	Sex	Age	UART Number	MRN	Client Address							Concented to PCARD 1. Yes 2. No	Remark
						Region	Sub city/Zone	Woreda	Kebele	Ketena	Gote	Phone No.		

1.5. **Urban Health Extension Professional/ Peer Managed Community ART Refill or Distribution (UHEP_PCARD)**

ART Pharmacy Refill Register

Region :_____   Zone/Sub City: _____   Woreda:
_____

Name of Health Facility: _____   Ketena:_____   Name of PCARD
service provider: _____   Name of Health Post_____

PCARD ID:_____   Name of PCARD: _____

Appointment date of *1ˢᵗ Refill:* ____/____/_____   *2ⁿᵈ Refill:* ____/____/_____   *3ʳᵈ*
*refill:*____/_____/_____   *4ᵗʰ Refill:*____/_____/_____

S. No.	Name of community PCARD Member	Unique ART #	Age	Sex (M/F)	Address (Tele.)	Dispensed ART Regimen Code and pill count								Remark
						1ˢᵗ refill		*2ⁿᵈ refill*		*3ʳᵈ refill*		*4ᵗʰ refill*		
						Code	*pill count[3]*	*Code*	*pill count[3]*	*Code*	*pill count[3]*	*Code*	*pill count[3]*	
1.														
2.														
3.														
4.														
5.														
6.														
7.														
8.														
9.														
10.														
11.														
12.														