Ministry of Health

National Policy Guidelines For Community-Centred Models of ART Service Delivery (CommART) in Swaziland

SWAZILAND NATIONAL AIDS PROGRAMME (SNAP)

DIFFERENTIATED CARE FOR HIV CLIENTS IN SWAZILAND

[JUNE 2016]

MOH
HIV /AIDS
SNAP
SWAZILAND NATIONAL AIDS PROGRAM

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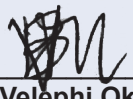
FOREWORD

Antiretroviral Therapy (ART) provision to people living with HIV (PLHIV) remains a key priority for Swaziland's Ministry of Health (MoH). The national goal is to achieve HIV epidemic control by decreasing HIV-related illnesses and deaths, and decreasing new HIV infections. Continued decentralization of the delivery of HIV care and treatment services has helped increase access to ART at decreased cost to the client. However, with increased ART coverage and good retention, it is becoming imperative that the MoH designs innovative ways to deliver quality HIV services to clients in a manner that is acceptable, clinically sound and efficient. The MoH acknowledges the need to minimize the client-related costs and opportunity costs incurred by ART clients as a result of frequent visits to facilities and extended waiting time within the facilities as ART client volumes increase. This document provides a national policy guide to support the implementation of different models of ART delivery in Swaziland.

This policy guide draws on an extensive review of local experience and evidence undertaken through pilot projects in 2014 and 2015, shared experiences from other country programmes and consultations with health care workers, communities and ART clients. This document is primarily intended for policy makers, health managers and implementing partners of HIV services at both facility and community level, as well as other national programmes including TB, non-communicable diseases (NCDs) or MNCH-SRHU, clinicians and other health service providers, PLHIV organizations and donors.

The Ministry of Health expresses its sincere gratitude to all those involved in the development and finalisation of this very important document.



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ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
APMR	ART Patient Monitoring Records
ART	Antiretroviral Therapy
ARV	Antiretroviral agent
CAGs	Community-based ART Groups
CMIS	Client Management Information System
CMS	Central Medical Stores
CommART	Community/Client-centred models of ART Service Delivery
FTCs	Facility-based Treatment Clubs
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
IPT	Isoniazid Preventive Therapy
LTFU	Lost To Follow Up
M&E	Monitoring and Evaluation
MoH	Ministry of Health
NARTIS	Nurse-led ART Initiation in Swaziland
NCDs	Non-Communicable Diseases
NGO	Non-Governmental Organization
NRL	National Reference Laboratory

ACRONYMS

OI	Opportunistic Infection
PLHIV	People Living with HIV
POC	Point-of-Care
RHMT	Regional Health Management Team
SHIC	Swaziland HIV Investment Case
SNAP	Swaziland National AIDS Programme
SWANNEPHA	Swaziland National Network of People Living with HIV and AIDS
SOPs	Standard Operating Procedures
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV and AIDS
VL	Viral Load

1 INTRODUCTION

1.1 BACKGROUND

Swaziland has made significant progress in addressing the HIV epidemic through the years, engaging national and international actors. The number of PLHIV receiving ART continues to rise each year. In 2015, it was estimated that 222,102 people were living with HIV, of whom 178,857 (80%) were eligible to start ART as per Swaziland National 2015 guidelines. From HMIS data, 147,274 people living with HIV (139,211 adults and 8,063 children) were active on ART by December 2015 [1]. Since 2011, the number of patients newly initiated on ART has been increasing steadily from 14,184 in 2011 to 19,408 in 2014 and sharply increased to 22,797 in 2015 [1]. This is partly due to the lowered ART eligibility threshold (from CD4 count of 350 to 500 cells/ml) as stipulated in the national 2015 HIV management guidelines [2].

The annual incidence rate among 15-49 year olds is expected to have declined from 2.9% in 2011 to 1.9% in 2015, and new infections among children at 18 months of age were estimated to be 11% of all exposed children in 2012, down from 19.6% in 2009 [3]. This remarkable success can be attributed to many factors, including successful decentralization of HIV services to the primary health care level, and development and implementation of the Nurse-led ART Initiation strategy in Swaziland (NARTIS) in 2011 [4]. In an effort to align with the UNAIDS 90-90-90 strategy to control HIV [5], Swaziland has rolled out the HIV integrated management guidelines recommending that the ART initiation threshold of all PLHIV be shifted from a CD4 cell count of 350 to 500 cells/mm3, and that in special groups, such as pregnant women and children under five, it is implemented regardless of CD4 cell count. The country also committed to adopt the “Test and Start” approach before the end of 2016 to provide treatment to all PLHIV as recommended by the World Health Organisation (WHO).

In this context, the Ministry of Health estimates that the need for ART will increase to reach more than 200,000 PLHIV by 2018 (Investment case 2014). Hence, there is a need to design and implement innovative strategies to provide ART to all eligible populations, to decongest the facilities and decrease client waiting time. There has to be a systematic process of increasing the number of treatment delivery points with ensured good clinical practice and

treatment outcomes as we further expand decentralized ART services to communities. Decentralizing ART services to the community will address the existing barriers to linkage to HIV care and poor retention rates over time. The community systems must be resourced, scaled up, linked and integrated with health systems [6]. Most community-based ART delivery modes have been able to demonstrate reduced burden for clients and the health system, increased adherence and retention in care and lower provider costs [7-13].

For ART service delivery, there is no single best approach that addresses the health needs of PLHIV, as well as the need to retain them in ART care for longer. Swaziland piloted different ART delivery models at both facility and community levels that have generated lessons and best practices to inform the implementation of this models for the country. The Swaziland models, other than mainstream care, are categorized as follows: Fast-track, Community ART groups, Facility treatment clubs (including teen clubs) and Outreach model.

This document serves as a toolkit that explains key operational guidelines. A complimentary document titled: ***Standard Operating Procedures for Implementing Community/client-centred Models of ART Service Delivery in Swaziland***, provide details on standard operating procedures (SOPs) to implement the different ART delivery models. The implementation of these models is aligned with the National Health Sector Strategic Plan II (2014-2018), which aims for universal reach to best quality care using a client-centred approach. Community/Client-centred ART delivery models seek to ensure efficient management of clients, paying particular attention to:

- client needs
- client's responsibilities
- client waiting time
- equity in allocation of services to sick clients and well clients.

The National AIDS Programme emphasizes client empowerment. This means clients need to be more informed and better able to negotiate their health care needs and take ownership for their health. Health care workers should adjust to this paradigm shift and allow clients to participate in decision making for their health care. The success of the different ART delivery models outlined in this guideline is dependent on client empowerment and participatory decision making between the health care worker and the client.

With the right investment and commitment at all levels of the health care delivery system, we are confident that Swaziland will achieve the Government´s vision

of zero new infections and ending HIV-related sickness and deaths, by 2022 and 2030 respectively. These guidelines for client-centred ART delivery will contribute to the achievement of this goal. This document provides guidance to policy makers, donors, implementing partners, health facilities, communities, civil society and supporting partners on the implementation of different models of ART delivery for PLHIV.

1.2 RATIONALE FOR ART DELIVERY MODELS

At the end of 2014, 125,421 people (76% of the eligible population) were on ART [4] and the number increased to 147,274 at the end of 2015 [1]. With the anticipated rise in the number of clients who will need to be on treatment with the change in the eligibility criteria for initiation of ART, various models of treatment delivery have to be implemented. This is to ensure that treatment is available for those who need it, that it is accessible and that it is provided with the standard of quality as prescribed in the integrated HIV management guidelines. The aims of client- and community-centred ART delivery models are to:

1. Reduce client-related costs, for accessing care

2. Allow equitable allocation of services time between stable and unwell clients

3. Reduce the health service burden at facilities by ensuring efficient management of stable clients

4. Empower clients to be actively involved in their care for improved clinical outcomes.

ART retention in Swaziland has been improving at each end-point of interest from 2008 to 2015; it has also improved in the trajectory from six months to 60 months, as shown in the cohorts from 2008 to 2015 in Table 1. The client-centred models ("CommART") are likely to improve long-term ART retention (greater than 36 months) because more than 64% of the clients lost to follow up (LTFU), in assessment of LTFU among ART clients in Swaziland, have reported lack of transport money (34.4%) and lack of family support (30%) as the causes of disengaging from care [14]. In the same report, 29.3% of LTFU occurred beyond 24 months [14] (presumably due to changing socio-economic dynamics of recovered and stable clients).

Table 1: Improvement in retention of ART clients from 2008 to 2015 (Source: HMIS)

Cohort	6 months		12 months		24 months		36 months		48 months		60 months	
Age (Years)	<15	15+	<15	15+	<15	15+	<15	15+	<15	15+	<15	15+
2008	88%	85%	82%	78%	75%	71%	68%	65%	62%	59%	57%	53%
2009	87%	85%	81%	78%	74%	71%	68%	64%	63%	58%	77%	69%
2010	87%	86%	80%	80%	73%	71%	65%	62%	80%	74%	76%	74%
2011	89%	88%	82%	80%	69%	69%	83%	78%	78%	78%		
2012	84%	87%	76%	77%	87%	82%	84%	83%				
2013	85%	86%	91%	88%	87%	87%						
2014	97%	96%	93%	92%								
2015	98%	97%										

Differentiated models of ART delivery simplify how ARV treatment, care and support is delivered. The models reflect the preferences and expectations of PLHIV while reducing the unnecessary burdens on the health system. Given the size of the HIV epidemic in Swaziland, good retention rates and the desire to move towards Test and Start, the health care services have to develop and implement new models of ART delivery. CommART models of ART delivery seek to tailor services to the different needs and priorities of the following group of clients:

(i) Stable clients:- who needs less attention for medical care, adherence and treatment support

(ii) Unstable clients:- who require individualized clinical reviews for medical care, adherence and treatment support.

(iii) New clients:- who require ART initiation and close attention for medical care, adherence and treatment support

The differentiated care approach is adapted from the WHO consolidated guidelines on the use of antiretroviral medicines for treating and preventing HIV infection: Recommendations for a Public Health approach 2016 [15]. The WHO

elaborates four service delivery components in the differentiated approach to HIV care centred on the client (i.e. PLHIV) and these are: service frequency, service intensity, service location as well as the nature of the healthcare worker providing the service. Figure 1 shows the different factors for each component that form the framework for the differentiated HIV care approach.

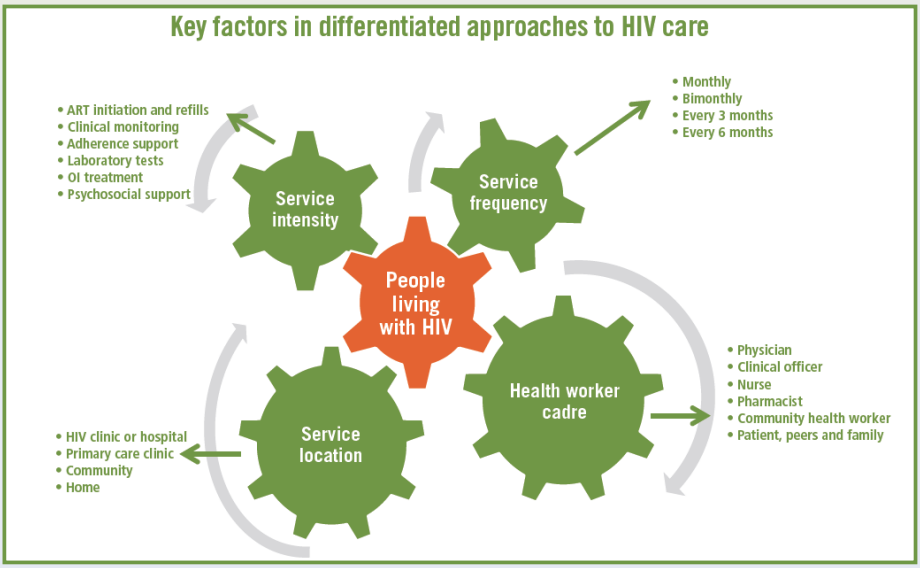


Figure 1: Key components for providing differentiated HIV care *(Courtesy of WHO, 2015)*

These novel models of care require that the health facilities lead and broadly engage with PLHIVs, community-based organizations, community structures and individuals on ART treatment. All the models are aimed at tailoring chronic ART care to the specific preference of a client with maximum engagement of clients in the continuum of care.

In implementing the ART delivery models, SNAP will ensure coordination of all the key stakeholders responsible for the ART service delivery at all levels of care. Figure 2 highlights the stakeholders that have to be engaged and health system areas that have to be strengthened for successful implementation of these guidelines.

ART Service Delivery: Capacitating health care workers	**Laboratory System:** Ensuring laboratory standards within models	**M&E Systems:** Review of existing tools	**Pharmacy System:** Supply chain and security of ART medicines	**Community Systems:** Active participation of community structures	**ART Clients:** Engagement in chronic ART care

National Level: SNAP, SI Unit, CMS, NRL, SWANNEPHA, Supporting Partners
Regional Level: RHMTs, Implementing Partners.
Health Facility Level: Facility Management, Health care workers (multidisciplinary teams), ART clients.
Community Level: Community organizations, ART clients, PLHIV support groups.

Figure 2: Systems to support the implementation of the models

2 GUIDING PRINCIPLES FOR DELIVERY OF ART SERVICES

Roll out of new ART service delivery models must not negatively impact on the quality of care. CommART seeks to empower ART clients and ensure that clients experience less waiting time at health facilities. Along the same line, CommART seeks to create additional time that should be afforded to unwell clients, who may require longer consultation time with nurses and doctors for thorough history taking and clinical examination. The following principles will guide the implementation of CommART in Swaziland:

1. **Informed consent:** All HIV-positive clients should be educated on the benefits of ART and the different service delivery models to make an informed choice and verbally consent to a preferred model.
2. **Human rights and dignity:** Privacy and confidentiality should be maintained in the delivery of ART in all these models to increase the level of comfort and trust by clients.
3. **Quality of care and good clinical practice:** ART standards of care should be maintained in all the service delivery models.
4. **Integration:** ART service delivery should be integrated with other care services e.g. IPT, NCDs, HMIS, M&E and stock supply management.
5. **Client-centred:** Services should be provided in a manner that addresses primarily the needs of the client and empower clients to play an active role in their care.
6. **Flexibility:** ART clients are allowed to switch to any of the models as they see fit without interrupting their treatment.
7. **PLHIV engagement:** Support groups of PLHIV should be engaged and involved in the implementation of ART service delivery models.

Note: A patient centred service provision is the standard

3 MODELS OF SERVICE DELIVERY IN SWAZILAND

3.1 OVERVIEW OF THE STANDARD PACKAGE OF ART CARE

A standard package of care for all clients on ART should include:

- ✓ Clinical monitoring of care, which includes taking a history, physical examination, monitoring for side-effects, screening for opportunistic infections and providing prophylactic treatment, screening and management of NCDs, cervical cancer screening and the management of other co-morbidities.
- ✓ Adherence and psychosocial support.
- ✓ Virological (viral load) monitoring.
- ✓ Immunological monitoring i.e CD4 cell count monitoring in the absence of viral load monitoring.

For stable clients, Swaziland recommends a defined package of care, adapted from the WHO recommendations, to include the following:

- Less frequent clinic visits (six-monthly) - *New!*
- Less frequent medication pick-up (three-monthly)
- Community-based care
- Cessation of CD4 cell count monitoring if viral load testing is available and viral load is undetectable.

Stable adult client: An adult client is regarded as stable and qualifying for ART if the following are fulfilled:

- aged 18 years or older
- on ART for 12 months or longer
- **undetectable** viral load (two consecutive viral load measurements are undetectable with the latest one taken within 6 months of eligibility date)
  - ✓ or, in the absence of viral load monitoring, client has a rising CD4 cell count or a CD4 cell count above 350 cells/mm^3
- does not have current TB, no concurrent OIs or any adverse drug effects
- not pregnant
- no other medical condition requiring more frequent clinical consultations, and
- has at least two ART visits at the facility.

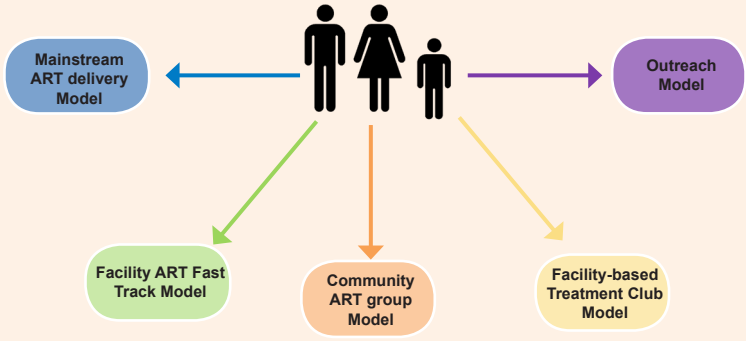
Clinicians confirm that the clients' eligibility and ensure enrolment is voluntary. A summary of inclusion criteria can be found in Appendix 1.

3.2 THE ART DELIVERY MODELS

Five models of ART service delivery are described in this document. These models are:

1. Mainstream care
2. Fast-track model
3. Facility-based treatment clubs (FTCs)
4. Community-based ART groups (CAGs)
5. ART outreach model.

These models should be offered to all eligible clients. Clients should make their choices as illustrated in Figure 3.



Models of ART delivery. PLHIV on treatment may choose any model of ART delivery and are free to switch from model to model for as long as they are eligible for the model of delivery.

Figure 3: Available ART delivery models

3.3 MAINSTREAM CARE

3.3.1 Groups prioritized for mainstream care

This model mainly provides HIV care to clients who require close clinical attention and/or monitoring from nurses and doctors. All facilities have mainstream care to provide clinical services to clients who are/have:

- Clinical complaints
- Moderate to severe side-effects

- Suspected treatment failure (clinical, immunological and/or virological lack of response to ART) and recent regimen switch (less than six months)
- Adherence issues including missed appointments; provided other models do not provide unique solutions to the adherence problem
- Newly initiated on ART (less than 12 months on ART)
- Detectable viral load
- Pregnant and breastfeeding women (**Note:** Pregnant women should receive ART refills during their focused ANC visits, breastfeeding women can be eligible for clubs under special considerations)
- Co-morbidities: TB disease, mental illness and substance abuse, or other conditions as justified by the clinician
- Transfer-in clients with less than two ART visits at the new facility.

3.3.2 Mainstream care package for clients presenting with advanced HIV disease

Patients presenting with advanced HIV disease with a CD4 cell count of <200 and/or WHO clinical stage III or IV should be prioritized for rapid ART initiation after actively ruling out opportunistic infections and should have intensified follow-up. In addition those presenting with CD4 cell count <100 should have the following tests performed:

- Cryptococcal antigen screening
- TB LAM testing- if they are symptomatic for TB

If positive, they should be given appropriate treatment and follow up procedures.

Note: The inclusion into mainstream care is not limited to the above list. The door for mainstream care is always open for those who may want to transition from other models, as well as those who will no longer be eligible for the other models for various reasons.

3.4 FAST-TRACK MODEL

The trademark of the fast-track model is the significantly shortened amount of time that **stable** clients spend waiting for ART refills in the clinic. To do this, ART refill visits must be considered separate to clinical visits. In the fast-track model, stable clients receive ART refills through a quick pick up of their pharmaceutical package at their health facility. They are not expected to undergo the regular clinic processes of vital signs, weight measurement, and pill count. Therefore it is important to examine patients during clinical visits to ensure that they are well enough to be fast-tracked at the next visit. It is also

important to empower fast-tracked clients to be able recognize and report signs and symptoms that require the attention of a health care worker. If the fast-tracked client is in need of clinical consultation, they should be referred back to mainstream care. Further, if a health care worker notices that a fast-track client may require clinical assessment due to changes in clinical conditions or other reasons such as defaulting treatment, they should be referred back for mainstream care.

Clients in fast-track model can have routine laboratory tests strategically requested to allow results to be fully communicated during the clinical visits.

In the majority of facilities, significant waiting times occur at two points:

(i) While waiting for clinical consultation by a doctor or nurse
(ii) At integrated dispensing points (time inefficiencies are often due to the mix of those requiring additional time for medicine explanation and those experienced with their treatment requiring less time for medicine and dosing information).

Note: Thorough considerations of client flows at facility level are required to address such possible bottlenecks. The components of services provided at fast track are summarised in Table 2.

Table 2: Summary of the Fast-Track Model

Summary of the Fast-Track Model		
	ART Refill Visits	**Clinical Consultations**
What services	• ART refill • TB screening • IPT refill • CPT refill	• ART refill • IPT initiation or refill • CPT refill • TB Screening • Adherence Support • Clinical Reviews • Laboratory Monitoring (CD4 count, HB, Creatinine and LFTs) • ART Prescription • Cervical Screening* • NCD Screening and management • Mental Health • Family Planning
Where	• ART clinic - nurses collect refills at pharmacy on behalf of clients and distributes at ART clinic **OR** • Dispensary - clients go straight to pharmacy for medicine pick up	• ART clinic • Laboratory
When/ frequency	• Every 3 months	• Every 6 months
Who	• Pharmacist/ Pharmacy Personnel (if ART is dispensed); or • Nurse/Expert client (if ART is distributed)	• Clinician (doctor or nurse) • Pharmacist/ Pharmacy Personnel • Laboratory Personnel
Indications for referral to mainstream care	• Presence of signs and symptoms of disease • Presumptive for TB • Missed appointment/ defaulting treatment • Detectable VL • Pregnancy	

*Cervical screening should be done annually for female clients

Note: Routine data should be provided by the ARV refill encounter prescription triplicate filled during the previous clinical visit. However, ensure that the actual visit date of refill of the client is recorded as outlined in the *standard operating procedures (SOPs)*.

3.5 FACILITY-BASED TREATMENT CLUBS (FTCs)

3.5.1 General Clubs

Facility-based treatment clubs can either be general groups, i.e., treatment clubs (FTCs) or for specific sub-populations (e.g., teen clubs). To maximize efficiencies in the delivery of ART care, a group of stable clients is enrolled in a treatment club where they receive their ART refills, symptom screening, psychosocial and adherence support. FTCs meet four times per year as a club and receive their treatment refill within the club. Following every other club visit, i.e., every six months, each member of the club will have a clinical consultation following their meeting. Clients will be enrolled into an FTC by an expert client (EC) or nurse.

Facility-based treatment groups serve the interest of a group. Through the group care model, services are provided at group level, resulting in shared general review time, as well as shared dispensing time. Clinically significant matters (e.g., an illness) should, however, be addressed at individual level through referral back to the mainstream care.

Note: The treatment clubs must create a forum for the group members to get to know each other and to comfortably discuss any matter that promote adherence to ART care. Group discussion topics should be varied and must be aimed at addressing the psychosocial needs, as well as knowledge gaps, of the group.

Table 3 summarises the services provided for facility-based treatment clubs.

Table 3: Summary of facility-based treatment clubs

Summary of facility-based treatment club service provision		
	ART Refill visit±	**Clinical Consultation**
What services	• ART refill • TB screening • Group counselling • Adherence support • IPT refill • CPT refill	• ART refill • IPT initiation or refill • CPT refill • TB Screening • Adherence Support • Clinical Reviews • Laboratory Monitoring (CD4 count, HB, Creatinine and LFTs) • ART Prescription • Cervical Screening* • NCD Screening • Mental Health • Family Planning
Where	• ART clinic	• ART clinic • Laboratory
When/ frequency	• Every 3 months	• Every 6 months
Who	• Nurse • Expert client/Adherence counsellor • Pharmacy Personnel	• Clinician (doctor or nurse) • Pharmacy Personnel • Laboratory Personnel
Indications for referral to mainstream care	• Presence of signs and symptoms of disease • Presumptive TB • Missed appointment/ defaulting treatment • Detectable VL • Pregnancy	

*Cervical screening should be done annually for female clients

There are a number of adaptations or flexibilities that can be utilized within the FTC model. The recommendation is for the group to have a maximum of 20 clients. The club can be facilitated by a clinician, nurse or expert client with appropriate training and support. Further, club members who develop a strong support network may consider becoming a community ART group, as described below.

Where appropriate, specific adaptations can also be made for sub-populations that require additional considerations. For example, clients with stable, non-communicable diseases may be eligible or "men's-only clubs" offered during convenient times for men (e.g., after hours) may be offered.

Note: Clubs sessions are health care worker driven and efforts should be made to have medicines brought to the club session/meeting room.

3.5.2 Special Clubs

3.5.2.1 Teen Clubs

Teen clubs are a specific adaptation of the club model designed to support adolescents. To be eligible for membership of a teen club, clients must be between 10 and 19 years of age and living with HIV. The eligibility criteria for teen clubs is flexible to support adolescents, including those with detectable viral loads. Teen clubs providing ART refills should have a clinician to support this services. Teen clubs should be divided by age and development level, and the size of the club should be adjusted based on the capacity of the facility. The services to be provided based upon the differentiated framework are illustrated in Table 4.

Table 4: Summary of Teen Club Refill Services

Summary of teen club service provision		
	ART Refill visit	**Clinical Consultation**
What services	• ART refill • TB screening • Group counselling • Adherence support • IPT refill • CPT refill	• ART refill • IPT initiation or refill • CPT refill • TB screening • Adherence support • Clinical reviews • Laboratory monitoring • ART Prescription • Cervical Screening* • NCD Screening • Family Planning
Where	• ART Clinic	• ART Clinic • Laboratory

Summary of teen club service provision		
	ART Refill visit	**Clinical Consultation**
When/ frequency	• Every month, but ART refills can be longer for stable adolescents	• Every 6 months for stable adolescents
Who	• Clinician and adherence support counsellor with training in adolescent friendly services	• Clinician (doctor or nurse) • Laboratory personel • Pharmacy personel • Expert client/Adherence counsellor
Indications for referral to mainstream care	• Presence of signs and symptoms of disease • Presumptive for TB • Detectable viral load • Missed appointments • Pregnancy	

3.5.2.2 Other clubs

Specific clubs can also be formed with special attention to the needs of the following population categories:

- Families and their children (e.g. Family Care clubs),
- Clients with well managed non-communication diseases (NCDs) on simplified treatment regimens (e.g. Diabetes Mellitus clubs),
- Mother and infant nutrition, and family planning methods (e.g. lactating women clubs).

These clubs enable specific procedures that may be required for such groups to be undertaken within the club.

3.6 COMMUNITY-BASED ART GROUPS (CAGs)

Community-based ART groups (CAGs) are a community-initiated strategy to reduce adherence barriers related to difficult access to care. CAGs have been commonly implemented with hard-to-reach groups and in rural settings. They rely on pre-existing social networks such as support groups. In urban settings, it is recommended that CAGs be promoted for groups of family members and workmates. A CAG is a self forming group and must have a minimum of two clients (referred to as *"treatment buddies"*) and a maximum of six clients. The efficiency (time and monetary) of this model is through cost sharing achieved by the rotation of clients (group representatives) in visiting the facility to collect ART treatment for group members.

The group members must meet at least 24 hours prior to the members' scheduled refill date. During this initial meeting, the booklets for group members are handed over to the group representative. The representative, with support by the group leader, will also ask general screening questions as elaborated in the standard operating procedures. Unwell group members should accompany the representative to the clinic so that their condition is reviewed.

Since every member must have at least one clinical review in six months with a nurse or a doctor, the length of period refill is dependent upon the size of the group. The smaller the group, the less frequent the refills, and the bigger the group, the more frequent are the refills, e.g., "treatment buddies" receive three-monthly refills while a larger group of six will receive monthly refills. Figure 4 provides an illustration on how the group size determines the refill appointment periods.

Number of members in group	Individual Member Clinical Visits					
	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
2	✓	x	x	✓	x	x
3	✓	x	✓	x	✓	x
4**	✓	x	✓	x	✓	✓
5**	✓	x	✓	✓	✓	✓
6	✓	✓	✓	✓	✓	✓

Key

✓	Group member scheduled for visit
x	No member scheduled to visit the clinic
**	The month(s) without scheduled member may differ but all members must be reviewed within 6 months

Figure 4: Timing of refill appointments depending on group size

After the visit to the facility, the group representative should meet with the group members within 24 hours preferably on the same day of collection to distribute and return the members' medicines and booklets. The facility-based HCWs must conduct random follow-up checks on group members to confirm timely receipt of medicines.

Figure 5 shows an artistic representation of a community ART group conducting a community group meeting before the visit by the group representative to the facility for medicine pick up. Table 5 provides a summary of services provided for community ART groups addressing the “What? Where? When? and Who?” questions of the implementation framework.

Source: MSF, Dec 2014

Figure 5: Artistic representation of a CAG conducting a group meeting

Table 5: Summary of community ART groups

Summary of community ART group service provision		
	ART refill (rotational)	**Clinical Consultation**
What services	• Peer support in group meetings • Medicine pick up by a group representative • Medicine distribution • IPT refill • CPT refill • TB screening by peers	• ART refill • IPT initiation or refill • CPT refill • TB Screening • Adherence Support • Clinical Reviews • Laboratory Monitoring (VL, CD4 count, HB, Creatinine and LFTs) • ART Prescription • Cervical Screening* • NCD Screening • Mental Health • Family Planning
Where	• Agreed community distribution point	• ART clinic • Laboratory
When/ frequency	• Every 1-3 months refill prescription depending on group size	• Every 3-6 months depending on group size
Who	• Medicine distribution: group representative • Peer support: all, group leader provides leadership role	• Clinician (doctor or nurse) • Pharmacy personnel • Laboratory personnel
Indications for referral to mainstream care	• Presence of signs and symptoms of disease • Presumptive TB • Detectable viral load • Missed appointment at facility • Missed appointment for group meeting • Pregnancy	

*Cervical screening should be done annually for female clients

Note: A member of a CAG (representative) must have a clinical and adherence review at each appointment visit. Facility HCWs can cross check with at least one other group member to verify that medicines were timeously distributed to the other group members.

3.7 ART OUTREACH MODEL

The purpose of the ART outreach model is to provide HIV care to underserved communities with the aim of taking services closer to clients' homes. In this model, clinical services are taken to the community and delivered by qualified health care providers. Therefore, all clients are eligible to access care from this model except acutely ill clients (i.e., it is not restricted only to stable clients). Acutely ill clients who require more frequent or intense clinical follow up and laboratory testing are up-referred to mainstream care (see Section 3.3).

The outreach model involves the movement of a clinical team from an accredited ART-providing health facility or public health unit to a location in the community that is convenient for both the health care system and clients. The community-based NGO should be linked to a facility to ensure successful referrals for clients who need mainstream care. Community establishments that are acceptable for outreach services include but are not limited to:

- School grounds
- Work places
- Churches
- Dip tanks
- Market places or grocery shops
- KaGogo Centres/ Health posts

Note: When conducting outreach services, outreach teams are encouraged to move out with as many health care services as feasible, as well as adequate capacity to deliver such services.

- A monthly schedule visit for outreach should be known by both the facility and the community.
- ART initiation should considered in this model

More outreach centres including Health posts (KaGogo Centres) may also serve as meeting places for community ART group members during their pre-medicine collection meetings as well as medicine distribution points for such groups. Where possible, ART outreach services should be integrated within

the existing outreach services provided by the facility to ensure efficiency and a comprehensive care package. To achieve this, facilities are encouraged to appropriately provide as many services as possible which including:

- ART initiation
- Management of non-communicable diseases (NCDs) for stable clients during outreach visits.
- Documented quality-assured point-of-care (POC) laboratory investigations should be provided and
- For those tests that are not POC, samples/specimens should be collected, labelled, logged and stored as per national sample transportation guidance until specimens are delivered to the laboratory.

The capacity of the mobile outreach teams to provide services in the community should be built through trainings and mentoring on documentation requirements, handling of laboratory specimens, provision of client health education and counselling, supply chain management and community management of NCDs. Supply chain systems must be in place to monitor and account for the movement, as well as correct monitoring of medical supplies in and out of the pharmacy. Table 6 overleaf provides a summary of ART outreach model services.

Table 6: Summary of the outreach model

Summary of the outreach model services		
	ART refills	**Clinical Consultation**
What services	• ART refill • TB screening • Group counselling • Adherence support • ART prescription • IPT refill • CPT refill	• ART refill • IPT initiation or refill • CPT refill • TB Screening • Adherence Support • Clinical Reviews • Laboratory Monitoring (CD4 count, HB, Creatinine and LFTs) • ART Prescription • Cervical Screening* • NCD Screening • Mental Health • Family Planning
Where	• Community setting	• Community setting
When/ frequency	• Variable, maximum of 3 monthly	• Variable, maximum of 6 monthly
Who	• Team of health care workers including clinical staff (doctors, nurses, pharmacy personnel, expert clients, adherence and HTS counselors)	• Clinician (doctor or nurse) • Pharmacy personnel • Laboratory personnel • Cough officers
Indications for up-referral to mainstream care	• Acutely ill or develops an OI • Missing outreach appointments (clients who miss their appointments should be called and asked to visit their clinics to pick up their medicines) • Pregnancy • Detectable VL	

3.8 SPECIAL CONSIDERATIONS

There are specific population groups that should also be considered when selecting the most appropriate models of ART delivery. Below, we summarize recommendations for certain population groups.

3.8.1 Considerations for children

Children living with HIV require frequent clinical support to ensure appropriate dosing and clinical monitoring. As a first step, facilities should consider having a "child" day at the clinic, where all children living with HIV are scheduled to visit on the same day of the week.

Sites should also consider "family centred clubs". Similar to the facility-based treatment clubs, family clubs are groups of 10-15 pairs of children and caregivers. Family clubs meet every month for group adherence support. Caregivers who are stable and HIV positive receive their ART. Children are weighed and have their dosage adjusted before having their medication prepared. This model allows for strong support networks to be developed and reduces the burden on clients as children and their caregivers have their appointment visits aligned.

3.8.2 Considerations for adolescents

Adolescents living with HIV face a number of challenges related to their HIV status and age. WHO recommends that "adolescent-friendly health services should be implemented in HIV services to ensure engagement and improved outcomes". Similar to the recommendation for children, as a first step, all facilities should have an "adolescent" clinical day where all adolescent visits are scheduled on the same day of the week. Further, staff who interact with adolescent clients should be trained to understand and handle adolescent issues.

3.8.3 Considerations for breastfeeding women

Treatment clubs for breastfeeding women can be formed and should aim to increase knowledge of women on infant feeding, family planning and mother and child nutrition. Pregnant women should receive ART refills during the ANC focused visits they should not have their refills in these models.

3.8.4 Considerations for key populations and clients with NCDs

FTCs, CAGs and outreach are designed to serve the interest of different groups. Facilitation for the creation of clubs and groups serving the interest of key populations and those with well-managed NCDs should also be prioritized to have their own clubs, CAGs or outreach ART refilling care points.

3.9 DEMAND CREATION

3.9.1 At Health Facilities

Facility health care workers (HCWs) shall create demand for the utilization of the services through client health education. Clients should be empowered to choose their preferred model for accessing the ART services and the HCW must conduct a clinical and psychosocial assessment to determine if the client is eligible according to the standard operating procedures. *Passive enrolment* involves clients asking to be enrolled in care models. *Active enrolment* involves health care workers actively assessing client eligibility and offering them the service model options. Both passive and active recruitment is recommended. Figure 6 summarizes the enrolment process for the ART service delivery models and Table 7 provides a summary of the models to which clients can be enrolled.

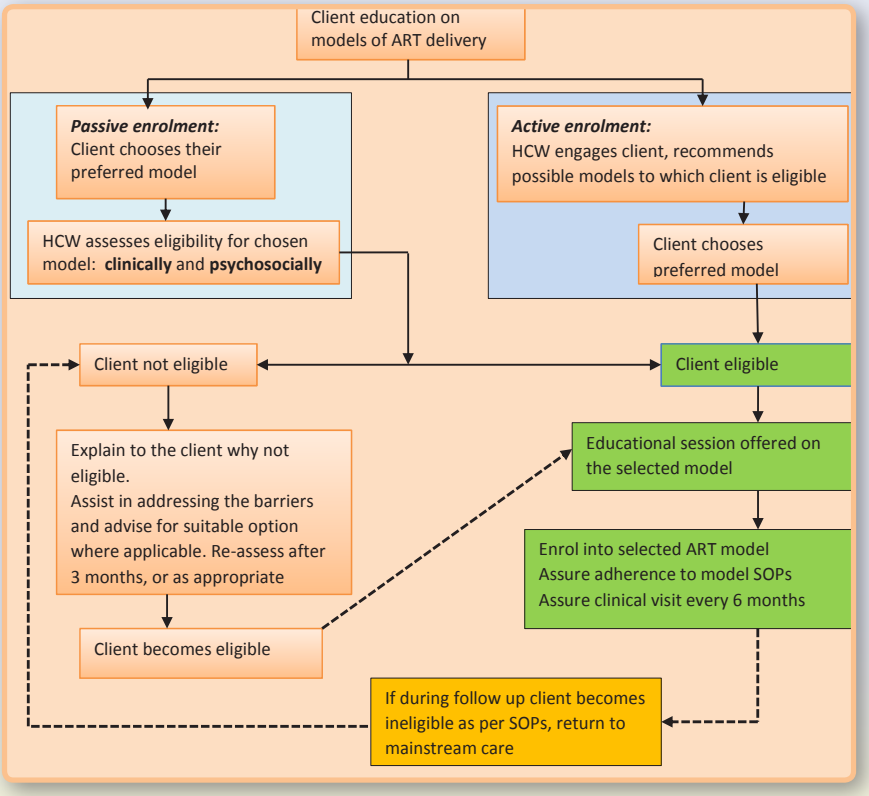


Figure 6: Process for assessing eligibility and enrolment to ART delivery models

3.9.2 At Communities

Existing networks especially support groups of PLHIV, workplace and key populations should be sensitized to create demand in the community.

Table 7: Summary of models of care in Swaziland

Models of ART delivery in Swaziland	Overview	Number of patient visits/ year	Priority implementation site	Benefits
Mainstream Care	For clients who require close clinical attention and/or monitoring	Variable	All ART sites	Intense clinical services available
Outreach*	Mobile teams from facilities take ART services to the community	1-12, dependant on number of outreach visits facility can afford	Hard-to-reach areas	Increasing access, reduced time and cost to clients
Fast-track	Clients skip the consultation and directly collect their ART refill	4 (2 ART refill visits + 2 clinical consultations)	High-volume sites, crowded facilities, where clients have constrained working hours & need early morning refills	Reduced waiting time, decreased congestion
Facility Based Treatment Clubs	Up to 20 clients meet for group counselling and ART collection	4 (2 ART refill visits and group + 2 clinical consultations and group)	High-volume sites, crowded facility, where clients have constrained working hours & need early morning refills, special groups/ populations	Reduced waiting time, decreased congestion, peer support
Teen Clubs	Groups of adolescents clients meet for group counselling, psychosocial support and, if stable, ART collection	Monthly teen club meetings, ART dispensed every 3 months for stable adolescents	All sites	Increased peer support, psychosocial support
Community Adherence Groups (CAGs)	Groups of 2-6 clients who take turns to visit the facility to get refills on behalf of the other group members	Variable – 2-4 clinical visits consultations at the facility (4-12 CAG meetings at community)	Where there are pre-existing networks, where clients stay in hard-to-reach areas, families	Increased peer support, decreased visits to the facility, reduced cost

*Clients who are acutely ill, develop an OI, miss outreach appointments, or who are pregnant, or who have detectable VL should be referred to mainstream care.

Community delivery points do not require any specialized infrastructure. The delivery point should be convenient for the health care worker and the client, as well as the community in which such service is delivered. Figure 7 shows the models of care under the two settings.

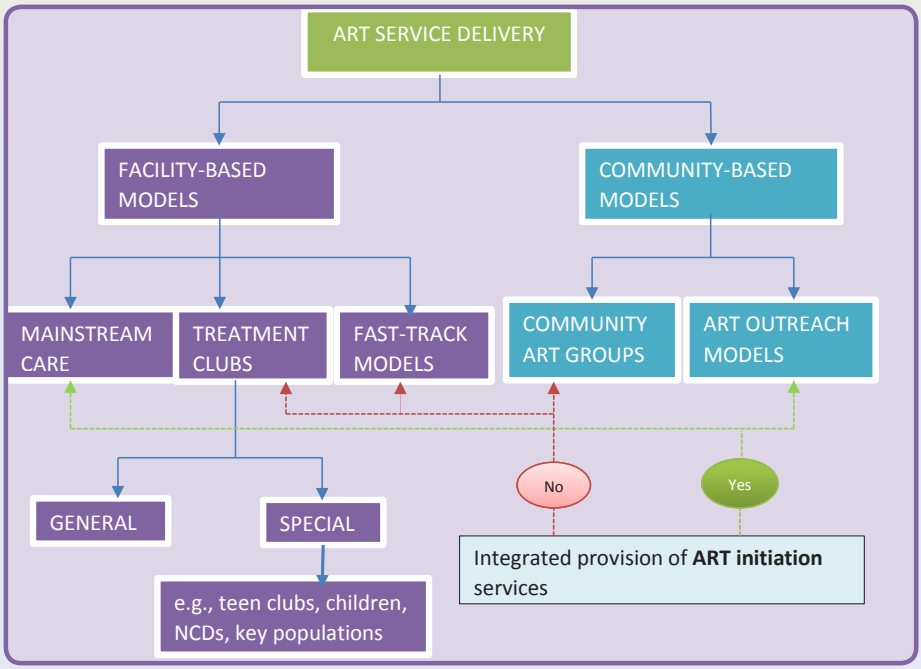


Figure 7: Summary of ART delivery models

4 SCALING UP COMMART ACTIVITIES

4.1 STRENGTHENING HEALTH SYSTEMS TO SUPPORT COMMART SCALE UP

According to the Swaziland HIV Investment Case (SHIC) 2014, scaling up ART will improve the health of PLHIV and avert new HIV infections through suppressed viral load in PLHIV. An estimated average 10,000 deaths per year were averted since the introduction of ART in 2003. The prevention gains of using ART in HIV positive clients are high considering that 85% of PLHIV on ART are virally suppressed. The SHIC proposes the adoption of Universal Access to HIV Treatment ("test and start") and intensified HIV diagnosis and retention in care. Modelling exercises show that this will avert 81% new infections in children aged 0 to 14 years and 43% in people over 15 years during 2014-2030. AIDS-related deaths among children will also reduce by 91%, but deaths among those older than 15 years will not be greatly affected since a majority of adults are already on lifelong treatment. Strengthening community-based testing strategies and universal access to ART through innovative ART service delivery models will be central to the success in achieving the 90-90-90 UNAIDS targets through improving access to care, as well as retention in care using client-centred models.

It will be essential that as the Swaziland programme increases access to these models of care, routine viral load monitoring is offered to these ART clients, to ensure viral suppression. Viral load monitoring in CommART offers outstanding opportunities to engage in operational research that are in line with the national research agenda as well global HIV priorities.

Scaling up ART also offers long-term cost savings in would-be spending on those infections averted and real economic returns in the form of increased labour productivity, subdued costs of orphan care and deferred medical care for opportunistic infections for those on early treatment.

Swaziland, in scaling up the ART service delivery models, requires greater focus on community service delivery points, with leadership and coordination at all the levels of health service delivery. National-level coordination will ensure establishment of a function to coordinate community HIV service delivery points. Systems strengthening at the regional level will ensure RHMT

capacity building for coordination in the implementation of diverse models of ART delivery. Facility support will ensure investments in capacity building of health care providers to improve collaboration within facilities and inter-departmental collaborations. The clinical, laboratory, pharmacy and monitoring and evaluation units will have to create systems for supporting scale up of these models. Community systems will be supported to ensure greater involvement of PLHIV and community structures to create an enabling environment for successful implementation of community-based ART models.

4.2 PHARMACY AND MEDICINE SUPPLY CHAIN SYSTEMS

An efficient and secure process for storage, distribution and appropriate utilization of antiretroviral (ARV) medications is critical to ensure a reliable medication supply at all levels. The four new ART delivery models of care can add pressure to the existing ART supply chain by introducing need for pooled distribution of medicines to clients if not properly planned.

ARV medicines will be managed at health facilities to enable effective distributions for the different ART delivery models. Successful management of the stock and supply chain is necessary for successful implementation of these models.

- ✓ As a general rule, compliance with the established national and health facility pharmaceutical standard operating procedure manual at all levels, while adapting and finding specific solutions to bottlenecks in the implementation of these practices, is essential. For example, **preparing medicines for ART clubs or ART outreach and/or designated fast-track distribution points all facilitate the implementation of the models and partly ensures that the aim of the new models is realized.** Additional requirements include:
  - Correct and secure packaging
  - Transport of medicines at peripheral health facilities/communities to support proper inventory control
  - Implementation of inventory management practices
  - Maintaining of an up-to-date register for all prescriptions and dispensaries
  - For all models, it is important that clients only receive a 1-3 month supply of ARVs. This decreases pressure on the ARVs supply chain. For community ART groups the quantity dispensed depends on the size of the group and should allow each member of the group to have at least one clinical review every 6 months.

- It is critical that reports about ART consumption are kept up to standard to inform stock management at the facilities and eventually at national levels.

✓ ART safety is also a concern: education on storing ART correctly, collecting ART for others, etc., must be provided and any irregularity should be managed accordingly. Regional and national structures can be of help in these cases. In different settings, the pharmacy procedures should be managed by the facility-based multidisciplinary teams (inclusive of pharmacy and laboratory personnel) to assure adequate attention to the supply chain issues.

Each model may have specific needs and procedures for ART management that have to be adapted to the implementation site. However, some general guidelines are provided here:

Pharmacy procedures for ART delivery models

- In different settings, the pharmacy procedures should be managed by the facility-based multidisciplinary teams (with stewardship of pharmacy personnel) to assure adequate attention to the supply chain issues.
- Pay attention to long-term ART side-effects, co-treatments, etc. If any concern arises, the client can be referred to mainstream care.
- Ensure that the **Right** ARVs are given to the **Right** client at the **Right** time at the **Right** dose in **Good** condition

4.3 LABORATORY PROCEDURES

Laboratory monitoring of HIV infection, staging of disease progression, monitoring of therapies, including management of antiretroviral toxicities, and the response to therapy are essential components of ART management. General laboratory monitoring for chronic ART care will follow requirements described in the Swaziland Integrated HIV Management Guidelines 2015 (see Chapter 4, Antiretroviral therapy) [2].

The Swaziland Health Laboratory Services will provide the laboratory services for the ART program within the existing laboratory network, consisting of main laboratories located in hospitals and health centres and mini-laboratories located in clinics and outreach sites.

The existing national sample transport system will facilitate the transportation of specimens from lower-level facilities to higher-level testing laboratories, including the return of client results. Laboratory specimen collection, handling,

storage and transport will follow the established facility specific or generic laboratory handbook.

General laboratory procedures for chronic ART care for stable adult clients are described in the Swaziland Integrated HIV Management Guidelines 2015 [2] and include CD4 cell count, viral load, haemoglobin, creatinine and liver function tests. CD4 cell count and viral load monitoring timing are summarized in Figure 8.

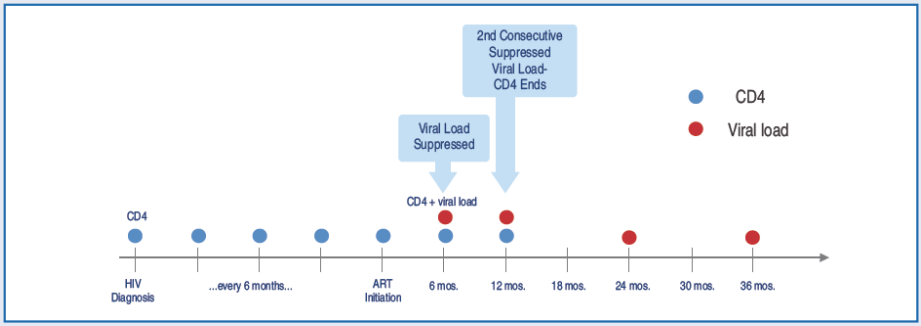


Figure 8: Timing of viral load and CD4 monitoring of stable adult clients

Communicating the Laboratory Results

All laboratory results and other client information should be communicated directly with the client to maintain client confidentiality. In the case of groups or clubs whose members receive routine laboratory tests at the same time, results can be disseminated to the group as "normal" to all **if** they are within normal ranges for the group members. Abnormal results can only be communicated to the specific individual. Clients will still have the opportunity to have their results discussed in detail during the individual counselling sessions. Clients are free to share their own results with their peers during club or group meetings.

4.4 MONITORING AND EVALUATION (M&E) SYSTEMS

4.4.1 Data Tools Use

Existing tools should be used to monitor client care. These include the *chronic care file, the ART patient booklets, ARV refill encounters (prescription forms) and the appointment registers*. Data tools will be revised to accommodate the new models of ART, as well as grouping of clients. Existing tools will be used in patient/client tracking and the roll out of client management information system (CMIS) will facilitate the monitoring of the models of ART service delivery.

To ensure proper registration and efficient handling of treatment clubs and community ART groups, specific registers will be designed and this will improve management of clubs and groups within a facility as well as reporting.

4.4.2 M&E Procedures

The general procedures for M&E must be followed. These procedures in relation to CommART are summarized here:

M&E Procedures

- **Document in the chronic care file the willingness of the client** to be part of the chosen model.
- **Complete ART prescription and request laboratory investigation when due**.
- **Ensure appointment dates** are given appropriately and follow missed appointments in all the models as done in the mainstream care utilizing available client tracking tools.
- Ensure clients' visits are recorded in appropriate tools and systems to avoid false defaulters.

4.4.3 Indicators under ART delivery models

Current national HIV care and treatment indicators will not significantly change due to roll out of ART delivery models. Additional indicators will be adopted to monitor implementation progress of ART delivery models. Through incorporating the model of care as one of the variables for data collection, existing indicators will be disaggregated by the model of care and outcomes can also be analysed according to the model of care.

To facilitate management of community ART groups and facility-based treatment clubs, registration books will be developed. These registers will facilitate the monitoring and evaluation of the number of groups a facility has formed as well as that of group and club members themselves.

The following will be monitored:

- Retention in care
- Viral suppression
- Number of CAGs and FTCs in a facility
- Compliance to medicine pick up time
- Dynamic of changing models by clients

Table 8 summarizes specific indicators to monitor the utilization of models of ART service delivery.

Table 8: Indicators for models of ART service delivery

Indicator	Numerator	Denominator	Frequency	Data source
Number of clients enrolled in a specific model in a reporting period	Number of clients enrolled in a specific model	Total number of active clients seen in the reporting period	Quarterly	- Clubs/ CAG registers - CMIS, APMR
Number of registered FTCs in a facility at the end of reporting period	*Number of registered FTCs at the end of reporting period*	*Not applicable*	*Quarterly*	*Club/CAG register*
Number of registered CAGs in a facility at the end of reporting period	*Number of registered CAGs at the end of reporting period*	*Not applicable*	*Quarterly*	*Club/CAG register*
Proportion retained in a specific model at (i) 6 months (ii) 12 months (iii) 36 months	Number of clients in care at (i) 6 and; (ii) 12 months (iii) 36 months from the beginning cohort	Number of clients enrolled in the model at the start of the reporting period (i.e. the beginning cohort)	(i) Semi-annually (ii)Annually	CMIS, APMR
Number of clients due for VL who receive VL testing (disaggregated by models: Mainstream, FTC, CAG, and Outreach)	Number of clients due for VL load with VL testing done	Number of clients due for VL testing	Annually	CMIS/APMR
Proportion of clients tested for VL who are virally suppressed (disaggregated by ART models: Mainstream, FTC, CAG, and Outreach)	Number of clients tested for VL who are virally suppressed during the reporting period	Number of clients who had VL testing done	Annually	CMIS/APMR
Proportion of clients changing ART models at least once during the reporting period	*Number of clients who changed models at least once during the reporting period*	*Number of clients enrolled into ART models during the reporting period*	*Annually*	*CMIS/ APMR Club/CAG register*
Proportion referred back to mainstream care due to becoming ineligible with specific model	Number of clients referred back to mainstream due to ineligibility during the reporting period	Number of clients ***reviewed*** at least once in the model during a reporting period	Annually	CMIS, APMR Club/CAG register

**Indicators in italics are to be monitored at facilities*

4.5 SERVICE DELIVERY INTEGRATION

This health care delivery model may assist in increasing quality and access to other programs that are key to the MoH; specifically to integrate IPT services, chronic NCDs and family planning. If programs take this route, it is necessary that experiences are documented and best practices shared whenever possible to influence scale up at national level.

4.6 TRANSITION BETWEEN THE ART DELIVERY MODELS

The rationale of different models of ART service delivery ideally serves the ART client through the course of his/her life. As personal circumstances change, clients may need to transition from one model to another and even change geographical regions, as illustrated in Figure 9. Special attention to maximize retention in care and assure documentation processes will be made to avoid loss or duplication of crucial data used in the national level processes.

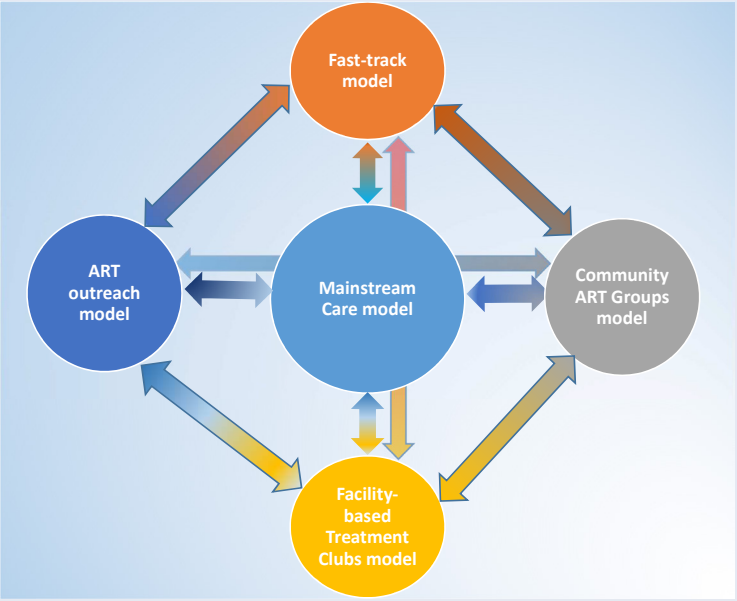


Figure 9: Transition between ART delivery models

4.7 ENGAGEMENT AND EMPOWERMENT OF ART CLIENTS IN CARE

The models of ART service delivery heavily rely on the education and engagement of the ART clients to play an active role in their care for many years. Issues like stigma, confidentiality, and trust in their peers and the health system, as well as concepts related to individual and collective responsibility or transition between models of care, are critical for ensuring successful long-term ART outcomes. It is key that programs implementing these models of care pay special attention to sustained activities that contribute to this component.

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6 APPENDIX

6.1 SUMMARY OF INCLUSION CRITERIA BY MODEL OF ART DELIVERY[γ]

CRITERIA	MODEL OF ART DELIVERY				
	Fast track	Treatment Club	Teen Club*	CAG	Outreach
Adult (18+years)	X	X	N/A	X	X
Adolescent (10-19 years)	N/A	N/A	X	N/A	X
12 months on ART	X	X	X	X	N/A
Undetectable viral load (two consecutive viral load measurements are undetectable with the latest one taken within the last 6 months of eligibility date) OR CD4 above 350 OR Evidence of rising CD4	X	X	X	X	N/A
No current TB	X	X	X	X	X
Not currently pregnant or breastfeeding±	X	X	X	X	X
No other medical condition requiring intensified clinical consultations	X	X	X	X	X
At least two ART visits at the facility	X	X	X	X	X

[γ]All clients are eligible for the mainstream model.
*Only adolescents with **undetectable** viral load are eligible for ART refills within a Teen Club. However, adolescents with high viral load will be encouraged to participate in the group but receive their ART refill through mainstream care with engagement of the parent/guardian

Important Note: Undetectable viral load: Refers to test results which show that the virus is below the limit of detection (this depends on the test machine platform used and can be <20, <100)

NOTES:


SWAZIS AND AMERICANS
IN PARTNERSHIPS TO FIGHT HIV/AIDS
PEPFAR


DEPARTMENT OF HEALTH & HUMAN SERVICES USA


CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION


URC
UNIVERSITY RESEARCH CO., LLC


ICAP
Global. Health. Action.
COLUMBIA UNIVERSITY
Mailman School of Public Health


USAID
FROM THE AMERICAN PEOPLE


AIDSFree
Strengthening High Impact Interventions
for an AIDS-free Generation


msh
Management Sciences for Health


psi
Swaziland
Healthy lives. Measurable results


MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS


BAYLOR COLLEGE OF MEDICINE
Children's Foundation
SWAZILAND


CLINTON
HEALTH ACCESS
INITIATIVE


IAS


World Health
Organization
REGIONAL OFFICE FOR Africa