



DIFFERENTIATED CARE FOR HIV:

A DECISION FRAMEWORK FOR ANTIRETROVIRAL THERAPY DELIVERY

It's time to *deliver* differently.



A woman wearing a purple knit cap and a white t-shirt is sitting in a red upholstered armchair. She is holding a small green object in her hands. The room has a textured, light-colored wall and a colorful patterned tapestry hanging on the left. In the foreground, there is a table with a white tablecloth, a bowl of oranges, and some papers. Another red armchair is visible in the foreground on the right.

Differentiated care: Relevant globally,
urgently relevant in sub-Saharan Africa.

It's time to *deliver* differently.

This *Decision Framework* focuses on antiretroviral therapy (ART) delivery in sub-Saharan Africa. The concepts presented here are applicable to a global audience. Further iterations will be developed to support other parts of the treatment cascade, specific sub-populations and other contexts. **This is the first step.**

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ABBREVIATIONS

ACs	Adherence clubs (South Africa)	NGO	Non-governmental organization
ART	Antiretroviral therapy	OI	Opportunistic infection
ARV	Antiretroviral	PEPFAR	President’s Emergency Plan for AIDS Relief (US)
CAG	Community ART groups	PLHIV	People living with HIV
CDC	Centers for Disease Control and Prevention (US)	PMTCT	Prevention of mother-to-child transmission
CDDPs	Community drug distribution points (Uganda)	PODIs	Points de distribution communautaires (DRC)
CARGs	Community ART refill groups (Zimbabwe)	PWIDs	People who inject drugs
COIM	Co-morbidity or co-infection	SOPs	Standard operating procedures
EMR	Electronic medical record	SW	Sex worker
FAQs	Frequently asked questions	TASO	The AIDS Support Organization (Uganda)
FDC	Fixed-dose combination	TG	Transgender
HCW	Health care worker	UNAIDS	Joint United Nations Programme on HIV/AIDS
IAS	International AIDS Society	USAID	United States Agency for International Development
M&E	Monitoring and evaluation	VL	Viral load
MACs	Medication adherence clubs (Kenya)	WHO	World Health Organization
MSF	Médecins Sans Frontières		
MSM	Men who have sex with men		

EXECUTIVE SUMMARY



Client

I have to walk a really long way to get to the clinic and still have to go every month to collect my ART – but I feel well and have other places to be.



National ART manager

We need to reach 90-90-90 and implement “treat all”. How are we going to get there with the resources we have?

These concerns from a client and an ART programme manager are at the heart of how we continue to scale up ART services. Worldwide, 36.7 million people are living with HIV and 17 million people are receiving ART. With the introduction of the WHO 2015 recommendation to “treat all” HIV-positive individuals with ART, health systems, often already under extreme pressure due to lack of human and financial resources, will need to re-examine how ART care is delivered.

Differentiated care is aimed at providing a framework for this re-examination of service delivery. **Differentiated care is a client-centred approach that simplifies and adapts HIV services across the cascade to reflect the preferences and expectations of various groups of people living with HIV (PLHIV) while reducing unnecessary burdens on the health system. By providing differentiated care, the health system can refocus resources to those most in need.**

Over the past decade, a range of innovative strategies to enhance retention and adherence to ART have been documented. These programmatic adaptations have been described as ways of “differentiating” how ART is delivered. This Decision Framework focuses on the provision of **differentiated ART delivery** and more specifically focuses on service models for stable clients. The framework is aimed at supporting HIV programme managers at the

national and district level to build models of ART delivery and guiding them on how to prioritize the implementation of differentiated ART delivery to address specific local programmatic challenges. The Decision Framework is supported by an online compendium of toolkits and best practices available at www.differentiatedcare.org.

In Part 1, an overview of differentiated care is provided. The case is made for why the Decision Framework is focusing on ART delivery and models of stable clients. Part 2 describes a 5-step plan to guide ART programme managers to prioritize which interventions to implement in response to the specificities of their own context. In Part 3, the key “elements” of a client, including their clinical characteristics, sub-population and context, are outlined. The “building blocks” of service delivery are presented in Part 4 with illustrative examples. Part 5 provides a conclusion followed by answers to frequently asked questions about differentiated ART delivery.

To implement “treat all”, the HIV community now needs to do business differently. Coordinated support from both donors and implementing agencies is needed to take on this challenge. We hope that this Decision Framework will be a practical tool to guide how to *deliver* differently with the aim of providing our clients with a quality HIV service when, where and how they want it.

“I believe we can end HIV by 2030 if we work together in harmony and without discrimination.”

- Jacquelyne Alesi, PLHIV, Uganda

COMMON CHALLENGES: WHY IT'S TIME TO DELIVER DIFFERENTLY



CLIENT PERSPECTIVE



Why must I queue to see a nurse and queue at the pharmacy if I'm only coming to collect my ART refill?

How can we support clients who are failing treatment if we are overwhelmed with adherent clients?



If I'm travelling so far to the clinic, why can't I collect treatment for others in my community?

How can we offer ART to all HIV-positive people if we don't get additional resources?



HEALTH CARE WORKER PERSPECTIVE

Why should I keep taking treatment if I feel healthy and the clinic is full of people who are sick?

How am I going to provide quality care to 100 clients today?



How will I keep my job if I have to spend a day a month at the clinic?

Why are new clients, sick clients and adherent clients all coming to the clinic at the same frequency?





PART 1

INTRODUCTION

WHAT IS DIFFERENTIATED CARE FOR HIV?

Over the past 15 years, innovative strategies to improve retention and enhance adherence have been piloted. In many high-prevalence countries, implementing partners have supported models of differentiated ART delivery, largely for stable clients. To support scaled-up and coordinated implementation, national programmes will have to provide guidance on differentiated ART delivery, endorse enabling policies and prioritize differentiated ART delivery.

Developed through technical and community consultations, the following statement outlines the definition of differentiated care:

What is differentiated care?

Differentiated care is a client-centred approach that simplifies and adapts HIV services across the cascade to reflect the preferences and expectations of various groups of people living with HIV (PLHIV) while reducing unnecessary burdens on the health system. By providing differentiated care, the health system can refocus resources to those most in need.

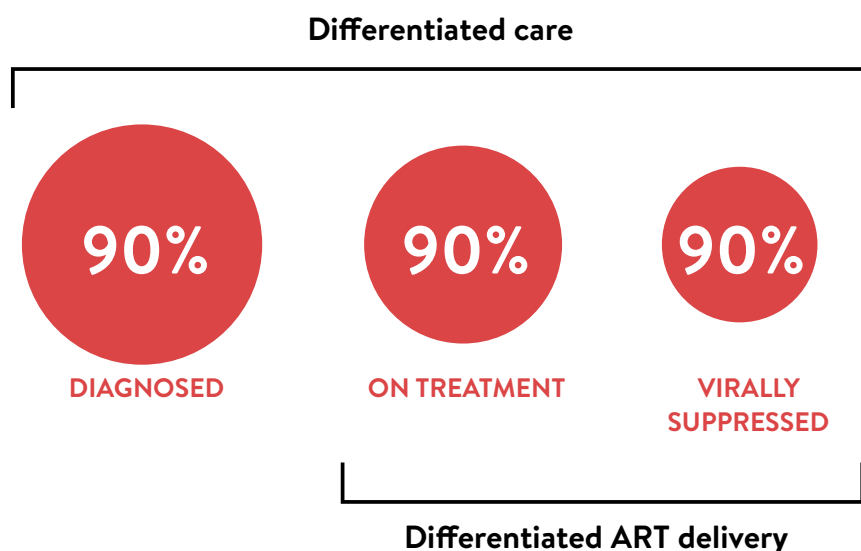
Differentiated care is aimed at enhancing the quality of the client experience, putting the client at the centre of service delivery while ensuring the health system is functioning in both a medically accountable and efficient manner. The central driver to adapting service provision is the client's

needs. From that starting point, one must also consider the specific client population(s) within which that client can be classified (e.g., pregnant women, adolescents, men, key populations) and the context where he/she lives and seeks care (e.g., urban or rural, conflict setting). These elements are further described in Part 3.

Differentiated ART delivery is a component of differentiated care

Differentiated ART delivery is a component of differentiated care. The principles of differentiated care are presented within the Decision Framework in the context of ART delivery (Figure 1). Differentiated care, however, applies across the HIV continuum and all three of the 90-90-90 targets (90% of people living with HIV should know their status; 90% who know their status should be on ART; 90% of those on ART should be virologically suppressed) (1). In other words, differentiated care is comprehensive: from testing people unaware of their HIV status to viral suppression of HIV clients enrolled in care. Further, differentiated care should be leveraged beyond HIV for other chronic conditions. PLHIV with chronic co-morbidities may have better health outcomes if their non-HIV health services are incorporated within their differentiated HIV care model.

Figure 1: Differentiated care is a concept that is applicable across the HIV care continuum



Differentiated care applies across the HIV care continuum. This Decision Framework focuses on differentiated ART delivery.

OBJECTIVES OF THE DECISION FRAMEWORK

The objectives of the Decision Framework for differentiated ART delivery are to provide:

- A **background** to the principles of differentiated care and ART delivery
- A **menu of examples** of differentiated ART delivery
- Guidance on how to **prioritize** which elements of differentiated care should be implemented in a given setting.

The framework is aimed at both national and district ART programme managers and, where appropriate, implementing partners, donors and others supporting or working with the national ART programme.

The Decision Framework is supported by an online compendium of toolkits and best practices available at www.differentiatedcare.org. The toolkits available on the website describe best-practice examples from the field of differentiated ART delivery, alongside practical tools to support implementation (e.g., standard operating procedures, job tools, M&E tools, training materials).

WHAT ARE THE CORE PRINCIPLES OF DIFFERENTIATED CARE?

Client-centred 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-centred care to improve the quality of HIV care services.

WHO Guidelines

Box 1: Recommendations on client-centred care

“Focused and organized around the health needs, preferences and expectations of people and communities, upholding individual dignity and respect, especially for vulnerable populations, and engage and support people and families to play an active role in their own care by informed decision-making.” (2)

To date, most ART services have been provided as standalone vertical services. However, with a growing and maturing cohort of clients, a more integrated approach is required to enable clients to have sustained viral suppression.

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. Differentiated care 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.

The guiding principles for differentiated ART delivery from the Swaziland National AIDS Programme can be found in Annex 1.



I have to walk a really long way to get to the clinic.

Mary, a client

Meet Mary on page 13

A FOCUS ON DIFFERENTIATED ART DELIVERY AND STABLE CLIENTS

The *Decision Framework for ART Delivery* is focused specifically on clients who are on treatment. This document places emphasis on differentiated models of ART delivery for stable clients.

Differentiating ART delivery

While the principles of differentiated care apply across the HIV cascade and indeed extend to other diseases (Figure 1), there is significant momentum, policy guidance and evidence for scaled-up implementation of differentiated delivery for stable clients. As ART cohorts have matured, a growing number of people in treatment programmes are virally suppressed and do not require frequent clinical and laboratory monitoring. By revising the models of delivery for stable clients, their retention and suppression will be improved. Further, by reducing the clinical burden of stable clients, these resources can be reallocated to clients most in need.

The *Decision Framework for ART Delivery* highlights differentiated models of ART delivery for stable clients with examples coming from high-prevalence, resource-constrained settings in sub-Saharan Africa. Details of how to define a stable client are outlined on this page. The majority of documented examples of differentiated ART delivery are for stable clients. In addition, and consistent with the burden of disease, the evidence is from high-prevalence settings in sub-Saharan Africa. With that focus, we have developed this structure that can be utilized for future adaptations. In other words, this is the first step.

Further iterations of this document will be developed to support other parts of the treatment cascade (e.g., testing and linkage, ART initiation), specific sub-populations (e.g., adolescents) and other contexts (e.g., low-prevalence settings). Differentiated care may have the largest potential benefit for client groups that currently have poor outcomes. Further implementation science is needed to understand how changes to models of delivery could improve outcomes for under-served client groups.

Definition of a “stable” client

Stable clients are those PLHIV on ART who are adherent and do not require frequent clinical consultation. However, the definition of a “stable” client has varied across the implemented differentiated models of ART delivery. It is dependent on access to resources, such as routine viral load monitoring, and was debated during the WHO guideline process.

In the 2016 Consolidated Guidelines, WHO published the following definition of a stable client:

WHO Guidelines

Box 2: Definition of stable individuals

“Stable individuals are defined 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.” (2)

There are examples of less strict definitions of “stable”. For example, in Zimbabwe and South Africa, clients are eligible for differentiated ART delivery following their first suppressed viral load 3–6 months after ART initiation. In differentiated delivery models from The AIDS Support Organization (TASO) in Uganda, clients are eligible after just 10 weeks of ART (see page 25).

Most definitions of stable include a minimum duration on ART and a measure of adherence or treatment success. A minimum definition is recommended and then districts and facilities can adapt the criteria. For example, the minimum definition may include clients being on treatment for at least one year and could be adapted to being on treatment for six months if the client has a suppressed viral load.

WHY DO WE NEED TO DIFFERENTIATE ART DELIVERY?

1. To improve clients' lives

Most importantly, differentiated ART delivery can improve the quality of care and access to treatment for PLHIV. It can better reach underserved populations and address issues surrounding stigma and discrimination that many PLHIV face when accessing HIV services. Differentiated ART delivery is responsive to the needs of PLHIV and often results in increased levels of adherence, client satisfaction and client empowerment (3).

2. To improve health system efficiencies and outcomes

Supporting clients to initiate ART is critical, but it is not enough – retention in care and adherence to effective treatments is required to achieve viral suppression. Retention data from many countries demonstrate that ART programmes globally face substantial challenges in maintaining clients on ART (4) with viral suppression (5). Data from sites where differentiated ART delivery has been adopted highlight that such interventions can be part of improving retention and adherence and achieving the second and third “90” outlined in the UNAIDS global targets (Figure 1) (6, 7).

When ART was first provided in resource-limited settings, the majority of clients were treatment naïve and presented

with advanced disease, and care was delivered in the same way for all clients, regardless of duration on ART, co-morbidities or other inter-current medical needs.

3. To support “treat all”

Worldwide, 36.7 million people are living with HIV and 17 million people are receiving ART (8). With the implementation of the WHO 2015 recommendation to “treat all” HIV-positive individuals on ART (2), health systems, often already under extreme pressure due to lack of human and financial resources, will have to re-examine how ART care is delivered.

4. To reach 90-90-90

Although there are 17 million people on treatment, treatment coverage is still below 50%. Clients who are not currently on treatment need to access ART within a service delivery model that meets their needs and expectations. Further, the health care system must support double the number of ART clients.

As highlighted within the most recent WHO guidelines, different packages of care are essential to address these diverse needs – **it's time to deliver differently.**



I need to improve the retention outcomes in my district.

Andrew
Meet Andrew on page 10



I feel healthy and need to be at work.

John, a client
Meet John on page 12

FOUR GENERAL MODELS OF DIFFERENTIATED ART DELIVERY

As HIV programmes in resource-limited settings have grown, the number of facilities providing care has increased dramatically. In addition to this decentralization, ART delivery has increasingly utilized task shifting. More recent innovations in ART delivery, or differentiated models of ART delivery for stable clients, can be categorized into four models:

- In **facility-based individual models**, ART refill visits have been separated from clinical consultations. When clients have an ART refill visit, they bypass any clinical staff or adherence support and proceed directly to receive their medication (e.g., appointment spacing and “fast-track” ART refill model from Malawi, pg. 29).
- **Out-of-facility individual models** describe those where ART refills and, in some cases, clinical consultations are provided to individuals outside of health care facilities (e.g., PODI model in DRC, pg. 18, CDDPs in Uganda, pg. 25). These models are inclusive of community pharmacies, outreach models and home delivery.
- In **health care worker-managed group models**, clients receive their ART refills in a group and either a professional or a lay health care staff member manages this group (e.g., adherence clubs in South Africa, pg. 23, teen clubs in Swaziland, pg. 17, MACs in Kenya, pg. 16). Health care worker-managed groups meet within and/or outside of health care facilities.
- In **client-managed group models**, clients receive their ART refills in a group but this group is managed and run by clients themselves (e.g., CARGs in Zimbabwe and CAGs in Mozambique, pg. 27). Generally, client-managed groups meet outside of health care facilities.

Within these models, all clients continue to have clinical consultations as part of their package of care (see page 11 and Annex 8 for more detail).

Multiple models can work in parallel so that a client can move between them during the course of their lifetime. Further, the models are flexible to accommodate clients who may want to or require up referral. By being up referred, the intensity of care is increased to reflect the increased clinical needs of the client.



I always feel rushed and am seeing too many clients. Why do I need to see my stable clients every month?

Jane, a nurse
Meet Jane on page 10



PART 2

BUILD A MODEL OF DIFFERENTIATED ART DELIVERY

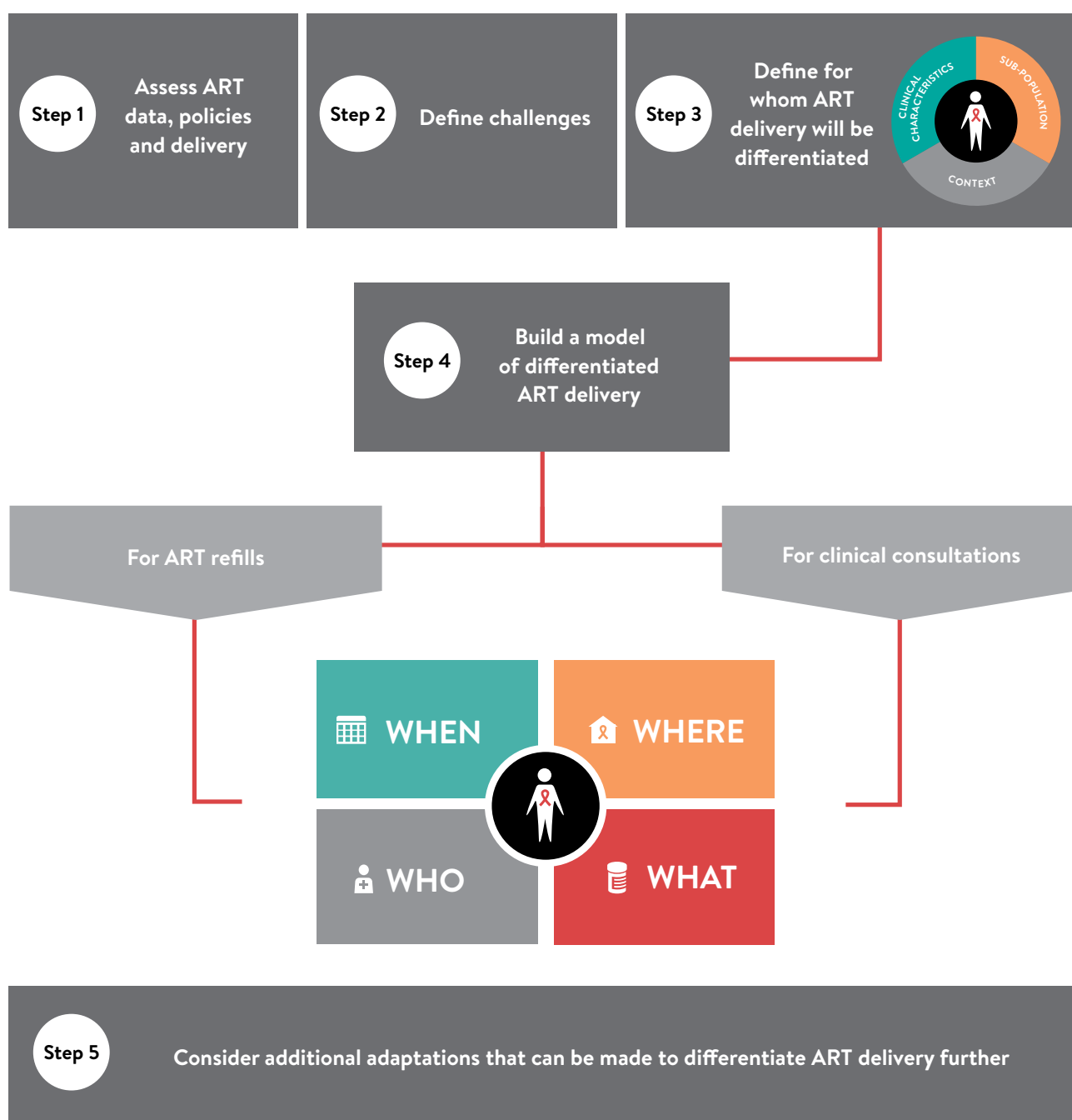
THE 5-STEP APPROACH TO DIFFERENTIATED ART DELIVERY

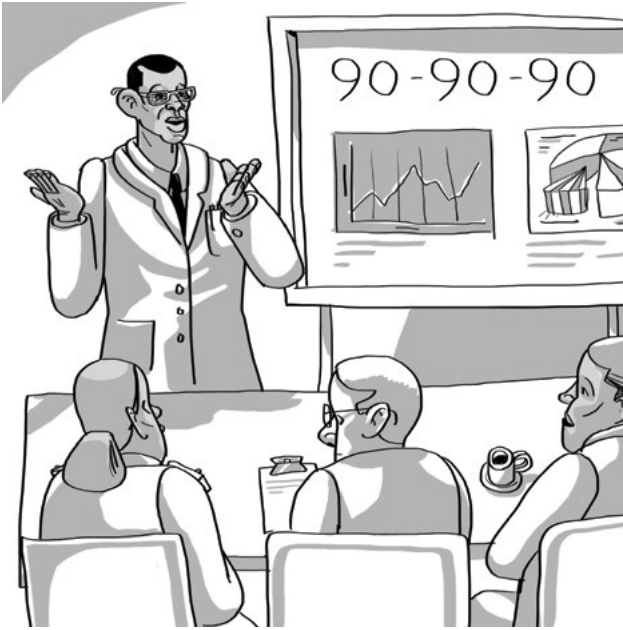
Now you will want to know how to prioritize differentiated ART delivery for stable clients in your setting. Depending on the setting, certain decisions may have to be made at national level and some locally. For example, what may work in an urban setting may not be suitable in a rural setting and vice versa.

National policy guidance should be developed and adopted at the district level. It is strongly encouraged that a decision made regarding the most appropriate model(s) is based on context and selected at the facility level to ensure ownership by both the community and health care workers.

The following 5-step plan can guide ministries of health in planning how to differentiate ART delivery (Figure 2).

Figure 2: 5-step approach to differentiated ART delivery





Meet Andrew

Andrew is a district ART manager. He has just attended a national review meeting where concerns were raised about poor ART retention in his district. His health care workers are also complaining that they are consulting with too many ART clients each day and they are feeling overburdened. Andrew is going to follow the five key steps for deciding how to differentiate ART delivery in his district.



Meet Jane

Jane is a nurse in a clinic within Andrew's district. She knows that many of her clients walk 2 hours each way to collect their ART. When she saw Andrew at a meeting, she told him that she feels bad that she can only spend a few minutes with each client, regardless of their needs. Her clinic offers HIV care two days a week and on these days, she sees 80 clients.

“I do understand why counseling is poor in the facilities because the nurses are overwhelmed. Effective counseling is not about numbers – I’m not a number, I’m a human being. The focus should be on the quality of service I receive. If we can shift the stable clients, it means there will be enough time for counseling the person who is unwell.”

- Vusi Matsebula, PLHIV, Swaziland

STEP 1: ASSESS ART DATA, POLICIES AND DELIVERY

It is important to have an understanding of what is happening in terms of client outcomes, policies and how ART services are currently being provided. An example of a survey performed to map the common examples of differentiated care at the national level, along with the survey tools used, can be found in Annexes 3 and 4.

(a) Assess the data

Routine monitoring and evaluation (M&E) data on retention helps determine what the challenges are at the site level. This checklist can be found in Annex 4. Relevant data includes the number of people on ART and retention data for specific sub-populations. It is also important to know if facilities have an appointment and tracing system.

(b) Assess the policies

A comparison of national-level policies with current WHO recommendations may also be undertaken. Policies should be reviewed in alignment with the building blocks (see Part 4 for more details) and to support differentiated ART delivery in general. Annex 5 provides a template for assessing the relevant policies to differentiating ART delivery.

(c) Assess the current models of ART delivery





An initial broad mapping of differentiated ART delivery is recommended to determine **what** is being implemented in-country and the **coverage of the models** (what proportion of health facilities are offering that model). At the district level, for each site, data should be collated describing service provision based on the building blocks and the elements. Examples of differentiated ART delivery are described in the literature and are outlined in Parts 3 and 4; the mapping may be carried out through a desk review of published literature and local country and partner activity reports in combination with a survey of district ART coordinators and implementing partners. Using these building blocks, assessment can also be made on how ART is delivered for other selected sub-populations.

Using the building blocks and elements approach, assess how ART is currently being delivered at each ART site for the clinical and refill appointment. Annex 4 gives an example of a checklist that you can use to perform this assessment.



Andrew reviewed the relevant policies related to differentiated care as outlined in Annex 5. Interestingly, many policies were in place to support differentiated care but were not yet being implemented. For example, the policies related to when, where and who.

In other instances, policy changes are required to support differentiated ART delivery and increased health system efficiencies. For example, the policies related to what.

 WHEN	The policies support a maximum ART refill of three months. In many facilities, refills were limited to one or two months.
 WHERE	The policies support the distribution of ART at peripheral health facilities. However, not all peripheral health facilities are providing ART.
 WHO	Clients are permitted to nominate a “treatment buddy” to collect an ART refill on their behalf. In some facilities, staff are unaware of this policy.
 WHAT	<p>The policies should be updated to recommend the cessation of CD4 count monitoring where there is access to routine viral load.</p> <p>A minimum definition of stable clients (see page 5) should be developed as a policy to enable differentiated ART delivery.</p>

STEP 2: DEFINE CHALLENGES

Based on Step 1, the challenges that can be addressed through differentiated ART delivery can be identified. You will also want to assess the health care worker and client perspectives to understand their challenges, as well as preferences and expectations. Annex 4 includes the perspectives of health care workers and clients in the assessment of differentiated ART delivery at the facility level.

At this stage, it is important to host a workshop and engage key stakeholders from both the health system and civil society to achieve the following objectives:

- Sensitize ART coordinators and implementing partners on the background and core principles of differentiated ART delivery.
 - Provide an opportunity for stakeholders to present existing examples of differentiated care implemented in their settings.
 - Present the outcomes of the national-level desk review.
- Summarize the findings from the consultations with health care workers and PLHIV.
 - Engage stakeholders in a plan for local/district situation analysis.

Based on the review of the data, delivery and policies, Andrew asks:



What are the current challenges for implementation?

Can these challenges be addressed locally or are they dependant on changes in national policy?

Which interventions can be made in the short, medium and long term?

“The amount of time we spend at the health facility in the queues – a queue for triage, a queue for the nurse, a queue at the pharmacy and a queue for the labs – it’s too much time. I want to come to the facility only twice a year... I have a life to live.”

- Patricia Asero Achieng, PLHIV, Kenya



Meet John

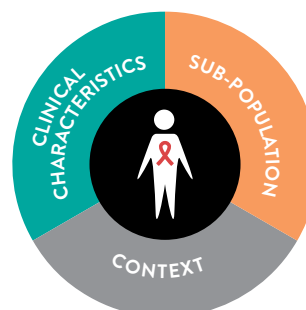
John has been on ART for five years. He attends the ART clinic at the district hospital in Andrew’s district every two months to collect his ART. He works in a local factory and has a difficult time explaining to his boss why he needs to take a day off every two months. Physically he feels really well and is happy to be at work. He arrives at the clinic at 7.30am, or earlier if he can, so he can get into the queue. Usually there are about 60 people waiting there and he sees the nurse at around 11am. As he is feeling well, he spends less than five minutes in her room. Next stop is the pharmacy, where there is a very long queue as everyone from the outpatients are also there to collect their medicines. Finally, by 2pm, he’s on his way home with his ART refill.

STEP 3: DEFINE THE POPULATION(S) FOR WHOM ART DELIVERY WILL BE DIFFERENTIATED

With a clear understanding of the current delivery programme and policies in place, you are ready to proceed with prioritizing differentiated ART delivery. Using the data and based on the policies, you can determine the challenges of clients and the health system. Based on the challenges, you can prioritize who ART delivery should be differentiated for. You may also choose multiple models to run simultaneously.

Using the three elements described in Part 3, consider the clinical characteristics, sub-population and context.

Figure 3: The three elements



STEP 4: BUILD A MODEL OF DIFFERENTIATED ART DELIVERY

Once you have defined who is eligible, you can proceed with building a model of differentiated ART delivery based on your data, policies and eligibility criteria. It is recommended to first define differentiated ART delivery using the building blocks detailed in Part 3.

For now, the emphasis is on the building blocks of when, where, who and what. The model mechanics, or the “how”, is also relevant to the implementation. However, specifying these details can come later and should be done at a facility level.

STEP 5: CONSIDER ADDITIONAL ADAPTATIONS

Presuming that you have differentiated ART delivery for stable clients, you can repeat Step 3 for additional populations. Alternatively, consider differentiating care for other groups according to the elements (Part 3, Annex 6).

After this 5-step process has been completed, it will be necessary to discuss at a district and/or facility level the specific model mechanics (e.g., criteria for up referral, relevant adaptations to M&E materials). Annex 7 outlines the key questions to answer after selecting a model of differentiated ART delivery.



Meet Mary

Mary lives in a rural village in Andrew’s district. She walks every month to her nearest clinic to collect her ART, which is two hours away. Last year Mary stopped her ART for two months because the river flooded. The river often floods during the rainy season, preventing Mary and others in her village from having access to the clinic.

A man in a green shirt is seen from the back, gesturing with his right hand towards a group of people sitting on a bench. The group consists of several women and children, some wearing headscarves. They are outdoors, with a bamboo grove in the background. The scene is brightly lit, suggesting daytime.

PART 3

WHAT ARE THE THREE ELEMENTS TO CONSIDER?

THE THREE ELEMENTS

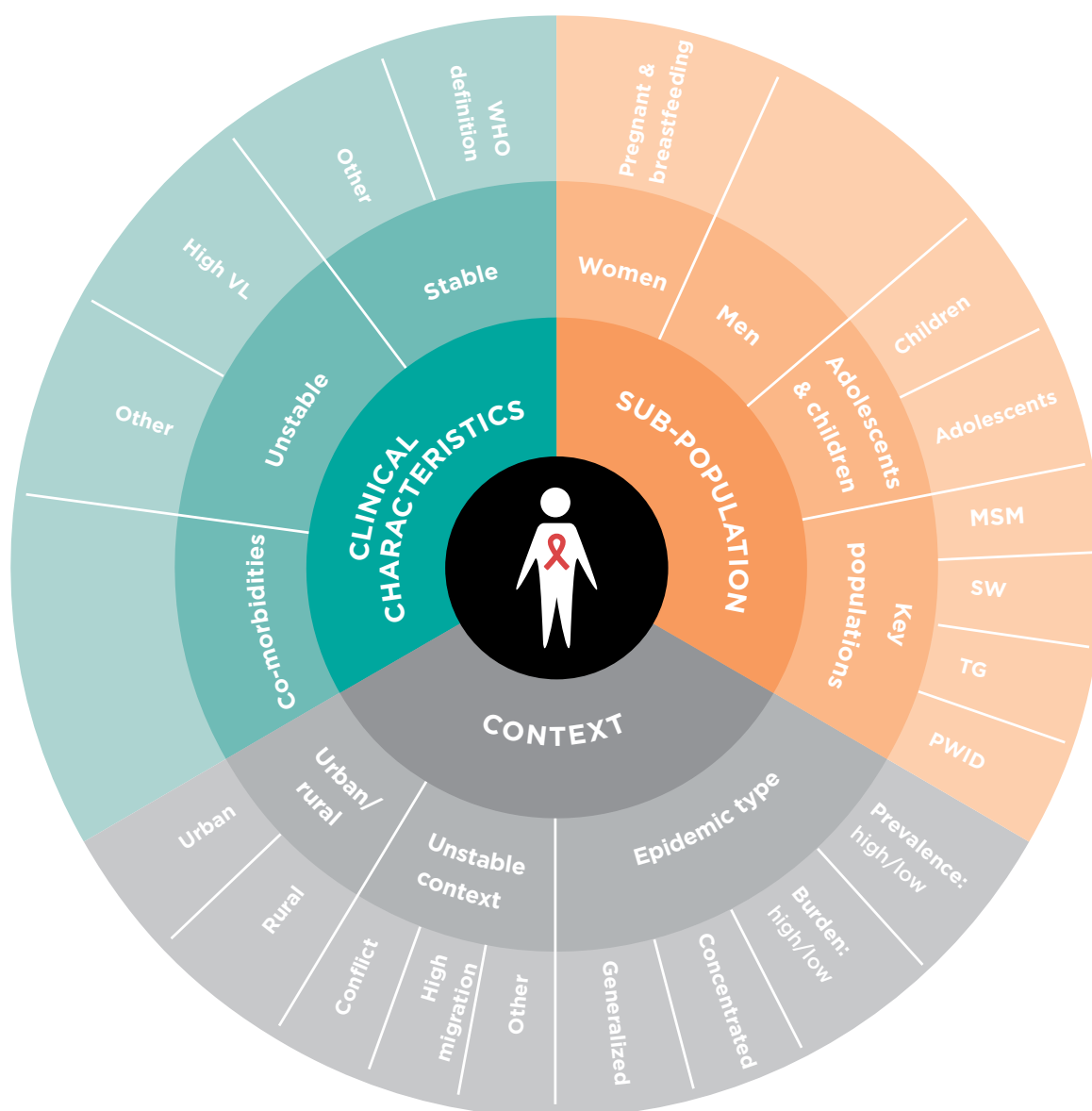
In order to provide client-centred care, there is a need to consider the clinical characteristics, sub-population(s) and context of your clients. This will allow you to build appropriate models of ART delivery using the building blocks described in Part 4. In this part, we discuss each of these three elements and present relevant case studies.

WHO defines four types of clients: patients presenting well, patients presenting with advanced disease, stable patients and unstable patients (2). Each of these client types will require different care packages to support their clinical needs. Clients will move between categories. However, the packages of care required for different types of clients must consider more than just their clinical characteristics.

Models of ART delivery should be differentiated according to the following three elements, as presented in Figure 4.

1. The clinical characteristics of the client (stable, unstable, co-morbid/co-infections)
2. The sub-population (e.g., adults, children and adolescents, pregnant and breastfeeding women, key populations, men)
3. The context (e.g., urban/rural, unstable context, epidemic type.)

Figure 4: The three elements



HOW DO WE DIFFERENTIATE BASED ON CLINICAL CHARACTERISTICS?

Based on clinical characteristics, clients can be defined as stable, unstable, and clients with co-morbidities or co-infections (Figure 4). A client can be determined as stable according to WHO’s definition or another definition (refer to page 5 for more details on how to define stable clients). Unstable clients may have a high viral load or another characteristic, such as a mental health condition or recently initiated on ART, that classifies them as unstable.

What happens to unstable clients?

As outlined in Part 1, a differentiated care approach provides care that is responsive to the needs of PLHIV. As a result, if a client is unstable or has a co-morbidity or co-infection, they should receive an intensified level of follow up and support.

Given that HIV is a chronic, life-long condition, some clients will experience episodes of “instability”, which need to be addressed. As a result, they may need to be up referred to the standard of care or require additional interventions (counselling and repeat viral load) for a short intensive period.

Some clients may not be achieving sustained viral suppression if the model of delivery does not address

their needs or expectations. Therefore, differentiated models may offer the greatest benefits to clients who currently are interrupting their ART treatment or are not virally suppressed.

Differentiated delivery can support clients managing multiple conditions

With an ageing cohort of PLHIV, increases in life expectancy of PLHIV and the prevalence of co-morbidities and co-infections, many clients may also require care for their co-morbidity or co-infection. If a stable HIV client has a co-morbidity or co-infection, they should receive an intensified level of follow up and support. By providing differentiated ART delivery for stable clients, the health system should concurrently be providing increased clinical support for those who require it.

While the Decision Framework is focused on differentiated models for stable ART clients, the principles and 5-step approach apply to clients who are unstable or have co-morbidities or co-infections. There are also examples of service delivery models where HIV and non-communicable disease management are integrated (Case study 1).

Case study 1:

Medication adherence clubs, Kenya

In Kibera, Kenya, the primary health care system was seeing a high volume of ART clients, as well as clients with hypertension and diabetes. Building on experience of group models for stable clients, the idea of medication adherence clubs (MACs) was developed. MACs are a group model for stable clients with HIV, hypertension or diabetes. To date, a total of 1,432 clients have been enrolled into 47 clubs. Clients are predominantly on ART (71%) and 29% have diabetes or hypertension. A total of 2,208 consultations were offloaded from the routine outpatient clinic and loss to follow up from the MACs was 3.5% (9). MACs are an example of health care worker-managed groups (page 7).



I am stable and virally suppressed, so I only have to come to the HIV clinic to get my ARVs every 3 months. Why do I need to come back every month just to get my hypertension medications?

HOW DO WE DIFFERENTIATE BASED ON THE SUB-POPULATION?

ART delivery should be differentiated based not only on clinical characteristics, but also by considering the challenges of sub-populations (Figure 4), including:

- Women, including pregnant and breastfeeding women
- Men
- Adolescents and children
- Key populations, such as men who have sex with men (MSM), sex workers (SW), transgender people (TG) and people who inject drugs (PWIDs).

Although the Decision Framework focuses on stable adult clients, the same concepts and principles from the building blocks outlined in Part 4 can be applied to provide appropriate models of ART delivery for specific sub-populations. Differentiating ART delivery for sub-populations can help improve access to HIV care by addressing the structural barriers and adherence issues that sub-populations often face.

Each sub-population will require a unique and comprehensive package of health care services to overcome particular challenges. Having specified refill days or times for certain sub-populations, where appropriate, may be one such innovation that will allow

clinicians and counsellors to focus on the specific medical and psychosocial needs of this population. For example, this will enable the utilization of available child- and adolescent-friendly tools more effectively than if paediatric clients are interspersed during a routine ART clinic.

Case study 3:

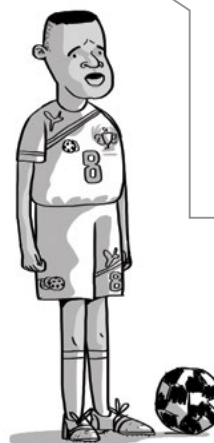
Harm reduction clinic, Mauritius

In response to the growing HIV epidemic among PWIDs, a partnership between civil society and the government of Mauritius initiated harm reduction practices in 2006 that includes methadone maintenance therapy and needle and syringe exchange in conjunction with the scale up of HIV testing and ART access. In 2014, 3,078 individuals accessed the services through fixed sites, vans, backpack outreach workers and peer educators. In total, 719,427 clean needles and syringes were distributed. The incidence of HIV among PWIDs in Mauritius declined from 68.1% in 2011 to 31.1% in 2014.

Case study 2:

Teen clubs, Swaziland

In Swaziland, teen clubs were developed to provide enhanced psychosocial support to adolescents living with HIV. Given the high attendance rates for the teen club programme, stable adolescents are increasingly supported to receive their ART refills within this model. National guidelines on community ART support the delivery of ART to stable adolescents within the teen club model, while encouraging all adolescents living with HIV to join a teen club for psychosocial support. Teens clubs are an example of a health care worker-managed group model (page 7).



I have to go the clinic every month – and I hate going. It's so boring! There are no other children there for me to play with.

HOW DO WE DIFFERENTIATE BASED ON CONTEXT?

In order to maintain quality ART delivery in specific challenging settings (e.g., conflict, urban/rural, high migration, low prevalence), modifications to how ART is delivered are required.

In addition to the consideration of contextual stability, the prevalence of HIV in a given setting will also impact on the specific challenges faced by clients and the appropriateness or extent of certain specific interventions.



I have bigger issues to worry about than my ART. The stigma and ignorance around HIV in my community are what keep me up at night.



Even though I was recently diagnosed, I feel that my ART is going well and that I don't need to come to the clinic too often.



Taking my ART is the easy part. Dealing with the judgmental staff at the clinic is what bugs me.

Case study 4:

“Points de distribution communautaires” (PODIs), Democratic Republic of the Congo (DRC)

In Kinshasa, DRC, PODIs were set up to support ART provision in a setting with a low coverage of ART. HIV services were centralized within hospitals, resulting in overcrowding and long queues with clients travelling long distances. Nearly half of the ART clients (43%) were receiving their ART refills from a PODI (7). High rates of retention have been observed (94.9% at six months, 89.3% at 12 months, 82.4% at 24 months) and transport costs have been reduced by two-thirds. The waiting time for a PODI ART refill is 12 minutes, compared with 85 minutes in the hospital. The PODI is an out-of-facility individual distribution model (page 7), an example of a community pharmacy.

SUMMARY OF THE THREE ELEMENTS

- ART delivery may be differentiated according to clinical characteristics, sub-population and contextual factors.
- During their ART journey, clients may have short-term medical needs requiring more intensive follow up or have other chronic co-morbidities that require an integrated approach to management.
- Delivery models for specific sub-populations can be designed using the building blocks approach. Given the structural barriers and adherence issues faced by sub-populations, additional considerations will be required.
- While the majority of documented models of differentiated ART delivery are from high-prevalence settings, the building blocks principles can also be applied in other contextual settings and existing models can be adapted to the local epidemic and local social and political environment.



Why do we all have clinic appointments on different days?



Having been HIV positive for most of my life, I feel supported by the community I come from. My HIV has to fit into my life seamlessly.



I started taking ART at my antenatal clinic and the integrated services are great. The clinic helped me disclose to my husband.



PART 4

THE BUILDING BLOCKS OF DIFFERENTIATED ART DELIVERY

THE BUILDING BLOCKS

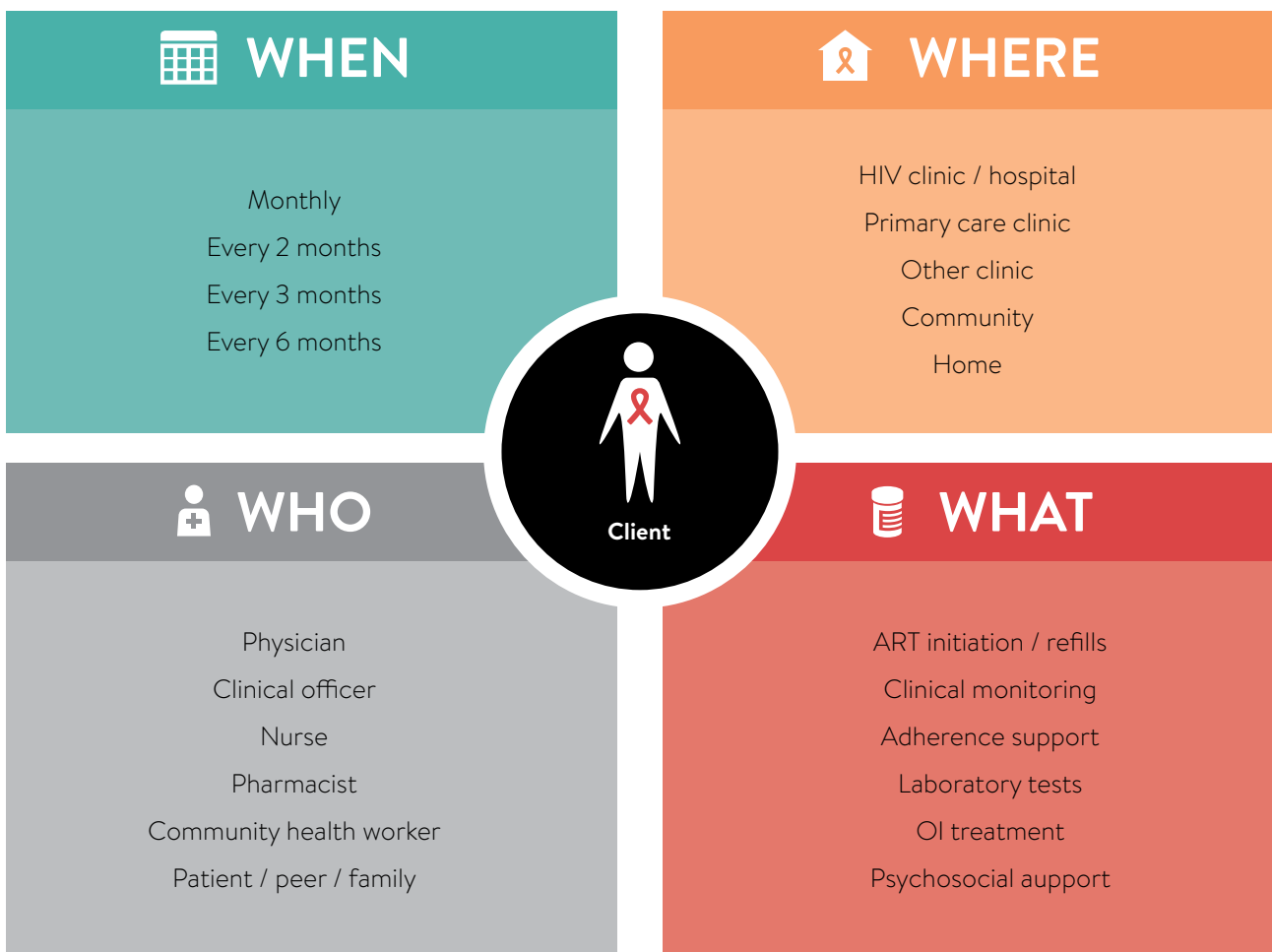
The building blocks of differentiated ART delivery centre on four questions: when, where, who and what (2, 3). The building blocks are the key components of building a differentiated model of service delivery (Figure 5).

As discussed in Part 1, in all models of ART delivery, the client is at the centre. It is up to the district health manager to work with health care workers and clients to determine which of the when, where, who and what blocks to include in the differentiated model of care. The stakeholders must

balance the goal of improving client outcomes with their ability to utilize the available health system resources.

The next section presents the four building blocks, highlighting relevant guidelines and provides examples from real-world differentiated models of ART delivery. You will also follow Andrew, the district ART manager, as he addresses the challenges of Mary, Jane and John with the building blocks.

Figure 5: The building blocks





“WHEN” IS ART DELIVERED?

Reducing the frequency of ART refills and clinical visits

Reducing the frequency of visits is a simple and efficient way of reducing the burden on both the client and the health care system. A key principle, linking all models of differentiated ART delivery, is separating “refill-only” visits from visits that require clinical, counselling and/or laboratory assessment. If a clinician prescribes ART for a three- to six-month period, then, for the intervening period, the client should be able to limit his/her interactions with the health system to only those needed to obtain his/her resupply of medication. If a sufficient refill can be provided at the clinical visit, the client would not have to see another health care worker until his/her next clinical appointment. Where routine viral load is available, as is the case in South Africa, clinical consultations for clients with suppressed viral loads can be reduced to once per year.

The WHO guidelines on the use of ART provide new recommendations on when ART is delivered and support less frequent contact for stable clients (see Box 3). The United States President’s Emergency Plan for AIDS Relief (PEPFAR) Technical Considerations go further, suggesting clinical visits could be every 12 months for stable clients (10). In Part 1 (page 5), the classification of “stable” client is discussed.



WHO Guidelines

Box 3: Recommendations on frequency of visits

- Less frequent clinical visits (3-6 months) are recommended for people stable on ART (strong recommendation, moderate-quality of evidence).
- Less frequent medication pickups (3-6 months) are recommended for people stable on ART (strong recommendation, low-quality of evidence) (2).

Utilizing the maximum duration of ART refills

Depending on local regulations and the strength of the supply chain, each setting should make the **maximum duration of ART** that may be given clear to the health workers. This will determine the frequency of a client’s visits. Following the WHO guidance, many countries are moving to three or even six-month schedules for clinical and refill visits. For support with extending ART refills, refer to the USAID multi-month scripting calculator available on the compendium website (www.differentiatedcare.org).



Remember John?

John was frustrated to be missing work to queue at the pharmacy for his ART refills. How did addressing the “when” of differentiated ART delivery help him?

Andrew, the district ART manager, introduced differentiated ART delivery at John’s clinic. The clinic has now increased the ART refill duration from a 2-month supply to a 3-month supply. This change means that John only has to come four times a year rather than six. John is happy that he’s not making excuses for missing work.

Extending or adapting service hours

In most resource-limited settings, ART is only available to be collected during clinic hours. **Adapting the timing of services** is a simple way to address access issues for specific clients. For example, providing refills for children and adolescents after school closing hours can decrease absences from school and enable the child to live a more normal life. Extending pharmacy opening hours earlier and later on specified days or allowing collection on Saturdays can support working clients who struggle to attend the clinic in working hours and may lose salary every time they have to visit a facility for an ART refill.

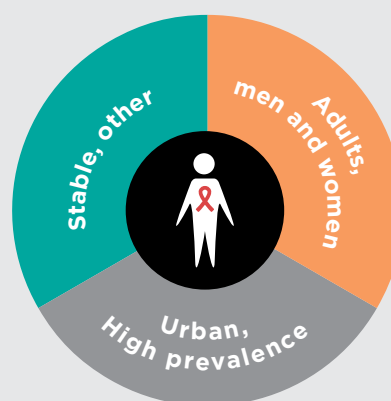
Example 1:

Adherence clubs (ACs), South Africa

Overview

In the Cape Town Metro health district of South Africa, clinics were congested with long waiting times for clients and unsatisfactory long-term retention in care. Adherence clubs (ACs) for stable adults were developed. Clients were eligible to join an AC after six months on ART if they had a viral load of <400 copies/mL (the nationally defined threshold for viral suppression). ACs are groups of 25-30 stable clients who receive their ART refills, support and care in the group and they are facilitated by a community health worker. At the ART refill visit before the annual clinical consultation, blood is drawn for routine monitoring, including viral load. ACs are an example of a health care worker-managed group model (page 7).

The three elements of ACs



The building blocks of adherence clubs

	ART REFILLS	CLINICAL CONSULTATIONS
WHEN	2-4 monthly	Annual
WHERE	Primary care clinics providing ART	Primary care clinics providing ART
WHO	Lay cadre (community health workers)	Nurse
WHAT	Pre-packed ART Group (25-30 clients) counselling session Brief symptom screen	Pre-packed ART Clinical consultation

Outcomes

As of March 2015, more than 34,000 clients were receiving their ART in this model (11), which is fully managed by the government. Between 2011, when ACs were first implemented, until 2015, the total ART cohort in the district doubled to nearly 130,000 clients. In an analysis of a representative sample of the adherence club cohort, 95% of clients were retained and 97% were virally suppressed 12 months after AC enrolment (12). Adherence clubs, with various adaptations, are now national policy in South Africa (13), Zimbabwe (14) and Swaziland (15), and are being implemented in areas of Namibia, and piloted in Zambia.



“WHERE” IS ART PROVIDED?

Decentralizing services closer to home

For many clients, physical access to ART remains a challenge. The time and travel costs of getting to the clinic, as well as persistent issues of stigma, remain barriers to retention and sustained viral suppression. Decentralizing HIV care – taking the services closer to the client’s home, either to a facility closer to home or to some place within the client’s community – is a strategy that can reduce both congestion at centralized sites and the burden on the clients.

Decentralization has been successful in many countries with ART shifting from central hospitals to primary care sites. In some settings, the concept of taking ART “closer to home” has been progressed further, with ART delivery provided at health facilities through community pharmacies, health posts, home-based services and other community structures.



WHO Guidelines

Box 4: Recommendations on decentralization

Decentralization of HIV treatment and care should be considered as a way to increase access to and improve retention in care:

- Initiation of ART in hospitals with maintenance of ART in peripheral health facilities (strong recommendation, low-quality of evidence);
- Initiation and maintenance of ART in peripheral health facilities (strong recommendation, low-quality of evidence);
- Initiation of ART at peripheral health facilities with maintenance at the community level (that is, outside health facilities in such settings as outreach sites, health posts, home-based services or community-based organizations between regular clinical visits) (strong recommendation, moderate-quality of evidence).

These recommendations apply to all adults, adolescents and children living with HIV (2). WHO has also made these recommendations for all key populations (16).



Remember Mary?

Mary was walking for more than two hours to reach the nearest clinic that provides ART. How did addressing the “where” of differentiated ART delivery help her?

Andrew, the district ART manager, acknowledged that additional ART facilities were needed. Six months later, the nurses in the local clinic had been trained to provide ART. This clinic was only a 15-minute walk away for Mary. She did not have to give up so much of her day to attend and she liked their local nurse who spent more time with clients during their visits.

How far to decentralize will vary according to context

In high-burden rural areas, the aim in many settings is to decentralize HIV care to all primary care sites. However, in low-prevalence urban settings, it may be inefficient to have HIV services in all clinics. Both from a logistical and quality-of-care perspective, it may be more efficient to provide ART at a few centralized sites. While initiation of ART and maintenance at the community level is not yet included in the WHO guidelines, it is the subject of current implementation science research.

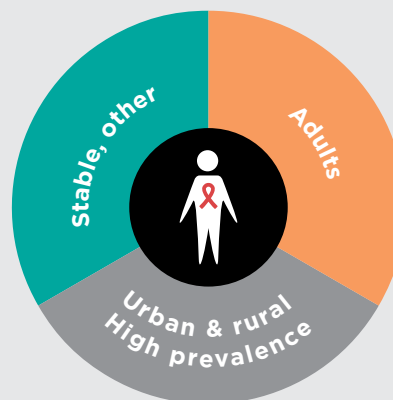
Example 2:

Community drug distribution points (CDDPs), Uganda

Overview

In Uganda, clients were travelling long distances to overcrowded facilities with long queues to collect their ART. The AIDS Support Organization (TASO), a local non-governmental organization (NGO), initially responded by instituting home delivery of ART. However, as client numbers grew, home delivery of ART became unfeasible. TASO then set up a number of community drug distribution points (CDDPs). Eligible clients (those who had spent >10 weeks on ART, CD4 >350 cells/mm³, adherence >95%) were referred to the CDDP closest to their home for both ART refills and clinical consultations. The CDDP is an out-of-facility individual model (page 7).

The three elements of CDDPs



The building blocks of community drug distribution points

	ART REFILLS	CLINICAL CONSULTATIONS
WHEN	2-3 monthly visits	6 monthly
WHERE	Community points closer to clients' homes	Primary care clinics providing ART
WHO	Lay health care workers	Nurse
WHAT	Pre-packed ART (2-3 months) Adherence counselling	Clinical consultation

Outcomes

As of 2015, 70% of TASO clients (about 50,000) receive their ART within this model, with 89% retained after five years. In a sample of 870 CDDP clients, 87% had an undetectable viral load. Further evidence from this model can be found in publications (17, 18). Other examples similar to the CDDPs include the PODI community pharmacy within the Democratic Republic of the Congo (7) (page 18), as well as community outreach models, private pharmacy distribution and ART “ATMs”.



“WHO” IS PROVIDING DIFFERENTIATED ART DELIVERY?

The importance of task shifting

The ability to assign certain tasks to less skilled cadres has greatly enabled the scale up of ART in resource-limited settings. Provision of routine HIV care and ART delivery is no longer the sole responsibility of doctors. In the past decade, nurses and lay health care workers have become increasingly involved in the provision of ART care. To implement task shifting and sharing, a review of regulatory frameworks in the country is often required and, in some settings, can remain a major barrier to scaling up of ART.



WHO Guidelines

Box 5: Recommendations on task shifting and task sharing

- Trained and supervised lay providers can distribute ART to adults, adolescents and children living with HIV (strong recommendation, low-quality evidence).
- Trained non-physician clinicians, midwives and nurses can initiate first-line ART (strong recommendation, moderate-quality evidence).
- Trained non-physician clinicians, midwives and nurses can maintain ART (strong recommendation, moderate-quality evidence).
- Trained and supervised community health workers can dispense ART between regular clinical visits (strong recommendation, moderate-quality evidence).

These recommendations apply to all adults, adolescents and children living with HIV (2). WHO has also made these recommendations on task shifting and task sharing for all key populations (16).

Dispensing versus distribution of ART

Based on new evidence, WHO recommends that both *distribution* and *dispensing* of ART can be done by cadres of staff other than pharmacists (see Box 5). These guidelines apply across age groups and sub-populations (i.e., adults, adolescents and children living with HIV) and have important implications on the *who* within differentiated models of ART delivery.



Remember Jane?

Jane’s role at the clinic has grown in recent years. She now initiates clients onto ART and prescribes treatment to her clients. Jane finds it boring when her day is filled with consultations to clients

who are healthy and stable and don’t need her clinical expertise. How did addressing the “who” of differentiated ART delivery help her?

Following a review of the data, policies and current models of delivery and speaking with health care workers and clients, Andrew, the district ART manager, supported differentiated delivery for stable clients. Community health workers now support stable clients to have increased self-management and Jane now focuses on new and unstable clients.

Lay cadres play a vital role in many differentiated models of ART delivery

The role of lay cadres is vital in many of the examples of differentiated ART delivery. Their role includes facilitating and/or forming groups, educating clients and supporting client self-management (19). It is essential to acknowledge the support and contributions of lay cadres. Task shifting has become an accepted practice, especially in many high-burden settings. However, ongoing training and supervision must be provided along with adequate remuneration to assure the quality of work (20).

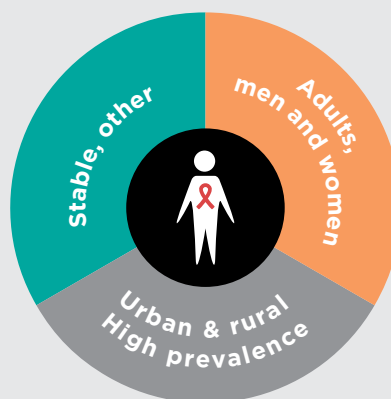
Example 3:

Community ART refill groups (CARGs), Zimbabwe

Overview

In Zimbabwe, the 2015 Operational and Service Delivery Manual includes recommendations for differentiated care across the cascade (14). Four differentiated models are presented as options: individual refill from pharmacy; the “club”: the family “ART group” refill; and community ART refill groups (CARGs). The CARG model was adapted from the pilot in Mozambique (21) and based on consultations with the Ministry of Health, health care workers and PLHIV, as well as considering contextual policies and resources. CARGs are self-forming groups of stable clients from the same geographical area. All members must be willing to disclose their status to each other. To be eligible, clients must have a viral load < 1000 copies/ml (or where VL is not available a CD4 > 200 cells/mm³), have been on ART for at least six months and have no other clinical condition requiring more frequent clinical consultations. CARGs are comprised of between four and 15 clients. A CARG is a client-managed group model (page 7).

The three elements of CARGs



The building blocks of community ART refill groups

	ART REFILLS	CLINICAL CONSULTATIONS
WHEN	3 monthly	12 monthly if viral load available, 6 monthly if viral load unavailable
WHERE	Within the community	Primary care facilities <i>The entire CARG goes together</i>
WHO	Client <i>The CARG nominates the client who is most in need of a clinical visit to go the facility and collect on behalf of the group</i>	Nurse
WHAT	Pre-packed ART Peer-support	Clinical consultation

Outcomes

Outcomes from the Zimbabwe CARGs model are not currently available (SOPs can be found at www.differentiatedcare.org). The model on which CARGs were developed, community adherence groups (CAGs), were originally implemented in rural Mozambique in response to having access to only one-month ART refills in an area with long distances to travel (21). Over four years, more than 5,500 clients joined a CAG with retention rates of 98% and 96% at 12 and 24 months, respectively (22).

The CARG model from Zimbabwe is a good example of how adaptations based on PLHIV feedback (e.g., the desire for larger groups) and context (e.g., CARG members have access to 3-month refills and so do not collect refills as frequently as the pilot model) has been implemented. Similar models have been implemented in Malawi (23), Swaziland (15) and South Africa.



“WHAT” SERVICES SHOULD BE OFFERED?

The medical needs of a client on ART will be different across the continuum of the client’s life. Given that stable clients have different needs during an ART refill visit versus a clinical consultation, it is necessary to define what package of additional services (if any) will accompany these two types of visits. For ART refill visits, options to consider include counselling, group counselling on topics relevant to stable clients, brief symptom screens related to ART and/or common comorbidities and co-infections, and peer support. In most examples, differentiated models of ART delivery for stable clients have excluded adherence support measures, such as pill counts. By decreasing adherence counselling to stable clients, there are increased resources available for intensified adherence counselling to clients with high viral loads.

WHO Guidelines

Box 6: The WHO package of care for stable individuals

“The package of care for stable individuals can include the following:

- less frequent (3–6-monthly) clinic visits;
- less frequent (3–6-monthly) medication pick-up;
- community-based care; and
- cessation of CD4 count monitoring if viral load testing is available.

While less frequent clinic visits are recommended for stable individuals, rapidly growing children (0–5 years old) and adolescents will need to be monitored more frequently for treatment dosing/weight changes and adherence support.” (2)

Stable clients still need regular clinical consultations

Stable clients should receive regular clinical consultations as part of their package of care. This should include management of other co-morbidities, provision of medications or drug refill, counselling and psychosocial support, and laboratory interventions. An example of a clinical visit checklist can be found in Annex 8.



Remember John?

John was receiving 2-monthly ART refills and coming to the clinic six times a year. How did the “what” of differentiated ART delivery help him?

Andrew, the district ART manager, reduced the frequency of clinical consultations for stable clients to once per year (from every six months) once routine viral load was available. Further, the facility began offering 3-monthly ART refills. As a result, John now has four visits a year – three for ART refills where he goes directly to the pharmacy and one clinical consultation. This differentiation has further reduced the time he spends at the primary care facility.

Considerations with expanded access to routine viral load

As access to viral load monitoring becomes increasingly available, adaptations should be made to models of ART delivery. With an objective measure of adherence, stable clients with viral suppression require only annual clinical consultations, as is the standard practice in South Africa. Further, clients who present with high CD4 cell counts and initiate ART may have a suppressed viral load after three or six months and be referred to a stable client model of ART delivery.

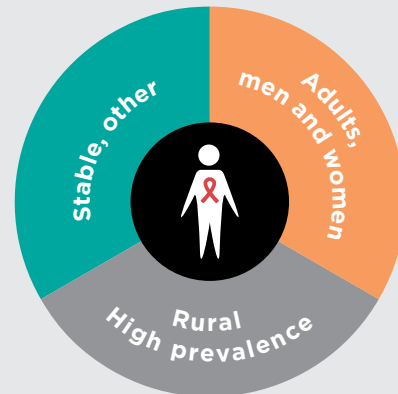
Example 4:

Appointment spacing and “fast-track” ART refills, Malawi

Overview

In rural Malawi, despite extensive decentralization of ART services to all primary care clinics, nurses were faced with queues of 40-50 clients per day. Clients were seeing a nurse at every visit and often waiting three to four hours to receive their ART refill. A facility-based individual “fast-track” model was developed for ART refills. Client eligibility criteria included: on ART more than six months; >18 years old; viral load <1,000 copies/ml; on first-line regimen; no ongoing OI (including TB) for three months; and not pregnant or breastfeeding. Clients in the model receive three months of ART directly from the pharmacy in between their 6-monthly clinical consultations. The model was for stable adults in a rural setting. Appointment spacing with fast-track refills is an example of a facility-based individual fast-track model (page 7).

The three elements of “fast-track” ART refills



The building blocks of appointment spacing and “fast-track” ART refills

	ART REFILLS	CLINICAL CONSULTATIONS
WHEN	3 monthly	6 monthly
WHERE	Pharmacy within primary care facility offering ART	Primary care facility
WHO	Lay health care worker who distributes pre-packed ART	Nurse
WHAT	Pre-packed ART	Clinical consultation Rescripting

Outcomes

As of March 2015, more than 50% of the district ART cohort (more than 15,000 clients) were enrolled in this strategy (19). Retention for those enrolled in the fast-track system was 97% at the 12-month follow up. In South Africa, the National Adherence Guidelines outline “spaced and fast lane appointments” as a repeat prescription collection strategy (13). Many facilities in other countries informally offer a quick pick-up visit for clients in between clinical visits but data from these models are limited.

A close-up photograph of a person wearing a red long-sleeved shirt, focused on writing on a form. The person's hands are visible, with the right hand holding a pink pen. The form is a medical or administrative document with various fields and text. In the background, there are rolls of paper and other forms on a desk, suggesting a clinical or office environment. The lighting is warm and focused on the person's hands.

PART 5

CONCLUSION

CONCLUSION

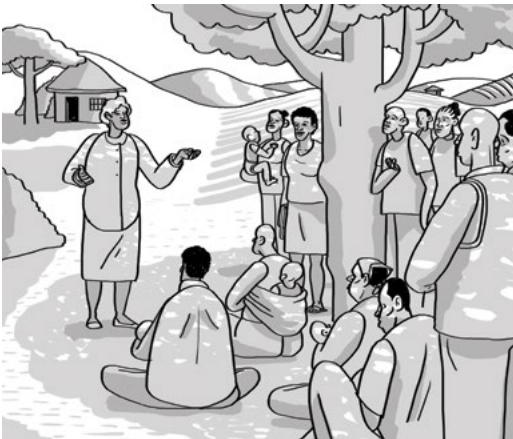
With the growing number of people on ART, differentiated ART delivery is part of the solution to maintain quality of care for clients and reduce the burden on health care workers. Adaptations to service delivery must be based on a stepwise assessment of the local context and be sensitive to the population's needs while delivering services in a more efficient way both for the health system and the client.

The Decision Framework uses the 5-step assessment plan incorporating the building blocks and elements of differentiated care to guide ART programme managers to examine changes that can be made in their services to deliver ART care. These changes must address the frequency and location of where ART services are delivered, who is providing the service, and the ongoing adaptation of services to the changing medical needs of the client, the sub-populations and contextual factors. By systematically considering these steps, a quality, client-centred approach to ART delivery can be achieved.

While differentiated ART delivery focuses primarily on stable clients in this first phase, further work and implementation science is needed to explore how services can be strengthened for clients failing treatment, those with other co-morbidities, and for sub-populations where treatment outcomes are sub-optimal. Likewise the principles of differentiated care, utilizing the building blocks and elements, can and should be applied across the HIV continuum and across other chronic diseases.

We hope that this framework and the accompanying compendium of practical tools helps you start differentiating ART delivery in your setting. Your feedback on this document is welcomed.

Email us at decisionframework@iascoiety.org or visit www.differentiatedcare.org for more details.



With differentiated ART delivery, Mary has been empowered and supports other PLHIV in her community.



With differentiated ART delivery, John is able to return to his day and not waste time queuing at the clinic.



With differentiated ART delivery, Andrew has seen improvements in client satisfaction and outcomes.



With differentiated ART delivery, Jane is able to provide quality care to her clients.

FREQUENTLY ASKED QUESTIONS (FAQs)

You will remember from Part 2 that Andrew was following the 5-step process for deciding how to differentiate ART delivery in his district. In this part, we respond to common questions raised about implementing differentiated ART delivery.

ART supply

Question: If longer refills are not available through national supply, does this mean we cannot differentiate ART delivery?

Answer: No. A current inability to provide longer refills should not be a barrier to differentiating ART delivery following the building blocks and elements approach. In fact, it was having access to only a one-month supply of ART that drove clients in Mozambique to develop community ART groups.

However, without a secure supply of ART, the potential gains of differentiating ART delivery may not be maximized. Strengthening of forecasting, procurement and supply chain requires ongoing investments.

Question: Does delivering ART to the community compromise drug security?

Answer: No. To date, in the countries where ART delivery has been differentiated into communities, there have been no documented or reported incidences of drugs not arriving, going missing or being stolen.

There are a number of steps that can be taken to avoid incorrect distribution or loss of drugs:

- Community leaders and community-based organizations representing PLHIV should be consulted and involved in the programme from its inception.
- All PLHIV receiving their ART through out-of-facility models should understand their regimen and know the name of their regimen and what the packaging for their formulation looks like.
- Prior to community distribution of ART, all drugs should be pre-packed at the facility.
- Dispensing of ART should be monitored within the standardized M&E system and any non-collection of ART should be reported to the facility.

Trained, supervised and motivated human resources

Question: Do we need additional staff to differentiate ART delivery?

Answer: Additional staff members are not required to provide differentiated ART delivery. However, health care workers must be engaged from the beginning of implementation so that they understand why the change is being made and how the intervention will be monitored.

The initial planning phase for differentiating ART delivery may require an experienced health care worker, such as the district ART coordinator, to kick-start training and initial reorganization of clinic flow.

Rather than prescribing what cadre of staff is needed for any given model, a review of how the service may be implemented in a given setting is encouraged. Many clinics have found local solutions to staffing differentiated models of ART delivery. For example, a specific midwife could be tasked with reorganizing client bookings and clinic flow to facilitate PMTCT integration, or a lay health worker or expert client could be assigned to facilitate an ART adherence club.

Question: Can volunteer lay workers facilitate differentiated ART delivery?

Answer: Lay cadres have been key to the success of many of the models of differentiated ART delivery. For example, lay cadres have facilitated paediatric days at the facility and the formation of community ART groups. Although volunteering can be highly effective when well coordinated, relying solely on voluntary services is not recommended for creating a long-term, sustainable and consistent provision of ART delivery. An assessment should be performed to clearly define what tasks are being carried out by lay workers, and advocacy for adequate recognition and remuneration should be supported.

Access to routine viral load monitoring

Question: Can ART delivery be differentiated in settings with limited or no routine viral load monitoring?

Answer: Yes. Although viral load monitoring facilitates differentiation of ART delivery by providing a quantitative assessment of treatment success, its absence should not be a barrier to differentiating care. Many models of differentiated care were established prior to the availability of viral load testing. Definitions of “stability” can be made as per the WHO recommendations using either immunological or clinical criteria.

However, access to viral load monitoring can reassure both the clinician and the client that ART is working effectively and provides a more solid foundation for moving forward with client self-management, reducing frequency of visits and moving to ART distribution in the community.

Question: How does access to routine viral load support differentiating ART delivery?

Answer: Scale up of viral load testing has primarily been seen as an intervention to identify treatment failure early and switch clients appropriately to second-line treatment. Using viral load to identify clients who are adherent and who may be able to be seen less frequently and in the community is an important outcome of routine viral load testing. Routine viral load monitoring can be cost effective if clients who are virally suppressed receive differentiated ART delivery based on the result (24). With a suppressed viral load, clinicians have an objective measure of adherence that can support less frequent clinical consultations. Reducing clinical consultations to every 12 months for clients who are virally suppressed should be considered with access to routine viral load monitoring.

Support from global donors

Question: Do global donors accept differentiated ART delivery?

Answer: Yes. Over the past five years, there has been extensive documentation of a number of interventions for differentiated ART delivery. Based on this experience to date, The Global Fund has developed a toolkit for differentiated care (25) and PEPFAR has included the concepts of differentiated ART delivery within its 2016 Technical Considerations (10) that guide the development of country operational plans. For many of these interventions, larger-scale implementation is now required within the frame of normal operations with quality monitoring and evaluation to ensure oversight of ART outcomes are monitored.

Member states “commit to build people-centred systems for health... by expanding community-led service delivery to cover at least 30% of all service delivery by 2030.”

– United Nations General Assembly, Political Declaration on HIV and AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030, June 2016

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ANNEXES



ANNEX 1:

Process for development of the Decision Framework

The International AIDS Society (IAS) has spearheaded the development of the *Decision Framework for ART Delivery*. To oversee this process and to develop an online repository of tools to support implementation of differentiated antiretroviral therapy (ART) delivery, the IAS has convened a multi-agency steering committee and technical working group composed of representatives of key international donor and implementing agencies (Bill & Melinda Gates Foundation, Centers for Disease Control and Prevention, Global Fund to Fight AIDS, Tuberculosis and Malaria, Joint United Nations Programme on HIV/AIDS, Médecins Sans Frontières, The Office of the U.S. Global AIDS Coordinator and Health Diplomacy, United States Agency for International Development, World Bank, World Health Organization), networks of people living with HIV (International Community of Women with HIV/AIDS), and members of several ministries of health. This work was informed by the engagement of civil society and communities in collaboration with the AIDS Rights Alliance of Southern Africa and the International Treatment Preparedness Coalition. The *Decision Framework for ART Delivery* has been endorsed for use by national ART programmes and country implementing partners supported by the agencies engaged in its development.

The following steps were followed:

- Desk review of peer-reviewed literature, systematic reviews, reviews of international guidance, and programme reviews of differentiated ART delivery
- Technical and steering committee meetings to develop content of the Decision Framework and plan future implementation across agencies
- Engagement with civil society through community consultations on the definition and implications of differentiated care
- Peer review of the Decision Framework through the technical working group members
- Dissemination and promotion of the Decision Framework through in-country pilots and in collaboration with the launch of the WHO service delivery guidelines.

ANNEX 2:

Guiding principles for differentiated models of ART delivery in Swaziland

An excerpt from the Swaziland National AIDS Programme (SNAP) “Guideline for Community-Centred models of ART service delivery in Swaziland”, 2016.

1. Informed consent: All HIV patients will 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 shall be maintained in the delivery of ART in all these models to increase the level of comfort and trust by patients
3. Quality of care and good clinical practice: ART standards of care will be maintained in all the service delivery models
4. Integration: ART service delivery will work towards integration of critical care to include IPT and NCDs as well as monitoring and evaluation systems and supply chain management of drugs
5. Flexibility: ART service delivery models will allow patients to switch into any of the models without interrupting their treatment. Flexibility will use an approach that is customer focused.
6. PLHIV engagement: Support groups of PLHIV will be engaged and involved in the implementation of ART service delivery models
7. Patient-centered: in such manner that addresses primarily the needs for chronic care conditions and supports empowerment of clients to be active part of their care.

ANNEX 3:

Template for mapping common examples of differentiated ART delivery at a national level

Province	District	Site	Facility type	Differentiated ART delivery at health facility*		Differentiated ART delivery within community*		
				Facility-based individual ART refill only	HCW-managed groups	HCW-managed groups	Client-managed groups	Out-of-facility individual model(s)
e.g. Northern	Northwest	X Clinic	Public/Private	MoH	-	-	MoH + x NGO	-

* Specify if differentiated ART delivery is available and if yes, who is supporting the delivery

Adapted from "Engaging the community to reach 90-90-90 – A review of evidence and implementation strategies in Malawi"

ANNEX 4:

Facility-level questionnaire for baseline assessment of differentiated ART delivery

Facility-level questionnaire on differentiated ART delivery	Site:
The elements of differentiated ART delivery	
Is ART delivery differentiated for stable patients?	
Is ART delivery differentiated for patients with a high viral load?	
Is ART delivery differentiated for patients with other medical needs?	
Is ART delivery differentiated for pregnant and breastfeeding women?	
Is ART delivery differentiated for children and adolescents?	
Is ART delivery differentiated for men?	
Is ART delivery differentiated for key populations?	
Is ART delivery differentiated for any contextual factors?	
The building blocks of differentiated ART delivery	
Where is ART delivered? (facility or facility & community)	
What is the schedule for clinical follow up in the clinic?	
What is the schedule for counselling follow up?	
What is the schedule for laboratory follow up?	
What is the maximum ART refill allowed for patients?	
What maximum refill (X months) is actually given routinely for stable clients?	
Do patients see the nurse every visit or are clinical and refill visits differentiated?	
Who performs the ART consultation?	
Do patients collect ART as individuals?	
Do patients collect ART in any group dynamic?	
Health care worker perspective	
How many days of the week is ART given?	
From what time is ART provided from and to?	
How many clients does each HCW see on an ART day?	
Client perspective	
How far are patients travelling to reach your clinic?	
How long do clients wait from when they arrive to when they leave?	
Monitoring and evaluation	
Number on ART	
Adult retention at 12 months %	
Adult retention at 48 months %	
Paediatric retention at 12 months %	
Paediatric retention at 48 months %	
PMTCT retention at 12 months %	
PMTCT retention at 48 months %	
Is there an appointment and tracing system?	

ANNEX 5:

Template for assessing relevant policies related to differentiated ART delivery

 WHEN	<p>What is the minimum frequency of clinical consultations/visits?*</p> <p>What is the maximum ART refill allowed?*</p> <p><i>*Do these recommendations apply to all adults, adolescents, children and key populations living with HIV?</i></p>
 WHERE	<p>Can ART be distributed at peripheral health facilities?*</p> <p>Can ART be distributed at the community level?*</p> <p><i>*Do these recommendations apply to all adults, adolescents, children and key populations living with HIV?</i></p>
 WHO	<p>Can non-physician clinicians, midwives and nurses maintain clients on ART?*</p> <p>Can trained and supervised community health workers dispense ART between regular clinical visits?*</p> <p>Can trained and supervised community health workers distribute ART between regular clinical visits?*</p> <p>Is there a policy that enables clients to send a “treatment buddy” or representative to collect their ART refills on their behalf?</p> <p><i>*Do these recommendations apply to all adults, adolescents, children and key populations living with HIV?</i></p>
 WHAT	<p>Are there any policies related to community-based care?*</p> <p>Are there any policies defining the criteria for a “stable” client?*</p> <p>Is there a policy supporting the cessation of CD4 count monitoring if viral load testing is available?*</p> <p><i>*Do these recommendations apply to all adults, adolescents, children and key populations living with HIV?</i></p>

ANNEX 6:

Considerations for other client groups

Based on the elements, repeat Step 3 for different groups of clients. Alternatively, highlight variations in how ART delivery is differentiated for these groups below.

As a first step, consider expanding the number of days of the week that ART is offered and/or extending hours of services.

CLINICAL

- A. Stable – other definition**
- B. Unstable clients (high VL)**
- C. Unstable (other)**
- D. Clients with co-morbidities**

Summary of service delivery model adaptations based on clinical characteristics:

SUB-POPULATION

A. Pregnant and breastfeeding woman

Summary of service delivery model for pregnant and breastfeeding women:

Appointment bookings on the same day?
Integration of ANC and ART services?
Club model?
Mother infant pair clinic?

B. Men

Summary of service delivery model for men:

Extended hours?

C. Children and adolescents

Summary of service delivery model for children and adolescents:

Appointment bookings on the same day?
Family model of ART delivery?
Support for adolescent transition to adult ART provision?
Additional psychosocial support for adolescents?

D. Key populations

Summary of service delivery model for key populations:

MSM?
SW?
PWID?
TG?

CONTEXT

A. Urban/rural

B. Unstable context

C. Epidemic type

Summary of service delivery model based on context:

ANNEX 7:

Outline of model mechanics – the “how”

The following outline should be completed following the 5-step approach to differentiated ART delivery. These are the nuts and bolts questions that determine how the model operates – the “how”. Only once the “where”, “when”, “who” and “what” have been selected can you proceed to the “how”. Examples of these can be found on the compendium website – www.differentiatedcare.org.

MODEL MECHANICS

	ART refills	Clinical consultations
Individual/group approach		
Who attends?		

Client recruitment

Where	
By whom	
Eligibility assessment	
Group formation	

HIV disclosure

Does it happen?	
If yes, where?	

Annual health care visit schedule for client

1.	
2.	
3.	
4.	
5.	
6.	

Alignment of ART refill and blood draw visit

Does it happen?	
-----------------	--

Alignment of ART refill and clinic visits

Does it happen?	
-----------------	--

Strategy and timing for actioning high VL/other red flag results

Strategy	
Minimum period for action/action failure risk	
Maximum period for action/action failure risk	

Clinical outreach from facility potential

By whom	
Detail	

ART refill preparation

Is ART pre-packed?	
If yes, by who?	

ART refill provision to group meeting location

How	
By	

Referral criteria

Criteria	
By	
To	
When	

Up referral to facility (return to standard of care)

Criteria	
Communicated by	

Client records

Facility clinical folder	
Client ART card	

Monitoring system

At group meeting venue	
At health care facility	

STAFFING

Impact of the model of ART delivery on:

Lay health care worker	
Nurse	
Facility manager	
Pharmacist/pharmacy assistant	
Data clerk	

TRAINING

CLIENT TRAINING	FACILITY STAFF TRAINING
Intensity of training required:	Intensity of training required:
Details:	Details:

ANNEX 8:

Sample clinical visit checklist from Swaziland National Standard Operating Procedures

Table 1: Checklist for 6-monthly clinical visits

Checklist for client ART clinical visits conducted every six months
<ul style="list-style-type: none">• Take clinical history, do physical examination and WHO staging or WHO T-staging.• Explore/manage opportunistic infections (OIs) and investigate all presumptive cases for TB.• Check and review if there are any available test results that are still to be communicated to the client.• Review the client's adherence record: check if client is on the right regimen and taking regimen correctly.• Assess any changes in the psychosocial well-being of the client that may influence chronic ART care.• Ensure that all necessary fields are completed in the chronic care file, appointment registers, client booklet and the ART patient monitoring records (APMR) or client management information system (CMIS). Prescription forms should be fully completed.• Screen the client for continued eligibility on the preferred model and find any relevant feedback from them.• Assure integration of other components of care: FP, IPT, NCDs, cervical cancer screening etc.• Document significant incidents in the client file.





DIFFERENTIATED CARE FOR HIV: A DECISION FRAMEWORK FOR ANTIRETROVIRAL THERAPY

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Follow these characters as they find solutions to common challenges in HIV care

I need to improve the retention outcomes in my district.



Andrew, a district ART manager

I have to walk a really long way to get to the clinic.



Mary, a client

I always feel rushed and am seeing too many clients. Why do I need to see my stable clients every month?



Jane, a nurse

I feel healthy and need to be at work.



John, a client