ICAP Approach to Differentiated Service Delivery

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Mailman School of Public Health

ABOUT ICAP

ICAP was founded in 2003 at Columbia University's Mailman School of Public Health. A global leader in HIV and health systems strengthening, ICAP provides technical assistance and implementation support to governments and non-governmental organizations in more than 21 countries. ICAP has supported work at more than 5,200 health facilities around the world. More than 2.2 million people have received HIV care through ICAP-supported programs and over 1.3 million have begun antiretroviral therapy.

Preface

This guide was developed as part of a four-part series that aims to support ICAP teams in the implementation of effective strategies that support reaching the global 90:90:90 targets.* The four documents describe ICAPs approach to:

1) **Targeted HIV Testing.** This document describes innovations that support an increase in yield in HIV testing, especially among subpopulations that have historically been hard to reach.
2) **Antiretroviral Therapy Initiation in the Era of Treat All.** This document describes approaches to ensuring high uptake and coverage of antiretroviral therapy (ART) in the context of the "treat all" approach.
3) **Differentiated Service Delivery.** This document describes key considerations for the implementation of differentiated service delivery models.
4) **Viral Load Scale-Up.** This document describes key considerations for preparing for national implementation and scale-up of routine viral load monitoring.

These guides can be used to assist countries in thinking through successful strategies to increase targeted HIV testing, improve ART coverage and retention in care, and maximize services to ensure viral load suppression. All four documents highlight areas that need to be prioritized, while maintaining a focus on critical issues not adequately covered in other resources. They are intended to complement the "ICAP Package of Care for People Living with HIV" (see Section VI: Tools).

The target audience of this guide includes clinical staff and health managers supporting implementation and scale-up of differentiated service delivery.

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* Targets are that 90 percent of all people living with HIV know their HIV status; 90 percent of all people with diagnosed HIV infection receive sustained ART; and 90 percent of all people receiving ART have viral suppression.

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Acronyms

ALHIV	Adolescents living with HIV
ART	Antiretroviral therapy
CAG	Community ART group
CrAg	Cryptococcal antigen
CTX	Cotrimoxazole
DQA	Data quality assessment
DSD	Differentiated service delivery
DSDM	Differentiated service delivery model
HCW	Health care worker
HF	Health facility
HIS	Health information systems
HIV	Human immunodeficiency virus
INH	Isoniazid
IPT	Isoniazid preventive therapy
OI	Opportunistic infection
MDT	Multidisciplinary team
M&E	Monitoring and evaluation
MOH	Ministry of Health
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission of HIV
SMS	Short Message Service
SOP	Standard operating procedure
TB	Tuberculosis
VL	Viral load
WHO	World Health Organization

Executive Summary

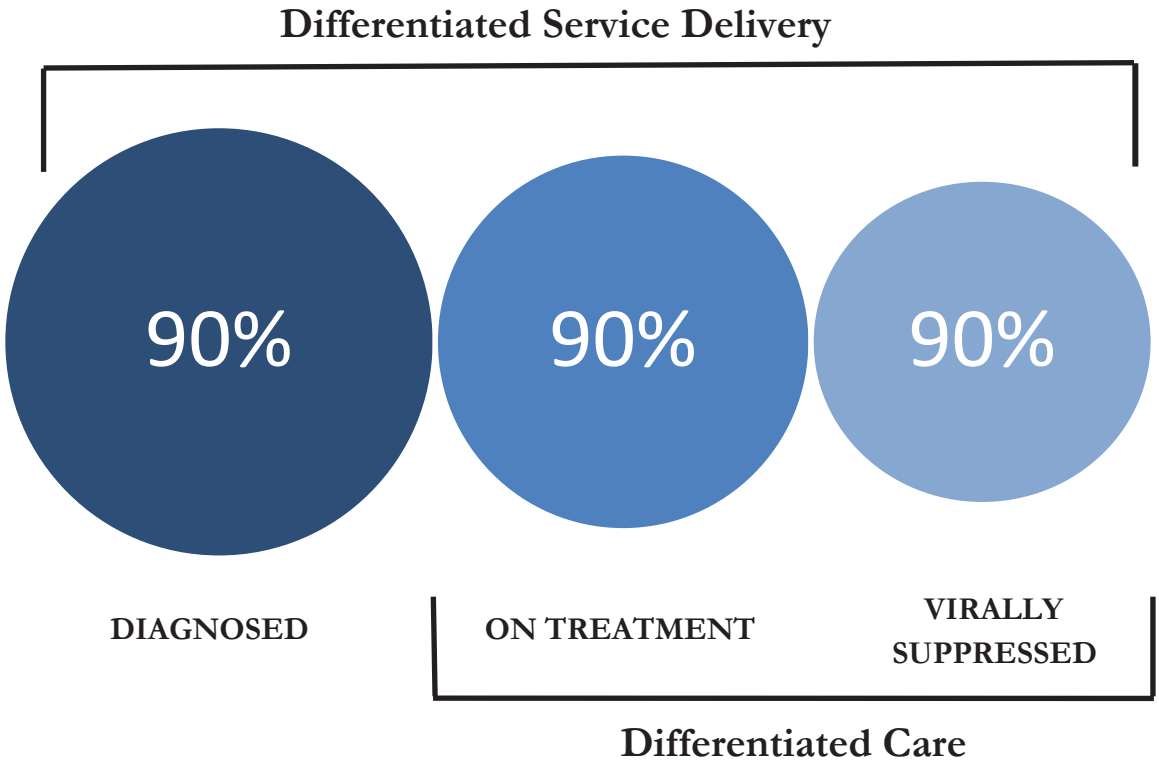
This document focuses on differentiated service delivery models for stable adults and adolescents, and includes a variety of clinical, monitoring, and evaluation resources from ICAP country programs and international organizations.

The document is divided into five main sections:

- The first section describes the **clinical criteria** for classifying patients as stable or unstable, and outlines the package of care and delivery of services (the WHAT, WHERE, WHO, AND WHEN) for well patients initiating ART, patients with advanced disease initiating ART, and stable and unstable patients.
- The second section describes the various **service delivery models** of differentiated care for **stable patients**, both in the community and health facility.
- The third section summarizes considerations for differentiated service delivery for **adolescents** living with HIV and **pregnant and breastfeeding women**.
- The fourth section highlights the **monitoring and evaluation of differentiated service delivery (DSD)**, including necessary adaptations to existing monitoring systems. This section includes country examples, monitoring and evalaution resource tools, and indicators.
- The final section describes **implementation considerations** for scaling up differentiated service delivery models and includes a dashboard to monitor progress towards full-scale uptake.

It is important to note that differentiated service delivery is applicable across the entire HIV care continuum, in support of reaching the 90:90:90 targets (see Figure 1). This guide focuses specifically on the **delivery of ART** to optimize patient care and treatment.

Figure 1. Differentiated Service Delivery vs. Differentiated Care



Introduction

In 2015, the World Health Organization (WHO) released a new recommendation to provide HIV treatment to all adults, adolescents, and children living with HIV, regardless of CD4 cell count or disease stage.[1] Among the challenges associated with implementing the "treat all" strategy is the anticipated increase in the number of patients enrolled in HIV care and treatment clinics, possibly exhausting the capacity to deliver quality care. Currently, HIV programs—particularly those in high prevalence areas—are overstretched and seeking efficient ways to deliver care and treatment that meet clients' diverse needs and lower barriers to care while optimizing efficiencies.

In most settings, HIV service delivery is primarily facility-based. In order to ensure that all people living with HIV (PLHIV) have access to ART, HIV service delivery must be simplified and standardized, focusing not just on decentralization and task-shifting, but also considering community-based models of care and ensuring more efficient procurement and supply chain management.[2]

Box 1. Differentiated Service Delivery is a client-centered approach that adapts HIV services across the cascade to reflect the clinical needs and preferences of various groups of PLHIV, while reducing unnecessary burdens on the health system.

Differentiated service delivery (DSD) is a client-centered approach to patient care that focuses on the preferences and expectations of PLHIV (see Box 1). It addresses the contexts and clinical characteristics of clients and aims to individualize care for patient populations using a public health approach. DSD seeks to create efficiencies in HIV service delivery to achieve program expansion, while ensuring that care meets the diversity of patient needs. The primary objective of DSD is to streamline and remove barriers to care for patients based on the intensity and level of services needed. Under the DSD approach, the sickest patients receive intensified care, while those with stable or less advanced disease receive appropriate care in the environment best suited to their specific needs. Differentiating services for sub-populations such as pregnant and breastfeeding women, children, adolescents, and key populations can help improve access to HIV care.

There are four key components of DSD:

1) **WHAT:** The type of service delivered (i.e., ART refill, clinical review, or both)
2) **WHERE:** The location of service delivery (i.e., in a health facility [HF] or the community)
3) **WHO:** Patient eligibility criteria and type of service provider
4) **WHEN:** The frequency of services for clinical review or ART refill[3]

The purpose of this document is to describe key considerations for implementation of DSD models (DSDM). The document focuses on DSDM for stable adults and adolescents.

I. Differentiated Service Delivery for Adults

Non-pregnant adults living with HIV can be categorized into two major groups:

1. Those in care, newly initiating ART, or on ART for less than a year
2. Those currently on ART for more than one year.

Patients newly initiating ART (group 1) are further divided into two sub-groups: a) those presenting well with early disease (i.e., higher CD4 counts); and b) those presenting with advanced disease (WHO stage III/IV or CD4< 200/mm^3) (see Figure 2). Depending on local context, PLHIV with poorly controlled HIV disease or co-morbidities can be classified as unstable. PLHIV who have been on ART for more than one year (group 2) are further classified as either stable or unstable based on a set of clinical, immunological, and virological criteria as per the WHO[4] (see Boxes 2 and 3). For patients who have been on ART for more than two years, a single viral load (VL) result <1000 copies/ml performed within the past 12 months should suffice to consider them stable if they meet all the other criteria listed in Box 3. The latter differentiation excludes children <10 years and pregnant and breastfeeding women.

Box 2. WHO Definition of a Stable Patient

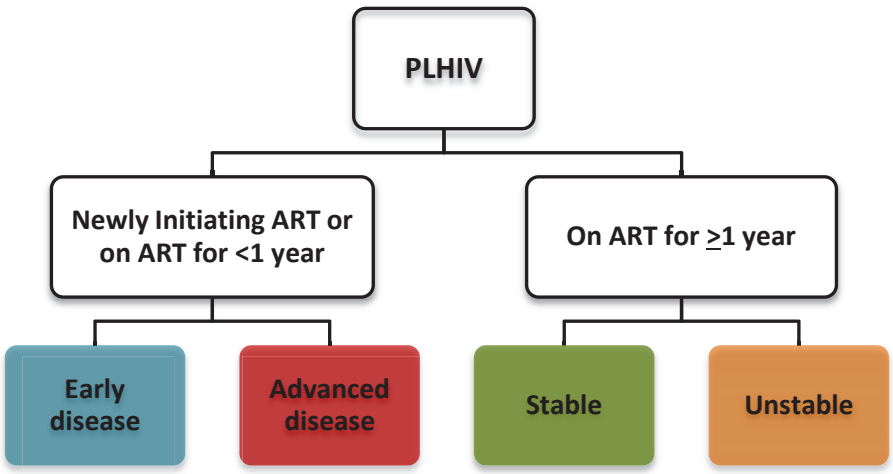
A patient who has:

- Received ART for at least one year and has no adverse drug reactions that require regular monitoring
- No current illnesses or pregnancy
- Is not currently breastfeeding
- Has good understanding of lifelong adherence
- Evidence of treatment success (i.e., two consecutive undetectable VL measures). In the absence of VL monitoring, rising CD4 counts or CD4 counts >200 cells/mm^3 and an objective adherence measure can be used to indicate treatment success.

It is important to appreciate that this categorization is fluid and that assessment of the patient should occur at regular intervals or whenever there is a change in an individual's clinical or immunologic stage. It is also important to note that the types of DSDM implemented will need to be modified depending on the epidemic type (high or low prevalence), care setting (urban, peri-urban, or rural), and resources available. For each group of PLHIV, differentiated service provision should take into consideration the following:

- **Clinical aspects of care** (provider, where service is delivered, and frequency)
- **Laboratory services** (type of test—e.g., VL, CD4 count, cryptococcal antigen [CrAg] screening—and frequency)
- **Adherence/psychosocial support** (provider, where support is provided, and frequency)
- **Medications** (who dispenses medication and refills, where, and frequency)

Figure 2. Overview of Patient Classification for Differentiated Care



Box 3. Classification of Patients as Stable or Unstable

Modified Patient Classification as Stable vs. Unstable
☐ Currently on ART >1 year ☐ >10 years of age, not pregnant, not breastfeeding ☐ Two consecutive VL results <1000 copies/ml within the last two years,* OR Rising CD4 or CD4 >200cells/mm^3, and objective adherence reported good** ☐ No adverse drug reaction requiring ongoing monitoring ☐ No active opportunistic infection (OI), including tuberculosis (TB) ☐ No concerns from health care team***
☐ **Yes** to all the above: **Stable** ☐ **No** to any one of the above: **Unstable**
*Interval between VL should not be less than six months. The most recent VL result should be within the past year. For patients who have been on ART for >2 years, a single VL result that is <1000/ml copies within the past year is sufficient. **Once daily regimen: <2 missed doses/month; Twice daily regimen:<4 missed doses/month OR reported timely drug pickup *** No substance abuse, mental illness, or comorbidity that requires close, frequent follow-up

Key Considerations for Sub-Populations:

For pregnant and breastfeeding women, children <5 years, adolescents, discordant couples, and key populations, ART should be initiated urgently and close follow-up should be provided following guidance presented for patients with advanced disease (Table 1B). Table 4 describes models of care for adolescents.

A. PLHIV Presenting Well with Early Disease

Patients presenting with earlier HIV disease (CD4 >200 cells/mm^3, WHO stage I/II) need adherence and retention support after ART initiation. This can be provided initially in the HF with the option to transition to the community once the patient is stable on ART (see Table 1A). Refer to Annex 1 for the "ICAP Package of Care for PLHIV."

Table 1A. PLHIV Presenting Well with Early Disease

When	What	By Whom	Where
First Visit (Time 0)	**Clinical visit:** HIV diagnosis confirmation; CD4 testing (baseline); WHO Staging; TB Screening; adherence support and counseling **Drug:** ART and CTX initiation	Clinician+	ART clinic
Week 2	**Clinical visit:** Assess for side effects/toxicity; adherence assessment, support and counseling; assignment of patient to peer support group **Drug:** ART and CTX refill for 1 month	Nurse or lay counselor	ART clinic
Month 1–2	**Clinical visit:** Assess for clinical symptoms via symptom checklist and check for side effects/toxicity; initiate IPT; adherence assessment, support, and counseling **Drug:** ART, INH, and CTX refill for 1 month	Nurse or lay counselor	ART clinic
Month 3	**Clinical visit:** Assess for side effects/toxicity; adherence assessment, support, and counseling; link to community adherence counselor **Drug:** ART, INH, and CTX refill for 3 months	Clinician+	ART clinic
Month 4–5	Adherence assessment, support, and counseling	Lay counselor	Community/home or fast-track at ART clinic
Milestone Visit: Month 6	**Clinical visit:** Monitor side effects/toxicity; adherence assessment, support, and counseling **Lab: VL sample collection** **Drug:** INH refill for 1 month; ART and CTX refill for 3 months	Clinician+	ART clinic
Month 7	**Clinical visit: VL results delivered to patient**; assess for clinical symptoms via symptom checklist and check for side effects/toxicity; adherence assessment, support, and counseling; stepped up counseling and support based on VL results **Drug:** ART and CTX refill for 1-3 months based on VL	Clinician+	ART clinic
Month 8–11	**VL > 1000** (Refer to ICAP VL SOP)** **Clinical visit:** Assess for clinical symptoms via checklist; adherence assessment, stepped up counseling, and support **Drug:** ART and CTX refill for 1 month **Lab:** Repeat VL between M9 and M11 after good adherence has been achieved	Lay counselor, clinician, or nurse for repeat VL result	ART clinic
	VL<1000 Adherence assessment, support, and counseling **Drug:** ART and CTX refill for 3 months	Lay counselor	Community/ home or fast-track at ART clinic
Milestone Visit: Month 12	**Clinical visit:** Assess for clinical symptoms via symptom checklist **Lab: Second VL sample collection**; adherence support and counseling **Drug:** ART and CTX refill for 3 months Note: Patient is classified as "**STABLE**" or "**UNSTABLE**" based on clinical evaluation and VL results of specimen collected at 12 months	Clinician+	ART clinic

+ Clinician includes physicians, nurses, clinical officers, and medical technicians

** "Standard Operating Procedures on Viral Load Monitoring for ICAP Clinical Staff and Health Care Workers" (Annex 2)

At every contact with patients, health care worker (clinician, nurse, or lay counselor) will assess the patient and classify him/her as "early" or "advanced" disease, and refer to the appropriate follow-up as indicated.

Acronyms: **TB** = tuberculosis, **ART** = antiretroviral treatment, **INH** = isoniazid, **CTX** = cotrimoxazole, **IPT** = isoniazid preventive therapy, **VL** = viral load

B. PLHIV Presenting with Advanced Disease

Patients with advanced disease (WHO stage III/IV or CD4 < 200/mm^3) are at high risk for HIV disease progression and HIV-related complications and should receive a clinical package of care[5] designed to reduce the risk of morbidity and mortality, including rapid initiation of ART (once the risk of immune reconstitution inflammatory syndrome [IRIS] is excluded). They should receive cryptococcal antigen screening; screening for TB, with initiation of TB treatment or IPT as indicated; provision of CTX prophylaxis; and planning for intensive follow-up (see Table 1B). Refer to the ICAP in Kenya "Severely Immunocompromised Package of Care" (Annex 3), and "Differentiated Care for Adults at High Risk of HIV Disease Progression: A Call to Action" (Annex 4) for details on "WHAT" additional services should be provided for patients presenting with advanced disease.

WHO will be releasing new guidance on the minimum package of care for patients with advanced HIV disease later in 2017.[6] It is anticipated that this will include an enhanced package of care for patients with advanced disease, based on the results of the REALITY trial.[7] The REALITY trial evaluated an enhanced package of care for patients with CD4 <100 cells/mm^3, which included five days of azithromycin (500mg), a single dose of albendazole (400mg), 12 weeks of INH/pyridoxine (300/25mg), 12 weeks of fluconazole (100mg), and continuous cotrimoxazole. There was a 27 percent reduction in mortality compared to the standard of care, which was continuous cotrimoxazole.

Table 1B. PLHIV Presenting with Advanced Disease

When	What	By Whom	Where
First Visit (Time 0)	**Clinical visit:** HIV diagnosis confirmation; CD4 testing (baseline); WHO staging; CrAg and TB screening; OI screening; adherence support and counseling **Drug:** ART and CTX initiation	Clinician+	ART clinic
Week 2	**Clinical visit:** Management of co-existing OI; assess for side effects/toxicity; adherence assessment, support, and counseling **Drug:** ART and CTX refill for 1 month	Clinician+	ART clinic
Month 1-2	**Clinical visit:** Management of OI; assess for side effects/toxicity; initiate IPT; adherence assessment, support, and counseling **Drug:** ART, INH, and CTX refill for 1 month	Clinician+	ART clinic
Month 3	**Clinical visit:** Assess for side effects/toxicity; adherence assessment, support, and counseling **Drug:** ART, INH, and CTX refill for 1 month	Clinician+	ART clinic
Month 4-5	**Clinical visit:** Assess for side effects/toxicity; adherence assessment, support, and counseling **Drug:** ART, INH, and CTX refill for 1 month	Clinician+	ART clinic
Milestone Visit: Month 6	**Clinical visit:** Assess for side effects/toxicity; adherence assessment, support, and counseling **Lab: VL sample collection** **Drug:** ART, INH, and CTX refill for 1 month	Clinician+	ART clinic
Month 7	**Clinical visit: VL results delivered to patient;** monitor clinical symptoms via symptom checklist and check for side effects/toxicity; adherence assessment, support, and counseling; stepped up counseling and support based on VL results **Drug:** INH refill for 1 month; ART and CTX refill for 3 months	Clinician+	ART clinic
Month 8-11	**VL > 1000** (Refer to ICAP VL SOP)** **Clinical visit:** Assess for side effects/toxicity; adherence support; stepped-up counseling **Drug:** ART and CTX refill for 1 month **Lab***:* Repeat VL between M9 and M11 after good adherence is reported	Clinician+	ART clinic
	VL < 1000 **Clinical Visit:** Assess for side effects/toxicity; adherence assessment, support, and counseling **Drug**: ART and CTX refill for 3 months	Clinician+	ART clinic
Milestone Visit: Month 12	**Clinical visit:** Assess for side effects/toxicity **Lab: Second VL sample collection**; adherence counseling and support **Drug:** ART and CTX refill for 1 month Note: Patient is classified as "**STABLE**" or "**UNSTABLE**" based on clinical evaluation and VL results of specimen collected at 12 months	Clinician+	ART clinic

+ Clinician includes physicians, nurses, clinical officers, and medical technicians

** "Standard Operating Procedures on Viral Load Monitoring for ICAP Clinical Staff and Health Care Workers" (Annex 2)

At every contact with patients, health care worker (clinician, nurse or lay counselor) will assess the patient and reclassify him/her as "early" or "advanced" disease, and refer to the appropriate follow-up if indicated.

Acronyms: **CrAg** = cryptococal antigen, **TB** = tuberculosis, **ART** = antiretroviral treatment, **INH** = isoniazid, **CTX** = cotrimoxazole, **IPT** = isoniazid preventive therapy, **OI** = opportunistic infections, **VL** = viral load

C. PLHIV Stable on ART

Stable patients who have been on ART for at least one year can be seen less frequently and receive their ART via a fast-track approach at an ART clinic, in the community, or at home (with clinical visits at the HF every 3–6 months and VL monitoring annually) (see Table 2A). It is important to reclassify patients after each VL and/or clinical assessment and address who, what, when, and where the patient should be managed. Transitioning patients from facility-based ART pickup to community-based ART distribution requires close monitoring to ensure that the patient is linked to the distribution group and no gaps in treatment occur.

Table 2A. Stable Patients on ART for One Year or More

What	By Whom	Where
Clinical assessments every 3–6 months	Clinician+	ART clinic
Lab: VL monitoring every 12 months*	Clinician+	ART clinic
Psychosocial/adherence support every 3–6 months	Lay counselor or community health care worker	Community/home, fast-track at clinic, or facility-based distribution group
Drug pickup every 3–6 months	Lay counselor or community health worker	Community/home, fast-track at clinic, or facility-based distribution group

+ Clinician includes physicians, nurses, clinical officers, and medical technicians
*Reclassify patients after each viral load and/or clinical assessment

D. PLHIV Unstable on ART

Unstable patients on ART for less than one year are also at high risk for poor clinical outcomes, including complications and/or treatment failure. Such patients need close clinical monitoring, most of which will need to be provided in the HF. They should be provided with enhanced adherence support[8] and VL testing, and reclassified based on VL result and clinical assessment (see Table 2B).

Table 2B. Unstable Patients on ART for Less Than One Year

What	By Whom	Where
Clinical assessments every 1–2 months	Clinician+	ART clinic
Lab: VL monitoring every 3 months after enhanced adherence support*	Clinician+	ART clinic
Psychosocial/adherence support** every 1–2 months	Lay counselor, adherence counselor, or pharmacist	ART clinic
Drug pickup every 1–2 months	Lay counselor, adherence counselor, or pharmacist	ART clinic

+ Clinician includes physicians, nurses, clinical officers, and medical technicians
*Reclassify patients after each viral load and/or clinical assessment
** Refer to ICAP Enhanced Adherence Plan Tool (see Annex 11)

II. Differentiated Service Delivery for Stable Patients

ART provision for stable patients can be simplified and streamlined to improve efficiency and quality by down-referring patients to decompress HF, moving treatment closer to the community, or fast-tracking patients picking up medication in the HF. The following sections, along with Table 3, summarize the various programmatic innovations that have been used to provide differentiated ART services to stable patients.

A. Facility-based ART Delivery

Stable patients on ART are given the option to pick up medication refills in the HF. These visits are separate from clinical consultations; patients can either be fast-tracked to the pharmacy to pick up refills or pick up medication when they attend facility-based adherence club meetings.

i. Fast-Track ART Refill

Stable patients should be fast-tracked when they come to the clinic and access the pharmacy directly for refills, without having to see a clinician. This can be achieved by shortening the registration period. Once registration is complete, the receptionist directs the patient to the pharmacy or designated dispensing point for drug pickup. Medication should be pre-packaged and labeled at least a day in advance and stored at the drug pickup point. At the time of drug pickup, the pharmacist or health care worker (HCW) administers a quick symptom screen and performs an adherence check. The patient is discharged home unless he/she reports a complaint or has a positive screen on the checklist (see Annex 5). Patients should be given the option to see a clinical provider if there are any concerns noted after the checklist is completed. The pharmacist or HCW must provide a monthly summary of drug pickup for patient monitoring and reporting.

ii. Facility-based ART Groups

Group distribution of drugs for stable patients may be offered to those attending adherence clubs at the facility. Clubs are facilitated by peer educators or expert clients, with referrals to nurses and/or doctors when required. They also function as peer support groups. They typically consist of groups of up to 30 patients who meet every two to three months for less than an hour. During the group session, essential tasks, such as weighing and symptom-based health assessments, are provided by a trained peer educator or community health worker who acts as the club facilitator. Assessments are captured in patient records (see Annex 6) and monitored by clinic staff via a monthly reporting form. The group facilitator completes the monthly reporting form for patient monitoring and reporting. Any patient reporting symptoms is referred to the ART clinic for prioritized assessment by a clinician. All members of the club see a nurse twice per year: once for blood tests and then two months later for their annual clinical check-up. The club facilitator is also responsible for completing the club register (example shown in Annex 7).

B. Community/Home ART Delivery

Stable patients on ART are given the option to pick up medication refills at a designated place in the community or to form a group in which the members take turns collecting drugs from the HF and delivering them to individuals in the community ART group (CAG). The success of community ART models depends on sufficient, reliable support and resources, including: a cadre of lay workers; a flexible and reliable medication supply; access to quality clinical management; and a reliable monitoring system for patient care (ideally including VL). The models also require ongoing evaluation and further adaptation in order to reach more patients who are at high risk of loss to follow-up. At a minimum, there should be: a register to document attendance and medication pickup, a simple checklist to be used for screening, and an attendance monitoring form (example shown in Annex 8) for verification of activities by the HCW and the CAG representative.

i. Community ART Distribution Points

Members from networks of PLHIV form a group and pick up their medication from a fixed point in the community. A lay worker dispenses medications, measures weight, conducts symptom-based screening, and facilitates peer support by expert patients after medication is distributed. Patients attend the distribution point every three months for ART refills and report to the HF biannually for clinical consultation and blood tests (with VL conducted annually). The lay workers also provide referrals for clinical care for clients with a positive screen or complaints. Patients who do not show up for their visits are traced by peer counselors through phone calls or home visits. The distribution points can also offer free HIV testing and counseling at the community level. Community distribution points require lay workers for staffing, secure spaces to store medication, and a means of transportation to bring medication from the HF to distribution points. There should be a mechanism for feedback of information collected at the distribution point to the HF where patients are referred for clinical care, as well as a monitoring and evaluation (M&E) system to monitor adherence and retention, with feedback to the HF.

ii. Community Health Worker/Peer Educator-led Community-based ART Groups

ART adherence clubs for patients stable on ART are facilitated by a community health worker or non-clinical staff member, such as a peer educator, depending on the local context. The group is composed of approximately 15–30 stable patients who meet every two to three months. The group facilitator provides quick clinical assessment, referral (where necessary), peer support, and distribution of pre-packaged ART. Members go to the clinic twice each year for clinical follow-up.

iii. Patient-led Community ART Groups

Members of a group of stable ART patients in a community take turns collecting drugs from the clinic and delivering them to the rest of the group. Group members also provide one another with adherence support and outcome monitoring. The group is composed of 5–8 stable ART patients who are trained on specific roles and responsibilities, including recognizing symptoms that require referral to clinic, using tools to collect minimum attendance information, and how to communication with HCW. They meet monthly at the home of a CAG member or a community venue to distribute medication and provide one another with adherence support. Each member receives a clinical consultation and blood tests when they visit the clinic. It is important that there be a nurse or peer educator assigned to monitor the group and verify that medications have been picked up and signed for.

Table 3. Summary of Differentiated Service delivery Models of ART Distribution for Stable Patients[†]

Where	Facility-based ART Distribution		Community/Home ART Distribution		
Type	**Fast-track ART refill**	**Facility–based adherence clubs**	**Community ART distribution point**	**Peer Educator-led community ART refill group**	**Patient-led community ART group**
Setting	Urban/rural	Urban	Urban/rural	Rural	Rural
Who *Provider* *Clients*	Pharmacy technician or Nurse	Pharmacy technician, Nurse, or peer or lay counselor Group of 25–30 patients	Community nurse or peer or lay counselor	Peer or lay counselor Group of 15–30 stable patients	PLHIV Group of 5–8 stable patients
Where	Clinic pharmacy in facility offering ART	Meeting space in facility offering ART	Community venue closer to patient home	Community venue closer to patient home	Patient's house or community venue
What	-Medication pickup (ART, CTX, INH) -Quick symptom screen -Adherence monitoring -Provision of condoms	-Medication pickup (ART, CTX, INH) -Quick symptom screen -Adherence monitoring -Psychosocial support -Provision of condoms	-Medication pickup (ART, CTX, INH) -Quick symptom screen -Adherence monitoring -Psychosocial support -Provision of condoms	-Medication pickup (ART, CTX, INH) -Psychosocial support -Provision of condoms	-Medication pickup (ART, CTX, INH) -Psychosocial support
When	Every 3–6 months	Every 2–4 months	Every 2–3 months	Every 2–3 months	Monthly
How	Pre-packaged medications	Pre-packaged medications	-Pre-packaged medications -Space to store medications at community level	-Pre-packaged medications at HF -Host picks up medications on day of clinical visit to HF	-Pre-packaged medications at HF -Host picks up medication on day of clinical visit to HF
M&E	-Register to document medication pickup -Symptom check list	-CAG register -Attendance monitoring form -Symptom checklist	-CAG register -Attendance monitoring form -Symptom checklist	-CAG register -Attendance monitoring form	-CAG register -Attendance monitoring form

[†] Modified from Bemelmans M, Baert S, Goemaere E, et al. Community-supported models of care for people on HIV treatment in sub-Saharan Africa. *Trop Med and Int Health.* 2014;19(8):968–977.

III. Differentiated Service Delivery for Other Subpopulations

A. Differentiated Service Delivery for Other Subpopulations

i. Adolescents

Adolescents living with HIV (ALHIV) have distinct needs due to rapid physiological, psychological, and behavioral changes.[9] Generally, ALHIV have inferior clinical outcomes compared with adults and are at higher risk of being lost to follow-up (less than two-thirds of adolescents are able to maintain 95% adherence[10]). ALHIV are often grouped with children or adults, so there is limited adolescent-specific evidence for service delivery. Vertically and horizontally-infected adolescents have some similarities, but may also have different needs and diverse clinical conditions that require different service delivery approaches. WHO recently completed a review of DSDM for ALHIV and found six DSDM targeting adolescents, including youth/teen clubs, CAGs, multi-month prescription, community-based ART, and Saturday adolescent-focused services. There were three additional models that included both adolescents and children. All models were implemented in high-prevalence, generalized epidemic areas that included urban, peri-urban, and rural areas. Two of the adolescent-specific models were HCW-managed groups, two were variations of the client-managed group model, and two were a combination of HCW-managed and facility-based individual (fast-track) models. Table 4 highlights the key differences in the nine models identified by WHO.

ii. Pregnant and Breastfeeding Women

In most high-burden countries, PMTCT and HIV care has been integrated for pregnant and breastfeeding women using a one-stop model. Therefore, DSDM will need to provide not only integrated care, but also take into consideration the different challenges women face along the entire PMTCT continuum, including during pregnancy, the postpartum period, and the transition back to HIV care. Different DSDM for pregnant and breastfeeding women have been implemented to support their access to essential services (such as adequate ART) during vulnerable periods along their care continuum (e.g., time of delivery). In some countries, like South Africa, postpartum women are integrated into community adherence clubs or postnatal clubs, which are facilitated by lay counselors or mentor mothers.

Table 4. Summary of Differentiated Service Delivery Models for ALHIV*

Model type	HCW-managed group	Client-led group	HCW-managed group	HCW-managed group	Facility-based individual	Facility-based with community support	Facility-based individual	Facility-based individual	Out-of-facility individual
Name of Model	**Youth Club**	**Adolescents in CAG**	**Saturday Teen Club**	**Swazi Teen Club**	**Saturday Teen Clinic**	**Community Adolescent Treatment supporters (CATS)**	**Three-Month Refill**	**MMP/ (SPEEDI)**	**C-BART**
Setting	Urban/rural	Urban/ rural	Urban	Peri-urban	Peri-urban	Urban	Urban/rural	Urban	Urban
Who	20–30 patients	20–30 patients							
Eligibility criteria	12–25 years; >12m ART; 2 VL <400; Well	>12–18years; >6m on 1st line; CD4 >200; Well & disclosed	9–23 years; On ART; Disclosed	10–19 years >6m on ART*; 1 VL <1000; Well	13–24 years; >6m on ART; Disclosed; Well	17–23 years	No criteria known	0–25 years; >6m on ART; 1 VL <1000; Well	>1 year
Clinical review:									
Who	Nurse	Nurse	Nurse/doctor	Nurse/doctor	Doctor	Nurse	Nurse	Nurse/doctor	Outreach team
When	Annually	Every 6m	Every 2m	Every 6m	Every 2m	Every 3m	Every 3m	Every 4–6m	Every 3-6m
Where	PHC	PHC	Tertiary/PHC	PHC	PHC		PHC	Specialized clinic	Community
ART refill:									
Who	Lay HCW	Peer	LHCW/ clinician	LHCW/ clinician	LHCW/ doctor	Nurse	Nurse	LHCW/ clinician/ pharmacist	Outreach team
When	4x2m then 1x4m	Monthly	Every 2m	Every 3m	Every 2m	Every 3m	Every 3m	Every 2-3m	Every 3-6m
Where	PHC	Community	Tertiary /PHC	PHC	PHC	PHC	PHC	Specialized peds clinic	Community
Additional information	http://www.differentiatedcare.org/Models/Youth Clubs/Details#	MSF program in Tete	http://dignitasinternational.org/hiv/teen-club/ https://botswanateenclub.wordpress.com/			CATS provide weekly home visits and monthly support group activities			

*Modified from proceeding of WHO consultation on HIV DSDM for specific populations and settings, November 16–18 2016, Geneva, Switzerland.

Acronyms: **HCW** = heath care worker, **PHC** = primary health center, **LHCW** = lay health care worker, **M** = month, **MMP** = Multi-month prescription, **SPEEDI** = Standardized Pediatric Expedited Encounters for ART Drugs Initiative, **C-BART** = Community-based ART

IV. Monitoring and Evaluation Considerations

DSD diversifies the "who, what, when, and where" of HIV program design. For example, for those doing well on ART, programs may offer fast-track services, less frequent visits, multi-month prescribing, facility-based ART clubs, and/or CAGs. Other DSD services are tailored to patients with advanced HIV disease or those experiencing virological failure; these may include more frequent assessments, closer clinical and laboratory monitoring, and intensified clinical and psychosocial interventions. Differentiated services may also be developed for children, adolescents and young people, pregnant and breast-feeding women, key and vulnerable populations, and other patient profiles.

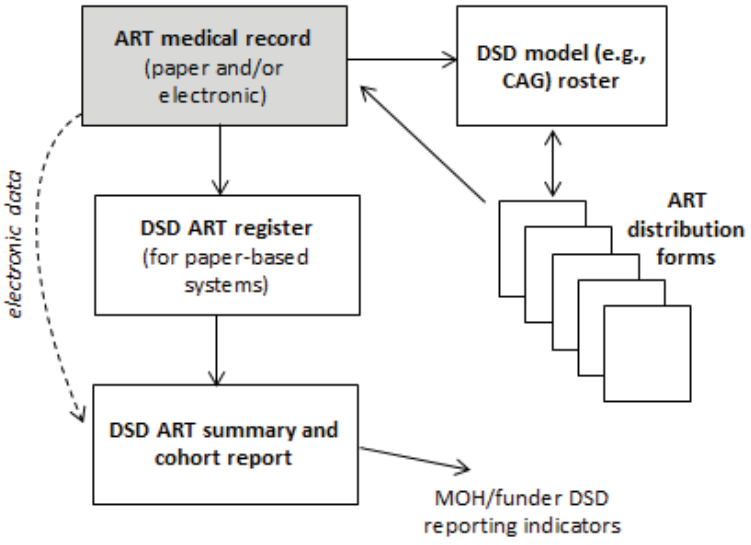
These changes present a challenge for existing HIV program M&E systems. In order to account for diversifying services and to provide accurate, complete, and timely data for reporting purposes and program improvement, adaptations will need to be made to M&E tools (including those for data collection, monitoring, and reporting), M&E strategies, and program evaluation metrics. New assessment methods that measure unique aspects of DSD, such as its impact on quality of patient care and provider productivity, may also be needed. The adoption of specific M&E processes focused on DSD will need to be adapted to specific contexts and based on characteristics of the existing M&E and DSD systems.

Adaptations to existing M&E systems may include:

1) **Updating existing health information systems (HIS) tools**, such as the patient ART medical record, to capture key elements of DSD care and **introducing new tools** to capture services provided to patients receiving varied HIV services, including those taking place outside of the clinical setting
2) **Establishing an effective data flow** between any new tools and the patient HIV medical record
3) **Establishing and defining indicators** to be routinely reported that adequately describe uptake and outcomes of diverse facility- and community-based services
4) **Developing and implementing tools and systems to generate data summaries** for DSD, including data for calculating new indicators to enable evaluation of the programs

To optimize implementation and ensure sustainability, these M&E systems and tools should be developed and subsequently implemented in collaboration with the Ministry of Health (MOH) and other stakeholders, and, wherever possible, should incorporate prevailing global guidance and lessons learned from other settings. An overview of M&E system elements for potential adaptation, along with additional M&E considerations for implementers of DSD, is presented below.

Figure 3. Illustrative M&E Data Flow for DSD



Note that these recommendations envision a system where DSD care elements are integrated as much as possible into existing HIV programs and build on tools—such as the patient ART medical record and electronic medical record—to streamline systems for data collection and reporting (see illustrative data flow in Figure 3). This integration

may not be achievable in the short-term in some contexts; however, as diverse delivery models become standard and indicators required by MOH and funders begin to require data specific to DSD, minimizing the use of non-integrated, parallel tools will be critical.

Lastly, note that these M&E considerations focus on supporting DSDM for stable patients. M&E approaches for DSD for other subpopulations (e.g., adolescents, pregnant and breastfeeding women, and some unstable patients) may differ and will require development as specific DSD strategies for these subpopulations become better established.

A. Tools to Document DSD

In general, DSD-specific information is not captured by currently available patient ART medical records or other national M&E tools. For example, current HIS tools generally do not record longitudinal information on patient eligibility for DSDM, the model of care the patient is receiving, or the type of services provided (e.g., facility-based club attendance, community-based ART pickups, or fast-track ART refills). Such additional information is needed both to inform clinical management of patients and to provide data for M&E and quality improvement efforts. In addition, it is anticipated that patients may move back and forth across various service delivery models based on their clinical status or psychosocial needs. Therefore, for effective implementation of DSD, MOH ART medical records and related tools, such as summary registries and patient databases (described below), will require adaptation, resulting in a new set of tools that capture services delivered. In some cases, new M&E tools will need to be developed.

i. Adapting the Patient ART Medical Record

Most national HIV care/ART medical records do not currently document key DSD information, such as the **classification of patients** as stable/unstable and eligible/not-eligible for DSD over time, or the **type of DSD services** provided to the patient. Whether or not these indicators are aggregated and used at higher levels of the health system, they are important for individual patient care. DSD eligibility, DSDM, and DSD services provided should be added to the national ART medical record to support routine monitoring of DSD implementation (see Table 5).

1. DSD Eligibility

At present, most guidelines determine eligibility for specific DSDM using specific demographic, clinical, laboratory, and psychosocial criteria. Therefore, these variables need to be assessed and documented at regular intervals and eligibility classifications recorded at each time point. Facility-based records, including the patient ART record, will likely require adaptation to document patients' eligibility status at regular intervals (e.g., every six or 12 months). DSD exclusion criteria will also need to be assessed regularly and documented over time in order to determine the coverage by such a model at a specific HF or

Table 5. Illustrative Data Elements to be Added to ART Medical Record

Data Element	Instructions/Responses
Type of visit	□ Clinic visit □ Fast-track ART □ Facility–based adherence club □ Community ART distribution point □ Peer-led community ART group □ Patient-led community ART group
For clinic visits only:	
Patient stable?	□ Stable □ Unstable If unstable, how?: _____
Patient eligible for fast-track, adherence club, or ART group?	□ Eligible □ Ineligible If ineligible, why?: □ Unstable □ Other: _____
DSDM assigned	□ HIV clinic-based ART □ Fast-track ART □ Facility-based adherence club □ Community ART distribution point □ Peer-led community ART group □ Patient-led community ART group
Group ID	ID number assigned by facility to club or group (for patients assigned to a facility-based adherence club or community ART group)
For non-Clinic visits only:	
ART pickup date	Date ART was received by the patient or, for groups, date ART was picked up by a group member
ART supply provided	Document the supply of ART provided (e.g., 1 month)
Comments	May note TB symptoms or diagnosis, pregnancy, adherence problems, or health problems requiring HIV clinic follow-up

program, and to enable transitioning patients from one model of care to another.

2. Documenting DSDM and Services Received

In addition to documenting eligibility for DSD, the patient ART medical record will also need to record at each visit whether or not the patient is assigned to receive DSD; whether or not s/he is actually receiving DSD; which type(s) of DSD services are being provided; and where (e.g., community, pharmacy, laboratory). As many DSDM involve service provision outside of the HF and at times other than an HIV clinic visit, the ART medical record should be updated to record the dates of patient ART pickup, supply of ART provided, and other services (such as counseling, laboratory testing, etc.) that did not coincide with HIV clinic visits. Additional fields, such as TB screening, pregnancy status, family planning services, ART adherence assessment results, and assessment of other co-morbidities may be added depending on the scope of information collected in non-facility-based DSD care. The possible service delivery fields available for inclusion in an adapted ART record will be defined by the data elements collected in any new M&E tools introduced for use in less-intensive ART (described below).

In summary, data collected or managed in the ART medical record under DSD should include all of the standard elements of care for patient clinic visits, including clinical, adherence-related, laboratory, and pharmacy data, as well as new information, including the classifications discussed above; information on the model of DSD the patient has been assigned to receive; an assigned ID number for the CAG or site (as applicable); and longitudinal information on services provided, such as ART pickup dates and information from routine assessments such as TB screening and adherence monitoring. It is important to recognize that DSDM are evolving and thus flexibility is required to be able to add new elements to the medical models adopted as they are incorporated into programs.

ii. Adapting Pharmacy Tools and Systems

Irrespective of whether patient ART records sufficiently capture patient classification, DSDM, and DSD care received, tools and systems within pharmacies at facilities that support DSD may require adaptation to ensure that services are provided most effectively. For example, pharmacies may implement systems to facilitate the planning for expected ART pickups (e.g., to allow for prepacking of medications), as noted in the draft ART refill appointment diary developed by Kenya's MOH (see Figure 4).

Figure 4. Snapshot of Kenya MOH Draft ART Refill Appointment Diary[9]

HIV CARE & TREATMENT REFILL APPOINTMENT DIARY
SCHEDULED VISITS

S/N	Unique ID	Name [First, Middle, Last]	ART Refill Model [Use codes]
1			
2			
3			
4			
5			
6			

ART REFILL ATTENDANCE SUMMARY

Fast Track	Community ART Distribution – HCW Led	Community ART Distribution – Peer Led	Facility ART Distribution Group	Total

ART REFILL MODEL CODES

FT = Fast Track
CADH = Community ART Distribution – HCW Led
CADP = Community ART Distribution – Peer Led
FADG = Facility ART Distribution Group

iii. New Tools to Document DSD Services

Patient ART medical records and other M&E tools, such as facility appointment registers, will likely not be available at the point of service in community-based DSDM. Therefore, tools to document participation and record patient information as services are provided over time will need to be developed and implemented. Such tools should be tailored to reflect the documentation needs for the individual DSDM (e.g., facility-based adherence clubs, community ART distribution points) that are active or planned in a specific setting.

Example: Community ART Groups

In this DSDM, stable and asymptomatic patients attend an HIV clinic once or twice a year for routine clinical and laboratory assessments, while drug distribution, adherence assessment, symptom screening, and in some cases psychosocial support are provided in the community. From the M&E perspective, associated challenges include: ensuring the HF has a complete record that includes out-of-facility services, fostering clear, two-way communication between HF and community systems, ensuring proper identification of patients who default from care, and avoiding double-counting of patients. For peer- and patient-led CAGs, at least two new tools will be required: a roster of patients included in each club or group linked to a specific facility, and a register or form documenting ART distribution and other services provided (the latter to be completed at each ART distribution event for each group).

The **roster of patients** in a specific CAG may be designed to document characteristics of the club/group—such as its ID number, meeting location, and focal person—and to record the identities (name, ART number) and contact information for patients who have been members of the club/group. In addition, the roster can be used to track patient entry and exit from the group. An example of a CAG roster, used by Médecins Sans Frontières, is shown in Figure 5.

Figure 5. Roster of Patients Included in CAGs (Source: Médecins Sans Frontières)[10]

Facility name: Focal person name: Meeting area:

CAG number: Focal person contact number:

CAG member number	ART number	First name	Surname	Sex	DOB	Mobile number	Date ART initiation	Date joined CAG	Date permanently left CAG
1					../../....		../../....	../../....	../../....
2					../../....		../../....	../../....	../../....
3					../../....		../../....	../../....	../../....

**Reason for leaving CAG:* 1.TFO 2.Moved to other CAG 3.Permanently returned to Clinic Care 4.LTFU 5.Died 6.Other

The roster of patients will likely be maintained in the HF, as part of a file or binder containing rosters for all clubs and groups for patients associated with the facility. Alternatively, this information could be collected and managed using an electronic system.

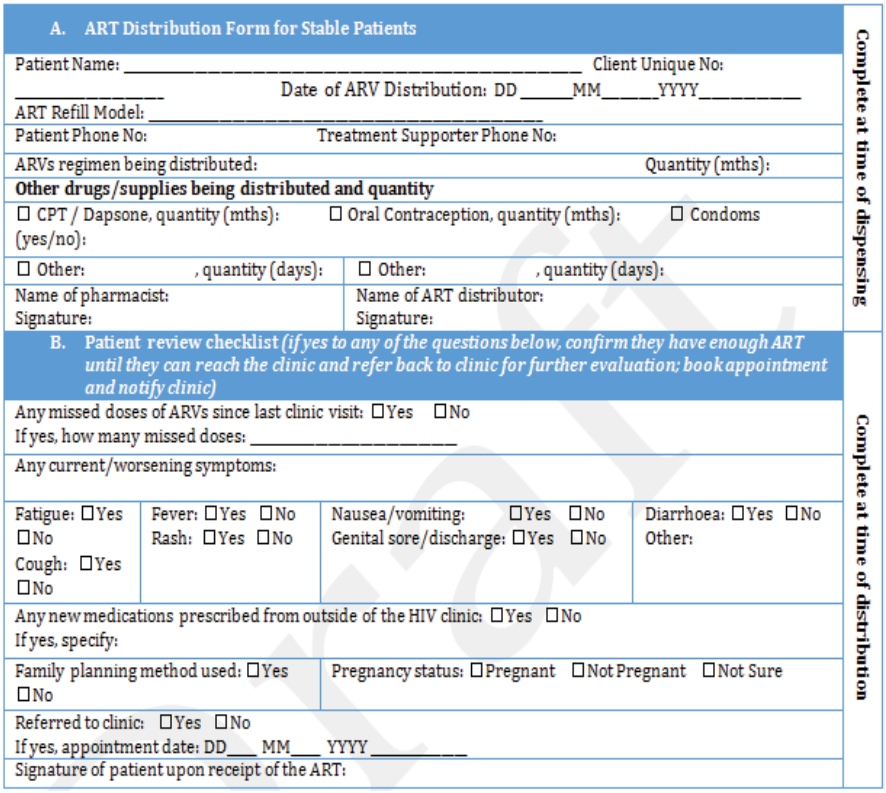
A separate document, such as a **register or form used specifically to collect information on ART pickups and other patient services over time**, will also likely be required. The intent of this document is to capture information on services received outside of the facility setting, and to communicate this information back to the facility for transcription into facility-based tools, such as the patient ART record. Since this document will in certain contexts be removed from the facility and completed in community settings, implementing this document as a paper-based longitudinal register may be cumbersome and introduce risks to the confidentiality and security of patient information. Therefore, it is advised that paper-based data collection on services provided in community settings be designed as cross-sectional tools, that they utilize initials or other identifiers, and that they avoid inadvertent disclosure of HIV-positive status if misplaced. This tool may also be implemented via secure mobile or tablet electronic technology and incorporate some longitudinal information collected previously from the patient, as discussed below.

Information on services provided in the context of CAGs may be collected at both the points of ART dispensing (i.e., by the pharmacy) and at final distribution to the patient in the community. The data elements captured on this form or register may include: patient identifier, dates of ART distribution to the patient, quantity of ART provided, and additional fields reflecting other care elements, such as adherence assessments, TB screening, family planning and pregnancy-related items, and/or assessment of symptoms or psychosocial issues that may require referral to the facility. An example of this is the draft "Community ART Distribution Form" developed by Kenya's MOH (see Figure 6), which reflects many of these elements. This

form captures key information from community-based ART distribution and is designed to be returned to the facility to supplement information collected in the patient ART medical record.

It should be noted that the updated ART medical record and new paper and/or electronic records should ideally be designed to allow for two-way communication that will enable effective, appropriate services in both the facility and community settings.

Figure 6. Draft Community ART Distribution Form (Source: Kenya MOH)[9]



A. ART Distribution Form for Stable Patients — *Complete at time of dispensing*

Patient Name: _____ Client Unique No: _____

Date of ARV Distribution: DD _____MM_____YYYY_____

ART Refill Model: _____

Patient Phone No: Treatment Supporter Phone No:

ARVs regimen being distributed: Quantity (mths):

Other drugs/supplies being distributed and quantity

☐ CPT / Dapsone, quantity (mths): ☐ Oral Contraception, quantity (mths): ☐ Condoms (yes/no):

☐ Other: , quantity (days): ☐ Other: , quantity (days):

Name of pharmacist: Name of ART distributor:

Signature: Signature:

B. Patient review checklist ***(if yes to any of the questions below, confirm they have enough ART until they can reach the clinic and refer back to clinic for further evaluation; book appointment and notify clinic)*** — *Complete at time of distribution*

Any missed doses of ARVs since last clinic visit: ☐Yes ☐No

If yes, how many missed doses: _____

Any current/worsening symptoms:

Fatigue: ☐Yes ☐No Cough: ☐Yes ☐No	Fever: ☐Yes ☐No Rash: ☐Yes ☐No	Nausea/vomiting: ☐Yes ☐No Genital sore/discharge: ☐Yes ☐No	Diarrhoea: ☐Yes ☐No Other:

Any new medications prescribed from outside of the HIV clinic: ☐Yes ☐No

If yes, specify:

Family planning method used: ☐Yes ☐No | Pregnancy status: ☐Pregnant ☐Not Pregnant ☐Not Sure

Referred to clinic: ☐Yes ☐No

If yes, appointment date: DD___ MM___ YYYY _____

Signature of patient upon receipt of the ART:

Note that for individuals in a patient-led CAG, the use of paper records, such as group registers, raises concern regarding confidentiality and security of patient information, especially if these records are not returned to the facility immediately after completion. For these groups, if feasible, use of secure mobile technology for data collection and submission to the facility is advised. This would require that at least one member of each ART group have adequate technology available (e.g., a standard phone for SMS text messaging or an encrypted smartphone for more advanced data collection approaches). If paper tools must be used, they should be designing to avoid using full names of patients or any other information that, if misplaced, could disclose patient HIV-positive status.

In the case of other DSD models of care that are developed for different patient populations; for example, those with advanced disease or those unstable on ART, eligibility for such a model will require documentation. In addition, information on delivery of specific interventions provided over time within the HF and, as applicable, within the community or home settings will require documentation. M&E modules will need to be developed to document these services.

In summary, documentation requirements for the various DSDM will differ. For example, while a separate roster and cross-sectional service documentation system may be appropriate for CAGs, they may not be required for patients receiving fast-track ART refill services. Details regarding the types of tools, the specific data elements to be recorded, and who records them (and where and when) should be determined based on the procedures and roles and responsibilities of HCW/peers/patients under the respective DSDM.

B. Data Flow Between New Tools and the Patient ART Medical Record

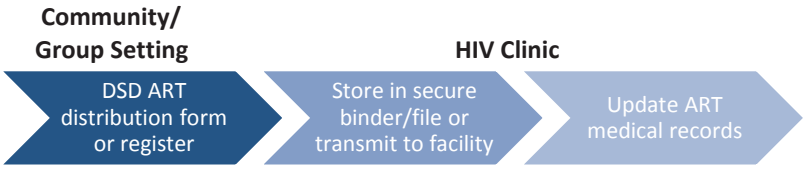
As described above, service delivery information under DSD—in particular for patients receiving less-frequent facility-based services, or services outside of the HIV facility—will likely be collected using multiple tools that are filled out at points of service in the facility and community. At the same time, services for unstable/advanced patients may require more detailed patient-level information and potentially community-based information. To facilitate effective patient clinical management, M&E/reporting, and quality improvement efforts, a defined set of key elements from DSD-specific registers and/or forms (such as the form depicted in Figure 6 above) should be transcribed into the patient ART medical record. Thus, it will be critical to ensure that information collected is routinely transported or transmitted to the HIV facility in a timely, secure, standardized way, and that patient records or databases are promptly updated with these data, as appropriate.

Patient data from DSDM may be reported to facilities using a range of methods, depending on the available technology at each treatment site. Suggested methods include:

i. Paper Records

Any paper records, such as ART distribution forms or registers, should be returned to the HF by HCW, community health workers, peers, or the designated patient for community patient groups (as applicable) on the same day as ART is distributed to patients. Collection of personally-identifying information (such as full names) and other information that may disclose patient HIV status if confidentiality is breached should be minimized as much as possible on paper forms. Tools that contain sensitive, identifiable patient information must be stored in a secure location in the HF. A specified file or binder to compile and manage these forms should be established, and roles and responsibilities for keeping the file or binder up-to-date and secure should be outlined for facility staff.

Figure 7. Flow of Paper-based Data from DSD Services Settings to HIV Clinic



After the DSD-specific ART distribution forms or registers are compiled in the facility, the next step will be the routine process of retrieving ART medical records for patients receiving DSD and the manual abstracting of information from these tools to update the patient ART records (see Figure 7). Note that this abstracting process may at times require clinical expertise; for example, to properly interpret and summarize information regarding patient symptoms reported and to initiate any follow-up actions required for patients.

ii. Electronic Mobile Technology

As part of a strategy for electronic collection and management of patient data under DSDM (see Box 4), data elements that might otherwise be collected on a paper form or register can be collected using mobile technology, such as standard secure cell phones, smartphones, or tablets. Following a defined format, standard cell phones may be used by HCW, community health workers, peers, or patients in CAGs or other DSD settings to send SMS text messages containing group member IDs, ART pickup dates, and other desired clinical information to specified HF staff. This information would then be transcribed into tools based at the facility (for example, DSD-specific patient forms or registers, such as those described above) and subsequently used to update the patient ART medical record, or the data could be transcribed directly into the patient ART medical record or database.

A more secure and user-friendly approach would be to implement data collection via secure **smartphones or tablets**, if feasible. In this scenario, HCW, peers, or patients would use encrypted smartphones or tablets to access a customized application designed to collect the paper form or register data elements—ideally in a simple, streamlined fashion. When data entry is complete, the record can be submitted to a secure database server and be automatically deleted from the mobile device to reduce risk of unauthorized access to patient data. Data from the server can be downloaded by/for facilities for manual updating of facility-based records and/or merging with facility electronic ART records data.

iii. Use of Adapted Facility-based Tools

In cases where services are provided within the HF—such as the fast-track ART refill—existing tools will need to be adapted to capture some of the required information at points where services are provided to patients. For example, in the case of fast-track ART refill, to the extent that pharmacy staff will be performing additional duties for these patients, countries may consider adapting the electronic pharmacy register to incorporate desired fields, such as those described for the community ART distribution form (see Figure 6).

Box 4. Electronic Data Systems for DSD

To capture and summarize information required to monitor DSD care, introduction and/or adaptation of electronic systems (e.g., a facility-based patient-level database linked to systems for mobile patient data collection and use) will become an even higher priority in the context of DSDM. Some benefits of electronic data systems for DSD include:

1) An **electronic patient HIV care/ART medical record database**, updated to capture the DSD data elements described here, would provide the flexibility to generate aggregate data summaries for each less-intensive ART modality.

2) Use of **electronic mobile data collection** technology, such as smartphones or tablet computers, for collection of patient data outside of the HIV clinic (i.e., for less-intensive ART care) can streamline the process of submitting data to the relevant HF for updating patient HIV care/ART medical records. Such technology may also be used to routinely provide basic patient summary information to HCW for use in the provision of less-intensive ART (e.g., patient's last VL result, next clinic appointment, etc.). In addition, mobile systems could incorporate biometric measures to document unique patient identities and reliably link patient data to facility electronic ART records.

C. Performance Indicators to Monitor DSD

Most current M&E HIV/ART indicators do not include information on patient uptake or outcomes for DSDM. For example, PEPFAR ART outcome indicators, such as retention and viral suppression, are defined to measure outcomes only during the first 12 months of ART. However, eligibility for DSDM for stable patients requires that they have viral suppression for 6-12 months after ART initiation. Thus, to monitor and evaluate provision of DSD, indicators assessing new DSDM uptake and outcomes among these patients will need to be implemented. Some **recommended indicators** are listed in Table 6. These indicators may be disaggregated into meaningful sub-categories, such as age group, gender, and service delivery model.

Indicators should be designed with country stakeholders, including MOH and others; reflect the elements of DSDM used nationally; and respond to national priorities. Detailed guidance on calculating indicators, including numerators and denominators, should be developed for use during training and implementation.

Table 6. Illustrative Recommended Indicators for M&E of DSD[1,2]

1. Number of ART patients newly classified as eligible for DSDM (i.e., at 6–12+ months after initiation)
2. Number/percentage of newly-eligible ART patients initiating DSDM
3. Number of ART patients receiving care under DSDM
4. Number/percentage of enrolled patients with a clinical assessment at the HF 6, 12 months after initiating DSD
5. Number/percentage of patients receiving DSD who received a VL test 12 months after initiating less-intensive ART
6. Number/percentage of patients receiving DSD who are virally suppressed 12 months after initiating less-intensive ART
7. Number/percentage of patients receiving DSDM with the following outcomes:[3]
    a) In care, maintains DSDM classification
    b) In care, switched to entirely clinic-based ART
    c) Lost to follow-up or stopped ART
    d) Dead

[1] Indicators 2–6 should be disaggregated by DSDM type.
[2] All indicators may be disaggregated as desired by age group and gender.
[3] Patients with documented transfer-out should be removed from the denominator.

D. Tools and Systems to Generate Aggregate Reports for DSD

DSD-specific indicators similar to those suggested in Table 6 may be implemented as elements to be included in routine reports submitted by facilities or other entities. Such indicators may be established for internal monitoring by programs and implementers, and to help assess and ensure quality of care as DSD is implemented. Keep in mind that existing paper tools, such as national ART registers, are designed neither to collect DSD-specific data elements, nor to track cohorts of patients from the point they initiate DSD ART models (6–12+ months after ART initiation). Existing registers are therefore unable to generate aggregate reporting data for DSD indicators.

To facilitate site-level reporting of DSD M&E data, new systems for aggregation of relevant data will be needed. These may be new queries of electronic patient-level databases updated with DSD-specific data elements, such as longitudinal DSD eligibility classification and ART models received, or new or adapted paper ART registers populated with information from updated ART medical records for tallying aggregate results for patients assigned to new DSD ART models.

i. Facilities with Electronic Patient-level Databases Collecting DSD Data Elements

Countries with MOH patient-level databases containing electronic ART medical records are advised to update these databases to include any changes made to paper ART medical records, as discussed above. With these changes in place, electronic data should be sufficient to monitor uptake, retention, and outcomes under DSD in these facilities. New queries of the data may be developed to automatically calculate values for national reports or custom indicators for quality monitoring. Given the increased complexity of monitoring and reporting with new models under DSD, this option is highly recommended.

ii. Facilities Relying on Paper Tools for Reporting

Sites exclusively using paper records will need to rely on revised ART registers—or new registers used specifically for patients receiving new DSDM—to monitor uptake and outcomes under DSD. Registers may be developed or revised to include the following data elements for each patient. Since many of these items will change over time, this information should be organized by time (e.g., monthly), since first initiation of DSD services:

- Date of patient classification for DSDM
- Patient DSD eligibility classification: stable/unstable, and eligible/ineligible for less-intensive ART services
- DSDM start date
- DSDM type (e.g., fast-track, CAG, facility ART club)
- ART delivery group/club ID
- ART pickup dates and quantity dispensed
- HIV clinic visit dates
- VL results
- Additional information, such as adherence and development of symptoms
- Whether or not patient is still receiving DSD services
- Reasons for switching DSDM, such as pregnancy, development of OI, increased VL, HCW concern, adverse drug reaction, or patient preference

The addition of these columns or creation of a separate register for patients receiving DSD would permit tallying for purposes of M&E. The elements of the register should, at a minimum, be designed to allow for the calculation of all required indicators. **Adapted quarterly ART cohort reports** for these DSD patients can also be developed and implemented for calculation of retention outcomes, using information from this DSD patient register.

E. Other M&E Issues under DSD

Data Quality Assessment (DQA)

The introduction of new M&E tools, roles and responsibilities (including peer and patient data collection), data flow (including community-based data collection), and reporting requirements under DSD will introduce new scenarios where errors, missing data, and poor timeliness of data submission can occur. Traditional DQA strategies—including identifying data elements to assess, sampling records, comparing values for analogous paper and/or electronic data elements, and re-counting aggregate tallies—may be adapted to the new tools and systems implemented under DSD. Essential for proper conduct of these adapted DQA will be ensuring access to the full set of raw documentation used to collect data for stable patients receiving DSD (i.e., rosters, registers, and forms).

Programs and implementers should ensure that facilities have well-functioning organizational systems to store and manage this documentation. These systems should allow individuals conducting DQA to easily find needed documentation for any given patient whose data is selected for inclusion in a DQA. Where paper documentation is not available (e.g., with electronic mobile data collection), strategies for assessing the quality of data (such as range and logic checks, and period confirmation with patients and HCW) may be adopted.

Identifying Defaulters and Patients Lost to Follow-up

Patients receiving DSDM will have a clinic visit as infrequently as every six months. At present, defaulter tracing is often initiated within facilities for patients who have missed appointments (and not picked up ART), or who have not had a clinic visit within a certain period of time (e.g., three months). To enable the detection of missed visits in new DSDM for stable patients, ART pickup dates reported will need to be incorporated into existing tools and registers. Criteria for defaulting would need to be adapted to incorporate this ART pickup information and account for expected gaps between ART refill visits. With appropriate procedures in place to identify defaulters under DSD, standard procedures for defaulter tracing and subsequent classification of patients as lost to follow-up may be conducted.

Linkage and Referral

Under the new modes of ART care/distribution, patients may be identified outside of the clinical setting—in some cases by peer outreach workers or by other ART patients—as requiring clinical follow-up. Core M&E system components, described in the sections above, should be designed to: 1) document the patient's condition and needs in an as clear and systematic way as is feasible; 2) transmit this information to responsible facility HCW in a prompt and reliable fashion; 3) document that the information was received and record any actions taken. As forms/registers are developed and roles and responsibilities are outlined under DSD, these kinds of scenarios should be kept in mind. For referrals to other HF from settings outside of the HIV clinic, national MOH referral tools should be used and guidelines observed.

Data Confidentiality and Security

The critical importance of data confidentiality and security cannot be overstated. In particular, the collection and use of data in community settings (in some cases by peers and patients) may present new challenges. Use of encrypted mobile technology, such as smartphones or tablet computers, in community settings is a potential solution; however, it is likely that many settings will rely on less secure methods, such as paper tools or standard cell phone/SMS approaches. It is important that all plans for data collection, transport, storage, or use under DSD prioritize the security of patient information.

Evaluation of Impact of DSD Model on Patient Outcomes

To evaluate the impact of the DSDM, an outcome such as patient retention at the facility might be compared before and after implementation of the DSDM. The retention period would be defined for a relevant time period (e.g., 18 or 24 months after ART initiation). Alternatively, if comparable facilities within a specific setting are providing and not providing the new DSDM, retention could be compared before and after for these facilities (a "difference within difference" comparison). Due to a lack of comparability between patients within a given facility receiving DSD and those not receiving DSD, a comparison across these groups within a facility would not provide meaningful results.

More generally, as DSDM are planned and implemented, conducting periodic structured assessments of facility-level characteristics related to DSD is highly recommended. Findings from these assessments may be used to track progress in implementation of key DSD elements (e.g., establishment of specific DSDM, roles and responsibilities in ART distribution, use of M&E tools) within facilities over time and may, if feasible, be linked with patient clinical data to identify trends in patient outcomes as uptake of DSDM increases.

In addition, as the purpose of DSD models of care is to enhance coverage, efficiency, and quality of care, other M&E approaches may be necessary. For example: surveys of patient satisfaction and provider satisfaction, assessment of provider patient load and productivity, and cost-effectiveness of DSDM.

F. Summary of M&E Considerations

With increasingly broad implementation of DSD, countries, funders, and program implementers will seek to effectively monitor DSD uptake and outcomes among eligible patients. A variety of DSD ART refill models, including ART groups, fast-track refills, and community ART distribution models, are in use in some contexts. In this guide, we propose a streamlined M&E approach that integrates DSD care elements into the standard patient ART medical record (paper and/or electronic) across DSDM types, as illustrated in Figure 3. A cascade of DSD-specific indicators is proposed in Table 6.

As country programs, funders, and implementers gain experience in implementing DSD, strategies for refining M&E systems components will emerge. We encourage the embracing of DSDM and the adoption of critical M&E elements to supplement current systems. Lastly, in order to achieve the goal of coverage, quality, and efficiency, appropriate assessments need to be conducted and indicators adopted in order to measure the effect of DSDM on patient outcomes and health system performance.

V. Key Considerations for DSD Implementation

The approach to DSD (especially regarding who provides care and where, see Table 3) will depend on the type of patient, the subpopulation (pregnant women, children, key populations, etc.), facility type, and local context. At the national level, policies and guidelines are needed to clearly define the "who, what, where, and how" of the DSDM to be utilized. Facilities with a low patient load may want to consider maintaining their current model of care if patient retention and adherence are optimal. However, making changes to fast-track stable patients will decrease wait times and may improve patient satisfaction. A facility assessment checklist for community ART distribution can be found in Annex 10. In addition, ICAP has created a dashboard to help countries monitor progress toward full-scale implementation of DSD (see Table 8).

Table 7. Key Considerations for DSD Implementation

	National/Health Facility Level	Community Level
Policy/ Political Commitment	• Functional technical working group that includes members of HIV program, PMTCT program, implementing partners, health workers, and PLHIV • National guidelines updated to include treatment for all • Clinical fora such as technical working groups or MDT at HF level, including pharmacists/dispensers • Approved policy and guidelines/protocols for community-based care, including ART distribution at community level, guidelines on differentiated care, training curricula, job aids, etc.	• Functional community health group that meets regularly and includes key community leaders, community activists, and health champions (peer educators, health staff, etc.) • Community awareness around updated treatment guidelines • HIV public health campaigns • Established coordination meetings between community leaders and representatives and HF management team • Accreditation of local pharmacy distribution points
Human Resources	• Endorsement of task-shifting, including nurse initiated and managed ART and lay counselors to support adherence and patient monitoring • Core competencies of each health cadre defined	• Endorsement of task-shifting adherence and lay counselors to support community adherence and patient monitoring • Recognition of peer educators/lay counselors as a key health cadre • Strategy for retaining community health workers • Strategy for ongoing training and support of community health workers
Infrastruct-ure	• Facility storage space for additional commodities (e.g., ART supplies) at regional level • Upgrading of pharmacy and dispensaries to provide private space for patient interactions	• Community storage space for ART supplies/distribution site that is secure • Community venues to host community group meetings
Commodities	• Adequate medication supply • Reliable supply chain management (including distribution of inventory, management, and procurement) • Simplification and harmonization of treatment regimens	• Support for self-care, including treatment literacy pamphlets • Supply chain assessment and stock management • M&E system to monitor distribution and stock • Audit system for monitoring stock usage
Lab	• Algorithm for VL Monitoring* • Transport system for VL specimens	• Algorithm for VL monitoring* • Point-of-care VL • Transport system for VL specimens from community to HF lab
Quality Assurance and Supervision	• Pharmacist ensures oversight and supervision of pharmacy staff • Quarterly patient review board meetings to ensure adequate treatment and support to patients failing treatment or with advanced disease	• Reporting adverse events • Adherence assessment tools • Supervision tools for monitoring community ART distribution
M&E/ Information Systems	• M&E tools allow for patient DSDM eligibility, DSDM assigned, and services provided • Tools document ART pickups under DSD • Data flow between new tools and the patient ART medical record • Performance indicators to monitor DSD • Tools and systems to generate aggregate reports for DSD • Data quality assessments • Identifying defaulters and patients lost to follow-up • Linkage and referral systems and forms • Data confidentiality and security • Evaluation	• Tools documenting ART pickups under DSD • Data flow between new tools and facility • Linkage and referral systems and forms

Acronyms: **HF** = health facility; **MDT**= multidisciplinary team; **VL** = viral load
*Refer to Annex 2

Table 8. ICAP Differentiated Care Dashboard

Policies	National HIV treatment policies prohibit or impede DSDM	National policies do not mention DSDM	National policies include DSDM but do not actively promote these models of care	National policies actively promote the use of DSDM for stable patients	National policies actively promote the use of DSDM for diverse groups*
Guidelines	National HIV treatment guidelines do not include DSDM		National HIV treatment guidelines include DSDM but do not provide detailed and specific implementation guidance		National HIV treatment guidelines provide detailed and specific guidance on implementation of DSDM
Diversity of DSDM services	No DSDM services have been implemented	DSD is available for stable patients only, and only one model has been implemented**	DSD is available for stable patients only, and only two models have been implemented	DSD is available for stable patients only, and ≤3 models have been implemented	DSDM is available for diverse patient groups
National DSD Scale-up Plan	None	DSD scale-up plan discussions and meetings ongoing	DSD scale-up plan draft available	DSD scale-up plan developed and approved by MOH	DSD scale-up plan being actively implemented
Coordination	None	DSD activities fall under the purview of existing groups; progress updates are presented in standing meetings not focused on DSDM (e.g., a care and treatment TWG)	DSD activities are coordinated by a dedicated group (e.g., a sub-TWG or equivalent)	National DSD Focal Person spearheads DSD planning and coordination	DSD progress reported in annual program reports and/or annual national review meetings in place
Community Engagement	None	PLHIV representatives and/or civil society are engaged in DSD implementation	PLHIV and/or civil society representatives are engaged in both DSD implementation and design of DSDM	PLHIV and/or civil society representatives are engaged in both implementation, design, and evaluation of DSDM	PLHIV and/or civil society representatives are systematically engaged in DSD policy development, design, implementation, and evaluation
Training Materials	DSD training materials are not available	Some DSD training materials have been developed by organizations piloting DSD/ implementing partners	National DSD in-service curricula for either professional health workers or lay health workers (but not both) are available and in use	National DSD curricula for both professional health workers and lay workers are available and in use	National DSD pre-service and in-service curricula are available and in use
SOPs and Job Aids	None	Implementing organizations have piloted standard operating procedures (SOPs) and job aids for stand-alone DSDM projects	National SOPs and job aids are available for only one DSD model	National SOPs and job aids are available for two DSD models	Step-by-step national SOPs and job aids are available for ≥3 DSDM
M&E System	No M&E system elements for DSD are in place or in development	Development of new M&E tools and systems for DSDM is planned or underway	Some new or adapted tools (e.g., registers, patient cards, monthly reports) and/or M&E guidelines have been implemented	A majority of DSDM M&E elements are in place, but they are not comprehensive or fully integrated into routine M&E systems	All elements of an M&E system for DSD are in place and integrated into one national M&E system for HIV/ART services
Coverage	None	DSDM is available at <25% of HF providing ART	At least one DSDM is available at 25–49% of HF providing ART	At least one DSDM is available at 50–75% of HF providing ART	At least one DSDM is available at >75% of HF providing ART
Quality of DSD Services	No quality standards have been specified for DSDM	Quality standards for specific DSDM have been defined, but DSDM quality has not yet been evaluated	Larger DSD programs have been evaluated and show impact on process and/or outcome indicators	DSD programs have quality management protocols in place and ongoing quality improvement activities	Demonstrated, consistent, high-quality DSD services exist across sites
Impact of DSD Services	Unknown	Some pilot programs have been evaluated and show impact on process indicators (e.g., patient and/or provider satisfaction, wait times, retention in care)	Some pilot DSDM programs have been evaluated and show impact on outcome indicators (e.g., viral suppression, morbidity, mortality)	DSDM models have been evaluated at scale, using process and/or outcome indicators	DSDM models have been evaluated at scale, showing impact on acceptability to clients and health workers, quality of care, patient outcomes, and efficiency

* **"Diverse patient groups"** includes DSDM for stable patients plus at least one additional group (unstable patients, patients at high risk of disease progression, adolescents and young people, pregnant and breastfeeding women, key and vulnerable populations, migrants and mobile populations, etc.)

** **DSDM for stable patients** include but are not limited to: appointment spacing with multi-month dispensing, fast track refill visits, HF-based clubs, community ART groups, community ART pickup ("PODI")

VI. Tools

To access these tools, copy and paste the URL below into your web browser. Note that not all hyperlinks will work directly from Word.

Annex 1: ICAP Package of Care for People Living with HIV
http://icap.columbia.edu/resources/detail/icap-package-of-care-for-people-living-with-hiv

Annex 2: Standard Operating Procedures on Viral Load Monitoring for ICAP Clinical Staff and Health Care Workers
http://icap.columbia.edu/resources/detail/standard-operating-procedures-on-viral-load-monitoring

Annex 3: ICAP Severely Immunosuppressed Package of Care (SIPOC) (Kenya)
https://cquin.icap.columbia.edu/resources/severely-immunosuppressed-package-of-care-sipoc/

Annex 4 Differentiated Care for Adults at High Risk of HIV Disease Progression: A Call to Action
https://cquin.icap.columbia.edu/resources/call-to-action/

Annex 5: ICAP Community ART Group Symptom Checklist
https://cquin.icap.columbia.edu/resources/community-art-group-symptom-based-checklist/

Annex 6: ART Distribution Form for Stable Patients (Kenya)[9]
https://cquin.icap.columbia.edu/resources/art-distribution-form-for-stable-patients/

Annex 7: Community ART Group Register (MSF)[10]
https://cquin.icap.columbia.edu/resources/cag-register/

Annex 8: CAG Attendance Monitoring Form (Zimbabwe)
https://cquin.icap.columbia.edu/resources/cag-group-monitoring-form/

Annex 9: CAG Quarterly Report Form (Malawi)
https://cquin.icap.columbia.edu/resources/quarterly-cag-supervision-form-for-health-surveillance-assistance/

Annex 10: Community ART Distribution Assessment Form (Kenya)
https://cquin.icap.columbia.edu/resources/kenya-community-art-distribution-assessment-form/

Annex 11: ICAP Enhanced Adherence Plan Tool
http://icap.columbia.edu/resources/detail/viral-load-toolkit-tools

Other Implementation Tools for Community ART Groups

- Differentiated care for HIV: A decision framework for antiretroviral therapy delivery. IAS; 2016. http://www.differentiatedcare.org/Guidance
- Community-based antiretroviral therapy delivery. UNAIDS and MSF; 2015. http://www.unaids.org/sites/default/files/media_asset/20150420_MSF_UNAIDS_JC2707.pdf
- ART adherence club report and toolkit. MSF. https://www.msf.org.za/about-us/publications/reports/art-adherence-club-report-and-toolkit
- How to implement community ART groups. MSF; 2014. http://www.msf.org/sites/msf.org/files/cag_toolkit.pdf

- Estratégia de grupos de apoio e adesão comunitaria [National strategy for adherence support community groups]. Mozambique MOH; 2015. https://mozlivinglibrary.files.wordpress.com/2014/09/estrategia-gaac.pdf
- Closer to home: Delivering antiretroviral therapy in the community: experience from four countries in Southern Africa. UNAIDS and MSF; 2012. https://issuu.com/msf_access/docs/aids_report_closertohome_eng_2012

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[9] Differentiated care: operational guide [DRAFT]. Nairobi: Ministry of Health, National AIDS and STI Control Program; 2017.

[10] Community ART group toolkit: how to implement the CAG model. Cape Town: Médecins Sans Frontières, Southern Africa Medical Unit; 2013.