

Kingdom of Cambodia

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Ministry of Health

**Standard Operating Procedure on
Appointment-spacing and Multi-Month Dispensing (MMD) of
Antiretroviral (ARV) Treatment for People Living with HIV in Cambodia**



**National Center for HIV/AIDS, Dermatology and STD
(NCHADS)**

January 2020

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Director of NCHADS



Dr Ly Penh Sun

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
AMC	Average Monthly Consumption
ART	Antiretroviral Therapy
ARV	Antiretroviral
CHAI	Clinton Health Access Initiative
CMS	Central Medical Store
DB	Database
DMU	Data Management Unit
FHI-360	Family Health International-360
GHSC-PSM	Global Health Supply Chain-Procurement Supply Management
HIV	Human Immunodeficiency Virus
LMU	Logistic Management Unit
MMD	Multi-Month Dispensing
NCHADS	National Center for HIV/AIDS Dermatology and STD
OI	Opportunistic Infection
PDMO	Provincial Data Management Officer
PLWH	People living with HIV (patients)
PW	Pregnant Women
R&R	Report & Request form
SoH	Stock on Hand
SOP	Standard Operating Procedure
UNAIDS	United Nations Programme on HIV and AIDS
USAID	United States Agency for International Development
US-CDC	United States Center for Disease Control
WHO	World Health Organization

I. Background

In Cambodia, the government has set a goal for the elimination of new HIV infections by 2025. The country has achieved significant progress over the last several decades in reducing the prevalence of people living with HIV (PLWH). The majority (81%) of PLWH know their status (AEM 2018), while 99% of enrolled patients are on anti-retroviral therapy (ART). Of the 83% who had a viral load test, more than 95% are virologically suppressed (NCHADS 2018).

By adopting HIV Clinical Management Guidelines, adapted from World Health Organization (WHO) guidelines, Cambodia has successfully implemented “Test and Treat” whereby patients diagnosed as HIV-positive promptly begin ART (NCHADS 2016). Following WHO guidelines, the National Center for HIV/AIDS, Dermatology and STD (NCHADS) issued a letter to all ART sites recommending that stable patients should be given three months or longer spacing (up to 6 months) for ARV treatment (NCHADS 2017). This approach is known as appointment-spacing and multi-month dispensing, or MMD. WHO recommends 3- to 6-month clinical visits (strong recommendation, moderate quality evidence),¹ and 3- to 6-month medication pickups (strong recommendation, low-quality evidence)² for stable ART patients (WHO 2016, p.259).

WHO cites systematic studies across multiple countries that have shown that reduced frequency of clinical visits among stable individuals was associated with significantly better retention, with no difference in mortality outcome. Further, reduced frequency of ART refills has been associated with improved retention in care and no evidence that appointment-spacing and MMD leads to additional complications or disengagement from care (WHO 2016, p. 260).

Based on the available evidence and success stories such as those cited, more and more countries are scaling-up the implementation of appointment-spacing and MMD. This Standard Operation Procedure (SOP) is designed to help ART service providers in Cambodia implement appointment-spacing and MMD for eligible patients – that is, patients whose condition is determined to be stable – which will reduce the need for frequent visits and help to reduce providers’ workload.

Rationale

Appointment-spacing and MMD is one of the new service delivery models that aim to increase service efficiency and decrease congestion through a reduction in clinical visits and ARV pickup appointments for stable HIV patients on antiretroviral therapy (ART).

From a stock management and supply perspective, patients consume the same quantities of ARVs in a year whether they are re-supplied monthly or less frequently. Therefore, over the long-term, once MMD becomes the norm, no additional quantities are required in the delivery system to meet the forecast consumption of stable patients. However, the quantities of ARVs in stock at facilities does need to be adjusted at the initiation of MMD and to meet future and evolving needs of patients.

With the introduction of 3- to 6- months refill, it is essential to consider how to space patients across the implementing months. We recommend a 3 to 6 months phased approach to

¹ When routine clinical consultations are due, they should be coordinated with planned medication pickup to reduce visit frequency

² ARV supply management should be strengthened to ensure availability of ARV medicines and prevent stock-outs in the context of less frequent medication pickup.

implementing MMD to allow for workloads and ARV stock needs to adjust to the change in the dispensing guidelines.

II. Objectives

The objectives of this SOP are to:

- Define eligible criteria for appointment-spacing and MMD of ARVs in Cambodia
- Describe implementation process of appointment-spacing and MMD for ART clinical staff and HIV care related team

III. Definition of Stable Patient, Appointment-spacing and Multi-Month Dispensing (MMD)

In Cambodia “**Stable Patient**” is defined as follows:

- patient who is on ART at least one year;
- with no adverse drug reactions or ARV drug-drug interaction (DDI) requiring regular monitoring;
- with no suspected or confirmed TB, no other opportunistic infection (OI), who is not on prophylaxis;
- who is not pregnant/breastfeeding women;
- who has good understanding of life-long treatment and adherence; and
- who had the last two consecutive confirmed (between 10 to 14 months) undetectable VL <40 copies/ml or undetected.

Appointment-spacing and MMD is an approach that simplifies and adapts HIV/AIDS care services to reduce frequent clinic visits and medication pick-ups, frees up healthcare resources, and improves efficiency of care and management for patients.

IV. Eligibility Criteria for appointment-spacing and MMD

A patient is considered eligible for appointment-spacing and MMD if they are both stable, as per define criteria above, and they meet the following additional criteria:

- Age \geq 20 years
- On first line ARVs regimen

V. Process for appointment-spacing and MMD Implementation

Step 1: Initial Assessment

- Assess capacity of ART sites before starting the appointment-spacing an MMD implementation.
- Create a list of stable patients. With assistance of Data Management Unit (DMU)/NCHADS, the ART service data clerk and the provincial data management officer (PDMO) should produce a list of stable patients for appointment-spacing and MMD by regimen generated from ART database (see annex 2).
- Develop appointment-spacing and MMD implementation plan. With the generated list, the ART team, led by ART team leader, should develop a plan to start off appointment-spacing and MMD implementation. The total number of stable patients should be divided into 3 to 6 months assigned period of intervention to see how many patients per day, needed screening and MMD prescription.

Step 2: Management of ARVs Stock and Supply Arrangement

At the initiation of MMD, stock-on-hand (SoH) at the site level will need to be higher than usual during the period of transition from monthly dispensing to MMD. Additional stock should be available only for the initial months until the dispensing smooths out to the same levels as during monthly supply. Additional stock must be pre-positioned at ART sites prior to initiating MMD.

Given that MMD will require 3 to 6 months to fully implement, the current ARV stock-on-hand at ART pharmacy will be insufficient. Therefore, the pharmacy unit should submit the request to NCHADS logistics unit by using the Report & Request (R&R) form, dividing stable patients equally for two quarters. That is, half of MMD-eligible patients will be included in the R&R form in the request for the first quarter, while the rest will be reported in the next quarter.

The R&R form is an excel sheet developed for quantifying ARVs requested from ART sites in each quarter of the year aligning with the distribution plan from the central medical store (CMS) to ART sites. This form is automated with some fill-in sections for data inputs. The R&R form and user guide can be found in Annex 3.

The pharmacist is mandated to use the current quarterly-based requisition (R&R request form) to report to NCHADS the number of stable patients broken down by regimen, planned to get 3 to 6 months drug-refill. The number of patients will receive from Data Clerk or Data Management Officer (DPMO).

How to report and calculate the number of stable patients at each site using the R&R form:

- Recommended first line (1L) regimen (the first initiation should use the preferred regimen, TLD and use TLE as alternative).
- Report separately between the normal patients and stable patients on MMD
- Increase the calculation of required drugs to 8 Average Monthly Consumption (8 AMC) for the regimens with MMD

Table 1: Example of the calculation of ARVs using report and request form (R&R form) at ART site

a) Tenofovir/Lamivudine/Dolutegravir (TLD)

Quarter	Condition with exemplified case (N=100, Stable/(MMD)=60, Non MMD =40)	Actual report	Previous report	Calculation QTY required	Additional information
1	MMD	30	0	$(30-0) \times 8$	Received TLD 90 Tabs/Btl
	Non MMD	70	100	$70+(70-100) \times 6$	Received TLD 30 Tabs/Btl
2	MMD	60	30	$((60-30) \times 8) + (30 \times 6)$	Received TLD 90 Tabs/Btl
	Non MMD	40	70	$40+(40-70) \times 6$	Received TLD 30 Tabs/Btl
3 and Subsequent	MMD	60	60	$((60-60) \times 8) + (60 \times 6)$	Received TLD 90 Tabs/Btl
	Non MMD	40	40	$40+(40-40) \times 6$	Received TLD 30 Tabs/Btl

b) Tenofovir/Lamivudine/Efavirenz (TLE)

Quarter	Condition with exemplified case (N=100, Stable/(MMD)=50, Non MMD =50)	Actual report	Previous report	Calculation QTY required
1	MMD	25	0	MMD $(25-0) \times 8$
	Non MMD	75	100	Non-MMD $= (75+0) \times 6$
2	MMD	50	25	MMD $= (50-25) \times 8$
	Non MMD	50	75	Non-MMD $= (50+25) \times 6$
3 and Subsequent	MMD	50	50	MMD $= (50-50) \times 8$
	Non MMD	50	50	Non-MMD $= (50+50) \times 6$

Step 3: Management of Patients Eligible for appointment-spacing and MMD

- Filter list for the appointment

List of stable patients generated from the database should be submitted daily (or weekly) to ART team consisting of ART team leader, clinicians, and counselors- lay counselors (see Annex 2).

- **Prepare schedule for stable patient visits**
 - Based on an agreed list, manage schedule of appointment-spacing.
 - Involve and define a fast-tracked process to minimize patient waiting time once the patients already been prescribed MMD.

- **Clinical and adherence assessment by the clinician (on the visit day)**
 - Review the individual case based on the stable list, including the review of medical history, previous visits records, and results of latest lab results especially VL test. Focus on chief complaint and physical examination to see if there are any OIs and other current diseases (more information refers to clinical guideline) and the status of adherence.

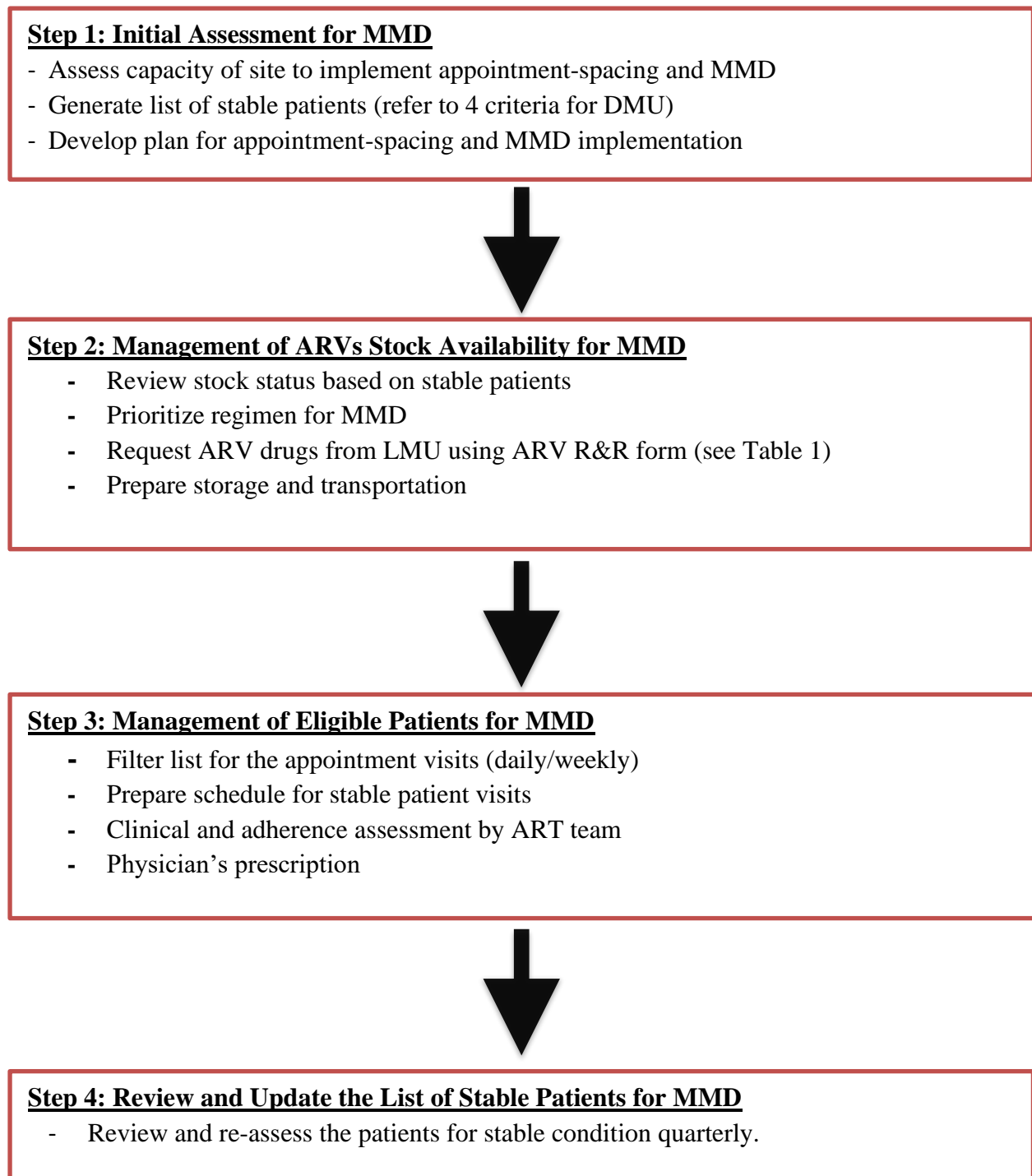
- **Physician's prescription**
 - Once the decision is made to transition the patient to MMD, the clinician refers the patient back to liaised counselor for special session of long month ART.
 - The counselor then sensitizes the patient, providing them with additional information involving long month refills. The counselor should discuss with the patient what to do in the event they lose their medication; how to manage/store multiple bottles of ARV drugs; the possible side effects they may experience between clinic visits; and possible treatment failure that could occur as a result of taking the incorrect dosage. They should also provide the schedule for the next visit.

Step 4: Review and Update the List of Stable Patients

- ART site team should review and re-assess the patients for stable condition quarterly.

Activity Flow for MMD Implementation

Figure 1: Activity Flow for MMD implementation at ART clinic



VI. Monitoring

6.1 Indicators

Indicator: % of active ART patients who received MMD during the reporting period	
Numerator	Number active ART patients who received MMD during the reporting period
Denominator	Total number of active ART patients in the reporting period.
Disaggregation	by 3, 4, 5, 6, >6 months

6.2 Monitoring process:

The data primarily will be tracked using the existing standardized recording and reporting formats and registers of the HIV program. The frequency of follow-up is maximum of 3 to 6 months intervals between clinical reviews.

VII. References

- NCHADS, (2018). Cambodian Asian Epidemic Model: Impact modelling & analysis
- NCHADS (2016). National HIV clinical management guidelines for adults and adolescents. <http://nchads.org/Library/Guideline> and Strategic Planning.
- NCHADS (2017). Guidance letter on Antiretroviral Treatment, Appointment and Defining of Lost to follow up in Cambodia. <http://nchads.org/Library/Guideline> and Strategic Planning.
- NCHADS (2018). Cambodia National HIV cascade: Database report on the ART in 2018. <http://nchads.org/Library/Report>.
- WHO (2016). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommended for frequency of clinic visits and medication pickup, Chapter 6: service delivery, page 259-260: <https://www.who.int/hiv/pub/arv/arv-2016/en/> [accessed October 2019]
- PEPFAR (2018). Differentiated Models of ART Service Delivery: Overview and Best Practices. Presentation to PEPFAR Implementing Partners. November 13, 2018

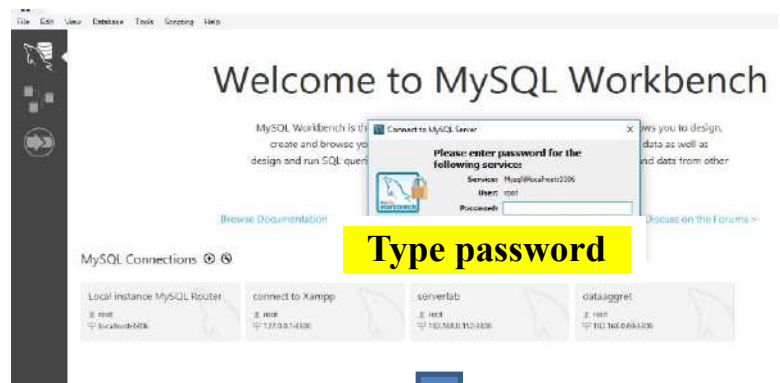
VIII. Annexes

Annex 1: Checklist for MMD implementation

Activities	Status			Remarks
	Done	incomplete	Not done	
1. Initial assessment for MMD				
1.1 generate data of stable patient from ART DB				
1.2 create a list of stable patients quarterly				
1.3 develop a plan to space the patients for MMD correctly				
2. Orientation and training on MMD				
2.1 Orientate to clinic managers/ART staffs on MMD implementation				
3. Implementation of MMD				
3.1 pharmacist reviewed stock status based on available ARVs				
3.2 staff aware of prioritize regimen for MMD				
3.3 staff aware of R & R form: the utilization, refill, and buffer				
3.4 staff filled out R & R form correctly				
3.5 stable patients are re-assessed routinely				
4. Monitoring on MMD implementation				
4.1 ARVs shortage existed in the past 3 months				
4.2 Patients on MMD are recorded properly and reported routinely				
4.3 MMD SOP, job-aid, related MMD tools are available at ART clinic				

Annex 2: The process of running script to generate stable patients from ART Database

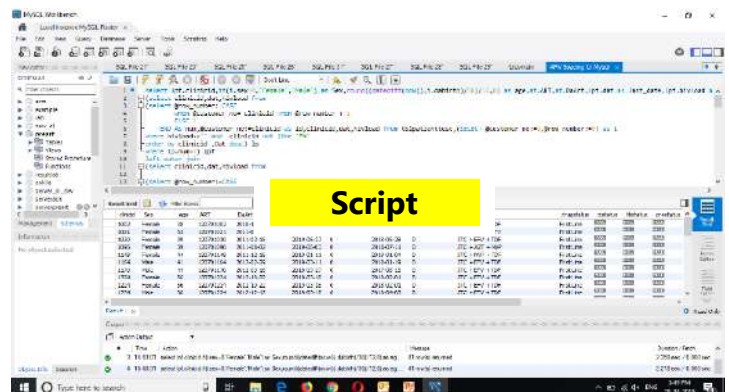
1. Open SQL Workbench, then connect to MySQL Server → enter password → click OK.



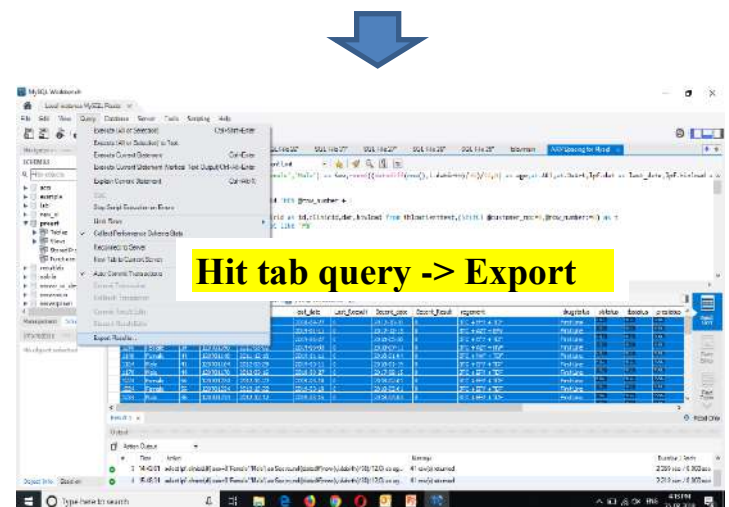
2. on screen interface, click icon “Edit” to see drop down menu.

Search for a folder named “ARV Spacing for MySQL”.

With an extension of MySQL, select file for use → click “open box” to explore file named “ARV Spacing for Mysql”. Click on the first icon on the left & upper corner; the “MySQL Workbench” will pop up.

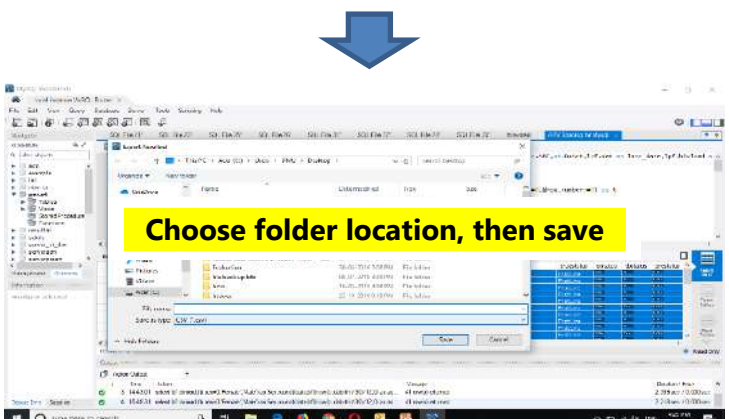


On “Local instance MySQL Router” screen appeared as sub-window.



3. Tap “Query” to export results/data to an Excel spreadsheet

4. Chose folder location to store the file, then hit the button “Save”



Annex 3: Report and Request (R&R) for ARVs

របាយការណ៍ស្តីពីចំនួនអ្នកជំងឺតាមប្រភេទប្រជាជនប្រចាំត្រីមាស ទី:

១ ឆ្នាំ ២០២០

ប្រភេទទិន្នន័យ:

ចម្លងពីផ្នែកគ្រប់គ្រងទិន្នន័យ

ចំនួនអ្នកជំងឺពេញវ័យតាមប្រភេទប្រជាជន						ចំនួនអ្នកជំងឺកុមារតាមប្រភេទប្រជាជន Number of PEDIATRIC case per regimen														
Number of ADULT case per regimen						Number of PEDIATRIC case per regimen														
ប្រភេទប្រជាជន 1L Regimens	ត្រីមាស Actual quarter	ត្រីមាស Previous quarter	ប្រភេទប្រជាជន 2L Regimens	ត្រីមាស Actual quarter	ត្រីមាស Previous quarter	ប្រភេទប្រជាជន 3L Regimens	ត្រីមាស Actual quarter	ត្រីមាស Previous quarter	ប្រភេទប្រជាជន Regimens	ត្រីមាស Actual quarter										សរុប total quarter
										ទំងន់ក្រុមតាមប្រភេទប្រជាជន Weight band by regimens										
										3 - 3.9	4 - 5.9	6 - 9.9	10 - 13.9	14 - 19.9	20 - 24.9	25 - 29.9	30 - 34.9	35 - 39.9		
TDF/3TC/EPV400 (MMS)			TDF/3TC+ATV/r			DRV+DTG+TDF+RTV			ABC/3TC+DTG											
TDF/3TC/DTG (MMS)			TDF/3TC+LPV/r			DRV+DTG+ABC+RTV			AZT/3TC+EFV											
TDF/3TC/EPV400			AZT/3TC+ATV/r			DRV+DTG+3TC+RTV			ABC/3TC+EFV											
TDF/3TC/DTG			AZT/3TC+LPV/r			DTG+DRV+AZT+RTV			TDF/3TC/EPV400											
AZT/3TC+EFV			ABC/3TC+ATV/r			DTG+DRV+RTV			TDF/3TC/DTG											
AZT/3TC+DTG			ABC/3TC+LPV/r			TDF/3TC/DTG+DRV+RTV			AZT/3TC+LPV/r											
AZT/3TC+TDF			AZT/3TC+TDF+ATV/r			DTG+DRV+ABC/3TC+RTV			ABC/3TC+LPV/r											
ABC/3TC+EFV			AZT/3TC+TDF+LPV/r			DTG+DRV+AZT/3TC+RTV			TDF/3TC+LPV/r											
ABC/3TC+DTG			TDF+ABC+ATV/r						AZT/3TC+ABC+LPV/r											
AZT/3TC+ABC			TDF+ABC+LPV/r						AZT/3TC+TDF+LPV/r											
PreP Program			AZT/3TC+ABC+ATV/r						AZT/3TC+ATV/r											
TDF/3TC			TDF+EFV+ATV/r						ABC/3TC+ATV/r											
PEP Program			3TC+EFV+LPV/r						TDF/3TC+ATV/r											
TDF/3TC/DTG			3TC+EFV+ATV/r						AZT/3TC+ABC+ATV/r											
			ABC+EFV+LPV/r						TDF+ABC+ATV/r											
			ABC+EFV+ATV/r						AZT/3TC+ABC											
			TDF+EFV+LPV/r						TDF/3TC											
			TDF/3TC/EPV400+ATV/r						TDF+ABC+LPV/r											
			RTV100						RTV100											

ចំនួនអ្នកជំងឺពេញវ័យសរុប Total number of adult patients						ត្រីមាស Actual	ត្រីមាស Previous	ចំនួនអ្នកជំងឺកុមារសរុប Total number of pediatric patients						ត្រីមាស Actual	ត្រីមាស Previous
						-	-							-	-

បានរៀបចំឯកភាព

ប្រធានខ្សែស័ព្ទ

ធ្វើនៅ.....ថ្ងៃទី.....ខែ.....ឆ្នាំ ២០.....

អ្នកធ្វើរបាយការណ៍

ប្រធានមន្ទីរពេទ្យ

ប្រធានមន្ទីរពេទ្យ



មជ្ឈមណ្ឌលជាតិប្រយុទ្ធនឹងជំងឺអេដស៍

ស៊ើបអង្កេត និង កាមាតា

របាយការណ៍ស្តីពីស្ថានភាពស្តុកស្តុន និង អ្នកជំងឺតាមប្រភេទប្រជាជនប្រចាំត្រីមាស ទី

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total patients previous quarter

ស្រុក/ក្រុង	ខេត្ត	សរុប
កំពង់ចាម	កំពង់ចាម	៦.០

ប្រភេទឱសថ Description	កម្រិត Dosage (mg)	ប្រភេទ Form	ឈ្មោះផលិតផល Product code	អាវុយ Avail?	ស្ថានភាពចំណុះ Starting Stock	ចំនួនចូល Incoming	ចំនួនចេញ Outgoing			ការកែតម្រូវ Adjustment	តុល្យភាព Balance	ចំនួនបញ្ជី A.L.S. code	ចំនួនសុំ Request	ថ្ងៃផុតកំណត់ First Expiry	ចំនួន First Exp. Qty	សង្ខេប Observation
							Sep-19	Oct-19	Nov-19							
Zidov. + Lam. (AZT/3TC)	300/150	tabts	60	NE0110	y						0					
Zidov. + Lam. (AZT/3TC)	60/30	tabts	60	NE0113	y						0					
Tenofovir + Lam + EPV (TDF/3TC/EPV)	300/300/400	tabts	30	NE0273	y						0					
Tenofovir + Lam + DTG (TDF/3TC/DTG)	300/300/90	tabts	30	NE0274	y						0					
Tenofovir + Lam + DTG (TDF/3TC/DTG)	300/300/90	tabts	90	xxxx	y						0					
Tenofovir + Lam (TDF/3TC)	300/300	tabts	30	NE0272	y						0					
Abacavir + Lam (ABC/3TC)	600/300	tabts	30	NE0014	y						0					
Abacavir + Lam (ABC/3TC)	120/60	tabts	30	NE0017	y						0					
Atazanavir + Rito. (ATV/r)	300/100	tabts	30	NE0015	y						0					
Nevirapine (NVP)	10/ml	BTL	1	NE0190	y						Run-out		5			
Efavirenz (EFV)	600	tabts	30	NE0022	y						0					
Efavirenz (EFV)	200	caps	90	NE0051	y						0					
Lamivudine (3TC)	150	tabts	60	NE0090	y						0					
Zidovudine (AZT)	240ml	ml	1	NE0302	y						Run-out		4			
Abacavir (ABC)	300	tabts	60	NE0010	y						0					
Abacavir (ABC)	60	tabts	60	NE0016	y						0					
Tenofovir (TDF)	300	tabts	30	NE0270	y						0					
Tenofovir (TDF)	200+90	tabts	120	NE0141	y						0					
Lopi. + Rito. (LPV/r)	100+25	tabts	60	NE0142	y						0					
Lopi. + Rito. (LPV/r)	40/10	granule	120	NE0143	y						0					
Lopi. + Rito. (LPV/r)	80+20/ml	ml	60	NE0152	y						0					
Ritonavir (RTV)	100	tabts	30	NE0220	y						0					
Darunavir (DRV)	600	tabts	60	NE0047	y						0					
Darunavir (DRV)	400	tabts	60	xxxx	y						0					
Dolutegravir (DTG)	50	tabts	30	NE0048	y						0					
Condom	49mm	units	144	NE0437	y						0					

បានរៀបចំឯកភាព

ប្រធានខ្សែស័ព្ទ









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អ្នកធ្វើរបាយការណ៍

Appointment Spacing and MMD

- Patients that are stable, uncomplicated and adherent can receive appointment-spacing and MMD of antiretroviral therapy (ART) for HIV.
- App-spacing and MMD can help to reduce burden on patients and health workers.
- In order to be eligible for app-spacing and MMD, patients must meet the criteria below.
- Patients should be screened at every visit, since eligibility for app-spacing and MMD can change.

ELIGIBILITY CRITERIA FOR MULTI-MONTH REFILLS:








To be determined by data manager		AGE	20 years or older
		TIME ON ART	On ART for at least 12 months
		VIRAL LOAD	Has at least two consecutives confirmed (between 10 to 14 months) undetectable VL <40 copies/mL
		ARV REGIMEN	On first-line ART TLD and TLE 400mg only, unless pharmacist gives permission
To be assessed by clinician at every visit		SIDE EFFECTS	No adverse drug reactions or ARV drug-drug interaction (DDI) requiring regular monitoring.
		OIs	No suspected or confirmed tuberculosis or other opportunistic infections
		ADHERENCE	Good understanding of life-long treatment and adherence
		PREGNANCY	Not pregnant or lactating

Appointment-Spacing and MMD

JOB AIDE FOR COUNSELLORS

- Patients that are stable, uncomplicated and adherent can receive appointment-spacing and MMD of antiretroviral therapy (ART) for HIV.
- With receive appointment-spacing and MMD patients only have to come to the clinic 2 times every year for appointments, but they have an important responsibility to maintain adherence and monitor their health between appointments.
- Counsellors should discuss the following messages with patients receiving 6-months refills, in addition to any standard counselling messages.

COUNSELLING MESSAGES FOR PEOPLE ON App-Spacing and MMD:

	SIDE EFFECTS AND ILLNESS	What will you do if you have any side effects or feel sick before your appointment?	<i>Come back to the facility immediately.</i>
	STORAGE	How will you store your medications?	<i>Keep them in a safe place, away from sunlight and moisture.</i>
	ADHERENCE	How will you remember to take your drugs daily?	<i>Confirm patient has a plan and could describe how to keep good adherence.</i>
	HEALTHY HABITS	How are you taking care of yourself to make sure you stay healthy?	<i>Discuss healthy eating and exercise. Maintain health to get app-spacing and MMD</i>
	NEXT APPOINTMENT	When is your next appointment?	<i>Confirm patient understands schedule and will return to clinic.</i>
	PREGNANCY	For women: Is there any chance you could become pregnant in the next 6 mo?	<i>If you become pregnant, come back to the facility immediately for monitoring.</i>
	QUESTIONS	Do you have any questions about the new appointment schedule?	<i>Give patient a chance to ask questions.</i>

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