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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)

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Phnom Penh, 13. 13an. 1. 90.20.

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), and 3- to 6-month medication pickups (strong recommendation, low-quality evidence) 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 consecutives 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≥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) x 8	Received TLD 90 Tabs/Btl
1	Non MMD	70	100	70+(70-100) x 6	Received TLD 30 Tabs/Btl
2	MMD	60	30	$((60-30) \times 8) + (30 \times 6)$	Received TLD 90 Tabs/Btl
2	Non MMD	40	70	40+(40-70) x 6	Received TLD 30 Tabs/Btl
3 and	MMD	60	60	((60-60) x 8) + (60 x 6)	Received TLD 90 Tabs/Btl
Subsequent	Non MMD	40	40	40+(40-40) x 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) x 8	
1	Non MMD	75	100	Non-MMD = $(75+0) \times 6$	
2	MMD	50	25	$MMD = (50-25) \times 8$	
2	Non MMD	50	75	Non-MMD = $(50+25) \times 6$	
3 and	MMD	50	50	$MMD = (50-50) \times 8$	
Subsequent	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

- o Based on an agreed list, manage schedule of appointment-spacing.
- o 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

Step 1: Initial Assessment for MMD

- Assess capacity of site to implement appointment-spacing and MMD
- Generate list of stable patients (refer to 4 criteria for DMU)
- Develop plan for appointment-spacing and MMD implementation



Step 2: Management of ARVs Stock Availability for MMD

- Review stock status based on stable patients
- Prioritize regimen for MMD
- Request ARV drugs from LMU using ARV R&R form (see Table 1)
- Prepare storage and transportation



Step 3: Management of Eligible Patients for MMD

- Filter list for the appointment visits (daily/weekly)
- Prepare schedule for stable patient visits
- Clinical and adherence assessment by ART team
- Physician's prescription



Step 4: Review and Update the List of Stable Patients for MMD

- Review and re-assess the patients for stable condition quarterly.

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

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VIII. Annexes

Annex 1: Checklist for MMD implementation

Activities		Status		
		incomplete	Not done	Remarks
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 mangers/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 \rightarrow enter password \rightarrow click OK.

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

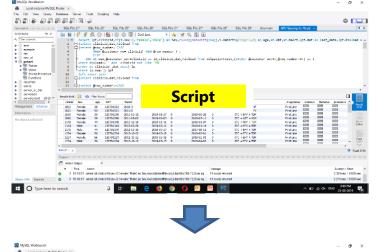
Search for a folder named "ARV Spacing for MySQL".

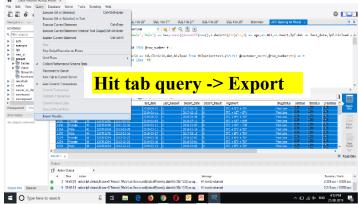
With an extension of MySQL, select file for use → click "open box" to explore file named "ARV Spacing for Mysql". Click on the first icon on the left & upper corner; the "MySQL Workbench" will pop up.

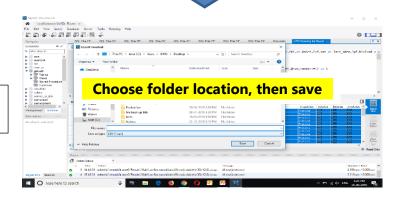
On "Local instance MySQL Router" screen appeared as sub-window.

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

របាយការណ៍ស្តីពីចំនួនអ្នកជំងឺតាមរូបមន្តព្យាបាលប្រចាំត្រីមាស ទី: ចម្លងពីផ្នែកគ្រប់គ្រងទិន្នន័យ ១ ឆ្នាំ ២០២០ ប្រភពទិន្នន័យ: ចំនួនអ្នកជំងឺពេញវ័យតាមរូបមន្តព្យាបាល ចំនួនអ្នកជំងឺកុមារតាមរូបមន្តព្យាបាល Number of PEDIATRIC case per regimen Number of ADULT case per regimen ត្រីមាសថ្មី Actual quarter ត្រីមាស ត្រីមាសថ្មី ^{ត្រីមាស} ត្រីមាសថ្មី ត្រីមាស រូបមន្តព្យាបាល ចាស់ ត្រីមាសថ្មី រូបមន្តព្យាបាលទី១ រូបមន្តព្យាបាលទី២ រូបមន្តព្យាបាលទី៣ ទំងន់កុមារតាមរូបមន្តព្យាបាល Weight band by regimens សរុប ចាស់ ចាស់ ចាស់ Actual Actual 3 - 4 - 6 - 10 - 14 - 20 - 25 - 30 - 35 total quarter 19.9 TDF/3TC/EFV400 (MMS) DF/3TC+ATV/r RV+DTG+TDF+RTV BC/3TC+DTG TDF/3TC/DTG (MMS) TDF/3TC+LPV/r RV+DTG+ABC+RTV AZT/3TC+EFV TDF/3TC/EFV400 AZT/3TC+ATV/r DRV+DTG+3TC+RTV BC/3TC+EFV DF/3TC/DTG AZT/3TC+LPV/r TG+DRV+AZT+RTV TDF/3TC/EFV400 AZT/3TC+EFV ABC/3TC+ATV/r OTG+DRV+RTV TDF/3TC/DTG AZT/3TC+TDE AZT/3TC+TDF+ATV/r OTG+DRV+ABC/3TC+RTV ABC/3TC+LPV/r AZT/3TC+TDF+LPV/r TG+DRV+AZT/3TC+RTV TDF/3TC+LPV/r ABC/3TC+EFV ABC/3TC+DTG DF+ABC+ATV/r AZT/3TC+ABC+LPV/r AZT/3TC+ABO TDF+ABC+LPV/r AZT/3TC+TDF+LPV/r AZT/3TC+ABC+ATV/r AZT/3TC+ATV/r PrEP Program TDF+EFV+ATV/r ABC/3TC+ATV/r PEP Program 3TC+EFV+ATV/i AZT/3TC+ABC+ATV/r TDF/3TC/DTG TDF+ABC+ATV/r BC+EFV+LPV/r BC+EFV+ATV/i AZT/3TC+ABO TDF+EFV+LPV/r TDF/3TC DF/3TC/EFV400+ATV/ TDF+ABC+LPV/r RTV100 ត្រីមាសថ្មី ចំនួនអ្នកជំងឺកុមារសរុប ចំនួនអ្នកជំងឺពេញវ័យសរុប ចាស់ ចាស់ Total number of adult patients Total number of pediatric patients ធ្វើនៅ.....វិថ្ងទី វែខ បានឃើញនិងឯកភាព ប្រធានឱសថស្ពាន អ្នកធ្វើរបាយការណ៍ ត្រលាខតម្លីរយេខវិ ក្រសួងសុខាភិបាល ប្វោយអារណ៍ស្តីពីស្ថានភាពស្តួកឱ្យសថ និច អ្នកបំចីពយតាមរួបមន្តព្យាប្វាលប្រចាំត្រមាសនី 0ළු0ළු ද්ෂු ල មជ្ឈមណ្ឌលជាតិប្រយុទ្ធនឹងជំងឺអេដស៍ សើស្បែក និង កាមរោគ ឈ្មោះទីតាំងសេវា ស្រាកប្រតិបតិ ខេត្ត- ក្រង 6.0 លបរិច្ឆេទ៖ថ្ងៃទី ឆ្នាំ ចំនួនចេញ Outgoi ស្រាដើមគ្រា បរិមាណ លេខក្នុង ចំនួនខែ មខន្ទិសថ ចំនួនពែតំរូវ ពកិលាត់ ទី។ ដពកំណត់ ទី១ Avail. Product A.L.S. irst Exp. Qty កំប៉ុង Sep-19 Oct-19 Nov-19 Stock code crude Zidov. + Lam. (AZT/3TC) 60/30 NE0113 0 Tenofovir +Lam + EFV (TDF/3TC/EFV) 0 30 NE0273 Tenofovir +Lam + DTG (TDF/3TC/DTG) 0 300/300/50 tabs 30 NE0274 vir +Lam + DTG 0 300/300/50 tabs 90 XXXX (TDF/3TC/DTG) Tenofovir + Lam (TDF/3TC) Abacavir + Lam (ABC/3TC) 300/300 30 NE0272 0 30 120/60 30 NE0017 0 300/100 30 NE0015 0 levirapine (NVP) 10/ml BTL NE0180 Efavirenz (EFV) 200 Lamivudine (3TC) 150 Zidovudine(AZT) 240ml mL NE0302 Run-ou 300 tabs 60 NE0010 Abacavir (ABC) Tenofovir (TDF) 100+25 tabs 60 NF0142 0 40/10 120 NE0143 Ritonavir (RTV) NE0220 600 NE0047 Darunavir (DRV) 400 60 0 Dolutegravir (DTG) 30 50 NE0048 0 144 NQ4377

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:

AGE 20 years or older To be determined by data manager **TIME ON ART** On ART for at least 12 months Has at least two consecutives confirmed **VIRAL LOAD** (between 10 to 14 months) undetectable VL <40 copies/mL On first-line ART **ARV** TLD and TLE 400mg only, unless pharmacist gives **REGIMEN** permission No adverse drug reactions or ARV drug-SIDE EFFECTS drug interaction (DDI) requiring regular monitoring. c**linician** at every visit To be assessed by No suspected or confirmed tuberculosis Ols or other opportunistic infections Good understanding of life-long **ADHERENCE** 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?	Come back to the facility immediately.
+	STORAGE	How will you store your medications?	Keep them in a safe place, away from sunlight and moisture.
P i	ADHERENCE	How will you remember to take your drugs daily?	Confirm patient has a plan and could describe how to keep good adherence.
626	HEALTHY HABITS	How are you taking care of yourself to make sure you stay healthy?	Discuss healthy eating and exercise. Maintain health to get app-spacing and MMD
	NEXT APPOINTMENT	When is your next appointment?	Confirm patient understands schedule and will return to clinic.
*	PREGNANCY	For women: Is there any chance you could become pregnant in the next 6 mo?	If you become pregnant, come back to the facility immediately for monitoring.
?	QUESTIONS	Do you have any questions about the new appointment schedule?	Give patient a chance to ask questions.

