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Multi-month Dispensing (MMD) for Children and Adolescents Living with HIV

Final Report on Core Funding Activity: Improving MMD for CLHIV

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Executive Summary

Multi-month dispensing (MMD) is the provision of three to six months of antiretrovirals (ARV) and other medicines required for treatment of people living with HIV (PLHIV). The World Health Organization (WHO) recommend MMD for all PLHIV on Antiretroviral therapy (ART) including children and adolescents living with HIV (CALHIV). For children living with HIV who are between two and four years of age, MMD with three months of ARVs (MMD 3) is recommended while MMD six months is preferable for those children age 5+ years.

As per PEPFAR Country Operational Plan 21, there has been global progress in scale up of MMD for adults. However, CALHIV have not yet benefited as widely from important differentiated service delivery intervention. In the current context of the COVID-19 pandemic, increasing the number of eligible PLHIV receiving 3- and 6-month MMD is even more critical in order to avoid unnecessary visits to clinics, safeguarding both PLHIV and health care workers (HCWs) from the risk of exposure to COVID-19. USAID's centrally funded mechanisms, ACHIEVE, RISE, and EpiC are coordinating efforts to leverage the current supportive WHO and national policies to ensure that CALHIV receive MMD even as they are transitioned to optimized ART regimens. The ACHIEVE/RISE/EpiC projects received Headquarter Bridge Funding (HBF) from USAID to support scale-up of MMD for CALHIV in Nigeria and Burundi, by strengthening the skills of service providers in both care and treatment as well as OVC projects, improving linkages between facility- and community-level services, addressing providers' concerns about pediatric dose adjustments as well as optimizing orphan and vulnerable children (OVC) platforms for case management of CALHIV.

A baseline qualitative assessment was conducted to understand the processes, opportunities and challenges associated with pediatric MMD in both countries, while routine treatment and OVC programmatic data were collected at baseline (Q1FY20, October-December 2019) and at the end (Q2FY21, January-March 2021) of the project to assess trends of MMD uptake and viral load coverage and suppression over time. Routinely collected data in Nigeria showed the proportion of children < 15 years on MMD 3+ increased from 21% in quarter one of FY20 to 90% as of the second quarter in FY21, an over fourfold increase, while the proportion of children < 15 years with viral load suppression (VLS) increased from 65% to 86%. In Burundi, the proportion of children on MMD3+ was < 1% at baseline and increased to 49% at end line and VLS increased from 72% to 92%. In both countries ART regimen optimization occurred simultaneously.

The COVID-19 pandemic has led to adaptations in service delivery for CALHIV in order to ensure treatment continuation and these changes have influenced pediatric MMD scale up in these countries. The adaptations included offering MMD for CALHIV even if documentation of a suppressed VL was not available, a key requirement pre-pandemic.

Key lessons learned from this work include the realization of having providers (HCW as well as OVC and CCW) trained, mentored and confident to prescribe appropriate ART regimens for CALHIV according to weight, the need of facility-level monitoring of ART transition of CALHIV onto optimized ART regimens and strong partnership with OVC programs as an opportunity to provide home-based support for ART adherence among CALHIV on MMD in between clinical visits.

Acknowledgment

This final report was developed by the ACHIEVE (Silvia Kelbert, Tom Ventimiglia, Flavia Bianchi, Daniel Watkins)/RISE (Ruby Fayorsey, Nandita Sugandhi)/EpiC (Catarina Casalini, Moses Bateganya) pediatric MMD team. The team would like to acknowledge and thank the Nigeria and Burundi colleagues that supported in-country work as well as everyone who provided content, comments, feedback, and insights into this work, including the USAID team.

Acronyms

ART	Antiretroviral therapy
ARVs	Antiretroviral drugs
CALHIV	Children and Adolescents Living with HIV
CCW	Community Case Workers
DTG	Dolutegravir
EFV	Efavirenz
HCW	Health care worker
HBF	Headquarter Bridge Funds
LPV/r	Lopinavir-ritonavir
MMD	Multi-Month dispensing
PLHIV	People Living with HIV
OVC	Orphan and Vulnerable Children
TLD	Tenofovir/Lamivudine/Dolutegravir
VLS	viral load suppression
WHO	World Health Organization

Background

Multi-month Dispensing of Antiretroviral Therapy for Children and Adolescents Living with HIV (CALHIV)

Multi-month dispensing (MMD) is the provision of three to six months of antiretrovirals (ARV) and other medicines required for treatment HIV and associated infections/conditions. MMD is a differentiated service delivery (DSD) approach and aims to simplify treatment by reducing visit frequency. MMD has been linked to improved treatment continuation and achievement of sustained viral suppression while also reducing the client's burden to access care and the health system's burden[1].

WHO recommends MMD for all PLHIV on ART including CALHIV. For children living with HIV age 2- < 5 years old, MMD three months is recommended (besides clinical follow up by phone, electronically or in-person) while MMD six months is preferable for those children age 5+ years.[2] Caregivers should be allowed to pick up the child's medication without bringing the child unless the child is due for a clinical visit. For children requiring Co-trimoxazole and/or Tuberculosis Preventive Therapy (TPT), a three to six month supply of those medications should be provided at the same time as antiretroviral therapy (ART) pickup.[3]

As per PEPFAR Country Operational Plan 21, there has been progress in scale up of MMD for adults[4]. Much of this progress has been made in response to COVID-19 related restrictions that has prompted countries to reduce clinic visits and relax restrictions regarding dispensing quantities. However, CALHIV have not been prioritized enough to benefit from this important intervention. This is due to multiple factors including but not limited to[5]:

- Policy and guideline restrictions that do not allow for MMD implementation or limit eligibility for MMD to adult populations or only certain ages of CLHIV (such as those >10 years).
- In most countries, where viral load suppression is the main criteria for eligibility for MMD, low rates of viral load coverage and viral load suppression among CALHIV are additional challenges on scale up of MMD in this population.
- Lack of confidence among HCWs to prescribe MMD to pediatric patients
- Shortages or limited stocks of pediatric ARV formulations, including those for optimized pediatric regimen
- Concern about less frequent clinical follow up; perceived weight changes requiring dosing or regimen adjustment; perception that caregivers or adolescents may not adhere to the recommended regimen and dosing; a need for follow-up following recent transition to new ARV formulations or regimens; poor health or advanced HIV disease (AHD) in a child.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6116392/
[2] https://www.state.gov/wp-content/uploads/2020/12/PEPFAR-COP21-Guidance-Final.pdf
[3] https://www.state.gov/wp-content/uploads/2020/12/PEPFAR-COP21-Guidance-Final.pdf
[4] https://www.state.gov/wp-content/uploads/2020/12/PEPFAR-COP21-Guidance-Final.pdf
[5] ACHIEVE/EpiC/RISE. 2020, September 10. Improving multi-month dispensing (MMD) for Children and Adolescents living with HIV (CALHIV) in Burundi and Nigeria: HBF activities, Baseline results (ppt presentation).

Headquarters Bridge Funds (HBF) and ACHIEVE/RISE/EpiC Collaborative Work

In the current context of the COVID-19 pandemic, increasing the number of eligible PLHIV receiving 3- and 6-month MMD is even more critical in order to avoid unnecessary visits to clinics thus safeguarding both PLHIV and HCWs from the risk of exposure to the virus causing COVID-19. USAID's centrally funded mechanisms, ACHIEVE, RISE, and EpiC are coordinating efforts to leverage on the current supportive WHO and national MMD policies in PEPFAR supported countries to ensure that CALHIV receive optimized ART regimens and are transitioned to MMD. This includes ARVs, TPT, cotrimoxazole prophylactic treatment (CPT) and other continued medications as appropriate (e.g. family planning methods for adolescents).

The ACHIEVE/RISE/EpiC projects received HBF from USAID to support scale-up of MMD for CALHIV, by improving linkages between facility- and community-level, addressing providers' concerns about pediatric dose adjustments and regimen changes, as well as optimizing orphan and vulnerable children (OVC) platforms for case management for CALHIV.

This report summarizes key activities and deliverables developed under this HBF initiative in response to various data collection activities to better understand the MMD uptake and context in each selected implementation country. The report also highlights lessons learned, best practices and recommendations that the ACHIEVE/RISE/EpiC team consolidated during this process that can be adopted to other countries.

Country Participation

After discussions with USAID headquarters, country missions and ACHIEVE/EpiC/RISE team, Nigeria and Burundi were selected for implementation of this activity.

Objectives and Deliverables

Primary and Secondary Objectives

Primary objective:

- Improve the enrollment of CALHIV eligible for MMD in 3- and 6-month MMD in selected states/regions and sites in Nigeria and Burundi.
- Build on Case Management approach to foster collaboration between HIV treatment programs and OVC platform
- Support optimization of pediatric ARV regimens and dosing to CALHIV receiving MMD

Deliverables

1. Qualitative and Quantitative baseline and final assessment on status of pediatric MMD in select sites in Burundi and Nigeria: led by ACHIEVE
2. Technical briefer to highlight MMD with MOH and providers: led by ACHIEVE
3. Two technical guides: one for health providers and one for OVC workers to support scale up of MMD among CALHIV: led by RISE and ACHIEVE, respectively
4. Key messages on treatment literacy, self-efficacy for CALHIV and caregivers: led by EpiC

The project was implemented between May 2020 and June 2021 (see Annex IV for detailed timeline), with data compiled from (Q1FY20, October-December 2019) as baseline and Q2FY21 for endline.

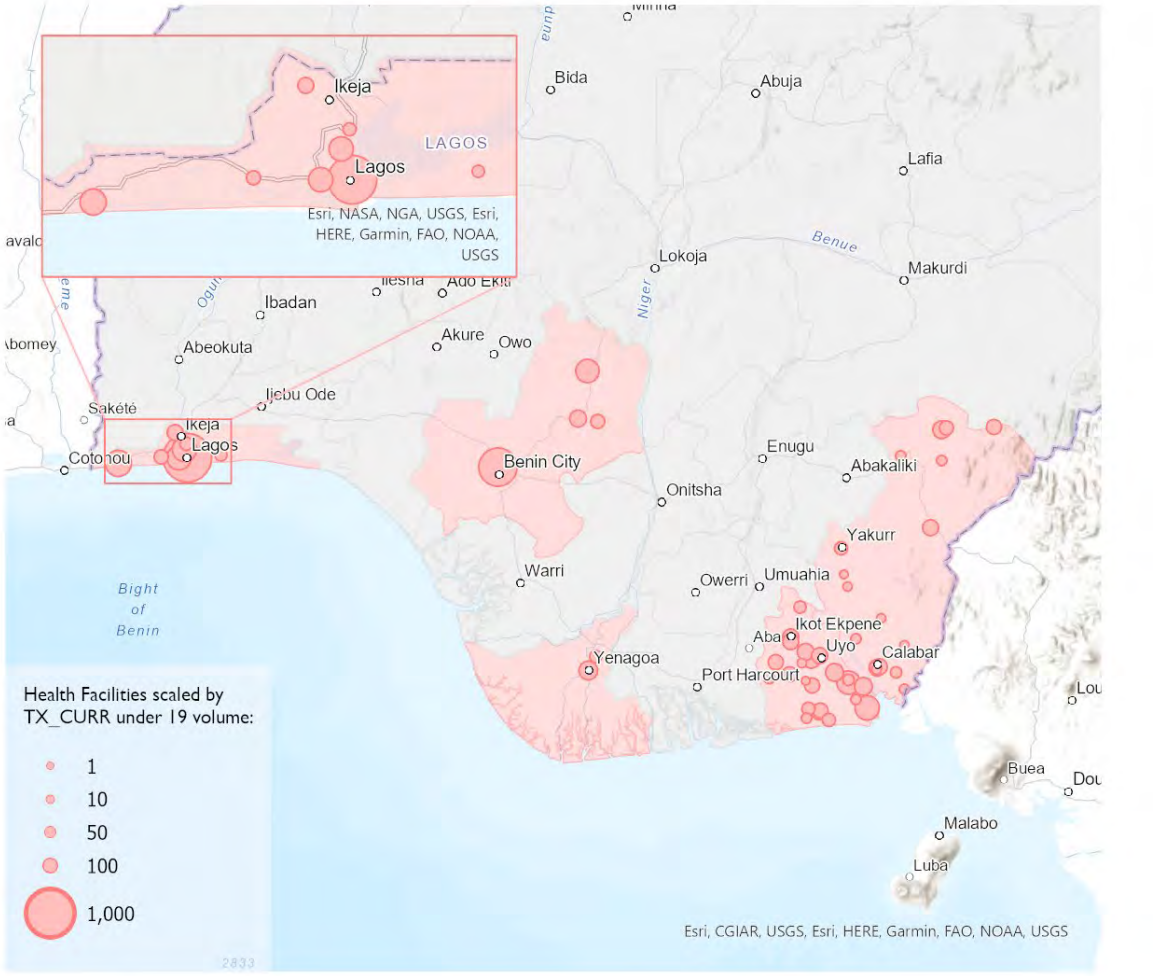
Understanding pediatric MMD: quantitative and qualitative assessment

A baseline, facility-level qualitative assessment was conducted to understand the process, opportunities and challenges associated with pediatric MMD in both countries, while facility-level, routine programmatic data were collected at baseline and end of the project to assess trends over time of MMD uptake and viral load coverage and suppression. The total number of sites sampled per activity are listed in Table 1.

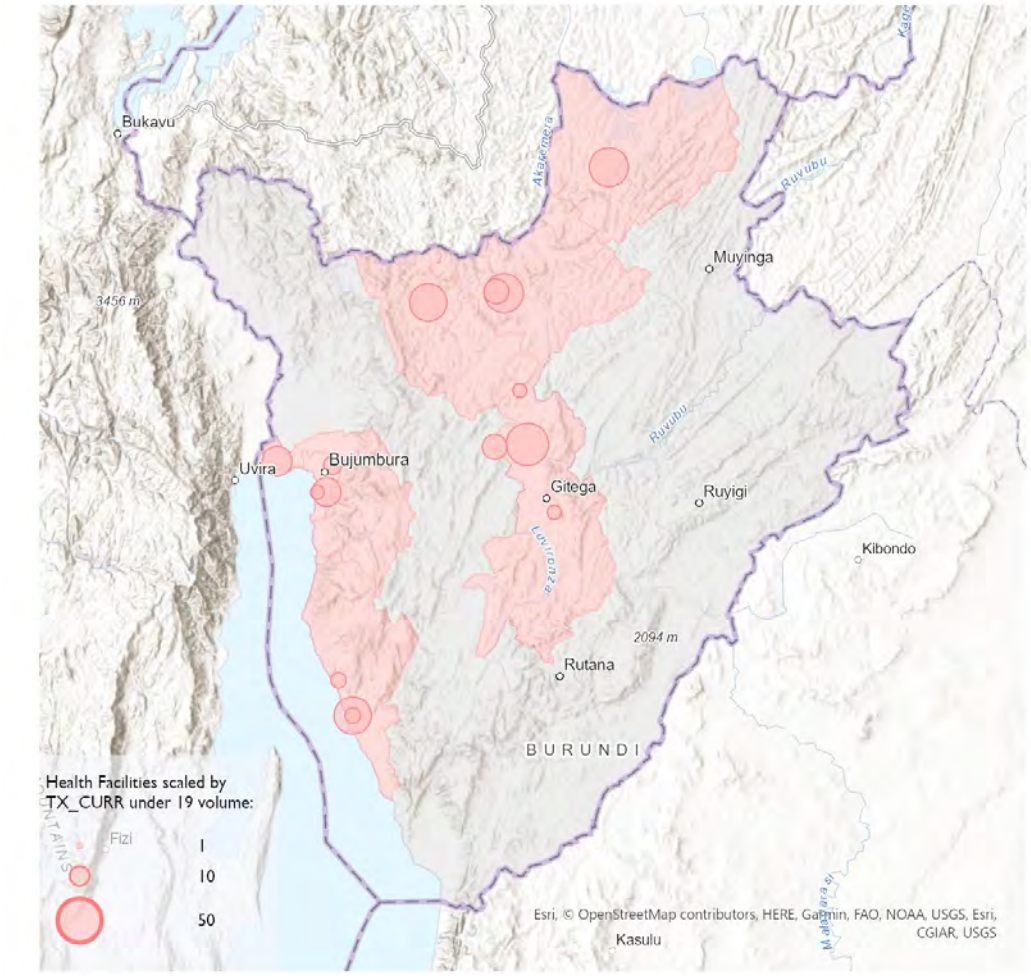
Table 1: Number of sites selected by IP and supporting Global Award

Country	Global Award (TA Partner)	In country Mech (Prime)	Total # of states/ regions covered by the IP	Total # of states covered by data collection activities	Total # of districts covered by data collection activities	Total # of ART sites support by the IPs	Total # of sites selected for quantitative data*	Total # of selected sites for qualitative data*
Nigeria	EpiC	SIDHAS and SHARP (FHI 360)	5	5	19	236	50	10
	RISE	Jhpiego/ICAP	4	2	9	91	10	10
	Total		**9**	**7**	**28**	**327**	**60**	**20**
Burundi	EpiC	RAFG (FHI 360)	3	3	4	196	12	4
	RISE	ICAP	4	4	4	88	5	5
	Total		**7**	**7**	**8**	**284**	**17**	**9**
	Grand Total						**77**	**29**

*In Nigeria, the assessment was conducted in Akwa Ibom, Bayelsa, Edo, Lagos, and Cross River states (Map 1); in Burundi, the assessment was conducted in Bujumbura, Kayanza, Kirundo, Ngozi, Gitega, Rumonge provinces (Map 2).



Map 1: Selected sites and regions, Nigeria



Map 2: Selected sites and regions, Burundi

Qualitative Data Collection and Analysis:

To understand the processes involved in the identification of CALHIV eligible for MMD, prescription and dispensing of ARVs, site assessments and interviews with clinic staff and OVC project personnel were conducted by each IP (FHI 360, Pact and ICAP). A questionnaire (with open and closed-ended questions) developed by the ACHIEVE/RISE/EpiC pediatric MMD team in consultation with pediatric technical staff in both countries were used.

As a first step, 29 sites were sampled based on the number of CALHV <19 years of age on treatment, disaggregated by age bands, the availability of a wide variety staff supporting and implementing MMD for CALHIV and available resources to conduct the site assessment given the limited time to collect data and duration of this activity. The purposeful sample included 20 sites in Nigeria and 9 sites in Burundi (Table 1). These were a subset of sites included in the quantitative data collection; 30 % and 50% of sites included in the qualitative assessment were among those selected for the quantitative data collection in Nigeria and Burundi respectively. To fully understand the context, interviews were conducted with several cadres of staff involved in MMD activities (from identification of eligible children to dispensing of ARVs) at the

facility and OVC project level: clinicians, nurses, pharmacist dispensers, case managers, and OVC staff and volunteers. Project staff worked with facility management teams to identify potential interviewees based on inclusion criteria. We aimed to speak with three providers per site including a medical doctor, nurse and/or pharmacist dispenser; however, we interviewed any staff most closely involved with MMD. In total, 33 staff from 9 sites in Burundi and 85 staff from 20 sites in Nigeria were interviewed. In light of COVID-19 restrictions, interviews were mostly conducted over the phone and in person only when local COVID-19 restrictions allowed and in compliance with social distancing regulations (wearing masks and social distancing for any in person interactions). Once potential participants were identified, they were invited to participate in the interviews; participation was completely voluntary. Personal identifying information was not collected.

Questions in the site assessment tool (Annex II) were used to document the process associated with identifying CALHIV for eligible MMD, as well as prescribing/dispensing procedures. Additionally, questions sought to elucidate successes, gaps and challenges associated with MMD for CALHIV with special focus on OVCs and their caregivers, from a provider perspective. Finally, the assessment identified any communication, education and monitoring tools used by clinic staff and the policies and guidelines that guide MMD implementation.

For community-based OVC programs that support CALHIV, staff and community-based workers from the supporting IPs participated in the assessment. The OVC program assessment was similar to the facility assessment and documented processes around supporting MMD for CALHIV in community-based programs. Content analysis of the interview data was conducted for each interview/assessment to identify the main processes, challenges, gaps, priorities and needs associated with scaling up MMD for CALHIV. Reoccurring ideas, texts and patterns were highlighted, as well as outliers. Results were analyzed by country and compared across countries and presented according to main priority area.

Finally, as part of the site and OVC program assessments, a desk review of job aids, standard operating procedures (SOPs), policies and guidelines for MMD for CALHIV at the facility/program level was conducted to assess quality of available tools.

Quantitative Data Collection and Analysis:

To understand trends in pediatric MMD and viral suppression over time, IPs collated routinely-collected treatment data from 77 health care facilities (60 in Nigeria and 17 in Burundi) for the periods FY20Q1 to FY21Q2, where FY20Q1 serves as a baseline and FY21Q2 serves as an endline. Sampled ART sites were selected from all sites supported by the EpiC, TMEC, or Reaching an AIDS Free Generation (RAFG) mechanisms in Burundi, and the RISE, SHARP, and SIDHAS mechanisms in Nigeria. Each IP was responsible for final selection of sites for inclusion, and provided data aggregated at the project level.

Data was disaggregated by period, ARV dispensing quantities, and fine age bands for ages 0-19. ARV dispensing quantities following the general PEPFAR usage and were defined as: MMD < 3 for clients receiving anything less than 3 months of ARVs, including no multi-month dispensing; MMD 3 – 5 for clients receiving 3 to 5 months of ARVs; and MMD 6 for clients receiving 6 months of ARVs. Using this data as provided directly by partners allowed for a finer analysis by age bracket, as the standard DATIM reporting data for ARV dispensing quantities only disaggregates age using a coarse age bracket (under/over 15 years of age).

In addition, supplemental data on viral suppression rates for the same mechanisms, periods, and selected sites, disaggregated by fine age bands for ages 0-19, was provided directly from DATIM, using the standard PEPFAR indicator definitions for viral load testing and suppression.

Data relating to beneficiaries served by PEPFAR OVC programs for children and families affected with HIV were collected from local IPs operating in the same Burundi and Nigeria regions and states as EpiC and RISE (described above) and working with the ACHIEVE project. For the OVC data, baseline data were collected for the period FY20Q3, and end line data were collected for the period FY21Q2. In Burundi, baseline OVC data were collected in collaboration with three local IPs that were working under Pact's global ACHIEVE award: Society for Women against AIDS in Africa (SWAA) Burundi, Great Lakes Inkingi Development (GLID), and Croix Rouge du Burundi (CRB). End line OVC data were collected through Conseil pour l'Education et le Development (COPED), a new, local prime IP implementing the WIYIZIRE Program. In Nigeria, the Association for Reproductive and Family Health (ARFH) and Center for Clinical Care and Clinical Research (CCCRN), two local prime IPs responsible for implementing OVC programs in the subnational areas where the MMD pilot facilities were located, provided baseline and end line OVC data.

Descriptive statistics were used to analyze and represent the quantitative facility and OVC data, calculating: (1) total and proportions of CALHIV, including OVC, on MMD over time, disaggregated by age and ARV dispensing quantity; and (2) viral load suppression over time, also disaggregated by age for both countries. Data for both MMD and viral suppression is aggregated, either at the facility or the program level, not the individual level; individual or cohort analyses are therefore not possible. However, the study uses associations between these two datasets with the working assumption that these broadly include the same population.

Ethical considerations

A non-research determination (NRD) was granted by Johns Hopkins University (JHU) prior to the start of data collection (Jhpiego, an affiliate of JHU, is a consortium partner under ACHIEVE and served as the lead organization in the baseline and endline data collections on behalf of the ACHIEVE/RISE/EpiC team). COVID-19 restrictions and mitigation strategies were considered across all data collection activities.

Findings from qualitative and quantitative pediatric MMD assessment

Qualitative Findings:

Interviews were held with 33 facility staff in Burundi (12 ICAP and 21 EpiC) across nine health facilities; and 85 facility staff (49 ICAP and 36 EpiC) in 20 Nigerian sites as part of site assessments. Findings are presented by key priority areas.

Identifying eligible clients for MMD and prescribing and dispensing practices:

The baseline site assessments revealed that timely identification of eligible CALHIV and dispensing ART followed different models across the two countries (Table 2). In Nigeria, case managers (lay workers) were responsible for identifying eligible client although some sites reported that dispensing pharmacist and other facility support staff were involved. In 70% of sites in Nigeria, a doctor, clinical officer or nurse are responsible for prescribing ART and recommending refill quantities (MMD 3 or 6) and a dispensing pharmacist or pharmacy technician is responsible for dispensing the medication. In Burundi, 56% of sites

reported that a nurse was responsible for both identifying eligible clients and prescribing and a dispensing pharmacist dispensed the medication. The remaining sites operated under different models: identification and prescription were usually conducted by a clinician or nurse, while dispensing was done by a nurse with the support of a counselor.

In Nigeria, viral load suppression was listed as an important criterion in determining eligibility for MMD as well as the patient's adherence, absence of opportunistic infections, TB status, weight and ARV stock on hand. In Burundi, over 50% of sites followed the national guidelines to determine eligibility for MMD, which didn't include MMD for pediatric population; but some staff at some sites considered CALHIV as unstable thus not eligible for MMD. Additional criteria for determining eligibility for MMD for CALHIV included the HIV status of the caregivers and their ability to follow up, viral suppression, and the overall health status of the CALHIV. Two sites in Burundi noted that stability on medication (tolerates medication well, with no known side effects) was the main criteria used for MMD in these age group.

Table 2: Identifying eligible clients for MMD and prescribing and dispensing MMD

	Nigeria		**Burundi**	
	Jhpiego/ICAP/RISE (10 sites)	**FHI 360/SIDHAS and SHARP (10 sites)**	**ICAP/RISE (5 sites)**	**FHI 360/RAFG (4 sites)**
Identifying CALHIV eligible for MMD	Case manager, data clerk, pharmacists		Nurse, clinician or nurse or counselor	
Prescribing MMD	Clinician or nurse		Nurse	
Dispensing MMD	pharmacist		Nurse, counselor or nurse	
Selection criteria MMD	VLS (n=13) Adherence (n=8) lack of OIs or comorbidities (n=4) TB negative (n=2), weight (n=2) stock on hand (n=1) client proximity (n=1) disclosure (n=1) pairing with caregiver on MMD (n=1)		VLS (n=5) Caregiver status and ability to follow up (n=3) CALHIV health status (n=3) CALHIV stability (n=2)	
COVID19-impact on MMD	Non-VLS became eligible (n=11)		All PLHIV became eligible (n=6)	
Stockout management*	Pharmacist notifies State Supply Chain Officer who informs Supply Chain Advisor. The advisor then redistributes drugs from other facilities with sufficient stock	Facility backstop contacts the State Logistic Management Coordinating Unit, and redistribute from other facilities	Support service pharmacy manager reports shortages to the facility director who then prepares an emergency order that is sent to the district	Never had a stock out and they calculate stock based on TXCURR*4 so that a 3-month supply is given to patients and one month is maintained at the facility

The COVID-19 pandemic and the need to adjust service delivery with subsequently relaxation of pre-pandemic eligibility for MMD contributed to the scale-up of MMD in both countries. In Nigeria, 55% of sites mentioned that eligibility for MMD had been expanded during COVID-19. For example, respondents from four sites mentioned that unsuppressed PLHIV on ART became eligible for MMD 3, while other sites noted that MMD for CALHIV started fully during the early COVID-19 period. Prior to that, unsuppressed clients received monthly refills. In Burundi, 60% of sites responding to the site assessment reported changes to eligibility as a result of COVID-19, generally expanding access to all PLHIV, with MMD3 for unsuppressed client if stock was available.

Monitoring Patient Adherence to Treatment:

Treatment adherence among CALHIV on MMD was not assessed in the same way across all sites. In Nigeria for example, 75% of sites reported assessing adherence, with most sites 60% of sites reporting multiple approaches to assessing adherence. Respondents described the approach to assess adherence, with 50% sites mentioning that it is done through phone calls (two sites specifically mentioned *Closer User Group lines*), eight reporting home visits (some saying that this is used when caregivers or children cannot be reached by phone), and three referred to assessing adherence during routine visits where a pill count is conducted. In Nigeria, 20% of sites reported that adherence was assessed during support group activities for adolescent via self-report. All facilities reported that processes had changed in support groups due to COVID-19. At the time of the site assessments, two sites had stopped holding the group meetings, one site was holding them remotely/virtually, and the last had changed the frequency of meetings from monthly to quarterly. In Nigeria, respondents listed the following data collection and reporting tools used to assess adherence:

- Interval Tracking Checklist (see Annex III);
- Client tracking and termination form that was designed to assess adherence;
- 90-day adherence calendar;
- ART care card;
- Pharmacy order forms;
- Daily pharmacy worksheet
- Lafiya Management Information System (LAMIS)

Case managers were most commonly mentioned as being responsible for monitoring adherence (7/15) but in some sites this is also done by pharmacists and/or adherence counselors.

In Burundi, staff from two sites described the use of peers to support non-adherent clients but they did not specify the process and four sites out of nine use CHWs to check in with caregivers and CALHIV by phone or in person, with CHWs maintaining records of these check ins. Two of these sites also mentioned Réseau Burundais des Personnes séropositives (the Burundi Network for People living with HIV (RBP+) supporting, a local community implementing partner provides community adherence and retention support.

Dealing with Stock-outs:

Critical to successful scale-up of MMD is availability of stock. As such, the site assessment sought to understand the frequency of ARV stockout and how sites prevented and or/addressed this challenge. In Nigeria, the approach to stockouts were consistent across sites. In 50% of sites, the pharmacist or

dispensing pharmacy notifies the State Supply Chain Officer who informs the Supply Chain Advisor. The Supply Chain Advisor then redistributes drugs from other facilities with sufficient stock. In the rest of the sites, sites contact the facility backstop, who then will contact the State Logistic Management Coordinating Unit, and redistributes from other facilities. These steps were noted by multiple sites to occur in this order. Most sites mentioned that they reduced the quantity of drugs given to patients on MMD when there are stock shortages (e.g. 1 month instead of 3 months), rationing what is available while avoiding splitting the pack size.

In Burundi, there was some variation between sites as well. In 56% of sites, the Support Service Pharmacy Manager reports shortages to the facility director who then prepares an emergency order that is sent to the district. Two of these facilities noted that they sometimes ask other facilities to help them when they have insufficient stock. The remaining 48% of sites reported that they had never had a stock out and that they calculated stock based on the availability of a 4-month supply of treatment per patient, so that a 3-month supply is given to patients and one month is maintained at the facility as buffer.

Perceived challenges related to enrollment of CALHIV on MMD Reported by Providers

Table 3 summarizes a ranking exercise, whereby providers from each site were asked to rank from lowest (0) to highest (5) any challenges affecting enrollment of CALHIV on MMD, from their perspective as providers, from the perceived perspective of caregiver of CALHIV/beneficiaries and challenges associated with the health system. In Burundi, the highest-ranking challenges associated with enrollment of CALHIV on MMD included stockout or shortage of ARVs for MMD, lack of training to prescribe MMD, worry that the caregiver of CALHIV would sell the ARVs and lack of storage of ARVs in the caregiver's home. In Nigeria, the challenges differed slightly. The highest-ranking challenge was a fear that the child requires more frequent follow-up. This was followed by not trusting that the CALHIV or their caregiver would adhere or manage the ARVs as prescribed and limited stock of ARVs for CALHIV in the health system.

Table 3: Ranking of Challenges Related to Enrollment of CALHIV on MMD by Site

Category	Issue	Total Burundi (n=9)	Total Nigeria (n = 20)
Provider challenges	Stockout or shortage of ARVs for 3 and/or 6 months MMD	2.33	1.35
	Frequent dose adjustment needed	1.44	1.40
	Uncomfortable prescribing MMD for C/ALHIV	2.22	1.50
	Lack of training to prescribe MMD/mentoring or supervision on MMD	2.44	1.15
	Unavailability of VL test results	2.22	0.85
	Unable to identify C/ALHIV eligible for MMD	1.22	0.55
	Lack of time to identify eligible CC/ALHIV	1.56	1.60
Beneficiary issues	Does 0t believe that C/ALHIV/caregiver will adhere/manage ARVs as prescribed	2.22	2.35
	Child is ill and needs to be followed more frequently	1.78	2.45
	C/ALHIV/caregiver s'caregivers' failure to/unable to/unwilling to disclose to family member or community and hence to failure confidentially store a large supply of ARVs	1.89	0.30
	Caretaker's failure to/unable to/unwilling to disclose to the C/ALHIV and hence failure to confidentially store a large supply of ARVs	1.33	0.45
	C/ALHIV/caregiver want to see provider more frequently	1.78	0.65
	Worried C/ALHIV/caregiver will sell ARVs	2.56	0.60
	Lack of storage (space) for ARVs at home	2.44	0.55
Health system challenges	Limited stock of ARVs for C/ALHIV in the health system	2.00	2.25
	Lack of national policies and SOPs for MMD with clear recommendations t	1.78	0.75
	Policies issues/ requirements for eligibility for MMD as per national recor	1.67	0.95

N = number of sites sampled in each country.

Priorities and Needs for MMD Enrollment:

In Nigeria, the most commonly mentioned priorities for support were ensuring adequate ARV stock (mentioned by 70% of sites), reducing turnaround time of VL test results and nutritional support. In Burundi, ensuring adequate ARV stock was mentioned by five sites and capacity building for providers was mentioned by four sites. When adequate ARV stock was mentioned in both countries, it was often a specific reference to pediatric formulations.

In Nigeria, 35% of sites mentioned the need for Information, Education and Communication (IEC) materials for patients/caregivers. Sites also mentioned the need for MMD-specific registers and registers or follow-up of clients by pharmacists and quick reference materials for health care providers. Finally, sites also highlighted the need for SOPs to be used by HCWs to ease identification of CALHIV who are eligible for MMD and also to help in monitoring adherence. Weighing scales were a priority for 20% (4/20) sites. In Burundi, respondents listed data collection and reporting tools available at facility level but not necessarily standardized such as VL sample tracking register to track VL samples sent to the labs and a register used by CHW to track patients who were lost to follow-up. Two sites mentioned a need for new registers specifically for children and adolescents.

Improving Collaboration Between Treatment and OVC Partners to Support MMD:

At baseline, results from the site assessments indicated considerable potential to improve collaboration between treatment and OVC partners, especially in Burundi. As a starting point the data systems were not interoperable or linked so it was not possible to calculate how many CALHIV enrolled into OVC programs were receiving MMD and vice versa. In some sites in Nigeria the team had to line list all the clients in order to check their MMD status. Collaboration between treatment and OVC partners to ensure MMD for CALHIV was scaled up and was reported to be frequent in 55% (11/20) of sites in Nigeria and occasional in 30% (6) of sites. Only two sites said there were few collaboration opportunities and/or no

longer collaboration due to conclusion of the project. Another site in Nigeria that reported frequent collaboration noted that COVID-19 related restrictions had made it challenging to continue the collaboration. Recommendations to strengthen collaboration included more frequent coordination by IPs in home visits, support groups and refills, as well as funding and attending monthly meetings between treatment partners and OVC programs. Sites also recommended greater collaboration with OVC partners to identify and follow-up with HIV-positive OVC, with prompt referrals for OVC who test positive at the facility.

In Burundi, five of the nine sites reported no collaboration, three said collaboration was occasional and only one site reported frequent/good collaboration. When sites provided input on how to strengthen such collaboration moving forward, the focus was often on what the OVC partners could do. For example, it was suggested that they could provide transportation assistance or nutritional supplementation for CALHIV, reach hard to reach CALHIV, have a skills acquisition program for OVCs, organize coordination, planning and M&E meetings etc. Other suggestions included making sure that OVC workers were trained in managing CALHIV in home or community-based settings. In both Nigeria and Burundi, joint learning sessions were implemented between facility and OVC staff to provide capacity building opportunities. While these suggestions do highlight the kinds of support OVC programs might provide, they do not readily identify means for increasing collaboration. The only concrete suggestions made for improving collaboration were joint meetings, inclusion of OVC program staff in adolescent approaches (such as Operation Triple Zero groups), and reconciliation of data with OVC partners.

OVC Program's Involvement in MMD:

In Nigeria, both OVC IPs reported coordinating with treatment partners to identify CALHIV on MMD and providing a range of support services, including communicating about ART pick-ups, supporting household or community level ART distribution, educating caregivers and/or CALHIV on MMD, and monitoring and supporting adherence. Both OVC IPs also played a role in identifying CALHIV not on MMD, either through home visits or facility records review and flagging for follow-up by the treatment partner. Key personnel involved include facility-based OVC cadres (Case Manager/Linkage Facilitator) and Community Case Worker. In Nigeria, both OVC IPs mentioned improving ARV stocks/supply chain as the top priority. Other priorities listed by the IPs included: development of tools, advocacy with MOH, disclosure education for caregivers, and including MMD in the national OVC MIS. In both Nigeria and Burundi, participants listed ARV stockouts and lack of disclosure of HIV status to CALHIV as the main challenges associated with MMD enrollment.

At the time of the baseline qualitative assessment in Burundi, the local IPs implementing the OVC program under ACHIEVE (SWAA, GLID and CRB) reported they were not playing any role in MMD for CALHIV. However, OVC program staff identified the following MMD-related priorities:

1. Training OVC cadres in MMD
2. Addressing ARV stockouts
3. Stronger coordination with treatment partners
4. Education for beneficiaries

Other priorities mentioned included development of tools for identifying and supporting CALHIV on MMD and their caregivers, inclusion of MMD-related indicators in data collection and case management tools and SOPs improving strategies for promoting decentralized drug distribution, and training or logistical support for beneficiaries/caregivers on ARV storage.

In Burundi, the IPs also listed the following challenges associated with MMD enrollment:

- Lack of coordination with facility partners
- Lack of skills/training for OVC partners
- Lack of SOPs
- Perception that CALHIV will not adhere to MMD.

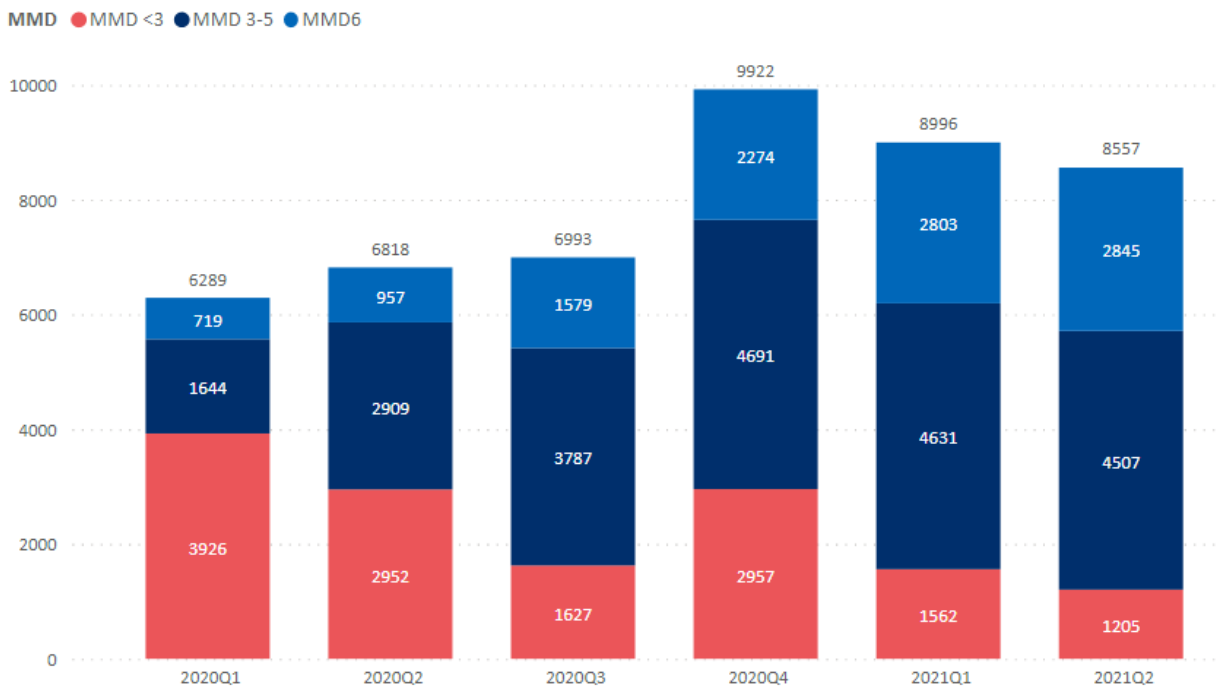
Quantitative Findings: Facility-level Treatment Programs

Nigeria:

Results are presented for both mechanisms in FY20 and FY21 Q1 and Q2 based on the data provided by partners as described above, unless otherwise noted.

Overall, there was a steady increase in the absolute numbers of children aged 0-19 on MMD 3-5 and MMD 6 over time from FY20Q1 to FY21Q1, with a slight decrease in absolute numbers FY21 Q2 (Figure 1).

Figure 1: Number of CALHIV (ages 0-19) on MMD by dispensing quantity by quarter, EpiC and RISE sites, Nigeria (FY20Q1-FY21Q2)



However, as Figures 2 and 3 show below, there was a steady and determined increase in both the proportion of CALHIV on MMD3 and MMD6 (Figure 2), and overall rates of MMD coverage (defined as the sum of MMD 3 – 5 and MMD6, divided by the total TX_CURR result, Figure 3) over time across all age brackets, from 38% in FY20Q1 to 86% in FY21Q2. For the under-10s, this is driven by increasing rates of MMD3 – 5, with MMD 6 remaining constant throughout the period; for the ages 10-19, however, a significant proportion of CALHIV were initiated on MMD6 by FY21Q2.

Figure 2: Proportion of CALHIV (ages 0-19) on MMD by dispensing quantity by quarter, EpiC and RISE sites, Nigeria (FY20Q1-FY21Q2)

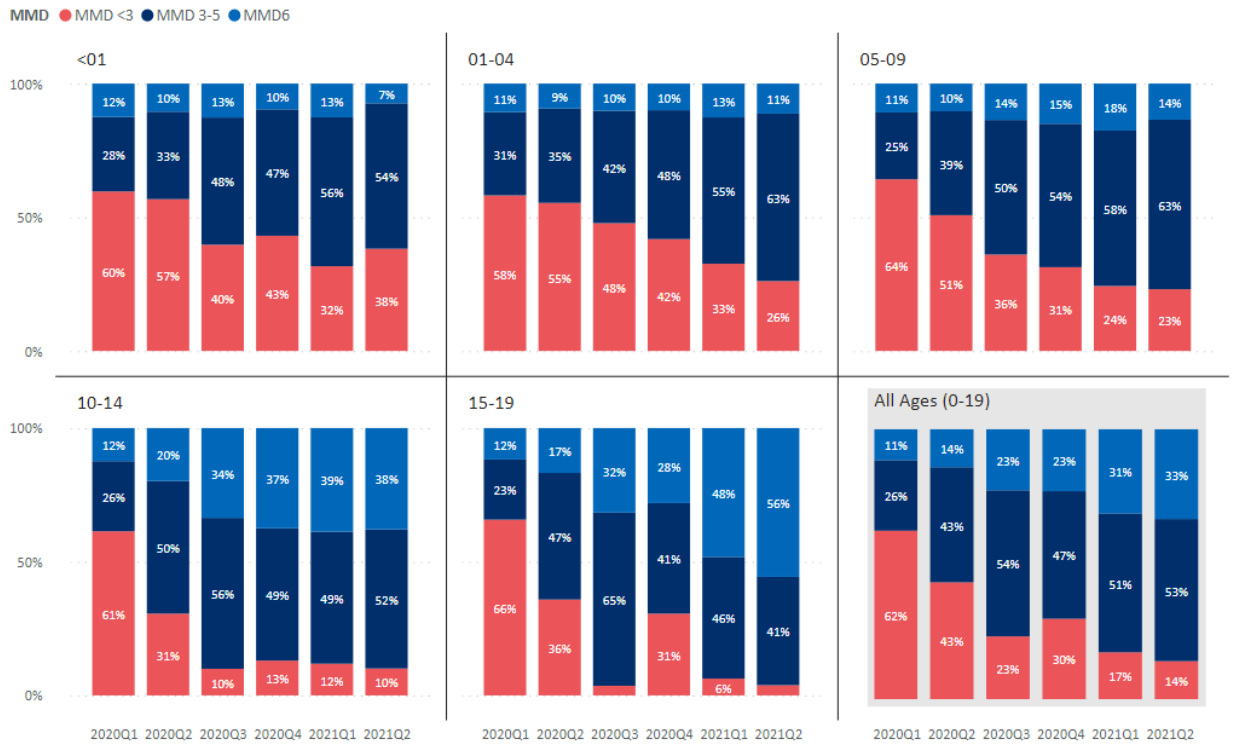


Figure 3: MMD3+ coverage rates by age and quarter, EpiC and RISE sites, Nigeria (FY20Q1-FY21Q2)

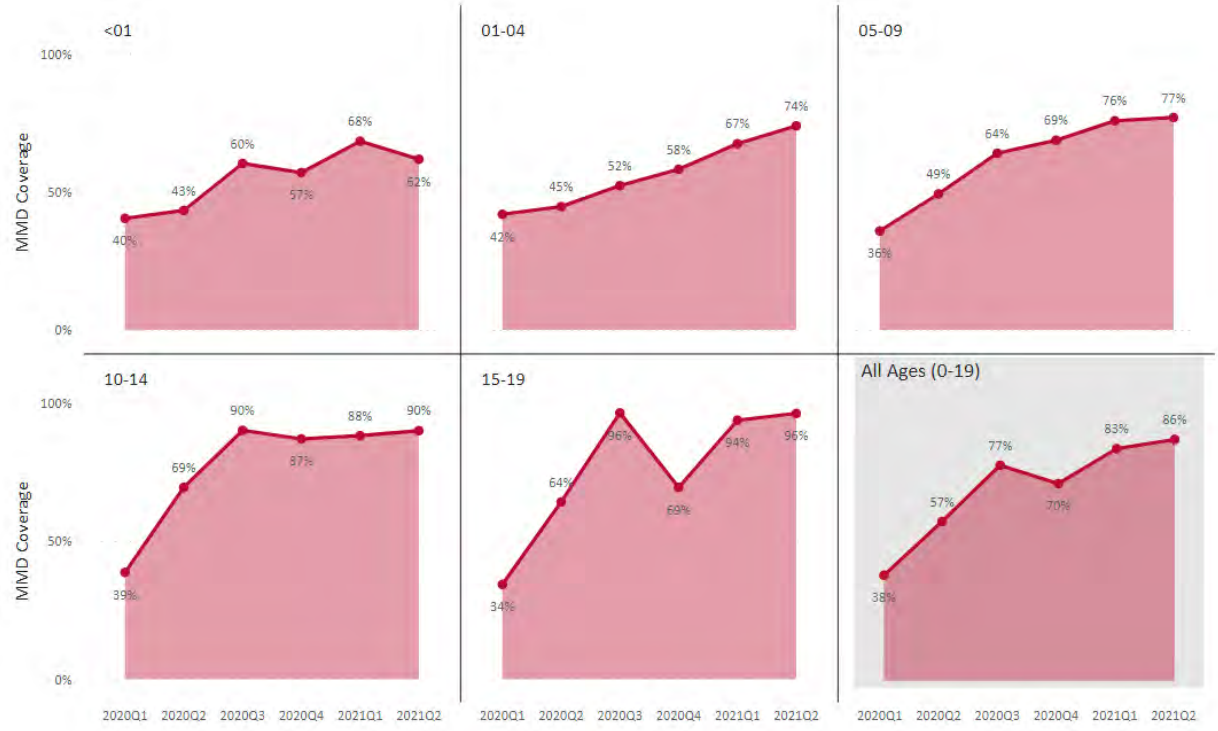
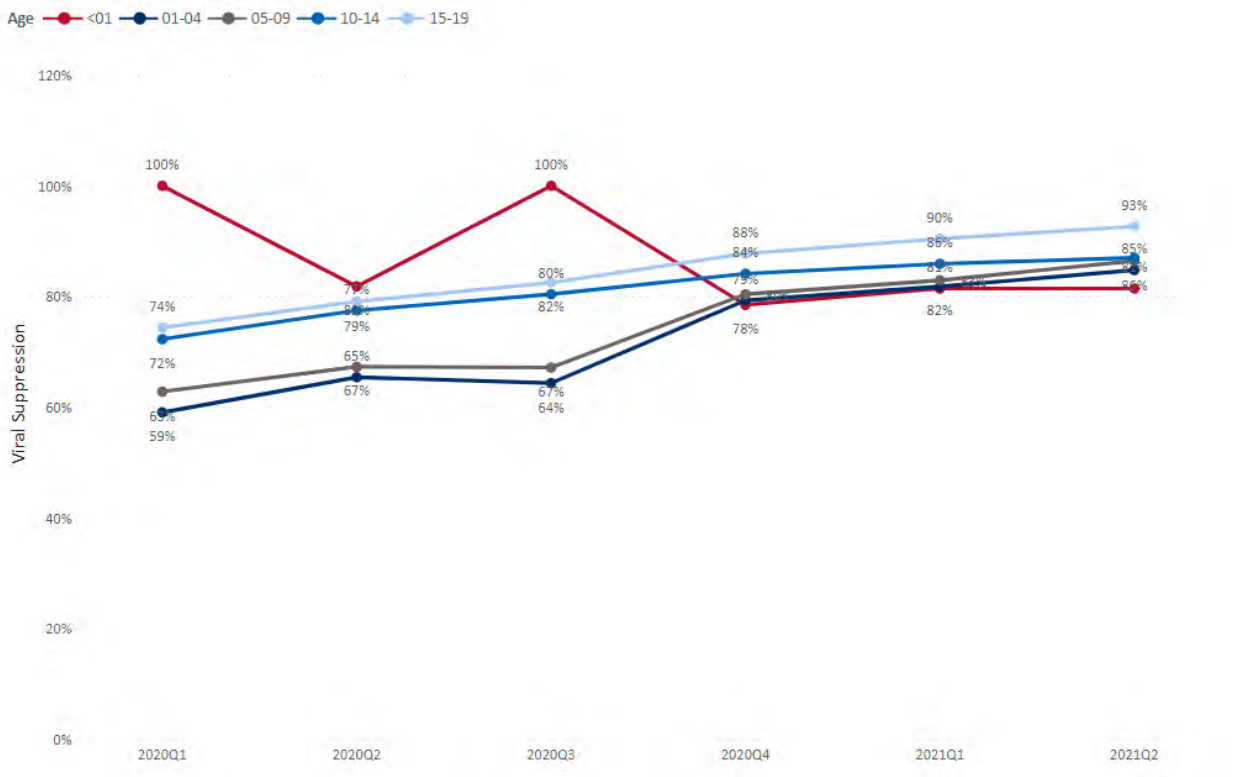


Figure 4 shows the viral load suppression rate trend for the same age groups over the same time, for EpiC and RISE supported sites. There is a steady increasing trend in VLS in all age groups with the exception of <1 years of age, which as the data table below shows has a lower absolute value over time compared with other age brackets. This is partly due to the prioritization of shifting to optimized regimens in this period: 99 % of CALHIV were on optimal regimen by Q2FY21 (70% on tenofovir/lamivudine/dolutegravir and 29% on abacavir/lamivudine/lopinavir/ritonavir. By FY21 Q2, 86% of CALHIV had achieved viral suppression.

Figure 4: Viral Suppression rates by age bracket by quarter, EpiC and RISE sites, Nigeria (FY20Q1-FY21 Q2)



Quarter	2020Q1		2020Q2		2020Q3		2020Q4		2021Q1		2021Q2	
Age	TX_CURR	% Suppressed	TX_CURR	% Suppressed	TX_CURR	% Suppressed	TX_CURR	% Suppressed	TX_CURR	% Suppressed	TX_CURR	% Suppressed
<01	233	100.00%	229	81.82%	229	100.00%	708	78.47%	246	81.43%	204	81.43%
01-04	1287	59.04%	1318	65.40%	1320	64.34%	1589	79.29%	1551	81.79%	1060	84.76%
05-09	1808	62.79%	1902	67.29%	1869	67.15%	2186	80.40%	2214	82.91%	2177	86.43%
10-14	1601	72.28%	1559	77.46%	1608	80.41%	2059	84.11%	2276	85.89%	2423	86.99%
15-19	1360	74.37%	1810	79.08%	1967	82.49%	3380	87.75%	2709	90.43%	2693	92.65%

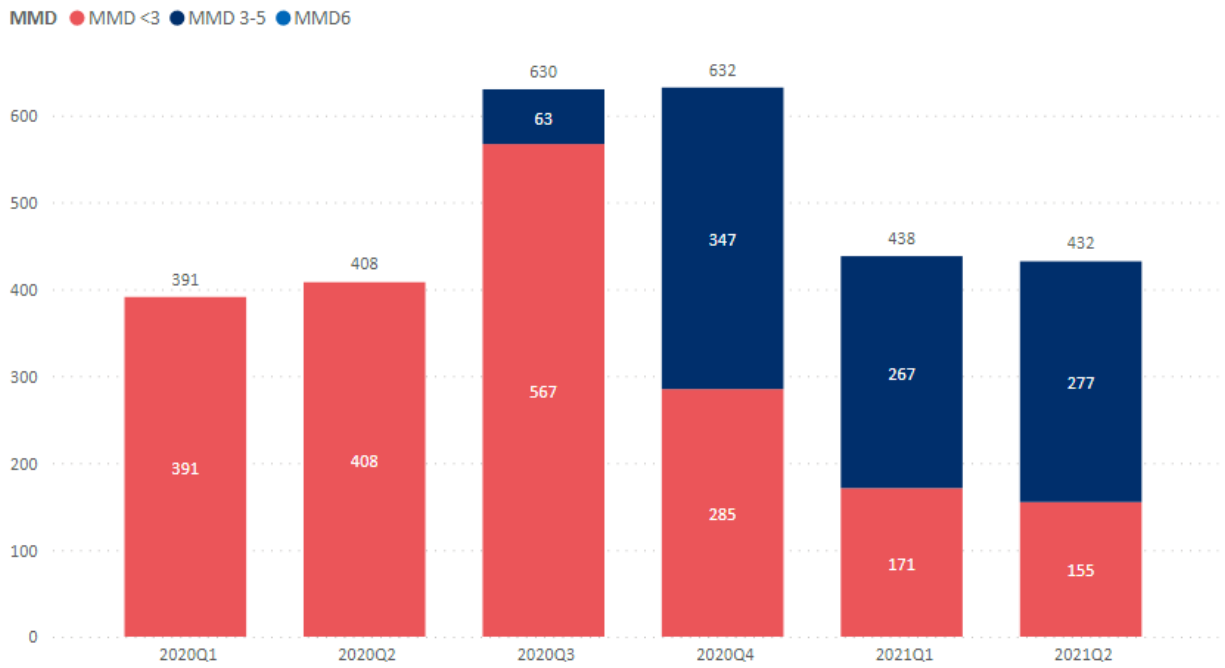
Figure 5 then compares these two rates for MMD coverage and viral suppression over time by age bracket. Overall, there has been an increase in both MMD coverage and viral suppression over time, with 38% MMD coverage and 74% viral suppression in FY20Q1, to 86% for both values by FY21Q2. There is some variation by age bracket, with both the 10-14 and 15-19 age brackets have achieved over 90% MMD coverage, with the 15-19 age bracket seeing a 93% viral suppression rate in the same period.

Figure 5: MMD3+ coverage and viral suppression rates by age and quarter, EpiC and RISE sites, Nigeria (FY20Q1-FY21Q2)

<u>Burundi</u>:

Results of MMD scale up efforts in Burundi present a different picture to that of Nigeria, in large part due to significant contextual differences. MMD scale up was not approved until part way through the study period, as shown by the first MMD results appearing inn FY20Q3 only; MMD6 is still not yet approved for CALHIV. However, data from Burundi-based IPs, as seen in Figure 6 show a significant uptake in MMD 3-5 over time in absolute terms, with a decline in FY21 as a function of an overall dip in TX_CURR values.

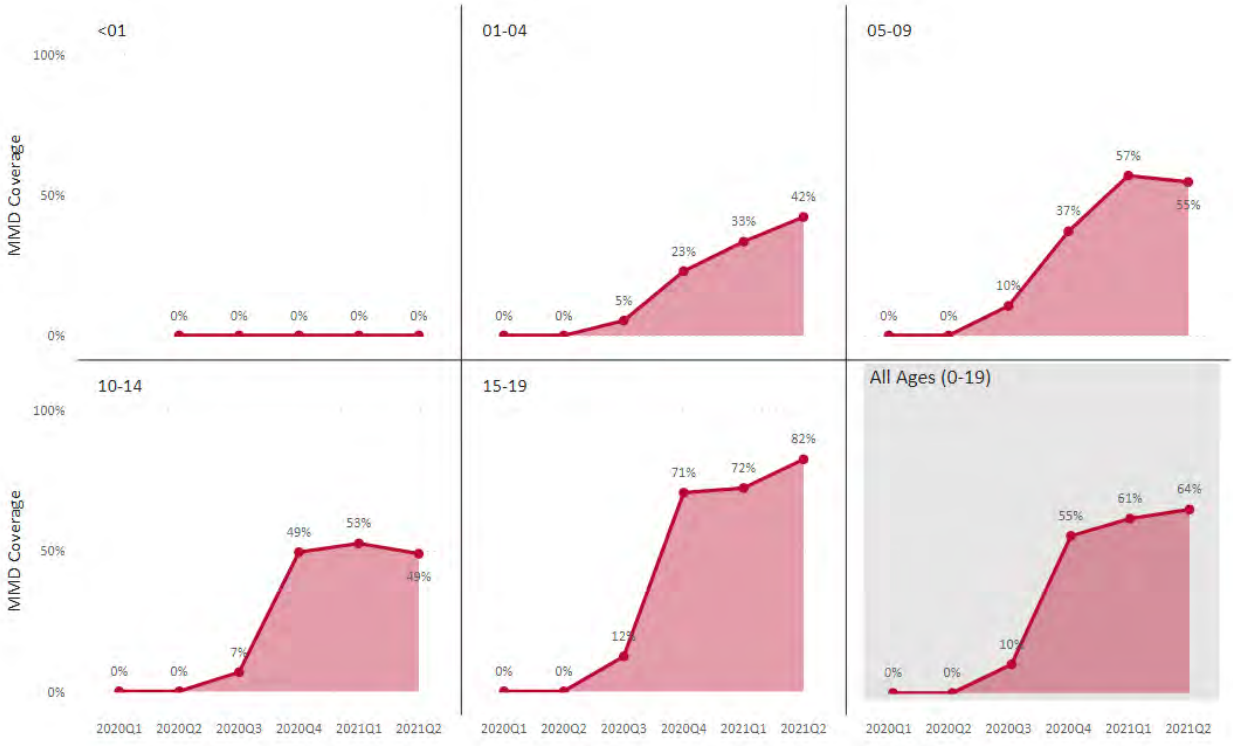
Figure 6: Number of CALHIV (ages 0-19) on MMD by dispensing quantity by quarter, RAFG (FHI 360) and RISE supported sites, Burundi (FY20Q1-FY21Q2)



When viewed in proportion terms, however, this shows a significant achievement in a short amount of time, with MMD coverage expanding from 10% of all CALHIV in FY20Q3 to 64% by FY21Q2. This is higher amongst older CALHIV populations, with MMD coverage in FY21Q2 at 82% for the 15-19 age bracket. MMD coverage is still zero for infants less than 1 year of age, due to policy guidance.

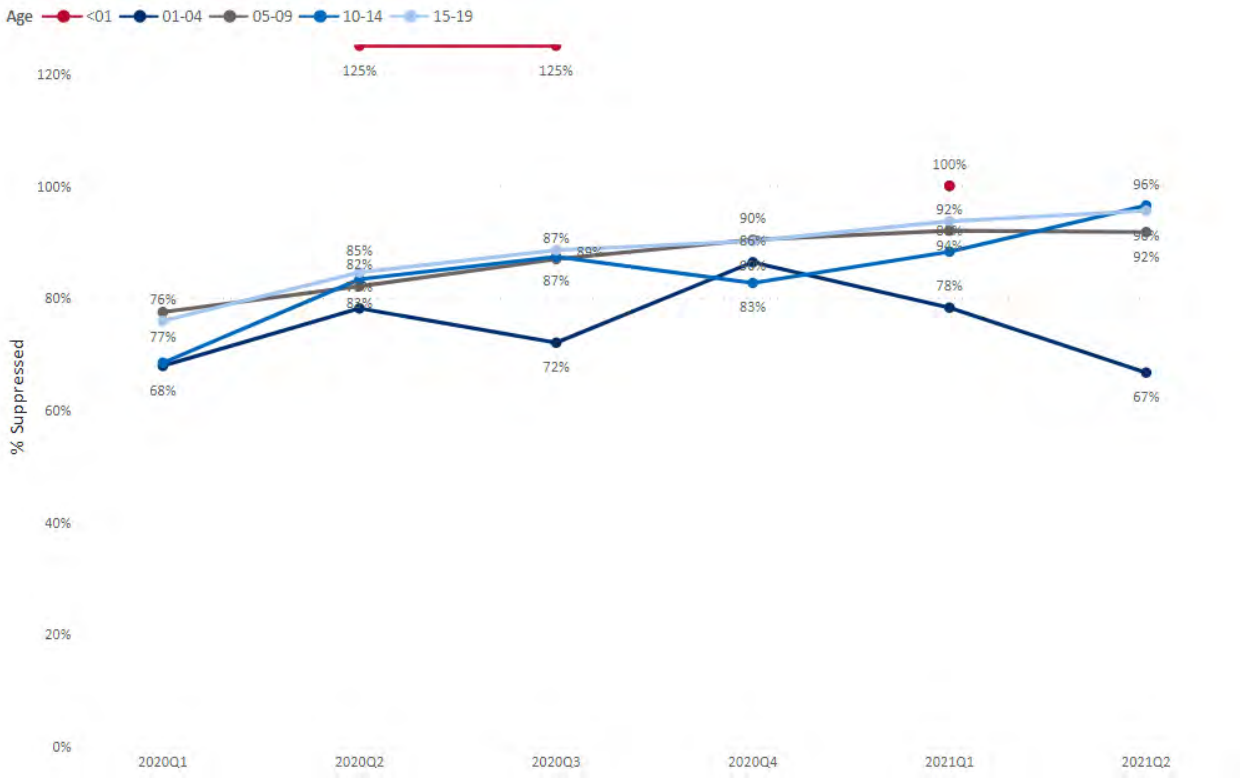
Figure 7: Proportion of CALHIV (ages 0-19) on MMD by dispensing quantity by quarter, RAFG (FHI 360) and RISE supported sites, Burundi (FY20Q1-FY21Q2)

Figure 8: MMD3+ coverage rates by age and quarter, RAFG (FHI 360) and RISE supported sites, Burundi (FY20Q1-FY21Q2)



At the same time, Burundi has seen progress in viral suppression rates over time (Figure 9), from 71% to 88% for all age brackets 0-19 in the period under review, and from results in the 60-70% range in FY20Q1 to above 90% for the age brackets 5-9, 10-14, and 15-19 alike (suppression rates among infants under 1 years of age are affected by a low absolute value). This is partly attributable to efforts to increase the proportion of children on optimal regimen, with the complete phase-out of Nevirapine during program implementation. Overall, 77% of children < 15 years were on optimal regimens by Q2 2021.

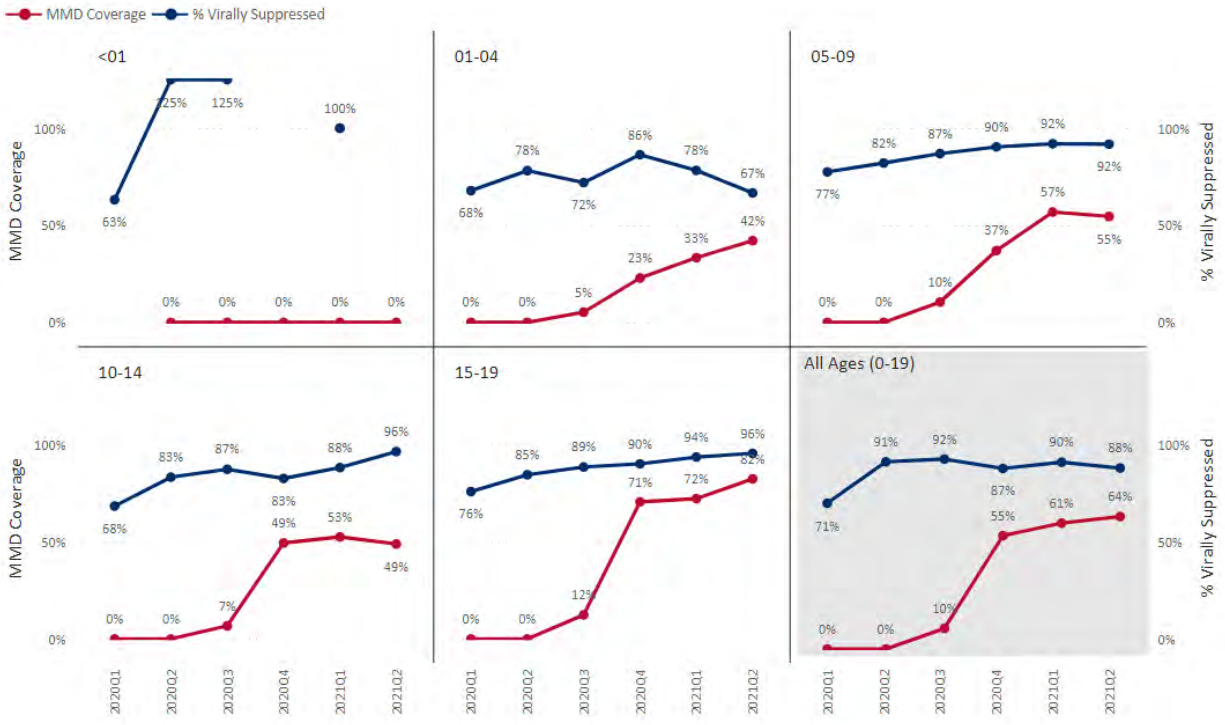
Figure 9: Viral Suppression rates by age bracket by quarter, RAFG (FHI 360) and RISE supported sites, Burundi (FY20Q1-FY21 Q2)



Quarter	2020Q1		2020Q2		2020Q3		2020Q4		2021Q1		2021Q2	
Age	TX_CURR	% Suppressed	TX_CURR	% Suppressed	TX_CURR	% Suppressed	TX_CURR	% Suppressed	TX_CURR	% Suppressed	TX_CURR	% Suppressed
<01	0		1	125.00%	1	125.00%	3		1	100.00%	2	
01-04	24	67.86%	19	78.13%	38	72.00%	35	86.36%	21	78.26%	19	66.67%
05-09	74	77.48%	65	82.08%	124	86.92%	127	90.38%	88	92.00%	88	91.75%
10-14	95	68.42%	97	83.33%	177	87.35%	178	82.67%	137	88.24%	135	96.48%
15-19	198	75.90%	226	84.54%	290	88.53%	289	90.17%	191	93.67%	188	95.54%

Taking these two rates together (Figure 10) shows that MMD coverage and viral suppression rates did not always follow the same trajectory: for the 1-4 age bracket, viral suppression declined as MMD coverage increased, while for the 10-14 age bracket, MMD coverage declined slightly as suppression increased. Overall, however, and as shown more clearly among the 15-19 age band, there were improvements in viral suppression rates, from 71% in FY20Q1 to 88% in FY21Q2, as MMD was introduced.

Figure 10: MMD3+ coverage and viral suppression rates by age and quarter, RAFG (FHI 360) and RISE supported sites, Burundi (FY20Q1-FY21Q2)

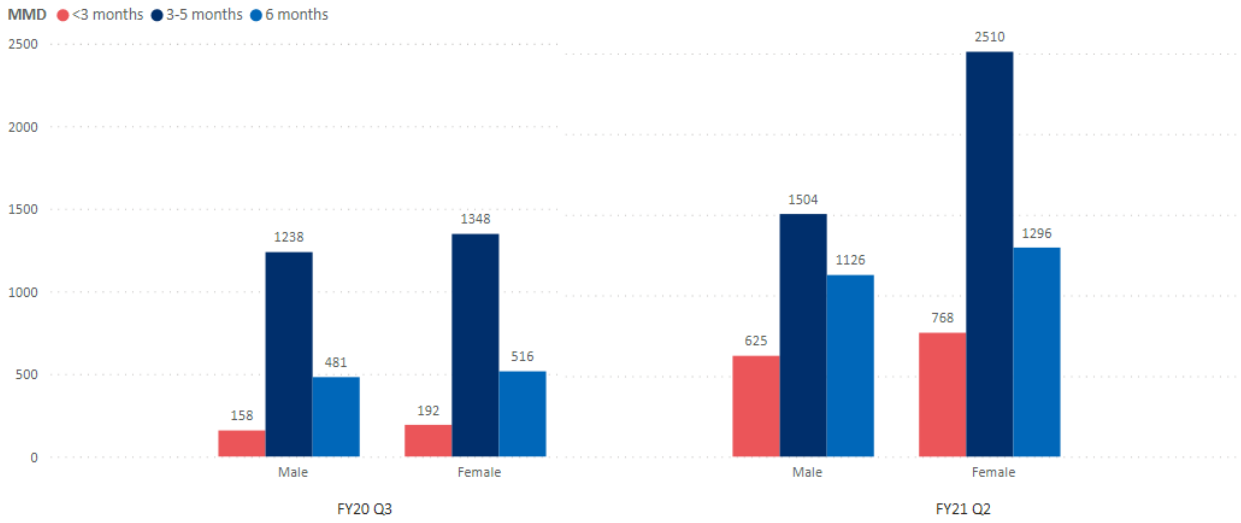


Quantitative Findings: OVC Programs

<u>Nigeria</u>:

In Nigeria, data on MMD at both baseline and end line are for active OVC beneficiaries in the ARFH and CCCRN programs as a whole, not limited to those accessing treatment at the MMD pilot sites. As shown in the graph below, the number of CALHIV enrolled in the two OVC programs who were on three or more months of MMD significantly increased between baseline and endline, for both females and males.

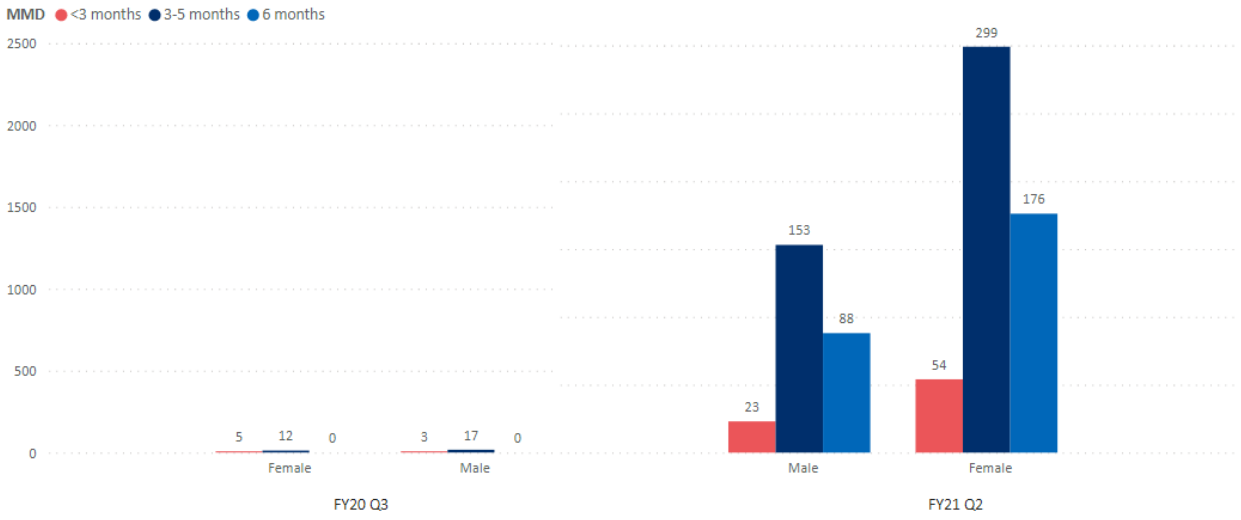
Figure 11: Number of OVC Beneficiaries <18 Receiving MMD: Nigeria (FY20Q3 vs FY21Q2)



Burundi:

In Burundi, OVC on MMD data at baseline come from 10 MMD pilot sites, six of which had CALHIV from the OVC program on MMD. End line data are from 164 treatment sites in the OVC project area, of which 75 had OVC CALHIV on MMD 3 or 6 (Figure 12). As in Nigeria, the number of female and male CALHIV enrolled in OVC programming in Burundi and on three or more months of MMD increased greatly between baseline and endline.

Figure 12: Number of OVC Beneficiaries <18 Receiving MMD: Burundi (FY20Q3 vs FY21Q2)



Key implementation considerations

As noted above, this project was undertaken within the context of ongoing programmatic activities focused on scale up of pediatric MMD. Rapid scale-up of MMD was more urgently needed due to the COVID 19 pandemic, that resulted in lockdowns and travel restrictions that limited the ability of caregivers to return to health facilities to pick up ARV refills for their children.

As part of this work, treatment partners and country staff in both Nigeria and Burundi held weekly pediatric meetings via Zoom to review age and regimen-disaggregated data together, discuss ongoing challenges and plan implementation activities for this project. Examining and reviewing disaggregated data by utilization of MMD, age, regimen and facility enabled the teams to better target challenges to pediatric MMD as well as work towards improving viral load suppression rates. Efforts to optimize regimens also benefited as review of pediatric-specific data identified gaps in prior transition efforts revealing that the indication for dolutegravir (DTG) 50 mg for children and adolescents >20 kg had not been widely implemented. Transitioning older children from LPV/r-based regimens to DTG 50 mg enabled them to benefit from a superior regimen while preserving remaining stocks of LPV/r pellets for younger children.

In Burundi the national program was making a slower transition to DTG-based regimens due to large stocks of efavirenz (EFV) that needed to be used up to avoid wastage. This resulted in tenofovir/lamivudine/dolutegravir (TLD) being mainly prescribed for newly initiating patients while existing patients were maintained on EFV-based regimens. After discussion with the national program, policies were updated in June 2021 to specify that all adolescents should also be transitioned DTG-based regimens.

In Nigeria, close communication with health facilities also identified shortages of pediatric ARV formulations as another major barrier to providing MMD. Clinical teams worked closely with district managers and a two-pronged solution was implemented wherein OVC case managers were able to deliver ARVs to CALHIV during home visits. In addition, collaboration with district managers continued to direct pediatric ARV to facilities with a higher volume of younger children and redistribute stock across facilities as needed. Over time, shortages of pediatric ARV formulations became less of a problem as supply chains were adjusted to meet facility-specific demand.

Clinical case discussions were also used to build capacity across healthcare workers, OVC case managers and district health officials. Real-world cases from each country were used and presented during multidisciplinary case conferences to address critical issues that are essential to successful pediatric HIV care and treatment such as weight monitoring, selection of appropriate formulations and developmentally-appropriate counseling including disclosure.

In addition to the initiatives above, in both countries the MMD collaboration resulted in more frequent sharing of information between OVC programs and the treatment partners, including the information on the MMD and viral load status of children on ART who were enrolled in the OVC programs. This information sharing allowed the OVC programs to better orient their regular home visits to support OVC CLHIV on MMD between clinic visits as well as to identify and refer OVC CLHIV on MMD in need of clinical support. In addition, it allowed the OVC programs to play a role in identifying eligible OVC CLHIV not on MMD and referring to facilities for assessment. In both countries, training was conducted for OVC staff and volunteers to orient them to their role in supporting MMD and familiarize them with the materials developed for their use (Technical Guide for OVC workers, Job Aids; see next section).

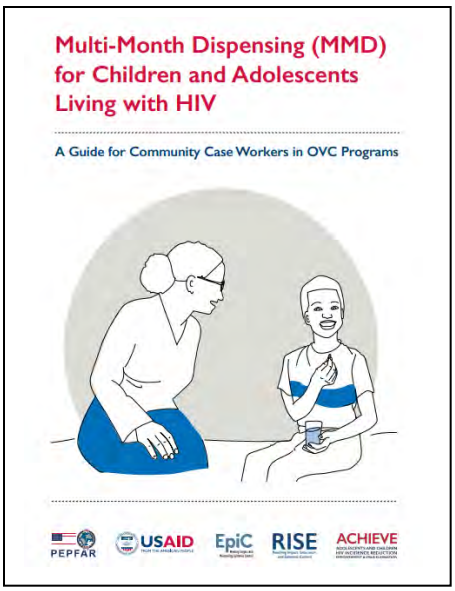
Responding to the Needs: Deliverables

1) Technical Guide for Healthcare Workers on Pediatric Multi-Month Dispensing (MMD)

Summary: a guide for health care providers responsible for assessing MMD eligibility and prescribing 3MMD or 6MMD for CALHIV, addressing the specific barriers identified to support MMD uptake among CALHIV on ART, including provider concerns about less frequent clinical follow-up. This technical guide includes information on how to optimize treatment in the context of MMD, including defining eligibility criteria, optimizing regimens and formulations, strengthening supply chain management, client sensitization, and systems for monitoring between clinical visits, including the importance of partnerships with community-based programs such as OVC program. Overall this provides a description of required competencies for HCW's in selecting optimal regimens, clinical management of CALHIV on ART, managing the ARV supply chain, and pediatric counselling; a discussion of M&E for MMD, including tool templates. This document is available in English and French and can be accessed here.

2) Technical Guide for Community Case Workers on MMD For Children and Adolescents Living With HIV

http://ovcsupport.org/resource/guide-multi-month-dispensing-mmd-for-children-and-adolescents-living-with-hiv/



Summary: a guide to assist OVC program personnel (community- or facility-based case management workers) to understand the importance of MMD and to understand their role and responsibilities in supporting MMD for CALHIV. Includes background information on MMD (what MMD is, why MMD is beneficial, which children are eligible for MMD) and reference material on ARVs and optimized regimens; an explanation of the role played by OVC workers in supporting CALHIV to start and continue on MMD; reminders on the role of OVC workers in supporting CALHIV in terms of adherence to treatment, viral load monitoring, and other elements of their health and well-being; guidance on when to refer CALHIV on MMD for clinical support and on identifying eligible CALHIV not yet on MMD; examples of modifications to standard OVC program data collection and reporting tools to incorporate MMD. Available in: English, French, Kirundi (forthcoming), Hausa (forthcoming), Yoruba (forthcoming). In June and July 2021, community case workers, supervisors, and OVC project staff were oriented in Nigeria and Burundi on this Technical Guide and trained in using the literacy treatment job aids in their case management with ALHIV and caregivers of CALHIV on MMD.

3) Job Aid for Health Care Providers, Case Workers, And Other Counselors to Discuss ARV MMD with Caregivers of Children and Adolescents Living With HIV

4) Job Aid for Health Care Providers, Case Workers, And Other Counselors to Discuss ARV MMD with Adolescents Living With HIV

Summary: two tools (one for use with CLHIV and their caregivers; and one for use with ALHIV) formatted as counselling cards (with images on the front and key messages on the back), to be used by facility- or community-based providers and case workers to guide discussions on MMD with CLHIV and their caregivers or with ALHIV. It includes a series of questions to be asked of caregivers/CLHIV or ALHIV about MMD to facilitate a counseling session and corresponding talking points and key messages for the provider/case worker/counselor. Topics covered include basic information about MMD of ARV medications, benefits of MMD, how to ensure success on MMD, and when to contact a health worker or other source of support between visits to collect ARV medications. Available in English, French, Kirundi, Hausa (forthcoming), Yoruba (forthcoming).

Using the findings from the qualitative assessment and from the literature, EpiC developed the content for MMD literacy material for CALHIV. The content aimed at addressing issues that were potentially preventing providers to offer MMD and clients to accept MMD. The content also addresses disclosure in connection to ART adherence, and it was geared towards reassuring clients about the possibility to connect with the clinic staff and/or peer network in between refills. Furthermore, the material describes the benefits of MMD in relation to having more free time for self-care, family and business, and the reduced cost of that, resulting in more savings. Selling, sharing ARV and drugs supply are also addressed.

The job aides were field tested in both countries and reviewed the ACHIEVE/RISE/EpiC and USAID colleagues.

5) Multi-Month Dispensing of Antiretroviral Medications and You
https://www.fhi360.org/sites/default/files/media/documents/resource-mmd-calhiv-guide.pdf

Summary: Two hand-out brochures, one written for CLHIV and their caregivers and another for ALHIV, with basic information on MMD in a question and answer format. The content includes information about MMD eligibly, its benefits, how to transport and store ARVs, and who to contact between scheduled clinic appointments. AVAILABLE IN: English, French, Kirundi, Hausa (forthcoming), Yoruba (forthcoming)

The hand-out brochures were field tested in both countries and reviewed by the ACHIEVE/RISE/EpiC and USAID colleagues.

Lessons learned: Key Takeaways

Pediatric MMD required comprehensive efforts across multiple stakeholders at the national, district, facility and community level. The ongoing programmatic activities carried out by IPs (treatment and OVC) and focused on scale up pediatric MMD were a testament of these productive. Key lessons learned during the implementation of this work include:

- Providers trained, mentored and were confident to prescribe appropriate ART optimized regimens for CALHIV according to weight, played a critical role on scale up MMD
- Continued monitoring of viral load coverage, impacted on viral suppression
- Realtime monitoring of ART transition of CALHIV onto optimized ART regimens, improved VLS rates
- Mentoring, technical assistance and use of tools and roll out of a pediatric regimen application, provided an opportunity to rapidly transition CALHIV into optimized regimen and transition them to MMD
- Rollout of Community ART groups were used as a platform to scale up MMD
- Regular stock monitoring, allowed to adequately forecast ARVs for MMD
- Combined efforts to empower clients and caregivers enhanced their knowledge about MMD and its benefits
- Partnership with OVC program, created an opportunity to support ART adherence among CALHIV on MMD, to alleviate concerns by the providers and to ensure appropriate community/home support between clinical visits
- Regular data review meetings, enabled identifying gaps and solutions for fast tracking pediatric MMD. Granular data (disaggregated by age, sex, ARV regimen, viral load status) promoted further discussion and course correction actions between programs.
- Coordinated efforts between OVC and treatment programs improved data sharing
- COVID-19 pandemic led to adaptation in service delivery for CALHIV in order to continue supporting treatment continuation. This included offering MMD for CALHIV without viral suppression as a requirement, as well as for non-virally suppressed clients.

Final considerations

This work offered a valuable snapshot of substantial progress on CALHIV receiving MMD. It also highlighted improvement in other HIV related outcomes (e.g. VLS) resulted from comprehensive and increased support for scale-up of optimal drug regimens and pediatric MMD in selected states/ regions in Nigeria and Burundi supported by PEPFAR. Despite such promising results, and due to the nature of this work, the findings cannot be generalized to other areas in Nigeria and Burundi as we could not include all sites implementing pediatric MMD in Nigeria and Burundi, and our sample of sites or CALHIV were not intended to be representative. Still, some of the challenges and barriers to access pediatric MMD may be similar across sites and implementing partners and recommendations could be applicable beyond the sites included in this activity.

In addition, this work was conducted during COVID-19 pandemic and a number of restrictions in place, which raised additional challenges for service delivery but at the same time created an enabling environment for innovative health care system adaptations to continue offering HIV services (including pediatric MMD) for CALHIV during this period. Our ability to collect timely data and conduct multiple rounds of data collection was also affected by the COVID-19 pandemic. For example, in some cases interviews for site assessments were conducted over the phone which could potentially affect the quality and quantity of qualitative data collected. Data quality verification, including completeness, is an on-going process and not all data were validated at the time of final analysis. This speaks to both facility and OVC data.

Conclusions and Recommendations

As efforts to scale up pediatric MMD in PEPFAR support countries continue, below are key recommendations for Nigeria and Burundi more specifically. It could also serve to support other countries moving forward on these efforts.

- Approval of the pediatric MMD materials developed by respective Nigeria/Burundi Ministry of Health and its roll out
- Disseminate materials to other countries for adaptation, as appropriate
- Explore and identify opportunities for further field testing of the materials in other contexts
- Explore additional opportunities to conduct pediatric MMD assessment among CALHIV and caregivers to provide valuable insight on the needs and challenges associated with access to MMD treatment and support with these target populations
- Formalize the expansion on the MMD eligibility criteria issued by the Nigeria and Burundi government under the COVID-19 pandemic; particularly for Burundi, expand the MMD eligibility to CLHIV < 10 years age
- PEPFAR and USAID to capitalize on this work and continue to foster close collaboration between OVC and treatment partners, from case management to coordinated monitoring systems, data use and reporting approach
- Strengthen collaboration between OVC, treatment and supply chain management partners to jointly discuss and propose course correction actions to ensure availability of pediatric formulation across all levels (at facility, district, provincial and central level)
- As OVC programs continue to prioritize CALHIV, pediatric treatment and monitoring HIV outcomes (e.g., MMD, VLS, etc.) continue to be well integrated into case management approaches and tools with an ongoing need for capacity building and supportive supervision for case care workers
- Efforts on mentoring and continuous quality improvement of HCW and OVC providers on pediatric optimized regimens, importance and role of MMD to continue

Annexes

Annex I: Priority criteria used for selection of countries for pediatric MMD work

The priority criteria below supported the discussions between Nigeria and Burundi team for selection.

- Presence of ACHIEVE (or other Pact OVC program) and at least one of RISE/EpiC mechanisms offering pediatric ART services;
- Permissive MMD policy already in place;
- No major MMD challenges on supply chain management for pediatric ARVs; availability of optimized ART regimens;
- Access to viral load testing for pediatric HIV population; ideally VL coverage of at least 60% across different age groups (2-4, 5-9, 10-14 and 15-19 years);
- Ability of OVC programs to enroll (all) CALHIV on MMD into their OVC programs

Annex II: Pediatric MMD baseline assessment tools

Improving MMD for C/ALHIV assessment tool – V11, August 14, 2020

USAID FROM THE AMERICAN PEOPLE

PEPFAR U.S. President's Emergency Plan for AIDS Relief

Improving MMD for C/ALHIV Assessment Tool - Facility

1. Introduction:

The multi-month dispensing (MMD) for children and adolescents living with HIV (C/ALHIV) Assessment has two components. The first component (section A) is a questionnaire which contains open and closed-ended questions to be administered to facility staff by implementing partner staff. The second component (section B) is an excel date entry form for the extraction of routinely collected, facility-level data for key HIV program indicators. This assessment is intended to document processes, strengths and gaps in rolling out MMD to C/ALHIV at the health care facility. Findings will be used to inform communication, educational and implementation activities to improve MMD for C/ALHIV as well as recommendations shared with USAID.

Interviews will be administered by implementing partner staff to a sample of health care facility staff offering MMD to C/ALHIV, including nurses, clinicians, pharmacists and counselors. For the facility assessment, at least one nurse and one clinician should be interviewed, per facility.

Interviews will be conducted in English in Nigeria and French or Kirundi in Burundi. Participants will be invited to participate in a phone interview during which time answers will be captured electronically by implementing partner staff. Participants will be invited to participate in a group interview, during which time other colleagues from the facility will be included in the phone call. A group call will be proposed during an initial contact by the implementing partner staff; participants will be given a choice between a group call or a one-on-one interview should they prefer. The interview will meet privacy and confidentiality standards. Participation is voluntary; there are no consequences for refusing to participate in the interview. Verbal consent by the participants will be obtained.

Upon completion of all interviews, data will be aggregated and submitted the IP focal person.

2. Inclusion Criteria for Interview Participants:

To identify appropriate participants for interview, please refer to inclusion criteria below. Please work with facility to identify potential interview candidates. As part of the initial recruitment and information sharing, request that the management team provide information to potential participants about the data collection activity and ask them if they would be willing to learn more about potential participation. If potential participants are interested in participating, they should provide their name and phone number to the facility or program managers, who will then share the list with implementing partner staff for recruitment purposes.

1.1 Facility Staff Inclusion Criteria for Interviews: Up to three participants per health facility should be interviewed, including at a minimum, one nurse and one clinician. Interviews should be conducted with health facility provider **directly involving in provision of MMD for C/ALHIV** (nurses, clinicians, pharmacist/assistant, counselors, case manager etc.).

3. Instructions for Conducting Interviews:

- Prior to the interview, project staff should have contact details for all interview participants and interview dates and times should be confirmed with each participant either by call or text message. Participants will be contacted twice: first, to request their participation and set a time and date for the interview and second, to conduct the interview.
- As part of the initial contact to organize the call time and date, implementing partner staff should ask participants if they are willing to participate in a group call with the other participants from their facility. If participants agree, group calls should be organized with all participants from the same facility at a convenient time/date. If participants do not want to participate in group calls, dates and times should be arranged with each individual participant.
- Prior to the interview, implementing partner staff should have the full list of questions and computer available to document answers.
- At the start of the call, implementing partner staff should introduce themselves, remind the participant of the purpose of the call and confirm that the chosen time remains convenient for the participant to conduct the interview. If the participant is still willing to conduct the interview, proceed with interview. If not, a new time and date should be selected and reminder/confirmation should be sent three and one day before the new time/date.
- Proceed with introductory statement which includes a request for the participant to provide verbal consent. In the introductory statement, each implementing partner should provide a description of the organization they work for including global mission, specific program or work in country, location of offices in country, region/districts and facilities supported.
- At the end of the interview, review answers. If more information or details are needed, please ask clarifying questions before the end of the call.
- Upon completion of the interview, provide your name and phone number to participant and let them know they may contact you if they have any questions.
- Thank the participant for their time and participation.

4. Instructions for Completion of Assessment:

- The program assessment has two components: Section A: the questionnaire to be completed through interviews with facility staff and Section B: a data collection tool for routine, site-level data. Please see the excel-based tool included. Data should be extracted by implementing partner staff from program registers and other data collection tools and entered into the excelform.
- Upon completion, please return both components to:
- For questions regarding this assessment, please contact:

5. Introductory statement prior interview:

Dear health care team providing care for C/ALHIV,

*My name is_____and I work for_____[**please describe organization.]** Today, I am conducting a brief interview with health care providers and community workers like you to collect information on multi-month dispensing (MMD) of antiretrovirals (ARVs) for children and adolescents living with HIV (C/ALHIV). I will ask a series of open- ended and closed-ended questions to understand how, when and why MMD occurs for C/ALHIV in your facility. We are interviewing health care providers from facilities across the country to learn more about MMD and answers from all these interviews will help us develop strategies and recommendations to improve and scale up MMD and also improve collaboration between HIV treatment and Orphan and Vulnerable Children (OVC) programs. We will be writing a final report for the Ministry of Health and USAID with our recommendations to enhance MMD strategies. This report will be produced in October, 2020.*

More specifically, we are interested in knowing what is working well and understanding the main challenges and gaps associated with MMD in your facility. Please feel comfortable to be honest with your answers. Your answers will be combined with answers from other participants; I will not link your answers to you at any time during the data capture, analysis or reporting.

The interview will take approximately 30 to 45 minutes. I will ask you questions and then document them as you respond. Your participation is entirely voluntary and you may refuse to participate or stop the interview at any time without any professional or personal consequences to you. I have your name and contact details to be able to conduct this interview by phone. Please note however, that I will not document or include your name as part of the interview and I will not discuss your participation with anyone not associated with this study. I will not discuss your answers to your manager or other facility staff.

*[**If group call**]: Since we are a group, I ask that each participant respect the privacy of the other participants and refrain from speaking about this interview with others outside the call unless permitted by your colleagues.*

If you have any questions during the interview, please do not hesitate to ask me. I will also provide you with my name and phone number and you may call or message me if you have any questions associated with this interview.

Are you willing to participate in this interview?

Thank you for your time. Let's start the interview.

FACILITY ASSESSMENT – for Treatment Partner only

Implementing Partner:	
Project/Country:	
Region/Province:	
District:	
Facility Name:	
Name of Interviewer:	
Interviewer Contact details (phone number and email):	
Interview Date (DD/MM/YYYY):	
Number of Interview Participants:	
Role in MMD Service Delivery:	**Number of Participants:**
Clinician	
Nurse	
Counselor	
Case Manager	
Pharmacist/assistant	
Other:	

SECTION A: MMD for C/ALHIV SERVICE IMPLEMENTATION

1. What month/year did multi-month dispensing (MMD)of ARVs start at this facility:
_MM/YYYY

2. *What does this facility offer in terms of multi-month dispensing* (check all that apply, more than one answer is possible):

   a) For CLHIV 2-4years (☐ <3M; ☐ MMD for 3 Months; ☐ MMD for 6 Months ; ☐ MMD for other time period, specify)
   b) For CLHIV 5-9 (☐ <3M; ☐ MMD for 3 Months; ☐ MMD for 6 Months ; ☐ MMD for other time period, specify)
   c) For CALHIV 10-14 (☐ <3M; ☐ MMD for 3 Months; ☐ MMD for 6 Months ; ☐ MMD for other time period, specify)
   d) For CALHIV 15-19 (☐ <3M; ☐ MMD for 3 Months; ☐ MMD for 6 Months ; ☐ MMD for other time period, specify)
   e) None of the option: please explain:

3. *For C/ALHIV on ART. Please provide information to answer the following questions*. (Please use as much as space as needed to complete your answers):

a) Is there a specific provider responsible for identifying, prescription and dispensing of MMD? If so, please specify for each step (identifying, prescribing, dispensing):
b) What are the selection criteria/guidelines used to identify CALHIV eligible to MMD? Is it the same criteria used for adults: *Have selection criteria for MMD among C/ALHIV been affected by COVID19?*
c) What is the system/process used to identify C/ALHIV eligible for a viral load test?
d) What is process to ensure an eligible C/ALHIV has a VL test done?
e) What is the average turnaround time from blood sample collection to VL test results returned to the site? Communicated to the patient?

4. *Please explain what are the systems in place to assess C/ALHIV ART adherence in between ARVs pick up, when given <3, 3-5 and 6MMD* (Prompt: Is there peer or facility support between refills?).

5. *How and where are data on MMD for C/ALHIV captured* (Prompts: What variables are captured and reports? Where are data documented – please list all variables and tools i.e. client card, registers, appointment books, dispensing logs etc.? Who documents data in each tool? How frequently?)?

6. *Are data about MMD uptake used or reviewed by facility staff to inform service implementation and improvement? If so, what date are reviewed, how frequently and by whom?*

7. *What is the process used to quantify ARV stock/needs to provide MMD from the facility* (Prompts: how are forecasts quantified? Are medication dispensing records reviewed routinely (i.e., at least monthly) to identify clients (including 3 or 6-month MMS/MMD clients) who have missed medication pickups? How often are ARVs delivered to the facility? Is it a strict/set delivery schedule or can delivery be flexible based on need?)

8. *How much stock is currently at hand at your facility (express it in months of stock – check all that apply:*

1	TLD (300/300/50) bottles of	30 pills:	90 pills:	180 pills:
2	ABC/3TC 120/60 mg bottles of	30 pills:	90 pills:	180 pills:
3	ABC/3TC 60/30mg bottles of	30 pills:	90 pills:	180 pills:
4	AZT/3TC 60/30 mg bottles of	30 pills:	90 pills:	180 pills:
5	EFV 200mg bottles of	30 pills:	90 pills:	180 pills:
6	EFV 600 bottles of	30 pills:	90 pills:	180 pills:
7	NVP 50 mg dispersible bottles of	60 pills:	180 pills:	X pills:
8	NVP 200 mg tablets bottles of	60 pills:	120 pills:	X pills:
9	LPV/r oral liquid	X ml:	X ml:	X ml:
10	LPV/r 100/25 mg tablets	60 capsules:	120 capsules :	X capsules:
11	LPV/r 100/25 mg tablets	60 capsules:	120 capsules :	X capsules:
12	LPV/r 200/50 mg tablets	60 capsules:	120 capsules :	X capsules:
13	LPV/r 40/10 mg pellets or granules (specify:)	60 capsules:	120 capsules :	X capsules:

14	ATV/r (300/100) in bottles of	30 pills:	90 pills:	180 pills:
15	TDF/3TC 300/300	30 pills:	90 pills:	180 pills:
16	AZT/3TC/NVP 60/30/50 mg	30 pills:	90 pills:	180 pills:
17	AZT/3TC/NVP 300/150/100 mg	30 pills:	90 pills:	180 pills:
18	ABC+3TC+EFV in bottles of	30 pills:	90 pills:	180 pills:
19	TDF+3TC+EFV in bottles of	30 pills:	90 pills:	180 pills:
20	TDF+FTC+EFV in bottles of	30 pills:	90 pills:	180 pills:
21	TDF+FTC+NVP in bottles of	30 pills:	90 pills:	180 pills:
22	TDF+3TC+NVP in bottles of	30 pills:	90 pills:	180 pills:
23	ABC+3TC+NVP in bottles of	30 pills:	90 pills:	180 pills:
24	Other:	30 pills:	90 pills:	180 pills:
25	Other:	30 pills:	90 pills:	180 pills:

9. *What happens in case of shortage and/or stock outs of ARVs? Who is first notified and what are the subsequent steps taken to report this to a higher level? For patients on MMD how do you deal with times when you are low on stock?*

10. *What do you see as a major challenge related to enrollment of C/ALHIV on MMD*: (Please rank challenges, where 1 is a "minor" challenge):

a) Challenges by the provider

1	Unable to identify C/ALHIV eligible for MMD	
2	Uncomfortable prescribing MMD for C/ALHIV	
3	Frequent dose adjustment needed	
4	Stockout or shortage of ARVs for 3 and/or 6 months MMD	
5	Lack of training to prescribe MMD/mentoring or supervision on MMD	
6	Lack of time to identify eligible CC/ALHIV	
7	Unavailability of VL test results	
8	Other:	

b) Challenges related to beneficiaries (from providers' perspective)

1	Does not believe that C/ALHIV/caregiver will adhere/manage ARVs as prescribed	
2	Child is ill and needs to be followed more frequently	
3	Worried C/ALHIV/caregiver will sell ARVs	
4	C/ALHIV/caregiver want to see provider more frequently	
5	C/ALHIV/caregiver's failure to/unable to/unwilling to disclose to family member or community and hence to failure confidentially store a large supply of ARVs	
6	Caretaker's failure to/unable to/unwilling to disclose to the C/ALHIV and hence failure to confidentially store a large supply of ARVs	
7	Lack of storage (space) for ARVs at home	
8	Other:	

c) Challenges related to health system (from providers' perspective)

1	Limited stock of ARVs for C/ALHIV in the health system	
2	Policies issues/ requirements for eligibility for MMD as per national recommendations (VL VL tests < 1,000 copies/ml, etc.	
3	Lack of national policies and SOPs for MMD with clear recommendations to C/ALHIV at the health facility	
4	Other:	

11. What do you see as a 2-3 priority actions needed in order to scale up MMD among C/ALHIV in our context?

12. Please complete the table below regarding availability of tools for MMD for C/ALHIV and treatment literacy currently available.

Tools		Available on site?	Please describe if and how providers use these tools. What is working well with these materials/tools? Are there are any needs or gaps?
Tools for HCWs and OVC case workers to support scale up of MMD among C/ALHIV	12.1 SOPs and job aids for HCW to assist on identification of C/ALHIV who are eligible for MMD but not yet receiving, for pharmacist for MMD dispensing based on weight and age band	☐ yes ☐ no	
	12.2 SOPs to identify C/ALHIV not yet enrolled into OVC program	☐ yes ☐ no	
	12.3 SOPs and treatment literacy materials for beneficiaries/caregivers to provide ongoing adherence support between clinic visits and MMD drug pick up	☐ yes ☐ no	
	12.4 Register tools to track MMD, retention and viral suppression rates among C/ALHIV	☐ yes ☐ no	

1. Are there any other types of tools, materials and/or processes that you would find helpful to support your daily work in providing services to CALHIV– if so, please describe the tools and materials and how you think they should be used and by whom:

2. In the last quarter, how do you rate the collaboration between the treatment and OVC programs in your area/facility? (please select the most appropriate answer):

1	2	3
No collaboration between treatment and OCV partners	Occasional collaboration between treatment and OVC partners	Frequent/good collaboration between treatment and OVC programs

Collaboration includes: weekly, monthly, quarterly data review meetings, case conferencing discussions, multi-disciplinary team meetings.

12. Moving forward, what would your team suggest to improve the collaboration between treatment and OVC partners to ensure MMD for C/ALHIV is scaled up?

[END OF ASSESSMENT FOR FACILITY PARTNER – PLEASE GO TO SECTION B - Treatment]

Annex III: Interval Tracking Checklist for MMD clients

INTERVAL TRACKING CHECKLIST FOR MMD CLIENTS

Name of Health Facility_____ Date_____

Patient Name_____ Client ID No_____ Age_____ Sex_____

Descriptive Address_____ Phone No. _____

Preferred Day of the Week/Time for call: _____ Next Appt Date: _____

Current Prescriptions	Current Clinical Status (WHO staging)	Last Viral Load Result (Enter value & date)

Interval Tracking Schedule *(Insert dates for proposed tracking)*

Month One (Date):		
	Yes	No
(i) Have you missed your ARV in the last three days?		
(ii) How many pills are left?		
(iii) Are you experiencing any side effects?		
(iv) Have you felt ill since the last time we met? (If ill probe further for symptoms/refer)		
(v) Have you missed your OI drugs in the last three days? (name drugs)		
Remark:		

Month Two (Date):		
	Yes	No
(i) Have you missed your ARV in the last three days?		
(ii) How many pills are left?		
(iii) Are you experiencing any side effects?		
(iv) Have you felt ill since the last time we met? (If ill probe further for symptoms/refer)		
(v) Have you missed your OI drugs in the last three days? (name drugs)		
Remark:		

Month Three (Date):		
	Yes	No
(i) Have you missed your ARV in the last three days?		
(ii) How many pills are left?		
(iii) Are you experiencing any side effects?		
(iv) Have you felt ill since the last time we met? (If ill probe further for symptoms/refer)		
(v) Have you missed your OI drugs in the last three days? (name drugs)		
Remark:		

Month Four (Date):		
	Yes	No
(i) Have you missed your ARV in the last three days?		
(ii) How many pills are left?		
(iii) Are you experiencing any side effects?		
(iv) Have you felt ill since the last time we met? (If ill probe further for symptoms/refer)		
(v) Have you missed your OI drugs in the last three days? (name drugs)		

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Remark:

Month Five (Date):			
		Yes	No
(i)	Have you missed your ARV in the last three days?		
(ii)	How many pills are left?		
(iii)	Are you experiencing any side effects?		
(iv)	Have you felt ill since the last time we met? (If ill probe further for symptoms/refer)		
(v)	Have you missed your OI drugs in the last three days? (name drugs)		
Remark:			

Month Six: (Date-Appointment reminder-2days/1 week to clients next appointment date):			
		Yes	No
(i)	Have you missed your ARV in the last three days?		
(ii)	How many pills are left?		
(iii)	Are you experiencing any side effects?		
(iv)	Have you felt ill since the last time we met? (If ill probe further for symptoms/refer)		
(v)	Have you missed your OI drugs in the last three days? (name drugs)		
(vi)	Do you remember when next you are coming to the hospital?		
(vii)	Will you be able to come to the hospital as scheduled?		
Remark:			

Guidance for Interval tracking for MMD clients:

- The clients that are commenced on MMD 3 or 6 are placed in a tracking pool for interval tracking for clinical support to ensure that contact still is maintained with the facility health service providers for the long period that the client is away from the health facility.
- Interval tracking for clinical support for patients on MMD 3 or 6 will be guided using the monthly phone discussion checklist for patients on MMD 3 or 6 that assesses for adherence to ART and OI preventive therapy and monitors for ADRs.
- Phone calls are made monthly in the 3- or 6-months refill period by the health service provider (Doctor/Nurse/pharmacist) and an appointment reminder at most one week prior to the 3 or 6-month clinic visit by the assigned case manager.
- The ACM should fill dates for the monthly call/home visit on the checklist at visit to the facility. The checklist will remain with the ACM to facilitate tracking till next appointment or other definitive outcomes.
- At least two (for MMD3) or three (for MMD 6) completed checklists within a 3 or 6 months MMD cycle are to be attached to last pharmacy order form that generated the 3- or 6-months ARV refill.
- Home visits by the assigned case manager is promptly conducted for clients that are unreachable via the monthly phone calls.
- Patients who cannot or whose assigned treatment supporter cannot be reached will become ineligible for MMD 3 or 6 during subsequent follow up clinic assessment visits.

Comment: _____

Outcome of client post 90/180 days *(Tick as appropriate):*

Returned: ☐ **Agreed to return on another date (enter date):** ☐ **LTFU:** ☐ **Died:** ☐

Name of Staff: *Designation:* *Signature & Date:* _____

Annex IV: HBF pediatric MMD timeline

Activity	Lead	Timeline (calendar year)				
		May 2020	**Jun-Sept 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**April- Jun 2021**
Start Up						
1. Kick off call	USAID	May 4				
Baseline and final assessment on status of pediatric MMD						
1. Development of assessment tool on status of MMD among CALHIV in selected countries	ACHIEVE		x			
2. Definition of criteria and selection of regions and priority facilities by country	ACHIEVE/ RISE/EpiC		x			
3. Baseline data collection	RISE/EpiC		x			
4. Final assessment data collection						x
5. Data analysis	ACHIEVE			x		x
Briefer on pediatric MMD						
1. Summary of key results on baseline assessment developed (PowerPoint) and presented to USAID (HQ and country)	ACHIEVE			x		
2. Key results presented to country focal points (treatment and OVC partners)	ACHIEVE/ RISE/EpiC			x		
Two technical guides for health providers and for OVC workers to support scale up of MMD among CALHIV						
1. Compilation of existing tools and adaptation/ development of technical guide	ACHIEVE/ RISE			x	x	
2. Orient key in-country stakeholders for pilot testing.	ACHIEVE/ RISE			x	x	
3. Pilot testing	ACHIEVE/ RISE			x	x	
4. Final deliverable shared with USAID and country teams	ACHIEVE/ RISE/EpiC					x
Key messages on treatment literacy, self-efficacy for CALHIV and caregivers						
1. Compilation of existing tools and adaptation/ development of technical guide	EpiC			x	x	
2. Orient key in-country stakeholders for pilot testing.	EpiC			x	x	
3. Pilot testing	EpiC			x	x	
4. Draft shared with USAID for inputs	EpiC				x	
Close out						
1. Final report						x