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OVERVIEW

INTERVAL is an effectiveness-implementation hybrid evaluation which uses a cluster randomized design to compare three- versus six-month ART dispensing in Malawi and Zambia. This presentation focuses on the implementation outcomes, collected from patients and providers in Malawi; effectiveness (retention in care and viral suppression) was studied separately.

Background

- Multi-month dispensing (MMD) of antiretroviral therapy (ART) is a differentiated model of care to help overcome health system challenges and reduce the burden of HIV care on clients by providing more than one month of ART at once.
- While three-month dispensing has been standard of care, there has been increasing interest and policy implementation on extending refill intervals to six months.
- We explore client and provider experiences with implementation of MMD in Malawi as part of the INTERVAL study.

Study Design

• Semi-structured in-depth interviews were conducted with 17 ART providers and 62 stable, adult ART clients from 10 health facilities in Malawi.



- Participants were evenly divided by arm and were eligible for an interview if they had been participating in the study for six months (providers) and one year (clients).
- Questions focused on perceived challenges and benefits of MMD implementation: primarily acceptability and feasibility for providers and clients

Table 1: INTERVAL study eligibility criteria for Malawi

$(1) \ge 18$ years

- (2) On ART \geq six months
- (3) On a first-line ART regimen as defined by country-specific guidelines at the time of the study (efavirenz/lamivudine/tenofovir)
- (4) No drug toxicity/tolerability issues within the prior six months
- (5) No period of > one month without medication possession in the last six months
- (6) No active opportunistic infection suspected (including TB) and not treated for an opportunistic infection in the last 30 days
- (7) Viral load <1000 copies/mL within the last six months
- (8) If female, not pregnant or breastfeeding

Understanding implementation from provider and client perspectives: The INTERVAL study on multi-month ART dispensing in Malawi

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Methods

- Interview guides used the socio-ecological model (SEM) to elucidate relevant implementation factors at the interpersonal, community, and organizational levels. Codebooks for analysis were based on this same model.
- IDIs were conducted in local language (Chichewa) in private locations at the health facilities (between 20-60 minutes each). Audio was recorded transcribed, translated to English, then independently coded.
- All transcripts were coded in Atlas.ti v8.3 using constant comparison, and coding disagreements were resolved by consensus.

INTERVAL study arm Variable Three months of ART Six months of ART n=32 n=30 Female, n (%) 16 (50%) 16 (53%) 40 (35 - 47) 43 (37 - 50) Median age, IQR 26 (87%) 25 (78%) Married, n (%) Disclosure of HIV status to primary sexual partner, n (%) 26 (81%) 26 (87%) Yes 0 (0%) 1 (3%) No 5 (16%) 4 (13%) No primary sexual partner Median household size (IQR) 5 (4 - 6) 5 (3 - 7) 2 (1 - 3) 1 (1 - 3) Median number of children (IQR) Employment, n (%) Formal employment 8 (25%) 16 (53%) 12 (40%) Informal employment 18 (56%) 2 (7%) 6 (19%) Not working Education, n (%) 2 (7%) 3 (9%) No education 19 (59%) 11 (37%) Primary 17 (57%) 10 (31%) Secondary or higher

Table 2: Demographics for ART clients participating in IDIs (n=62)

Table 3: Demographics for ART providers in IDIs (n=17)

Variable	ART Providers
	n= 17
Female, n (%)	9 (53%)
Median age	35
Dispensing ART for 4+ years, n (%)	12 (71%)
Job title, n (%)	
Clinical Officer	3 (18%)
Nurse	14 (82%)

Findings

- Longer dispensing intervals (6 months of medication supply) was very acceptable to clients, primarily due to fewer clinic visits -- which decreased costs, increased sense of normalcy, and afforded more time for incomegenerating activities.
- Providers also felt that longer dispensing intervals was highly acceptable due to reduced workload – but providers were concerned about feasibility at the client level, specifically clients' ability to store large volumes of ART at home, increased likelihood of sharing medication with family and friends, and clients' lack of motivation to seek care for illnesses that might occur between ART refill appointments.
- Clients disagreed with this: they emphasized the value of ART, and reported no problems with storage and only rare, short-term sharing, mostly with spouses.

Theme	Client	Provider	Agreement
Interpersonal level			
Storage	No significant challenges	Perception that challenges are common	No
Sharing	Only 2 patients reported sharing, all others denied	Common problem, particularly amongst partners (observed by pill count)	No
Communal level			
Carrying	Reported minimal challenges with easy adaptation strategies	Perception of challenges but with adaptation (carrying big bags)	No/Yes
Selling & alternative ART uses	No reports of personal experience; rumors only alternative uses – livestock and alcohol	No concern about selling; Rumors only for alternative uses – livestock and alcohol	Yes
Organizational level			
Return visits for health	Reported returning for acute illnesses	Observed delays in health seeking services (specifically in the 6 month arm)	No
Reduced visits	Beneficial for patients (cost and time)	Beneficial for patients (costs and time) and providers (workload)	Yes
Ideal ART interval	6 months	6 months	Yes

Table 4: Comparison of findings related to acceptability and feasibility by SEM theme



Implications for Dissemination & Implementation Science

- Both clients and providers perceived the implementation of multi-month dispensing (of up to six months) to be highly feasible and acceptable.
- Decreased clinic visits emerged as the strongest benefit of the extended refill intervals for both clients and providers.
- Providers' concerns about storage, sharing, and return visits to the facility did not emerge in client interviews.
- Qualitative studies to collect information on implementation experiences, from both clients and their providers, should be encouraged in other models of care.

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