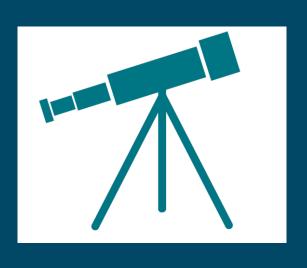
IMPACT OF 6-MONTHLY ART DISPENSING ON RETENTION IN MALAWI: A TARGET TRIAL EMULATION STUDY

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1363

BACKGROUND

- Malawi implemented 6-multi-month dispensing (6MMD) of antiretroviral therapy (ART) for clinically stable clients on HIV treatment during 2019 and scaled-up implementation in 2020.
- We compared retention in care at 12 and 24 months among clients who received 6MMD and those who did not receive 6MMD, and assessed predictors of retention.

METHODS

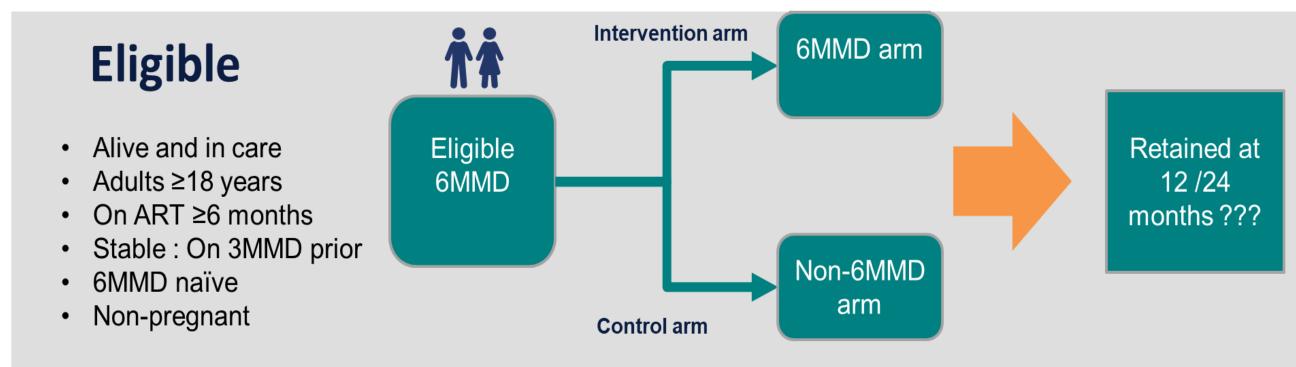
- We applied a target trial emulation (TTE) approach using routine clinical data from Malawi's Electronic Medical Record (EMR) system to identify ART clients eligible for 6MMD in 27 districts from January 2020 to December 2021.
- Eligibility was assessed at the start of each six-month period (Trial 1-4) as shown in Figure 1.

Figure 1. Eligibility assessment at trial baseline

Not Eligible

6MMD

All patients on ART at Trial baseline (Trial 1-4)

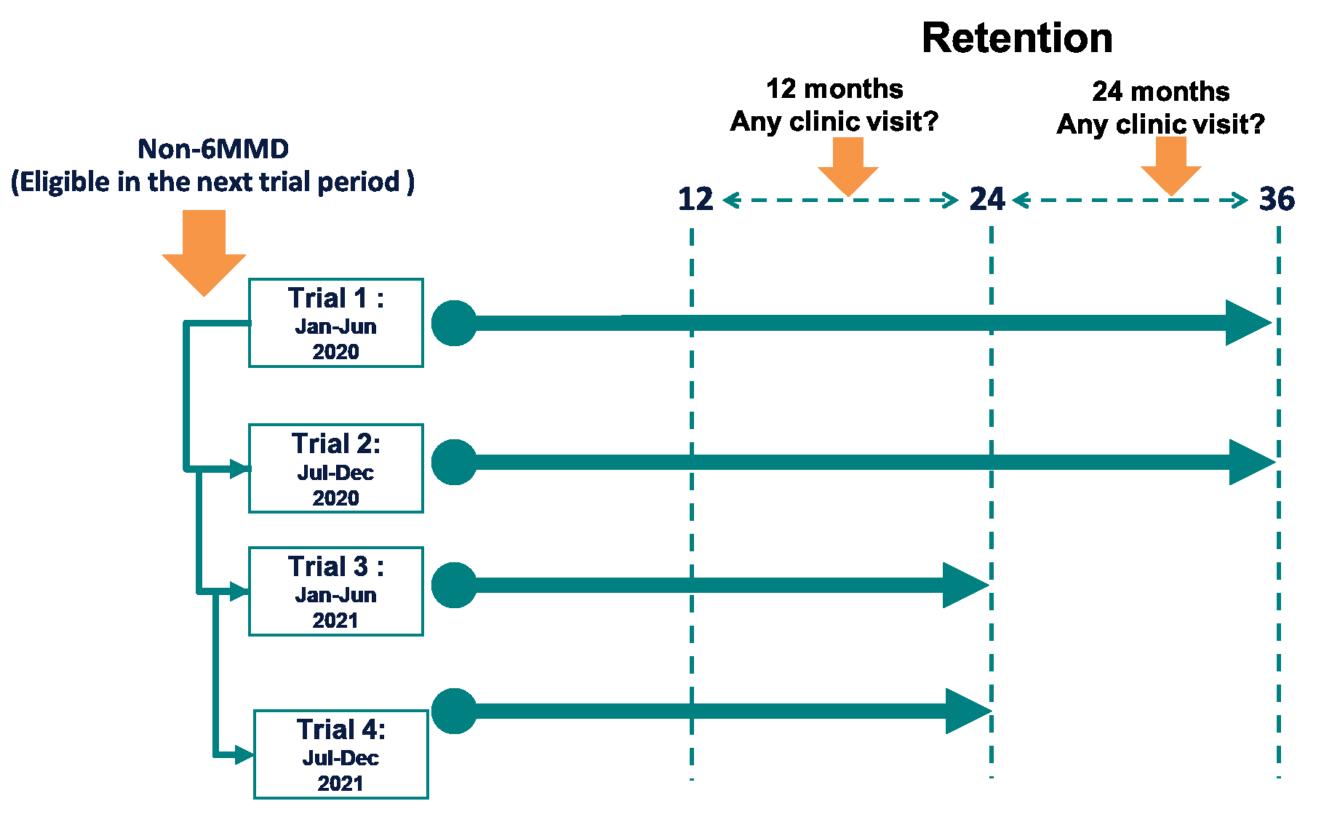


Not Eligible

- Alive and in care
- <18 years
- On ART <6 months
- Never on 3MMD6MMD non-naïve
- Pregnant women
- Retention at 12 and 24 months was defined as having a clinic visit within 12-24 (Trial 1-4) and 24-36 (Trial 1-2) months, respectively (Figure 2).
- Using an intention-to-treat approach, we estimated risk differences (RD) with 95% confidence intervals (CI) using a Poisson regression model with an identity link function and robust standard errors.
- Pooled RDs were estimated by accounting for within-subject variation in a Poisson regression model using data from all trials.

In Malawi, retention in care at 12 and 24 months was slightly higher among ART clients on 6MMD compared to those receiving shorter dispensing intervals.

Figure 2. Retention assessment for each trial

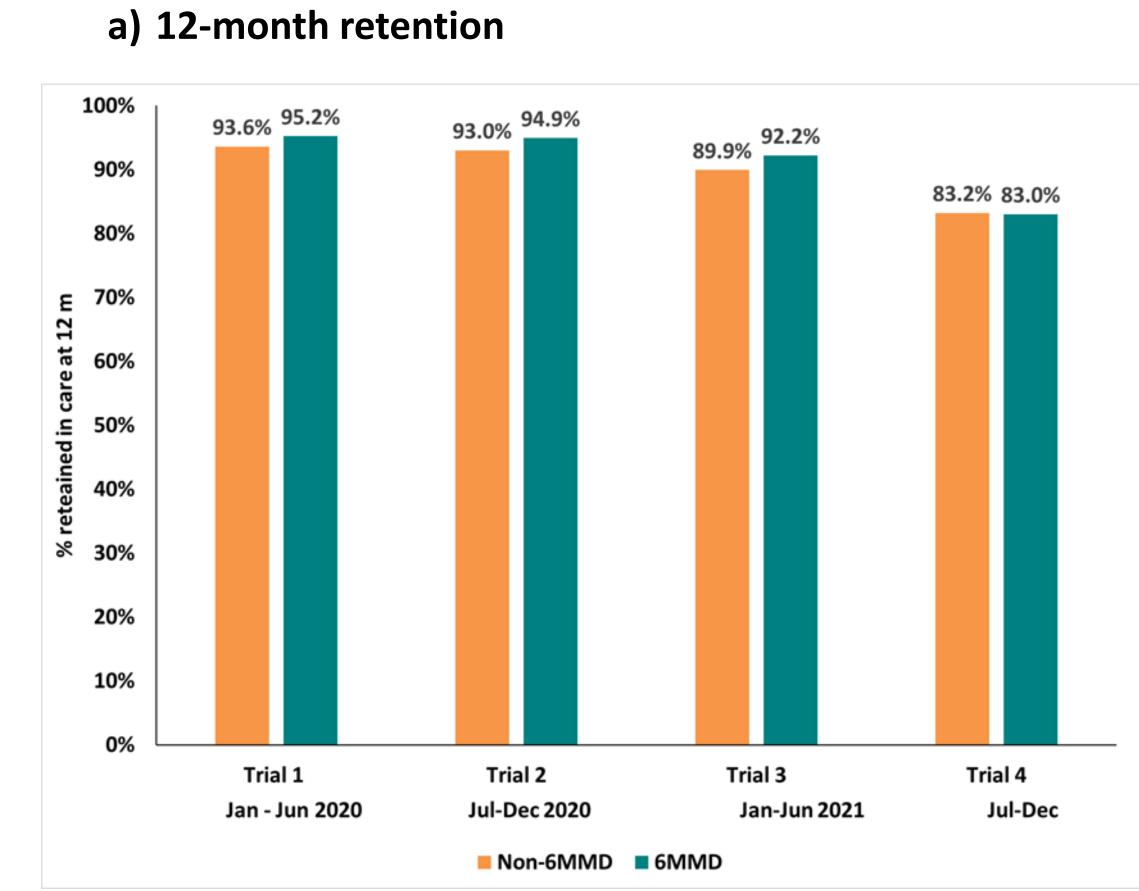


RESULTS

Table 1. Characteristics of individuals eligible for 6MMD

Characteristic	Never on 6MMD	Ever on 6MMD	Total
	N=41,926	N=148,940	N=190,866
Age in years (median, IQR)	33 (26,40)	39 (32,46)	38 (31,45)
Sex (female)	26,576 (63.4%)	89,311 (60.0%)	115,887 (61%)
Duration on ART in months (median, IQR)	23 (4,50)	39 (17,71)	37 (14,68)
Facility type			
Primary health care	21,596 (51.5%)	79,412 (53.3%)	101,008 (53%)
Hospital	20,330 (48.5%)	69,528 (46.7%)	89,858 (47%)
WHO clinical stage 1 at ART initiation	33,350 (79.6%)	106,014 (71.2%)	139,364 (73%)

Figure 3. Retention in care by 6MMD status



b) 24-month retention

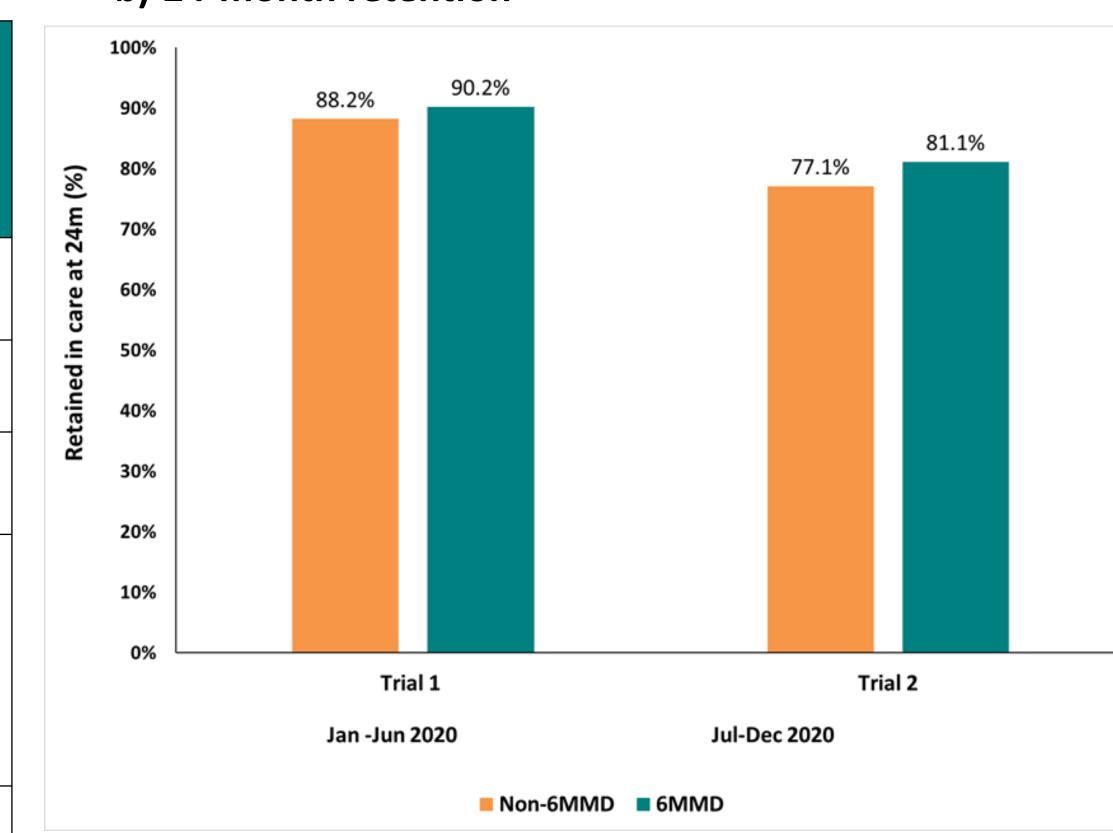
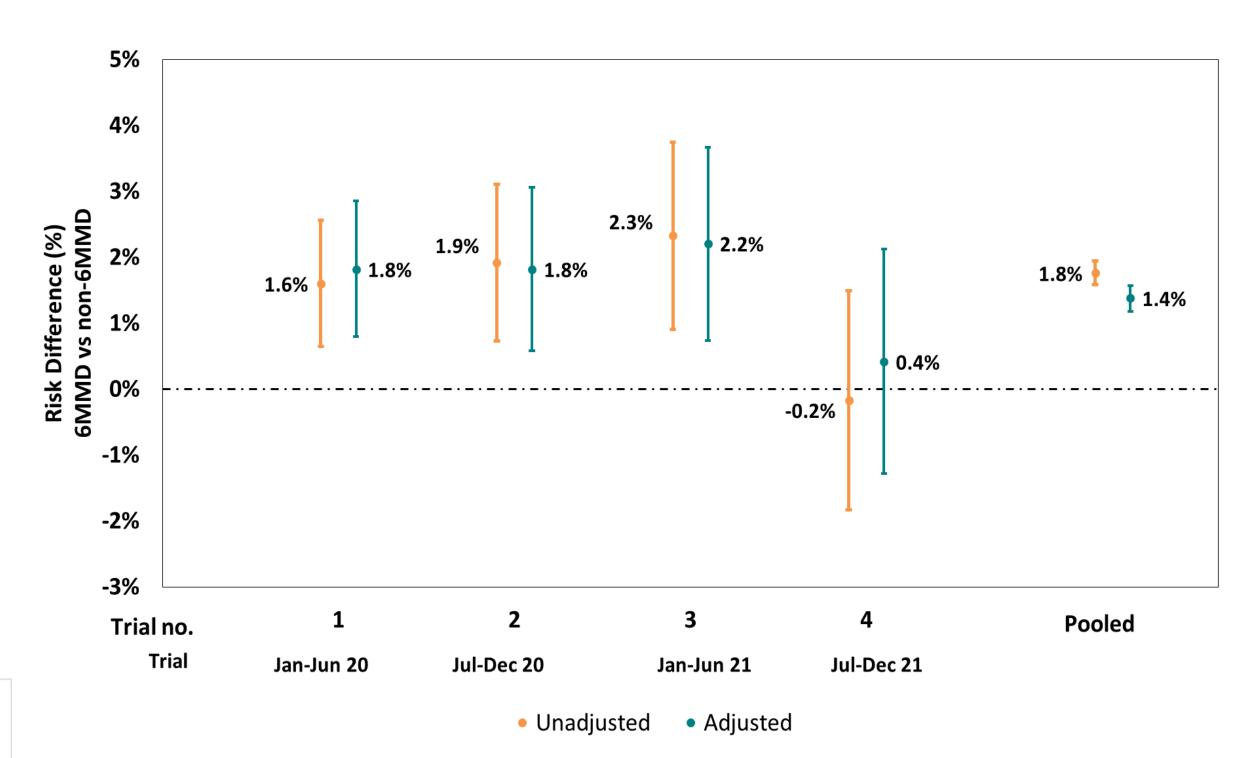


Figure 4. Risk differences for 12-month retention in care



- Of 190,866 unique eligible individuals (60% female, median age 38), **78% (212,722) were ever enrolled in 6MMD.**
- Retention at 12 months (Trials 1-4) and 24 months (Trials 1-2) was **consistently higher in the 6MMD group** than in the non-6MMD group (**Figure 3**).
- The pooled risk difference for retention for the 6MMD compared to non-6MMD groups was **1.38 (1.18–1.57) at 12 months (Figure 4) and 1.05 (0.76–1.35) at 24 months** (not shown).
- Across all trials, retention was higher for those who were female; ≥25 years; had mild HIV disease (WHO Stage 1/2) at ART initiation; received care at primary health care clinics; and were on ART longer at trial start.
- Results are limited by residual confounding that TTE methods cannot address; bias is likely with regard to who was offered 6MMD and who was not.

CONCLUSIONS

- We observed slightly higher retention rates in Malawi at 12 and 24 months among clients on 6MMD compared to those receiving shorter medication dispensing intervals.
- Future work to assess the impact of 6MMD on visit burden and resource use would offer a comprehensive view of the benefits to both ART clients and the health system.

