Malawi has aggressively scaled up access to antiretroviral therapy (ART) for HIV in recent years with over 600,000 people currently on ART in Malawi. Continued expansion of the ART program will be required to meet Ministry of Health (MOH) goals, and it will be critical to ensure that care is both more efficient and patient-centered to maintain outcomes with limited resources. In August 2016, the MOH officially adopted a policy of offering treatment to all individuals with HIV regardless of their health status. With this policy and other changes in recent years, the patient population has shifted to include more stable, healthy patients, creating an opportunity to refine the type of care needed by such patients.

Malawi has been a leader in developing pragmatic and innovative approaches to optimizing HIV service delivery, including the early adoption of Option B+ for pregnant women. In Malawi, models of care have emerged that categorize patients according to clinical stability and adjust ART services to tailor care to patient needs. While these innovations are being implemented to varying degrees in Malawi, they have not been systematically evaluated to assess how models operate and to identify lessons learned and opportunities for improvements.

### Evaluation Objectives

The Malawi MOH and the Clinton Health Access Initiative (CHAI) conducted a process evaluation in order to understand the extent to which ART patients in Malawi are differentiated based on their clinical stability and the characteristics and costs of three models of differentiated care offered in Malawi. Specifically, we explored the following aspects of three key models of differentiated care:

- Process and guidelines for implementation
- Extent of implementation in participating facilities
- Provider and patient perspectives on the models
- Costs of the service delivery models

### Description of Models of Differentiated Care

Models of differentiated care acknowledge the range of needs in the current ART patient population. By categorizing patients by clinical condition, the frequency, cadre, intensity and location of services can be tailored to the needs of patients. This evaluation focused on three models of differentiated care that may improve ART delivery by streamlining services for stable patients.

**Multi-month prescriptions (MMS)**

In the MMS model, stable patients receive refills of antiretroviral (ARV) medications for three or more months instead of one month at a time, so stable patients have four clinic visits per year instead of 12, in order to reduce burden on facilities and patients. MMS has been included in national ART guidelines since 2014 and is offered in all facilities nationwide.

**Fast-track refills (FTRs)**

The FTR model is implemented along with the MMS model such that stable patients visit the clinic four times a year. But instead of having four full clinical appointments, they have only two full clinical appointments and two refill visits in which services are provided by a lower level cadre. FTRs are implemented with support from MSF-France in one district in Malawi.

**Community ART groups (CAGs)**

CAGs are self-formed groups of four to eight stable ART patients from the same community or area. The members of the group rotate the responsibility of going to the clinic to collect the medication refill for all members of the group to reduce the number of facility visits for each patient. Group members meet at the community level before each appointment for adherence support and treatment outcomes monitoring by group members. CAGs were launched in Malawi with support from MSF-Belgium and are now being implemented by the government in two districts.
EVALUATION METHODS

FACILITY SELECTION

Thirty ART facilities (out of a total of 721 facilities nationally) were purposefully selected for inclusion in the study (Figure 1). Facilities were selected with the goal of achieving diversity in the sample and represent a wide array of situations and contexts from which lessons learned can be generated regarding the three models of differentiated care. This sample cannot be considered as nationally representative in a statistical or proportional sense. In assessing the diversity of the sample, the following characteristics were examined: 1) model of differentiated care being implemented, 2) geographic zone, 3) size of ART patient load, 4) facility owner (i.e. MOH or faith-based organization), 5) facility type, and 6) implementing partner activity.

TIMELINE

Data for this evaluation was collected in February to May 2016. Data was collected at one time point in each facility.

DATA COLLECTION

In each facility, a range of types of qualitative and quantitative data were collected to understand the implementation of models of differentiated care. Specific types of data collection included:

⇒ In-depth interviews with ART in-charges (n=32)
One-on-one, semi-structured interviews were held with the staff members responsible for the ART clinic to understand implementation processes, benefits and challenges.

⇒ Focus group discussions with patients (n=216 participants)
30 focus groups were held to explore patient perspectives on benefits, challenges and costs of seeking ART care.

⇒ Structured surveys with health care workers (n=136)
Surveys were orally administered to a range of cadres of health workers to understand their experiences and perspectives.

⇒ Reviews of patient clinical records (n=75,364)
Data was collected from patient records to understand eligibility for and participation in existing models of care. Electronic and paper-based records were used depending on the facility systems.

⇒ Observations of visit time and client flow (n=1,473)
Patients were timed as they passed through clinical appointments and information about services provided and cadre were recorded.

⇒ Questionnaires on facility characteristics (n=30)
Facility characteristics were recorded in relation to patient volume, stockouts, lab testing and more.

Figure 1. Map of study sites
ELIGIBILITY AND PARTICIPATION
Currently in Malawi, the government has issued eligibility guidelines for MMS, specifying that patients should be at least 18 years, have been on ART for at least 6 months, have no side effects or opportunistic infections, be on a first-line regimen, and have good adherence. To be eligible for FTRs and CAGs, patients must meet these criteria and also not be pregnant or lactating. Under the guidelines for MMS (excluding the criteria on adherence because consistent data was not available), 86% of patients were considered stable and eligible for MMS, and 78% of patients were eligible for FTRs and CAGs. Across all facilities, 69% of patients were receiving MMS (refills of three months or longer). In facilities offering the FTR and CAG models, 67% and 6% of patients were accessing the models, respectively.

HEALTH WORKER AND PATIENT PERSPECTIVES
Feedback from patients and providers was generally positive with respect to MMS, FTRs and CAGs. Specifically, participants believed that the models reduced the burden on both health workers and patients and improved patient adherence and retention. In the health worker survey, 56% of health workers believed that MMS improved patient adherence and 22% thought that MMS had no impact.

At the same time, participants identified a number of challenges with the implementation of the models. In relation to all models, some health workers expressed concerns about perceived inability to catch early signs of treatment failure. Low stocks of cotrimoxazole, which is supposed to be provided with ARVs, can create a barrier for MMS and FTRs. In relation to CAGs, there were some reports of conflicts among group members and patient concerns about privacy.

ACCURACY OF PATIENT DIFFERENTIATION
In order to maximize the potential efficiency gains of these models, stable patients should be encouraged to participate. However, 23% of the patient population is eligible for MMS but not participating (Figure 2). At sites with access to CAGs, 87% of the population is stable but not participating, possibly due logistical challenges or disclosure concerns. An even more serious risk is presented by the patients that are not stable enough for the models but are participating according to available records. 6% and 7% of the patient population are participating in MMS and FTRs, respectively, but are not stable. In fact, 42% of unstable patients are receiving MMS. Therefore these patients may not be receiving the level of care they require to achieve good health outcomes.

Results indicate that in many facilities, a similar percentage of stable and non-stable patients are enrolled in the models, indicating that participation is sometimes not fully informed by a patient’s stability status (Figure 3).

COSTS OF DIFFERENTIATED MODELS OF CARE
The per patient per year costs of MMS, FTRs and CAGs are similar and represent an estimated 10% reduction in the annual unit cost of providing care to stable patients, compared to care for patients that receive none of these models. Cost reductions are largely due to decreasing the frequency of facility visits and shifting some elements of service delivery to lower level cadres (i.e., HSAs providing drug refills in the FTR model). However, in the case of FTRs and CAGs, cost reductions over the MMS model are somewhat offset by additional training and supervision costs required for implementation.

FINDINGS
RECOMMENDATIONS

Our findings suggest that there is potential for improvement in the implementation of models of differentiated care in Malawi. MMS is already the standard of care throughout Malawi; however, patients are not being differentiated properly in all cases, such that there are stable and eligible patients not receiving MMS and unstable, ineligible patients that are receiving MMS. Further improving patient differentiation will maximize the efficiency benefits of MMS and provide the highest quality of care possible. The FTR and CAG models are currently implemented on a more limited basis in Malawi. The additional benefits of FTRs and CAGs beyond what can be achieved through MMS do not appear large enough to justify an aggressive scale-up of these models. The following recommendations are suggested to facilitate improvements to the implementation of differentiated models of care in Malawi:

- **FOCUS ON SUSTAINING AND IMPROVING IMPLEMENTATION OF MMS NATIONALLY, BUT ALLOW OTHER MODELS TO BE REFINED IN SELECT SITES.** There is no one-size-fits-all strategy for providing ART. At the national level, the MMS model offers a high quality of care. At the same time, CAGs and FTR may offer additional benefits in some specific contexts; CAGs may increase the accessibility of services for patients in very remote areas, and FTRs may improve efficiency in sites where nursing and medical staff is overburdened but lower level cadres are available. While MMS should be sustained and improved nationally, implementing partners can be encouraged to continue efforts to refine other models in certain sites.

- **CLARIFY THE INCLUSION CRITERIA FOR PATIENTS TO BE CONSIDERED STABLE.** Inclusion criteria for models of differentiated care have evolved over time and it appears that some health workers may not be knowledgeable about the criteria. A first step towards ensuring accurate patient differentiation would be to adopt a clear set of inclusion criteria to determine which patients are stable and to disseminate the criteria broadly through official guidance and practical job aides. Criteria should also include guidelines for transitioning people in and out of the models of differentiated care as their eligibility status changes.

- **ALIGN PATIENT RECORD FORMS TO FACILITATE PATIENT DIFFERENTIATION.** The types of data required in paper-based and electronic patient records should be aligned with the stability criteria so that all necessary information is included. The layout of records can also be improved to prompt health workers to recognize the components of the eligibility criteria.

- **PROVIDE HEALTH WORKER MENTORSHIP TO REINFORCE GUIDELINES.** Support is needed for health workers to properly implement eligibility criteria by including eligible patients and excluding ineligible patients. Mentorship of patient differentiation can be incorporated into existing ART mentorship visits, and may involve a review of differentiation of patients from recent visits and discussions with health workers about questions and challenges related to the models of care.

- **ENSURE THAT PATIENTS RECEIVE ADEQUATE COUNSELLING TO UNDERSTAND CARE.** Counseling for patients should continue to ensure that they understand the care they are receiving, the importance of maintaining adherence despite less frequent visits, and know how and when to access additional services if they experience symptoms of treatment failure.

- **DEVELOP FEEDBACK CHANNELS TO UNDERSTAND AND ADDRESS CHALLENGES IN SPECIFIC MODELS.** Individual models of differentiated care will present unique challenges. The government and its partners should consider organizing a task force or other entity responsible for tracking key challenges and sharing best practices and lessons learned across sites.

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