# Process, impact and economic evaluation of differentiated service delivery models for HIV treatment in Mozambique

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## Abstract

Process, impact and economic evaluation of differentiated service delivery models for HIV treatment in Mozambique

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HIV treatment has been available in Mozambique since 2004. However, coverage and retention on antiretroviral therapy (ART) remains suboptimal. In November 2018, the Ministry of Health launched guidelines to implement eight Differentiated Service Delivery Models (DSDMs) for HIV treatment that aimed to increase health system efficiency and ultimately reduce HIV associated mortality. We conducted a process, impact and economic evaluation of the implementation of these models.

For the process evaluation, we applied the Consolidated Framework for Implementation Research (CFIR) to identify determinants of successful implementation of DSDMs through in-depth interviews of managers and providers. For the impact evaluation, an uncontrolled interrupted time series analysis compared 12-month retention after ART initiation in the pre- and post-implementation of DSDMs periods, and explored the effect of COVID-19 on ART retention. The economic evaluation consisted of a cost-effectiveness analysis of three years of DSDMs implementation (2019-2021), and a budget impact analysis for 2022-2024 period.

The CFIR constructs of Relative Advantage, Complexity, and Patient Needs and Resources, were identified as facilitators of implementation, whereas Available Resources and Access to Knowledge and Information were identified as substantial barriers. COVID-19 (an inductive theme) improved uptake of individual DSDMs that reduced patient visits, but interrupted implementation of group-based models.

Our impact evaluation included 613 facilities and 1,094,430 clients who started ART during the study period, of whom 65% were women and 7%, 20% and 73% were children, adolescents and young adults, and adults, respectively. The overall impact was an increase in 24.5 (95% CI, 21.1 to 28.0) percentage points in 12-month retention. The smallest impact was observed in children (6.1% (95% CI, 1.3% to 10.9%)) and the largest was observed in males (29.7% (95% CI, 25.6% to 33.7%). COVID-19 had a negative effect on 12-month retention (-10·0% (95% CI, -18·2% to -1·8)).

In the economic evaluation, the DSDMs dominated the conventional model of treatment by being less expensive and more effective in retaining clients 12-months after ART initiation. The mean increase in ART retention and decrease in costs were 14.9% and US$ 6,070,391 per

year, respectively, and their implementation was estimated to save approximately US$14 million to the health system from 2022 to 2024.

This dissertation contributes to implementation science literature by comprehensively evaluating the nationawide implementation of eight DSDMs and informing on their health and economic impact, as well as on the determinants of their successful implementation.

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# DEDICATION

To my husband, my hero and inspiration, and to my kids, whom I aspire to be an inspiration.

I love you!

# Chapter 1. INTRODUCTION

## 1.1 BACKGROUND

HIV infection is a public health problem in Mozambique, with a national prevalence of 13.2% in adults in 2015 [1]. HIV treatment has been available in Mozambique since 2004 [2], but despite substantial investment by the country's Ministry of Health (MISAU) and cooperating development partners, the health system is unable to ensure universal coverage of HIV care and treatment for the population [3]. In 2016, the benchmark for success was heightened through the adoption of the then 2020 Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 targets (90% of people living with HIV diagnosed, 90% of those diagnosed on treatment, and 90% of the ones on treatment virologically suppressed), and the World Health Organization (WHO) test and treat strategy that includes initiation of antiretroviral therapy (ART) for all HIV-positive individuals, regardless of clinical stage or CD4 T cells count [4,5]. To achieve these ambitious targets, innovative strategies to improve the health systems' HIV service delivery capacity were required.

In this context, in 2018, MISAU launched guidelines for the nationwide implementation of eight differentiated service delivery models (DSDMs) for HIV treatment, namely fast-track (FT), three-month antiretrovirals (ARVs) dispensing (3MM), community ART group (CAG), adherence club (AC), family-approach (FA), one-stop shop (OSS) for tuberculosis services (OSS-TB), OSS for maternal and child health (MCH) services (OSS-MCH), and OSS for adolescent-friendly health services (OSS-AFHS) [6].

## 1.2 THE DIFFERENTIATED SERVICE DELIVERY MODELS

Differentiated service delivery models (DSDMs) are defined as "a responsive, client-centred approach that simplifies and adapts HIV services across the cascade to better serve individual needs and reduce unnecessary burdens on the health system" [7,8]. There are many DSDMs for HIV prevention, testing, and treatment endorsed by WHO that are being adapted and implemented in many countries throughout Africa. DSDMs for HIV treatment are developed based on four building blocks: when, where, who, and what (figure 1). *When* refers to the frequency of service delivery and can be monthly, bimonthly, quarterly, and twice a year. *Where* refers to the place of service delivery and includes health facilities, communities, and home. *Who* refers to the person providing the service and can be a health worker, community health worker, client, peer, or family member. *What* is regarding the services offered, including ART initiation and refills, clinical monitoring, adherence support, laboratory tests, opportunistic infection treatment, and psychosocial support [9,10].

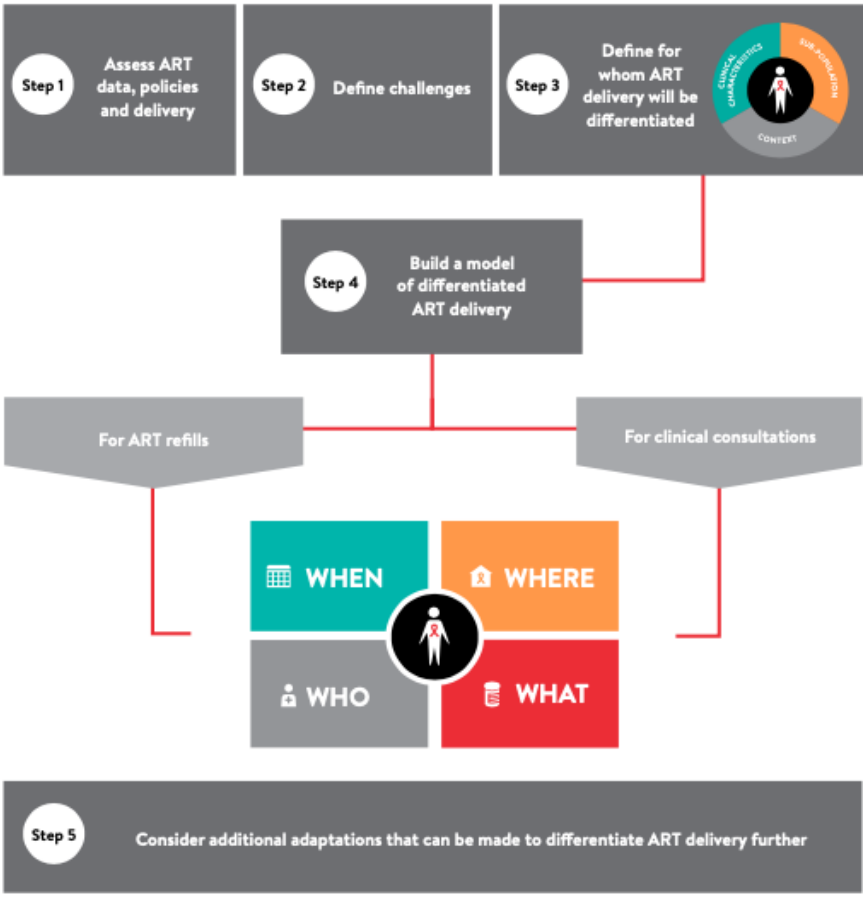


**Figure 1. Building process of DSDMs for HIV treatment**

FT, 3MM, CAG, and AC are applicable only for clients established on ART, defined as those enrolled in ART for at least six months, without opportunistic infections, and virologically suppressed (less than 1000 copies of HIV per milliliter of blood) at the last measurement.

FT and 3MM are individual models based at facilities. FT consists of semi-annual medical and laboratory follow-up visits and is implemented alone or combined with the 3MM model, which consists of quarterly dispensing of ARVs, and is implemented only in health facilities with sufficient ARVs storage capacity (based on MISAU's assessment). 3MM is not designed for stand-alone implementation - all clients enrolled in 3MM must also be enrolled in FT. [6]

CAG is a group model managed by clients whereby a group of three to six clients meet for peer-led ART adherence support in the community, take turns visiting the health facility for

individual observation and medication pick-up for all group members, and report to the health worker any clinical problems with other group members. Scheduling is based on the needs of group members (e.g., to see a clinician or use other services). As such, some members visit the health facility more frequently than others. However, all members should have a follow-up clinical visit and laboratory tests conducted semi-annually, at a minimum.[6]

AC is a group model managed by health-care workers held in the health facility, and consists of quarterly meetings of 15 to 30 group members for clinical observation, medication pick-up, and adherence support through group discussions focusing on treatment challenges and possible solutions. Discussions are led by a counselor, community health worker, or peer educator. A nurse collects samples for laboratory follow-up in a one-stop shop approach at the meeting location. Both CAG and AC models cannot be combined with any other model. [6]

FA and OSS-AFHS can be used by both clients established and not stablished on ART. FA is a group model managed by health-care workers and consists of scheduling appointments for the same day for family members from the same household enrolled in HIV treatment. Appointments are scheduled as a family session, and the frequency of visits depends on the composition and needs of family members. For children younger than two years of age or clients of any age not established on ART, visits are monthly; otherwise, visits are quarterly or semi-annually and medication pick-up monthly or quarterly, depending on whether the model is being combined with FT or 3MM.[6]

The OSS models are individual models based at facilities that integrate ART provision into specific services to avoid redundancy in client visits. OSS-AFHS consists of ART delivery integrated into services for adolescents and youth ages 10 to 21, and can be combined with FF and 3MM, depending on client's eligibility. OSS-TB provides ART to clients co-infected with TB who

are receiving TB services and OSS-MCH provides ART to pregnant and postpartum women and their children who are receiving MCH services. Both OSS-TB and OSS-MCH cannot be combined with other models, and the frequency of visits and ARVs prescriptions and pick-up is monthly.[6]

Laboratory tests for hemoglobin, serum creatinine and alanine aminotransferase are done monthly for OSS-MCH and semi-annually for all the other models. For all service delivery models, CD4 cells counts are scheduled every six months, and viral load is assessed annually after the first and second measurements at six and 12 months after ART initiation of treatment, respectively.[6] Table 1 sumarizes the description of the models being implemented in Mozambique.

## Table 1. DSDMs for HIV treatment being implemented in Mozambique

| DSDM | What (service offered) | Who (service provider) | When (frequency) | Where (place) | Composition | Particularity |
|---|---|---|---|---|---|---|
| Fast-track (FT) - Individual model based at facilities | Clinical observation | Clinician | Twice a year | Observation room | Individual | Can be implemented in isolation or combined with 3MM |
| | ARVs dispensing | Pharmacist/pharmacy technician | Monthly/quarterly | Pharmacy | | ARVs dispensed quarterly when combined with 3MM and monthly in health facilities without 3MM |
| | Sample collection for lab tests | Laboratory technician | Twice a year | Laboratory | | |
| Three-month ART dispensing (3MM) - Individual model based at facilities | ARVs pick-up | Pharmacist/pharmacy technician | Quarterly | Health facility | Individual | Offered only in combination with FT |
| Community ART group (CAG) - Group model managed by clients | Peer support | Client | Monthly | Community | Group (3 to 6 members) | Members take turns visiting the health facility for clinical observation; all members must be observed and have lab tests done at least twice a year<br>ARVs for all group members are dispensed monthly to the group member who visits the health facility<br>This model requires additional staff for activities coordination and implementation |
| | Clinical observation | Clinician | Variable | Observation room | | |
| | ARVs dispensing | Pharmacist/pharmacy technician | Monthly | Pharmacy | | |
| | Sample collection for lab tests | Laboratory technician | Twice a year | Laboratory | | |
| Adherence club (AC) - Group model managed by health-care workers | ART adherence support | Counsellor/peer educator/ community health worker | Quarterly | All activities take place in a selected space in the health facility | Group (15 to 30 members) | ARVs dispensing depends on the ARVs stock in the health facility<br>This model requires additional staff for activities coordination and implementation |
| | Clinical observation | Nurse | Twice a year | | | |
| | ARVs dispensing | Nurse | Monthly/quarterly | | | |
| | Sample collection for lab tests | Nurse | Twice a year | | | |
| Family-approach (FA) - Group model managed by health-care workers | Clinical observation | Clinician | Variable | Observation room | Group (varies according to the number of family members) | All the appointments of the family members are schedule for the same day<br>The frequency of visits depends on the existence and age of children and the clinical condition of all members of the family, and can be monthly, quarterly, or twice a year |
| | ARVs dispensing | Pharmacist/pharmacy technician | Monthly | Pharmacy | | |
| | Sample collection for lab tests | Laboratory technician | Twice a year | Laboratory | | |
| One-stop shop for tuberculosis services (OSS-TB) – Individual model based at facilities | Clinical observation | TB sector nurse | Monthly | All activities take place in the TB sector in the health facility | Individual | All HIV services are offered by a nurse in the TB treatment sector of the health facility |
| | ARVs dispensing | TB sector nurse | Monthly | | | |
| | Sample collection for lab tests | TB sector nurse | Twice a year | | | |
| One-stop shop for maternal and child health (OSS-MCH) services - Individual model based at facilities | Clinical observation | MCH nurse | Monthly | All activities take place in the MCH sector in the health facility | Individual | All HIV services are offered by a nurse in the MCH sector of the health facility |
| | ARVs dispensing | MCH nurse | Monthly | | | |
| | Sample collection for lab tests | MCH nurse | Monthly | | | |
| One-stop shop for adolescent-friendly health services (OSS-AFHS) - Individual model based at facilities | ART adherence support | Counsellor/peer educator/nurse | Quarterly | All activities take place in the AFHS sector in the health facility | Individual | All HIV services are offered in the AFHS sector of the health facility<br>Clinical observation depends on the client need<br>ARVs dispensing depends on the ARVs stock in the health facility |
| | Clinical observation | Nurse | Monthly/twice a year | | | |
| | ARVs dispensing | Nurse | Monthly/quarterly | | | |
| | Sample collection for lab tests | Nurse | Twice a year | | | |

# Chapter 2. PROCESS EVALUATION

## 2.1 RATIONALE

Similar to Mozambique, other countries in sub-Saharan Africa have adopted DSDMs to optimize the health system capacity to offer client-centred services and improve retention in care, which ultimately reduces HIV-related deaths [11,12]. Countries adopt the models that best suit their needs and adapt them to the specific context. Several studies have described the process of DSDMs' implementation in sub-Saharan Africa, including acceptability, feasibility and satisfaction, and measured the health and economic impact of different models [11–14].

Although the body of literature regarding DSDMs in sub-Saharan Africa is growing, general knowledge of the determinants of successful implementation is limited because relatively few studies have explored determinants of successful implementation, and the diversity of the models and various country contexts. Studies that explored successful implementation of DSDMs in specific countries in sub-Saharan Africa have identified drivers that included the providers' belief that DSDMs were beneficial for both clients and the health system, and the perceived relative advantage of the models when compared to the standard of care, and barriers that included limited availability and access to resources, limited access to training, stigma, and challenges with logistics [15–18]. However, the determinants of successful implementation of the adopted models in the specific context of Mozambique was yet to be studied.

### AIMS

The goal of our study was to describe managers' and providers' perspectives on the determinates of successful implementation of the DSDMs adopted in Mozambique, for all models as a package of HIV service delivery and for each model specifically.

## 2.2 METHODS

### 2.2.1 *Study setting and period*

The study was conducted from July to September 2021. Participants were from MISAU and implementing partners at all levels of Mozambique's health system – national or central, provincial, district, and health facility. National-level data was collected in Maputo city, the country's capital. Sofala province, a setting with high HIV prevalence and HIV treatment demand, including a nationally recognized HIV transmission hotspot – the Beira corridor [19], was purposively selected for data collection at subnational levels. In Sofala province, two districts (one rural and one urban) and four health facilities (one small and one large in each district) were selected. Health facilities are defined by the National STI-HIV/AIDS Program as small when they have less than 1000 clients enrolled in HIV treatment services, and as large otherwise.

### 2.2.2 *Sample size and data collection*

We applied purposive sampling to include at least 9 to 17 key informants so to satisfy the estimated minimum sample size to achieve code saturation of 90% [20,21]. The eligibility criteria were involvement on DSDMs' management or implementation at each level of the health system, for both MISAU and implementing partners. Semi-structured, in-depth interviews were conducted

with selected participants, including HIV program managers from the national, provincial, district, and health facility levels, and providers at the health facility level.

The interviews were conducted in Portuguese, using a semi-structured interview guide that was developed based on purposively selected constructs from the Consolidated Framework for Implementation Research (CFIR) by Damschroder et al in 2009 [22,23]. Questions included perception of barriers and facilitators in general and by selected CFIR constructs, for the intervention overall and for each model individually. Interviews were audio recorded and transcribed verbatim.

CFIR is a deterministic framework developed from previous frameworks and relevant theories in various disciplines [24], and is organized in 5 domains and 39 constructs (including subconstructs) [22]. We chose to use the CFIR given its pragmatic structure to study real world implementation and its applicability to guide data collection and analysis, as well as to contextualize the findings [25].

Constructs for this study were selected based on a literature review of known barriers and facilitators for DSDMs implementation in sub-Saharan Africa. Fifteen constructs from all five framework domains were included: (1) Relative Advantage, (2) Adaptability, (3) Complexity, (4) Design Quality and Packaging, (5) Cost, (6) Intervention Source, (7) Client Needs and Resources, (8) Implementation Climate, (9) Readiness for Implementation, (10) Knowledge and Beliefs About the Intervention, (11) Other Personal Attributes, (12) Planning, (13) Engaging, (14) Executing, and (15) Reflecting and Evaluating [11,15–18].

### 2.2.3 *Data analysis*

Analysis approach

We conducted a thematic analysis using an iterative deductive–inductive approach. For the deductive analysis, we used an initial list of codes created based on the 15 pre-selected CFIR constructs. Emerging themes (both non-CFIR and CFIR constructs) were added to the initial list and used to code subsequent interviews.

Coding description

Coding was conducted on the original interview transcripts in Portuguese, using ATLAS.ti software, version 9. Two investigators coded each interview transcript independently using the initial codebook and added new codes to it as they emerged from the data. A third investigator reviewed the work of the initial coders and identified new codes and disagreements. To achieve consensus on coding, the three investigators reviewed the disagreements and when consensus was not met, two other investigators acted as tiebreakers.

CFIR construct codes were rated as a function of valence and strength. Valence is the directional (positive or negative) influence of the construct on DSDM implementation, and is marked by '–' for negative influence (i.e. a barrier), '+' for positive influence (i.e. a facilitator), 'X' for mixed negative and positive influence, and '0' for a neutral code. Strength was determined by factors such as level of agreement across participants, strength of language, and use of concrete examples. A number "1" indicated weak influence and "2" strong influence in the intervention. The symbol "*" denoted the level of agreement among participants, meaning that comments were mixed – both positive and negative – and the attributed rating is an aggregated result [26]. Table 2 summarizes the code rating system.

**Table 2. Coding rating system**

| Rating | Description |
|---|---|
| -2 | Strong barrier |
| -1 | Weak barrier |
| -1* | Weak barrier as an aggregated result of positive and negative effect |
| 0 | Null meaning |
| X | Mixed (positive and negative) effect |
| +1* | Weak facilitator as an aggregated result of positive and negative effect |
| +1 | Weak facilitator |
| +2 | Strong facilitator |

### 2.2.4 *Ethics*

The University of Washington institutional Review Board and the Mozambique National Ethics Committee approved this study. Written informed consent for interviewing and recording was obtained from interviewees before all interviews. The names of participants and health facilities are concealed for ethical reasons.

## 2.3 RESULTS

### 2.3.1 *Study participants*

We included a total of 20 participants from which 11 were program managers at the national, provincial and district levels and 9 were frontline providers. Four providers (one in each health facility) were also managers at the health facility level. Table 3 shows participants' characteristics.

**Table 3. Overview of study participants**

| Level of the Health System | Number of participants | Sex | | Institution | |
|---|---|---|---|---|---|
| | | Female | Male | MISAU | Implementing partners |
| National | 5 | 2 | 3 | 2 | 3 |
| Provincial | 2 | 0 | 2 | 1 | 1 |
| District | 4 | 2 | 2 | 4 | 0 |
| Health facility | 9 | 5 | 4 | 8 | 1 |

### 2.3.2 *Non-CFIR barriers and facilitators*

The identified non-CFIR-related determinants were COVID-19 and Sustainability. COVID-19 was the most cited non-CFIR determinant, mentioned across all levels of the health system and by all participants. However, its influence differed depending on the model. Notably, COVID-19 served as a facilitator for loosening restrictions on client eligibility for DSD models that reduced client visits (FT, 3M), but temporarily interrupted implementation of group models (AC, CAG). Sustainability was cited as a barrier for AC and CAG models by national-level managers and frontline providers. Because implementation of these models requires additional human resources, typically hired by projects from implementing partners, there is no continuity when the projects end. Illustrative quotes related to these determinants are presented in Table 4.

**Table 4. Illustrative quotes of non-CFIR barriers and facilitators**

| **Determinant** | **Illustrative quotes** |
|---|---|
| COVID-19 | *"But if we are to analyse model-by-model, we will see that it [COVID-19] was harmful for CASGs and Adherence clubs, and much more beneficial for the three-monthly dispensing. All those patients who were on CASGs and Adherence clubs were moved to three-monthly dispensing."* (Provincial level) |
| Sustainability | *"…about the adherence clubs, sometimes a project comes and make them work. But when that project is over, practically those groups will fall apart*." (Health facility level) |

### 2.3.3 *CFIR barriers and facilitators*

Across all levels of analysis and across all DSDMs, Relative Advantage, Complexity, Patient Needs and Resources, and Reflecting and Evaluating, were the most important CFIR constructs identified. These constructs are described in the sections that follow, along with other constructs, by health system level and DSDM.

Barriers and facilitators by health system level

*National level*

National-level managers reported that the currently implemented DSDMs were advantageous compared with the standard of care because they were tailored to clients' needs, were easy to implement, and led to better service and client outcomes. The managers also perceived that the planning process before implementation and continuous monitoring were important facilitators for successful implementation.

Participants at the national level also reported that all models were adaptable to the local context, given that the country selected and designed the models considering the country's needs and resources. The changes made in the DSDMs to respond to the COVID-19 pandemic was also seen as models' adaptability. Although participants considered adaptation a facilitating factor at the national level, they did not expect lower levels of the health system to make adaptations to the models.

MISAU's and implementing partners' managers had different perceptions about the role of external policies and incentives and external change agents. MISAU managers identified these constructs as facilitators for the models that were supported and funded by external organizations, but as barriers for the models without this support, as lack of funding and incentives discourages

their implementation, even if providers believe that these models are beneficial for clients. They perceived that implementing partners favour the implementation of some models over others, thus limiting the range of models being implemented in the health facilities they supported. Implementing partners' managers perceived those constructs as facilitators for DSDMs in general, given that there is a global support for the implementation of DSDMs. However, they mentioned that some models are cheaper than others.

*Provincial and district levels*

Participants at the provincial and district levels identified the same determinants as those at the national level, except for adaptability as a facilitator and external change agents as barrier. They considered adaptability to be neutral because they were not supposed to adapt the models but were expected to implement them as recommended by the national level. At these levels, they emphasized planning, readiness for implementation, and provider training as important facilitators.

*Health facility level*

At the health facility level, the main barrier identified was lack of training and resources for both small and large, and rural and urban health facilities. With a few exceptions, frontline providers affirmed that they were not trained to implement the DSDMs. They explained that there was lack of resources for HIV treatment services in general, including for all DSD models, and insufficient human resources for models that required dedicated staff (AC, CAG). In the small health facilities, in addition to a lack of human resources and materials, the lack of adequate space was the main challenge to implementing AC, OSS-AFHS, and OSS-TB. For the 3M model, stock-outs of ARVs were identified as a weak barrier, given that stock-outs were less frequent than they had been at the beginning of the implementation of DSDMs. However, participants described a recent stock-out of ARVs packages for monthly dispensing, which forced the pharmacy to

dispense ARVs for 3 months even for clients not enrolled in the 3M model, because the three-month packages were the only ARVs available.

Providers perceived that DSDMs were beneficial because they reduced their workload. They also believed that the models addressed client needs, based on their assumption that the treatment program used in DSDMs was less demanding and hence reduced the time and resources clients invest in treatment, ultimately allowing clients to engage with other activities. Providers believed that a vital need for clients was related to addressing HIV stigma, which affected clients' adherence to the treatment in general, including the DSDMs. Therefore, they considered that another major benefit of the FT, 3M, and FA models was the reduction in the number of visits to health facilities because it would reduce stigma associated with HIV treatment, as others would not think that the clients were in HIV treatment if they visited the health facility only twice a year. However, they believed that the downside was that clients who had not yet disclosed their HIV status, due to fear of being stigmatized, were afraid to take home the ARVs for 3 months, because it would be harder to hide from household members. Providers in urban settings believed that clients in urban areas were afraid to share their HIV status with others due to fear of stigma, and thus avoided group models, making these models inappropriate for urban context.

Finally, participants from all health facilities perceived monitoring and evaluation as an important facilitator for successful implementation of the models, although they thought that using a paper-based system was inefficient. They also perceived that all models were relatively easy to implement when compared to the standard of care, especially FT and 3M. CAG and AC were considered more complex among the DSDMs; however, they did not consider their relative complexity as a barrier. Illustrative quotes of determinants by CFIR constructs are presented in Table 5.

**Table 5. Illustrative quotes of barriers and facilitators by CFIR constructs**

| Determinants by CFIR constructs | Illustrative quotes |
|---|---|
| **Relative Advantage** | |
| Facilitator | *"Compared to the model used previously there are many advantages. For example, there is no overload for the staff working at the district service level, this is the first point. Second, there isn't much crowding at the program level."* (District level) |
| **Adaptability** | |
| Facilitator | *"The models are adaptable to the local context, so much that the strongest proof is the simplification that we have made in the criteria for the three-monthly dispensing of ARVs] [in the COVID-19 context]"* (National level) |
| **Patient Needs and Resources** | |
| Facilitator | *"I believe that the range of options has become increasingly variable, and they are often adjusted to the needs of or the context in which the client is, rural context or other."* (National level) |
| **Structural Characteristics** | |
| Barrier | *"The health system has different levels, and we have a very high turnover of personnel. So, what happens is that many times, we can train a certain group of providers, but then, six months or a year later, the [trained] provider may no longer be in the same health facility."* (National level P3) |
| **Available Resources** | |
| Barrier | *"We don't have a physical space for AFHS [Adolescent-friendly Health Services], and we don't have clinical staff for the same. Regarding 1-stop shop for tuberculosis, I can say the same as for AFHS; we do not have a physical space specifically for tuberculosis services."* (Health facility level P17) |
| **Access to Knowledge and Information** | |
| Facilitator | *"We carried out training at the level of health centres, so that each clinician, each MCH [maternal and child health] nurse, who follows up clients, can have more or less what is... the use or implementation of the same models at the level of health facilities."* (District level P9) |
| Barrier | *"So to say that the team that is here at the health facility was not trained on differentiated service delivery models."* (Health facility level) |
| **Knowledge and Beliefs About the Intervention** | |
| Facilitator | *"Honestly, I think it's even better, because it made our activities a little more dynamic, right? Especially the fast-track for example, it helped a lot."* (Health facility level P13) |
| **Planning** | |
| Facilitator | *"The guidelines were made, the circulars sent to the provinces, the training on DSD were also done in advance before its implementation. So, I think that [planning] was a facilitator."* (National level P5) |

| | |
|---|---|
| **External Change Agents** | |
| Barrier and Facilitator | *"In the same way that the implementing partners' interest is a facilitator, it is also a barrier. If the partner is interested in GAG, he will turn his back on the other models, saying, 'Okay, fine, do it, but that's not what I'm interested in.'"* (National level P2) |
| **Reflecting and Evaluating** | |
| Facilitator | *"So, we are constantly monitoring this, we and the districts that are implementing it, to see what difficulties they are encountering and together we can work out some strategies to overcome them."* (National level P8) |

Barriers and facilitators by CFIR construct and DSD model

When asked about the DSDMs in general, managers at higher levels of the health system tended to mention a wider list of DSDMs before being asked specifically about each of the eight models that we intended to study. At the health facility level, providers primarily mentioned the 3M model, unless another specific model was explored. We were informed that more than 80% of clients using DSDMs were enrolled in FT and 3M (3M is only implemented in combination with FT). Since the data collection at the health facilities was done in July 2021, we explored if this scenario resulted from the changes made in the context of COVID-19, given that in response to COVID-19, the eligibility criteria for 3M and FT were loosened and the AC and CAG models were temporary interrupted. According to the participants, although COVID-19 favoured FT and 3M, these models were the most implemented even before the pandemic, not only because they were considered the easiest to implement among all the models, but also because they were believed to significantly reduce the workload and were largely supported by implementing partners. In Table 6 we present a summary of the determinants of DSDMs implementation as aggregated ratings of CFIR constructs by model.

**Table 6. Aggregated ratings of CFIR constructs by DSDM**

| CFIR constructs | Differentiated service delivery models | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | FF | 3MM | AC | CAG | FA | 1-stop MCH | 1-stop AYFS | 1-stop TB |
| **Intervention Characteristic** | | | | | | | | |
| Relative Advantage | +2 | +2 | +2 | +2 | +2 | +2 | +2 | +2 |
| Adaptability | +1* | +1* | +1* | +1* | +1* | +1* | +1* | +1* |
| Complexity | +2 | 2+ | +1* | +1* | +1* | +2 | +2 | +2 |
| Cost | +2 | +2 | -1 | -1 | +2 | +2 | +2 | +2 |
| **Outer Setting** | | | | | | | | |
| Patient Needs and Resources | +2 | +2 | +1* | X | +2 | +2 | +2 | +2 |
| External Police and Incentives | +2 | +2 | -1* | -1* | 0 | 0 | 0 | 0 |
| **Inner Setting** | | | | | | | | |
| Structural Characteristics | 0 | 0 | -1 | -1 | -1 | -1 | -1 | -1 |
| Networks and Communications | +1 | +1 | +1 | +1 | +1 | +1 | +1 | +1 |
| Culture | +1 | +1 | +1 | +1 | +1 | +1 | +1 | +1 |
| Implementation Climate | | | | | | | | |
| Tension for Change | +1 | +1 | +1 | +1 | +1 | +1 | +1 | +1 |
| Compatibility | 0 | 0 | 0 | -1* | 0 | 0 | 0 | 0 |
| Relative Priority | +2 | +2 | -1 | -1 | +1 | +1 | +1 | +1 |
| Goals and Feedback | +1 | +1 | +1 | +1 | +1 | +1 | +1 | +1 |
| Readiness for Implementation | | | | | | | | |
| Available Resources | +2 | +1* | -2 | -1* | 0 | -1 | -2 | -1 |
| Access to Knowledge and Information | X | X | X | X | X | X | X | X |
| **Characteristics of Individuals** | | | | | | | | |
| Knowledge and Beliefs About the Intervention | +1* | +1* | +2 | -1* | +2 | +2 | +2 | +2 |
| Other Personal Attributes | X | X | X | X | X | X | X | X |
| **Process** | | | | | | | | |
| Planning | +1 | +1 | +1 | +1 | +1 | +1 | +1 | +1 |
| Engaging | | | | | | | | |
| External Change Agents | +2 | +2 | -1* | -1* | 0 | 0 | 0 | 0 |
| Executing | +1* | +1* | -2 | -2 | +1* | +2 | +1* | +1* |
| Reflecting and Evaluating | +1* | +1* | +1* | +1* | +1* | +1* | +1* | +1* |

**Legend:** -2, strong barrier; -1, weak barrier; -1*, weak barrier as an aggregated result of positive and negative effect; 0, null meaning; X, mixed (positive and negative) effect; +1*, weak facilitator as an aggregated result of positive and negative effect; +1, weak facilitator; +2, strong facilitator.

**Abbreviations:** 3MM, three-month ARV dispensing; AC, adherence club; CAG, community adherence group, FA, Family-approach; FT, Fast-track; OSS-AFHS, One-stop shop model for adolescent-friendly health services; OSS-MCH, One-stop shop model for maternal and child health services; OSS-TB, One-stop shop model for tuberculosis treatment services.

## 2.4 DISCUSSION

Our study is the first of its kind to explore barriers and facilitators for the implementation of DSD models for HIV treatment in Mozambique, as perceived by managers and providers. The use of a standardized implementation science framework (i.e. CFIR) and of an iterative deductive-inductive approach, as well as the inclusion of managers and providers from all levels of the health system at MISAU and implementing partner organizations, enabled us to gather strong data on the determinants of successful implementation of DSD models in Mozambique.

The two non-CFIR determinants identified in the study were COVID-19 and Sustainability. The general impact of COVID-19 was perceived differently among participants. Some understood its influence as neutral given that clients enrolled in models that experienced interruptions were transferred to FT and 3MM models. However, other providers reported that the general impact of COVID-19 was positive because it resulted in the eligibility criteria for enrolment in FT and 3MM to be loosened, which allowed more clients to be enrolled in those models. Sustainability was identified as a barrier for AC and CAG as they require additional staff for group management, that are commonly hired for this purpose by implementing partners through projects with limited lifetime, given that MISAU's providers are normally overworked due to lack of human resources [27]. When the projects are over, the groups are discontinued for lack of a group manager. According to the CFIR proposed by Damschroder et al in 2009 [22], sustainability was identified as an important non-CFIR barrier. However, in 2020, Means et al proposed the addition of a new domain to CFIR, the Characteristic of Systems, under which Sustainability could be coded as a Resource Continuity construct [25].

The most influential determinants of successful implementation from a CFIR-guided lens were the constructs of Relative Advantage, Complexity, Patient Needs and Resources, and

Reflecting and Evaluating, which were identified as facilitating factors across all models by participants at all levels of the health system, and Available Resources and Access to Knowledge and Information, identified as barriers at the health facility level. Our findings were consistent with those of other studies on barriers and facilitators of DSDMs implementation in similar settings [15–18].

In a study conducted from 2016 to 2017 in South Africa, including healthcare providers, Department of Health and implementing partners, and three groups of HIV clients (new, established, and those not established on treatment or not adhering to care), Pascoe et al found that providers reported feeling insufficiently trained and described access to adequate resources for implementation as critical [16]. In our study, frontline providers at health facilities identified lack of training as an important barrier to successful implementation, a perspective that was not shared by managers at district, province, and national levels. These differing perspectives regarding Access to Knowledge and Information (including training) may be a reflection of the high turnover of frontline providers that is a reality of the Mozambique health system [27]. Managers at levels higher than health facilities believed that providers offering the DSDMs received training, whereas frontline providers reported that previously trained colleagues had been transferred to other health facilities, were new, or had been recently transferred from other sectors or health facilities and had not yet received training.

A 2017 study of clients from a tertiary health facility in Ghana identified stigma as an important barrier for community-based service delivery [17]. Stigma was also described by providers in our study as the main reason for non-adherence to the CAG model in urban areas. Providers believed that clients in urban contexts preferred individual-based models that did not require them to disclose their HIV status to others. However, the large amount of ARVs dispensed

in the 3M model was also described as potentially challenging for clients who had not disclosed their HIV status to household members.

Zakumumpa et al explored the perspectives of clients and HIV service managers on barriers to the implementation of differentiated ART service delivery in Uganda in 2019, employing a multi-level analytical framework that analysed individual-level factors, health system factors, community factors, and context [15]. Among other system-specific barriers not explored in our study, the study revealed several notable findings. At the individual level, stigma and fear of detachment from health facilities by clients established on ART enrolled in community-based models were identified as important barriers. At the health system level, constraints included insufficient training of health workers in DSDMs and supply chain challenges related to dispensing multi-month ARVs. ARV stock-outs were also identified as an important barrier in a study conducted in Uganda in 2021, by Kintu et al [18]. At the community level, limitations included stigma and insufficient funding for full operationalization of community drug pick-up points. In addition, the frequent physical address changes among urban clients were reported as a challenge for the implementation of CAGs. The determinants described in our study findings are supported by findings from Zakumumpa et al. Stigma and a lack of resources were also identified by Pascoe et al and Adjeteye et al. Interestingly, in our study and the study by Zakumumpa et al, CAGs (referred by them as client groups of rotating ARVs refill pick-ups) were described as unsuitable for urban environments; however, the reasons given by participants were different. In our study, ARV supply challenges for three-month dispensing were perceived as a weak barrier to implementation, because the problem was infrequent at the time of the study. However, we found that stock-outs of ARVs packages for monthly dispensing forced the dispensing of three-months ARVs for clients not enrolled in the 3MM model.

In our study, frontline providers believed that the DSDMs were beneficial for clients, and health facilities offered the models despite challenges related to a lack of resources and training. Providers also reported that the implementation of DSDMs was not optional, given that the decision was made at the national level and passed down through the provincial and district levels to the health facility level. This top-down decision-making process is typical of the vertical hierarchical system that characterizes Mozambique's health system [28]. Although this approach is often considered negative for the implementation of new interventions [29], providers in our study did not consider it a barrier or facilitator, but simply as the *modus operandi* of the health system in Mozambique.

We acknowledge the important role of data collectors and analysts on the findings in qualitative research. Participants were interviewed by a study team totally independent and with no influence over the institutions from which the participants were selected and they were informed that their perspectives wouldn't be judged but used to contribute to the knowledge on determinants of DSDMs in the country. The interpretation of the findings presented are shaped by the views of the main data analysts - Mozambican medical doctors and implementation scientists, familiar with the Mozambican health system and the process of health programs implementation.

Our study has several limitations. First, although we used the levels of the health system as the unit of analysis, the study was not designed to generate data on implementation determinants at the micro, meso, and macro level and should not be interpreted as such. Second, though the used approach allowed us to triangulate the perspectives of participants at different levels of the health system, we did not consider participants' maximum variation regarding some relevant characteristics such as cadre and years of work. Third, the aggregated rating of barriers and facilitators used is subject to reductionism, even though we used the rating rules recommended by

CFIR developers [26]. Finally, while the perspectives collected are of great importance, we recognize the added value of exploring clients' perspectives on these determinates, including exploring perspectives by sociodemographic characteristics, which was hindered by the COVID-19 safety measures at the time of data collection. Future studies should explore clients' perspectives on the determinants of successful implementation for a more comprehensive understanding of this subject.

In conclusion, our study identified determinants for successful implementation of DSDMs, based on managers' and providers' perspectives at all levels of the health system in Mozambique. Although the findings cannot be generalized for all providers in Mozambique, they provide an insightful description of barriers and facilitators to be addressed and leveraged for successful implementation of DSDMs in Mozambique. In general, the implemented models were considered advantageous for both the health system and clients when compared with the standard of care. However, successful implementation requires broadly available resources and ongoing training for frontline providers. In addition, COVID-19 served as a facilitator by loosening inclusion criteria and expediting access to some DSD models, which could be leveraged to optimize the design and implementation of DSDMs in Mozambique and other countries.

# Chapter 3. IMPACT EVALUATION

## 3.1 RATIONALE

In November 2018, the Mozambique Ministry of Health (MISAU) decided to implement nationwide eight differentiated service delivery models (DSDMs) for HIV treatment that had been piloted individually and used at small scale around the country.[2,6] The eight adopted models were tailored to the country's context and included fast-track (FT), three-month antiretrovirals (ARVs) dispensing (3MM), community ART group (CAG), adherence club (AC), family-approach (FA), one-stop shop (OSS) for tuberculosis services (OSS-TB), OSS for maternal and child health (MCH) services (OSS-MCH), and OSS for adolescent-friendly health services (OSS-AFHS).[6]

These models are expected to maximize MISAU's capacity to deliver HIV services using the available infrastructure and human resources, without compromising the quality of care and ultimately lead to a reduction on HIV associated mortality. The proposed theory of change of the DSDMs starts by reducing unnecessary visits for clients enrolled on DSDMs and redirecting the resources to those who need them the most (clients not enrolled on the DSDMs). This will lead to a reduction of providers' workload, resulting in more time to dedicate to clients not enrolled on DSDMs. This is expected to increase clients' satisfaction and retention on ART, that will lead to viral suppression and finally decreased associated mortality (figure 2).[6]

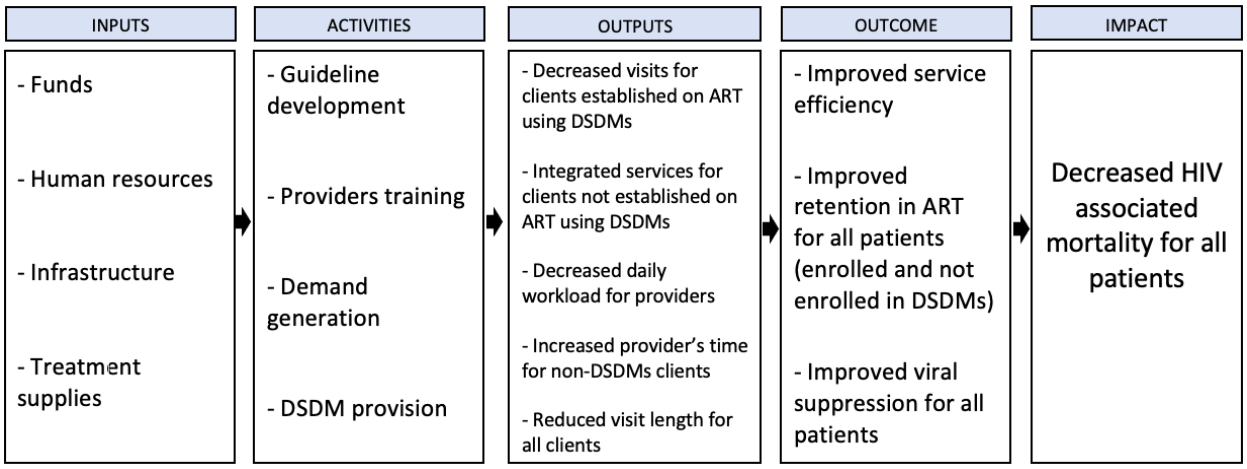


**Figure 2. DSDMs logic model**

In the last years, there has been an extensive use of DSDMs in sub-Saharan Africa, aiming to offer client-centred services, improve retention on ART, and ultimately reduce HIV-related deaths. The popularity of DSDMs increased during the COVID-19 pandemic, as innovative approaches to limit health facility visits and to delivery ARVs in the community for those unable to pick them up at the health facilities were urgently needed.[30–32]

However, it is difficult to draw an overall picture of the impact of the DSDMs because of the inconsistency of the study designs, outcomes and comparison groups.[11] In general, implemented studies focused on a specific model, used retention in care and viral suppression as the outcome of interest, and reported effectiveness to be equivalent or better than the conventional model of care.[12,33,34] To our knowledge, the impact of national level implementation of DSDMs for all clients enrolled in care, regardless of the enrolment in DSDMs, was yet to be studied.

## 3.2 AIMS

Our primary aim was to measure the impact of the DSDMs on retention in treatment 12 months after ART initiation, and our secondary aim was to explore the effect of COVID-19 on the referred retention.

## 3.3 METHODS

### 3.3.1 *Study setting*

In Mozambique, HIV treatment has been offered free of charge in public health facilities since 2004.[35] As of December 2018, 1,212,562 clients were enrolled in ART, representing 55% of people living with HIV (PLHIV) in the country.[36] The treatment guidelines evolved from offering ART only to clients on WHO disease stage 3 or 4, or with CD4 cells count bellow 200 units per milliliter of blood, in 2004, to the Test and Treat strategy, in 2016.[37]

In November 2018, after pilot testing the eight DSDMs at different scales and tailoring them to the country's context, MISAU launched guidelines for the nationwide implementation of DSDMs. Since then, efforts have been made to offer as many models in as many health facilities as possible across the country.[6]

### 3.3.2 *The status quo and the intervention*

The status quo or conventional service delivery model consists of monthly individual scheduled appointments for clinical observation and medication prescription and dispensation. The intervention is a combination of the conventional and the eight DSDMs of HIV treatment described in chapter 1.

### 3.3.3 *Study design, outcome, and period*

An uncontrolled interrupted time series design was applied to compare the outcome (the percentage of clients retained in ART at 12 months after initiation) before and after nationwide implementation of the eight DSDMs. A 12-month rollout period between the pre- and post-intervention periods was included to account for the lag for the outcome to be observed. For both primary and secondary aims, the pre-intervention period was from January 1, 2017, to November 30, 2018, and the rollout period was from December 1, 2018, to November 30, 2019. For the primary analysis, the post-intervention period was from December 1, 2019, to June 30, 2021. For the secondary analysis, the post-intervention period included the period without COVID-19 from December 1, 2019, to March 31, 2020, and the period with COVID-19 from April 1, 2020 (the beginning of the implementation of the COVID-19 response measures in the country), to June 30, 2021. These periods refer to when the outcome was assessed, and the corresponding cohort starting dates are a year earlier.

### 3.3.4 *Study participants*

We included data from all clients enrolled on HIV treatment from January 2016 to June 2020 (i.e. follow-up through June 2021) in health facilities using the electronic patient tracking system (EPTS), which feeds the Mozambique antiretroviral therapy (MozART) database.[38]

### 3.3.5 *Data sources and data management*

Client data (sex, age and dates of ART initiation, follow-up visits, and medication pick-up) were extracted from MozART, which contains individual monthly data of clients enrolled in HIV treatment in health facilities using the EPTS. Data in MozART is from the cohorts of 2012 onward;

however, we included only the data starting from 2016 that corresponds to the "test and treat" strategy era, for the pre- and post-intervention periods to be comparable in all aspects other than the implementation of DSDMs. In December 2018 (when DSDM implementation began), MozART contained data for 742 (51%) of the 1,455 health facilities providing ART in Mozambique, of which 613 (83%) offered ART in the beginning of the study period (January 2016) and were included in the analysis.

We constructed patient cohorts based on ART initiation month. In accordance with national guidelines, we defined clients as retained if after 12 months of ART initiation they were not lost to follow-up, deceased, transferred out or stopped treatment, and had not missed a clinical or ARVs refill visit in the 60 days before the end of the 12-month period.[39]

### 3.3.6 *Statistical analysis*

We used descriptive statistics to summarize clients' demographics during the study period and conducted segmented regression analyses by fitting a generalized estimating equation (GEE) model with an independence working correlation structure and cluster-robust standard errors to account for clustering at the health facility level and for possible informative cluster size.[40,41] For the primary analysis, we assumed a change in the slope from the pre-intervention to rollout and from the rollout to the post-intervention periods, and no immediate level change between pre-intervention and rollout periods, but an immediate change between the rollout and post-intervention periods. In addition, for the secondary analysis, we assumed a slope change and an immediate level change between the post-intervention period without COVID-19 and the post-intervention period with COVID-19. Models for the primary (1) and secondary (2) analyses were fitted as follows:

$$\mu_{(y_{ij})} = \beta_0 + \beta_1 * (\text{time}) + \beta_2 * (\text{time since rollout}) + \beta_3 * (\text{DSDM}) + \beta_4 * (\text{time since DSDM}) \quad (1)$$

$$\mu_{(y_{ij})} = \beta_0 + \beta_1 * (\text{time}) + \beta_2 * (\text{time since rollout}) + \beta_3 * (\text{DSDM}) + \beta_4 * (\text{time since DSDM}) + \beta_5 * (\text{COVID-19}) + \beta_6 * (\text{time since COVID-19}) \quad (2)$$

where $\mu_{(y_{ij})}$ is the mean 12-month retention on ART; *time* is a continuous variable for time of retention measurement in months starting from January 2017; *time since rollout* is a continuous variable for time in months with values starting from December 2018 (the beginning of rollout period) and a value of zero before that; *DSDM* is a dummy variable with a value of one during the implementation of DSDMs and zero before that; *time since DSDM* is a continuous variable for time in months with values starting from December 2019 (beginning of the post-intervention period) and a value of zero before that; *COVID-19* is a dummy variable with a value of one during the period of the COVID-19 response measures and zero before that, *time since COVID-19* is a continuous variable for time in months with values starting from April 2021 (beginning of the COVID-19 response measures in Mozambique) and a value of zero before that; $\beta_0$ estimates the baseline 12-month retention in January 2017; $\beta_1$ estimates the change in retention that occurs for each month before DSDMs; $\beta_2$ estimates the monthly change in retention during rollout; $\beta_3$ estimates the immediate change in retention from rollout to post-DSDMs periods, $\beta_4$ estimates the monthly change in retention during the post-intervention period; $\beta_5$ estimates the immediate change in retention from pre- to post-COVID-19 periods; and $\beta_6$ estimates the monthly change in retention during the post-COVID-19 period. The post-intervention trend is estimated by adding the coefficients associated with time before intervention, time during rollout, and time after intervention. The post-COVID-19 trend is estimated by adding the coefficients associated with

time before intervention, time during rollout, time post-intervention without COVID-19, and time post-intervention with COVID-19.

We defined a counterfactual trend as the expected trend if the DSDMs had not been implemented (i.e. $\mu_{(y_{ij})} = \beta_0 + \beta_1 * (\text{time})$). The impact of the DSDMs was calculated as the percentage points difference between the estimated 12-month retention based on the modeled trend from the data and the estimated 12-month retention based on the counterfactual trend, at the end of the study period.

For the primary analysis we included sex and age groups - children (ages 0 - 14), adolescents and young adults (ages 15 - 24), and adults (ages 25 and older) as effect modifiers. The analyses were performed using R statistical software version 4.2.[42]

### 3.3.7 *Ethics*

This work was approved by the Mozambique National Ethics Committee (634/CNBS/20) and the University of Washington Institutional Review Board (FWA#00006878). MISAU gave administrative approval to use client data (1984/GMS/002/2020).

## 3.4 RESULTS

We studied data from 613 health facilities, 45% of which were from the country's north region, 18% from the central region, and 37% from the south region; 25% urban and 75% rural. Between January 1, 2016, and December 31, 2020, 1,094,430 people started ART. Of these, 65% were female and 7% were children, 20% were adolescents and young adults and 73% were adults. Figure 3 presents the sex and age distribution of the cohorts from which we calculated the 12-

month retention in ART by year, during the study period. There was no change in the distribution of demographic characteristics over time.

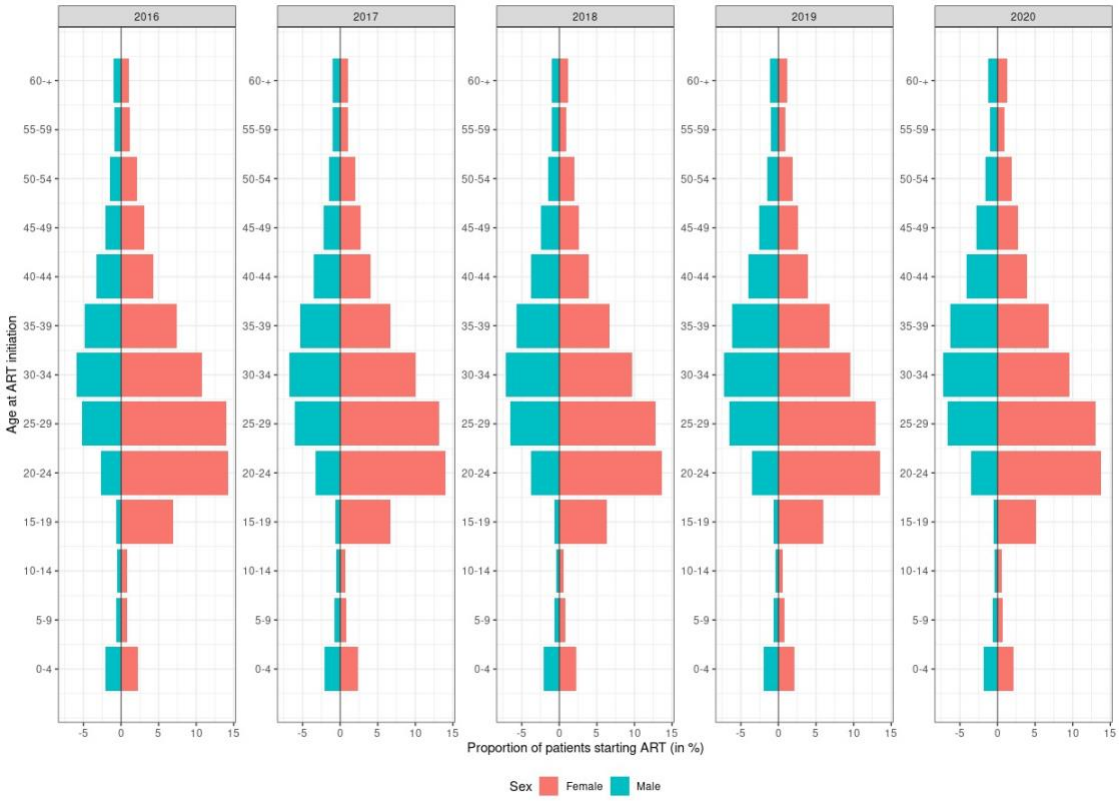


**Figure 3. Demographic characteristics of the studied cohorts**

Table 7 shows the modeled trends of the 12-month retention in ART over the time periods, overall and by sex and age. At the baseline (January 2017) the estimated 12-month retention was 67.4% (95% CI, 65.8% to 68.9%). There was a negative month-to-month change in the mean retention during pre-intervention (-0.4% (95%CI: -0.5% to -0.4%)) and rollout (-0.7% (95%CI: -0.9% to -0.6%)) periods. This was followed by a positive immediate change from rollout to post-intervention periods (6.8% (95%CI: 5.5% to 8.0%)) and a positive month-to-month change during the post-intervention period (0.7% (95%CI: 0.6% to 0.9%)). The stratified analysis shows similar trends by sex and age, although with different magnitude.

**Table 7. Trend of the 12-month retention in ART over the time periods**

| | Baseline 12-month retention in ART % (95% CI) | Pre-DSDMs period trend* % (95% CI) | Rollout period trend* % (95% CI) | Immediate change from rollout to post-DSDMs period % (95% CI) | Post-DSDMs period trend* % (95% CI) |
|---|---|---|---|---|---|
| **Overall** | 67.4 (65.8 to 68.9) | -0.4 (-0.5 to -0.4) | -0.7 (-0.9 to -0.6) | 6.8 (5.5 to 8.0) | 0.7 (0.6 to 0.9) |
| **Sex** | | | | | |
| **Female** | 67.3 (65.7 to 68.9) | -0.4 (-0.4 to -0.3) | -0.7 (-0.9 to -0.5) | 6.5 (5.3 to 7.7) | 0.7 (0.6 to 0.8) |
| **Male** | 67.3 (65.6 to 69.0) | -0.6 (-0.7 to -0.5) | -0.8 (-1.1 to -0.6) | 7.1 (5.5 to 8.7) | 0.8 (0.9 to 1.0) |
| **Age** | | | | | |
| **0-14** | 65.7 (63.7 to 67.7) | -0.2 (-0.3 to -0.1) | -1.1 (-1.3 to -0.8) | 0.3 (0.1 to 0.4) | 0.7 (0.6 to 0.9) |
| **15-24** | 62.7 (60.8 to 64.7) | -0.5 (-0.6 to -0.4) | -0.8 (-1.1 to -0.6) | 7.1 (5.3 to 8.9) | 0.9 (0.8 to 1.1) |
| **>24** | 68.8 (67.2 to 70.4) | -0.4 (-0.5 to -0.4) | -0.7 (-0.9 to -0.5) | 6.7 (5.4 to 8.0) | 0.7 (0.6 to 0.9) |

The time series for the 12-month retention in ART starting in January 2017 and ending in June 2021, overall and by sex and age, are presented in Figure 4. The estimated 12-month retention in the beginning of the study period is between 60% and 70%. Although there is a difference in the magnitude of changes in trends over time, all groups have a similar trend, described as negative and steady trend in the pre-intervention period, a positive immediate change from the rollout to the post-intervention periods, and a positive and steady trend in the post-intervention period.

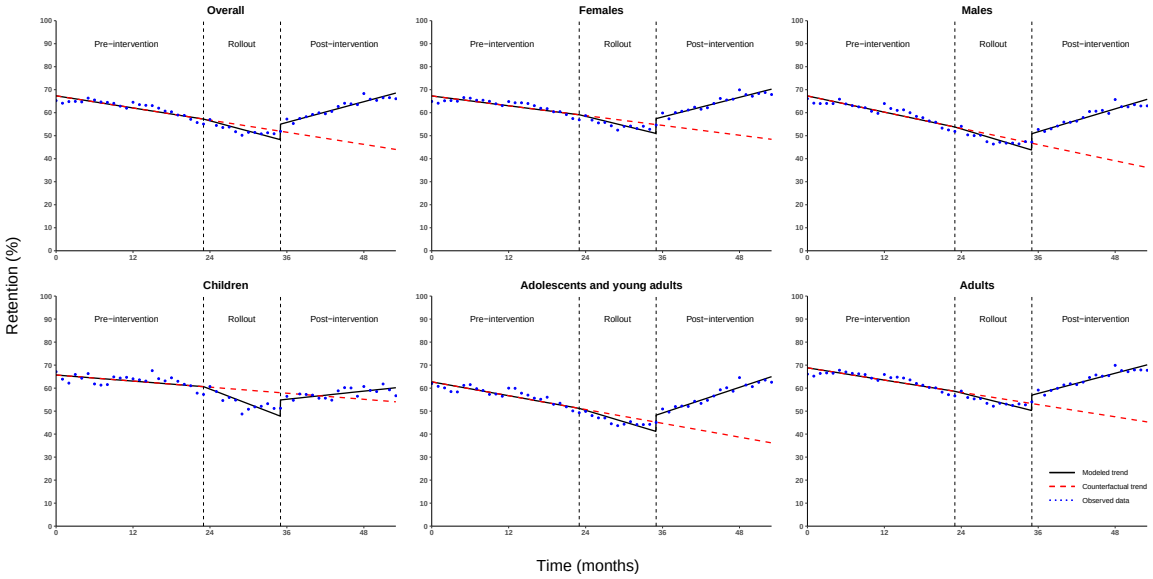


**Figure 4. Observed and expected trend of 12-month retention in ART in the presence or absence of DSDMs, overall and stratified by sex and age categories.**

Table 8 shows the estimated impact of DSDMs by group. The overall impact was an estimated increase of 24.5 (95% CI, 21.1 to 28.0) percentage points in the retention. The smallest estimated impact was observed in children (6.1%; 95% CI, 1.3% to 10.9%) and the largest impact was observed in males (29.7%; 95% CI, 25.6% to 33.7%).

**Table 8. The overall impact of DSDM in 12-months retention on ART.**

| | **Estimated modeled 12-month retention by the end of the study period % (95% CI)** | **Estimated counterfactual retention by the end of the study period* % (95% CI)** | **Overall impact of the DSDMs on 12-month retention % (95% CI)** |
|---|---|---|---|
| **Overall** | 68.6 (66.6 to 70.6) | 44.0 (40.8 to 47.3) | 24.5 (21.1 to 28.0) |
| **Sex** | | | |
| **Female** | 70.3 (68.3 to 72.2) | 48.5 (45.3 to 51.7) | 21.8 (18.4 to 25.2) |
| **Male** | 65.8 (63.7 to 68.0) | 36.2 (32.4 to 40.0) | 29.7 (25.6 to 33.7) |
| **Age** | | | |
| **0-14** | 60.2 (57.7 to 62.6) | 54.0 (49.7 to 58.4) | 6.1 (1.3 to 10.9) |
| **15-24** | 65.0 (62.5 to 67.5) | 36.2 (32.0 to 40.3) | 28.8 (24.2 to 33.4) |
| **>24** | 70.1 (68.2 to 72.1) | 45.3 (42.0 to 48.6) | 24.8 (21.4 to 28.2) |

For the secondary analysis, the estimated baseline 12-month retention and the pre-intervention trend were the same as for the primary analysis. The estimated immediate change from rollout to post-intervention without COVID-19 periods was 3.62% (95% CI, 2.44% to 4.79%) and the estimated month-to-month change in the mean retention during the post-intervention period without COVID-19 was 1.36% (95% CI, 0.88% to 1.84%). There was a negative immediate change from the post-intervention period without COVID-19 to the post-intervention period with COVID-19 (-0.28% (95% CI, -1.6% to 1.05%)), and a positive (but lower, compared to pre-COVID) month-to-month change in the mean retention during the post-intervention period with COVID-19 (0.66% (95% CI, 0.49% to 0.83%)).

Figure 5 shows the time series for 12-month retention in ART for the secondary analysis. Trends from the pre-intervention to the post-intervention period without COVID-19 are similar to trends in the primary analysis. We observed a very small negative immediate change from the

post-intervention without COVID-19 to the post-intervention with COVID-19 periods and a positive and steady trend in the post-intervention period with COVID-19, although less steep than the trend in the post-intervention period without COVID-19. The overall effect of COVID-19 on the 12-month retention in ART was estimated to be a decrease of approximately 10 percentage points (-10.0% (95% CI, -18.2% to -1.8)).

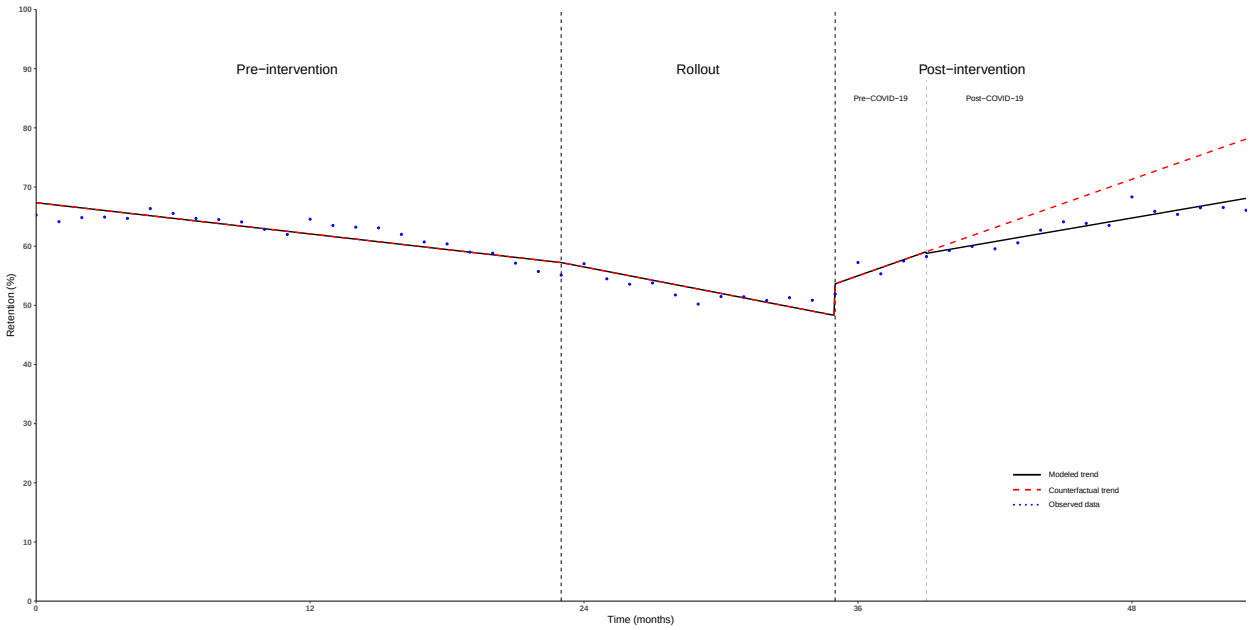


**Figure 5. Observed and expected trend of 12-month retention in ART in the presence and absence of COVID-19**

## 3.5 DISCUSSION

Our analysis of data from 613 health facilities in Mozambique in June 2021 shows a significant and positive impact of the DSDMs on 12-month retention in ART. Results showed an estimated increase of 24.5 percentage points in retention during the nationwide implementation of DSDMs compared with the period before implementation.

These findings support results from previous studies of individual models in Mozambique that reported decreases in loss to follow-up for clients enrolled on CAGs and ACs.[2,43,44] Other studies reporting on specific models compared to a conventional treatment delivery model in Africa found an increase in retention from 2% to 14% in clients enrolled on DSDMs.[12] However, studies in Kenya and South Africa reported high loss to follow-up in AC.[11] In our study, the models were not studied individually but as an intervention composed by the eight DSDMs plus the conventional care because we aimed to assess the effect of the implementation of the DSDMs as a package of HIV services being offered in Mozambique, instead of considering the effect of each of the implemented models. Therefore, our results are not discriminated by model of treatment.

Our findings were modified by sex and age. The impact of DSDMs was estimated to be higher for males. This finding supports the knowledge that DSDMs are especially beneficial for men, not only because they have worse retention in ART than women in conventional care, but also because DSDMs address important challenges that men face.[45,46] Challenges include the need to work and provide for their families that results in them missing visits or abandoning treatment, and the need to have control of both their treatment schedule and opportunity to interact with peers in an empowering environment, which are crucial for affirming their masculinity.[47]

Our estimates showed a much lower impact on children compared with the other two age groups. It is known that children have lower rates of HIV diagnostics, enrollment in ART, and viral suppression, as well as low enrollment on DSDMs, which could explain the comparatively lower estimated impact. This also highlights the need to implement more DSDMs for children, as has been advocated.[48,49]

COVID-19 had an immediate and sustained negative impact on the outcome. MISAU reported an abrupt increase in the number of missed visits for clients enrolled in ART in the early phase of the COVID-19 pandemic, when resonse measures were implemented in the country. Measures included temporarily interrupting group models (AC and CAG) and loosening eligibility criteria for enrollment in FT and 3MM models to reduce visit frequency for as many clients as possible, aiming to limit COVID-19 transmission in health facilities. For clients who missed visits, alternative ARV delivery models were offered, including community dispensing.[3,50] These factors may be associated with the negative impact of COVID-19 on ART retention; however, this was an exploratory analysis for which the counterfactual scenario for impact calculation was estimated based on only four measurements of the post-intervention period without COVID-19 (from December 2019 to March 2020), which are insufficient to confidently estimate a trend in an interrupted time series.

Strengths of our study include the large amount of data from both rural and urban public health facilities from all 11 provinces of the country, which is likely to comprehensively reflect the aspects of HIV treatment in Mozambique, and the large number of time point measurements that enabled us to confidently estimate underlying trends of the outcome before and after the intervention. Our results may not have accounted for other secular events that affected 12-month retention on ART; however, we included only data from the "test and treat" strategy era of treatment and excluded data from before 2016, aiming to address the secular trend source of bias.

In conclusion, we demonstrated that the implemented DSDMs had a positive impact on 12-month retention in ART. In addition, we generated a hypothesis that COVID-19 negatively influenced the referred retention.

# Chapter 4. ECONOMIC EVALUATION

## 4.1 RATIONALE

Since November 2018, Mozambique is implementing eight differentiated service delivery models (DSDMs) for HIV treatment, aiming primarily to increase service efficiency and ultimately reduce HIV associated mortality. These models were tailored to the country's context and included fast-track (FT), three-month antiretrovirals (ARVs) dispensing (3MM), community ART group (CAG), adherence club (AC), family-approach (FA), one-stop shop (OSS) for tuberculosis services (OSS-TB), OSS for maternal and child health (MCH) services (OSS-MCH), and OSS for adolescent-friendly health services (OSS-AFHS). [6]

Given that the implemented models reduce visit frequency for stable clients and integrate services for those using other services at the health facility, there was an expectation that this implementation would we be economically advantageous for both the services provider, the Mozambique ministry of health (MISAU), and its clients.[6]

There is a growing body of literature on economic evaluation of DSDMs, as they have been extensively implemented in sub-Saharan Africa. However, it is difficult to assess their overall economic impact because of the specificity of the cost per each DSDM and conventional care in each country, and because of inconsistent results of the attained health outcomes.[51,52] Studies have reported inconclusive results, with DSDMs varying from being cost saving to more expensive, depending on the type of model and the comparator conventional care. For example, a review of the costs of DSDMs in several African countries, found that the cost of DSDMs varied from 11.4% less to 9.2% more, compared to conventional care.[53] As such, the economic impact

for each model needs to be assessed in country specific context.[11,51,52] However, the economic impact of DSDMs in Mozambique was yet to be studied.

## 4.2 AIMS

We aimed to conduct a cost-effectiveness analysis (CEA) and a budget impact analysis (BIA) of the implementation of the eight DSDMs in Mozambique to inform MISAU of their economic impact.

## 4.3 METHODS

### 4.3.1 *Setting*

The study was conducted nationwide in Mozambique, where MISAU is the only official HIV service provider, offering both DSDMs and convectional care for HIV treatment free of charge. Eligible clients have the right to choose to be enrolled in DSDMs or conventional care with no negative consequences to their service provision.

### 4.3.2 *The status quo and the intervention*

Conventional care consists of monthly scheduled appointments for clinical observation and medication prescription and dispensation. Laboratory tests include haemoglobin, creatinine, alanine aminotransferase, and CD4 count performed semi-annually, and viral load performed annually after the first and second measurements at six and 12 months after ART initiation of treatment. The intervention is a package of the eight DSDMs and the conventional care, described in detail in chapter 1.

### 4.3.3 *The CEA and BIA*

The outcome of interest for both the CEA and BIA was 12-month retention after ART initiation, comparing DSDMs implementation period to a counterfactual scenario (i.e., if the DSDMs had not been implemented). The CEA was conducted first from MISAU's perspective and secondarily from the societal perspective, considering the three years of the DSDMS implementation (2019 to 20121) as the time horizon. The BIA was conducted from MISAU's perspective over a three-year period (2022 to 2024).

#### 4.3.3.1 <u>The model</u>

For these analyzes, we constructed a decision tree model (Figure 6) for each year of the study period, based on the estimated percentage of enrolment in each treatment model.

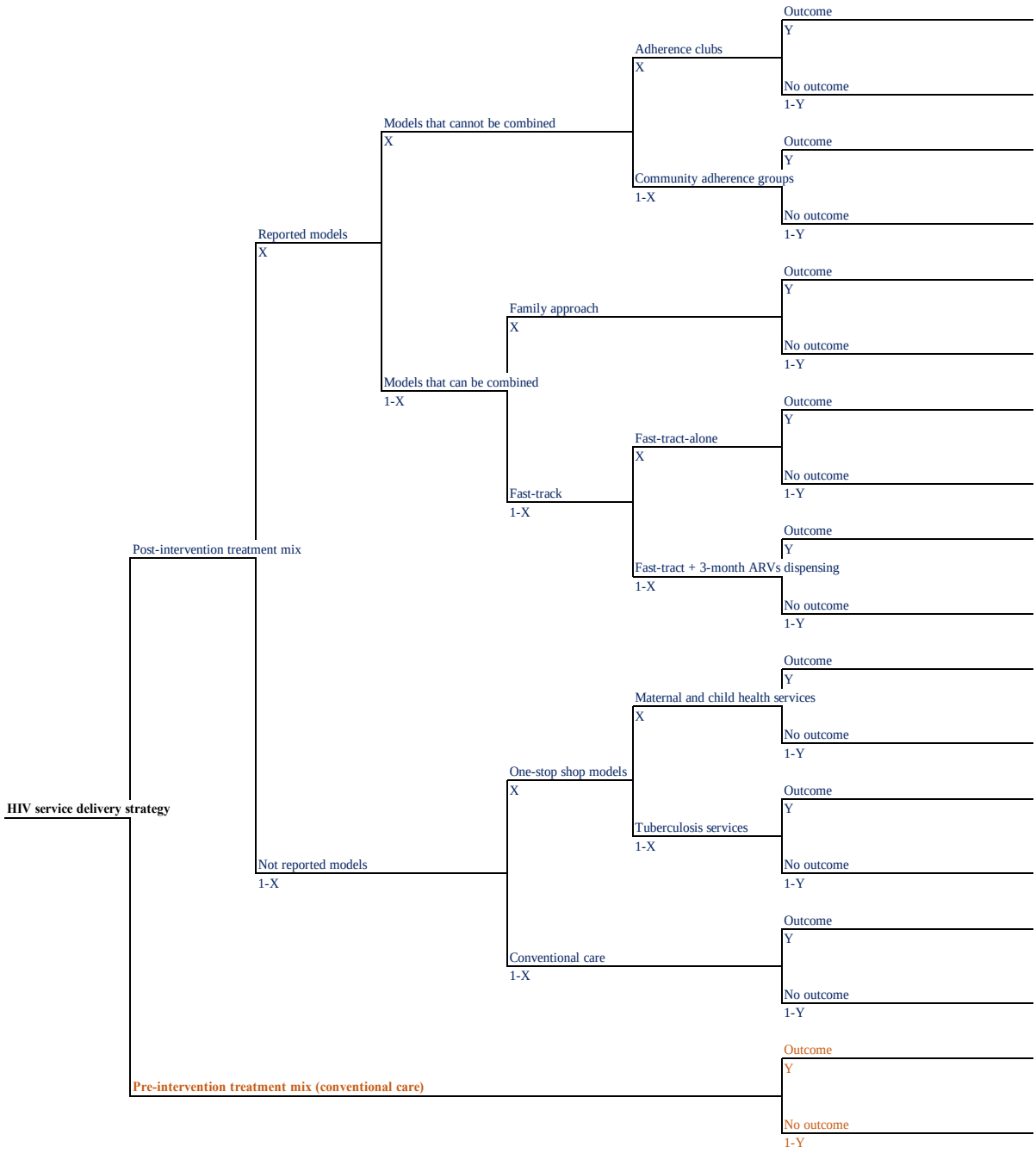


**Figure 6. The decision tree model employead for CEA and BIA**

**Legend**: X, branch probability; Y, outcome probability.

The percentage of enrolment in each DSDM was estimated based on data from the country's President's Emergency Plan for AIDS Relief (PEPFAR) monthly monitoring database

(Analyzing Joint Underperformance and Determining Assistance - AJUDA) for the models reported (AC, CAG, FA, FT, and 3MM) and from MISAU's HIV/AIDS national programme annual reports for the OSS-MCH and OSS-TB models [9]. Although it is known that the OSS-AFHS model is being implemented in Mozambique, there is no available data regarding the percentage of enrolment in this model. Therefore, we conservatively considered the clients enrolled in this model as enrolled in the conventional model. The percentage of clients not enrolled in any DSDM is also not reported. We estimated it by calculating the difference between the total number of clients enrolled in ART and those enrolled in at least one DSDM reported.

In the AJUDA database, the sum of the reported number of clients enrolled in each model is more than the reported number of clients enrolled in at least one model. This happens because a client can be enrolled in more than one DSDM (for models that can be combined); however, each model is reported individually, resulting in duplicate reporting for the combined models. Because the data on which DSDMs are being combined and double reported are unavailable, we estimated the percentages of enrolment in each DSDM for our model as follows:

1) Given that both AC and CAG cannot be combined with any other DSDM, we assumed that the data for these models were not duplicated and used the reported numbers to estimate the percentage of enrolment in these models.

2) Although FA can and is being implemented in combination with FT alone or with FT plus 3MM, we assumed that clients enrolled in FA were not enrolled in any other model and used the reported number of clients in this model to estimate the percentage of enrolment.

3) To estimate the percentage of enrolment in FT alone, we subtracted the number reported for FA from the number reported for FT. This is based on the assumption that any duplications

reported would conservatively be counted only in the FA model, because FA is less economically advantageous than FT, due to more clinical visits.

4) To estimate the percentage of enrolment in FT combined with 3MM (given that 3MM cannot be provided alone, but only in combination with FT), we subtracted the estimated numbers of enrolment in AC, CAG, FA, and FT alone from the reported number of clients enrolled in at least one model.

For the OSS-MCH and OSS-TB models, we used data from MISAU's HIV/AIDS national programme annual reports, which include the number of patients enrolled in ART in these services. Given that all patients enrolled in ART in these services are reported as enrolled in the respective OSS model, we used these numbers to calculate the percentages of enrolment in these models from the total number of clients enrolled in ART.

#### 4.3.3.2 Costs estimation

For the CEA we first estimated the economic costs from MISAU's perspective and secondarily from the societal perspective. For the BIA, financial costs were estimated from MISAU's perspective. Costs were estimated for both DSDMs and conventional model per patient-year, and for the BIA they included ARVs, laboratory tests, and service provision interactions (clinical and pharmacy visits and group interactions). For the CEA from MISAU's perspective, the costs also included DSDMs start-up and training, and for the CEA from the societal perspective they also included clients' opportunity costs.

ARVs costs were obtained from MISAU's HIV/AIDS national programme. Laboratory test costs were obtained from the central laboratories from the National Institute of Health in Mozambique. Service provision interactions for both conventional care and DSDMs were

estimated based on a literature review of HIV treatment in sub-Saharan Africa. The conventional care costs included infrastructure use, human resources, and overhead. For DSDMs we included costs for specific visits or activities in addition to, or in substitution of, the conventional model visits, according to the characteristics of each DSDM.

To calculate the cost of each conventional care visit, we compared the costs and services offered at each visit for the conventional care described in other studies and counted the costs applicable to the Mozambique context. When only annual costs were presented, besides the services offered, we also considered the number of visits offered in the model of care in those studies to estimate the costs per visit.

To calculate the cost per person per each club meeting of the AC model, we included the costs applicable to the Mozambique context based on the breakdown of costs found in the literature, when available. These included 1) nurse time, 2) pharmacy technician time, 3) club facilitators time, 4) ongoing club mentorship, and 5) infrastructure and overheads. The total cost of visits per person-year for clients enrolled in AC was calculated by multiplying the cost per club meeting by four (the number of clubs meeting per year). CAG interactions costs were extracted from the literature. To calculate the cost per person per year for CAG, we included costs for 2 conventional care interactions and 10 CAG interactions.

We considered the cost of each clinical and pharmacy visits for FA and FT models to be the same as for the conventional model, and we added group model management for the FA model. The total cost of these visits per person-year for clients enrolled in FA was calculated by adding the cost for group model management to the clinical and pharmacy visits and then multiplying the cost per visit by 12 (the number of visits per year). The total cost of clinical visits per person-year for clients enrolled in FT was calculated by multiplying the cost per visit by 2 (the number of

clinical visits for this model per year), and the total cost of pharmacy visits per person-year for these clients was calculated by multiplying the cost per visit by 4 or by 12, depending on whether the FT model was combined or not with the 3MM model. Given that the 3MM model consists of antiretrovirals dispensing quarterly in combination with the FT model, the cost of the 3MM model per person-year was calculated as the cost per each conventional pharmacy visit multiplied by 4 and is included in the cost for FT combined with 3MM model.

The economic and financial costs of the models described above were similar. The economic costs of OSS-MCH and OSS-TB for the CEA were estimated as described for AC interactions, given that the services offered in these OSS models are the same as in the AC model. To determine the financial costs of the OSS models interactions for the BIA, we considered it to be half of the estimated economic costs, assuming that the other half of the costs would be covered by the primary services (MCH and TB) used by the clients.

DSDMs start-up costs included guideline development and distribution, demand generation activities, and initial training, and were estimated based on the information provided by MISAU's HIV/AIDS national programme. Ongoing training costs were estimated based on MISAU's estimations.

Clients' opportunity costs included travel time to the health facility and time spent at the health facility for service provision. The total opportunity cost per conventional care interaction was estimated as a half-day of wages, based on the country's average wage, considering on average one hour of travel time and three hours of time spent at the health facility. Medication pick-up visits (for the 3MM model) were estimated to be 1.5 hours, AC interaction and CAG interactions in the community were estimated to be 3.5 and 1 hour, respectively. For the FA model, we considered half of the opportunity costs of the conventional visit, assuming that clients using the

FA model reduce their visits by half because members of the same household are scheduled on the same day [10–12]. Opportunity costs were estimated in Mozambique metical and converted to US dollars (US$) using the 2021 annual average exchange rate of 63.25 metical per US$1. All other costs were estimated in US$, and no discount was applied.

#### 4.3.3.3 Effectiveness

Effectiveness was estimated by comparing the periods before and after DSDMs implementation, as described in chapter 3. We applied an uncontrolled interrupted time series design to compare the outcome (retention at 12 months after ART initiation) before and after implementation of the DSDMs nationwide, using data from all clients enrolled in HIV treatment from January 2016 to June 2020 (i.e., follow-up data through June 2021) in health facilities using the electronic patient tracking system, which feeds the Mozambique antiretroviral therapy (MozART) database [14]. We used a segmented regression analysis by fitting a generalized estimating equation model with an independence working correlation structure assumption and cluster-robust standard errors to account for clustering at the health facility level and for possible informative cluster size.

#### 4.3.3.4 Sensitivity analysis

We conducted a one-way sensitivity analysis (OWSA) by imputing the lower and higher estimated costs for the following categories: 1) conventional services interactions 2) AC interactions, 3) CAG interactions, 4) ARVs, 5) laboratory tests, 6) start-up and training, and 7) opportunity costs. Interactions for other models were not included in this analysis because their costs were estimated based on conventional care or AC and CAG interactions. Table 9 shows the model's inputs for the CEA and BIA.

**Table 9. CEA and BIA models inputs by study period**

| Data inputs | Value (range) by year | | |
|---|---|---|---|
| | **2019** | **2020** | **2021-2024** |
| **Percentage of enrolment** | | | |
| Conventional care | 49.7 | 19.9 | 20 |
| Adherence Club | 0.2 | 0.2 | 0.2 |
| Community Adherence Group | 8.7 | 9 | 8.9 |
| Family Approach | 1.8 | 3.3 | 3.7 |
| Fast-track alone | 20.8 | 34 | 38 |
| Fast-track combined with 3MM | 11.8 | 22.2 | 19.3 |
| One-stop Shop MCH | 5.4 | 9.2 | 8.9 |
| One-stop Shop TB | 1.5 | 2.2 | 1.8 |
| **Population size** | 1,338,100 | 1,402,902 | 1,535,575 |
| **Client opportunity cost per hour (US$)** | 1.6 (0.8-2.4) | 1.8 (0.9-2.6) | 1.2 (0.6-1.7)[54] |
| **Costs for the health system (US$)** | **2019-2024** | | |
| Antiretrovirals per year (first line) | 43 (38.7 – 47.3) | | |
| Laboratory tests per year | 64 (57.6 – 70.4) | | |
| Conventional care clinical interaction† | 4.47 (1.11 – 10.32) [51,55–58] | | |
| Conventional care pharmacy interaction† | 1.12 (0.28 – 5.58) [5,11,16–18] | | |
| Adherence Club and One-stop Shop MCH and TB interactions‡ | 6.67 (5.87 – 16.52) [51,55,59] | | |
| Community Adherence Group interactions | 2.77 (1.37 – 9.8) [57,59–61] | | |
| DSDMs coordination for Family Approach visits§ | 0.4 (0.26 – 0.53) | | |
| Start-up and training costs | 383,466.67 (345,120.00 – 421,813.33) | | |

Abbreviations: 3MM, three-month antiretrovirals dispensing; DSDMs, differentiated service delivery models; MCH, maternal and child health; TB, tuberculosis.

†Conventional care visits to the health facility include clinical observations, antiretroviral therapy support, and medication prescription and pick-up at the health facility pharmacy. These visits were divided into clinical and pharmacy interactions to simplify the cost estimation of the models family-approach, fast-track, three-month ARVs dispensing, which were based on comparative activities with conventional care.

‡ For the budget analysis impact, the costs for One-stop Shop MCH and TB interactions were considered half of the economic cost, assuming that the other half was covered by the primary services used by clients in these models.

§Estimated from costs breakdown for adherence clubs and community adherence groups.

### 4.3.4 *Ethics*

This work was approved by the Mozambique National Ethics Committee (634/CNBS/20) and the University of Washington institutional review board (FWA#00006878). MISAU gave administrative approval to use patient data (1984/GMS/002/2020).

## 4.4 RESULTS

### 4.4.1 *Cost-effectiveness Analysis*

#### 4.4.1.1 Costs

From MISAU's perspective, the estimated economic costs per person-year for each model of treatment, including ARVs and laboratory tests costs, from the most to the least expensive, were US$187 for OSS-MCH and OSS-TB, US$ 179 for FA, US$174 for conventional care, US$144 for CAG, US$134 for AC, US$129 for FT alone, and US$120 for FT combined with 3MM. From the societal perspective, the cost per person-year was US$251 for conventional care, US$245 for OSS-MCH and OSS-TB, US$218 for FA, US$165 for CAG, US$162 for FT alone, US$153 for AC, and US$138 for FT and 3MM.

We calculated the total costs for DSDMs and conventional care by category, and the cost difference between them by study period, from the health system and societal perspectives (Table 10). The mean costs for DSDMs and conventional care from health system perspective were US$173,391,277 and US$179,461,668, respectively. The main drivers of cost for conventional care were service provision interactions followed by laboratory tests, while for DSDMs were laboratory tests followed by service provision interactions. The opportunity costs were US$221,314,340 and US$253,770,621 for DSDMs and conventional care, respectively.

## Table 10. Total cost for DSDMs and conventional, by cost category and study period

| Cost category | 2019 costs (US$) | | | 2020 costs (US$) | | | 2021 costs (US$) | | | Study period mean costs (US$) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | DSDMs | Conventional | Difference | DSDMs | Conventional | Difference | DSDMs | Conventional | Difference | DSDMs | Conventional | Difference |
| **MISAU's perspective** | | | | | | | | | | | | |
| Services interactions | 51,647,955 | 67,336,021 | -15,688,066 | 44,766,695 | 67,523,554 | -22,756,860 | 49,717,206 | 62,722,026 | -13,004,820 | 48,710,618 | 65,860,534 | -17,149,915 |
| ARVs | 44,592,183 | 43,153,725 | 1,438,458 | 49,466,325 | 43,433,846 | 6,032,479 | 55,795,118 | 47,211,253 | 8,583,864 | 49,951,208 | 44,599,608 | 5,351,600 |
| Lab tests | 66,369,760 | 64,228,800 | 2,140,960 | 73,624,297 | 64,645,724 | 8,978,573 | 83,043,896 | 78,130,056 | 4,913,840 | 74,345,984 | 69,001,527 | 5,344,458 |
| Start-up and training | 406,800 | - | 406,800 | 371,800 | - | 371,800 | 371,800 | - | 371,800 | 383,467 | - | 383,467 |
| Total | 163,016,697 | 174,718,546 | -11,701,849 | 168,229,116 | 175,603,124 | -7,374,008 | 188,928,019 | 188,063,335 | 864,684 | 173,391,277 | 179,461,668 | -6,070,391 |
| **Societal perspective** | | | | | | | | | | | | |
| Clients' opportunity costs | 218,821,182 | 252,291,176 | -33,469,994 | 218,509,418 | 260,589,602 | -42,080,185 | 226,612,421 | 248,431,083 | -21,818,662 | 221,314,340 | 253,770,621 | -32,456,280 |
| Total | 381,837,879 | 427,009,722 | -45,171,843 | 386,738,534 | 436,192,727 | -49,454,193 | 415,540,440 | 436,494,418 | -20,953,978 | 394,705,618 | 433,232,289 | -38,526,671 |

#### 4.4.1.2 Effectiveness

Table 11 presents the effectiveness results of the implementation of DSDMs, calculated as the difference in the percentage of the outcome comparing DSDMs and conventional care, per year of the study and the study period mean. Overall and by year of the study, the DSDMs were more effective than conventional care in retaining clients 12 months after the initiation of ART.

**Table 11. Effectiveness of DSDMs overall and by study year**

| Study period | 12-month retention in care % (95%CI) | | Effectiveness (95%CI) |
|---|---|---|---|
| | DSDMs | Conventional | |
| 2019 | 55.05 (53.08 – 57.00) | 51.95 (49.92 – 53.99) | 3.09 (0.55 – 5.62) |
| 2020 | 64.05 (62.40 – 65.70) | 46.67 (43.84 – 49.51) | 17.37 (14.44 – 20.31) |
| 2021 | 68.65 (66.56 – 70.55) | 45.04 (40.78 – 47.29) | 24.52 (21.06 – 27.98) |
| 3 years of the study | 62.55 (60.94 – 64.15) | 47.55 (44.86 -50.25) | 14.99 (12.19 – 17.79) |

#### 4.4.1.3 Incremental cost-effectiveness ratio

For the three years of the study period (2019-2021), the mean cost difference comparing DSDMs to conventional model of treatment was US$-6,070,391 and US$-38,526,671 from health system and societal perspective, respectively, and the mean effectiveness difference was 15%. The incremental cost-effectiveness ratio was not calculated given that DSDMs were less expensive and more effective, thus dominating the conventional model of care.

#### 4.4.1.4 Sensitivity analysis

Service provision interactions for the conventional care, and start-up and training were the most and least influential cost category, respectively, in the primary analysis (Figure 7). A sensitivity analysis of the opportunistic costs resulted in a change of US$+/-12,724,053 from the US$-38,526,671 from base case scenario in the secondary analysis.

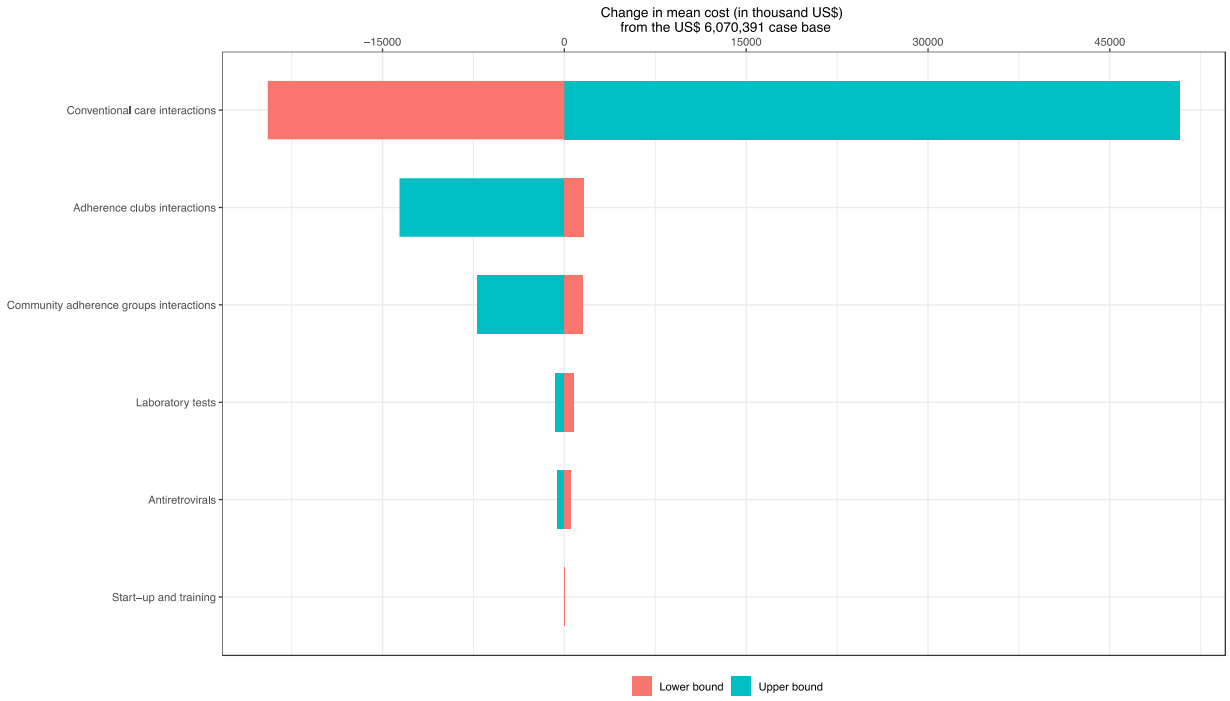


**Figure 7. Tornado diagram of one-way sensitivity analysis**

### 4.4.2 *Budget Impact Analysis*

Considering a population of 1,535,575 enrolled in HIV treatment in each year from 2022 to 2024, and the same treatment mix observed in 2021, we estimated an effectiveness of 24.5% and financial costs of US$550,118,496 and US$564,190,006 for DSDMs and conventional care, respectively. Other than the financial cost per person-year for OSS-MCH and OSS-TB, which was estimated at US$147, the costs per person-year for all other models, as well as the main drivers of the total costs, were the same as for the CEA.

## 4.5 DISCUSSION

Our study analyses the economic impact of the nationwide implementation of eight DSDMs in Mozambique, using a conservative approach to inform MISAU on the least expected benefit of the implementation of these models for both the health system and its clients, through a CEA and BIA. Our study findings revealed that DSDMs were less expensive and more effective in retaining clients 12 months after ART initiation, compared with conventional care. We estimated that the implementation of these models will result in savings of approximately US$14 million to the health system between 2022 and 2024.

The main objective of this analysis was to inform MISAU on the cost-effectiveness and budget impact of DSDMs for informed decision-making. However, given that one of the most acclaimed benefits of the implementation of the DSDMs is that they reduce treatment burden to its clients, we also explored the societal perspective of this implementation by including two important treatment related costs for the clients - the travel time and the time spent at the health facility to access treatment services. The implementation of DSDMs during the three years of study was estimated to have saved US$6 million for the health system and US$32 million for its clients, supporting the theory that these models are expected to be economically beneficial to the health system and its clients.

When comparing the cost of each model per person-year to conventional care, from MISAU's perspective, the OSS-MCH, OSS-TB, and FA models were more expensive, whereas CAG, AC, FT alone, and FT combined with 3MM were less expensive. The OSS models were the most expensive because each interaction in integrated services is more expensive than each interaction in conventional HIV care, and both conventional care and OSS-MCH and OSS-TB have the same number of interactions given that they consist of monthly visits. However, this

comparison does not account for the fact that OSS models offer more services than what is offered in the conventional care. FA models were also estimated to be more expensive because of the additional costs of group model management. Given that FA can be combined with other models with less service interactions, such as FT and 3MM, the cost per year per client using the combined models is expected to be lower than for FA alone. However, we used a conservative approach by assuming that clients using FA were not using other models. AC, CAG, FT alone, and FT combined with 3MM are less expensive than conventional care because they have fewer service provision interactions.

From the societal perspective, the conventional model of care was more expensive than all the other individual DSDMs. This is because conventional service provision interactions are more frequent and longer in duration than DSDMs's interactions. FT, 3MM, CAG, and FA models save clients' opportunity costs by reducing the frequency of visits to the health facility. FT and 3MM increase the visit spacing, CAG has monthly community meetings instead of health facility visits, and FA benefits clients who are also caregivers by offering services for both caregivers and their dependents during the same visit to the health facility. OSS and AC models save opportunity costs by making the interactions shorter, given that all services are provided in one place, which reduces the waiting time between different services in the health facility.

Comparing our results to other studies in sub-Saharan Africa is challenging for two reasons: 1) our estimation of service interaction costs for each type of delivery model was based on a literature review of these studies, 2) the costs are context driven and influenced by both service delivery costs and the characteristics of the models in each country. However, similar to what has been described in other studies, we found that some DSDMs are less expensive and others are

more expensive than conventional care, depending on the services offered in each model, where they are offered, and when they are offered [4–7,18–21].

Estimating the costs of each model and the percentage of enrolment in each model was challenging due to the unavailability of country data on model costs, the heterogenicity of costs - when available - due to different country contexts and specificity of the models in these contexts, and the scarcity of data for some models such as OSS and FA [11,13]. It was difficult to estimate the percentage of enrolment in each model because there is not an established routine reporting system for these service delivery models and the reporting system available does not include data for OSS-AFHS nor reports which models are being combined. Therefore, we assumed that the only models being combined were FT and 3MM (because 3MM is designed to be offered only in combination with FT), and we used other data sources and an exclusion method to calculate the percentage of enrolment in conventional care. Through this approach, all clients not included in the reported models were assumed to be enrolled in conventional care, which includes clients enrolled in the new DSDMs being piloted in the country, such as six-months and private pharmacy dispensing of ARVs. This explains the estimated increase in enrolment in conventional care from 2020 to 2021, attributed to the increase in the piloted models in the country during this period [3,62].

The main limitations of our study were the simplicity of the model used to assess the economic impact of a complex infectious disease such as HIV and the short time-horizon for the CEA, which did not allow us to measure the full benefit of the intervention. Therefore, our findings are an underestimation of the true benefit of the intervention for both the health system and its clients. However, the findings from this study are useful to provide evidence on the benefit of implementing DSDMs in Mozambique compared with conventional care models.

In conclusion, we found that DSDMs were more effective in retaining clients 12 months after ART initiation and less expensive than conventional care to the health system and its clients. Their implementation was estimated to have generated cost savings to the health system from 2022 to 2024.

# Chapter 5. CONCLUSION

The overall goal of this dissertation was to conduct a comprehensive evaluation of the implementation of an important strategy to improve HIV care - differentiated service delivery models (DSDMs) for HIV treatment. Qualitative research, impact evaluation and economic evaluation were the implementation science methods applied in this disseration, and important findings were identified through this work.

First, we described determinants (barriers to be addressed and facilitators to be leveraged) of a successful implementation of differentiated service delivery models in Mozambique, using Consolidated Framework for Implementation Research (CFIR). Overall, the DSDMs were found to be advantageous for the health system and patients when compared with the conventional care. The CFIR constructs of Relative Advantage, Complexity, Patient Needs and Resources, and Reflecting and Evaluating were identified as drivers of implementation, whereas Available Resources and Access to Knowledge and Information were identified as substantial barriers. COVID-19, a non-CFIR identified determinant, temporarily interrupted implementation of group-based models, but it expedited individual models by loosening the inclusion criteria; this experience can be leveraged to optimize the design and implementation of differentiated service delivery models in Mozambique and other countries.

Second, we demonstrated a positive and significative impact of the implemented DSDMs on 12-month retention in ART, and we found that this impact was modified by sex and age, with males having the greatest, and children the smallest observed impact. We also generated a hypothesis that COVID-19 negatively influenced the retention in ART.

Third, we found that the DSDMs being implemented in Mozambique dominated the conventional model of care by being more effective in retaining clients 12 months after ART

initiation and less expensive to the health system as well as to its clients, and that their implementation was estimated to save approximately US$14 million to the health system from 2022 to 2024.

The implications of these findings for policy and practice include robust evidence supporting the implementation of DSDMs strategies to optimize the HIV service delivery system, both from the health outcomes and from economic perspectives. Findings also highlight that the DSDMs' acceptability by managers and providers, as well as their perceived simplicity and advantage for both the health system and the HIV services users, should be accompanied by availability of resources and ongoing training for frontline providers for successful implementation.

This dissertation fills an important evidence gap on the implementation of DSDMs nationwide in Mozambique and in similar contexs, and directs future implementation studies to explore strategies to improve their impact on children, as well as to model a more comprehensive economic impact of these models by extending the time horizon and studying outcomes such as quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs), given the expected effect of DSDMs on patient's quality of life and survival.

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