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HIV treatment engagement interventions for men in Malawi: a mixed-methods economic evaluation

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Dissertation

**HIV TREATMENT ENGAGEMENT INTERVENTIONS FOR MEN IN
MALAWI: A MIXED-METHODS ECONOMIC EVALUATION**

by

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DEDICATION

In loving memory of my grandmother, P.C. Saraswati, and the summer days we spent
gathering wildflowers and berries.

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ABSTRACT

Background: Men in sub-Saharan Africa have lower rates of HIV treatment initiation and retention than women. In this mixed-methods study, we created a structured decision-making framework comparing the three interventions tested in the Identifying Efficient Linkage Strategies for Men (IDEaL) trial in Malawi: 1) home-based counseling with lay cadre healthcare workers (HCWs); 2) home-based counseling with lay cadre HCWs plus home-based ART initiation; and 3) stepped interventions deployed sequentially until ART initiation occurred (home-based lay cadre counseling, motivational interviewing with a psychosocial counselor, and home-based ART initiation).

Methods: This study was guided by the Assessing Cost-Effectiveness (ACE) framework. First, we conducted in-depth interviews with high-level international and Malawi-based stakeholders to understand their perceptions and priorities. We analyzed transcripts using thematic content analysis. Next, we conducted an incremental cost-effectiveness analysis of the IDEaL interventions. Finally, we created a decision-making framework for stakeholders deciding whether to adopt and implement the IDEaL interventions. The

framework included trial data on the following criteria: effectiveness, intervention cost, feasibility, equity, acceptability, sustainability, and “other considerations.”

Results: Both international and Malawi-based stakeholders prioritized client acceptability but diverged elsewhere: international stakeholders prioritized effectiveness while Malawi-based stakeholders prioritized long-term costs, feasibility, and sustainability. Both groups prioritized facility-based interventions and highly valued person-centered care. Average incremental costs per client were higher for the home-based ART (\$44) and stepped (\$35) interventions than for the counseling-only intervention (\$28). The most expensive aspect of the interventions was HCW travel to community-based settings. All three interventions performed better than a standard of care comparison on 6-month retention in HIV care; differences in retention across arms were not statistically significant. The incremental cost-effectiveness ratio (ICER) for the stepped arm compared to the counseling-only arm was \$101/participant with a successful outcome (95% CI: -\$219, \$1,284). The lay cadre counseling-only intervention was the most acceptable, feasible and sustainable option.

Conclusion:

Person-centered, male-tailored counseling with HCWs contributed to the success of the IDEaL interventions and was highly valued by clients and healthcare workers.

Counseling with lay cadre HCWs should be prioritized over more expensive

interventions, such as community-based psychosocial counseling and ART dispensation for increasing men's engagement in HIV care.

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CHAPTER 1: INTRODUCTION

Significance

Over the past decades, antiretroviral therapy (ART) has saved and improved the lives of millions of people living with HIV.¹ Policy and technological changes (such as streamlined ART initiation and HIV self-testing kits) have reduced barriers to testing and initiation, but early retention in care (in the first 6 months after initiation) remains an especially challenging phase in the path toward long-term care retention.² Nearly half of treatment discontinuation in the first year of care occurs in the first three months after initiation.³

ART initiation and retention lag among men in sub-Saharan Africa (SSA), leading to losses in life expectancy and continued transmission of the virus.^{4,5} In 2022, an estimated 89% of adult men in SSA living with HIV knew their status, 78% were on ART, and 73% were virally suppressed, significantly lower than the corresponding levels for women (93%, 86%, and 80%) with the greatest differential drop-off in accessing ART.⁶ Men face multi-level barriers to engaging in care, including female-focused healthcare services, negative healthcare worker perceptions, and labor-related mobility.^{4,7-9}

In growing recognition of this issue, multilateral institutions and foundations have launched initiatives to improve access to HIV care for men in SSA. However, little is known about which interventions are most effective or cost-effective for men who are not

engaged in HIV treatment.

IDEaL Trial Summary

The Identifying Efficient Linkage Strategies for Men (IDEaL) trial in Malawi aimed to address this gap by developing and testing three male-tailored interventions for men who are aware of their status but not engaged in treatment. All HCWs delivering the intervention were men. The intervention arms are:

- 1) *Low-Intensity*: tracing, community-based male-tailored counseling, and facility navigation with a lay cadre HCW.
- 2) *High-Intensity*: tracing and community-based male-tailored counseling with a lay cadre HCW, followed by the offer of facility-based ART initiation with navigation with a lay cadre HCW or community-based ART initiation with a nurse.
- 3) *Stepped*: three interventions of increasing intensity deployed every two-weeks until ART (re-)initiation occurs:

- Step 1: Low-intensity intervention (described above)
- Step 2: Community-based motivational interviewing and facility navigation with a psychosocial counselor
- Step 3: Community-based ART initiation with a nurse

The primary study outcome was a composite of ART initiation within 3-months of enrollment and retention in care 6-months after initiation.

Study Aims and Objectives

The primary aim of this dissertation is to offer Malawian stakeholders a structured framework to help inform decision-making on adopting and scaling-up interventions to improve ART initiation and early retention rates among men. The decision-making framework includes information on the effectiveness, cost-effectiveness, and suitability of these interventions in the Malawian context. Specifically, the dissertation's objectives are:

- *Objective 1:* Explore the perspectives and priorities of stakeholders regarding ART initiation and early retention interventions for men, focusing on their decision-making criteria, preferred interventions, and perceptions of the barriers and facilitators to scaling-up potential interventions.
- *Objective 2:* Assess the costs and incremental cost-effectiveness of the ART initiation and early retention interventions deployed in the IDEaL randomized controlled trial and analyze the costs of participants' first 6-months of HIV care.
- *Objective 3:* Develop a decision-making framework and recommendations for national scale-up of these interventions, based on the results from Objectives 1 & 2 and trial data on implementation factors (e.g., acceptability, feasibility, equity).

In the text that follows, I will first provide background on the scope and current status of global HIV treatment efforts, focusing on men's barriers to care and HIV treatment in SSA and Malawi. Next, I will provide a detailed description of the IDEaL trial followed

by a literature review of initiation and early retention interventions for men. The three subsequent chapters include the methods, results and discussions for each of the dissertation's objectives.

CHAPTER 2: BACKGROUND

This chapter starts with a broad overview of the global scope and impact of the HIV epidemic. Next, it describes progress and remaining challenges in providing accessible treatment to people living with HIV (PLHIV), focusing on SSA. Next, it describes sex disparities in treatment uptake and the barriers men experience in accessing and staying in care. The chapter concludes with a summary of the Malawian healthcare system and HIV/AIDS treatment in Malawi.

HIV/AIDS: Scope of the Epidemic

Human immunodeficiency virus (HIV) attacks the body's immune system by destroying CD4 cells. Left untreated, it can progress to advanced HIV disease, and then AIDS.

People living with advanced HIV disease and AIDS are immunocompromised and more susceptible to infections (e.g. tuberculosis, pneumonia) and certain types of cancers (e.g. lymphoma).¹⁰ HIV is most commonly spread through unprotected sexual contact but can also be spread through blood contamination, needle sharing, or from mother-to-child during pregnancy or breast-feeding.¹¹

Though there is no widely available cure or vaccine for HIV/AIDS, antiretroviral therapy (ART) can halt the progression of HIV to AIDS. Without ART, PLHIV can expect to live 8–10 years,¹² but with consistent ART they can live a full lifespan, though with fewer morbidity-free years.¹³ PLHIV with CD4 counts in a normal range (greater than

500) are unlikely to transmit the virus to others, making ART a critical tool in HIV prevention as well as treatment.¹⁴

In 2019, HIV/AIDS was the second most fatal infectious disease globally, after tuberculosis.¹⁵ HIV incidence peaked in the late 1990s at over 3 million per year and has since declined to around 2 million.¹⁵ HIV/AIDS-related deaths peaked in 2004 at 1.84 million but are now less than half that figure.¹⁵ In contrast, the number of PLHIV is at a peak of 36 million.¹⁵ The global scale-up of ART is largely responsible for the decline in HIV/AIDS incidence and deaths and the corresponding increases in life expectancy and prevalence.¹

The prevalence and impact of HIV/AIDS varies greatly globally. The average global death rate from HIV/AIDS is 11 per 100,000 per year, but it is more than ten times higher in many countries in SSA; Lesotho, Eswatini, Mozambique, Botswana, and South Africa have HIV/AIDS death rates greater than 250 per 100,000.^{15,16} In SSA, HIV/AIDS is the leading cause of death^{1,15} and has wide-ranging impacts beyond loss of health and life, including stigma, job loss, health care expenditures, and strained family relationships due to blame for contracting and transmitting the virus.¹⁷ The effects of HIV/AIDS on society are so broad and significant that both the Millennium Development Goals and Sustainable Development Goals (SDGs) dedicated specific goals and targets to improving care and treatment for PLHIV and ending the epidemic.^{18,19}

The HIV Treatment Cascade

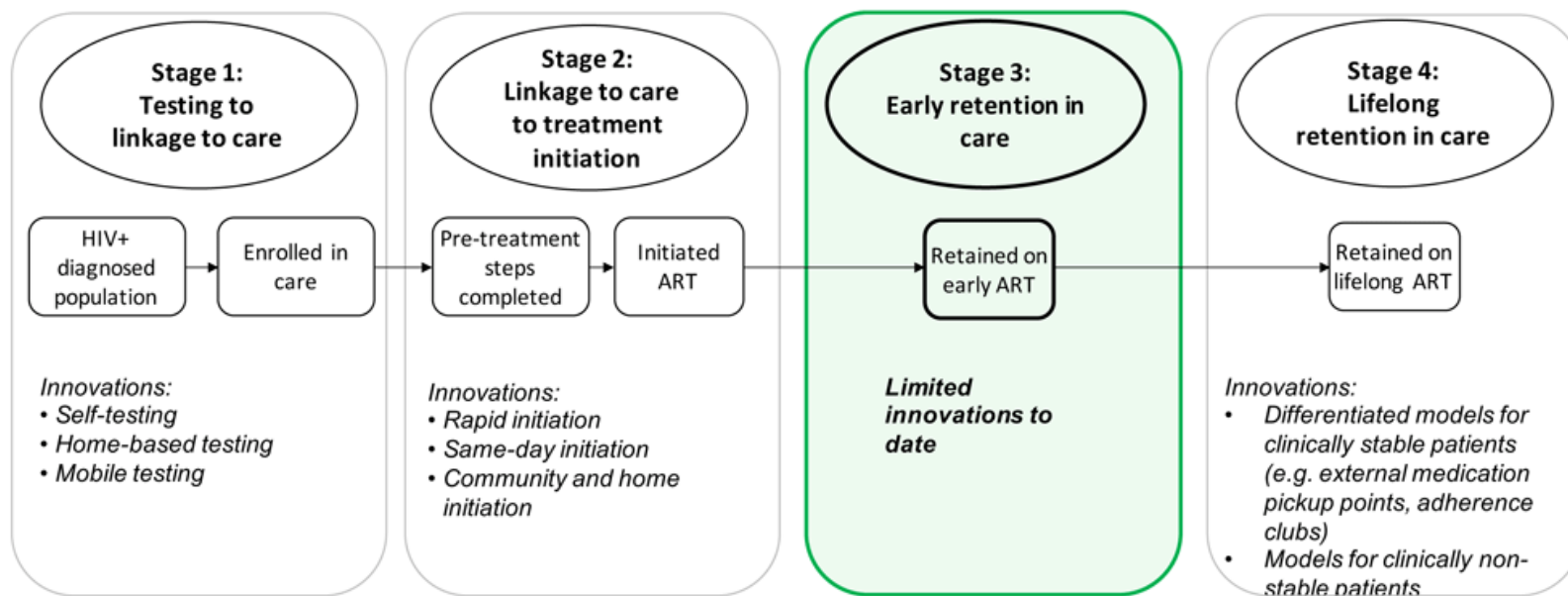
ART was not widely available in SSA until the early 2000s, when the production of generic drugs led to a precipitous drop in ART costs.²⁰ People in SSA accessing ART more than tripled from 7.8 million to 27.4 million from 2010 to 2020.²¹ This global scale-up of ART has averted an estimated nearly 21 million AIDS-related deaths and is considered one of the greatest public health achievements of the 21st century.²²

Despite this progress, approximately 10 million PLHIV globally are still not on ART.⁶ To bring attention to this gap, the Joint United Nations Programme on HIV/AIDS (UNAIDS) set the “95-95-95” targets: by 2025, 95% of PLHIV will know their status, 95% of those diagnosed will be on ART, and 95% of those on ART will be virally suppressed.¹ There is still much ground to cover: in 2022, 86% of PLHIV were aware of their status, 89% of those who were aware were receiving ART, and 93% of those receiving ART were virally suppressed.⁶

Recent technological and policy advances have facilitated diagnosis and treatment uptake among individuals who have never initiated ART. Individuals who are reluctant to visit healthcare facilities can now take HIV tests at convenient and private locations using HIV self-testing (HIVST) kits.²³ Additionally, in the mid-2010s (when Universal Test and Treat (UTT) policies were implemented in SSA), PLHIV became eligible for ART regardless of their CD4 counts, which greatly streamlined the process of initiating ART.²⁴

Despite these advances, there has been little innovation in the early ART retention period (≤ 6 months after (re-)initiation). (Figure 1) This period is associated with high rates of treatment interruption and discontinuation; several studies in South Africa have shown 6-month treatment retention rates of 75–85%.^{25,26} A recent retrospective cohort analysis of 33,821 adults in South Africa (re-)initiating treatment between 2018-2022 found that 70% of clients who disengaged within one year disengaged in the first 6-months.²⁵ Treatment interruption is major public health problem, as it can result in reduced short and long-term reductions CD4 cell-counts,²⁷ increased rates of hospitalizations and progression to advanced HIV disease,²⁸ drug resistance,^{29,30} and increased risk of transmission to sexual partners.³¹ Treatment interruptions can also lead healthcare workers (HCWs) to feel and express frustration and anger toward clients, which in turn increases these clients' reluctance to return to care.²⁸ In sum, treatment interruptions significantly burden both individuals and resource-constrained health systems.

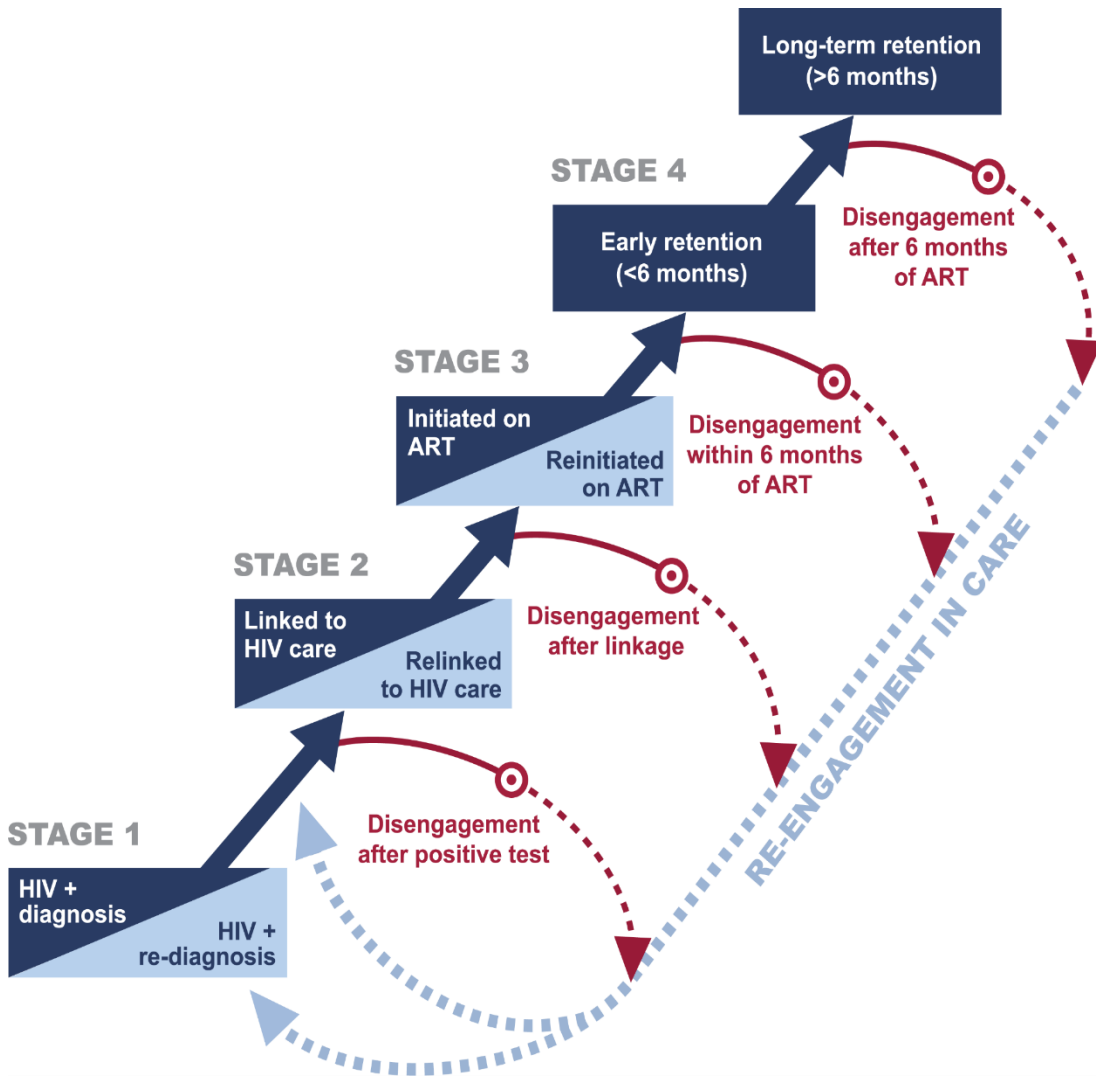
Figure 1. Innovations in service delivery along the HIV treatment cascade



From: Rosen S, Grimsrud A, Ehrenkranz P and Katz I. Models of service delivery for optimizing a patient's first six months on antiretroviral therapy for HIV: an applied research agenda. *Gates Open Res* 2020, 4:116 (doi: 10.12688/gatesopenres.13159.1)

The first 6-months after (re-)starting care is an especially challenging period for clients. Burdensome service delivery models during the early retention period should be reconsidered in the current era now that newer ART medications require fewer substitutions and cause fewer side-effects, and healthy patients (re-)initiating ART may not require frequent follow-up visits.² New and returning ART clients in sub-Saharan Africa have largely been excluded from streamlined differentiated service delivery (DSD) models and are required to make frequent trips to health facilities, which is especially difficult for clients who live far away from facilities or have competing time demands due to poverty.^{2,32} During the early retention period, newly diagnosed clients may be accepting and understanding their HIV diagnosis, disclosing their status to loved ones, and learning how manage their medication and navigate ART clinics.³³ Clients who are re-initiating may be facing the same barriers they faced in the past, leading to a cyclical process of initiating, discontinuing, and reinitiating treatment (Figure 2).³⁴

Figure 2. Cyclical cascade of HIV care



From: Ehrenkranz P, Rosen S, Boulle A, et al. The revolving door of HIV care: Revising the service delivery cascade to achieve the UNAIDS 95-95-95 goals. PLoS Medicine. 2021;18(5):e1003651. doi:10.1371/journal.pmed.1003651

Barriers to ART Initiation and Early Retention among Men

In sub-Saharan Africa, 78% of men living with HIV are on ART, compared with 86% of women.⁶ Men initiating ART are more likely to have advanced HIV disease, to disengage from care, and to die while on treatment.^{35–37} Indeed, a cohort analysis of ART initiates in South Africa found that cumulative mortality over a 12-year period was 33% for men and 19% for women; men were 72% more likely to die during the study period.³⁸ Addressing disparities in treatment engagement is critical for reducing both HIV transmission and mortality.^{39–41}

Men face multi-level barriers to ART initiation and early retention. Men are less familiar with healthcare facilities and fewer opportunities for health education, HIV counseling and testing because they have fewer routine healthcare visits.^{8,42} Additionally, men sometimes feel less comfortable with female HCWs, who comprise the vast majority of staff providing HIV services.^{8,43,44} Compounding these barriers, some HCWs have negative perceptions of men as “bad clients” and perpetrators which can lead to unsupportive or even hostile encounters.^{8,28,43,45,46} Even highly motivated men may delay and/or interrupt treatment due to long wait times and frequent appointments that conflict with work demands and related mobility.^{9,47–49}

A recent qualitative study found that the most common facilitator of ART initiation among men was knowing healthy and productive men in the community who are on ART. The study also found that peer and spousal support were the most common

facilitators for retention, while positive facility experiences supported both initiation and retention.⁴⁹

Until recently, male-specific barriers have been relatively unaddressed in funding and advocacy efforts.^{50,51} However, several initiatives have brought attention to the issue, including a 2017 UNAIDS report, the formation of the “Global Men and HIV Technical Working Group” (MENHT) jointly chaired by WHO and UNAIDS, and MenStar, a joint PEPFAR/private foundation initiative.^{52–54}

Country Profile: HIV Treatment in Malawi

Malawi is a small, landlocked country in southeast Africa with a young, rapidly growing population of about 20 million people.⁵⁵ Malawi has one of the lowest GDPs per capita in the world⁵⁶ and its predominantly rural population (82%) and agriculture-based economy is particularly vulnerable to natural disasters.⁵⁷ According to the 2019 Integrated Household Survey (IHS), poverty is most severe in rural areas, where 57% of the population lives below the Government of Malawi’s poverty line, compared with 19% in urban areas. Poverty and the level of completed education are strongly associated; 71% of households headed by someone who never attended school are living in poverty, compared with 14% of those headed by a graduate of secondary education.⁵⁸

Malawi’s healthcare system, managed by the Ministry of Health (MoH), is organized into primary, secondary, and tertiary care. Primary healthcare, including treatment for

common illnesses such as HIV, is provided by health centers and clinics. Secondary healthcare (surgery and specialized care) is provided by 26 district hospitals. Complex tertiary care is only offered at four hospitals, all in urban areas.⁵⁹

Malawi's healthcare system faces severe resource constraints. According to the World Health Organization, Malawi is among 57 countries confronting a "critical shortage" of health workers⁶¹ — its healthcare workforce vacancy rate is 51%.⁶⁰ In rural areas there are only 0.7 healthcare workers per 1,000 people compared with 1.8 per 1,000 in urban areas.^{61,62} Trained mental health workers are especially scarce; consequently, interventions to improve mental health access often use a task shifting strategy.⁶³

Providers and staff face heavy workloads, leading to burnout, long patient wait times, and short, hurried appointments.⁶⁴ Another challenge is a lack of infrastructure and equipment. According to the Harmonized Health Facility Assessment (HHFA), on average, facilities only have 38% of the essential medicines in stock at any given time and only 31% of the recommended facility density.⁶⁵ This lack of facility density leads to long travel times for patients, especially in rural areas.⁶² Most households do not own bicycles or motorized transport and it is common for the nearest facility to be more than a four hour round-trip walk from patients' homes.^{42,62}

Currently, nearly one million people are living with HIV in Malawi: 62% are women, 38% are men, and 5% are children under 15 years old.⁶⁶ Malawi has made remarkable progress combatting the HIV epidemic despite its health system challenges. HIV/AIDS

deaths have decreased by 86% from their peak of 81,000 in 2004¹⁵ and viral suppression among all PLHIV has increased from 39% in 2012 to 85% in 2021.⁶⁶ Still, HIV/AIDS is the leading cause of death in Malawi, accounting for approximately 12% of deaths in 2019.¹⁵ HIV prevalence varies across regions; among adults ages 15-49, HIV prevalence is higher in the southern region of Malawi (10.3%) than the northern (5.8%) and central (4.9%) regions, and nearly twice as prevalent in urban areas (14.6%) as in rural areas (7.4%).^{67,68}

Men in Malawi have lower rates of engagement across the HIV treatment continuum. Ninety-eight percent of women living with HIV are on ART compared with 83% of men, and 92% of women are virally suppressed compared with 78% of men.⁶⁶ While data on early retention in care for Malawian men is not available, a cohort study of pregnant women in Malawi showed that 2/3 of loss-to-follow-up in the first year occurred in the first 6 months of care.⁶⁹ It is likely that a similar pattern exists among men.²⁵

Of the 754 sites offering ART across the country, 63% are public facilities, 13% are private sector facilities, 19% are faith-based NGOs, and 5% are non-faith-based NGOs.⁶⁹ Only private sector clinics charge a fee for ART.⁶⁹ As Malawi nears the UNAIDS 90-90-90 goals,⁷⁰ it is shifting from a strategy of widespread HIV testing to a focus on vulnerable and harder-to-reach populations.⁶² Malawi has implemented several differentiated service delivery models for stable patients to improve long-term ART retention. Multi-month dispensing is a common practice, with 93% of patients receiving

at least 3 months dispensation.⁶⁹ However, there are few interventions to re-engage individuals in care.

Malawi's HIV program is vulnerable to changes in international donor funding, the source of more than 97% of its expenditures.⁷¹ While levels of donor funding have stayed fairly stable over the past decade,⁷¹ future funding is uncertain,⁷² and the Malawian budget has limited capacity to cover any reductions.⁷³

Summary

Antiretroviral therapy (ART) has improved and saved millions of lives over the past decades. However, ART initiation and retention lag among men in sub-Saharan Africa, leading to losses in life expectancy and continued transmission of the virus.^{4,5} Men face multi-level barriers to (re-)engaging in care, including negative healthcare worker perceptions and the costs of transport and lost wages.^{4,7,8} Recent innovations have reduced barriers to testing and initiation, increasing the importance of early retention in care (<6 months) in the path toward long-term care engagement.

CHAPTER 3: LITERATURE REVIEW

This literature review identifies research on interventions to increase ART initiation and early retention rates among men in SSA under UTT and describes their effectiveness and cost-effectiveness. This literature review also describes gaps in the current evidence base across 1) populations represented, 2) methodological approaches used, and 3) outcome measurements. It concludes with a summary of gaps in the literature. This review informed the list of intervention options discussed with stakeholders in the Objective 1 qualitative in-depth interviews and provided context for the decision-making framework developed in Objective 3.

ART Initiation and Early Retention Interventions for Men in SSA

Most research on ART initiation and early retention has focused on either women or the general population,^{74,75} and has found that several interventions may be effective. These include home- or community-based ART distribution to improve access to care,⁷⁶⁻⁷⁹ intensive, peer-based counseling to help clients navigate intra- and inter-personal barriers to care,^{80,81} and same-day ART initiation to streamline initiation.^{26,82} While this evidence is promising, it is not known whether these strategies work for men. Further, most of these studies were implemented prior to UTT, which dramatically changed the process of and populations participating in ART initiation.

Interventions were included in this review if they: 1) were conducted under UTT policies (which started for most countries in SSA in 2016); 2) included quantitative data related to ART initiation or re-initiation and/or early retention for males (< nine months after initiation); 3) reported findings for the general adult male population (i.e. not special populations); 4) had a sample of at least 30 men; 5) had a study site located in SSA (using the United Nations sub-regions of Africa); and 6) had a manuscript or abstract available in English. We searched multiple databases (PubMed, Medline, Cochrane Central Register of Controlled Trials, and the CABI Global Health) and conference abstracts for the poster and oral presentations from the Conferences on Retroviruses and Opportunistic Infections (CROI) and the International AIDS Society (IAS). We also searched Google Scholar to identify additional gray literature.

Interventions Identified

Overall, 15 data sources met all eligibility criteria. One data source⁸³ reported on two different interventions that met the eligibility criteria, therefore we included 16 interventions in the data synthesis. We identified and categorized the interventions into five types as follows: facility-based services (n=3); community-based services (n=4); outreach (n=4); counseling/peer support (n=3); and conditional incentives (n=2) (Table 1).

Table 1. Description of intervention types*

Intervention Type	Definition (examples)	n (%)
Facility-based services	Interventions that primarily focused on changes to protocols or services within facilities.	3 (19%)
Community-based services	ART dispensed outside the health facility	4 (25%)
Outreach	Community-based activities to identify those in need of ART services and/or to promote linkage to a health facility	4 (25%)
Counseling/peer support	Ongoing, intensive counseling to identify and resolve barriers to care	3 (19%)
Conditional incentives	At least one opportunity to receive monetary/non-monetary incentives conditional on one's engagement in ART services	2 (13%)

**Details of each study to follow in Table 2.*

Settings and Populations of Interventions with Male-Specific Data

All but one (15/16, 94%) of the interventions took place in southern and eastern Africa, with one intervention in Western Africa.⁸⁴ Almost half (7/16, 44%) of interventions were among rural populations, a quarter (4/16, 25%) among urban populations and almost a third (5/16, 31%) included both urban and rural populations (Table 2).

Only two interventions (13%) focused exclusively on men. The rest included both men and women. The number of men participating in each intervention ranged from 33 to 3,010 (Table 3). None of the studies specified sexual orientation or whether participants were cis- or transgender.

Most interventions (14/16, 87%) enrolled individuals who were not currently on ART (four only enrolled newly diagnosed clients and 10 enrolled both newly diagnosed and re-initiating clients). No interventions disaggregated findings by ART status (initiating v. re-initiating treatment) at the time of enrollment. One intervention (6%) targeted individuals who had previously declined ART when offered a lighter-touch intervention (community HCT and facility escort, or a USD \$5 transport incentive). Two interventions (13%) enrolled individuals who were actively on ART at the time of enrollment and focused only on early retention.

Table 2. Studies included in literature review, by intervention type

Study	Study design	Study Year, Country	Population	Setting	Comparison (C)	Intervention
Facility-based services						
Ahmed, 2020	Retrospective Cohort	2016-2018, Ethiopia	Men and women	Rural	Initiated ART >7 days after diagnosis	Same day ART initiation after diagnosis in facility
Rosen, 2019	RCT	2017-2018, South Africa & Kenya	Men and women	Urban	ART initiation within 2 weeks	Clinical algorithm for same-day ART initiation in facilities
Maskew, 2020	RCT	2018, South Africa	Men and women	Urban	ART initiation within 2 weeks	Clinical algorithm for same-day ART initiation in facilities
Community-based Services						
Labhardt, 2018	RCT	2016-2017, Lesotho	Men and women	Rural	HBHCT and referral to nearest facility	C + Same-day home based initiation with 30-day supply of ART
Katbi, 2019	Uncontrolled Trial	2015, Nigeria	Men and women who declined ART	Rural	N/A	Individual and group adherence counseling, home based initiation with 30-day supply of ART, weekly phone calls from physicians
Mwango, 2020	Uncontrolled Trial	2018-2019, Zambia	Men and women	Urban, Rural	N/A	Community and male-specific (e.g. school, worksite, home) HCT outreach and education + on-site ART initiation or facility escort and ongoing peer-counseling
Maina, 2019	Uncontrolled Trial	2016, South Africa	Male and Female Farmworkers	Rural	N/A	Home and mobile HIV/TB testing + on-site ART initiation

Outreach						
Grasso, 2021	Uncontrolled Trial	2017, Namibia	Men and women	Urban, Rural	N/A	Facilitated facility linkage by CHWs (after home testing)
Choi, 2020	Uncontrolled Trial	2018, South Africa	Men and women at local bars	Rural	N/A	Male CHWs outside shebeens (alcohol venues) conducted HIV screening, rapid testing, counseling, and facilitated linkage and/or transportation to facility for ART initiation.
Mwango, 2020	Uncontrolled Trial	2018-2019, Zambia	Men and women	Urban, Rural	N/A	Index testing services in home + facility escort. Follow-up home visit if individual did not initiate ART.
Baisley, 2019	Uncontrolled Trial	2017, South Africa	Men and women	Rural	N/A	Home-based HCT + facility linkage, SMS after 2 weeks, and nurse call after 2 more weeks if not initiated.
Counseling/Peer Support						
MacKellar, 2018	Uncontrolled Trial	2014-2017, Tanzania	Men and women	Urban, Rural	N/A	Facility escort, treatment navigation, weekly support calls, 5 peer-delivered counseling sessions, and 2 in-person visits for HIV testing of partners and family members over a 90-day period.
MacKellar, 2021	Uncontrolled Trial	2015-2018, Eswatini	Men and women	Urban, Rural	N/A	Mobile HCT + facility escort and treatment navigation, weekly telephone support and appointment reminder calls, 5 peer-delivered counseling sessions, and 2 in-person visits for HIV testing of partners and family members over a 90-day period.
Hlongwa, 2022	Uncontrolled Trial	2020, South Africa	Men	Urban	N/A	At least monthly individual HIV counseling sessions with male peer counselors. Tailored services included facility escort, treatment navigation, case-management, and assisted disclosure to partners and family members over 6 months

Incentives						
Fahey, 2020	RCT	2018, Tanzania	Men and women	Urban	Standard of care	C + 6 conditional monthly incentives of \$4.50 for clinic attendance C + 6 conditional monthly incentives of \$10.00 for clinic attendance
Barnabas, 2020	RCT	2017-2018, South Africa	Men with phones	Rural	Motivational text messages	C + 3 conditional lottery incentives (phone, data, \$100 gift card) for clinic registration, ART initiation, and viral suppression at 1, 3, and 6 months

Table 3. Study results, by intervention type

Study	# Males living with HIV (Total)	ART Status	Intervention	Initiation-related outcomes			Early retention-related outcomes		
				Outcome Definition (Time Frame)	Inter-vention	Compar-ison	Outcome Definition (Time Frame)	Inter-vention	Compar-ison
Facility-based Services									
Ahmed, 2020	468 (988)	Newly diagnosed	Same-day ART initiation				<30 days late for clinic visit (6 months)	77%	88%
Rosen, 2019	422 (1077)	Not on ART	Algorithm for same-day initiation (excluding TB symptoms)	ART initiation (1 month)	85%*	74%	Clinic visit (5-8 months)	51%	54%
Maskew, 2020	220 (593)	Not on ART	Algorithm for same-day initiation (allowing TB symptoms)	ART initiation (1 month)	90%*	66%	Clinic visit (5-8 months)	76%*	63%
Community-based Services									
Labhardt, 2018	47 (137)	Not on ART	Home-based HCT + ART initiation	Linkage-to-care (3 months)	66%*	34%			
Katbi, 2019	239 (541)	Previously declined ART	Home-based ART initiation with ongoing support	ART initiation + 4-week facility visit	58%				
Mwango, 2020	2272 (5714)	Newly diagnosed	Community-based HCT + ART initiation + ongoing peer support	Linkage-to-care	97%				
Maina, 2019	2519 (3415)	Newly diagnosed	Home- and mobile-based HCT + ART initiation	ART initiation	92%				
Outreach									

Grasso, 2021	206 (510)	Not on ART	Home-based HCT + follow-up visits	ART initiation	94%				
Choi, 2019	33 (48) ^a	Not on ART	Community-based HCT + facility escort	ART initiation	45%				
Mwango, 2020	2186 (5260)	Newly diagnosed	Home-based ICT + facility escort + follow-up visit	Linkage-to-care	88%				
Baisley, 2019	120 [†] (427)	Newly diagnosed	Home-based HCT + SMS + phone follow-up	ART initiation (6 months)	27% ^b				
Counseling/Peer Support									
MacKellar, 2018 ^b	310 (752)	Not on ART	Peer-counseling + case management	ART initiation (3 months)	85%				
MacKellar, 2021 ^b	438 (824)	Not on ART	Mobile HCT + peer-counseling + case management	ART initiation (1 month)	96%				
Hlongwa, 2022	3010 (3010)	Not on ART	Peer-counseling + case management				Retained in care	95%	
Conditional Incentives									
Fahey, 2020 ^c	200 (330)	Initiated or re-initiated ART in past 30 days	Conditional incentives of 4.50 USD (6 total)				Retained in care (6 months)	88%	84%
			Conditional incentives of 10.00 USD (6 total)				Retained in care (6 months)	91%*	84%
Barnabas, 2020	131 (131)	Not on ART	3 Conditional non-monetary lottery incentives	ART initiation (6 months)	93%	76%	Viral suppression (6 months)	66%	59%

Associated information (e.g., published study protocols, data from authors) were consulted if insufficient detail was provided in the publication itself.

*Significant at $p \leq 0.05$

^a Calculated using information in the publication

^b Post-universal treatment data only

^c Results include both men and women, article methods or results stated that there were no significant differences in outcomes by sex.

Study Designs

Of the 16 interventions, five (31%) were randomized clinical trials (RCTs), one (6%) was a retrospective cohort study, and 10 (63%) did not have comparison groups. Study design varied by intervention type: all the facility-based service and conditional incentive interventions were RCTs or retrospective cohort studies, whereas generally the peer support, outreach and community-based services interventions did not have comparison groups.

ART Initiation and Early Retention Measures

Overall, 13/16 (81%) of the interventions measured ART initiation and 6/16 (37%) measured early retention. Across all interventions, ART initiation rates ranged from 27-97% and early retention rates from 47-95%.

Measurement of outcomes varied substantially across interventions. Nearly half (7/16, 44%) of the interventions had unspecified time frames. Of the thirteen studies measuring treatment (re-)engagement, the most frequent measure was ART initiation (8/13, 62%), followed by linkage-to-care (3/13, 23%), and completion of a four-week refill appointment (1/13%, 8%). One study (1/13%, 8%) did not measure (re-)engagement and two (2/13, 16%) studied individuals who had recently initiated ART. Initiation measurement periods ranged from same day to six months. Of the six studies measuring early retention in care, 5/6 (84%) measured visit attendance and one measured viral suppression. The time period for early retention measures ranged from approximately

five-eight months after initiation.

All studies examining incentive- and facility-based interventions had specified time frames and included early retention outcomes, while none of the studies examining outreach and community-based services did.

Description of Interventions

Facility-based interventions focused exclusively on same-day ART initiation (n=3). One retrospective cohort study examined early retention rates among individuals who initiated ART on the same day compared to those who did not, under the same care guidelines.⁸⁵ Two RCTs examined the impact of clinical algorithms (i.e., screening tools) to facilitate same-day ART initiation among clinically-eligible clients.^{86,87}

All community-based ART interventions (n=4) provided immediate ART initiation and counseling in community, home, and/or work settings.^{83,84,88,89} Two of these interventions provided ongoing monitoring and counseling to encourage adherence after initiation, while two provided single counseling services at initiation.

Outreach interventions offered in-person or phone-based reminders to attend facility visits (n=4),^{83,90-92} escorted clients to the facility for initiation (n=2),^{83,91} or provided transportation to facilities (n=1).⁹¹ One small outreach study was tailored for men; male

CHWs were stationed outside alcohol venues and offered patrons HIV counseling and testing (HCT) and escort to a facility if desired.⁹¹

All peer-based support/counseling interventions (n=3) included ongoing (ranging from 90-180 days) counseling from peers living with HIV, usually at clients' home or other private community-based locations.⁹³⁻⁹⁵ Duration and location of counseling were based on client preferences and needs. One peer support study was tailored for men and delivered by male peers living with HIV.⁹⁶

Two RCTs assessed the impact of conditional incentives.^{97,98} One study offered fixed monetary incentives (\$4.50 USD or \$10 USD) for each monthly clinic visit to individuals who had initiated or re-initiated ART in the past 30 days;⁹⁷ the other offered lottery non-monetary incentives (mobile phone, data, or a US \$100 gift card) for clinic registration, ART initiation, and/or viral suppression.⁹⁸

Economic Evaluations of Interventions

One community-based peer support study studied intervention costs.⁹⁴ This program cost \$44 USD per client served, and would have cost \$18 if offered in the facility instead of in the community.⁹⁴ The incremental cost-effectiveness of this program on ART initiation is unknown, as this study did not have a comparison group.

Summary

Despite years of evidence of men's suboptimal ART outcomes, research on effective interventions studying initiation and early retention for men in SSA remains scarce. We identified only 16 eligible interventions that included sex-disaggregated data. Most interventions did not have a comparison group and outcome measures were inconsistent.

Despite the limited research available, this review provides some insight into what works for men. Studies with control groups provided evidence that same-day facility ART initiation increased ART initiation but were inconclusive for early retention, suggesting that same-day initiation alone may not be sufficient to increase men's retention in care.^{85–}

⁸⁷ Interventions offering incentives showed mixed findings. One community-based care study with a comparison group showed that home-based ART initiation improves initiation rates, but it did not measure retention.⁸⁸ The rest of the studies did not have comparison groups. However, peer support interventions showed promise with high rates of initiation and early retention.^{93–95}

Numerous studies had weak study designs and methodology. Only five randomized controlled trials were identified. Most of the included studies did not include a comparison group, limiting their generalizability and replicability. Additional methodological weaknesses, including inconsistent outcome definitions and timeframes, made it difficult to draw conclusions across studies of similar interventions. There is an especially urgent need for studies measuring early retention among men who recently

started or re-started ART -- only six interventions included early retention outcomes, and findings were largely inconclusive. Only one study measured intervention costs, leaving great uncertainty about the costs and costs-effectiveness of initiation and early retention interventions for men in SSA.

Future research should disaggregate findings by sex, as men may respond differently to interventions than women given their unique facilitators and barriers to care engagement. A recent systematic review on interventions in SSA to improve long-term retention among men who are stable on treatment identified only 14 studies with sex-disaggregated data published between 2005-2019, with none exclusively targeting heterosexual men.⁷⁶ Interventions that are tailored for men could provide convenient and accessible services to accommodate work-related travel and time constraints, offer opportunities to interact with male healthcare workers and peers living with HIV, and connect successful treatment outcomes with the ability to provide for their families.^{49,99,100} To improve men's ART outcomes, a wide variety of interventions should be evaluated. None of the included interventions examined the impact of structural changes to the health system, such as integrating HIV with non-HIV care, receiving care from male health care workers, extended hours, or male-only clinics. In addition, only two interventions included an mHealth component.^{92,98} Recent literature shows that access to smartphones and other technology is rapidly increasing among individuals in SSA¹⁰¹ and mHealth may be a key strategy for young and mobile male populations who cannot be reached through other approaches.^{102,103} Finally, none of the interventions included traditional health

practitioners or religious leaders – groups who could potentially reach men who are out of care.^{104,105}

Conclusion:

Awareness of and focus on men's lower levels of ART engagement is increasing. Yet little is known about what types of interventions are effective or cost-effective for men who are not engaged in care. This knowledge gap requires urgent attention so that programmatic interventions can be informed by rigorous, decision-relevant evidence specific to men in the region.

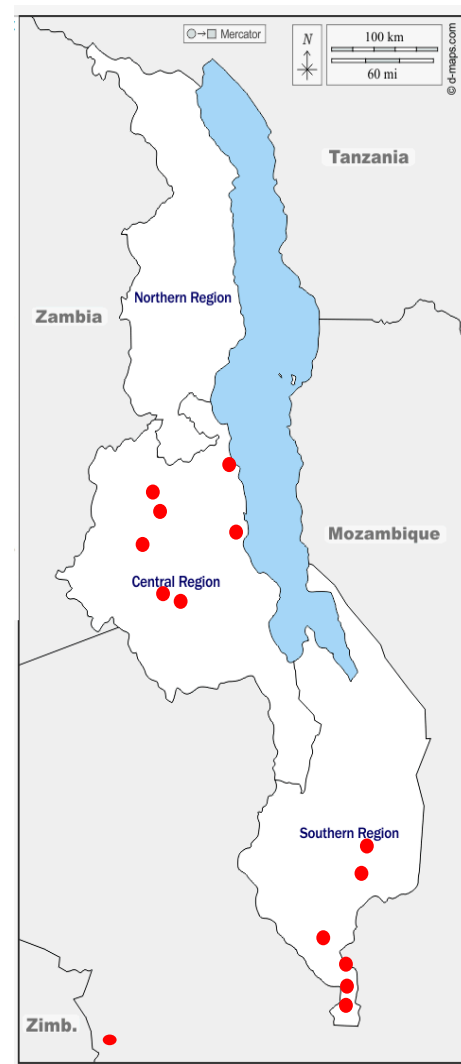
CHAPTER 4: IDEAL TRIAL AND DISSERTATION OVERVIEW

This chapter describes the Identifying Efficient Linkage Strategies (IDEaL) randomized controlled trial, which tested the impact of three male-specific interventions on ART (re-) initiation and six-month retention among men in Malawi who were aware of their HIV status but not engaged in care.¹⁰⁶ The study population, interventions, and outcomes are described below. This chapter concludes with an overview of this dissertation's overall aim, three objectives, and theoretical framework.

IDEaL Trial Description

IDEaL trial participants were recruited from 24 health facilities in Malawi (Figure 3). These facilities varied by level (hospital/health center), management (government/NGO), location (rural/urban), and region (central/southern Malawi). Participants were identified through medical chart reviews and in-person recruitment at facilities. Eligibility criteria included: 1) male sex 2) ≥ 15 years of age, 2) living in facility catchment area, and 3) tested HIV-positive and a) did not initiate ART within 7-days of testing, b) initiated ART but were ≥ 7 -days late for their 30-day ART

Figure 3. IDEaL study sites



refill appointment or c) initiated ART and attended their first refill appointment but were ≥ 28 -days late to care.

Interventions

Three interventions were compared in the trial: 1) a low-intensity intervention (male-specific counseling and facility navigation), 2) a high-intensity intervention (male-specific counseling, outside-facility ART initiation, and facility navigation for the first facility refill visit), and 3) a stepped intervention that grew more intensive over time. In all three arms, men who did not (re-)initiate ART were contacted for up to three months. All HCWs employed by the study were male, and counseling interactions were tailored to male-specific concerns and motivations regarding HIV and treatment. (Figure 4)

The IDEaL trial did not have a standard of care (SOC) arm but another recent RCT in Malawi, the Engaging Men through HIV Self-testing with Differentiated Care (ENGAGE) trial, did.¹⁰⁷ The ENGAGE trial ran concurrently to the IDEaL trial and had the same eligibility criteria, but was implemented in different clinics so its findings are not directly comparable with IDEaL's, but it can serve as a useful reference point.

Arm 1: Low-Intensity

Participants were traced in the community and received one-on-one intensive counseling in the community by a lay cadre counselor (called a Patient Supporter in Malawi).

Patient supporters offered participants facility escort and navigation at the health facility of their choice. Men who refused facility-based ART initiation were offered up to three additional counseling sessions (by phone or in person) over a period of six weeks until they engaged in care or informed the patient supporter that they no longer wished to be contacted.

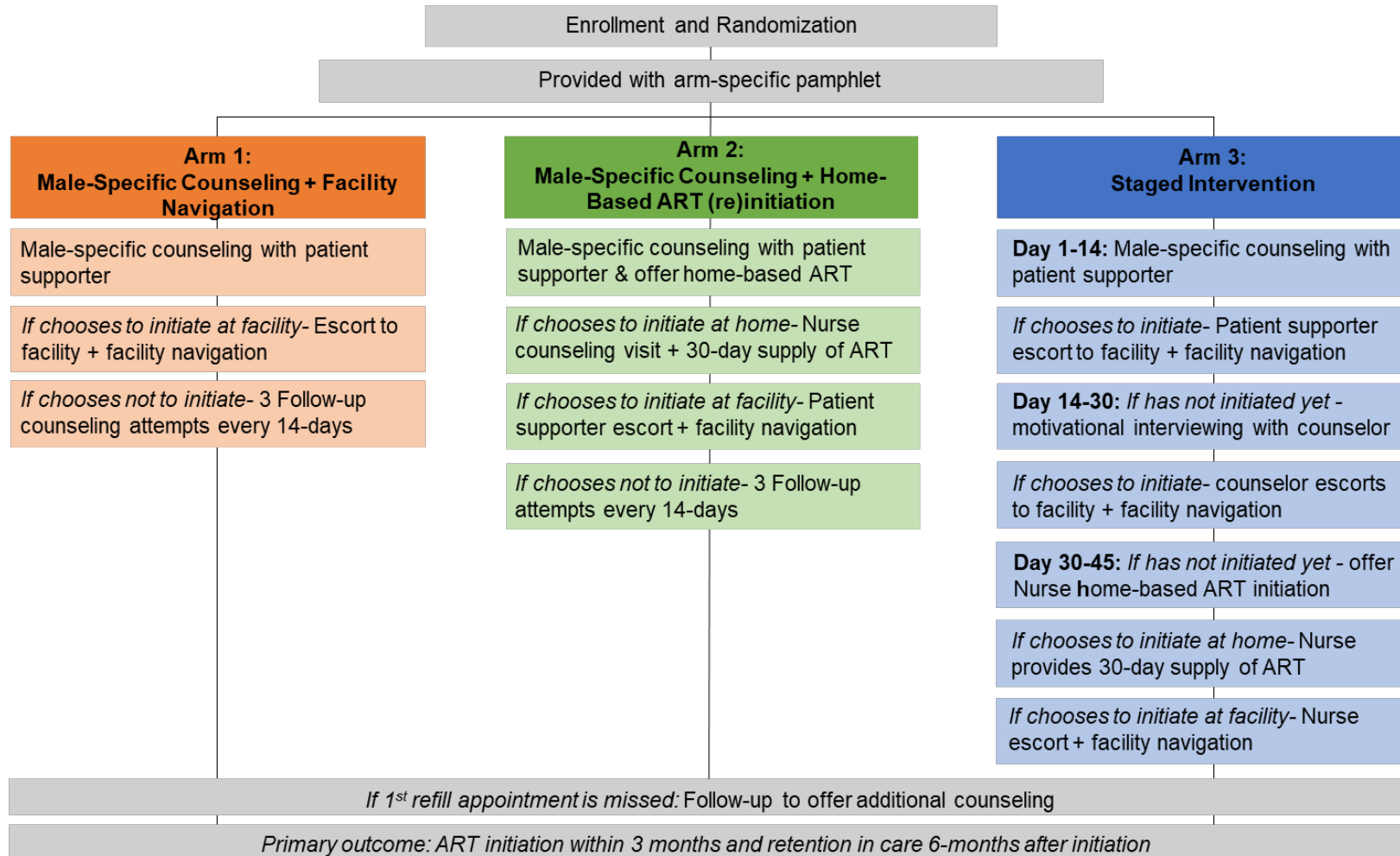
Arm 2: High-Intensity

In the high-intensity arm, men were first offered a single counseling session with a patient supporter (as described in Arm 1 above). At the end of the session, they were offered home or community-based ART initiation with a male study nurse. If they accepted, the patient supporter contacted a study nurse and the nurse attempted to schedule an appointment with the participant. If they refused, the patient supporter offered to meet them at the facility for initiation and navigation. If a man was not ready for ART initiation, the patient supporter followed-up up to three times, offering the option of either facility- or home-based initiation. Men who met with the nurse received client-centered counseling and WHO staging. Those classified as WHO Stage 3 or 4 were not eligible for outside-facility ART and were offered facility escort and/or navigation with the nurse (either the same day or another day) at a nearby health facility. Men classified as WHO Stage 1 or 2 were offered ART on the spot. If the man

refused ART, the nurse continued to follow-up to offer a home/community-based visit to initiate ART for up to 6 weeks.

Men who received home-based nurse ART initiation received facility navigation with the nurse at the 4-week ART refill appointment and, when possible, the nurse served as the ART provider for this appointment. In rare cases, nurses provided men with a home-based 4-week ART refill.

Figure 4. Services offered in IDEaL interventions until participants initiate ART.



Adapted from: Dovel K, Balakasi K, Hubbard J, et al. Identifying efficient linkage strategies for men (IDEaL): a study protocol for an individually randomised control trial. *BMJ Open*. 2023;13(7):e070896. doi:10.1136/bmjopen-2022-070896

Arm 3: Stepped Arm

In the stepped arm, participants were offered a more intensive intervention every 2 weeks until they initiated ART. Each step is described below:

- *Step 1 (male-specific counseling + facility navigation)*: Participants first received the services described in Arm 1 above: a counseling session in the community or home with a patient supporter and facility escort and navigation. If participants did not initiate ART at the facility within two weeks, patient supporters offered them counseling with a male mentor (psychosocial counselor).
- *Step 2 (motivational interviewing)*: The male mentor then reached out the participants to schedule a time to meet in the community. The mentor provided ongoing, one-on-one in-depth counseling, motivational interviewing, and “check-ins” as often as preferred by the participant during a two-week period.

Participants were offered facility escort and navigation with the mentor for the initiation visit, and the mentor also attempted to meet participants at the facility to support during their 4-week refill appointment as well.
- *Step 3 (outside-facility ART initiation)*: If a man did not initiate after two-weeks of interactions with the male mentor, the mentor offered the option of home- or community-based ART initiation with a male nurse (described in Arm 2 above). The mentor made an appointment for the nurse visit and shared the participants’ contact information with the nurse, who would then make three attempts to offer home-based ART initiation.

Outcomes

The study's primary outcome was the proportion of men retained in HIV care 6-months after initiation. A successful outcome was defined as initiating ART within 90 days of enrollment and being ≤ 28 -days late for the scheduled ART appointment 6-months after initiation. The secondary outcome was ART initiation -- defined as completing the initiation visit at the facility or at home within 90 days of enrollment. These outcomes were assessed through medical chart reviews. Individuals without a medical chart outcome were traced in person, and their health passport (a pocket medical record where providers record data during health visits) was reviewed to collect the ART outcome. The study used an intention to treat approach: men who died or were lost to follow-up were counted as not achieving study outcomes.

Additionally, a baseline survey at enrollment included questions on demographics and previous engagement with health services. Follow-up surveys (2- and 4-months after enrollment) measured exposure to and acceptability of the interventions, changes in demographics since enrollment, adverse events, and several other topics.

Dissertation Overview and Objectives

The primary aim of this dissertation was to provide stakeholders in Malawi with a structured framework to help inform decisions to adopt and scale interventions to improve ART initiation and early retention rates among men. The decision-making framework includes analysis of the effectiveness, cost-effectiveness, and suitability of

these interventions in the Malawian context. Specifically, the dissertation's objectives are to:

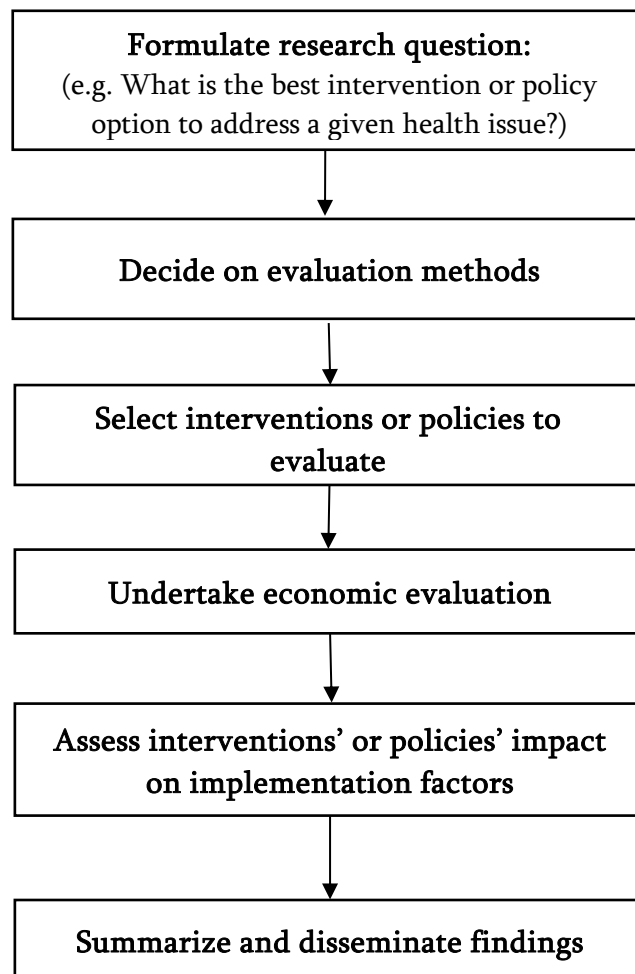
- *Objective 1:* Explore the perspectives and priorities of stakeholders regarding ART initiation and early retention interventions for men, focusing on their decision-making criteria, preferred interventions, and perceptions of the barriers and facilitators to scaling-up potential interventions.
- *Objective 2:* Assess the costs and incremental cost-effectiveness of the ART initiation and early retention interventions deployed in the IDEaL randomized controlled trial and analyze the costs of participants' first 6-months of HIV care.
- *Objective 3:* Develop a decision-making framework and recommendations for national scale-up of these interventions, based on the results from Objectives 1 & 2 and IDEaL trial data on implementation factors (e.g., acceptability, feasibility, equity).

Theoretical Framework

We chose the Assessing Cost-Effectiveness (ACE) approach to priority setting as the theoretical framework for this study because it emphasizes rigorous economic evaluation, stakeholder engagement, and incorporation of a broad range of considerations that influence successful policy or program adoption.¹⁰⁸ The ACE approach is based on principles from economic theory, ethics, and social justice and builds upon other priority setting approaches.¹⁰⁸

The ACE approach begins with a research question to identify the best policy or intervention options to address a health issue. The evaluation team agrees on study methods and selects the interventions or policies to evaluate. The team completes an economic analysis of each option and considers the impact of each option on implementation factors such as equity and sustainability.^{108,109} Finally, the team summarizes the main challenges associated with each intervention or policy option and identifies strategies to ameliorate or address them, for example, by redesigning or piloting interventions (Figure 1).¹⁰⁸ The evaluation team seeks stakeholder input throughout the study to ground the evaluation in due process.

Figure 5. Overview of the Assessing Cost–Effectiveness (ACE) approach



Adapted from: Carter R, et.al., Priority setting in health: origins, description, and application of the Australian Assessing Cost-Effectiveness initiative. Expert Rev Pharmacoecon Outcomes Res. 2008;8(6):593-617. doi:10.1586/14737167.8.6.593

The ACE framework typically uses published data to model and compare the cost-effectiveness of different intervention or policy options,^{109,110} but we are able to compare interventions tested in the same RCT using primary data from the trial and feedback from the trial's implementation team.

CHAPTER 5: STAKEHOLDER PERSPECTIVES AND PRIORITIES

Stakeholder input can improve intervention design, translation, adoption, and scale-up of successful strategies. However, stakeholder perceptions are not systematically explored, and multi-level stakeholders are often not consulted.¹¹¹⁻¹¹⁴ A deeper understanding of stakeholders' priorities and constraints can also help researchers offer decision-relevant information, such as data on expected costs and outcomes for different implementation and scale-up scenarios.^{115,116}

To our knowledge, no published literature on stakeholder perceptions of interventions for new or returning ART clients or men in sub-Saharan Africa exists. We explored qualitatively stakeholder perceptions of interventions for this population and decision-making criteria for adopting interventions. We compared the views of internationally based and Malawi-based stakeholders. Malawi was an ideal study setting as it has been in the vanguard of innovative public health strategies in the region (such as Option B+ and HIV self-testing) despite its highly resource-constrained health system.¹¹⁷⁻¹²⁰

Methods

In Objective 1, we conducted in-depth interviews with international stakeholders (foundations, multilateral organizations, and NGOs) and Malawi-based stakeholders (Ministry of Health and local implementing partners) to explore stakeholder perspectives and priorities regarding interventions targeting new or returning ART clients. We

compared the perspectives of international and Malawi-based stakeholders. We integrated the findings from this study into the decision-making framework and recommendations in Objective 3.

Data Collection

We aimed to recruit policy and programmatic stakeholders who were experts on DSDs and/or retention in care for new or returning ART clients. We sampled purposively to represent different organizations, including international foundations, multilateral organizations, non-governmental organizations (NGOs), the Malawi Ministry of Health (MoH) and local implementing partners within Malawi. Though clients and community-based organizations are important stakeholders, they were not included in the sample as this study focuses on policy and guidelines decision-making.

We identified twenty-nine potential participants through internet searches and the research team's professional networks. We added eight additional contacts through snowball sampling. Each invited stakeholder received two direct outreach attempts by email. We continued recruitment until we reached saturation of themes within the interviews.¹²¹ We sampled similar numbers from international and national stakeholder categories intentionally to enable comparison between the two groups. We developed an interview guide based on the ACE framework as well as literature on interventions to improve engagement in care among new or returning ART clients in sub-Saharan Africa.^{122,123} The interview guide included open-ended questions about

stakeholders' HIV-related priorities, perceptions of factors influencing non-initiation or attrition immediately following initiation, challenges and solutions for financing and implementing relevant interventions, and desired data to inform decision-making. Probes related to challenges and interventions specific to men were included.

Stakeholders also completed two interactive tasks. First, they rated five scale-up decision-making criteria commonly used in the Assessing Cost-Effectiveness (ACE) approach (cost, effectiveness, equity, feasibility, acceptability) as “lower,” “moderate” or “high” priority. We encouraged them to rate no more than three criteria as high priority, and at least one as lower priority. We asked stakeholders to verbalize their thoughts as they completed the task, following the “think-aloud” method,¹²⁴ for qualitative research. After the task was complete, we offered participants the option to rate any additional decision-making criteria and engaged them in retrospective reflection about the activity and reasons for their ratings.

Following the same format as the previous task, stakeholders rated the relative priority of seven ART initiation and early retention interventions. Options included monetary incentives, non-monetary incentives, community-based care, ongoing peer/mentor support and counseling, eHealth, facility changes, and multi-month dispensing, as well as an open-ended category for other interventions of interest. To construct an average rating of each intervention, we assigned each high-priority rating ten points, each moderate-priority rating 5 points, and each lower-priority rating 0 points.¹²⁵

We conducted two pilot interviews to refine and finalize the data collection tool (Appendix 1). Two researchers conducted each interview in English via video conference. We requested verbal consent and collected information on employment position, years of experience in the HIV field, and gender. We recorded the interviews and transcribed them verbatim.

Data Analysis

We developed a codebook using a priori codes informed by the existing literature and the theoretical framework,¹⁰⁸ as well as inductive codes based on emergent themes.¹²⁶ Using Atlas.ti v9,¹²⁷ two researchers (KP and KH) piloted the codebook with six interviews and four researchers (KD, SH, KH, and KP) reviewed coded transcripts, discussed discrepancies and refined the codebook. One researcher (KH) coded the remaining data and other researchers performed spot checks on half of the transcripts to ensure consistency. We extracted coded texts and performed thematic content analysis.¹²⁸ In the present analysis, we compared and explored differences in themes by international and national stakeholders. We prioritized themes mentioned by many participants and explored divergent views.

Results

Participant characteristics

We conducted 22 interviews between October 2021 and March 2022: 13 with internationally based organizations and 9 from national organizations (Table 1).

Stakeholders had varied levels of experience with HIV service policies, guidelines, and practice, ranging from 2–21 years working in the HIV field.

Table 4. In-depth interview participant characteristics

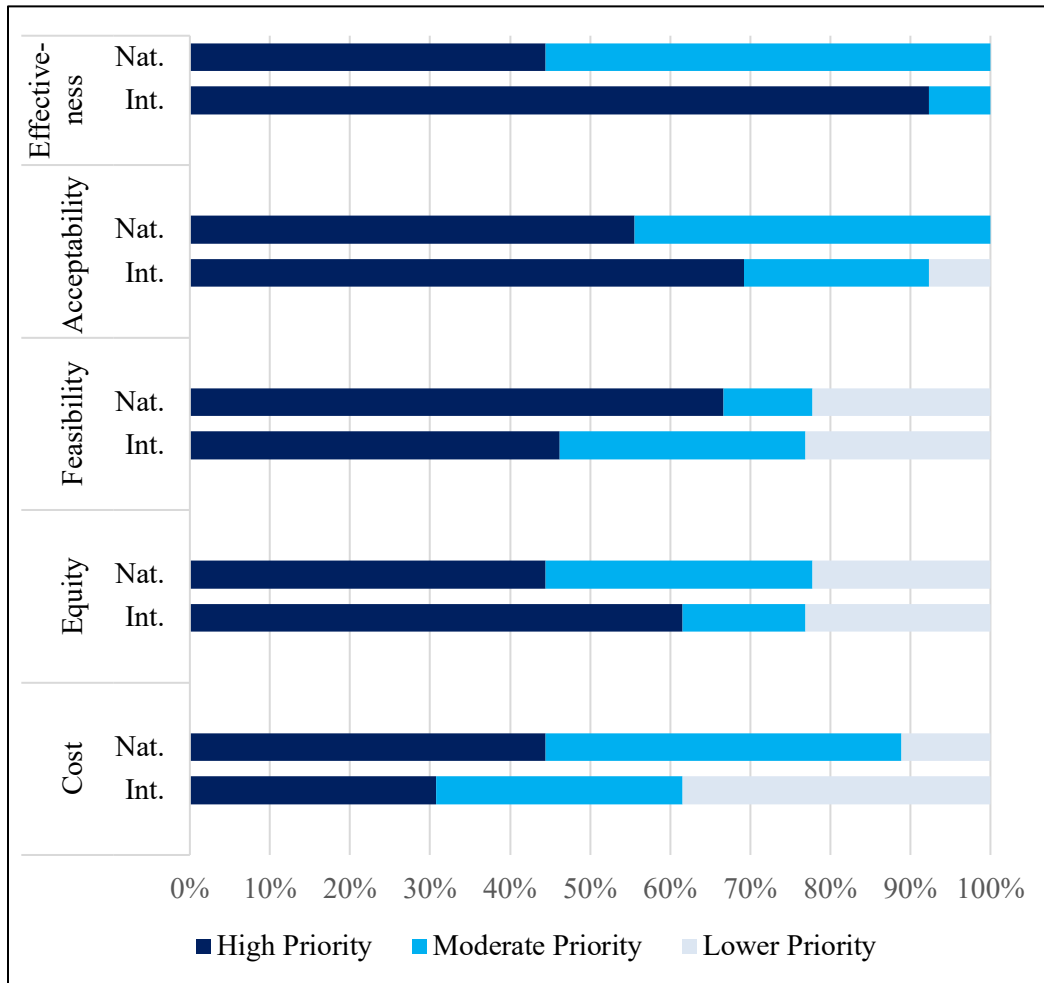
Characteristic	N (%) (N = 22)
Location	
International	13 (59)
National	9 (41)
Gender	
Male	15 (68)
Female	7 (32)
# of years in current role (Range)	5 (1–20)
Mean # of years working in HIV field (Range)	14 (2–21)

Intervention adoption decision-making criteria

Overall, effectiveness was the highest rated consideration, and cost was the lowest (Figure 5). About half of stakeholders pointed out that decision-making criteria are interrelated, which makes it difficult to fully distinguish them. For example, feasible interventions are also low-cost, and equitable interventions may lead to better long-term outcomes. Most stakeholders explained their criteria for adopting interventions is the

same for men as for other populations, though several noted that assuring client acceptability and appropriateness would be especially important.

Figure 6. Decision-making priorities by national and international stakeholders



Nearly all international stakeholders rated effectiveness as high priority, compared with less than half of national stakeholders. International stakeholders often described effectiveness as their first consideration: “There's no use in implementing something that will not help us reach the expected outcome.” Fewer than half of international

stakeholders prioritized feasibility because they believed that implementation challenges can be overcome through innovation, change management, and quality improvement if an intervention is important enough.

"Even if an intervention doesn't seem feasible, initially, if you can continually create evidence that... it's effective, then systems can be built to figure out how that [can] work." -International stakeholder

In contrast, national stakeholders largely believed that while effectiveness is important, feasibility and sustainability are even more important. National stakeholders emphasized the need to select interventions that fit within existing systems and can be implemented within human resource and equipment constraints.

"If [an intervention] is not feasible it will not come close to success...it needs to be straightforward and fit well into the rest of the programs and activities that are already present. It needs to fit well with the healthcare workers' capacities and capabilities." -National stakeholder

"For a long time, as you know, the whole HIV program like in Malawi is donor dependent, donor driven ... after the project mode has been phased out, it's very difficult for us as a country to maintain it. So...[it] is necessary to make sure that we have sustainable interventions that can be implemented without donor support." – National stakeholder

Nearly all national stakeholders rated cost as moderate or high-priority compared with less than two-thirds of international stakeholders. International stakeholders saw ongoing costs of interventions as minimal after initial investments and believed interventions become more efficient or cost-saving over time:

"Just because [something] is expensive today, we might figure out a way to do it more cheaply later." -International Stakeholder

“In the long-term, [care] would be less costly if you aren’t... spending that much time caring for people that are coming in with advanced disease.” -International Stakeholder

In contrast, nearly all national stakeholders were deeply concerned about the costs of interventions because they were tied to sustainability, citing an expectation that reductions in donor funding are imminent. As one national stakeholder summarized, “it’s easy to find funding for innovations, but very hard to find funding to sustain services.”

“We know that every year the funding that goes into programming [for] HIV goes down.... If we’re talking about introducing a certain innovation, are we able to sustain this? When [a donor] is no longer there, this intervention...will die a natural death.” -National Stakeholder

The majority of both international and national stakeholders rated acceptability as high-priority, especially client acceptability. As one international stakeholder summarized: “if clients don’t like it, then it’s just going to fail, so it doesn’t really matter how cheap and easy it is to do.” Healthcare worker acceptability was also seen as important due to the importance of staff satisfaction and the difficulty of implementing programs without healthcare worker buy-in.

“I think some things might be not acceptable to healthcare workers but super acceptable to people living with HIV or vice versa...but I would advocate that maybe if health care workers don’t love [an intervention] but it is great for communities and people living with HIV, then we’ve got to try [it].” -International stakeholder

Stakeholders discussed the tradeoff between equity and efficiency, explaining that reaching key populations and serving rural areas may be costlier but is still worthwhile.

A couple of national stakeholders prioritized efficiency over equity.

“At the end of the day [it comes down to] the number returned into care because that will make it more cost-effective. Yes, I may want to ensure equity by having those extended working hours, but I’m only seeing eight men. And will eight men improve overall retention for [the] country?” -National Stakeholder

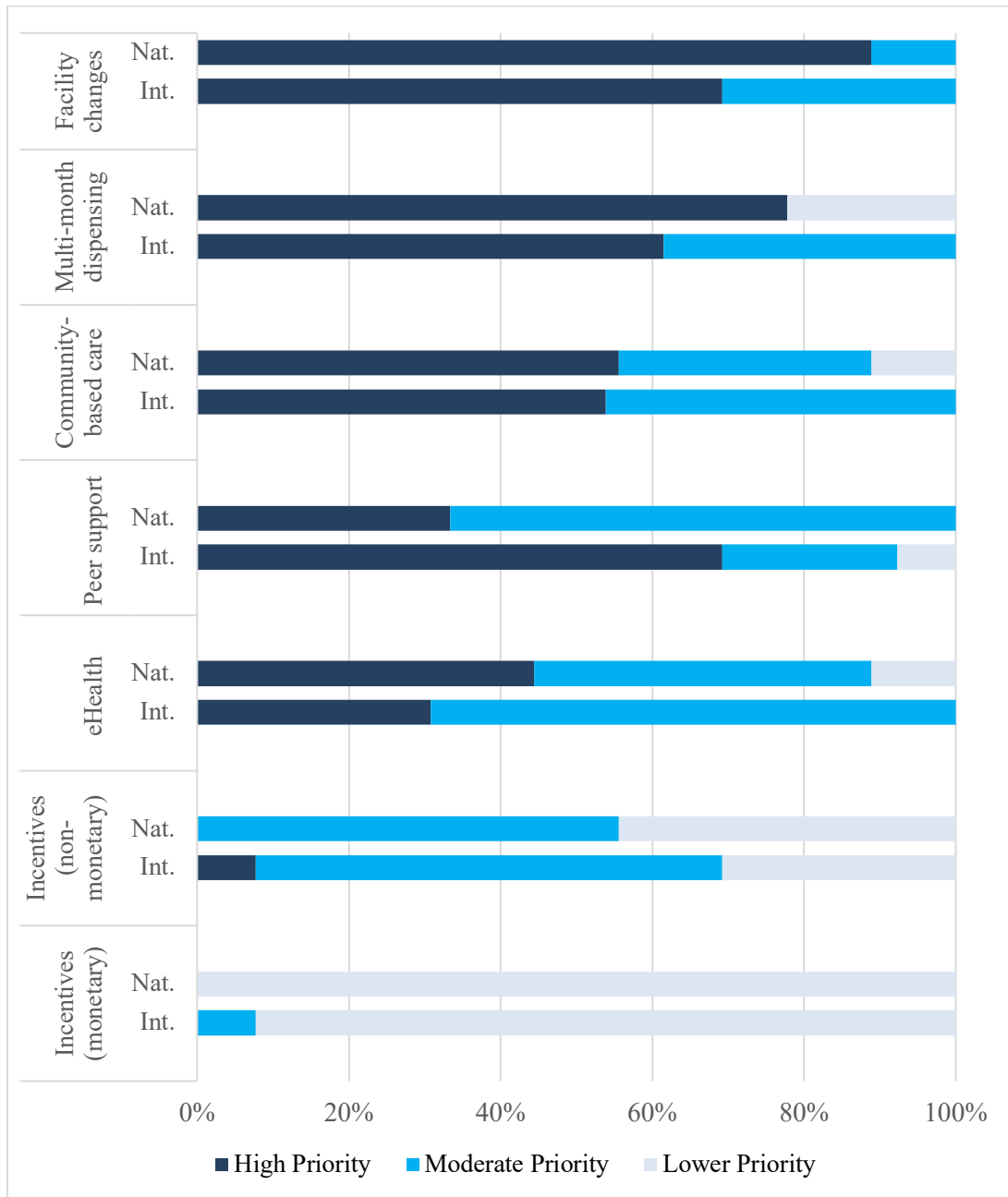
Preferred interventions for new or returning ART clients

Overall, international and national stakeholders had similar intervention preferences.

(Figure 6) They noted that multiple models are needed to address the diverse causes of treatment interruption. Their highest-rated interventions were facility changes and multi-month dispensing (MMD). International stakeholders were more interested in ongoing peer support/counseling than national stakeholders (Table 8).

Stakeholders were interested in facility-based interventions to support men’s engagement in care. More than a third discussed male-friendly clinics, in which men can have all their needs met in one setting by healthcare workers who are sensitized to their needs. They also emphasized the importance of extended facility hours and positive provider-client interactions (e.g., confidentiality, respect, and addressing stigma).

Figure 7. Intervention priorities rated by national and international stakeholders



Facility-based Interventions

Most international and national stakeholders prioritized facility-based service delivery improvements (like extending hours of services and reducing wait times) because these changes can be achieved within existing systems and infrastructure. They saw facilities as the foundation of HIV service delivery and central to client experiences of care.

“We already have the facilities in place, but what we have not done is to try to look at things like the client flow, opening hours. This could be easily done.” - National Stakeholder

A couple of stakeholders supported segmenting facility-based care so more intensive services with seasoned healthcare workers are offered to the clients most in need of additional support.

“We already have workflows that are stripped to the bare bones. The reality is that at most sites, patient consultations only take a few minutes and are often not conducted by a trained health worker. There isn't any room to simplify any further, and so the question is what we can add for patients who need it rather than simplifying.” - National Stakeholder

Multi-month Dispensing (MMD)

Both international and national stakeholders prioritized MMD because it is highly feasible, acceptable, low-cost, and frees up facility resources to support high-risk clients. Several stakeholders emphasized that new or returning ART clients may require several visits before being given MMD to ensure they are adequately prepared for lifelong treatment, however international stakeholders largely believed MMD should be offered as early as possible.

“My assumption is that people look at the first six months of ART and dread the amount of work it involves for them as clients...the less they have to do, the less onerous it will seem to them, and we hope that will make [ART clinics] feel like something they want to do and want to stick with.” -International stakeholder

Peer Support and Counseling

Peer support was prioritized highly by international stakeholders mainly because it was seen as highly effective. In contrast, such support was only prioritized moderately by national stakeholders, as they saw it as expensive and human-resource intensive.

Different peer-support models discussed included one-on-one peer mentoring, peer support groups, and psychosocial counseling. National stakeholders were in favor of a newly implemented MoH program in which a facility-based psychosocial counselor provides support to clients living with depression, anxiety, and substance use disorder. Stakeholders believed peer support must be provided in addition to interventions addressing service accessibility.

“We use peers a lot... But if you just make it easier to access services then you won't need all of this additional support.” -International stakeholder

Community-based Care

Both groups rated community services as moderate priority. They discussed several models, including Community Adherence Groups (CAGs), community initiation and refills, and home-based services. The perceived benefits of these models included reduced client time and cost for services and reduced risk of unwanted status disclosure and HIV-related stigma due to facility visits that lack privacy. Despite these benefits, both international and national stakeholders were concerned about the human resources

required to implement community services. For this reason, several believed that community services should be limited to key populations or those who were especially ill.

“It’s very difficult to imagine how this will be done at scale in the national program. We have to remember that this takes health workers away from the facilities [and] it takes many more nurses to see the same number of clients if you send them out in the community. So I think in a health system that is overall understaffed, it is a great luxury to send nurses to meet people in the community.”
-National Stakeholder

E-Health Strategies

Many stakeholders rated e-Health interventions as moderate priority. Most stakeholders described e-Health as a new, “untapped” platform that could increase the reach of existing interventions, such as peer support, health education, appointment reminders, SMS check-ins between visits, and tracing clients with missed visits. Yet several believed the technology and evidence was not yet ready for implementation widely throughout settings like Malawi.

Stakeholders discussed both equity benefits and concerns related to e-Health interventions. Several stakeholders noted e-Health’s unique potential to reach harder-to-reach populations such as youth, men, and mobile and rural populations. However, more than half discussed uneven access to phones and internet as a critical barrier to effective and equitable e-Health interventions, particularly in resource-constrained settings like rural Malawi. National stakeholders noted that individuals often share phones with

relatives, creating a risk of unwanted disclosure.

Incentives

Monetary and non-monetary incentives were the lowest-rated interventions across stakeholders. Stakeholders perceived incentives as highly effective but still dismissed the possibility of implementing them due to their costs and complex logistics. Stakeholders also believed that incentives may reduce clients' intrinsic motivation for lifelong treatment.

“If you tell them, ‘we can give you transport money’ and then we don’t have it, the next time they don’t show up. But if at the beginning you did not tell them that [they would] receive cash, they would find their own means to come to the clinic. [Because of incentives] they develop a dependency syndrome. -National Stakeholder

Stakeholders did note that targeted incentives can improve equity by supporting poorer clients in meeting daily needs and overcoming socioeconomic barriers to care but were concerned that other clients would find targeted incentives unfair and discourage ART services among general populations. Some suggested that free or low-cost non-monetary incentives (like stickers displayed on a tree) could instead be used to reward or appreciate clients for their engagement in care.

Overarching Service-Delivery Priority: Person-Centered Care

Person-centered care (PCC) emerged organically as a high priority strategy to integrate into any intervention. Stakeholders defined PCC as services that were flexible and

tailored to clients' holistic needs as individuals. The three components of PPC discussed most frequently were: 1) segmented care, 2) integrated care, and 3) positive and empowering interactions with healthcare worker interactions.

Segmented Care

Many international and national stakeholders expressed the view that services should be adapted to meet the needs of diverse groups, such as clients returning to care v. stable clients, men, key populations, clients who prefer private services, and clients with psychosocial needs: "...it's not a one size fits all approach... what works for female sex workers may not necessarily work for MSM" (international stakeholder).

A few international stakeholders noted that segmented delivery models that are well-matched to clients' needs are more efficient and may lower overall health system costs while allowing health systems to implement costlier interventions for clients who need intensive support. However, one national stakeholder emphasized that tailoring services for different populations is an "extra project" that is not funded by the government and would require additional training and adequate staff to spend time with clients.

Integrated Services

Integrated services were a priority for both international and national stakeholders, although several national stakeholders believed that integration is costly and infeasible. Stakeholders described the holistic benefits of integrated care, including reduced costs for

clients (because visits are combined), decreased risk of unwanted disclosure of one's HIV status, and improved overall health outcomes.

“They come to the clinic, they get their ART refilled, and tomorrow they're supposed to go to the clinic to get their diabetes medication or hypertension medication, that to me is a bad idea. [If we had a] one stop center where you get your ART refills and your other medications, I think that would help. -National Stakeholder

Positive and Empowering Interactions with Healthcare Workers

Positive client-healthcare worker interactions, in which healthcare workers are non-judgmental and friendly, were considered key to retaining clients in care and reducing their experiences of HIV-related stigma. As one national stakeholder stated, interactions with healthcare workers should be “empowering and supportive” rather than “coercive and threatening.” Stakeholders believed that counseling sessions should not be “generic,” but rather should be tailored to clients’ concerns and designed to build trust, so clients feel comfortable discussing their personal barriers to treatment. About a quarter of international and national stakeholders noted that clients do not receive enough support and education when initiating ART, which leads to future treatment interruptions.

“If there is no time to discuss [treatment barriers] and to encourage disclosing such issues they will of course be dropping out because they had chronic adherence issues or retention problems that haven't been addressed. And I think that can only be addressed if there is ... more time given for [clients] to fully understand [their diagnosis] and [problem-solve] with treatment supporters and family members.” -National Stakeholder

“What I've seen from my own experience is that most providers don't understand that we are all human beings. We also have other things that we do, apart from coming to the clinic to get the medication. So sometimes when a client misses an appointment and when he comes for a refill, the way they are treated it's more like

they're being punished. So, [if we] change the attitudes of our providers, I don't think we are going to be struggling with each of retention and even initiation.”
-National Stakeholder

Nearly all international stakeholders and a couple of national stakeholders emphasized that healthcare workers should empower clients by offering them choices in how they receive care, such as community or facility-based, an option for peer support, and the choice of different facilities. A few stakeholders noted that client needs change over time and explicitly asking about client preferences on an ongoing basis can help identify and meet changing needs.

“[If] as a client I make a choice...whether it is home-based care or whether it is multi-month dispensing, that's the one that is acceptable for me and therefore I'm likely to adhere to that intervention and have improved linkage and early retention.” -National Stakeholder

Table 5. Stakeholder perceptions of interventions

Intervention	Average Rating*	Positive Perceptions	Negative Perceptions
Facility efficiencies (e.g., extended hours, improving workflows)	9.0	-Acceptable (clients) -Feasible -Low-cost	
Multi-month dispensing	7.9	-Acceptable (clients, policymakers) -Feasible -Low-cost	
Community-based ART delivery	7.5	-Acceptable (clients) -Equitable	-High cost -Infeasible (complexity + HR requirements)
Ongoing peer support	7.4	-Acceptable (clients) -Effective	-High cost -Infeasible (complexity + HR requirements)
e-Health	6.6	-Effective (high future potential) -Low-cost	-Evidence and interventions not ready for widespread scale-up -Inequitable (lack of access to phones and internet)
Incentives	3.3 (non-monetary) 0.2 (monetary)	-Acceptable (clients) -Effective (increases short- term motivation)	-High cost -Ineffective (reduces long-term motivation) -Infeasible (determining and tracking eligibility)

*Rating scale: High Priority=10 pts, Moderate priority=5 pts, Low Priority=0 pts

Discussion

In resource-constrained countries, policymakers implementing interventions make difficult trade-offs across multiple criteria (e.g. effectiveness, equity, budgetary and practical constraints, and political considerations) when choosing interventions to implement and scale up. In this study we explored how stakeholders make these decisions in the context of new or returning ART clients in Malawi. Our study suggests that both national and international stakeholders prioritize client acceptability but diverge in other areas: program effectiveness was a higher priority for international stakeholders, while ongoing costs, feasibility and sustainability were higher priorities for national stakeholders. Despite these differences, international and national stakeholders had similar intervention preferences; they prioritized simple, low-cost, facility-based interventions that remove barriers to care, such as multi-month dispensing and extended facility hours. Most stakeholders attributed their interest in various DSD models to PCC, whereby clients are provided tailored services with positive and empowering healthcare worker interactions.

Our analysis suggests notable differences in how international and national stakeholders perceive the long-term costs of interventions. International stakeholders viewed interventions as having low ongoing costs after initial investments. In contrast, national stakeholders were deeply concerned about the long-term costs and resource requirements of interventions. National stakeholders described experiences of watching new programs end after donors left. Additionally, international stakeholders believed that factors such

as cost and feasibility could be addressed through particular implementation strategies.

This view was not expressed by national stakeholders.

These findings highlight differences in power, experiences, and knowledge of both the global and local history and context. There is growing consensus that external funding should be aligned with national priorities.^{129,130} However, transitioning from preferred narratives to actual practice may be slow. Currently, key donor funding institutions drive the process of intervention selection and many initiatives are managed by numerous NGOs (some local and some internationally based) rather than national governments.¹³¹ International donor funds predominately support vertical programs rather than infrastructure or health system strengthening efforts.¹³² A robust decision-making process may start with a range of intervention options selected by the Ministry of Health, with donors choosing among them. This would help ensure that international and national stakeholders are working together to fund programs are country-owned, sustainable, and coordinated.

Despite differences in their decision-making criteria, international and national stakeholders had similar intervention preferences, perhaps as a result of their ongoing discussions. Interestingly, cost and feasibility considerations seemed to have the greatest influence on intervention preferences, though effectiveness and acceptability received the highest importance ratings in the think-aloud activity. As found in another qualitative study,¹³³ high-level stakeholders favored simple interventions with minimal costs that

remove structural barriers to care (e.g. extended hours, MMD) over those that were described as highly effective but requiring additional systems, human resources, and ongoing monitoring (e.g. peer support and community-based care).

Stakeholders universally agreed on the importance of PCC, despite their concerns about resource constraints and sustainability challenges. In line with findings from previous PCC studies,¹³⁴ stakeholders were more interested in PCC's impact on health system goals (e.g. retention in care, reducing costs) than client goals (e.g. living a full life). They viewed PCC as a strategy to reduce healthcare costs by improving the effectiveness and efficiency of programs and recognized the critical importance of client choice and tailored, respectful, holistic care in improving adherence and hence outcomes. Additional evidence on the impact of PCC and best practices from sub-Saharan Africa are urgently needed. PCC practices were developed in high-income countries, and little quantitative evidence on PCC in LMICs exists.¹³⁵ Some aspects of PCC (such as segmented and integrated care) will require additional resources to be successfully implemented and sustained in historically vertical, disease-specific programs with scarce resources. In such contexts, innovative, evidence-based strategies for offering tailored and/or integrated services at a low-cost may be needed. However, recent qualitative research in Malawi suggests that returning male ART clients value positive and empowering relationships with healthcare workers more than where and how ART is delivered,¹³⁶ suggesting that key components of PCC could be taken to scale at low-cost.

Our study has several limitations. First, the think-aloud priority setting tasks did not fully mimic real-world situations, in which stakeholders consider many nuances of a particular context. Second, there may have been social desirability bias or differences between expressed and revealed preferences. We believe this was minimal as the interviewers expressed neutrality and encouragement toward all comments and stakeholders were frank and casual in their remarks. Third, not all stakeholders were represented in this study; clients and community advocacy groups were not included in the study but are critical stakeholders. Fourth, the quantitative results of the two ranking tasks should be interpreted with caution, due to the small sample size. Fifth, some findings may not be generalizable beyond Malawi, particularly concerns about phone access. Despite these limitations, we believe that the priorities and preferences expressed by stakeholders in this study are reflected in real-world decision-making.

Conclusion

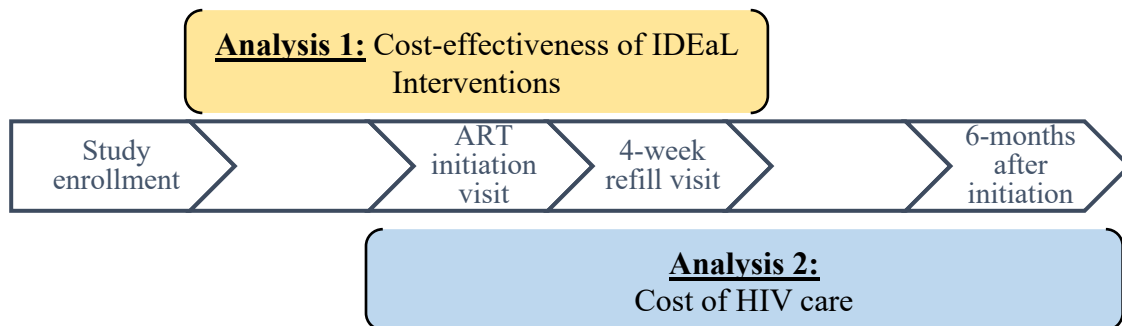
We found that top priorities of international and Malawi national stakeholders regarding DSD interventions for new or returning ART clients are effectiveness, feasibility, sustainability and client acceptability. International stakeholders should recognize and act upon the greater priority national stakeholders place on feasibility and sustainability. Person-centered care was emphasized by all stakeholders and should be incorporated into any intervention for new or returning ART client. Findings can inform HIV treatment intervention development and research. Further research is needed to understand how

differing priorities affect public health discussions, decision-making, and impact, and how to ensure national and local needs are prioritized.

CHAPTER 6: COST-EFFECTIVENESS ANALYSIS OF THE IDEAL TRIAL

This chapter describes the results of the two distinct but overlapping analyses: 1) an incremental cost-effectiveness analysis of the three IDEaL interventions and 2) an estimate of the cost of the first 6-months of HIV care for participants who (re-)initiated treatment within 90-days of study enrollment. The costing periods for both studies are shown in Figure 8. Both analyses are from the provider perspective and employed micro-costing methods.

Figure 8. Time periods for costing analyses



Methods

The first analysis focused on comparing the incremental costs of the three IDEaL interventions. We estimated the costs incurred for each participant for services after enrollment through the 4-week refill visit since this is the point at which intervention services in all arms were complete. In the second analysis we estimated the cost of HIV care (visits and ART medications) from the ART initiation visit through 6 months of

follow-up for each participant. The data for these analyses were drawn from several sources: 1) IDEaL trial records for services received by participants, 2) financial and human resource data from the implementing partner (Partners in Hope) for data on unit costs, and 3) key-informant interviews with staff providing intervention services (e.g., patient supporters, mentors, and nurses) for estimating the time associated with each type of intervention. We excluded research-related costs, such as participation stipends and survey data collection.

Resource use per patient

First, we created a comprehensive inventory of the resources used in the IDEaL interventions through review of the study protocol and discussions with study team. In total, 25 IDEaL-specific resources (combined for all study arms) were identified. For each study participant, the quantity (number of units) of each IDEaL-specific intervention resource was determined from study records kept by HCWs.

The patient-level quantities of ART medications and clinic encounters were drawn from two data sources: a nation-wide electronic medical record (called Baobob) and a nationally standardized paper-based ART record (called Mastercard) that is updated by providers at every clinical encounter and kept at the facility. We combined these two data sources into one dataset. Laboratory exams were excluded as data on quantities were not available.

Unit Costs

All costs are reported in 2022 U.S. dollars (US\$) using the 2022 average annual exchange rate (934.1 MWK/US\$).¹³⁷ The supplemental file “IDEaL Costs Analysis” provides all primary and secondary data used to estimate unit costs in this analysis.

IDEaL-specific intervention services were provided by four cadre of healthcare workers (HCWs): 1) tracers (research assistants), 2) patient supporters (treatment supporters); 3) mentors (psychosocial counselors), and 4) nurses. Research assistants traced the target population via phone and community visits and completed enrollment and randomization for the IDEaL study. We excluded the costs of this initial tracing as part of the incremental cost-effectiveness analysis as these services were identical for all arms for the study.

We estimated the full monthly cost to the employer for each category of IDEaL healthcare worker including salary, benefits, equipment and related costs, and training for the IDEaL interventions (Table 4). For equipment and training, we assumed a useful life of 3-5 years and a real discount rate of 10% based on the Government of Malawi’s cost of borrowing during the study period and the prevailing inflation rate.^{138,139} We then calculated the full labor cost per working hour for each category of healthcare worker, taking into account working days per month.

Next, we estimated the HCW time associated with each IDEal resource. HCWs kept patient-level records on time spent for each encounter for some resources (e.g., counseling). If patient-level data was not available, we used HCW time estimates for each resource. First, we identified the discrete tasks (e.g., travel to the community, successful tracing, unsuccessful tracing) involved in delivering each resource. Then we interviewed 13 HCWs from a sample of five facilities about the minimum, average, and maximum duration of each of these tasks. Finally, we combined these tasks to estimate the average time spent providing each resource. We multiplied these time estimates by the corresponding healthcare worker cost per hour to estimate the unit cost for each IDEal-specific intervention service.

We used a standard cost-outcomes model¹⁴⁰⁻¹⁴³ to estimate the unit cost per facility ART visit by averaging costs at two study facilities: a rural primary health center and an urban district hospital. Patients interacted with four cadre of healthcare workers at ART visits at these facilities: 1) patient supporters (lay health workers), 2) nurses, 3) clinical officers (providers), and 4) data clerks. We calculated the monthly labor cost for the ART clinic using salary and benefit information and data on the number of workers staffing each ART clinic day. We divided total monthly labor costs for the ART clinic by the total number of visits per month to produce a variable unit cost per facility encounter including both clinical and non-clinical time (e.g., paperwork, meetings, and breaks). The final estimated unit costs for the rural and urban sites were similar.

Table 6. Methods for estimating unit costs

Resource: Data Sources	Method for estimating cost
<p>IDEaL staff time for intervention-specific services: Interviews, study records, human resources records, expense reports</p>	<p><i>IDEaL Intervention cost study only:</i> IDEaL intervention-related staff time was defined as any time a patient supporter, mentor, or nurse travelled, traced, or interacted with a client. We multiplied 1) the estimated time spent on each IDEaL-specific service by 2) the total labor cost per hour for each cadre to calculate the unit cost for each IDEaL resource. Details are below:</p> <p>1) <u>Time spent on each IDEaL-specific service:</u> For some activities (e.g., counseling), time spent was drawn from patient-level recorded by healthcare workers. For the other activities, we interviewed healthcare workers from a sample of five facilities to estimate the average time spent on each IDEaL-specific intervention service.</p> <p>2) <u>Total labor cost per working hour:</u> For each cadre, total monthly costs to the employer were divided by total working hours per month (based on leave and working days) to calculate a total hourly cost for each cadre for implementing the IDEaL interventions. This included:</p> <ul style="list-style-type: none"> • <i>Salaries and benefits</i> (severance, medical, and funeral) were added and this quantity was divided by total working hours per month (considering leave and working days) to yield the cost of salary and benefits per working hour (8 hours/day). • <i>Training:</i> Ideal healthcare workers received three trainings with an assumed useful life of 3 years. We calculated the total cost per day for training (including labor cost of trainers and trainees, lodging, transport, per diems, and venue) and multiplied it by the number of person-days of training for each cadre. • <i>Equipment and Consumables:</i> The annualized cost of equipment (e.g., bicycles for lay cadre, motorcycles for nurses) and monthly airtime and public transport reimbursement were included in total hourly cost
<p>Drugs: Malawi Ministry of Health prices</p>	<p><i>Cost of care study only:</i> We calculated the number of days of ART dispensed during the 6-month follow-up period after ART initiation. We created a maximum cutoff (# of days in the follow-up period) for this quantity to avoid counting drugs prescribed before the follow-up period but intended to be consumed beyond the follow-up period.</p>
<p>Variable cost per facility visit: Human resource department records</p>	<p>We sampled two study facilities (a rural health center and an urban hospital). We calculated the total monthly labor cost for each facility’s ART clinic using records of salary, benefits, and days spent working in the clinic (by cadre). Total monthly labor costs were divided by the estimated number of ART clinic visits per month (as reported by the facility leaders) to produce a unit cost per visit.</p>

Reporting results

Cost-effectiveness of IDEaL interventions

We first estimated the cost of IDEaL services from enrollment through the 4-week follow up visit after ART initiation. This estimated included facility visits attended during this period but not the cost of drugs. We calculated costs per study participant from the provider perspective by multiplying unit cost estimates by patient-level resource usage data. For each IDEaL intervention, we reported average cost per arm as means in 2022 USD. We also estimated the mean and 95% CIs for the difference in costs between the study arms using linear regression. We evaluated the cost-effectiveness of three study arms based on incremental cost-effectiveness ratios (after excluding dominated intervention arms).¹⁴⁴

HIV cost of care analysis

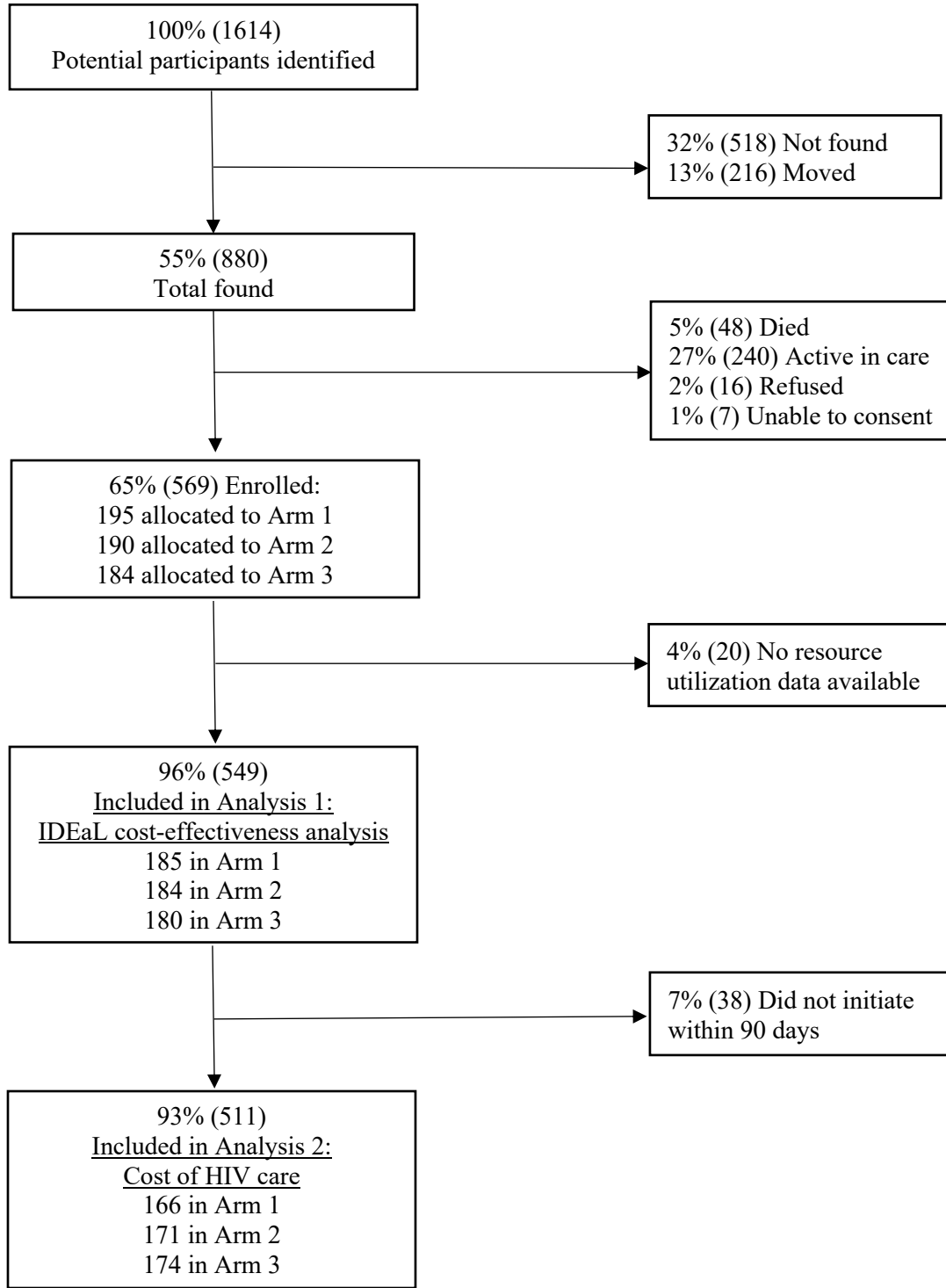
We calculated the average costs of the first 6-months of HIV care for participants who initiated care within 90-days of study enrollment (included visit and drug costs) and stratified these results by study arm and by those achieving or not achieving the primary study outcome (6-month retention in care). We also estimated the mean and 95% CIs for the difference in costs between these groups using linear regression.

Results

Study sample and retention outcomes

The IDEaL randomized controlled trial was described in detail in Chapter 4. Of the 569 participants in the trial with outcome data, 20 had missing resource utilization data and were dropped from the analyses. All 549 of the remaining participants were included in the incremental cost-effectiveness analysis of IDEaL interventions. Five hundred and eleven of these 549 participants (re-)initiated care within 90 days of trial enrollment. These participants were included in the cost of HIV care analysis. The consort diagram is presented in Figure 9.

Figure 9. IDEaL trial consort diagram



Preliminary IDEaL study outcomes for the costing sample are presented in Table 7. The primary outcome is 6-month retention in care (a composite of initiating ART at participating health facilities within 90 days of enrollment and confirmed to be in care 6-months after initiation).¹⁴⁵ Overall, 77% of men in Arm 1 (lay cadre community-based counseling), 71% (95% CI: 64%, 78%) of men in Arm 2 (home-based ART initiation), and 84% (95% CI: 77%, 91%) in Arm 3 (stepped interventions of increasing intensity) achieved the primary outcome of 6-month retention in care.¹⁴⁶

Table 7. Initiation and retention outcomes by study arm for costing sample

	<u>Arm 1:</u> Counseling-only (n = 195)	<u>Arm 2:</u> Home-based ART initiation (n = 190)	<u>Arm 3:</u> Stepped Care (n = 184)
Retained in care at 6-months ^a (95% CI) ^b	77%	71% (64%, 78%)	84% (77%, 91%)

Note: For costing sample (n=549) only. Based on preliminary results from the IDEaL trial

^aRetention is a composite outcome of initiated care \leq 90 days after enrollment and retained in care at 6-months.

^b95% CI from linear regression model comparing Arms 2 and 3 to Arm 1

Unit costs

Collectively, the two analyses included in this chapter include three categories of costs: facility-based ART visits, ART medications, and IDEaL intervention-specific activities. The IDEaL staff hourly cost included facility staff costs and IDEaL intervention-specific costs (e.g., training and equipment) on a per hour basis (Table 8). IDEaL staff hourly costs ranged from \$2.58 for patient supporters, \$6.87 for psychosocial counselors, and \$9.87 for nurses — an additional 38.2%, 7.8%, and 20.8% higher than base hourly costs for these cadres, respectively (Table 9).

Table 8. Healthcare worker salary components (2022 USD)

	Lay Cadre		Psychosocial Counselor		Nurse		
Category	Costs	%	Costs	%	Costs	%	Details
Monthly gross salary	224.5	83.2%	666.8	67.2%	847.2	81.8%	Medical and GPA insurance, mobile airtime, and expected value of severance and death benefits
Monthly Benefits	45.4	16.8%	248.6	25.0%	271.1	26.2%	
Total staff cost per month	269.9	100%	915.5	100%	1,118.3	100%	Total standard employer costs (used for facility visit costs)
Total staff cost per hour	1.9		6.3		7.7		Assumed 217 working days per year and 8 working hours per day

Table 9. Total cost per HCW hour, including IDEaL-specific expenses (2022 USD)

Category	Lay Cadre		Psychosocial Counselor		Nurse		Details
	Cost	%	Cost	%	Cost	%	
Monthly salary per HCW	269.9	100%	915.5	100%	1,118.3	100%	
Additional IDEaL-specific costs per HCW per month	103.1	38.2%	77.5	7.8%	294	20.8%	
Of which:							
Mobile airtime	2.3		0.0		0.0		
Public transport reimbursement	23.0		16.3		0.0		
Equipment-related costs on per month basis	8.1		0.0		234.1		Bicycles (patient supporters) and motorcycles (nurses)
Trainings on per month basis	72.0		61.2		59.9		Patient supporters: 8 days, psychosocial counselors: 5 days, nurses: 8 days. Assumed useful life of 3 years.
Total cost per IDEaL HCW per month	373.0	138%	993.0	108%	1,412.3	121%	
Total cost per IDEaL HCW per hour	2.6		6.9		9.8		Assumed 217 working days per year and 8 working hours per day

In most cases, IDEaL HCWs attempted to visit one client per trip to the community. HCWs reported lower tracing durations when they found a participant (i.e., successful attempt) because they otherwise spent extra time searching multiple locations. Nurses and psychosocial counselors (who used motorcycles and public transportation respectively) reported lower round trip travel time than lay cadre HCWs, who relied on bicycles. Despite longer travel times, lay cadre community visits were less costly than those with psychosocial counselors or nurses (Table 10).

Table 10. Staff time and unit costs for IDEaL resources

Activity	Mean (hours)			Unit Cost (2022 USD)		
	Lay Cadre	Psychosocial Counselor	Nurse	Lay Cadre	Psychosocial Counselor	Nurse
Phone calls	0.1	0.05	0.07	0.3	0.4	0.5
“Successful” ^a community visit attempt: round-trip travel and tracing	3.1	1.7	1.5	8.0	12.0	15.0
“Unsuccessful” community visit attempt: round-trip travel and tracing	4.1	2.2	1.9	10.5	14.9	18.4
In-person counseling	1.1	0.9	0.8	2.8	5.5	7.6
Home-based clinical assessment + ART dispensing	N/A	N/A	0.3	N/A	N/A	2.6
Facility navigation	0.3	0.4	0.2	0.7	2.7	1.5

Note: Counseling time determined from client-level records. Other time estimates self-reported by HCWs.

^aVisit considered successful if HCW found and interacted with client. Longer tracing times were reported for unsuccessful visits.

The total variable cost per facility visit was \$4.48 (Table 11). Details of the calculations are available in the supplemental file “IDEaL Costs Analysis”. Nearly all study participants were on the national first-line ART regimen (TDF/FTC/EFV) with a daily

cost of \$0.15 (\$4.54 per 30-day supply). Laboratory test data were not available, however this is unlikely to influence the results because few labs are done in the first 6 months on treatment.¹⁴⁷ A successful home-based ART visit with a nurse cost \$25.13 – this was calculated by multiplying the hourly wage of nurses (loaded with IDEaL-specific costs) by the average time spent on a successful home-based ART visit (including round-trip travel and tracing, counseling, clinical assessment, and ART dispensation) (Table 11).

Table 11. Unit costs for HIV care

Resource	Unit	USD (2022)
Facility-based ART visit	1 visit	4.48
Home-based ART visit ^a	1 visit	25.13
ARTs ^b	1 day	0.15

^a*Includes time spent on round-trip travel and tracing, counseling, clinical assessment, and ART dispensation. ART initiation sometimes required more than one visit attempt, but for this analysis we used the cost of a successful home-based ART initiation visit.*

^b*Based on fixed-dose combination of TDF/FTC/EFV.*

Quantity of resources and costs of IDEaL interventions

Table 12 summarizes resource utilization during the IDEaL intervention period (defined as all IDEaL-specific activities and ART visits after enrollment through the first ART refill visit). The total number of phone calls, community visits, and ART visits was similar across arms, but were provided by different cadres and in different locations. In Arm 1, all community visits were with lay cadre HCWs, whereas in Arm 2, 41% were with nurses, and in Arm 3, 27% were with psychosocial counselors and 3% were with

nurses.

Table 12. Average resource utilization per participant for IDEaL interventions*

	Arm 1: Counseling-only	Arm 2: Home-based ART initiation	Arm 3: Stepped Care
Phone calls	0.7	1.0	0.7
Total community visits	1.9	2.5	2.3
Patient Supporter	1.9	1.5	1.6
Psychosocial Counselor	0	0	0.6
Nurse	0	1.1	0.1
Total ART visits	1.8	1.6	1.9
Facility-based	1.8	1	1.8
Home-based	0	0.6	0.03

**Selected resources. The intervention period is defined as all activities after enrollment through the first ART refill visit.*

The average costs of the IDEaL interventions per participant were \$28 for Arm 1, \$44 for Arm 2 (95% CI: \$39, \$49), and \$35 (95% CI: \$30, \$44) for Arm 3. On average, Arm 2 cost \$16 more than Arm 1, and Arm 3 cost \$7 more than Arm 1 (Table 13). Arm 2 had the highest cost due to its greater use of nurses, who have higher hourly wages. The 95% CIs for the mean cost differences reported in Table 13 are positive (and do not overlap 0), so the null hypothesis of no differences in costs for Arms 2 and 3 compared to Arm 1 is rejected at a 5% significance level.

Table 13 also reports an incremental cost-effectiveness ratio (ICER) of Arm 3 compared to Arm 1 of \$101 (95% CI: -\$219, \$1,284). Arm 2 was dropped from the incremental cost-effectiveness analysis because it had the least success in achieving the primary

outcome and the highest cost. This ICER is based on point estimates with significant uncertainty. Given the wide range of its 95% CI, it is not clear that Arm 3 is cost-effective compared to Arm 1.

Table 13. Average costs (2022 USD) for IDEaL interventions

	Arm 1: Counseling- only	Arm 2: Home-based ART initiation	Arm 3: Stepped Care
Cost per client (2022 USD)	27.9	44.0	35.1
Mean cost difference from Arm 1 (95% CI)*		+16.2 (11.4, 20.9)	+7.3 (2.5, 12.0)
Of which:			
Lay cadre-led activities	19.9	15.1	16.0
Nurse-led activities	0.00	24.5	2.0
Psychosocial counselor-led activities	0.00	0.00	9.0
Facility visits	8.0	4.5	8.1
Incremental cost effectiveness ratio: Arm 3 compared to Arm 1 (95% CI)			101.5 (-219, 1284)

Note: The intervention is defined as all IDEaL-specific activities and facility visits after enrollment through the first ART refill visit. Costs are from the provider perspective and include ART visit costs but not ART medication costs.

**95% CI from linear regression model comparing Arms 2 and 3 to Arm 1*

The subgroup analysis showed that participants who did not achieve the primary outcome had substantially higher mean costs than those who did (Table 14). Participants who did not initiate after a few visit attempts accrued costs from additional follow-up visits and were less likely to eventually initiate and be retained in care. Eighty-three percent of participants who received 3 or fewer total visit attempts were in care 6-months after initiation, compared with 49% of those who received four or more visit attempts.

Table 14. Cost of IDEaL interventions by primary outcome (2022 USD)*

	Arm 1: Counseling- only	Arm 2: Home-based ART initiation	Arm 3: Stepped Care
Achieved primary outcome, n=425 (77%)			
Total cost (mean)	25.2	40.4	32.5
Mean cost difference from Arm 1 (95% CI) ^a		+15.2 (10.7, 19.7)	+7.3 (3.0, 11.6)
Did not achieve primary outcome, n=124 (23%)			
Total Cost	37.0	52.7	49.6
Mean cost difference from Arm 1 (95% CI) ^a		+15.7 (2.4, 29.1)	+12.6 (-3.2, 28.4)

Note: The intervention is defined as all IDEaL-specific activities and facility visits after enrollment through the first ART refill visit. Costs are from the provider perspective and include ART visit costs but not ART medication costs.

**The primary outcome is a composite outcome of initiated care < 90 days after enrollment and retained in care at 6-months.*

*^a*95% CI from linear regression model comparing Arms 2 and 3 to Arm 1*

Costs and resource utilization during first 6-months of HIV care

Of the 549 IDEaL participants with resource utilization data, 38 (7%) did not initiate ART within 90 days of IDEaL enrollment, 86 (16%) initiated ART within 90 days but were not retained in care at 6-months, and 425 (77%) initiated ART within 90 days and were retained in care at 6-months (met the primary outcome). This analysis focuses on the latter group to avoid conflating intervention effectiveness and cost of care across arms.

Table 15 summarizes resource utilization, starting with the ART initiation visit, during the first 6-months of HIV care by arm and subgroups achieving and not achieving the primary outcome. Mean number of ART visits was similar across arms, though with

more home-based visits in Arm 2. Participants who were retained in care at 6-months had much higher levels of ART coverage (M=96%, (173/180)) than those who did not (M = 47%, (175/180)). On average they had 1.3 visits more than those not achieving the primary outcome.

Table 15. Average resource utilization in first 6-months of HIV care by subgroup

Row Description	<u>Arm 1:</u> Counseling-only	<u>Arm 2:</u> Home-based ART initiation	<u>Arm 3:</u> Stepped Care
Subgroup: Achieved primary outcome*, n=425 (78%)			
Subgroup size	143	130	152
Total ART visits	3.2	3.4	3.2
Facility-based	3.2	2.7	3.2
Home-based	0	0.7	0.01
Days of ART	173	170	175
Subgroup: Initiated but did not achieve primary outcome, n=86 (16%)			
Subgroup size	23	41	22
Total ART visits	1.9	2.0	1.8
Facility-based	1.9	1.3	1.7
Home-based	0.0	0.73	0.1
Days of ART	89	80	89

Note: The primary outcome is composite of initiated care \leq 90 days after enrollment and retained in care at 6-months.

The mean costs of the first 6-months of HIV care were \$40 for Arm 1, \$48 for Arm 2, and \$41 for Arm 3 for IDEaL participants who achieved the primary outcome (Table 16). For this subgroup, Arm 2 cost \$7 more than Arm 1, and Arm 3 cost \$0.50 more than Arm 1. Arm 2 had the highest cost due to its home-based ART initiation visits. The 95% CI

for the mean difference between Arm 2 and Arm 1 is positive, so we reject the null hypothesis of no difference in mean costs between these two arms at a 5% significance level. However, we do not reject the null hypotheses of no difference in mean costs between Arm 3 and Arm 1 because the 95% CI includes 0. Participants who initiated but were not retained in care at 6-months had much lower costs: \$22 for Arm 1, \$29 for Arm 2, and \$23 for Arm 3.

Table 16. Costs of first 6-months of HIV care by primary outcome (2022 USD)*

	<u>Arm 1:</u> Counseling- only	<u>Arm 2:</u> Home-based ART initiation	<u>Arm 3:</u> Stepped Care
Initiated and retained in care at 6-months, n=425 (78%)			
Total cost (mean)	40.5	48.8	41.0
Mean cost difference from Arm 1 (95% CI)**		+7.3 (5.7, 8.9)	+0.5 (-1.1, 2.0)
Of which:			
Home-based ART visits	0.00	16.82	0.3
Facility-based ART visits	14.3	12.03	14.3
ARTs	26.2	25.70	26.5
Initiated but not retained in care at 6-months, n=86 (16%)			
Total Cost	22.0	29.0	23.0
Mean cost difference from Arm 1 (95% CI)		+7.0 (3.0, 11.0)	+1.0 (-3.6, 5.6)

Note: Care starts at the first ART visit after study enrollment and ends at the last appointment 6-months from enrollment. Costs are from the provider perspective. Primary outcomes are based on preliminary data from the IDEaL trial.

**The primary outcome is a composite outcome of initiated care ≤ 90 -days after enrollment and retained in care at 6-months.*

***95% CI from linear regression model comparing Arms 2 and 3 to Arm 1*

Discussion

The primary objective of this chapter was to estimate the incremental costs of providing the IDEaL interventions. The secondary objective was to estimate the costs of HIV care for participants who initiated ART. We found that the mean cost of IDEaL interventions per participant were lowest for Arm 1. Arm 1 (community-based lay cadre counseling only) cost \$28 per participant, as compared to Arm 2 (community-based lay cadre counseling and home-based ART initiation), which cost \$40 per participant, and Arm 3 (stepped interventions of increasing intensity), which cost \$35 per participant. These costs include IDEaL-specific activities and the ART initiation and the first refill visit, but not medication costs or ART consultation visits that took place after the first refill visit through the 6-month follow-up period. For IDEaL participants who were retained in care 6-months after ART initiation, mean costs for ART visits and medication for the first 6-months of HIV care were \$40 for Arm 1, \$48 for Arm 2, and \$41 for Arm 3. Arm 2 (nurse-led home-based ART) had higher costs than the other two arms due to the higher costs of home-based ART initiation.

This study's findings have several implications. In all study arms, participants who did not achieve the primary outcome received more visit attempts (and higher mean costs) than those who did. To increase cost-effectiveness, programs could cap the number of attempted community visits per clients. 90% of men who were retained in care at 6-months received 3 or fewer community-based visit attempts. If community visit attempts were limited to three per client, total community visits costs would decrease by 40%.

Second, the most expensive aspect of the IDEaL interventions was travel and tracing time, which comprised approximately 80% of HCW time spent delivering the intervention. Programs could reduce transportation costs by implementing the IDEaL counseling curriculum in facility settings or identifying opportunities to meet with multiple men per community visit. Additionally, programs may consider delaying the start of tracing efforts to allow men more time to return to the facility of their own accord and offer them male-specific facility-based after treatment interruptions. However, further research is needed explore the effectiveness of facility-based male-tailored counseling.

Third, participants meeting the primary outcome had very high levels of ART coverage (96%) as compared to those who initiated ART but were not retained at care at 6-months (47%), though there was only a median difference of one visit between the two groups (3 v. 2) during the follow-up period. More clients were likely eligible for 90-days of ART dispensation at their third visit. These results are consistent with a recent study which found a spike in treatment interruptions two months after initiating.²⁵ The IDEaL interventions ended after the first refill visit, but some men may need longer ongoing support throughout the first 6-months of care, as well as supportive policies (such as multi-month dispensing) to reduce barriers during the early retention period.

The study has several limitations. Time estimates for most IDEaL-related tasks (e.g. travel and tracing time) were based on HCW interviews and subject to recall bias. HCWs

reported average travel durations so it was not possible to determine variation in cost by distance from facilities from IDEaL study data. However, comparison of costs by study arm was not confounded by home location because of the individually randomized study design. As is common, the unit cost calculations relied on many assumptions (e.g. discount rate and useful life of equipment and training). The full details of the assumptions used to calculate unit costs can be found elsewhere (See supplemental file “IDEaL Costs Analysis”). Another consideration is that we started costing after the trial enrollment visits. Accordingly, the cost of tracing by research assistants to enroll clients was not included in this study. While tracing for study enrollment would not take place in routine care, the information research assistants shared with HCWs about client locations and availability to participate is expected to have reduced tracing time for subsequent visits and thus total costs. However, these costs would not affect comparison of the costs of the three study as the same protocol was followed across arms. Additionally, given this study’s focus on incremental costs, we omitted program-level costs above the clinic level. We also omitted fixed facility costs as these generally do not change with the number of patients seen and there is no generally agreed upon approach to allocate fixed costs to a visit.¹⁴¹

Conclusion

Community-based counseling with lay cadre HCWs was less costly and had similar effects on 6-month retention care as compared with more intensive interventions, such as community-based psychosocial counseling and ART. Given the relatively high costs of

travel to communities, future programs should explore ways to reduce travel costs, such as capping visits/client, and identifying strategies to meet with multiple clients per community visit. Further research is needed to assess the effectiveness of alternative models to provide male-tailored counseling with reduced HCW travel time, such as facility-based counseling.

CHAPTER 7: DECISION-MAKING FRAMEWORK

Adoption and scale-up of effective public health interventions is essential for population health improvement, but funding is highly constrained in low-income settings. Decision-makers (e.g., from Ministries of Health, multilateral organizations, and foundations) make difficult tradeoffs when selecting interventions and implementation strategies. Their decisions involve consideration of multiple criteria (e.g., effectiveness, equity, budgetary and practical constraints, political considerations, and opportunity costs) and scale-up strategies (e.g., coverage levels across the country, populations targeted, combinations of interventions).¹⁴⁸ Compounding these challenges, policymakers often lack locally-relevant, comparable data on all the pertinent aspects of intervention options.^{149–151} As a result, policymakers are often only able to make ad-hoc, opaque decisions.¹⁴⁸ There are systematic approaches to health priority-setting, such as program budgeting and marginal analysis (PBMA)¹⁵² and multi-criteria decision analysis (MCDA),¹⁴⁸ but they are rarely used in routine practice due to their complexity and resource requirements.^{149,153} In this environment, impact evaluations can be more influential if they include relevant information on implementation factors organized into a framework that facilitates comparison with other intervention options.^{111–116} The primary aim of this chapter is to offer Malawian stakeholders a structured framework to help inform decision-making on adopting and scaling-up the IDEaL interventions using findings from objective one and two and other ideal trial data.

Methods

We developed the decision-making framework using a sequential mixed-methods study design, placing equal priority on qualitative and quantitative data.¹⁵⁴ First, we conducted in-depth interviews (IDIs) with high-level international and Malawi-based stakeholders.¹⁵⁵ Findings from this study revealed the distinctive features of the decision-making context and guided our selection of appropriate research questions for the decision-making framework. We then reviewed several intervention scalability frameworks (i.e., the Intervention Scalability Assessment Tool,¹⁵⁶ the Proctor framework,¹⁵¹ the Consolidated Framework for Implementation Research,¹⁵⁷ the ACE approach,^{109,110} and the OECD Evaluation Criteria¹⁵⁸) to identify relevant constructs for each research question. Using qualitative and quantitative data from the IDEaL study (Appendix 2 and 3),¹⁵⁵ we summarized the most significant impacts of implementing each intervention. Table 17 includes details on data used in the framework.

The ACE approach emphasizes due process through transparency and stakeholder feedback.¹⁰⁸ As such, we consulted stakeholders throughout the development of the decision-making framework and integrated the qualitative data from these interactions with quantitative data from the trial.¹⁵⁴ Representatives from the IDEaL research team and Partners in Hope Malawi (the IDEaL trial's implementing partner) reviewed drafts and gave feedback through a group discussion.

Table 17. Study data included in decision-making framework

Data Source	Population	N	Time frame	Data used	Data analysis	Decision-making factors
Baseline Survey	Study Participants	569/569 (100%)	At study enrollment	Demographic data	Stratification of outcomes and costs by age, urban/rural and wealth	Equity
Midline Survey	Study Participants	539/569 (95%)	2 months after study enrollment	Patient satisfaction and willingness to recommend intervention to a friend	Quantitative statistics	Acceptability (clients)
Medical chart review	Study Participants	522/569 (92%)	6-month follow-up period	Outcome data (6-month retention in care and ART initiation within 90 days)	Stratification of outcomes and costs by age, urban/rural and wealth	Effectiveness, equity
In-depth Interviews	Study Participants	36	2-3 months after study enrollment	Perceptions of IDEaL interventions, reasons for (re-)initiating or not	Qualitative thematic analysis	Acceptability (Clients)
In-depth Interviews	High-level decision-makers	22	Nov. 2021-Mar. 2022	Perceptions of potential interventions, decision-making criteria	Qualitative thematic analysis	Acceptability feasibility, sustainability (decision-makers)
HCW Focus Group Discussions	IDEaL HCWs	20	6-9 months after intervention start	Intervention acceptability and perceptions of implementation barriers and facilitators	Rapid qualitative analysis	Acceptability (staff)
Costing data	Study Participants and Staff	549	Throughout intervention period	Patient-level resource utilization data, secondary data on unit costs, HCW interviews	Economic evaluation	Cost, acceptability (clients), Sustainability, Equity

Definitions of Factors Included in the Decision-making Framework

The IDEaL decision-making framework includes constructs related to effectiveness, cost, acceptability (to clients, healthcare workers, and decision-makers), equity, feasibility, sustainability, and other considerations. The working definitions, evaluation questions, and data sources for each of these implementation factors are described below and in Table 18.

Effectiveness: We define effectiveness as the extent to which the interventions achieved their intended outcomes. The two measures of effectiveness were the IDEaL trial's primary outcome of 6-month retention in care (defined as initiating ART within 90 days of enrollment and being \leq 28-days late for the last scheduled ART appointment prior to 6-months after initiation) and secondary outcome of ART initiation (defined as completing an ART initiation visit at the facility or at home within 90-days of enrollment).

Intervention Cost: IDEaL's costing analysis was conducted from the provider perspective and included all intervention-related costs per study participant after enrollment through the first ART refill visit, when all three IDEaL interventions are complete. Costs per study arm are summarized as means.

Equity: We defined equity as “the impact of the intervention on inequity in the distribution of disease and health status, and access to, or utilization of, specific intervention(s).”¹⁰⁹ We assessed equity considerations qualitatively through discussion and feedback with the trial’s research and implementation team.

Acceptability: We defined acceptability as stakeholders’ perceptions that an intervention is “agreeable, palatable, or satisfactory.”¹⁵⁹ We focused on three groups that would be highly impacted by the IDEaL interventions or have a crucial role in their scale-up: clients, HCWs and decision-makers. We assessed client acceptability using findings from client IDIs and client satisfaction questions from the IDEaL baseline and 2-month follow-up surveys. We also assessed changes in self-reported negative interactions with HCWs at the participant’s previous facility visit from baseline to midline.

Work-related time constraints are a known barrier to men’s HIV treatment access.^{47,48} Therefore, we estimated the time clients spent accessing care in each intervention arm using client-level interaction data collected by HCWs and medical records data on the number of facility visits. We assumed clients spent 4.9 hours to travel to and attend a facility-based visit based on a prior study in a similar setting.¹²²

We assessed HCW acceptability based on FGDs with IDEaL HCWs and decision-maker acceptability based on IDIs with high-level international and national decision-makers.¹⁵⁵ Additionally, we reviewed the Malawi Ministry of Health’s strategic plans to assess the

alignment between the IDEaL interventions and the initiatives and priorities described in the documents; this was another indication of decision-maker acceptability.

Feasibility: We defined feasibility as “the extent to which an implementation target can be deployed successfully within a given setting.”¹⁵⁹ We gathered feedback from the implementing organization and analyzed qualitative data from the IDEaL staff FGDs to assess facilitators and barriers to implementation of the interventions during the IDEaL trial.

Sustainability: Sustainability has two major aspects: 1) the extent to which an intervention can be maintained or institutionalized within a service setting after start-up funding,¹⁵⁹ and 2) the likelihood that interventions result in sustained behavior change among clients and HCWs.¹¹⁰ In IDIs, Malawian decision-makers expressed that the level of ongoing funding needed, human resource requirements, simplicity, and compatibility with existing programs and systems are the most important determinants of sustainability.¹⁵⁵ Malawi’s severe staffing shortages and recent currency devaluation have limited the provision of basic services and are expected to worsen without additional investments.⁶⁰ Given this context, we estimated the HCW time required to implement each IDEaL intervention component. We also assessed the likelihood that the interventions would result in sustained behavior change among clients and HCWs based on findings from staff FGDs and client IDIs, and input from the research and implementation team. We assessed the simplicity and compatibility of the interventions

based on our knowledge of existing initiative in Malawi and the design of each intervention.

Other Consequences: This factor includes intended and unintended spillover effects not accounted for in the primary effectiveness analysis or the cost-effectiveness analysis, as well as potential higher-level impacts on systems or norms. Our assessment of this factor was informed by the FGDs with IDEaL HCWs and input from the research and implementation team.

Table 18. Implementation factors included in the decision-making framework

Implementation factor	Evaluation questions	Data Sources
Client Acceptability	To what extent are clients satisfied with the interventions?	<ul style="list-style-type: none"> Participant satisfaction survey data
	To what extent do the interventions respond to men's needs?	<ul style="list-style-type: none"> Client time estimates (using resource-utilization data and literature) Participant IDIs and survey data
Healthcare worker Acceptability	To what extent are intervention deliverers satisfied with the intervention services?	<ul style="list-style-type: none"> Healthcare worker FGDs
Decision-maker Acceptability	To what extent do the interventions fit with decision-makers' priorities and constraints?	<ul style="list-style-type: none"> Stakeholder IDIs Malawian Ministry of Health strategic plans
Feasibility	To what extent were the implementing organization and healthcare workers able to implement the interventions?	<ul style="list-style-type: none"> Healthcare worker FGDs Input from the implementation team
Effectiveness	To what extent do the interventions achieve their outcomes?	<ul style="list-style-type: none"> Trial outcomes (6-month retention and ART initiation) by arm
Intervention Cost	How much do the interventions cost?	<ul style="list-style-type: none"> Study records and medical records by arm
Equity	What are the interventions' impacts on equity of access to HIV treatment?	<ul style="list-style-type: none"> Input from the research and implementation team
Sustainability	How complex are the interventions? How compatible are they with existing programs and systems?	<ul style="list-style-type: none"> Input from the research and implementation teams
	How much HCW time is required to implement the interventions?	<ul style="list-style-type: none"> Cost analysis using study records and trial data
	How likely are the interventions to result in sustained behavior change among HCWs and clients?	<ul style="list-style-type: none"> Healthcare worker FGDs Input from the research and implementation teams
Other Consequences	To what extent do the interventions lead to changes in system or norms or have spillover effects?	<ul style="list-style-type: none"> Healthcare worker FGDs Input from implementation team

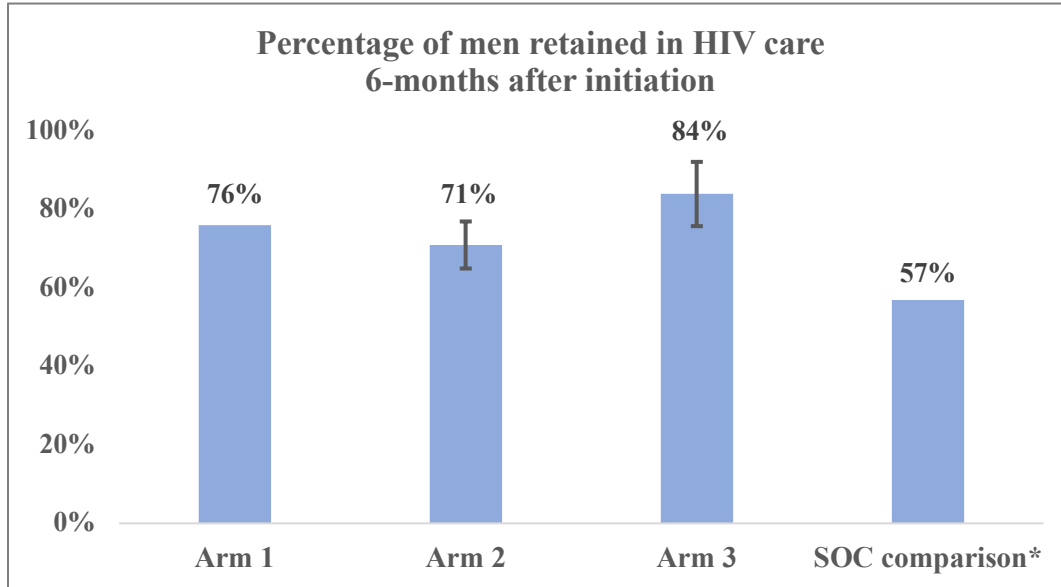
Results

Below we describe and summarize the key findings for each decision-making factor (Tables 19–21).

Effectiveness

Overall, 76% of men in Arm 1 (lay cadre community-based counseling), 71% (95% CI: 65%, 76%) of men in Arm 2 (home-based ART initiation), and 84% (95% CI: 76%, 91%) in Arm 3 (stepped interventions of increasing intensity) met the primary outcome of 6-month retention in care. In the ENGAGE trial's SOC arm, 67% of clients initiated ART within 90 days;¹⁴⁶ 22 percentage points lower than the 89% observed in IDEaL's Arm 1. If we conservatively assume that drop-off rates for the first 6-months of care were similar for both studies, IDEaL's Arm 1 would have initiated and retained 19-percentage points more men than SOC at 6-months (76% v. 57%) (Figure 10).

Figure 10. IDEaL trial outcomes and SOC comparison



Note: Based on preliminary results from the IDEaL and ENGAGE trials. Retention is a composite outcome of initiated care < 90 days after enrollment and retained in care at 6-months. Error bars represent 95% CIs in comparison to Arm 1.

*Modeled from the standard of care comparison from the ENGAGE trial which ran concurrently with IDEaL with the same eligibility criteria but in different facilities

Cost

The average costs of the IDEaL interventions per participant are \$28 for Arm 1, \$44 for Arm 2 (95% CI: \$39, \$49), and \$35 (95% CI: \$30, \$40) for Arm 3. Arm 2 has the highest cost due to greater use of the labor of nurses, which is more expensive than that of other HCWs; hourly wages including all IDEaL-specific costs were \$9.78, \$6.87, and \$2.58 per hour for nurses, psychosocial counselors, and lay cadres, respectively.

In all study arms, participants who did not achieve the primary outcome have substantially higher mean costs than those who did; participants who did not initiate

relatively quickly were less likely to eventually initiate and accrued additional costs from follow-up visits.

The Malawian government uses fully dynamic cost-effectiveness models to allocate funding to its HIV programs; these models include primary and secondary transmission over a 15-year time horizon.¹⁶⁰ Their mathematical models ranked ART scale-up as the most cost-effective HIV-related intervention, assuming annual treatment costs of \$165 per person.¹⁶⁰ The cost of Arm 1 (excluding facility visit costs) was \$20 per participant. This intervention may be of interest to the MoH because it focuses on men who are disengaged from care, a crucial population for reducing HIV transmission.¹⁶¹

Equity

All three IDEaL interventions reduce gender inequities in access to care, as men in Malawi have lower rates of treatment engagement than women.¹⁶⁰ Also, the interventions likely reached a poorer than average population in Malawi as it was only implemented in public and NGO facilities. Community-based tracing may be less successful for men who are highly mobile (often for work). This population was recently found to comprise approximately a third of men with treatment interruptions in Malawi.⁹ Special consideration should be given to strategies to reach these men.

Client Acceptability

Clients reported very high satisfaction scores (97% or higher) in all three intervention arms. In IDIs, men emphasized the importance of two aspects of the interventions: 1) positive, friendly, ongoing interactions with male HCWs; and 2) a male-tailored counseling curriculum that resonated with their concerns and goals. While men appreciated the home-based ART initiation offered in Arm 2, they did not consider it essential, especially because it was a one-time service.¹³⁶ Clients did not have a strong preference for which HCW cadre provided the counseling sessions.¹³⁶

We chat about business and my farming. He encourages my adherence and says that I can still be leader in my community despite my HIV status. I ask him how to face my issues. Yes, we are indeed friends. -Client, 37 yrs, Central region

Across arms, only 1% of IDEaL clients reported dissatisfaction with their first facility visit after enrolling in the IDEaL interventions, compared with 9% at their last visit before enrolling ($p \leq 0.0001$). This pattern was similar for each arm, but sample sizes were too small to test for statistical significance by arm.

On average, men spent less time participating in Arm 2 (M = 6.7 hours, SD = 3.0) than in Arm 1 (M = 10.0 hours, SD = 2.7) or Arm 3 (M = 10.2 hours, SD = 2.3). Arm 2 participants were offered home-based ART initiation early in the intervention, eliminating the travel and waiting time associated with the ART initiation visit. When given the choice, 75% of Arm 2 participants chose home-based initiation over facility-based initiation. However, men were willing and able to initiate ART in facilities; initiation rates were not statistically different across intervention arms.

Healthcare worker Acceptability

In FGDs, IDEaL HCWs expressed pride in their new skills (e.g., male-specific counseling and motivational interviewing) and approaches for interacting with clients (e.g., friendliness, grace, respect). They believed these strategies helped men with multiple treatment interruptions overcome their barriers to long-term retention in care. HCWs appreciated the opportunity to help clients understand how the health benefits of treatment could help them meet their life goals. They valued the trust and emotional closeness they developed with clients in longer, deeper conversations, and drew a stark contrast between these interactions and those occurring at facilities IDEaL HCWs believed that clients shared their true reasons for defaulting with them, opening the door to collaborative problem-solving. For example, clients shared how negative interactions with HCWs left them feeling disrespected and unwilling to return to care.

When they ask questions and I explain the answers to them, they listen attentively. When I ask questions they answer diligently. You can't even tell that you spent a lot of time together because everyone is participating actively. You are chatting and when you are chatting time [passes quickly.] -Lay Cadre HCW, 6-months after rollout

The facility staff would warn us that a client was an impossible case and they had no idea how we would handle him. But we would use the [strategies] in the male-specific counselling guide and have a positive impact. The person who was considered impossible would return to care and the staff would be amazed. We were very confident of a positive impact each time [we worked with someone]. These results are different from the general counselling offered before the study because the male-specific counselling addresses [men's] specific issues. -Lay Cadre HCW, 9-months after rollout

In sum, HCWs found the IDEaL interventions to be highly acceptable.

Decision-maker Acceptability

The IDEaL interventions are well-aligned with decision-makers' priorities. In IDIs, both Malawian and international decision-makers emphasized the need for tailored interventions designed specifically for populations with lower rates of treatment engagement and the importance of person-centered care for retaining clients in care.¹⁵⁵ More than two-thirds believed that negative interactions with HCWs were a major factor in treatment disengagement but considered it a difficult issue to address.

Studies in the region consistently show that unfriendly providers... are a very significant barrier to retention...we only have a few sites where this has been appropriately addressed. A nurse or a clinician [may start out] motivated, but they will lose that motivation if they don't feel supported and are faced with endless queues. -National decision-maker

Making the staff friendlier keeps coming up in all the research [but] that's a really tough intervention. No one knows how to do it, and we certainly don't know how to do it at scale. -International decision-maker

However, decision-makers may be reluctant to implement community-based interventions; they perceive them as highly effective but expensive, human-resource intensive, and logistically complex.¹⁵⁵

The 2020–2025 Malawian National Strategic Plan for HIV and AIDS acknowledges the problem of lower rates of treatment engagement among men. In the plan, men are listed as a high-risk population.¹⁶⁰ The plan aims to increase ART coverage among men by 15 percentage points (72% to 87%) compared to 7 percentage points among women (89% to 96%).¹⁶⁰ However, the plan does not include any strategies specifically designed or targeted for men, possibly due to the lack of well-studied, scalable interventions for men,

or the perception (reaffirmed in the strategic plan) that lower rates of treatment engagement among men are due to gender norms related to health-seeking behavior.¹⁶⁰

Feasibility

In FGDs, all HCW cadres expressed a high level of confidence in their ability to deliver all aspects of the IDEaL intervention (e.g., male-specific counseling, motivational interviewing, tracing, facility navigation). They felt well-supported by the study trainings and supervision and felt that the male-specific counseling curriculum was well-structured, comprehensive, and locally relevant. HCWs were able to address clients' concerns about status disclosure due to HCWs' home visits by using strategies like parking their health facility-issued motorcycles outside villages and walking in to attract less attention. They also felt capable of partnering with clients to develop tailored solutions to treatment barriers.

[I] praise our curriculum and the motivational interviewing manual. The topics equip a counselor with guidance on how best to assist a client. In normal counselling sometimes you just flow with the situation, and you can get misguided, but when the approaches are [clearly described], you know where to take the discussion and can provide solutions. -Psychosocial Counselor, 6-months after rollout

Arms 2 and 3 are more complex than Arm 1. These interventions involve training several HCW cadres, engaging up to three different HCWs in delivering the intervention, and equipment management: the nurses' motorcycles required servicing and registration.

Sustainability

HCW time is the main resource required to implement the IDEaL interventions. HCW time was similar across arms (mean per participant of 7.7, 8.4 and 7.8 hours for Arm 1, Arm 2 and Arm 3 respectively), but Arms 2 and 3 required more costly labor from nurses and psychosocial counselors. Travel and tracing were particularly time-intensive – HCWs spent 80% of their time traveling and tracing and only 20% interacting with clients. HCWs usually did not visit more than one client when they traveled to communities, likely because the IDEaL interventions were focused on a specific population. In a routine setting, training for the IDEaL interventions would take approximately 6 hours, split between training on male-specific counseling, and person-centered counseling skills.

Though the IDEaL interventions officially end after a client's first ART refill visit, they may have long-term impacts on clients' retention in care. HCWs provided comprehensive support; they encouraged status disclosure, helped create transportation and emergency refill plans, corrected misperceptions about ART, and fostered personal self-efficacy, motivation, and resilience. These skills and knowledge are critical for long-term care engagement. Nevertheless, the IDEaL interventions do not directly alter systems, and persisting barriers (e.g., negative interactions with HCWs) may still lead to treatment discontinuation.

Other Considerations

While the IDEaL interventions aim to intervene at the individual and interpersonal levels of the social-ecological model,¹⁶² they may also influence health systems and communities. For example, in IDIs, IDEaL HCWs described how the results they were able to achieve demonstrated to their facility-based colleagues that men were willing to initiate or re-engage in care if they were treated with respect. The IDEaL HCWs became champions for men; holding their colleagues accountable for treating clients poorly and advocating for their colleagues to receive client-centered communication training.

[My clients in Nkhotakota said that a certain HCW] didn't treat them properly and they felt so bad they just stopped [treatment]. I assured them I would find a solution. I raised the issue at a staff meeting and we had a good discussion. Of course, there were some objections, but at the end of the day the atmosphere changed. Now those clients are coming in for treatment. -Nurse, 9-months after rollout

Findings from the HCW IDIs indicate that the IDEaL interventions may improve HCW work satisfaction and fulfillment by improving relationships with patients. Improving staff satisfaction is one of the MoH's core goals given Malawi's healthcare workforce shortages and turnover.⁶⁰ Additionally, HCWs' improved communication skills may enrich all their patient interactions, not just the IDEaL population (men living with HIV who are not engaged in care).

The IDEaL interventions may also have spillover effects at the interpersonal and community levels. In FGDs, HCWs described how correcting misconceptions about HIV transmission improved relationships among family members.

Most people here in Nsanje don't understand [HIV transmission]. One man blamed his daughter for [giving him] HIV because she [had cuts on her hands] while cooking. – Lay Cadre, 9-months after rollout

In some cases, HCWs supported men in disclosing their status, which led to sexual partners getting tested and starting HIV treatment. Men who started and continued treatment and/or developed relationships with other men living with HIV due to the interventions are shifting community norms — men who are openly on treatment and seen as healthy and strong can inspire other men in their community to start treatment.¹⁶³

Table 19. Cost and effectiveness of IDEaL Interventions

Factor	Indicator	<u>Arm 1:</u> Counseling-only	<u>Arm 2:</u> Home-based ART initiation	<u>Arm 3:</u> Stepped Care
Effectiveness	Retained at 6-months ^a (SOC comparison: 57%) ^b	76%	71% [95% CI: 65%, 76%] ^c	84% [95% CI: 76%, 91%]
Intervention Cost	Cost per participant (from health system perspective)	\$28	\$44 [95% CI: \$39, \$49]	\$35 [95% CI: \$30, 40]

Note: The intervention is defined as all IDEaL-specific activities and facility visits after enrollment through the first ART refill visit. Costs are from the provider perspective and include costs of IDEaL activities and ART visits but not ART medications.

^a*Retention is a composite outcome of initiated care \leq 90 days after enrollment and retained in care at 6-months*

^b*Modeled from the standard of care (SOC) arm in the ENGAGE trial in Malawi which ran concurrently with the same eligibility criteria, but is not directly comparable because it was implemented in different facilities.*

^c*95% CI from linear regression model comparing Arms 2 and 3 to Arm 1*

Table 20. Implementation considerations for IDEaL Interventions

Factor	Indicator	<u>Arm 1:</u> Counseling-only	<u>Arm 2:</u> Home-based ART initiation	<u>Arm 3:</u> Stepped Care
Acceptability (Clients)	Client Satisfaction (self-reported via midline survey)	≥ 97% of participants were satisfied with each intervention.		
	Change in negative interactions with HCWs at facilities (self-reported via baseline and midline surveys)	9% to 0.5%	11% to 3%	11% to 3%
	Most impactful aspects of interventions (self-reported in interviews)	- Participants valued male-specific messaging and positive interactions with study HCWs more than temporary home-based ART.		
	Average time participants spent receiving counseling and accessing HIV treatment during intervention period	<u>10.1 hours</u> Counseling: 1.1 Facility visits and travel: 8.9	<u>6.7 hours</u> Counseling and HB-ART: 1.5 Facility visits and travel: 4.9	<u>10.3 hours</u> Counseling and HB-ART: 1.3 Facility visits and travel: 9
Acceptability (Healthcare Workers)	HCW perceptions (self-reported via focus groups)	- HCWs appreciated improved skills and relationships with participants. - HCWs perceived intervention strategies to be highly effective.		
Acceptability (Decision-makers)	Decision-maker perceptions (self-reported via interviews and described in strategic plans)	- Decision-makers prioritize person-centered care and tailored interventions - Decision-makers perceive community-based care and peer support interventions to be too resource-intensive		
Feasibility	HCW and implementing organization perceptions (self-reported via focus groups)	- HCWs were confident they could deliver all intervention components (e.g., tracing, counseling, facility navigation)		
Equity	Research team and implementing org. perspectives (self-reported via focus groups)	- Improves gender equity in access to HIV care.		

Sustainability	Average hours HCW spent per participant	<u>Total: 7.7</u> <i>Lay cadre: 7.7</i>	<u>Total: 8.3</u> <i>Lay cadre: 5.8</i> <i>Nurses: 2.5</i>	<u>Total: 7.7</u> <i>Lay cadre: 6.2</i> <i>Psychosocial counselors: 1.3</i> <i>Nurses: 0.2</i>
	Proportion of time spent on tasks	- Approximately 80% of HCW time spent traveling and tracing and 20% spent interacting with men in all arms		
	Simplicity and compatibility with existing programs and systems	Compatible with existing tracing programs	Involves up to two HCWs per client and motorcycle management	Involves up to three HCWs per client and motorcycle management
	Likelihood of sustained behavior change among HCWs and clients	<ul style="list-style-type: none"> - HCWs and clients developed sustainable skills and knowledge through counseling intervention. - Interventions did not directly alter health system, so systems-level barriers to accessing treatment may persist 		
Other Considerations (Spillover Effects)	HCW and implementing org. perspectives (self-reported via focus groups)	<ul style="list-style-type: none"> - HCWs' improved communication skills may benefit all clients, not just the target population (men who are not engaged in care) - Can improve facility-level understanding of men's barriers to care - Can result in testing and treatment of men's partners 		

Note: The intervention period is defined as all IDEaL-specific activities and facility visits after enrollment through the first ART refill visit.

Table 21. Summary of considerations for adopting IDEaL interventions

Factor	<u>Arm 1:</u> Counseling-only	<u>Arm 2:</u> Home-based ART initiation	<u>Arm 3:</u> Stepped Care	Summary
Effectiveness	X	X	X	- All three arms had better outcomes than SOC ^a - No statistically significant differences in 6-month retention in care across arms, though Arm 3 performed the best.
Cost	X			- Arm 1 is the least costly.
Acceptability	X	X	X	- All arms are highly acceptable to HCWs and clients. - Decision-makers favor person-centered care but are hesitant to implement community-based interventions due to resource limitations.
Equity	X	X	X	- All three interventions improve sex equity in access to HIV care.
Feasibility	X	X	X	- All arms were successfully implemented in the study setting.
Sustainability	X			- Arm 1 is the least complex and has the lowest ongoing costs.

^aStandard of care (SOC) reference from the ENGAGE trial which ran concurrently in Malawi with the same eligibility criteria, but is not directly comparable because it was implemented in different facilities.

Discussion

Men face multi-level barriers to accessing HIV care. Men have less experience navigating healthcare facilities and have fewer entry points for health education, HIV counseling and testing than women of reproductive age.^{8,42} It has been shown that HCWs have negative perceptions of men which can lead to unsupportive or even hostile encounters.^{8,28,43,45,46} Men may also delay and/or interrupt treatment due to long wait times and frequent appointments that conflict with work demands and related mobility.^{9,47-49} These barriers result in lower rates of HIV testing and treatment and higher rates of mortality among men.³⁵⁻⁴¹ In this study, we developed a comprehensive decision-making framework comparing the three interventions tested in the IDEaL trial to improve initiation and early retention in HIV care among men in Malawi. We found that the simplest intervention (Arm 1: community-based lay cadre counseling only) performed equivalently or better than the other interventions on every decision-making criterion. All three interventions were highly acceptable to clients and HCWs, but the lay cadre counseling-only approach was the cheapest and most feasible of the three. Differences in effectiveness across the three intervention options were not statistically significant.¹⁴⁶ The equity impacts of these interventions greatly depend on implementation strategies, but all three interventions improve sex equity in HIV care.

The Kingdon framework for agenda setting includes three factors that determine a political issue's priority among policymakers: 1) recognition of the problem's existence, which is often in response to data, 2) a political environment that is supportive of action,

and 3) the existence of a feasible and acceptable policy or programmatic solution.¹⁶⁴ Our analysis shows that that decision-makers are aware that men have poorer access to HIV care and believe that improving HCW communication with men is a driver of this issue, but are not aware of effective strategies for addressing this problem.¹⁵⁵ The IDEaL trial and other recent studies^{93,165} fill this gap by showing that it is possible to train HCWs to provide friendly, empowering, and person-centered care to men.

Despite the convergence of the factors necessary to motivate political change, sustainable scale-up of interventions is challenging and requires changes to culture, systems and practice.^{166,167} According to a systematic review completed by Bulthuis et al., the most important factors associated with successful scale-up efforts are 1) the availability of adequate financial, human, and material resources, 2) the simplicity of the intervention, 3) the involvement of advocates and champions at the local and national level, 4) the creation of a strategic plan, 5) sufficient and continuous training and supervision, and 6) monitoring and evaluation. In Malawi's highly-resource constrained environment, cost and human resource considerations are especially critical for successful intervention adoption. The IDEaL interventions could be adapted to be less resource-intensive, as is common for interventions studied in clinical trials.^{168,169} Adapting the IDEaL interventions for successful and sustainable scale-up will require stakeholder engagement, piloting, and evaluation.¹⁶⁸

Two findings from the IDEaL study point to more efficient ways to provide counseling to men. First, the study showed that lay cadres can provide counseling sessions to men at a lower cost than other cadres with comparable outcomes. Second, both clients and HCWs believed that the *quality* of counseling interactions were more important than the setting in which they were delivered.¹³⁶ To lower travel costs, facility-based counseling sessions could be provided to men who are newly-diagnosed or returning after a shorter treatment interruption. These sessions should preserve the core aspects of the IDEaL counseling sessions that drove success, such as friendliness, longer length, discussion and action on personal barriers, and tailored counseling focusing on the benefits of ART most important to the individual.¹³⁶ Community-based tracing and counseling could be limited to men who have had longer or multiple treatment interruptions. If community-based interventions are cost-prohibitive in rural areas, other program models, such as phone-based counseling and visiting multiple men per community visit should be considered.

Further, to prevent treatment interruptions caused by negative HCW interactions, male-sensitization training and best practices for implementing male-specific person-centered care could be integrated in existing MoH trainings. These best practices should be simplified, systematized, and properly resourced so they do not increase HCWs' already heavy workload. Healthcare workers can be taught brief yet effective strategies for responding to clients' concerns so they have the tools and skills to have more positive interactions with clients. For example, IDEaL HCWs and clients reported that clients felt validated when HCWs apologized on behalf of the healthcare system for past negative

healthcare experiences. Such practices can both improve men's engagement in care and reduce HCW burnout and turnover by creating more meaningful interactions with clients. Performance metrics are not sufficient for changing HCW behavior, especially when the goal is authentic positive interactions with clients.¹⁷⁰ Instead, national and organization-level policies and guidelines that enable HCWs to flexibly respond to men's needs should be put in place.¹⁷⁰

Our decision-making framework has several limitations. First, we did not assess differences in implementation across different types of clinic sites; this would have provided a better understanding of the contextual issues associated with the success of IDEaL interventions. Second, the decision-making framework only included the intervention options that were studied in the IDEaL trial. While this was by design, future decision-making frameworks may include a broader range of options. The decision-making framework also did not include analysis of differential outcomes by subgroup, though it is critical for program implementers to design strategies tailored for subgroups of men with lower treatment engagement rates, such as young and highly mobile men.⁹ Finally, this study's findings on travel time may not be generalizable as Malawi is more rural than many other countries in Sub-Saharan Africa. Despite these limitations, we believe the decision-making framework offers robust, comprehensive, and relevant information that can inform adoption and implementation decisions as well as future research.

Conclusion

Person-centered, male-tailored counseling with HCWs contributed to the success of the IDEaL interventions and was highly valued by clients, healthcare workers, and decision-makers. Counseling with lay cadre HCWs should be prioritized over more expensive interventions for increasing men's engagement in HIV care, such as community-based psychosocial counseling and community-based ART initiation. This decision-making framework can support stakeholders' decisions to adopt and tailor the IDEaL interventions so they are contextually appropriate and adequately resourced.

APPENDICES

Appendix 1: Stakeholder In-Depth Interview Guide

Interview Questions:

1. Within your program/work, what do you see as the top two or three HIV-specific priorities or concerns that need to be addressed in the upcoming years?
2. Within ART initiation and early retention: What factors keep individuals from engaging in care?
 - a. Do you think these are the same factors that keep men from engaging in care? We know that men have lower rates of ART engagement than women. Why do you think this is?
3. What do you see as the biggest need and/or gap in knowledge for ART initiation or re-engagement in Malawi/SSA?
4. Based on the literature, we see seven overarching types of interventions to support early ART engagement for individuals who are known HIV+ but aren't engaging in ART through routine care. We are interested in what types of interventions you'd like to see implemented in [Malawi/sub-Saharan Africa] at scale. Could you please categorize each intervention as "high interest," "possible interest," or "lower interest/not feasible"? As you are categorizing please talk aloud about why you put them in that category.
 - Incentives (monetary)
 - Incentives (non-monetary)
 - Community-based care (e.g. home and community-based ART initiation and/or refills)
 - Ongoing peer/mentor support and counseling (facility or community based)
 - eHealth Strategies (e.g., text message or smart phone apps)
 - Facility changes (e.g. extended hours, simplified workflows, services tailored for specific populations)
 - Multi-month dispensing
 - Any other intervention type you want to add?

Would you change your categorizations if these interventions were specifically targeted/tailored directly to men (male-only)? Why or why not?

5. Are there any challenges to implementing your top three interventions? What would be required to best facilitate the scale-up of your favorite three interventions within Ministries of Health or at country-wide scale-up (e.g., what resources are available)?
6. What kinds of information on costs and/or outcomes would be most helpful for you to decide whether or not to implement your top three intervention options?

7. Based on the literature, we see five outcomes related to implementing interventions at scale. We'd like you to think about these outcomes, and categorize whether they would be lower-, mid-, or high-importance when deciding whether to scale-up an ART initiation and/or retention intervention. Please talk aloud why you put each outcome in that bucket and what aspects of the outcome are most important.

- Feasibility (ease of integrating with existing resources, programs and practices)
- Acceptability (to stakeholders, providers, and patients)
- Intervention Effectiveness
- Intervention Costs
- Equity (i.e., does it reach all populations / hard-to-reach populations)
- Other (Specify)

Would you change your categorizations if these interventions were specifically targeted/tailored directly to men (male-only)? Why or why not?

Appendix 2: Analysis of Ideal Staff Focus Group Discussions

The IDEaL research team conducted five focus group discussions (FGDs) with 20 HCWs delivering the interventions after HCWs had experience delivering the interventions.

There were two FGD with patient supporters, one with nurses, one with mentors, and one with nurses and mentors. They ranged from 5–13 participants and 2–3 hours in length (Table 22). These FGDs included questions on the acceptability of the interventions to staff and clients and perceived barriers and facilitators to implementation. They took place in English and Chichewa and were recorded, translated, and transcribed.

Table 22. Healthcare worker focus group discussion characteristics

#	Healthcare worker Cadre	Time after intervention start	# of participants
1	Nurses	6 months	10
2	Mentors	6 months	4
3	Nurses and Mentors	9 months	13
4	Patient Supporters	6 months	10
5	Patient Supporters	9 months	11

We analyzed the focus groups using rapid qualitative analysis, a rigorous and efficient method for analyzing semi-structured data.^{171,172} In rapid analysis, qualitative data is condensed into structured templates rather than manually coded. The summary template was organized by deductive domains based on the ACE framework. We added inductive sub-domains based on a review of the first two FGDs.¹²⁶ (Appendix 3) Summary memos were presented to other teammates for feedback and discussion.^{173,174}

Appendix 3: Staff Focus Group Discussion Summary Memo Template

IDI Information

Time point:

Provider Type:

General Summary

Clients + Their Experiences
Client Acceptance of Intervention

Healthcare Workers + Their Experiences
Experiences implementing Manual/Intervention (Fidelity/Feasibility)
Motivational Interviewing/Communication/Relationships with Clients

Handing over/Receiving handover to/from other HCWs
HCW Satisfaction
Other Successes and Challenges of Intervention
What HCWs need to support them/Recommended Changes

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