Impact of HIV Self-Testing on Costs, Access, and Socioeconomic Equity in HIV Testing in Malawi

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Declaration by Candidate

I, Linda Alinafe Sande confirm that the work included in this thesis is my own. Information obtained from other sources has been acknowledged accordingly.

Signed: ________________________

Date: 18th September 2022

Abstract

Introduction: HIV testing services in Malawi are predominantly through facility-based provider testing. In 2016, the World Health Organization recommended HIV self-testing (HIVST) to complement existing testing approaches. HIVST services are provided in both facility and community settings through primary (direct distribution to the final user) or secondary distribution (distribution through an index or sexual contact who will pass the kit along to the final user). In this thesis, I evaluated the impact of distributing HIVST free at the point of use on costs, access, and socioeconomic equity in HIV testing in Malawi.

I had four main questions: 1) what was the cost of accessing facility-based provider HIV testing services in Malawi?; 2) what was the cost of providing HIVST in Malawi, South Africa, Zambia, and Zimbabwe?; 3) how can socioeconomic status be measured in a low-income setting such as Malawi?; 4) how does HIVST affect socioeconomic equity in uptake of HIV testing and the distribution of subsidies from HIV testing in Malawi?

Data: I used a combination of nationally representative publicly available datasets and data collected as part of the Self-Testing AfRica (STAR) project which was a multi-country project aimed at generating evidence and catalysing the market for HIVST.

Methods: There were four main evaluations that were conducted as part of this thesis. The first was an evaluation of costs of accessing testing. The costs of accessing HIV testing services were collected as part of a baseline household survey evaluating the impact of community-based distribution of HIVST in Malawi.

The second evaluation was a descriptive analysis of costs of providing HIV testing services in four countries in Southern Africa. I used ingredient-based costing approach combining bottom-up and top-down costing approaches.

The third evaluation was the construction of a standard of living index using secondary data collected in a Living Standards Measurement Study for Malawi. I constructed a shorter standard of living index that can be easily incorporated in household surveys. The aim of this objective was to develop an index that could be used in the equity evaluation of this thesis.

The final evaluation explored socioeconomic equity in uptake of HIV testing and over-testing for HIV using the STAR endline household survey data. Combining the provider cost and uptake data, I further evaluated the distribution of subsidies from HIV testing using benefit incidence analysis (BIA).

Results: From the cost evaluation, the self-reported average cost of accessing HIV testing services in Malawi was US$3.18 (range: U$2.66-3.71). Men reported user costs twice as high as women with lost income on average, accounting for 83% of total costs.

The costs of providing HIV testing varied with the testing approach. Facility-based provider testing had lower unit costs than HIVST, regardless of HIVST distribution modality. The cost of providing HIV testing services ranged from USS$5.77 (range: US$3.46-9.76) in facility-based provider testing to US$15.09 in secondary distribution of HIVST integrated in public primary healthcare facilities. Cost of the test kits and personnel were key cost drivers across all testing approaches.

I also constructed a standard of living index for Malawi with the aim of using it to measure socioeconomic status in the equity evaluation. This standard of living index comprised of housing characteristics, household assets and human capital variables.

Finally, I evaluated socioeconomic equity in uptake of HIV testing services and the distribution of subsidies from testing for HIV. Full sample showed equity in the socioeconomic distribution of testing and subsidies from HIV testing. Over-testing in standard of care was associated with a higher degree of inequalities concentrated among the richer than in areas with HIVST. Distribution of subsidies was not in accordance with need especially for the poorest in areas with HIVST. Full sample analysis concealed socioeconomic inequalities that were evident when analysis was disaggregated by gender.

Conclusion: Conventional testing, despite having lower provider costs than HIVST, is associated with higher user costs. HIVST is recommended to improve testing uptake among populations left behind. HIVST improves uptake of testing in such groups but is associated with increasing socioeconomic inequalities. Socioeconomic equity implications associated with HIVST should be considered when implementing and scaling up HIVST.

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Dedication

I dedicate this journey to the memory of my parents♥.

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List of Abbreviations

ANC	Antenatal care
ART	Antiretroviral therapy
BIA	Benefit incidence analysis
CBDA	Community-based distribution agent
CHAM	Christian Health Association of Malawi
CRT	Cluster randomised trial
DHO	District health office
DALYs	Disability adjusted life years
DHS	Demographic Health Survey
EHP	Essential Health Package
FSW	Female sex workers
HDI	Human Development Index
HIC	High income country
HIV	Human Immunodeficiency Virus
HIVST	HIV self-testing
HSA	Health surveillance assistant
HTS	HIV testing services
ICER	Incremental cost-effectiveness ratio
IHS	Integrated Household Survey
KM	Kilometre
LMICs	Low-and-middle income countries
MPI	Multidimensional Poverty Index
MLW	Malawi-Liverpool-Wellcome Trust Clinical Research Programme
MoH	Ministry of Health
MSM	Men who have sex with men
NHS	National Health Service
NGO	Non-governmental organisation
OOP	Out-of-pocket payment
OPD	Outpatient department
PCA	Principal component analysis
PITC	Provider-initiated testing and counselling
PLHIV	People living with HIV
PrEP	Pre-exposure prophylaxis
PSI	Population Services International
SES	Socioeconomic status
SLA	Service level agreement
SoC	Standard of care
SSA	Sub-Saharan Africa
STAR	Self-Testing AfRica
STI	Sexually transmitted infection
TB	Tuberculosis
UNAIDS	The Joint United Nations Programme on HIV/AIDS
VCT	Voluntary counselling and testing centre
VMMC	Voluntary medical male circumcision
WHO	World Health Organization

Chapter 1: Background

1.1. HIV/AIDS situation and UNAIDS fast-track targets

Globally, there are 37.7 million people living with HIV (PLHIV) (2). In 2020 alone, there were 1.5 million new global HIV infections and 680,000 AIDS-related deaths (2). Sub-Saharan Africa (SSA), especially Eastern and Southern Africa has the highest HIV burden. The region has 20.6 million PLHIV accounting for 55% of all global PLHIV (2). In 2020, the region accounted for 45% (670,000) of global new HIV infections and 46% (310,000) of AIDS-related deaths (2).

The HIV/AIDS epidemic has not affected all subgroups in the region the same way. For instance, girls and young women aged 15-24 years in SSA are twice as likely to be living with HIV than young men in the same age group (3). This age group of girls and young women also acquire HIV 5-7 years earlier than men (3). Gender-based violence including sexual abuse, poor access to education and health services, lack of access to social protection and lack of skills for coping with inequities and injustices leave them vulnerable to HIV in addition to limiting their access to treatment (3).

The other subgroup increasingly affected by the epidemic are men. Despite men having a lower HIV burden, they have a higher HIV-related mortality than women (4). Men are less likely to test for HIV, get initiated on treatment, be retained in care and present late for treatment often with advanced disease (4-6).

There are several factors responsible for men's low uptake of testing and delayed treatment seeking behaviour. These include, fear, perceived low risk, adopting partner's status as proxy for their own, gender norms and practices that dissuade care seeking, limited entry points in the primary healthcare system, inflexible clinic operating hours, poor recognition of men's distinct health needs, high opportunity costs to accessing care including distance travelled, and perception that clinics are women spaces, among other factors (2, 4-9).

Inequality in testing uptake has also been observed alongside socioeconomic differences. Literature on socioeconomic distribution of testing for HIV has shown differences in uptake of testing by education, literacy, urban versus rural residency and wealth (9-17)· The level of education achieved by an individual has been shown to be positively associated with testing uptake (10, 14, 15, 17). One possible explanation for the positive association between education and testing uptake could be the challenge of accessing messages related to HIV testing among the least educated individuals (9).

Another explanation could be through socioeconomic status (SES). Education is an important indicator of SES. High SES is an important enabler of testing uptake. Poorer individuals are less likely to take up testing (9, 11, 14, 16, 18). The interaction between SES and user costs can be experienced through lack of resources to enable access to testing. Higher wealth allows for ease of payment for costs of accessing testing (9, 14). Accessing HIV testing is associated with both direct and indirect user costs that act as important access barriers especially in settings with fragile livelihoods (19). The opportunity cost of suspending income generating activities and taking time off work has shown to discourage testing (14, 19).

The Joint United Nations Programme on HIV/AIDS (UNAIDS) recognises that there are groups of people that are at a higher risk of acquiring HIV, more vulnerable and affected more than others (20). Such populations have been left behind in the AIDS response. Leaving critical populations behind fuels the epidemic by contributing to new infections, the number of PLHIV and treatment costs (21). In 2014, UNAIDS released the fast-track strategy aimed to end AIDS as a public health threat by 2030 (21). The strategy includes the 95-95-95 targets. The 95-95-95 targets aim that by 2030; 95% of all PLHIV are aware of their HIV status, 95% of PLHIV who know their status are on treatment and 95% of PLHIV on treatment have their viral load suppressed to undetectable levels (21). Undetectable viral load means that the virus cannot be sexually transmitted from an HIV positive person to an HIV negative person hence breaking the transmission path.

Eastern and Southern Africa has been leading in progress towards reaching the fast-track targets (2). By 2020, 87% of PLHIV in the region were aware of their status, 72% were on treatment, and 65% of PLHIV on treatment had suppressed viral loads (22). Despite the region still accounting for the largest HIV/AIDS burden, new HIV infections in the region have also fallen by 16% from 800,000 in 2018 to 670,000 in 2020 (2, 23). However, more needs to be done to get to the UNAIDS 95-95-95 targets.

For the next section, I explore Malawi's profile and HIV/AIDS situation before moving along to summarising various approaches of testing for HIV and finalising with the thesis rationale.

1.2. Malawi country profile

1.2.1. Geography, population, and economy

Malawi is a relatively small but densely populated country located in Southern Africa. Malawi shares borders with the Republics of Mozambique, Tanzania, and Zambia. Administratively, the country is divided into three main regions: Northern, Central, and Southern. The regions are composed of districts. There are a total of 28 districts across all three regions.

Malawi has a population of 17.5 million with an average annual population growth rate of 2.9% (24). The population is predominantly youthful, about 51% of the population is aged under 18 (24, 25). The population is also predominantly rural, about 84% of the population reside in rural areas (24, 25).

The country's GDP per capita is US$626.82, making Malawi a low-income country and one of the poorest countries in the world (26, 27). Approximately 69.2% of the population live below the international poverty line of US$1.90/day and 51.5% live below the national poverty line of US$201.59 a year (28, 29). The incidence of poverty is higher in rural areas, 59.5% against 17.7% for urban areas (24). Not only is poverty in Malawi associated with rural residency, but also lower education levels and belonging to a female headed household (29). Fifty-eight percent of female-headed households are poor against 49% of male headed households (29). Households where the head has no formal education are also more likely to be poor, with the poverty incidence falling as the education level of the household head increases (29).

Malawi's economy is predominantly agricultural driven. About 80% of the population are engaged in some form of agricultural activity (27). However, this engagement is largely subsistence and rain dependent leaving the population vulnerable to weather shocks and food insecurity (27).

About 62.9% of the population are considered to be low food secure with only 27.2% of the population considered marginal to high food secure (30). In terms of income distribution, the degree of inequality is higher in urban than in rural areas (29). The Gini coefficient as a measure of inequality ranges from 0 (perfect equality) to 1 (perfect inequality) (31). The Gini index for Malawi is 0.423: 0.499 for urban areas and 0.320 for rural areas (29). This means that rural residents in Malawi are more socioeconomically homogeneous than urban residents.

1.2.2. HIV/AIDS situation in Malawi

Malawi has nearly a million PLHIV accounting for 5% of PLHIV in the Eastern and Southern Africa region (2). In 2020, the country reported 21,000 new HIV infections and 12,000 AIDS-related deaths (2).

Despite this, the country has made progress towards ending AIDS as a public health threat by 2030. Malawi has experienced a 45% fall in new infections, from 38,000 in 2018 to 21,000 in 2020 (2, 32).The country has also made progress towards the UNAIDS fast track targets from 90% on the first 95 in 2018 to 91% in 2020; 78% on the second 95 in 2018 to 86% in 2020; and, 61% on the third 95 in 2018 to 81% in 2020 (2, 32).

As with the global and regional AIDS response, there is a gender disparity in the progress towards the UNAIDS targets with men lagging behind women for all three 95s. By 2020, 94% of women living with HIV were aware of their HIV status against 90% of men (2). For the second 95, 89% of women living with HIV aware of their status were on treatment against 83% of men (2). Finally for the third 95, 85% of women on treatment were virally supressed against 79% of men (2).

1.2.3. Malawi healthcare system

Formal healthcare in Malawi is provided by the public sector through the Ministry of Health (MoH), private-for-profit and private-not-for-profit institutions (33). MoH provides about 60%

of healthcare in the country (34). This is followed by the Christian Health Association of Malawi (CHAM), which is an umbrella body for church-owned private-not-for profit healthcare facilities. CHAM provides about 29% of all health services: 16% of all outpatient care and, 26% of all inpatient care (34, 35).

MoH is estimated to own about 55% of all healthcare facilities in the country, 14% are owned by CHAM and the remainder are owned by private-for-profit institutions, other non-governmental organizations (NGOs), statutory institutions and private companies (34, 36). There are more MoH health facilities in urban and peri-urban areas while CHAM facilities are predominantly in rural areas (37).

Healthcare in Malawi is provided in a 4-tier system with interlinked referrals. The four tiers are: community/outreach services, primary, secondary, and tertiary facilities. The community services are delivered through community initiatives, village clinics, health posts and community health workers (38). These services are provided by health surveillance assistants (HSAs) who are responsible for a catchment area of 1,000 people (34). HSAs are community health workers employed by MoH as the first point of contact with the primary healthcare system. They possess secondary school education and receive a 12 weeks training to provide preventive care, family health, family planning and immunisation services (39).

The primary tier is composed of dispensaries, maternity facilities, health centres, community, and rural hospitals (38, 40). Health facilities providing primary care are referred to as health centres. These facilities offer both outpatient and inpatient services and conduct minor procedures (34).

The secondary tier acts as referral facilities for the health centres in addition to offering additional inpatient and outpatient services for their catchment populations (40). This level of care is composed of MoH facilities referred to as district hospitals and CHAM hospitals with an equivalent capacity (34).

The highest level of care available in Malawi are tertiary facilities that act as referral centres for the secondary tier facilities and offer professional training, conduct research, host research studies and provide support to the secondary-level facilities (40). The tertiary facilities also provide specialised care at regional level (34). In practice, there have been challenges with gatekeeping such that the tertiary facilities also end up providing substantial primary and secondary care services in addition to the specialised care (34).

Services in the public facilities are free at the point of use except for services offered in optional inpatient paying wards (36). Services at CHAM and the private sector facilities have user fees that are paid either out-of-pocket (OOP) or using health insurance (34, 36). CHAM services are also subsidised by the MoH, and some preselected services are provided free at the point of use through service level agreements (SLAs) with the Ministry.

Under the SLAs, CHAM provides preselected services free at the point of use and the MoH subsequently reimburses the CHAM facilities for the services provided (41). Components of the SLAs were determined using the Essential Health Package (EHP) as part of universal health coverage (42). EHP is a minimum package of services provided free at the point of use for diseases that are the common causes of morbidity and mortality (36).

EHP is composed of: reproductive and maternal services, new born and child health services including integrated management of childhood illnesses, essential vaccines, tuberculosis (TB)and malaria care, community health services, neglected tropical diseases, HIV and nutrition care, treatment of mental health and pre-cancerous cells, management of diabetes and hypertension and some dental care (43).

Finally, in terms of access to care, about 85% of the Malawi population live within an 8 kilometre (KM) radius to a health facility (36). HIV testing services (HTS) are provided at all levels of the healthcare system as outpatient and provider-initiated testing and counselling (PITC) services. At community-level, HIV testing is provided through both outreach services and NGOs. HIV testing is largely provided free at the point of use although the private sector may charge user fees. In the public sector, there may be an additional charge to purchase health passports (booklets used as patient files).

1.3. HIV testing services

This section summarises the provision of HTS in Malawi and other similar settings. HTS are provided by both professional staff and trained lay providers. Lay providers are individuals with no formal profession or paraprofessional training but are trained to deliver specific healthcare services (44). In Malawi, the lay providers are also referred to as HIV diagnostic assistants and are supported by different funding partners but supervised by the HSAs. With HIV testing, lay providers are trained to deliver all testing services including, pre-test counselling, sample collection, interpreting results, and post-test counselling.

The World Health Organization (WHO) recommends an annual HIV test for all sexually active individuals in high HIV burden settings and for people with an ongoing HIV-related risk in all settings (44). Retesting is recommended for patients with a potential sexually transmitted infection (STI), or being treated for a STI, patients with confirmed or presumptive TB, outpatients with clinical conditions indicative of HIV and patients with a recent HIV exposure (45). Testing every 3-6 months (most frequent testing) is only recommended based on individual risk factors such as key populations with an STI or individuals taking pre-exposure prophylaxis (PrEP) (44).

WHO also recommends offering HTS as a strategic mix of approaches of: facility-based testing, community-based testing, partner services and HIVST (45).

Facility-based provider testing

Facility-based provider testing involves testing in healthcare facilities through stand-alone testing centres [voluntary counselling and testing (VCT) centres], laboratory and testing routinely offered by providers [provider-initiated testing and counselling (PITC)] (45). In VCT centres, testing is often client-initiated and services are usually run by NGOs (44).

In PITC, a healthcare provider offers testing to clients receiving other care or with symptoms indicative of HIV including TB. WHO recommends PITC to all clients with unknown or previously a negative HIV status in all clinical facilities in high HIV burden settings (44). This is because PITC offers an opportunity to systematically diagnose HIV with the aim of facilitating patient access to HIV treatment and support services (46). In addition, VCT has a limited reach and need to be complemented by other approaches.

The challenge with facility-based provider testing is that clinics are overly busy, with testing often involving long waiting hours (47, 48). In addition, visiting facilities for testing requires travel, transport, and other costs which can be a hindrance to care seeking especially for individuals who do not have a pressing reason to visit a healthcare facility (47, 48). Community-and home-based testing approaches are recommended in such cases as they are convenient, associated with reduced travel distances, and access costs (48).

Community-based testing

Community-based testing involves testing in communities away from healthcare facilities. This approach was recommended as a way to extend and expand testing services to populations not frequenting facility-based testing such as key populations and their partners, men, and young people (44). Testing services in the community uses various modalities including fixed points such as mobile outreach in markets and, home-based. The testing services are often provided by trained lay providers and peers (45). Community-and home-based testing reaches PLHIV earlier than facility-based testing as it reduces barriers to access such as distance to facilities and user costs (49).

However, testing in community-based, home-based, and facility-based settings tend to be conducted by healthcare providers. Literature has shown that individuals especially in closely knit societies may have concerns about confidentiality with provider testing (48). In addition, men are not optimally reached with such conventional testing approaches as they do not visit healthcare facilities as much as women and may not be home with home-based provider testing.

HIV self-testing

HIVST is a novel testing approach that involves the self-sampling, performing and interpreting for HIV using either saliva (oral) or blood (50). HIVST is provided as clinically restricted, semi-restricted and non-restricted (open access) (51). HIVST provided as clinically restricted is when self-test kits are provided by health workers or peers to specific populations (assisted testing). HIVST provided as semi-restricted is when a health worker or a volunteer provides pre-test information and some counselling before distributing kits for users to test themselves. Finally, HIVST provided as open access which is when HIVST kits are publicly available for users to take up and test privately.

HIVST can be distributed through community-based, facility-based, online platforms, secondary distribution, retail outlets, pharmacies and vending machines and workplace distribution channels (52).

Community-based distribution channel involves distributing HIVST kits in communities. This includes distributing through mobile outreach, at events or home-based including door-to-door (52). Facility-based distribution involves distributing HIVST kits in healthcare facilities through primary and/or secondary distribution. Primary distribution is distributing HIVST kits for primary recipient's own use. Secondary distribution on the other hand, is distributing HIVST for another's use (52). Online distribution of HIVST involves making HIVST available through online platforms that include social media, dating apps and digital media (52). Individuals discretely order the kits that they either pickup at a pickup point or get delivered to their address of choice. Retail outlet involves providing HIVST at a cost through private-owned businesses (45). Finally, HIVST has also been distributed though workplace channels. This involves primary and/or secondary distribution in workplaces using external or peer distributors.

In 2016, WHO recommended HIVST as a safe, accurate and effective approach to reaching people who would not have tested otherwise (50, 52). HIVST offers additional advantages over and above conventional testing including offering an added pathway to obtain care and treatment (51). Similar to community-based and home-based testing , HIVST addresses key access barriers associated with conventional HIV testing approaches such as high opportunity costs coming from missed work, direct user costs; long distances to testing facilities; long lines to access testing; and concerns about confidentiality and stigma (53-59). HIVST has the added advantage over conventional provider testing approaches in that it allows for discreet and convenient testing in private and thereby reaching additional PLHIV not presently reached by conventional approaches (51, 60, 61). Furthermore, empirical evidence has shown that HIVST increases uptake of HIV testing among key populations and the general population, including men, young people, and first-time testers (44, 57, 62-64).

One of the main limitations with community-based testing, home-based testing and HIVST however, is poor linkage to antiretroviral therapy (ART) after testing (65-67). One explanation for this low linkage is that despite these three testing approaches bringing testing services closer, newly identified HIV positive people would still require healthcare facilities for follow-on care. As such, PLHIV still requiring visiting facilities for linkage services would face the same access barriers they faced with facility-based testing (65, 68, 69).

It is recommended with such approaches to have linkage strategies to ensure timely linkage of PLHIV to treatment (69). Such linkage services include SMS reminders and transport facilitation. In the absence of such linkage interventions, literature has shown that linkage to care will be low (66).

Partner services

Finally, all testing approaches presented above are encouraged to incorporate partner services. Partner services involve an offer of testing to sexual or drug injecting partners of PLHIV. This is done through multiple approaches including patient or provider-assisted referral (assisted partner notification or index testing) for partners of PLHIV (45). Partner services have an advantage of being effective at identifying additional PLHIV who may have not tested otherwise (45). Secondary distribution of HIVST falls under partner services.

1.4. Rationale for thesis

The rationale of this thesis was to understand the societal costs of testing and the impact of HIVST on socioeconomic equity. There were three parts to this work. The first was to estimate the cost of providing and accessing conventional facility-based provider testing services. Estimating these costs would not only help contribute to knowledge on the role played by costs in providing and accessing conventional facility-based provider testing, and but also help put costs of HIVST into context. The second aspect was to estimate costs of providing HIVST. This was aimed to inform the affordability of HIVST before recommending it for scale-up.

The third aspect of this thesis was to evaluate the socioeconomic gradient of HIVST. There is an existing socioeconomic inequality in uptake of conventional HIV testing services with the poor not testing as much as the richer (70). One explanation for this are high access costs associated with facility-based provider testing. HIVST reduces such costs by bringing testing closer to the users through both primary and secondary distribution. However, HIVST is a new technology. The poor tend to take up new technologies later and slower than the richer (71). I sought to establish the overall impact of these two effects by determining if HIVST would worsen the existing socioeconomic inequality associated with HIV testing.

1.5. Overview of thesis

Chapter 1 is the introduction chapter where I have presented the scope and outline of the thesis. I also presented the global and local HIV situation. Chapter 2 is a literature review. Here, I present definitions and theories used throughout the thesis. I also present measures of inequalities as presented in literature. Chapter 3 presents the conceptual framework and thesis aims and objectives as well as more detail of the bigger project in which this PhD was embedded, and my role in this project.

Chapter 4 is a methods chapter where I construct and validate an index of standard of living that is shorter than the one frequently used in the setting. The constructed index can be incorporated in household surveys in low-income settings such as Malawi. The goal of this work was to use this index in the equity evaluation in chapter 7, although this was not possible due to project timeline restrictions. In chapter 5, I focus on understanding the role played by user costs in access to HIV testing services. Men and women encounter different barriers to access, I further explore if there is a gender difference in costs of accessing testing.

Chapter 6 is a descriptive analysis of costs of providing HTS. Here, I compare costs of providing facility-based provider testing and three distribution modalities of HIVST across four countries in Southern Africa. Chapter 7 draws on the results from chapter 6. In chapter 7, I evaluate equity in uptake of HIV testing and the distribution of subsidies from testing. Chapter 8 is the thesis discussion. In this chapter, I also offer policy recommendations and provide limitations of the work included in this thesis. I also use this chapter to reflect on what I would have done differently.

Table 1. 1: Thesis Outline

Chapter	Content
Chapter 1	Introduction
Chapter 2	Review of literature
Chapter 3	Thesis aims and objectives
Chapter 4	Constructing and validating a standard of living index
Chapter 5	Costs of accessing HIV testing services
Chapter 6	Costs of providing HIV testing services
Chapter 7	Equity in uptake of HIV testing and distribution of subsidies from testing
Chapter 8	Thesis discussion and policy recommendations

Chapter 2: Review of Literature

2.1. Introduction

The chapter is split into three parts. In part I, I present literature on HIVST in the context of low-and-middle-income countries (LMICs) including an overview of HIVST costing studies. This section is a build-up from the brief background literature on HIV testing services and HIVST presented in Chapter 1. In part II, I discuss theories of social justice, frequently encountered definitions of equity in literature and policy documents and theories exploring inequalities in uptake of interventions and new technologies. In Part III, I present measures of quantifying health inequalities in the distribution of health and healthcare relevant to this thesis.

2.2. Part I: Literature on HIV self-testing in the context of low-and-middle income countries

2.2.1. Studies on impact of HIV self-testing

This section is an extension of the brief HIVST background introduced in chapter 1. As indicated earlier, HIVST offers a viable HIV testing alternative for populations left behind by current testing approaches. A number of studies have evaluated the impact of HIVST in LMICs, majority of which were conducted in Southern Africa.

The main selling point for HIVST is its positive impact on uptake of HIV testing. HIVST has been shown to increase testing uptake regardless of the population group (55). Four randomised trials conducted in Malawi reported HIVST as being associated with high population uptake, and increasing testing among adolescents, partners of women attending ANC, and people attending outpatient care services (72-75).

One of the Malawi trials showed that community-based distribution of HIVST increased recent testing by 16% in the trial arm when compared to the standard of care (SoC) (75). A trial on community-led distribution of HIVST, which is the likely distribution approach if community-based distribution was scaled-up, also showed higher testing uptake in the HIVST arm than SoC (76). Another trial in Zambia reported that HIVST reached men and groups not reached through home-based HIV testing (77). A trial among fishermen in Uganda reported HIVST as increasing testing uptake among men even when kits were distributed through peer networks.

Overall, regardless of distribution modality, HIVST appears to be associated with increased uptake of testing among different populations including higher uptake than facility-based testing (78, 79).

HIVST has also been shown to be acceptable among users in LMICs (80). Whether distributed by women attending ANC or peers among a fishing community, HIVST was demonstrated as acceptable to both the distributors and recipients (80, 81). A 2011 study in Malawi showed that 56.4% of participants reported HIVST as their preferred option for future testing (80).

One of the concerns with HIVST is on lower linkage to prevention or treatment services after a self-test. However, HIVST distributed by trained volunteers and even secondary distribution combined with financial incentives has been shown to increase linkage to follow-on treatment and prevention services (74). In trial settings, HIVST had a comparable proportion of PLHIV linked to ART as that of standard facility-based HIV testing, although this may not still be the case in routine implementation (82).

There have also been concerns about social harms after screening positive with an HIVST kit. So far, HIVST has been associated with low rates of social harms. A mixed methods study in Malawi reported 0.011% of the participants involved in self-testing or offering self-test kits reporting serious social harms (83). Similar minimal social harms have been reported in different trials across the Southern and Eastern Africa region (75, 80, 81, 84).

2.2.2. Studies evaluating costs and cost-effectiveness of HIVST in LMICs

Various studies have explored costs of distributing HIVST. A significant proportion of these studies have been mathematical modelling studies evaluating cost-effectiveness of the different modalities of distributing HIVST (85-89). As with the trials presented above, HIVST distribution in these modelling studies was associated with higher rates of testing (89). The cost-effectiveness of HIVST however, depends on the distribution modality and the underlying HIV prevalence (85).

Over a longer-term period (20-years), HIVST is expected to be cost saving and to be associated with health gains (89). Another modelling study showed the epidemiological impact of HIVST as highest in community-based distribution among adult men and young people (85). The cost-effectiveness of community-based distribution of HIVST was also reported in a study in Malawi (87). In all these modelling studies, the cost-effectiveness of these HIVST modalities depended on the underlying HIV prevalence and the length of time for which the modality was implemented.

A modelling study comparing six modalities of HIVST distribution in South Africa reported the largest epidemiological impact in secondary distribution to partners of ART patients (86). This modality, however, was the least cost-effective (86). Across all the six HIVST distribution modalities in this study by Jamieson *et al*. (2021), primary distribution to the general population in taxi ranks and workplaces was the most cost-effective distribution (86). Finally, HIVST has also been reported as cost-effective when distributed across a peer network among MSM in Uganda (88).

On average, an HIVST kit costs more than equivalent test kits currently in use. This is due to packaging and marketing costs (89). Delivering HIVST is also likely to cost more than conventional testing due to the distribution approaches used. HIVST in LMICs has been distributed in research settings often using a parallel supply chain with minimal economies of scale and scope. With wide scale-up, HIVST distribution is expected to gain from both economies of scale and scope and thereby, expected to have falling unit costs. Cambiano *et al*. (2015) expected HIVST distribution that had minimal health worker involvement at the point of screening to cost less than facility-based conventional testing (89).

Costings studies of HIVST distribution have reported costs ranging from US$3 to US$20 per kit distributed depending on setting and distribution modality. So far, lower average costs have been reported in either facility-based settings or scenario analyses assuming MoH scale-up.

A modelled scenario with MoH scale-up in Uganda reported a cost per kit distributed of US$3.70 (90). Other studies have reported unit cost of US$4.87 in a sex worker model in South Africa, US$4·99 in primary care settings in Malawi (73), US$5.70 in a community-led distribution in Malawi (76), US$8.78 in a community-based distribution also in Malawi (91), US$9.45 and US$13.96 at a smaller scale and non-MoH implementation in Uganda (90) , US$13.84 and US$16.42 in community-based distribution in Zimbabwe and Zambia, respectively (92), and US$18.07 in HIVST integrated in mobile HTS in South Africa (93).

In relation to this thesis, the cost evaluations presented above were often reported as standalone without a comparator. Unless accompanied by a cost-effectiveness analysis, it is challenging to determine the affordability of HIVST without some form of comparator. In this thesis, I further present a cost analysis of the comparator (facility-based HIV testing) to provide some context to costs of distributing HIVST in the setting.

In addition, all costing studies included in this thesis were on a larger scale than the cost evaluations presented above, allowing for an exploration of economies of scale. The studies included here that had a larger scale distribution of HIVST explored different distribution modalities other than those reported in this thesis (76, 93). Studies reporting on similar distribution modalities were implemented in countries where the costs may not be easily adopted to represent Malawi which is low-income country (92). Finally, some of the studies reported here presented a combination of observed and modelled costs to evaluate costs at scale-up (90, 94). In this thesis, I present observed costs which offer a more realistic picture as to the cost of HIVST distribution at a larger scale.

This thesis, therefore, fills a gap in HIVST cost analysis by presenting costs of distributing HIVST alongside a costing study of conventional testing. Furthermore, for one of the distribution modalities, I present costs of distributing in four countries to give a detailed outlook at costs in different settings. Finally, I present a head-to-head comparison of three HIV testing modalities to allow for a comparison on which testing modalities may be more feasible in the setting.

The next section moves away from costs by exploring literature on inequalities and equity. I start by reviewing theories of social justice, then explore the relationship between socioeconomic status and inequalities before presenting on a selective measure of inequalities.

2.3. Part II: Overview of equity and theories of social justice

Equity concerns are important to resource allocation as they ensure the allocation of resources to people with the greatest need. There has been extensive literature and discussions on defining equity in the distribution of health and healthcare, such as (95-102). There has also been a debate on how to define equity in economics and policy documents. Here, I present some of these competing definitions.

Equity is used to refer to systematic differences in the distribution of a commodity, in this case, health and healthcare (103, 104). Concerns about equity in distribution are rooted in concerns around social justice, that is what is fair and just.

2.3.1. Review of theories of social justice

There are ethical theories that seek to inform the choice on how resources should be allocated. These theories provide a guide on what should be done to derive a fair and/or just distribution of resources (105). Here, I present five theories of social/distributive justice as frequently encountered in economics literature: Libertarianism, utilitarianism, egalitarianism, Rawlsianism, and the capabilities approach. There is a lack of consensus on the acceptable theory of social justice (105) but policy documents and economics literature tend to define equity in the egalitarian sense (106-110).

i. Libertarianism

The libertarian theory of social justice argues for economic and social structures that are capitalist in thinking. Libertarianism calls for the maximising of individual freedoms/rights and minimal government intervention, regulation and taxation (111). Key to libertarianism is the concept of libertarian constraint. The libertarian constraint prohibits coercion and argues for the entitlement of people to their property gained through voluntary transaction to do with it as they please (105), as opposed to heavy government taxation and regulation.

Libertarians' argument is that reduced government intervention and low taxation leaves high disposable income for people to spend as they please which will include spending on healthcare (111). They emphasize on two main individual rights, the right to life and right to possessions (101). Libertarianism especially in its classical form argues for freedom for individuals to choose what is best for themselves and their families (105) as opposed to government taking a paternalistic role.

In terms of healthcare, they advocate for healthcare to be provided by market-focussed insurers and providers (111). On the access side, libertarians argue for access to healthcare as part of society reward system, that is, the use of individual income and wealth to access better care if individuals so wish (112). The libertarian thinking has therefore, implied willingness and ability to pay as the dominant ethic in health care provision, best achieved in the market-oriented system (112).

The main criticism of libertarianism is on the concept of libertarian constraint. Libertarian constraint assumes that there is no room for trade-off between the degree of liberty and efficiency gains (105). Some restrictions in a society are necessary to ensure better social outcomes. These restrictions include restrictions on certain drugs that are prone to abuse. In addition, in promoting the market, libertarianism undermines the concept of market failure. The presence of the market is not a guarantee that all services will be provided in the amounts that are needed.

ii. Utilitarianism

The second theory of social justice is utilitarianism. The principle of utilitarianism in its classical form is concerned with maximising individual utilities (101, 105), such that a social welfare function is defined as the sum of individual utilities (105). The classical form also argues that in principle, utility can be measured in utils and compared across individuals although this has been revised in its modern use (105).

Under utilitarianism, a distribution is considered fair if there is the maximising of utilities of the highest number of people (99, 104). The principle of utilitarianism and its goals are often summarized by the statement, 'the greatest happiness for the greatest number' (99, 104).

Utilitarianism comes with three underlying assumptions that may be problematic. The first assumption is that the commodity under study can be redistributed from one group to another to achieve efficiency (99). Maximising utilities in utilitarianism can in theory, imply moving resources from the poor to the rich if the rich have a higher marginal utility (99). As expected, this may not be the most equitable distribution despite being the most efficient.

The second underlying assumption of utilitarianism is that individuals in a society have the same wants and capacity to benefit (113). This assumption raises concerns for individual autonomy especially in healthcare. Finally, utilitarianism assumes that individual utilities can be measured and compared (99, 104). Unfortunately, utility is an abstract concept that is difficult to measure. This introduces challenges in comparing gains from healthcare use among different individuals. Modern day use of utilitarianism has increasingly departed from such measurable utilities.

Overall, it has been argued that maximising the sum of individual utilities is not connected with the concept of equity (99). Despite being efficient, social justice would not be achieved when societal utilities have been maximised at the expense of the few individuals with lower marginal utilities. This however introduces the concept of a ‘bottomless pit’ (105). The bottomless pit is where societal resources are exhausted on the worst patients despite such patients’ health not improving much from the care (105).

iii. Egalitarianism

Another theory of social justice and one frequently encountered in economics literature and policy documents is egalitarianism. Egalitarianism in its strongest form argues for equality in distribution (114). Strong egalitarianism has been referred to as absurd when applied to the distribution of health as it would not be possible to achieve equality in health in a population, due to differences in underlying health endowments (98). The rest of this section refers to a weaker form of egalitarianism that departs from strong egalitarianism.

There are three goals in the application of egalitarianism to health (99, 101). The first and frequently used is distribution according to need. The second is equality of access and the third, is equality of health.

a. Distribution according to need

Distribution according to need is also referred to as ‘equal treatment for equal need’. Key to this goal is the separation of healthcare access from the ability to pay (115). People’s financial contribution to the healthcare system should not determine how much care they receive. In addition, individuals with the same need for care should receive the same amount of healthcare resources (99, 116).

This goal comes in two forms: horizontal and vertical equity (97). The horizontal form commonly referred to as horizontal equity, argues for the ‘equal treatment of equals’ while the vertical form (vertical equity) argues for treatment of people with unequal need differently (97, 105). This applies to both provision of care and healthcare financing. In financing, vertical equity would entail lower contributions from individuals/households with a lower ability to pay and higher contributions from individuals/households with higher ability to pay (117).

Despite the wide use of the ‘equal treatment for equal need’ principle, it has been criticised for insinuating coercion at the individual level that is, people would receive care regardless of their objections (118).

b. Equality of access

The second egalitarian goal is equality of access. Equality of access is defined as ensuring that patients seeking care face the same costs of access in the form of payments for treatment, distance travelled and waiting times (99). The argument is that healthcare systems should aim for equality of access and accept distribution of utilisation and health that is resulting from this (101).

Access is a multidimension concept, I talk about this in more detail in a later section. Equality of access has been defined with respect to all or just some of the different dimensions of access. For instance, some authors have defined equality of access based on affordability with the proposition that individuals facing similar costs or price for treatment have equal access (104, 118). This definition has been criticised for not taking into account ability to pay, that is, cost of care in relation to individual income or wealth (118). Two individuals may face the same cost of care, but one could be facing catastrophic expenses due to the individual level of income.

Empirical work has often proxied access to service utilisation although this has been criticized for misrepresenting access (106, 119). Utilisation does not reflect need for care as there may be individuals requiring care who may not use it due to other factors such as acceptability.

c. Equality of health

The final egalitarian goal is equality of health. The focus is not on the unattainable absence of inequality in health but on policies or interventions that for instance, redistribute healthcare services (101, 104). The argument is that health policies can influence the extent of inequalities and perpetuate or lessen systematic inequalities (101).

The egalitarian goal of 'equal treatment for equal need' has been argued as the most practical among health professionals, the public and health economists (106, 120, 121). This is also the most applied definition of equity in policy documents.

iv. Rawlsianism

The fourth theory of social justice is Rawlsianism also referred to as the maximin principle. The theory of social justice is based on John Rawls. Rawls argued for the fairness of social choices. He proposed for social choices to be made from a point of detachment from individual economic position referred to as the "veil of ignorance". This is a hypothetical situation where he argued that social justice in allocation of resources can be achieved if choices are made from a point where decision makers do not know if they would be in the worst situation in terms of health and economic position. If such is the case, the decision is likely to be one where the health of the worse off individual will be prioritised in resource allocation as individuals in the society would assume they may be the ones in the worst position (105). This would lead to Rawls' maximin principle.

Rawls' maximin principle is considered a type of egalitarianism (115). The principle argues that individuals in a society should have maximal liberty compatible with the same degree for everyone and that deliberate inequalities are necessary if they benefit the poorest (101, 113). When applied to health, the principle is translated as an equitable distribution of health and healthcare as one where the welfare of the least advantaged is maximised (98, 99, 122). This principle translates to among other alternatives, resources being allocated to those who are worse-off regardless of forgone improvement for others (115).

Unlike utilitarianism, Rawlsianism argues that the gain of the greater good should not justify the sacrifice by a few (123). He proposed that every individual in a society has an inviolability that should not be offset by the gain of the majority (123). The same view is held by Amartya Sen who argued that everyone deserves consideration individually as opposed to a distribution indifference view proposed by utilitarianism (124).

Rawls' veil of ignorance has been criticised for assuming that all individuals in the society are risk averse (105). Rawls' definition of social justice would not be achieved in a society with risk loving individuals as they would not agree with the allocation of resources that prioritises the worst-off. Such individuals would be willing to risk it even if they ended up in the worst position by not prioritising resource allocation for the worst-off individual.

The theory has also been criticised for being subject to the 'bottomless pit'. Some people have low capacity to benefit from more resources. What they may need at that point is either scientific breakthroughs or end life care but not more healthcare resources.

v. Capabilities approach

The final theory of social justice to be considered in this thesis is the capabilities approach by Amartya Sen. In his theory, Sen sought to answer the question 'equality of what?'. He introduced two concepts: capabilities and functionings. Functionings are an individual's achievements, that is, what an individual manages to do or to be (125). Capabilities on the other hand, are the real opportunities available to the individual (125).

This gives a distinction between actual versus potential activities and states of wellbeing (126). In this case, functionings are an individual's current state of being such as being in good health, being educated. Capabilities would be functionings the individual can achieve if they exhausted their potential (126). If for illustration purposes, an individual is considered as a production firm. Functionings would be the output based on inputs of production at the individual's disposal such as genetic resources and market and public goods (127). Level of output produced is dependent on the technical factors that affect the rate of conversion of the inputs into output (127). Sen gives examples of three conversion factors: personal, environmental and social conversion factors (128).

Capabilities are considered more important than functionings (125). An individual's capability to produce a given output which is also referred to as potential achievement, should matter more than the output that they produce. Therefore, social justice should focus on the potential achievable functionings of the individual as opposed to the observed output (functionings) (127).

In terms of 'equality of what?' It should be equality of capabilities as opposed to equality of functionings. Therefore, Sen's capabilities approach demonstrates the importance of increasing individual opportunities (128). The capabilities offer a set of feasible functioning vectors an individual can choose from (128). There should be room for human diversity and interpersonal variations when converting functionings into capabilities.

2.4. Equity versus inequality

Equity and equality concerns appear frequently in HIV/AIDS strategy documents such as [UNAIDS (2021a-e) [(107, 129-132)]. The frequent presentation of the terms together can lead to confusion about their respective definitions. Given that equity stems from the concept of social justice, equity is considered a normative and value-laden concept (95, 99, 133). It is about what is fair and just in addition to being inevitable and unavoidable (134).

Equality on the other hand, is descriptive and involves a presentation of facts without explicitly expressing the position of social justice (99, 133). Thus, inequalities are differences in health and healthcare distribution. Whitehead and Dahlgren (104) argued that inequalities in health become inequities when they are systematic, socially produced, and unfair. If there are non-random differences in health and healthcare in a society, then whatever consequence of that difference is socially produced and therefore, inequitable (104). Unfairness on the other hand, has to do with unjust social arrangements that generate and maintain such disparities (104).

2.5. Importance of ensuring equity in the distribution of health and healthcare

Ensuring equity in the distribution of health and healthcare is important for several reasons. First, ensuring the highest attainable health for everyone is a fundamental human right as stipulated in the WHO constitution (135). Good health is necessary for a flourishing and productive society (97, 115). If healthcare is also considered necessary for good health, then it would be unfair and unjust to limit its distribution to certain groups (such as only those who can afford to pay) as this would entail limiting individual productivity for reasons that can be avoided (104, 117).

Second, there exists a social gradient in health. A social gradient in health is a phenomenon where poorer individuals in a society have worse health than the richer (136). This phenomenon presents itself as a greater morbidity and earlier mortality among the poorer when compared to the richer (137). The social gradient in health is caused by several factors including inequalities in conditions of daily life; the mutual reinforcing nature of social location and material circumstances; unequal distribution of power, income, goods and services and unequal distribution of health-damaging experiences (136, 138, 139). The social gradient in health is both unfair and unjust. Ensuring that there is equity in the distribution of health and healthcare contributes to improved health of the poor and better health outcomes and reduction of the effects of the social gradient.

Finally, the poor have lower coverage and access to healthcare and life saving technologies (37, 140). Such systematic differences are inequitable as they place an already disadvantaged group of people at an even worse position (104, 141). This reduces their opportunities to be healthy and flourish (100). Therefore, health policy that does not consider existing systematic differences is considered to be ethically unsound and inefficient (142). Improving coverage of healthcare and cost-effective technologies to reach the disadvantaged groups is important to ensuring that the poor have improved health outcomes and productivity.

2.6. Approaches for exploring inequalities in health

Inequalities can be explored as either pure inequalities or socioeconomic inequalities (101). Pure inequalities focus on the distribution of health or healthcare disregarding the socioeconomic standing of the people included in the analysis (101). Such an analysis uses other variables of distribution such as age, race, and gender. Socioeconomic inequalities on the other hand, look at inequalities in terms of distribution across SES (101). Such an approach gives insight as to how much of health or healthcare resources the poor are receiving compared to the rich. This does not only allow for better targeting of interventions but also, ensures equity in the distribution of health and healthcare. This thesis focuses on socioeconomic inequalities with an additional disaggregation by gender.

2.7. Defining access

As indicated earlier, access is a multidimensional and complex construct as such it is rarely observed (143). What is often observed are indicators of access such as travel time to the nearest provider, waiting times at facilities, language matching between patients and providers and user charges (143, 144).

Though in practice, researchers often use utilisation to measure access to care (143, 145). Such a definition is also used in policy documents with access often taken to mean the receipt of treatment (101, 120). Utilisation as a measure of access although it remains useful, is narrow and does not capture individuals who may not have used the service despite having need. It further does not capture quality of care.

Other researchers have proposed to define access as to whether opportunities are available for people to use care (101, 119). Thiede *et al*. (2007) [(119)] defined access as the opportunity or freedom to use health services. Access in this case, is defined in terms of potential and not actual entry into the healthcare system by those with need (146). This definition distinguishes between having access which is the potential to use care, and gaining access which is actual entry into the healthcare system (146). The having and gaining access concepts are also defined as potential access and realised access, respectively (143).

Travassos *et al*. (2006) [(147)] further defined access as the degree of fit between a health system and its users. This definition is relational in that, individuals with better fit would be said to have better access than those with a lesser fit. Another definition is by Fortney *et al*. (2011) [(144)] who argued that access is the timely use of health services to achieve best health outcome. This is means that access is limited or poor if there is no timely use of care.

Goddard *et al*. (2001) [(143)] further argued for access as a supply-side and context-specific issue capturing the level of services available to individuals. Goddard *et al*. (2001) [(143)] argued that in some contexts such as in the United States, having health insurance may be considered as access while in Europe access would be considered in terms of ability to secure health services.

An overarching definition of access was provided by Thiede *et al*. (2007) [(119)]. They defined access as a multidimensional construct comprising of availability, affordability and acceptability, with information as crosscutting (104, 119). The next section presents each of these components in more detail.

Availability is also referred to as physical or geographic access (104, 119). It is defined as the presence of appropriate health services in the right places where they are needed (119). It can also be thought of as the opportunity to obtain care when there is need (146). Availability includes but is not limited to geographical access but also temporal presence of services and awareness of the existence of services.

The geographical aspect of availability looks at distance travelled to find services, provider options, in addition to travel options (119, 144). This aspect is especially important to rural populations who usually travel long distances to find care with no conducive and timely means of transport (148).

The other component of availability is the temporal aspect which looks at the time required to access care, the opportunity cost of time and time delay in seeking care when there is need (144). Time includes travel and waiting which can be an access barrier if the opportunity cost of such time is high. Time also includes health facility operating hours and feasibility of those with need to be able to use the system during those hours (119).

The final aspect of availability is awareness of the existence of services. There is usually a disparity in awareness of existence of services and their efficacy among different groups of people (143). This disparity may be due to language and cultural differences with providers, education level of the patients, and differences in health literacy may also impact awareness of services (143). Sometimes health literacy may be as a result of healthcare workers having different propensities to offer certain information based on race,SES and residential location (143, 149). This may also include healthcare workers being less likely to refer certain groups of people to specialised services despite the ready supply of such services.

The second dimension of access is affordability which is also referred to as financial or economic access (104, 119). Affordability is degree of fit between cost of services and the ability to pay (119). According to Thiede *et al*. (2017) [(119)] affordability is influenced by several factors including, individuals' eligibility to benefit from financing mechanisms that protect them from financial costs such as exemptions for OOP payments when seeking care. In addition, affordability is also influenced by amount, timing and frequency of income payments, availability of savings to pay for healthcare, ownership of assets to be translated to cash when need arises, access to credit and loans, and ability to incur indirect costs such as childcare costs when seeking healthcare (119).

The costs of seeking care on the affordability dimension can be categorised into direct and indirect costs. Direct costs are OOP payments when seeking care (150). They include direct healthcare costs such as consultation fees and direct non-healthcare costs such as cost of transport and food when seeking care (150). Indirect costs and the resources expended by individuals and their carers when seeking care. Such costs include income and/or productivity loses (150).

Costs whether perceived or actual have an impact on whether individuals seek care when there is need. For instance, the existence of a small flat rate co-payment even with the presence of exemptions of patient categories can hinder seeking care for lower income individuals (151). Even with services being offered free-of-charge, individuals incur variations in personal costs through travel and lost income which hinders care seeking (143). Such costs can also include informal payments (cash or in-kind) in public facilities where services are supposed to be free-of-charge (152).

The final dimension of access is acceptability, also referred to as cultural access (119). Cultural access is the relationship between healthcare services and individuals' as well as communities' perception of the services (119). It includes, compatibility in terms of language between providers and healthcare users, services offered, nature of providers offering the services (e.g. age and gender) and traditional as well as religious beliefs of the communities (119, 153). Some groups of people may not use care because they find services provided unacceptable or there is a disjoint between the providers and patients' day-to-day restrictions in their living condition due to for instance, religious restrictions (104, 133).

Quality is another important element of cultural access/acceptability. Quality has been classified into structure, process and outcome (143, 154). Structure is the setting and includes availability of materials and equipment, human resource and organisation structure such as methods of peer review (154). Process are the activities that are done when giving and receiving care such as the diagnosis and treatment process (154). Outcome is the effect of care on the patient and population's health status (154). Poor quality can lead to inappropriate use of healthcare, dissatisfaction and poor compliance with provider instructions, poor outcomes and deter future use (143).

Finally, information is a crosscutting dimension of access (147). It is considered an aspect that empowers healthcare users to make the right choices and thereby allows for the translation of 'potential access' to 'realised access' (147). Thiede *et al*. (2017) [(119)] propose that information is important to quality of the system and individual interaction across all three dimensions of access.

2.8. Working definitions

This next section presents working definitions for this thesis. The first working definition is of equity. As indicated earlier, the egalitarian definition of equity is the most frequently encountered (99). The horizontal equity principle of the egalitarian view of 'equal treatment for equal need' is the most preferred in economics and policy documents (106, 134, 155).

In addition, the egalitarian perspective of social justice also factors in need in distribution and ensures differentiated service delivery based on need, patient centred approach. A recurring theme in this thesis is that the HIV epidemic has not affected all groups equally. At every stage of the UNAIDS 95 targets, different groups have different needs. Equity from an egalitarian perspective ensures that need is explicitly considered in service delivery and resource allocation.

Furthermore, the egalitarian definition of equity has also been adopted in policy documents. Using WHO and UNAIDS as examples of HIV/AIDS policies, the WHO defines equity as the absence of differences that are considered unfair, avoidable, and remediable (109, 134, 156). This definition combines pure and socioeconomic approaches to exploring equity by including other dimensions such as sex, disability among other important dimensions. Furthermore, the WHO constitution argues for highest attainable health for all implying 'equality of health'.

UNAIDS has also called for an end to the AIDS epidemic as a public health threat (21). The call by UNAIDS has been to ensure that no one is left behind by ensuring that all PLHIV have access to care (20). UNAIDS appears to take an egalitarian perspective of social justice calling for both horizontal and vertical equity. This can be seen in the proposed fast-track targets which call for innovations to expand HIV services and better address patient needs (21). Such an approach calls for a patient-centred delivery of services including customised approaches based on patient needs. It advises against one size fit all approaches but instead proposes differentiated care based on patient needs.

Finally, I adopt a working definition of access as utilisation of care. My decision to define access as utilisation of care, despite its limitation, is because this is the most widely used definition. Access as service use is also easier to quantify and apply in practice (106, 119). Defining access as a multidimensional concept would involve collecting and aggregating data from all dimensions of access whose data would be complex and even more complicated to construct in practice.

2.9. Review of theories on equity in the distribution of new technologies and interventions

This section presents three theories used in explaining the uptake of new innovations and technologies. I start by presenting the theory of diffusion of innovation which explains how new innovations are taken up by individuals of different SES over time. I then move from individual-level to a broader societal perspective by presenting the inverse care law and inverse equity hypothesis.

i. Diffusion of innovation

This section explains the theory of diffusion of innovations in relation to SES based on Rogers (1983 & 2003) [(71) and (157)]. According to the theory, different groups of people adopt new technologies at different rates over time. SES is very critical in the adoption process. Higher socioeconomic groups in a society adopt earlier than lower socioeconomic groups.
The process of diffusion has four main elements: the innovation, communication channels, time, and a social system. The innovation can be an idea, practice or object that is considered new by individuals or any other unit/s of adoption. Newness of an innovation in this sense is subjective, that is, defined by the individuals themselves regardless of how much time has elapsed since the discovery of the innovation.

The second element of diffusion is the communication channel used to pass along information of the innovation. Mass media is considered the most rapid and efficient communication channel although interpersonal channels are more effective in persuading for innovation uptake. The effectiveness of these can differ even with close categories of products, such as male and female condoms (158). For instance, mass media marketing has been shown to be more effective in the uptake of male condoms while interpersonal communication is more effective in uptake of female condoms (158). An important aspect to remember with communication is that transfer of ideas tends to be between individuals who are similar in, for instance, SES and beliefs.

The third element is the social system. The social system can be individuals, firms in an industry or even villages in a geographical region. Innovations are diffused within a social system. The social system is composed of structures which are patterned arrangements of the members of the system such as the hierarchical ranking of individuals. This social structure facilitates or impedes diffusion of innovations through system norms and communication channels among other factors. For instance, adoption of high yielding variety seeds among farmers in India was shown to be positively correlated with prior adoption by neighbours (159).

The final element of diffusion is the time taken to decide on the innovation. This is the earliness or lateness of adoption and the number of people adopting within a given time (rate of adoption). The time element of diffusion is especially important in categorising adopters of an innovation.

Adopters of an innovation can be categorised into five broad groups based on when they adopted the innovation relative to other members of the social system. This relative earliness in the adoption of an innovation is also referred to as innovativeness. These five groups are: innovators, early adopters, early majority, late majority, and laggards. The adopters are on a continuum with the individuals with the highest degree of innovativeness being the innovators and those with the lowest innovativeness being the laggards.

Over time, the distribution of adopters of an innovation is an S-shaped curve as presented in Figure 2.1. This shows that when an innovation is first introduced in a society, only few members or groups adopt it and at a slower rate. Then more and more individuals/groups adopt the innovation with the passing of time. Eventually, the adoption levels off as majority of the population have adopted and only few are left without adopting. This is now the end of the diffusion process.

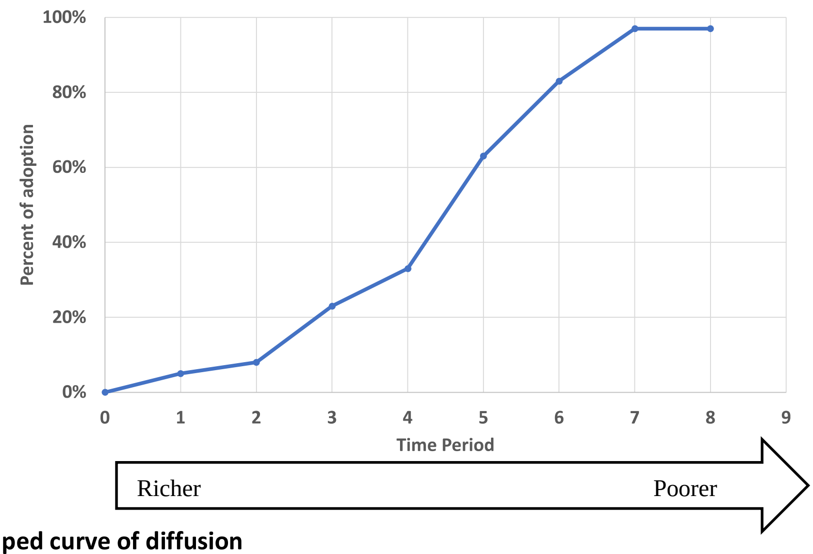

Figure 2. 1: S-Shaped curve of diffusion

According to the diffusion of innovation theory, adoption takes a normal distribution. Given a population and assuming complete adoption; early adopters constitute approximately 16% of the population. An additional 68% of the population adopt either as early majority or late majority. Then there is a remainder 16% of the population that constitute late adopters or laggards.

Individuals adopting a technology are further characterised by socioeconomic characteristics, personality values and communication behaviour. In terms of socioeconomic characteristics, earlier adopters tend to have more years of formal education; are more likely to be literate; have higher SES; and are more likely to have upward social mobility among other factors (71, 159).

The key limitations of the diffusion of innovation theory are that the theory tends to have a pro-innovation bias, places blame on the individuals for non-adoption, does not address over-adoption and may promote inequalities (157). The theory assumes that innovations are positive and should be adopted. However, not all innovations are positive and not all innovations should be adopted by all members of a social system. In some cases, an optimal outcome would be some individuals not adopting an innovation or adopting fewer units.

In addition, sometimes an innovation may have not been packaged well enough or was poorly/inadequately communicated for ease of adoption such that low adoption could be a supply-side problem as opposed to a demand-side problem. Finally, the difference in characteristics of adopters can promote inequalities in access to some life changing innovations by predisposing individuals in higher socioeconomic positions to adopt earlier than those in lower positions.

ii. The Inverse Care Law

Another theory exploring equity in access to care is the inverse care law by Tudor Hart (1971) [(160)]. The law argues that availability of good medical care varies inversely with need for care (104). This incorporation of need allows for this theory to move beyond inequalities in health to inequities in health (161). Through this theory, Tudor Hart describes a double injustice incurred in health, that is, the poor are not only more susceptible to illness but also receive less care (162). The law has been observed both within and between countries and is pronounced in places where health care is most exposed to market forces (160, 162, 163).

There are several limitations levelled against the inverse care law. First, the law is limited to healthcare need disparities related to social disadvantage, proposing horizontal inequity based on social disadvantage (162). However, the law does not give much explanation related to, how much care will be received by individuals at the same social disadvantage level but with different need (162). In addition, the law does not provide much information on the differences in quality of care received by individuals in the same socioeconomic group and thereby, offering an incomplete picture (162).

Factoring in quality in health research is important to understanding the nature and effectiveness of care received by the poor group. A study in Australia that proxied quality with the length of consultations demonstrated a positive relationship between SES and the rate of long plus prolonged general practice consultations (149). They reported that people in socioeconomically disadvantaged areas visited the general practitioners more often annually but were less likely to have long consultations. By simply observing quantity consumed there may be an argument for improved access for the poor despite falling quality or socioeconomic related quality discrepancies.

iii. Inverse equity hypothesis

A theory inspired by the diffusion of innovation and the inverse care law is the inverse equity hypothesis by Cesar G. Victora (2000). The theory argues that a new health intervention will increase inequities in access in its initial phase. This is because new interventions are likely to reach the higher socioeconomic groups first before reaching the poorer groups. Only after the richer groups have achieved an improvement in health would the intervention effectively reach the poor and the inequity gap decrease (164). The theory proposes for investments aimed at making new interventions widely accessible by the poorest to reduce the access gap between the rich and the poor.

The inverse equity hypothesis has been applied to different health interventions and diseases including the HIV epidemic in the SSA region. In the SSA region, the HIV prevalence appeared to have been high among higher socioeconomic groups during the first wave of the epidemic spread but in later years has been more associated with lower socioeconomic groups (165). The argument is that HIV prevention interventions have disproportionately benefited the richer in the early phases and therefore leading to faster falling incidence among the higher socioeconomic groups (165).

One of the frequently faced challenges with the inverse equity hypothesis is a data limitation (166). The hypothesis requires longitudinal observations to assess the changing inequalities. Unfortunately, many health studies especially in low-and-middle income settings are cross-sectional hence do not allow for analyses over time.

2.9.1. Relating theories to the thesis

The three theories presented in this section explain various aspects of inequalities. Everett Roger’s theory of diffusion of innovation emphasises on uptake of new interventions and classification of how different groups take up care. Despite the theory being useful in informing uptake of a new intervention such as HIVST, the theory of diffusion of innovation

does not explicitly incorporate equity effect of such uptake. Cesar G. Victora’s theory of inverse equity hypothesis has an advantage of explicitly incorporating equity implications.
The inverse care law though influential in the development of the inverse equity hypothesis, is more specific to service provision and quality (good) of the service. The distribution of HIVST is standardised and should not raise a lot of concern about quality of care. Therefore, the theories of diffusion of innovation and inverse equity hypothesis are more relevant to this thesis than the inverse care law. The theory of diffusion of innovation offers an understanding on who is taking up care and the inverse care hypothesis demonstrates the equity implications of such uptake.

2.10. Part III: Review of measures for quantifying the distribution of health and healthcare

In this section, I present a summary of measures applied in quantifying the distribution of health and healthcare, inequality measures.

Measures for quantifying inequalities involve the use of approaches that summarise information on the distribution of a commodity such as health (99). The choice of an appropriate measure is subjective and circumstantial (99, 167). Subjective because the process of summarising information involves suppressing certain information (99). Therefore, a researcher must decide if they are comfortable using a measure of inequality regardless of the suppressed information. For instance, a measure of inequality may simply compare distribution of a commodity in the poorest and richest socioeconomic groups and ignore distribution in the middle groups. Deciding to go ahead with such a measure involves a value judgement on the significance of the distribution of the commodity in the middle groups.

A measure of inequality is circumstantial because the choice of a measure also depends on the circumstance. If interest is in how the poorest are fairing against the richest, then capturing the gap would be more useful than measuring of inequality in the full population. Wagstaff & Paci (1991) [(168)] proposed that a measure of inequality should at minimum, fulfil the following requirements:

i. It should reflect the socioeconomic aspect of a distribution.
ii. It should reflect the entire population.
iii. It should be sensitive to changes in the socioeconomic distribution.

There is a wide range of measures of inequalities presented in literature. Some of the measures frequently encountered in economics literature include concentration curves, concentration indices, the range, index of dissimilarity and, slope and relative indices of inequality (106, 167-171). This section does not seek to discuss all these listed measures but to briefly discuss measures relevant to this work. In this thesis, I use the concentration curve and concentration index because they are the most frequently used measure of inequality (106, 170, 172). Both the concentration curves and concentration indices have an added advantage of capturing inequalities in the entire population and not just extreme groups. The concentration index in particular, satisfies all the three minimum requirements of a good measure of inequality as stipulated by Wagstaff & Paci (1991) [(168)]. I also discuss the range and frequency because I was interested in capturing the inequality gap between the poorest and the richest individuals. This was useful to understand if, and the degree to which the poorest individuals may be left behind. The range and frequency are also useful to demonstrating if the inverse equity hypothesis introduced earlier holds for HIV testing especially with the distribution of HIVST.

i. Concentration curve

A concentration curve is a graph plotting the cumulative distribution of health against the cumulative distribution of the population ranked by SES (101, 106). The cumulative proportion of the population is ranked from the poorest to the richest. Figure 2.3 presents an example of concentration curves.

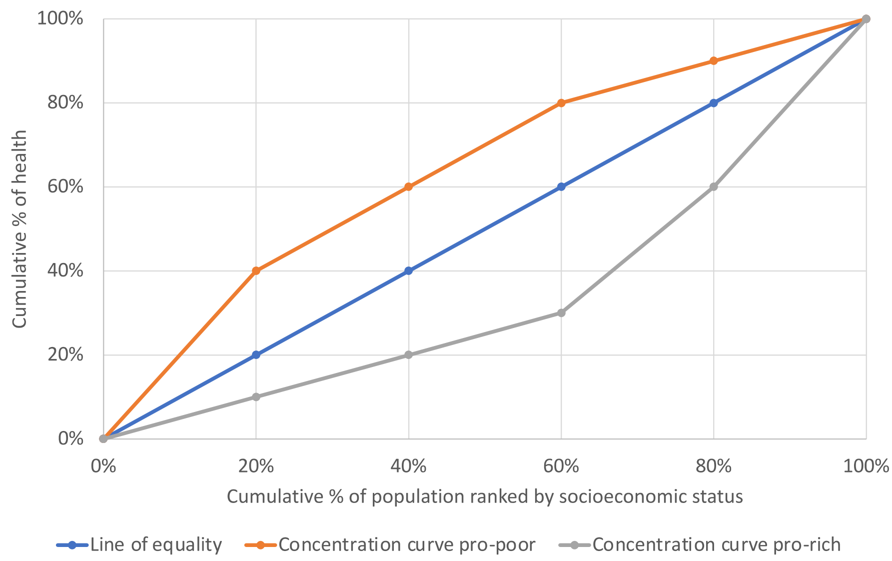

Figure 2. 2: Examples of health concentration curves

Inequality is interpreted against the diagonal line also referred to as the line of equality. The line of equality demonstrates a situation where everyone has the same level of health. The concentration curve is above the line of equality if the distribution of the health variable is concentrated among the poor (pro-poor). Similarly, the concentration curve will be below the line of equality if the health variable is disproportionately distributed in favour of the richer individuals (pro-rich) (106). The concentration curve is similar to another measure of inequality frequently used in development economics known as the Lorenz curve. The difference between the Lorenz curve and the concentration curve when used in health in the incorporation of SES. Unlike the Lorenz curve, the concentration curve captures socioeconomic distribution of health or ill health.

The main challenge with concentration curves is that they are in some cases, not possible to interpret. For instance, two concentration curves may cross such that it is not possible to determine which one of the two curves dominates the other. In some cases, interest is in the degree of inequality to compare two populations. Simply stating that inequality is concentrated among the poor or rich may not be sufficient for decision making. A summary statistic of the concentration curve is useful in such cases.

ii. Concentration index

The concentration curve can be summarised using a summary statistic known as the concentration index. The index quantifies the degree of inequality. The concentration index is calculated as twice the area between the concentration curve and the line of inequality (106). This can also be presented as:

Equation 2.1. $$Concentration\ index = \frac{2}{\mu} cov(h, r)$$

Where:

h is the health variable

r is the ranking of individuals using SES

μ is the mean

O'donnell & Van Doorslaer (2006) [(106)

The concentration index ranges from -1 to 1. The index is negative for a pro-poor distribution, positive for a pro-rich distribution and 0 for a perfectly equal distribution. The concentration index meets all three proposed requirements of an appropriate measure of inequality as proposed by Wagstaff & Paci (1991) (168)..

The limitation with the concentration index is that it is a population summary statistic. This implies that it does not give as much information about distribution in different groups in the population. The concentration index in this case, can conceal information about minority groups being left behind.

The concentration curve and concentration index are the most frequently used measures of inequality in health economics with Erreygers and Van Ourti (173) referring to them as the workhorse of the field.

iii. **The range/ratio**

The range is often used to capture the gap in the share of health between the poorest and richest groups of people in a population. The measure compares the health experience of the top and bottom socioeconomic groups (168). The range is often presented as a ratio of the outcomes of the two groups as presented in equation 2.4:

Equation 2.4. $$R = \frac{health_{max}}{health_{min}}$$

Where:

$health_{max}$ is a health outcome of the richest socioeconomic group

$health_{min}$ is a health outcome of the poorest socioeconomic group

World Health Organization (174)

The range takes a value of 1 if there is no inequality. The further the value is from 1, the greater the degree of inequality (174).

The range when using 10 percent of the richest against 10 percent of the poorest people is called the decile ratio (175, 176). The range does not have to be limited to socioeconomic groups, sometimes it can be a comparison of urban versus rural, manual workers versus white collar workers. The range/ratio is advantageous as it is an easy to measure and interpret.

The limitation of the range is that it simply compares two groups such as the bottom and highest socioeconomic groups, overlooking all groups in the middle (168). This is challenging when interest is in the distribution of health in an entire population. In addition, the range does not consider the proportionate sizes of each socioeconomic group (168). For instance, the lowest and highest socioeconomic groups would be given the same weight when estimating the range regardless of the groups being of different sizes. This becomes even more problematic when comparing different populations. The range may take the same value despite two populations having different percentage of people belonging to the top and bottom socioeconomic subgroups (177). Despite these limitations, the range is the most frequently encountered measure of inequality in literature and the most used measure to capture health gaps (167, 168) hence its inclusion in this chapter.

iv. Frequency

The final measure of inequality to be explored is the frequency. The frequency is used to capture the prevalence of health or ill health in one group against another. The goal is to capture how much more the frequency of a health outcome is in a socioeconomic group with respect to a reference socioeconomic group (177). This can be presented as for instance frequency of under-five mortality in the poorest socioeconomic group against the richest.

The use of frequency to compare inequality is advantageous in that it allows for easy comparison across groups as each group is compared against the same reference group (177). Frequency, however, does not give us enough information on inequalities in the entire population.

When the frequency is very low it has been encouraged to use the odds ratio as an approximation (177). The odds ratio gives the likelihood of an event. Odds ratio can be derived using either contingency tables or logistic regression.

Of all the measures of SES presented in this section, concentration index is the only one that meets all three requirements of a good measure of SES. This is probably why the concentration index is considered the workhorse of measuring inequalities in economics (170).

Table 2. 1: Summary of measures applied in quantifying the distribution of health variables

Measure/Formula	Key Uses	Output Generated	Strengths	Limitation(s)
Concentration curves	Demonstrates relationship between a health variable and SES against a line of equality	Each group's health distribution in relation to a line of equality	Reflects entire population and not just the lowest and highest socioeconomic groups	Can be difficult to establish dominance especially when curves cross
Concentration index	Captures socioeconomic inequality in health or health problems	An index capturing health distribution that can be compared against equality. Ranges from -1 to +1 with: negative value implying outcome is concentrated among the poor and positive value implying outcome is concentrated among the non-poor and 0 implying equality.	It reflects entire population and not just the lowest or highest socioeconomic groups Incorporates SES unlike the Gini index	Is relatively insensitive to inequalities in the middle socioeconomic groups Does not make clear assumptions around aversion of inequality or assumptions around social justice
The range	Compares health outcomes in two socioeconomic groups	Percentage health gap between the two socioeconomic groups	Ease of computation Straightforward interpretation	Disregards other groups Does not consider sizes of groups being compared
Frequency	Presents frequency of health or ill health against a reference group	Frequency gap between two different groups	Ease of computation Straightforward interpretation	Disregards other groups by focussing on just the two groups of interest

2.11. Chapter conclusion

In this chapter, I have presented definitions and theory around equity in access to care. I further presented how new technologies and interventions are hypothesised to affect equity. Finally, I presented a set of measures of inequalities used in the field of economics.

The key messages for this chapter are that the definition of equity is value-laden driven by concerns for social justice. This leaves equity as a concept open to subjectivity and therefore, requiring a researcher to take a stand on their definition of social justice and equity. I decided to define equity from an egalitarian viewpoint because it is the most frequently encountered definition in economics literature and policy documents.

Another key message is that equity considerations should be considered when introducing new public health technologies as such technologies may worsen any existing inequities. A discussion on equity in a distribution requires a measure of inequality to inform existing distribution as a starting point. The choice of a measure of inequality to be used depends on the overall question being answered although the concentration curve and concentration index are frequently used measure of inequality in health economics.

The next chapter presents the conceptual framework of this thesis that was motivated by the theoretical framework discussed in this chapter.

Chapter 3: Thesis aims and objectives

3.1. Self-Testing AfRica (STAR) Initiative

This PhD research was embedded in a bigger multi-country project known as the Self-Testing AfRica (STAR) project. In 2015, Unitaid funded the STAR project aimed at generating evidence and catalysing the market for HIVST. STAR implementation was in 2 phases. Phase 1 was implemented in Malawi, Zambia, and Zimbabwe. This phase of the project was aimed at generating evidence on effective, ethical and efficient modalities of distributing HIVST (53). Phase 2 of the project sought to build on phase 1 by scaling-up HIVST, optimising models of distributing HIVST and generating evidence for cost-effectiveness (60, 178). In phase 2, Eswatini, Lesotho and South Africa were added to the original STAR countries. STAR is the largest evaluation of HIVST to ever be implemented to date (55). In the first 15 months of the project, more than 600,000 HIVST kits were distributed across Malawi, Zambia, and Zimbabwe (55).

STAR's distribution modalities were designed to reach people with limited or low testing uptake. Targeted population included men, young people, female sex workers (FSW), truck drivers and men who have sex with men (MSM). In an evaluation of five of the eight distribution modalities explored, about half of all kits were distributed to men (55).

Distribution of HIVST kits was by Population Services International (PSI) in Eswatini, Lesotho, Malawi and Zimbabwe, Society for Family Health (SFH) in South Africa and Zambia and Wits Reproductive Health Institute (WRHI) in South Africa.

Table 3.1 presents a summary of models of HIVST implemented under STAR. Additional detail of STAR is available elsewhere, (179).

Table 3. 1: Self-Testing AfRica (STAR) distribution models

Model	Detail
Community-based	HIVST was distributed as a combination of door-to-door, hotspots, outreaches, and campaign style distribution approaches
Demand creation for uptake of voluntary medical male circumcision (VMMC)	HIVST was used for demand creation for VMMC in the communities and to improve efficiency in the VMMC clinics
Facility integration	HIVST was integrated in public facilities as both primary and secondary distribution. In primary distribution, HIVST was distributed to outpatients attending facility for other medical care. In secondary distribution, HIVST was provided to pregnant women attending antenatal care (ANC) or newly identified HIV positive patients and PLHIV attending antiretroviral clinics for index testing
Fixed points	HIVST was distributed in fixed locations often preselected locations

Key populations	HIVST was distributed to FSWs, MSM and truck drivers in hotspots
Mobile integration	HIVST was integrated into community mobile HTS clinics
Transport hubs	HIVST was distributed to commuters, taxi drivers and street vendors in taxi ranks
Workplace	HIVST was distributed in male-dominated workplaces such as farms, mining companies and security firms

Economic evaluation under the STAR consortium was conducted as collaborative under the STAR Economics Network. This was a collaboration of health economists from the Centre for Sexual Health and HIV/AIDS Research Zimbabwe (CeSHHAR Zimbabwe), Health Economics and Epidemiology Research Office (HE2RO) in South Africa, London School of Hygiene and Tropical Medicine (LSHTM), Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW) and Zambart in Zambia. Costing protocols and other methods were developed as part of a collaborative process in the network with additional country-specific changes.

3.2. Datasets used

There are four main datasets used in this thesis. The first dataset was cost data obtained through extensive costing work conducted in the STAR Economics Network. These costs were obtained through a collaborative process in the network and involved costing all models of distributing HIVST in the STAR consortium including conventional HIV testing approaches such as facility-based provider testing. I led on components of this costing work and those are the ones included in this thesis.

I have also used data obtained from two rounds of household survey data (baseline and endline) of a cluster randomised trial (CRT) in Malawi. The final dataset is secondary data obtained from the Malawi Fourth Integrated Household Survey (IHS4) which is a survey under the World Bank's Living Standards Measurement Studies (LSMS).

The costs and CRT datasets have been explained in more detail below and in their respective results chapters. The IHS4 has been explained in more detail in chapter 4 which is a methods chapter.

3.3. Conceptual framework

As introduced in chapter 2, equity is concerned with reducing unfair differences in health and healthcare. Efficiency on the other hand, is concerned with the best use of resources. Efficiency analyses in the form of economic evaluations are routinely used to inform health sector priority-setting decisions (180). In this thesis, I was interested in both efficiency and equity concerns in resources allocation. Figure 3.1 presents the conceptual framework guiding the thesis.

The top-left panel is an inequalities evaluation exploring the role of user costs in uptake of HIV testing services in Malawi. The overall aim is to explore the affordability dimension of access introduced in chapter 2 as part of Thiede *et al*. (2007)'s definition of access as a multidimensional concept (119). User costs act as an important barrier to healthcare access (119, 181). Understanding the role of user costs in uptake of HIV testing services in our context helps inform existing inequalities.

The top-right panel of the conceptual framework presents an efficiency evaluation in resource allocation for HIV testing. Here, I compare costs of providing HIV testing services in three HIV testing modalities. In the cost evaluation, I compare and discuss any potential efficiency gains in provision of HIV testing services. I then use a component of this cost evaluation as an input into an equity evaluation exploring socioeconomic equity in uptake of HIV testing services.

With these thesis analyses, I not only discuss efficiency concerns in resource allocation, but also equity implications of such health sector investments. Given the role of SES in equity evaluations, I further explore how SES is measured in LMICs. Here, I develop and validate a multidimensional index of SES with the initial aim to use this index to categorise individuals in the equity analysis. This analysis is captured by the bottom-right panel in Figure 3.1. The panel on the bottom-left then is the equity analysis. All three panels discussed above directly and indirectly feed into this equity analysis.

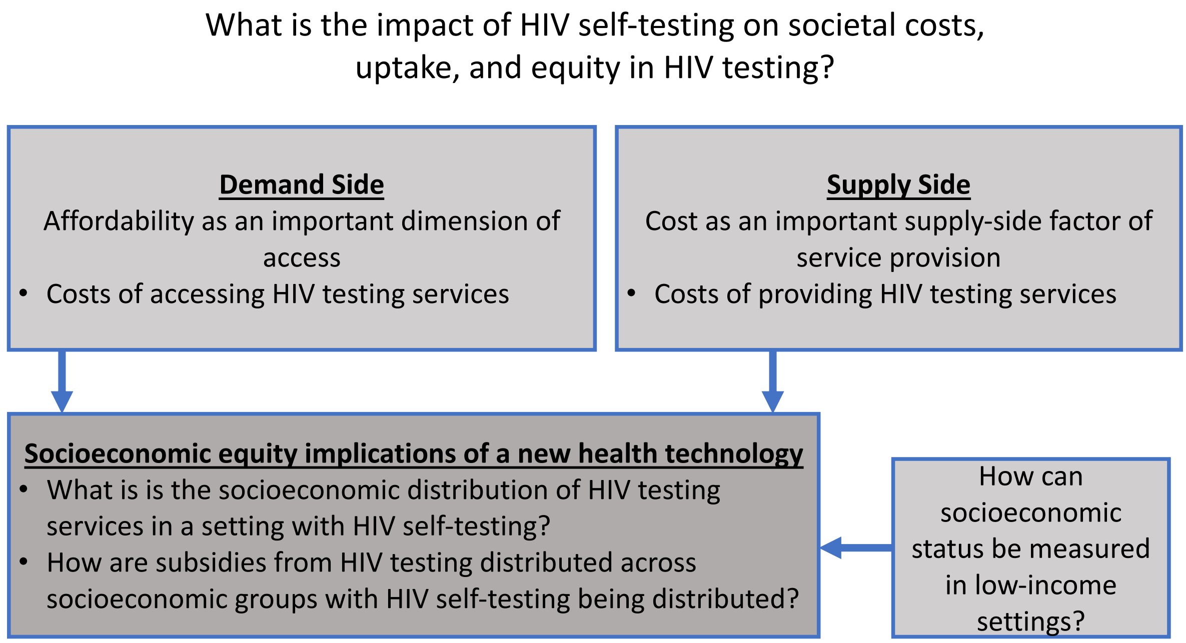

Figure 3. 1: Thesis conceptual framework

3.4. Thesis objectives

The overall objective was to evaluate the impact of distributing HIVST free at the point of use on societal costs and equity in uptake of HIV testing. I had four main objectives:

i. To determine costs of accessing HIV testing services.
ii. To determine costs of providing HIV testing services.

iii. To construct and validate a measure of SES that can be used to measure socioeconomic status in low-income settings.
iv. To evaluate socioeconomic equity in uptake of HIV testing and the distribution of subsidies from testing.

3.4.1. Societal costs of HIV testing services and supply side factors of HIV testing

Objectives one and two can be summed up as aimed at determining the societal costs of HIV testing services. Costing is the process of estimating the value of resources used in health interventions or services in a given setting such as a geographical setting, time period and population (182). A cost is the value of resources used in the production process of a good or service (183). Costing is a component of economic evaluations.

Costs estimates are useful to informing technical efficiency (182, 184). Technical efficiency looks at the best way to spend a given budget to produce a given set of services (184). Cost estimates in this case can be used to explore varying level and combination of inputs for optimal allocation of resources. Different sites delivering a service can also be compared to determine sites achieving technical efficiency. Cost estimates are also useful for medium and long-term planning as they are used to predict future expenditures through for instance, budget impact analyses (182, 184). Finally, a costing study is necessary if there is a new intervention being implemented or where there is need for primary cost data to inform implementation (184).

Costs can be estimated from either a provider's or societal perspective (185). A societal perspective gives a broader scope of the costs by combining costs of the provider and the clients which can include the patient, household and/or community (182). A provider's perspective is narrower by focussing only on costs of providing the services (183, 185). The choice of perspective depends on the need for the cost data. One approach recommended by Drummond, Sculpher (185) is to take a perspective based on who has commissioned or is to be informed by the costs. In such cases, a provider's perspective would suffice.

Total costs are then obtained by summing across all ingredients involved in the production process. Formally, total costs are defined as the entire cost of the production process (184). Average costs are also obtained from the total costs. These are derived by dividing the total costs by units produced.

In this thesis, I combined both societal and provider perspectives. Costs of providing facility-based provider HIV testing services were evaluated from a societal perspective. Costs of providing HIVST were evaluated from a provider's perspective. Chapters 5 and 6 present a descriptive analysis of these costs. I sought to answer the following questions:

i. What are the costs of accessing HIV testing services in Malawi?

ii. What are the drivers of these costs?
iii. Is there a gender difference in costs of accessing HIV testing services in Malawi?
iv. What is the cost of providing facility-based provider testing?
v. What are the costs of providing HIVST?

The costs would then feed into broader cost-effectiveness and equity analyses to inform the scale-up of HIVST. Conducting cost-effectiveness assessments of HIVST however, was beyond the scope of this thesis as these were already being evaluated by other health economists and modellers in the STAR Economics Network. I was however, interested in the socioeconomic equity impact of HIVST.

Cost analysis setting

The societal cost analysis is the backbone of this thesis. There were three main HIV testing approaches that were included in the cost analysis: facility-based provider testing, community-based HIVST and facility-based integrated HIVST. For practical and budget reasons, societal costs were estimated for facility-based provider testing only but provider costs were estimated for both community-and facility-based HIVST. The cost analysis of facility-based provider testing and community-based HIVST were restricted to Malawi. The cost analysis of facility based integrated HIVST were conducted on implementation in Malawi, South Africa, Zambia and Zimbabwe.

Costing alongside a cluster randomised trial in Malawi

Societal costs of facility-based provider testing were obtained alongside a CRT evaluating the impact of community-based distribution of HIVST. In this trial, HIVST kits were distributed using community-based distribution agents (CBDAs).

The CBDA CRT was conducted between 2016 and 2018 in Blantyre, Machinga, Mwanza and Neno districts in the Southern Region of Malawi. Twenty-two public primary care facilities were randomised 1:1 to either standard of care (SoC) or HIVST arms. In SoC, pre-existing testing (facility-based provider testing) was maintained. In the HIVST arm, CBDAs distributed HIVST door-to-door and on demand to residents aged above 16 years for at least 12 months. Figure 3.2. presents the testing pathways the catchment communities of the 22 primary care facilities during the trial period.

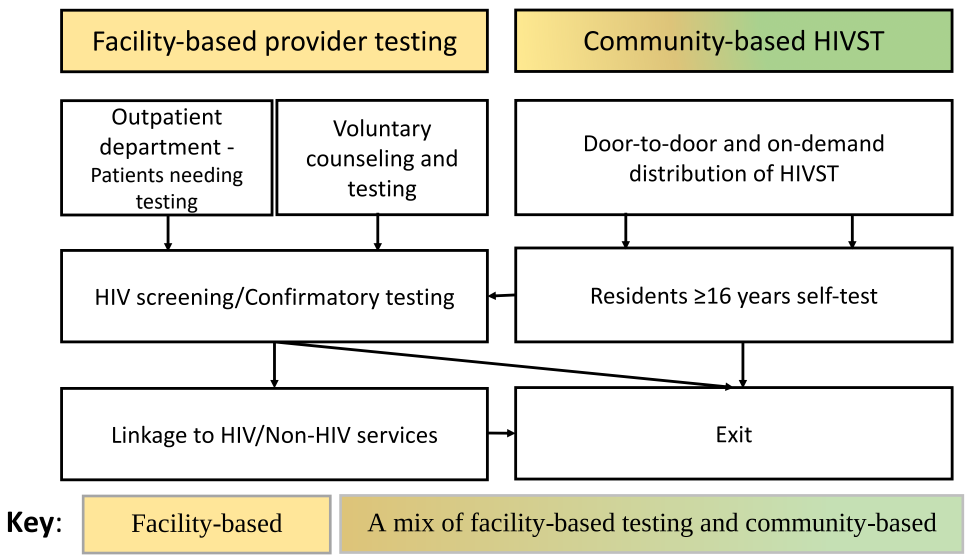

Figure 3. 2: Facility-based provider testing and community-based HIV self-testing patient pathways

In facility-based provider testing, patients entered the primary care system either as outpatients seeking to access other care in addition to HIV testing or were referred for HIV testing during clinic consultations including during ANC. Patients also accessed HIV testing as VCT, where they visited the healthcare facilities solely for an HIV test. After an HIV test, patients went through the outpatient department (OPD) for additional care, were linked to additional HIV care or exited the facility.

With community-based distribution of HIVST, recipients of HIVST tested in private at home. Those screening positive were encouraged to report to their nearest healthcare facility for confirmatory testing and linkage to care. Additional results of the CBDA trial are presented in Indravudh *et al*. (2021) [(57)].

A total of 273,729 HIVST kits were distributed by 203 CBDAs in catchment areas of the 11 public primary care facilities in the HIVST arm by the end of the trial. At endline, the CRT trial showed that recent testing (testing in the last 12 months) was higher in the HIVST arm (68.5%, n=1768/2582) than SoC (48.9%, n=1422/2908) (57).

For the cost analysis, I evaluated provider and user costs for facility-based provider testing. Here, I evaluated the societal costs of facility-based provider testing and the provider costs of community-based HIVST. User costs for facility-based provider testing were obtained from a baseline household survey of the CBDA CRT. Provider costs for both facility-based provider testing and community-based HIVST were obtained from extensive costing exercise in both SoC and HIVST arms.

Costs of integrating HIV self-testing in Malawi, South Africa, Zambia, and Zimbabwe

The second component of the costing work involved costing the distribution of HIVST integrated in public primary care facilities in Malawi, South Africa, Zambia, and Zimbabwe. Distribution of HIVST was either primary or secondary or a combination of both. This next section briefly summarises how HIVST was integrated in the facilities by country.

Malawi integration

Facility-based HIVST involved secondary distribution of HIVST to newly identified HIV positive patients and pregnant women attending ANC for their sexual contacts. This distribution was in public primary care facilities in Blantyre, Chikhwawa, Mulanje, and Zomba districts. There was no overlap between the public primary care facilities from Malawi included in the costing for facility-based HIV testing and the public primary care facilities included in the analysis of costs of integrating HIVST.

The implementation was through a three-armed pragmatic cluster randomised trial. The arms were SoC, HIVST_only and HIVST plus US$10 incentive. Twenty-seven public primary care facilities were randomised to the three trial arms, 9 facilities per arm. SoC was very similar to the facility-based conventional HIV testing approach. ANC and index clients received a letter of invitation for their sexual contacts to come to the healthcare facility for an HIV test.

In the HIVST_only and HIVST plus US$10 arms, the ANC and index clients received HIVST kits for their sexual contacts. In the HIVST_only arm only sexual contacts who screened positive after an HIVST test were encouraged to come to the healthcare facility for confirmatory testing. In the HIVST plus US$10 arm, all sexual contacts were encouraged to come to the healthcare facility regardless of their HIVST result. This was for them to be enrolled in a sub study evaluating their accuracy in the interpretation of an HIVST screening result. All sexual contacts who came to the clinic for the accuracy sub study were given US$10 as reimbursement for their time and to offset their transport costs. Additional details of the trial are available in Choko *et al*. (2021) [(56)]. Figure 3.3. provides a patient for the facility based HIVST distribution.

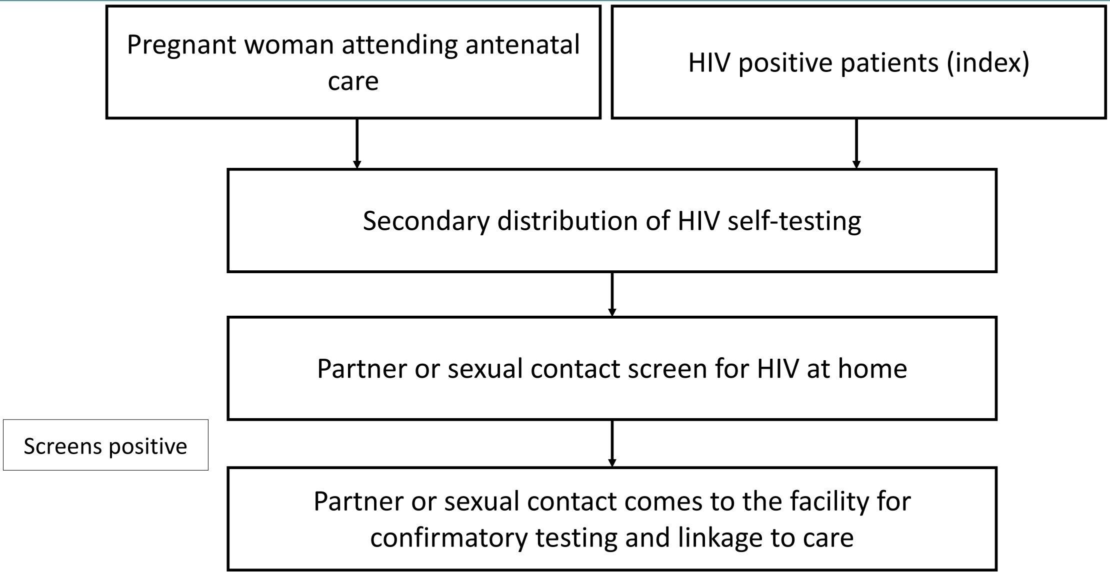

Figure 3. 3: Malawi and South Africa patient pathway

South Africa integration

Distribution in South Africa was similar to that of integrated distribution in Malawi as demonstrated in Figure 3.3. HIVST was distributed as part of secondary distribution to pregnant women attending ANC and newly identified HIV positive patients for their partners and sexual contacts. Self-testing was done at home with the partners and sexual contacts encouraged to come to the clinic if they screened positive.

Implementation in South Africa was in Dr Kenneth Kaunda district municipality in the Northwest Province, and Cities of Johannesburg and Tshwane in Gauteng Province. A total of 8 public primary care facilities across the three districts were included in the analysis.

Zambia and Zimbabwe integration

Distribution of HIVST in the public primary care facilities in Zambia and Zimbabwe was a combination of primary and secondary distribution approaches as demonstrated in Figure 3.4

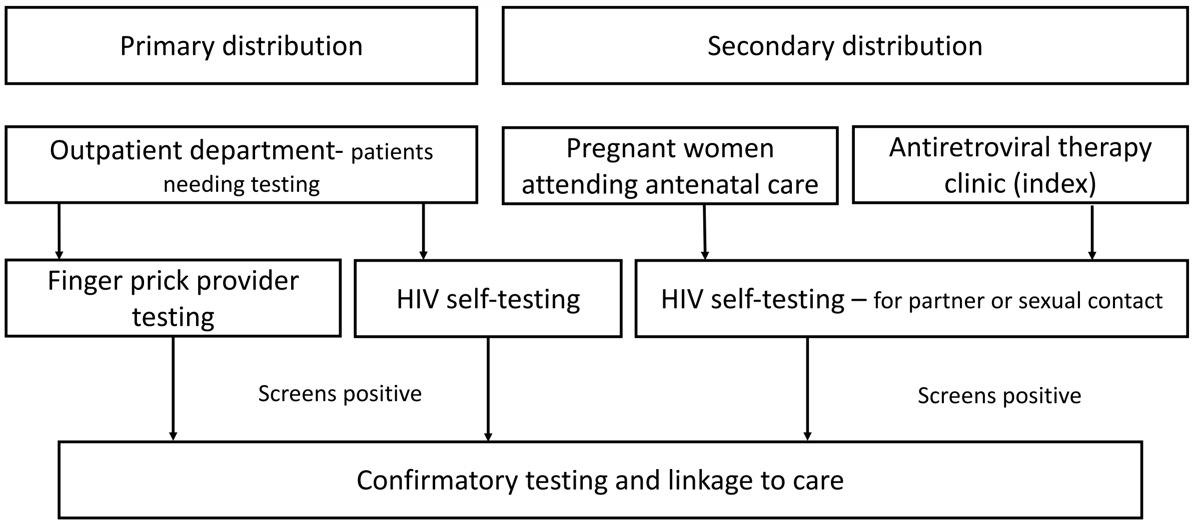

Figure 3. 4: Zambia and Zimbabwe patient pathway

During the implementation period, patients seeking outpatient care in need of testing had a choice between finger prick testing conducted by a provider or either assisted or unassisted HIVST. Patients screening positive received confirmatory testing and follow-on care based on country guidelines. Pregnant women attending ANC and HIV positive patients on treatment with partners with unknown HIV status also received HIVST kits for their partners and sexual contacts. Partners and sexual contacts screening positive were encouraged to come to the facility for confirmatory testing and linkage to care.

Implementation in Zambia was in two facilities in Lusaka district and implementation in Zimbabwe was also in two facilities in Mashonaland East.

Similar to Malawi, costs were evaluated from a provider's perspective across South Africa, Zambia and Zimbabwe. Focus was on costs of distributing HIVST with no additional follow-on costing activities.

3.4.2. Socioeconomic equity implications of a new health technology

Objectives one and two feed into an evaluation of the socioeconomic equity implications of distributing a new health technology free at the point of use. Only the Malawi CBDA CRT was included in the socioeconomic equity analysis. This was because the CBDA CRT had costs, service utilisation and sociodemographic data that could be used for the equity evaluation.

The need for this evaluation was because HIVST was a relatively new intervention in the setting and as I presented in the previous chapter, new technologies do not diffuse at the same rate among different socioeconomic groups, in other cases such technologies may worsen existing inequalities. I was therefore, interested in understanding the impact of community-based distribution of HIVST on socioeconomic equity in uptake of testing and the distribution of subsidies from testing.

However, as I set out to conduct the socioeconomic equity analyses, I realised measuring SES in a low-income setting such as Malawi was not as straightforward. This necessitated the construction and validation of a standard of living index to help distinguish the poor from non-poor as part of the equity evaluation. Here, I had two main questions:

i. How can I measure SES in Malawi?
ii. Can I construct a shorter standard of living index for such a setting?
iii. How does this index perform against existing measures?

After this analysis, I evaluated the impact of distributing HIVST on socioeconomic equity in uptake of HIV testing services. Here, I had two main questions:

i. Who in terms of SES is testing for HIV?
ii. How are subsidies from HIV testing distributed across different socioeconomic groups?

All these analyses then feed into policy recommendations for scale-up of HIVST.

3.5. Ethics

Ethics approvals were obtained from the following research ethics committees: the London School of Hygiene and Tropical Medicine (ref: 10566), (ref: 14916), (ref: 15465), (ref: 15408) and (ref: 11738); the Malawi College of Medicine Research Ethics Committee (ref: P.01/16/1861) and (P.02/18/2352); the Medical Research Council of Zimbabwe (ref: MRCZ/A/2038), the Human research Ethics Committee (Medical) of the University of Witwatersrand (ref: M180379); University of Zambia Biomedical Research Ethics Committee and the Institutional Review Board of Boston University School of Public Health (IRB: H-37713)

3.6. Intellectual ownership

This research was undertaken with support from Unitaid through the STAR project and MLW's core funding. Objectives 1 and 2 were conducted as collaborative work under the STAR Economics Network. Under the STAR Economics Network, I led on costing the facility-based provider testing and community-based distribution of HIVST in Malawi. I also led on the multi-country work evaluating costs of integrating HIVST in public primary care facilities.

Objectives 3 and 4 were conducted outside of this collaboration as these were additional student objectives that were not part of STAR Economics Network deliverables. I also led on these two objectives.

Aside from collaboration with the STAR economics network, my supervisors and advisory committee supported and advised on all elements of research in this thesis.

3.7. Chapter conclusion

As countries approach the last milestone to ending the AIDS epidemic, equity is becoming increasingly important especially because the HIV/AIDS epidemic is driven along gender and socioeconomic lines, among other inequalities. In addition, Covid-19 has exacerbated existing inequalities and is undermining gains in the fight against HIV/AIDS necessitating the need for deliberate action to ensure all vulnerable populations such as the poor are not left behind. Exploring equity in the delivery of HIV services and the implementation of new innovations such as HIVST is crucial to informing future targeting and implementation initiatives. However, equity concerns without exploration of affordability of such new interventions presents an incomplete picture. Ministries of Health and other implementing agencies need to be aware of the cost of providing HIV testing services including HIVST to inform resource allocation and budgeting. Finally, an exploration of access costs with conventional testing approaches helps enlighten the observed testing uptake patterns and strengthen the case for HIVST.

The next chapter is a methods chapter where I construct and validate a standard of living index using secondary data. This is objective 3 as was presented in this chapter.

Chapter 4: Constructing a standard of living index for Malawi

4.1. Introduction

This chapter presents literature and the results of work done in constructing a standard of living index for Malawi. The proposition is that a similar approach can be employed for other low-income settings although this measure is specifically for Malawi. There were three objectives for this chapter:

i. To understand how SES can be measured in a low-income setting such as Malawi
ii. To construct a shorter standard of living index for such a setting
iii. To compare the performance of this index against existing measures of SES

4.2. Measuring household standard of living (socioeconomic status)

Categorising people or groups of people using SES is important for planning of social services by informing where the poor who are likely to have the highest need reside, informing targeting of social services and public health interventions and tracking the impact of interventions (186, 187).

Measures of SES can be categorised into monetary and non-monetary. Monetary measures are popular especially among economists (188). There are two main monetary measures of SES: income and consumption expenditure. There are several non-monetary measures with wealth index and education as the frequently encountered measures in low-resource settings. The use of non-monetary measures has been increasingly wide due to the complexity of obtaining income and consumption expenditure data in LMICs, in addition to the absence of income and consumption expenditure data in demographic surveys such as the Demographic Health Survey (DHS) (188-191). This next section presents these measures of SES in more detail.

4.2.1. Monetary measures of SES

i. Income

Income as a measure of SES is composed of both earnings and transfers (106). It captures a household's command over financial resources (191). The use of income as a measure of SES is more common in high income countries (HICs) than in LMICs. This is because household income in HICs is frequently from one source, and this source is likely to be in the formal economy (191-193). In LMICs on the other hand, households more often obtain income from multiple sources that are a combination of formal and informal economies, in addition to self-employment (186, 188, 191-193). Home production is also more prevalent and important to households in LMICs (192) which leads to underestimation of household income if such sources are not included. This then makes obtaining accurate income data in LMICs more complicated than in HICs. Furthermore, income is very variable in LMICs due to seasonality and dependence on seasonal agricultural activities (194).

Given all these challenges, obtaining accurate income data in LMICs is a taxing activity (191-193). The seasonal variability in income data also makes predicting household income prone to substantial inaccuracies. Income data is also considered sensitive by respondents leading to higher non-response rates than other measures of SES (194). Furthermore, asking the household head or their partner to report on household income does not always lead to accurate reporting of earning of all members of the household (192).

ii. Consumption expenditure

A more stable and viable alternative to income is household consumption expenditure (186). Consumption expenditure measures how income is used without income's measurement errors (192).

In addition, consumption in the short term is less variable than income because households smoothen consumption by borrowing or using savings during income fluctuations (106, 186, 188, 191). Therefore, in settings where income heavily fluctuates such as in rural agricultural communities, consumption offers a more stable alternative measure of SES (186). In such settings, even observing consumption over a short period such as a week offers a better picture of annual and longer-term SES than income would have provided (186). The argument for smoothened consumption, however, should be conducted with caution to not assume frictionless borrowing (low transaction costs for borrowing) which is unrealistic in LMICs (191).

When consumption is used as a measure of SES, consumption expenditures are collected in household surveys using either diaries or recall (195). The recall approach requires respondents to recollect household expenditures over an extensive number of items in a given period of time (188). Where data collection is using diaries, respondents record their consumption daily for a couple of days, such as a week. In such cases, researchers conduct repeat visits to the households to ensure correct completion of the diaries (192). This approach has a considerable loss to follow-up, potential selection bias and Hawthorne effect from the repeat visits to the households (192). Hawthorne effect is when people change their behaviour due to being observed.

Another challenge with consumption expenditure approach is that there is a variation in data collection methods. This includes the use of for instance, diaries versus recall. In addition, there is also a wide variation in the reference period used. Some researchers collect household consumption data for as little as three days while other require recall of expenditure for longer periods of times such as months. This introduces additional recall bias if the recall period is very long but also affects comparability of findings across studies (195).

There is also a wide variation in the degree of detail of expenditures collected (195). Some researchers collect expenditures on durable and non-durable assets including once-off purchases of durables assets while others do not collect such detailed information. This affects comparisons and expenditure amounts collected. In addition, where information on household consumption expenditure is asked to one member of the household, there is potential of missed or underreporting of expenditures by other members of the household (192, 195). Collecting household expenditures is also tedious and expensive, involving lengthy data collection processes (188). In addition, despite consumption expenditures being more stable than income, there are still concerns that consumption expenditures can vary considerably over time (192).

Finally, consumption expenditure data are not readily available in nationally representative datasets. For instance, and to the best of my knowledge, the Malawi IHS is the only survey in the country collecting detailed consumption expenditure data. This introduces a challenge in measuring SES for researchers using other publicly available datasets for analysis such as the DHS.

4.2.2. Non-monetary measures of SES

i. Wealth index

Challenges with using income and consumption expenditure presented above, in addition to the absence of income and consumption expenditure data in epidemiological surveys motivated the use of household wealth as a measure of SES (189-191, 196). Household wealth is more advantageous over both consumption expenditure and income as wealth captures a household's more permanent status, is more easily measured, and requires fewer questions in a survey setting (196).

The choice to use a wealth index to measure SES was more pragmatic (190) in response to the challenges with income and expenditure in LMICs. Despite this, some studies have tried to validate the index against consumption expenditure. These studies have shown the wealth index to have a good agreement with consumption expenditure, depending on the number and types of assets and other socioeconomic variables included such as human capital variables (190, 192). Some researchers have shown a weak association between the wealth index and adult consumption expenditure (191), while others have argued that the index need not proxy consumption expenditure but be a measure of household's long-term living standard (189). Montgomery *et al*. (2000) (191) argued that development of the wealth index can be conceptualized in these two distinct approaches: the wealth index as a proxy for consumption expenditure when the expenditures are missing from the dataset, or the wealth index as a measure of a latent unobservable construct (household long-term SES).

Work around the development of a wealth index has revolved around the DHS and has been driven by staff at the World Bank and ORC Macro (192, 196). Therefore, the composition of wealth indices is frequently with reference to a set of variables included in the DHS. Traditionally, DHS collected data on household durable assets and housing characteristics that had a direct association with health (196). These variables were then used to construct the wealth index. The DHS wealth index is composed of housing characteristics such as type of flooring, access to utilities such as water source and electricity for lighting, ownership of durable assets, number of people sleeping per room, ownership of agricultural land, the presence of a domestic servant in the house and a set of country specific items (196).

When developing the DHS wealth index, the ORC Macro and World Bank teams included all indicators in the DHS that related to household durable assets, housing characteristics, access to services, having a domestic servant and land ownership (190, 196). The justification for the inclusion of a broader set of indicators was to increase variation across households, to reduce subjectivity if variables were selected *a priori* and to increase accuracy of the index when used as a proxy for consumption (190, 196). They did, however, leave out the type of occupation and level of education which are two main variables that would normally be associated with SES (196). This is because education and occupation were to be included as determinants of health and healthcare access.

Another prominent study on the wealth index was by Filmer and Pritchett (2001) [(189)]. Their index also contained durable items such as ownership of a television set, access to basic services such as sources of drinking water, types of toilet facility used by the household, housing characteristics and size of land holding. Montgomery *et al*. (2000) (191).noted that access to water and the type of toilet facility used, housing characteristics and ownership of household assets as the frequently encountered indicators included in wealth indices in literature (191).

Despite the wealth index having a practical motivation as a measure of SES and the proposition that it need not to have a strong association with both income and consumption expenditure (189-191, 196), it has been argued to be theoretically and practically superior (196). The index captures a household's long-term socioeconomic status and in developing countries, assets are a good indicator of a household's long-run economic status (189, 193). The index has also been shown to perform well and in some cases better than consumption expenditure in predicting certain variables such as child mortality, poverty and school enrolment as examples of its application (189, 197). Howe, Hargreaves (188) did however note that wealth indices with other items such as demographics, human capital and livestock in addition to consumer durable assets, housing characteristics and access to services showed stronger agreement with consumption expenditure.

One of the limitations of the wealth index is that it is context and time specific as shown with the inclusion of country-specific variables in the DHS (194, 196). Practically, it has been challenging to compare the household economic position across time and countries. Later work of the DHS team has worked on making the DHS wealth index more comparable across time and settings (198). In addition, the inclusion of assets and other utility variables tend to make the index urban biased with urban households more likely to be well-off (189). This has encouraged the use of separate rural and urban wealth indices especially in DHS analyses.

Another limitation with the wealth index is that its composition has been either on an ad hoc or a study specific basis (191). Researchers working in different contexts and sometimes in the same setting have ended up constructing wealth indices comprising an array of items with sometimes little to no justification for the inclusion of those items (191).

Finally, a key limitation with the wealth index is the choice of weights to use for each of the indicators included (189, 190, 192, 193). If an index is composed of housing characteristics and household assets, should the housing characteristics be given higher weights than household assets? Even among the household assets, which assets should carry more weight when categorising a household's SES? There are four main procedures that have been used to determine weights of indicators included in a wealth index: an arbitrary approach, market prices, means testing and a statistical procedure.

The arbitrary weighting procedure is considered the simplest approach (192, 193). The approach involves using equal weighting for each indicator included in an index. This means valuing ownership of an iron using the same weight as ownership of a car. Some researchers use prices to weight items included in an index. This approach places explicit or implicit prices on items in an index as weights (189). With this approach, the price is weighted according to the inverse proportion of the population such that items that are more common have a lower weight than those that are rare (192).

Frequently used by the World Bank for targeting, means testing is another alternative for weighting. Means testing uses regression analysis to predict welfare. A set of variables are entered in a regression analysis and are used to predict the dependent variable which can be a welfare variable (189). Wealth indicators such as durable assets and other socioeconomic variables can also be regressed on a socioeconomic variable such as consumption expenditure in one dataset, the coefficients from this regression can then be used as weights for those assets in another dataset (192).

The final weighting approach and approach used in the DHS is principal components analysis (199). Using PCA for weighting indicators in a wealth index was proposed by Filmer and Pritchett (2001) [(189)] in their work of predicting school enrolments. PCA is a data reduction approach that captures the most common information across variables. The goal of PCA is to decompose a set of data with correlated variables into a set with uncorrelated factors/principal components (200). This helps reduce the variability in the data. The variation in the data is explained as the principal components.

The first principal component explains the largest variability and is often the only one extracted with the assumption that it represents household SES (106, 196, 201). The challenge with PCA is that the approach assumes that the data are continuous while asset ownership is binary, leading to incorrect weights if the assumption is violated (192). A solution to this has been the use of tetrachoric or polychoric correlation coefficients and a correlation matrix. Another limitation is that despite its wide use, PCA remains a statistical and data driven approach with no theoretical backing for its use.

ii. Education

Education is the other non-monetary measure of SES frequently used in literature in LMICs. The use of education as a measure of SES seeks to capture the knowledge related assets of individuals but is also strongly related with income and occupation (191, 192, 194).

Education is often captured either as a continuous variable showing years of schooling, or categorical showing level of education completed. The capturing of education as a continuous variable, that is, years of schooling, assumes every year of education has an equal incremental contribution to SES and that time spent at school has greater importance than education achievements (192, 194). Capturing education as a categorical variable on the other hand, assumes that specific achievements have greater effect in determining SES (194).

The challenge with using years of schooling especially in LMICs is that repeating classes is more common than in HICs such that by using a continuous measure there is an implicit assumption that the year repeated conferred the same benefits as progressing to the next class (192). Education is however, easy to capture in household surveys and is associated with fewer measurement errors and reporting or recall bias.

4.3. Chapter aim

As indicated earlier, economists prefer monetary measures of SES such as consumption expenditure (188). One of the reasons for this preference is that monetary measures have a theoretical grounding as part of the consumption function. However, as presented earlier, obtaining income and consumption data in LMICs is challenging, unreliable, associated with measurement error, and expensive (188, 193, 194). As a result, assets have been used to measure household's SES as they reflect a household's long-term SES. Constructing an asset-based measure of SES has modest data requirements and avoids measurement errors (202).

A purely asset-based index of SES measures a household's unidimensional socioeconomic position. However, poverty is a multidimensional concept. As such, a measure of a household's socioeconomic standing needs to reflect the various dimensions of poverty. The Oxford Poverty and Human Development Initiative (OPHI) with the United Nations Development Programme's Human Development Report developed a multidimensional measure of SES known as the Multidimensional Poverty Index (MPI) (203). The MPI comprises three dimensions: health, education, and standard of living that are measured using 10 indicators (204-206). The dimensions in the MPI are similar to those in the Human Development Index created by the United Nations Development Programme (204). The selection of dimensions and indicators in the MPI was based on literature, relation to millennium development goals, theory, and practicality (206). There was an additional focus with the MPI on including indicators that have data that are more widely available to allow for international comparison (206).

An index similar to the MPI but one that is more country specific is the DHS wealth index which was already introduced earlier. The DHS wealth index is also multidimensional comprising assets and standard of living (196). Indicators included in the DHS are data driven often derived using PCA. One of the challenges with applying the DHS wealth index beyond the DHS is that the index has a long list of indicators. This may make it impractical in epidemiological surveys where measuring SES is not the primary focus. In addition, the DHS index includes fewer dimensions of poverty. As a matter of design, it leaves out human capital variables such as education and occupation.

Despite the usefulness of multidimensional indicators such as the MPI, they are developed to allow for international comparisons (198). This means that they may not be very precise for specific countries. In this chapter, I was interested in developing an index that was specific for Malawi. The DHS wealth index approach allows for the derivation of country-specific indices. As such, I adopted the DHS wealth index approach to develop an index for Malawi. However, and as noted earlier, the DHS index tends be composed of a long list of indicators which affects it practicality of being included in epidemiological surveys. In addition, the DHS wealth index does not include human capital variables. Here, I sought to develop a multidimensional index that included human capital variables similar to the MPI but specific for Malawi.

I also needed to account for one other limitation of the DHS wealth index. The index has been criticised for being urban-biased (207). This is because ownership of certain assets including access to publicly provided services such as electricity and piped water depend on the availability of infrastructure which may be more readily available in urban than rural areas (189, 192). As such, urban households may appear to be more well-off than rural households. In addition, ownership of certain assets may have different interpretation depending on the location. For instance, ownership of farmlands may demonstrate higher SES in rural areas but may not be equally reflective of wealth in urban areas (208).

One of the solutions to the urban bias is the construction of separate indices for urban and rural areas (207). I adopt the approach of developing separate indices for urban and rural areas, but I also develop a national-level index for researchers not interested in an area-based index.

4.4. Methods

4.4.1. Data

I used the fourth Malawi Integrated Household Survey to construct and validate the standard of living index. The choice of the IHS dataset was because this is the only nationally representative dataset collecting detailed consumption expenditure data. This allowed me to compare agreement between our standard of living index and consumption expenditure as one of the preferable measures of SES in low-income settings.

The IHS is conducted every five years by the National Statistical Office of Malawi with technical assistance from the International Food Policy Research Institute (IFPRI) and the World Bank. The dataset is freely available at https://microdata.worldbank.org/index.php/catalog/2936. It is a weighted household survey stratified into urban and rural strata. This analysis used Stata® 17 software.

4.4.2. Steps in constructing the wealth index

Step 1: Identifying indicators to be included in the wealth index

The first objective of this chapter was to construct a brief standard of living index. The DHS index is widely used and probably the most validated wealth index in many settings including Malawi. Therefore, I decided to have the DHS as my starting point as the indicators in the index have already been validated to measure SES in the context. In addition, indicators included in the DHS index are readily available and frequently included in public health research to evaluate determinants and access to health. The implication of this is that whatever indicators would be included in our standard of living index, would be indicators that are already frequently included in health research to allow for ease of adoption of the index.

I extracted a list of indicators used in constructing the wealth index for Malawi in the DHS. Table 4.1. presents a list of these indicators.

Table 4. 1: List of variables used to construct the Malawi wealth index in the Demographic Health Survey

Indicator category	Indicators
Housing characteristics	Source of drinking water, toilet facility, cooking fuel used, main floor material, main wall material, using electricity for lighting
Assets	Bed with mattress, bicycle, boat with motor, car/truck, animal drawn cart, motorcycle, telephone (landline), mobile phone, computer, television, *koloboyi* (basic paraffin lamp), paraffin lamp, lamp torch, sofa set, watch, refrigerator
Livestock ownership	Cattle, goats, sheep, pig, donkeys, chicken, other poultry
Other	Ownership of a bank account, number of household members per sleeping room, domestic servant, owns a house, owns land, land area

I then included human capital variables of the household head, highest education attained, engagement in formal employment, literacy, and gender. Howe *et al*. (2012) [(192)]showed that the wealth index had a stronger agreement with consumption expenditure if it included human capital variables (192). The decision to include these human capital variables to the index was to ensure that the constructed index had a higher agreement with consumption expenditure. I decided to include household head's human capital variables only because household head's variables specifically gender and education level have been shown to be highly predictive of a household's SES in Malawi (29). I decided to include literacy and engagement in formal employment, aside from household head's education and gender because I was interested in both proxying household's income and employability of the household head in the formal sector.

Step 2: Data preparation

The second step was to check if all the DHS wealth index indicators were also available in the IHS4. After this, I then recategorised non-binary variables into dichotomous as is the practice with DHS wealth index construction and for ease of incorporation in the wealth index (196). In addition, categorising variables into dichotomous is also helpful in the analysis and it reduces missingness in the responses which allows for ease of computation. The wider the response options, the lower the frequency of responses which affect the ability of the analysis software to compute the command.

All asset and livestock ownership indicators were already dichotomous and did not need to be recategorised. Table 4.2 presents a list of indicators available in the IHS4 survey and their dichotomous recategorisation prior to their inclusion in this analysis.

I excluded two indicators in the DHS wealth index: number of people sleeping in a room and the land area owned, as these indicators could not be meaningfully converted into binary indicators. Without a meaningful reference such as the ideal number of people to sleep in a room and the ideal land area to be owned, it was not possible to convert these indicators to their dichotomous equivalent. I did, however, include landownership as a dichotomous variable in the follow-on analysis.

Step 3: Splitting samples

When constructing an index, it is recommended to split the data into derivation and a validation datasets (209). This is because a prediction model should be able to demonstrate accurate prediction in another dataset other than the one it was developed in Auld *et al.* (2020) [(210)]. To do this, I split the IHS4 dataset into two, a derivation sample and a validation sample. The derivation sample was used to develop the standard of living index, while the validation sample was used to evaluate its performance on a different sample.

First, I randomly split the data into two subsets, to construct and validate a national-level standard of living index using Stata® 17's split sample command. I then constructed the national-level standard of living index on the derivation sample and cross-checked the performance of the index on the validation sample.

Given the urban bias as a limitation of the wealth index presented earlier, I also sought to construct an area-based index. To do this, I returned to the original dataset and split it into rural and urban datasets before randomly splitting each of these datasets further into two random samples for index development and validation. I ended up with urban derivation and validation datasets and rural derivation and validation datasets. Area-based standard of living indices were developed from the derivation datasets and cross-checked their performance on the validation datasets.

Table 4. 2: List of indicators used to develop the wealth index and their recategorisation

Indicator*	Options	Recategorisation
Source of drinking water	Piped into dwelling, piped into yard/plot, communal standpipe	Tap water
	Open well in yard/plot, open public well, protected well in yard/plot	Well
	Borehole	Borehole
	Spring, river/stream, pond/lake, dam	Surface water
	Tanker truck/bowser, bottled water, other	Other
Toilet facility	Flush toilet	Flush toilet
	VIP latrine, traditional latrine with roof	Pit latrine
	None	No toilet
	Other	Other
Main source of cooking fuel	Collected firewood, purchased firewood	Firewood
	Electricity	Electricity
	Charcoal	Charcoal
	Paraffin, gas, saw dust, other	Other
	Crop residues	Crop residue
Main source of lighting	Collected firewood, purchased firewood	Firewood
	Paraffin	Paraffin lamp
	Electricity	Electricity
	Battery/dry cell	Torch
	Candles	Candles
	Gas, grass, other	Other
Main floor material	Sand	Sand
	Smoothed mud	Mud
	Smooth cement	Cement
	Tile	Tile
	Wood	Other
	Other	
Main wall material	Grass	Grass
	Mud, compacted earth, mud bricks	Mud

	Burnt bricks	Burnt bricks
	Concrete	Concrete
	Wood, iron sheets, other	Other
Main roofing materials	Grass	Grass
	Iron sheets	Iron sheets
	Clay tiles, concrete	Tiles
	Plastic sheeting, other	Other

*Some indicators were lumped in the 'other' category due to their low response rates in IHS4

Step 4: Indicator selection

I used factor analysis to construct the standard of living indices. Factor analysis is a data reduction statistical procedure that uncovers patterns among a set of variables, and clusters highly interrelated variables into groups known as factors (200, 211). Variables under each factor explain an underlying construct and these variables are expected to have little to no relationship with variables under another factor.

Factor analysis is frequently applied in survey settings where a researcher seeks to assess if a lengthy tool can be grouped into shorter sets of questions (200). The approach is also useful in providing the simplest way to interprete a wide set of variables (211). There are two main types of data reduction approaches: common factor analysis (often referred to as factor analysis) and PCA (209). The difference between the two is that factor analysis presents factors based on their shared variance while PCA presents factors based on total variance of the variables included (200). PCA reduces the number of variables into a more manageable set but does not group variables that measure the same construct (200). Factor analysis on the other hand, performs data reduction and groups variables into sets measuring the same latent construct.

I chose factor analysis here because I was interested in understanding if the wide set of indicators included in the DHS including the human capital indicators could be summarised into a smaller subset grouped into one latent construct capturing a household's long-term SES. Factor analysis in this sense would not only be useful for data reduction but also inform if the indicators are highly interrelated and therefore explaining the same latent construct.

Filmer and Pritchet (2001) [(189)]suggested that the first latent construct was the one measuring household SES. In line with this, I also sought to only retain the first factor.

I then needed to decide which indicators to extract from the first factor. I observed each indicator's factor loading score and extracted only indicators that had factor loading scores that were above an *a priori* threshold. A factor loading is a measure of how much an indicator contributes to a factor (211). Indicators with high factor loading scores have the highest similarity with the underlying construct and therefore better explain the construct (209, 211). I used a factor loading of 0.4 as has been used elsewhere (200). The absolute value of a factor loading is what is important and not the sign (211). The signs simply show direction of correlation and not magnitude of effect (211). Therefore, I only extracted indicators with an absolute value of at least 0.4. Indicators with absolute value less than 0.4 were considered as not significant to measuring household SES in Malawi (the first factor that was extracted).

Step 5: Assessing reliability
After extracting the indicators under the first factor I needed to evaluate the internal consistency (reliability) of the index. Internal consistency is a form of reliability assessment that seeks to assess the homogeneity of indicators in a scale (209). A scale measuring the same underlying construct should be composed of items that are interrelated. Correlation of items in a scale is evaluated using Cronbach's alpha (α) (200, 209). Cronbach's alpha ranges from 0 to 1, with the value of alpha increasing as indicators in a scale have a higher correlation with each other (212). An acceptable value of alpha is considered to range between 0.7 to 0.90, with a very high alpha indicating redundancy of indicators included in the scale (209, 212)

I evaluated internal consistency of indicators in a scale by observing the value of alpha on the derivation sample. I also compared this alpha value with the alpha value of the same scale on the validation sample. I considered the index as internally consistent if it had an alpha above 0.7.

Step 6: Assessing validity
Validity is the degree to which an index is measuring what it purports to be measuring (200, 209). There are a number of types of validity available in literature. In this chapter I focused on criterion validity. Criterion validity looks at the relationship between the new scale and the 'gold standard' (209). Correlation coefficient is used to quantify the relationship between the new scale and the 'gold standard' (200, 209).

I observed the Spearman's rank correlation coefficient of our standard of living index and the DHS wealth index as well as consumption per adult. I compared with both DHS and consumption per adult because these are the preferable measures of SES in LMICs. I adopted Howe *et al*. (2012)'s [(188)] decision criteria where they defined a correlation coefficient of 0.7 or higher as a strong agreement, 0.5-0.7 as moderate agreement and less than 0.5. as a weak agreement.

4.5. Results

4.5.1. Descriptive statistics

A total of 12,447 household heads were interviewed in the IHS4. The sample had 81.8% rural households and 71.3% of the respondents were men. The IHS interviews household heads and a significantly proportion of household heads in Malawi are male, 64.8% according to the most recent national census (213).

The mean age of the respondents was 43 years with no significant difference in the mean age between urban and rural areas. A significant proportion of the sample, 61.8%, did not have any formal education qualification. More respondents in rural areas did not have formal education when compared to those in urban areas.

Forty-four percent of the respondents were categorised as living below the national poverty line: 51.9% in rural areas and 12.5% in urban areas. Finally, 16.1% of the respondents were categorised as extremely poor. The proportion of respondents categorized as extremely poor was also higher in rural areas, 19.1%, than in urban areas, 2.9%. Table 4.3. presents additional descriptive statistics.

Table 4. 3: Descriptive statistics

Variable		National level	Rural	Urban
Sample size		12,447	10,175 (81.8%)	2,272 (18.3%)
Gender	Male	8,874 (71.3%)	7,137 (70.1%)	1,737 (76.5%)
Mean age (min-max)		43 yrs (15-98)	44yrs (15-98)	41yrs (17-91)
Highest education qualification	None	6,480 (61.8%)	5,791 (69.7%)	689 (31.7%)
	Primary	1,320 (12.6%)	1,062 (12.8%)	258 (11.9%)
	Secondary	2,144 (20.5%)	1,280 (15.4%)	864 (39.8%)
	Vocational	318 (3.0%)	138 (1.7%)	180 (8.3%)
	Tertiary	219 (2.1%)	36 (0.5%)	183 (8.4%)
Living below the national poverty line		5,568 (44.7%)	5,283 (51.9%)	285 (12.5%)
Extreme poor		2,008 (16.1%)	1,943 (19.1%)	65 (2.9%)

4.5.2. Data reduction

All indicators proposed in the methods section were included in the analysis. Table 4.4 presents the list of the indicators and their frequency of responses. The data were then split into two random sets for the index development and cross-checking. The derivation sample had a sample size of 6,224 while the validation sample had a sample size of 6,223. I ran factor analysis on variables presented in Table 4.4 using Stata®'s Polychoric command as all indicators were dichotomous.

Table 4. 4: Frequency of responses of indicators

Indicator Category		Indicator	Frequency of responses	
			Yes	No
Housing characteristics	**Source of drinking water**	Tap water	22.8%	77.2%
		Well	10.5%	89.5%
		Borehole	61.4%	38.6%
		Surface water	4.97%	95.0%
		Other	0.3%	99.7%
	Toilet facility	Flush toilet	3.9%	96.1%
		Pit latrine	87.2%	12.8%
		No toilet	8.7%	91.3%
		Other	0.1%	99.9%

	Main source of cooking fuel	Firewood	80.8%	19.2%
		Electricity	2.2%	97.8%
		Charcoal	15.4%	84.6%
		Other	0.1%	99.9%
		Crop residue	1.5%	98.5%
		Grass	2.0%	98.0%
	Main source of lighting	Firewood	2.0%	98.0%
		Paraffin lamp	2.0%	98.0%
		Electricity	12.2%	87.8%
		Torch	74.4%	25.6%
		Candles	5.2%	94.8%
		Other	2.2%	97.8%
	Main floor material	Sand	2.6%	97.4%
		Mud	68.8%	31.2%
		Cement	28.2%	71.9%
		Tile & wood	0.3%	99.7%
		Other	0.1%	99.9%
	Main wall material	Grass	0.4%	99.6%
		Mud	37.4%	62.6%
		Burnt bricks	59.9%	40.1%
		Concrete	1.9%	98.1%
		Other	0.2%	99.8%
	Main roofing materials	Grass	50.1%	49.9%
		Iron sheets	49.3%	50.7%
		Tiles & concrete	0.3%	99.7%
		Other	0.3%	99.7%
Assets		Bed	37.7%	62.3%
		Bicycle	36.6%	63.4%
		Boat with motor	0.8%	99.2%
		Vehicles	2.3%	97.7%
		Motorcycle	1.8%	98.3%
		Telephone (landline)	0.3%	99.7%
		Mobile phone	49.7%	50.3%
		Computer	2.8%	97.2%
		Television	12.7%	87.3%
		Paraffin lamp	1.5%	98.5%
		Lamp torch	74.4%	25.7%
		Sofa set	11.8%	88.3%
		Clock	9.3%	90.7%
		Refrigerator	6.0%	94.0%
Livestock		Cattle	3.5%	96.5%
		Goat	16.9%	83.1%
		Sheep	0.2%	99.8%
		Pig	6.3%	93.7%
		Donkey	0.1%	99.9%
		Chicken	26.1%	73.9%
		Other poultry	2.2%	97.8%
Other		Bank account	24.4%	75.6%
		Owns land	72.7%	27.3%
		Owns house	72.7%	27.3%
		Household has a domestic servant	0.8%	99.3%
Human capital		Literacy	72.2%	27.8%

	Engagement in formal employment	15.1%	82.6%
	Gender	71.3%	28.7%
	No education	59.3%	40.7%
	Primary education	25.6%	74.4 %
	Secondary education	11.6%	88.4%
	Tertiary education	3.5%	96.5%

I repeated the process with the rural and urban derivation samples. The derivation sample for rural areas had a sample size of 5,088 while that for urban areas had a sample size of 1,136.

I extracted all indicators in the first factor that had an absolute factor loading above 0.4. Table 4.5 presents a list of all indicators included in the final factor analyses and their factor loadings.

All indicators with an absolute factor loading above 0.4 were extracted as explaining the underlying construct. At the national level, the standard of living index was composed of housing characteristics, assets, human capital indicators, access to a bank account, and ownership of a house. All these indicator categories were also significant in the urban and rural datasets, except access to a bank account and ownership of a house. None of the livestock indicators had high enough factor loadings to be extracted. Table 4.6. presents the final list of indicators extracted from the process of factor analysis.

Table 4. 5: Factor loadings of indicators included in the factor analysis in the derivation samples

Indicator Category	**Indicator**	**Factor Loadings**		
		National level	**Rural**	**Urban**
Housing Characteristics	Iron sheet roof	0.7696*	N.A	0.6846
	Cement flooring	0.8738*	0.7690*	0.7261*
	Pit latrine for toilet	-0.2402	0.0313	-0.6325*
	Brick walls	0.4218*	0.3519	0.4689*
	Charcoal for cooking	0.7599*	0.7748*	0.1988
	Torch for lighting	-0.6787*	-0.5417*	-0.7054*
	Open water source	N/A	-0.2105	N/A
Assets	Radio	0.2994	0.3020	0.1632
	Bicycle	0.1471	0.1962	0.2047
	Motorcycle	0.4173*	0.4295*	N/A
	Television	0.9487*	0.9188*	0.8950*
	Refrigerator	0.9013*	0.9312*	0.8974*
	paraffin lantern	0.0307	0.1914	N/A
	Bed	0.7830*	0.6789*	N/A
	Sofa set	0.8828*	0.8117*	0.7715*
	Clock	0.7858*	0.7045*	0.6693*
	Mobile phone	0.7380*	0.6389*	0.7469*
Livestock owned	Cattle	0.0528	0.0638	N/A
	Chicken	-0.0073	0.0714	0.0020
	Goat	-0.1558	-0.0038	-0.0860
	Pig	-0.0892	0.0130	-0.0688

	Other poultry	0.0354	0.1005	N/A
Other	Bank account	0.6466*	N/A	N/A
	Owns a house	-0.5737*	N/A	N/A
Human capital	Formal employment	0.6774*	0.6010*	0.4147*
	Secondary education or higher	0.8088*	0.7228*	0.7256*
	Literacy	0.5722*	0.5318*	0.5617*
	Gender	0.2133	0.1872	0.1485

*Indicator extracted under each factor

There was a total of 17 indicators in the national level standard of living index and 13 in the rural and urban standard of living indices, respectively. The same set of human capital indicators: engagement in the formal employment sector, possessing secondary education or above and being literate were retained in all three indices. The same set of assets were also retained in the national and rural indices. Ownership of a motorcycle and sleeping on a bed were, however, not significant to capturing household wealth in the urban dataset.

Table 4. 6: Extracted indicators for the standard of living indices

Indicator Category	National level	Rural	Urban
Housing characteristics	House with iron roof, house with cement floor, House with burnt brick walls, charcoal for cooking, torch for lighting	House with cement floor, charcoal for cooking, torch for lighting	House with iron roof, house with cement floor, house with burnt brick walls, pit latrine for toilet, torch for lighting
Assets	Motorcycle, television, refrigerator, bed, sofa set, clock, mobile phone	Motorcycle, television, refrigerator, bed, sofa set clock, mobile phone	Television, refrigerator, sofa set, clock, mobile phone
Other	Has access to a bank account, owns a house	N/A	N/A
Human capital	Engaged in the formal sector, has secondary education or higher, literate	Engaged in the formal sector, has secondary education or higher, literate	Engaged in the formal sector, has secondary education or higher, literate

In terms of housing characteristics, living in a house roofed using iron sheets, cement floor, and brick walls and using a torch as the main source of lighting were significant in capturing household SES at the national level and in urban areas. Using charcoal for cooking was also significant at the national level, while using a pit latrine for a toilet was significant in urban areas. In rural areas, living in a house with a cement floor, using charcoal for cooking and a torch as the main source of lighting were significant to household SES. Living in a house with cement floor and using a torch as the main source of lighting were the only significant household characteristic at the national level, that appeared in both rural and urban areas.

4.5.3. Reliability Assessment

Table 4.7. presents Cronbach's alpha values for each of the indices derived in Table 4.6. The indices' Cronbach's alpha values were within the acceptable range. There was high internal consistency of the indicators included in the indices. In addition, the alpha value of the indices in the derivation sample were comparable to the value of alpha in the validation sample across all three area datasets (national level, rural and urban). This demonstrated that the constructed indices were reliable across different samples.

Table 4. 7: Cronbach's alpha as a measure of reliability of the indices

Standard of living index	Sample	# of items in scale	Cronbach's alpha	Sample size
National level	Derivation	17	0.8643	6224
	Validation		0.8634	6,222
Rural	Derivation	13	0.7434	5,088
	Validation		0.7349	5087
Urban	Derivation	13	0.8105	1136
	Validation		0.8355	1136

4.5.4. Validity Assessment

Finally, I compared correlation between our standard of living indices and the DHS wealth index as well as consumption expenditure per adult. Across all three datasets, that is, national level, rural and urban, our standard of living indices had a strong agreement with the DHS wealth index as presented in Table 4.8. The agreement was highest in the national level index, 0.89 and lowest in the rural index, 0.74. Our standard of living indices had moderate to weak agreement with consumption per adult, 0.53-0.35. This implies that our indices can be used in place of the DHS wealth index but are not a strong proxy for adult consumption expenditure. The DHS wealth indices for national level, rural and urban areas also had moderate to weak correlation with consumption per adult.

Table 4. 8: Agreement with consumption expenditure per adult and the Demographic Health Survey wealth index

Index		DHS wealth index		Consumption per adult	
	Dataset	**Correlation coefficient**	**Agreement**	**Correlation coefficient**	**Agreement**
Our standard of living index	National level	0.8856	Strong	0.5091	Moderate
	Rural	0.7411	Strong	0.5248	Moderate
	Urban	0.8425	Strong	0.3475	Weak

4.6. Chapter discussion

In this chapter, I sought to construct a standard of living index that was shorter than the DHS wealth index but could proxy the DHS wealth index and consumption expenditure per adult using a nationally representative dataset. I constructed three standard of living indices to be used at: national level, for rural areas and for urban areas. The indices have a range of 13 to

17 indicators comprising housing characteristics, ownership of durable and non-durable assets, human capital indicators and access to the banking sector. Each of these three indices has a strong agreement with the DHS wealth index and therefore, can be used in place of the index. the indices also have a moderate to weak agreement with consumption per adult as such, cannot be used to proxy consumption expenditure.

As indicated earlier, the use of a wealth index was developed as a practical measure of SES for LMICs due to challenges with using household income and consumption expenditure. The index is frequently developed on a premise of measuring an unobservable concept, long-term household SES (189, 191). As such, the index need not have a high agreement or be considered as a proxy for consumption expenditure. However, Howe, Hargreaves (188) showed that longer and wealth indices that included human capital indicators had better agreement with consumption expenditure.

Here, I have shown that our wealth index had at best, moderate agreement with consumption expenditure regardless of the number of indicators included despite including human capital variables. Our indices included human capital indicators but had weak to moderate agreement with consumption expenditure. The DHS wealth index is longer than our indices but also had weak to moderate agreement with consumption expenditure. Montgomery *et al*. (2000) [(191)]in their study also reported low levels of agreement between wealth indices and consumption per adult.

The number of indicators included in an index (length of an index) is important not only to ensure improved correlation with existing measures (188), but also to ensure improved explanation power on the underlying construct. The number of indicators in the indices developed in this chapter range from 13 for the rural and urban indices and 17 for the national level index. This is shorter than the DHS wealth index for Malawi which is composed of 35 indicators (214).

A series of wealth and standard of living indices reviewed in a systematic literature review ranged from 9-31 indicators (188). Another study presented indices with 9-12 indicators (191). Filmer and Pritchet (2001) [(189)] developed a wealth index composed of 21 indicators. Our standard of living indices are therefore, within the range of other indices presented in literature. In the context of Malawi, our indices have an advantage of being shorter as such they can easily be incorporated in household surveys. They also have a strong agreement with the DHS wealth index such that they can be used instead of the longer wealth index.

The indices constructed in this chapter were based on the DHS wealth index and literature. As such, the indices contain indicators that are easy to collect in household surveys and have been extensively validated to measure SES. Our standard of living indices are composed on housing characteristics, ownership of durable and non-durable assets, human capital indicators and access to the banking sector. Such indicators have also been used elsewhere (188, 189, 191, 196). We further validated our indices on the validation sample. The indices maintained internal consistency captured using Cronbach's alpha showing that the indicators included were not spurious but consistent at explaining the underlying factor.

Finally, the index developed here allows us to distinguish between household SES. It is similar to the DHS wealth index in the development process. It shares similarity with MPI and HDI in that it is multidimensional. Unlike the DHS wealth index, the MPI and HDI include education as an additional dimension of poverty in addition to assets and indicators of standard of living. The DHS wealth index as a methodological choice, does not include human capital variables. In this index, I included these human capital variables to capture this additional dimension of poverty. The concept of using education to proxy to measure SES is widely acceptable as already presented earlier in this chapter. Here, I take a systematic approach to developing a multidimensional index for Malawi with an added advantage of developing area-specific indices (192, 198, 206).

4.7. Chapter limitations

The main limitation of this work is that the national level standard of living index may be rural-biased. This is because the IHS4 included 82% rural households. However, there was a high overlap of indicators included in the rural and urban indices showing that the bias may be minimal. In addition Malawi's has 84% of the population residing in rural areas (24), as such a nationally representative index should ably distinguish the majority of the sample who are likely to be rural dwellers.

The other limitation of this work is that the indices were not externally validated outside of the IHS4 dataset. However, the use of derivation and validation datasets as is common practice in instrument development offered an opportunity to internally validate the indices (209).

Finally, it is important to consider the context when interpreting household/individual socioeconomic classification from an index such as the standard of living indices constructed in this chapter. As indicated earlier, the use of the wealth index came about due to the need for practical solutions to measuring SES in LMICs. However, in poor countries such as Malawi, a household may be placed in the highest wealth quintile despite not being necessarily socioeconomically better-off in absolute terms (198). It is, therefore, important to consider the study objective before using these indices. If the objective is for targeting such as provision of social cash transfers, I recommend applying standard targeting approaches such as Brown *et al*. (2018), Grosh & Baker (1995) and Grosh & Glewwe (1996) [(215-217)]. The indices can however be used in socioeconomic equity evaluations exploring access to care and in analyses of SES as a confounder in epidemiological studies.

4.8. Chapter conclusion

In this chapter, I constructed standard of living indices to be used to measure household SES at national level, in rural and in urban areas. The constructed indices were composed of housing characteristics, ownership of assets, human capital indicators and access to the banking sector. They have a strong agreement with the DHS wealth index but moderate to weak agreement with consumption expenditure per adult. Future work should consider externally validating the indices. I further recommend considering the study objective before adopting and adapting these indices. The indices can be used in equity evaluations and epidemiological studies but perhaps not be used for targeting purposes.

The next chapters move away from the thesis methods to present results. In chapter five I present costs of accessing HIV testing services prior to the distribution of HIVST in Malawi. I use STAR community-based distribution of HIVST baseline trial household survey data for the analysis. Chapter five is the user costs component of the societal costs of HIV testing services introduced in Chapter 3.

Chapter 5: Costs of accessing HIV testing services

5.1. Introduction

This chapter presents results of a user costs analysis in Malawi. I start by briefly explaining the role of user costs in affecting access to primary health care services. This is an exploration of the affordability dimension of access introduced in Chapter 2 of this thesis.

5.2. Out of pocket payments for primary care in poor countries including Malawi

As introduced in chapter 2, there are two main types of costs incurred when accessing care: direct OOP payments and indirect costs. Direct costs have been reported as a deterrent to seeking care (218) especially for the poor in LMICs who have a high reliance on OOP payments when seeking care (219-221). Even when health insurance is there, co-payments, co-insurance and deductibles deter access to care (218).

Indirect costs also act as an important barrier such that even when direct treatment and medication payments are removed, it is not guaranteed that people will seek care (218). Transport costs, travel and waiting time and lost income have been shown to be more prohibitive than direct charges for care (218, 222). James *et al*. (2006) [(219)] reported such indirect costs to be as high as 20% of direct patient costs. Lost income is especially prohibitive for rural communities dependent on small scale farming activities as it affects time sensitive farming activities (223).

In Malawi where services in public and CHAM facilities (for EHP) are provided free of charge, the cost of transport and lost income during time spent at clinics has been shown to be prohibitive for rural farming populations (223, 224). Transport costs deter or delay seeking care especially in remote rural areas (219, 225). The cost of transport is especially prohibitive for rural farming communities during lean months as their income is seasonal (223).

I was interested in answering the following questions:

i. What are the costs of accessing HIV testing services in Malawi?
ii. What are the drivers of these access costs?
iii. Is there a gender difference in access costs?

I conducted the analysis using baseline household survey data from the Malawi STAR project community-based distribution of HIVST CRT, as described in chapter 3. Here, I present a published paper summarising these findings.

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Costs of Accessing HIV Testing Services among Rural Malawi Communities

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Cost of Accessing HIV Testing Services among Rural Malawi Communities

HIV testing is free in Malawi, but users may still incur costs that can deter or delay them accessing these services. We sought to identify and quantify these costs among HIV testing service clients in Malawi. We asked residents of communities participating in a cluster randomised trial investigating the impact of HIV self-testing about their past HIV testing experiences and the direct non-medical and indirect costs incurred to access HIV testing. We recruited 749 participants whose most recent HIV test was within the past 12 months. The mean total direct non-medical and indirect cost to access testing was US$2.45 (95%CI: US$2.11-US$2.70). Men incurred higher costs (US$3.81; 95%CI: US$2.91-US$4.50) than women (US$1.83; 95%CI: US$1.61-US$2.00). Results from a Tobit multivariable regression analysis suggest that men, participants aged between 25-64 years and those possessing complete secondary education incurred higher costs, whilst participants who accessed community-based HIV testing services or where testing took less time (i.e. more efficient) incurred lower costs. Providing HIV testing closer to people's homes and doing so efficiently will reduce the costs borne by users, and may particularly encourage those failing to test, such as men.

Introduction

Eastern and Southern Africa account for the highest numbers of people living with HIV (PLHIV), newly infected with HIV, and dying from HIV (UNAIDS, 2014b, 2016). HIV testing is an important preventive strategy and constitutes the entry point into the HIV care and treatment cascade (Ministry of Health, 2017). The global AIDS eradication initiative target that by 2020, 90% of all PLHIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy (ART) and 90% of all people receiving ART will have viral suppression (UNAIDS, 2014a). Ensuring that the 90% of PLHIV are aware of their status will support enrolment in HIV care and achievement of these global treatment goals (UNAIDS, 2014a).

However, despite impressive efforts in scaling-up availability of HIV testing and treatment services in the region, including freely available HIV testing at nearly all healthcare settings, testing uptake remains inadequate to reach the global goals (Church et al., 2017). Malawi has been leading the way in scaling-up HIV services (Lowrance et al., 2008; UNAIDS, 2014b) but an estimated 35% of men and 18% of women have never tested for HIV and 60% of young people aged 15-19 years have never tested (Ministry of Health, 2017). Uptake of HIV testing also remains low amongst poorer individuals and those with less formal education (Kim, Skordis-Worrall, Haghparast-Bidgoli, & Pulkki-Brännström, 2016).

Previous studies in Sub-Saharan Africa (SSA) have cited location, distance, waiting time, costs, confidentiality concerns, low perceived risk and infrequent contact with the health-care system as barriers to accessing HIV testing (Angotti et al., 2009; Morin et al., 2006; Musheke et al., 2013; Sharma, Ying, Tarr, & Barnabas, 2015). As far as costs are concerned, individuals incur substantial access costs when utilizing public sector HIV testing and treatment services even though they are provided free at point of use (Chimbindi et al., 2015; Lubega et al., 2013; Maheswaran et al., 2016; Pinto, Lettow, Rachlis, Chan, & Sodhi, 2013). However, evidence is lacking on the main costs associated with HIV testing especially in rural areas, and whether costs vary by different population groups or testing modalities, which limits efforts to minimize or offset testing costs to increase uptake.

In this study, we sought to examine the costs borne by users of HIV testing services in rural Malawi, whether certain population subgroups incur higher costs, and whether costs differ based on the mode of testing. To the best of our knowledge, this is the first study to identify and quantify specific costs of HIV testing in a rural setting. Other studies in the region have explored determinants of testing (Camlin et al., 2016; Helleringer, Kohler, Frimpong, & Mkandawire, 2009; Lépine, Terris-Prestholt, & Vickerman, 2014), costs of providing HIV services (Maheswaran et al., 2016; Mangenah, Mwenge, et al., 2017; Mwenge et al., 2017; Sharma et al., 2015), and costs of accessing tuberculosis (TB) treatment (Kemp, Mann, Simwaka, Salaniponi, & Squire, 2007) and antiretroviral therapy (ART) (Bergmann, Wanyenze, & Stockman, 2017; Chimbindi et al., 2015; Pinto et al., 2013; Rosen, Ketlhapile, Sanne, &

DeSilva, 2007). The few that have explored HIV testing access costs have either focused on urban settings (Maheswaran et al., 2016) or examined costs without considering lost income (Bergmann et al., 2017). The results of this study will inform the design of future HIV testing services and interventions aimed at overcoming financial barriers to testing.

Methods

Study setting and design

We undertook a baseline household survey as part of a cluster-randomised trial (CRT) investigating the impact of community-based distribution of HIV self-testing (HIVST) in rural Malawi (ClinicalTrials.gov Identifier**:** NCT02718274). The CRT was conducted in rural areas of Blantyre, Machinga, Mwanza and Neno in Southern Malawi. The CRT comprised a population of approximately 62,500 residents with 22 clusters defined by the service catchment area of a public primary health facility. The HIV prevalence in the four districts was approximately 11% (National Statistics Office & ICF Macro, 2017).

Ethical approvals were obtained from the College of Medicine Research Ethics Committee in Malawi and the Research Ethics Committee of the London School of Hygiene and Tropical Medicine. We obtained written informed consent from all participants before their interview.

The baseline household survey was undertaken between May 2016 and August 2016, before implementation of the HIVST intervention in 1 or 2 villages from each catchment area. A research assistant visited a selected household and administered an electronic individual questionnaire (brief or extended) to household members aged above 16. The extended questionnaire was administered to a random 25% of these participants and included questions on the costs of HIV testing as well as other questions on health care utilization and stigma. Details on the sample size calculation for the main trial can be found in the trial protocol available at http://hivstar.lshtm.ac.uk/.

Participants who reported accessing HIV-testing within the last 12 months were asked additional questions about their testing experience. These questions asked about: the location of testing, including whether facility- or community-based; if their most recent test was accessed separately from other health services or as part of antenatal care (ANC) or provider-initiated testing and counseling (PITC); total time taken to access HIV testing; and the direct non-medical and indirect costs they incurred. Respondents were also asked about ownership of eight household assets to classify households into wealth categories.

HIV testing in Malawi is freely provided. Individuals may voluntarily access HIV testing at a health facility; may be advised to test by a health professional (PITC); may be offered as part of routine ANC (accessed by both the pregnant women and their accompanying male partners) or TB care (also a form of PITC); or may have access to community-based HIV testing services (CBHTS) including through testing campaigns and outreach, home-based or door-to-door testing, workplace testing, mobile testing, and testing through educational institutions (Table 1).

Assessing costs of testing

We derived a list of potential costs based on the literature and previous work undertaken in Malawi (Kemp et al., 2007; Maheswaran et al., 2016; Pinto et al., 2013). We asked participants how much they had paid for the round trip to the testing facility, if they had paid any consultation fees related to testing, excluding any fees for other services they accessed at the same time (participants testing at private facilities may incur some service fees). Participants were also asked if they spent money on any food and drink items (food costs) while accessing testing and, if so, how much they spent. We also asked participants about any costs they might have incurred by paying a caretaker to watch their children for the time they sought testing (child care cost) and any other costs they might have incurred as they sought testing (other costs). We further asked participants to approximate the amount of money they would have earned during the entire time they took to access testing (lost income).

Statistical methods

All analysis was undertaken in STATA version 14.0 (Stata Corporation, Texas, USA). Costs were estimated in 2016 Malawi Kwacha (MWK) and converted to 2016 US dollars at an exchange rate of MWK 729.89/US$ (Reserve Bank of Malawi, 2017). We estimated household wealth using the principal component analysis (Batista et al.) method, with household assets as a proxy for wealth (Filmer & Pritchett, 2001), and we further classified wealth into five quintiles.

Cost data were categorised into direct non-medical costs and indirect costs. Direct non-medical costs included those directly incurred by participants (e.g. transport costs) and indirect costs refer to productivity losses as a result of accessing health services (e.g. loss of income). We include data for the entire sample who had complete cost data and present it using means with 95% confidence intervals. To assess the burden imposed on participants, we compared their total direct non-medical and indirect costs with the national poverty line of US$1.20/day. The poverty line was adopted from the Third Malawi Integrated Household Survey (IHS) of 2011, converted to US$ at the average 2011 exchange rate of MWK162.84/US$ (Government of Malawi, 2012; World Bank, 2018) and adjusted for inflation using the national gross domestic product (GDP) deflator for 2011 of 14% (World Bank, 2018).

To determine the significant predictors of costs, we estimated a multivariable Tobit regression model with a log-transformed dependent variable. Individual-level user cost data pose estimation challenges since individual-level medical expenditures or costs of treatment typically feature a spike at zero and are strongly skewed with a heavy right-hand tail (Jones, 2010). In such cases, ordinary least squares (OLS) estimator will generate biased results, which can be corrected for if using the Tobit model. In addition, to account for the clustering of the data by district, a fixed effect approach was used. We then applied a log-likelihood ratio test to identify the most parsimonious model between the restricted and unrestricted Tobit models and used the unrestricted model with fixed effects.

We explored socio-demographic and socio-economic variables and accessibility of testing centres as determinants of total costs.

$$Total\ Costs_i = f\begin{bmatrix} District, Gender, Wealth_{hh}, Age(Years), Education, Number\ of\ Children, \\ Time\ Taken\ (Hours), Reason\ for\ visiting\ testing\ centre \end{bmatrix}$$

To reduce the skewness in the cost data, we modelled the costs using a log transformation. We log transformed as $\ln(Totalcosts + 1)$ as suggested in literature (McCune, Grace, & Urban, 2002). Table 1 summarises the a priori expected signs of the determinants.

Results

Participants' characteristics

A total of 5,551 participants were recruited into the baseline survey and 1,388 responded to the extended questionnaire. A total of 749 (14%) participants reported having had at least one HIV test in the previous 12 months, making them eligible for this sub-study. Baseline characteristics of these 749 participants are presented in Table 2. In brief, 237 (32%) of the participants were men, 245 (33%) of the participants were aged 16-24 years and 131 (18%) had no formal schooling. Most of the participants, 621 (83%) reported facility-based testing as their most recent testing approach, 121 (16%) accessed community-based testing and 7 (1%) had other testing options. Among those who tested in a facility, more participants 566 (76%) accessed testing through PITC. In addition, men reported spending an average of 2.9 hours and women reported spending an average of 3.5 hours to access testing services.

Direct non-medical and indirect costs

Direct non-medical and indirect costs stratified by gender and cost-category are summarised in Table 3. A fifth of the participants incurred zero costs to testing. The median cost for all cost categories except lost income was US$0.00. Lost income had a median cost of US$1.37; US$2.06 for men and US$0.96 for women. The mean total direct non-medical and indirect cost per participant was US$2.45 [(95%CI: US$2.11-US$2.70) with lost income accounting for 83% of the total costs. Men incurred higher mean total direct non-medical and indirect costs to test than women: US$3.81 (95%CI: US$2.91-US$4.50) versus US$1.83 (95%CI: US$1.61-US$2.00).

Cost determinants

Table 4 summarises the Tobit regression results. After adjustment for district of residence, there is no difference in average costs incurred by participants in Blantyre, Machinga and Neno districts. Participants in Mwanza district, on average, incurred 31% higher costs than those in Blantyre district. On average, men incurred 31% higher costs than women.

Participants with some or complete secondary education incurred 27% and 62% higher costs, respectively, than those with no formal education. Having children increased the total costs by 3%, on average, for each additional child.

Wealth was also a significant determinant of the total costs incurred by participants. Participants in the middle and highest wealth quintiles, on average, incurred 17% and 15% higher costs, respectively, than those belonging to the lowest quintile. In terms of time taken to seek testing, each additional hour spent to access testing increased the total costs by an average of 4%. Participants who used community-based testing, on average, incurred 34% lower costs than those who used facility-based testing. Participants aged between 25-39 years and 40-64 years, incurred 30% and 34% higher costs respectively, than those aged between 16 and 24 years. There were no significant difference in total costs incurred by participants who visited a testing centre specifically for an HIV test and those who accessed testing as part of PITC.

Overall, all of the determinants, except belonging to the second lowest wealth quintile, had the expected signs. Although not significant, participants in the second lowest wealth quintile, on average, incurred 2% lower costs than those belonging to the lowest quintile.

Discussion

This study examined the costs borne by users when accessing HIV testing services in rural areas of Southern Malawi. Our findings indicate that the average cost of accessing HIV testing in rural Malawi is less than that reported in urban areas of the country (US$3.09 per test) (Maheswaran et al., 2016), yet rural testers' incur costs that is equivalent to twice the daily minimum income required for their basic needs (national poverty line at US$1.20 a day) (Government of Malawi, 2012). In a country where at least 51% of the population live below the poverty line (Government of Malawi, 2012), these costs are likely to be prohibitive for a large proportion of the population.

Our study has also demonstrated that there are significant average cost differences between men (US$3.81) and women (US$1.83). Historically, there has been low uptake of HIV testing and poor linkage into care amongst men compared to women, particularly in SSA (Camlin et al., 2016). We suspect that these high costs have contributed to this low uptake. Seeking testing imposes both a direct non-medical cost but also the lost opportunity cost of hours away from productive activities (Angotti et al., 2009; Ganesh, 2015; Musheke et al., 2013; Wolff et al., 2005). Our findings show that these opportunity costs comprise a significant proportion (83%) of the total testing costs in this population. For most, the prospect of learning their HIV status may not be a sufficient incentive to bear these costs (Angotti et al., 2009), unless they are already sick. This is further evidenced by the large proportion of men in our sample (70%) who accessed testing through PITC and very few (10%) voluntarily attended facilities for the sole purpose of learning their HIV status, suggesting that most men in rural Malawi access testing as an add-on to other health care services, rather than seek out testing independently.

Lost income accounted for a large proportion of the total costs incurred by participants, driven by long travel times and long waiting times at testing facilities. On average, participants spent three hours to access HIV testing services, with men spending less time (2.9 hours) than women (3.5 hours). Similar long wait times (3.4 hours) were observed among adults utilizing public sector HIV and TB services in South Africa (Chimbindi et al., 2015). These long waiting times contribute to the high opportunity costs of testing. Improving quality and staffing at HIV testing facilities, investing in rooms and possibly the efficiency (i.e. speed) of the HIV testing process could reduce waiting times at clinics and therefore reduce the time taken from employment and other activities.

Delivering HIV testing closer to people's homes or at times convenient to users may mitigate financial barriers to testing. We found that community-based testing is associated with a lower cost burden than facility-based testing, therefore decentralising testing services beyond static facilities may be necessary to increase uptake. The popularity, especially among men, of community-based HIV testing and HIVST models has been previously demonstrated (Angotti et al., 2009; Choko et al., 2015; Morin et al., 2006; Mwenge et al., 2017; Sebapathy, Van den Bergh, Fidler, Hayes, & Ford, 2012; Sharma et al., 2015; WHO, 2015). HIVST and other home-based testing can be advantageous in that they substantially reduce or completely eliminate costs borne by users when testing (Maheswaran et al., 2016; Sharma et al., 2015).

Financial and non-financial incentives also offer an alternative to reducing or offsetting testing costs and promoting uptake. Small non-monetary incentives are associated with significantly increased community testing and HIV case diagnosis (Sibanda et al., 2017). It is worth noting that although low financial incentives increase health care uptake (Choko et al., 2017; Mangenah, Sibanda, et al., 2017; Pettifor, MacPhail, Nguyen, & Rosenberg, 2012), different amounts of incentives have different levels of effectiveness. Incentives that cover transport and opportunity costs are generally associated with better testing and linkage to care than incentives equivalent to transport reimbursement only (Choko et al., 2017).

Study Limitations and Strengths

Our study used retrospective interviews to collect expenditure data for participants' most recent HIV test. This approach introduces potential for recall bias. We limited this recall bias by recruiting participants with an HIV test within a period of 12 months preceding the interview. In addition, there is potential for downward bias of the costs since individuals with high expected total costs were more likely not to have accessed testing. Our follow-up research will explore more advanced statistical models to reduce this downward bias.

Despite these limitations, our study adds valuable information to the literature on access to HIV testing. Unlike previous studies, our study included lost income as a cost to testing which enabled us to determine the full economic burden of testing on users in a rural setting.

Conclusion

Though HIV testing services are “free” in Malawi, users incur costs to access these services in rural parts of the country that are double the national poverty line. In these contexts, men incur higher costs to access HIV testing services than women, with lost income as the largest cost component. Increasing uptake of testing services, especially for men, will likely require bringing testing services closer to the communities, improving efficiency of facility-based testing and potentially introducing financial or non-financial incentives as a way to offset the total costs associated with this portion of the HIV cascade.

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Manuscript tables

Table 1: Descriptive Statistics

Variable	Regression Inclusion	Expected Direction
Gender	Indicator: - Men (reference group) - Women	Men are expected to incur higher costs than women to reflect their higher earning potential when compared to women
Age in Years	Continuous	Financial productivity is expected to increase with age hence raising the opportunity cost to testing
Education	Indicator: - No Formal Schooling (reference group) - Incomplete Primary education - Some Secondary Education - Complete Secondary Education - College or higher	Education as a proxy for earning potential, implying that the higher the level of education the higher the cost to testing
Number of Children	Continuous: Number of children the participant has	Number of children is positively associated with any child care costs a participant might have incurred while accessing testing
Test Location	Indicator: - Facility-Based Testing (reference group) - Community HTC - Other Place	Community-based HTC reduces logistic barriers hence lowers the opportunity cost to testing. Other place testing depends on where the person tested for example, if at home testing e.g. self-testing then lower costs than facility-based testing
Amount of Time Taken to Receive Testing	Continuous: Time taken (including travel) in hours to access HIV testing	The more time taken away from work to seek testing, the higher the cost to testing through lost income
Reason for visiting Testing Centre	Indicator: - Had other reasons for visiting a testing centre aside from HIV testing (reference group) - Visited a testing centre specifically for an HIV test	Visiting a testing centre for other reasons aside from HIV testing has potential of economies of scope hence reduced total costs
Wealth Index	Indicator: - Households are ranked into wealth quintiles with the poorest as the reference group	Wealth is a proxy for ability to pay; the higher the wealth quintile, the higher the participant's expenditure to access testing

Table 2: Participant Characteristics (n=749)[a]

	Men		Women	
	n	Percentage	n	Percentage
Gender	237	31.64%	512	68.36%
Age (Years)				
16-24	58	24.47%	187	36.52%
25-39	96	40.51%	205	76.56%
40-64	63	26.58%	102	19.92%
65+	20	8.44%	18	3.52%
Education				
No formal Schooling	19	8.02%	112	21.88%
Primary	160	67.51%	331	64.65%
Some Secondary	38	16.03%	57	11.13%
Complete Secondary	14	5.91%	12	2.34%
College or Higher	6	2.53%	0	0.00%
Wealth Index[bc]				
Highest Quintile	60	25.32%	89	17.38%
2nd Highest Quintile	45	18.99%	70	13.67%
Middle Quintile	28	11.81%	69	13.48%
2nd Lowest Quintile	40	16.88%	57	11.13%
Lowest Quintile	64	27.00%	227	44.34%
Test Location				
Hospital/Clinic/Health Centre	148	62.45%	295	57.62%
ANC Clinic	17	7.17%	106	20.70%
VCT Centre	24	10.13%	31	6.05%
Community/Mobile HTC	47	19.83%	74	14.45%
Other Testing Place	1	0.42%	6	1.17%
Number of Children				
≤5	190	80.17%	419	81.84%
5-10	43	18.14%	90	17.58%
>10	4	1.69%	3	0.59%
Reason for facility visit				
HIV Test	168	70.89%	283	55.27%
PITC	69	29.11%	229	44.73%
Time taken				
≤1 hour	73	30.80%	104	20.31%
1-3 hours	83	35.02%	181	35.35%
3-6 hours	66	27.85%	182	35.55%
>6 hours	15	6.33%	45	8.79%

[a]3 Participants had incomplete data

[b]Wealth index estimated through undertaking principal component analysis of responses to asset ownership and housing environment

[c]Assets selected in the baseline data did not do well in differentiating the poorest from one another

Table 3: **Direct non-medical and indirect costs by gender and cost category[a]**

	Men (US$)	Women (US$)	Total Sample (US$)

Cost Category		Mean (95% CI)	% of Men	Mean 95% CI	% of Women	Mean 95% CI	% of Total Sample
Direct non-medical costs	Transport	0.25 (0.15-0.36)	6.56%	0.16 (0.11-0.22)	8.74%	0.19 (0.14-0.24)	7.76%
	Consultation	0.03 (0.00-0.05)	0.79%	0.03 (0.01-0.04)	1.64%	0.03 (0.01-0.04)	1.23%
	Food	0.18 (0.14-0.22)	4.72%	0.13 (0.10-0.15)	7.11%	0.14 (0.12-0.17)	5.71%
	Other	0.05 (0.02-0.09)	1.31%	0.02 (0.01-0.04)	1.09%	0.03 (0.02-0.05)	1.23%
Indirect costs	Child Care	0.06 (0.02-0.11)	1.58%	0.01 (0.00-0.03)	0.55%	0.03 (0.01-0.05)	1.23%
	Lost Income[b]	3.24 (2.45-4.03)	85.04%	1.48 (1.31-1.65)	80.87%	2.03 (1.75-2.31)	82.86%
Total direct non-medical and indirect cost		**3.81 (2.91-4.50)**	**100%**	**1.83 (1.61-2.00)**	**100%**	**2.45 (2.11-2.70)**	**100%**

[a]All cost categories except lost income had median costs of US$0.00

[b]Lost Income had a median cost of US$1.37; US$2.06 for men and US$0.96 for women

Table 4: Multivariable analysis of log-transformed total direct non-medical and indirect Costs

Determinants (n=746)	Coefficient	95% Confidence Interval	P-Value
District			
Machinga	0.05	(-0.08-0.18)	0.365
Mwanza	0.31	(0.13-0.49)	0.001
Neno	-0.01	(-0.14-0.12)	0.946
Gender			
Female	-0.31	(-0.43-(-)0.20)	0.000
Wealth			
2nd lowest	-0.02	(-0.18-0.13)	0.697
Middle	0.17	(0.01-0.33)	0.040
2nd Highest	0.02	(-0.13-0.17)	0.668
Highest	0.15	(0.01-0.29)	0.070
Age (Years)			
25-39	0.30	(0.17-0.43)	0.000
40-64	0.34	(0.15-0.53)	0.000
65+	0.00	(-0.26-0.26)	0.994
Education			
Primary	-0.00	(-0.14-0.14)	0.978
Incomplete Secondary	0.27	(0.07-0.46)	0.013
Complete Secondary	0.62	(0.32-0.92)	0.000
College/Higher	0.18	(0.32-0.92)	0.946
Number of Children	0.03	(0.01-0.06)	0.986
Testing Location			
Community	-0.34	(-0.48-(-)0.20)	0.000
Other	-0.14	(-0.68-0.41)	0.688
Time Taken (Hours)	0.04	(0.01-0.06)	0.002
Reason for visiting testing centre			
HIV Test	0.08	(-0.03-0.18)	0.227
Constant	0.74	(0.47-1.01)	0.000

Table 5. 1: Inflation adjusted user costs (2021 US$)

Cost Category		Men		Women		Full sample	
		Mean (95% CI)	%	Mean (95% CI)	%	Mean (95% CI)	%
Direct Costs	Transport	$0.32 (0.19-0.47)	7	$0.21 (0.14-0.29)	9	$0.25 (0.18-0.31)	8
	Consultation	$0.04 (0.00-0.06)	1	$0.04 (0.01-0.05)	2	$0.04 (0.01-0.05)	1
	Food	$0.23 (0.18-0.29)	5	$0.17 (0.13-0.19)	7	$0.18 (0.16-0.22)	6
	Other	$0.06 (0.03-0.12)	1	$0.03 (0.01-0.05)	1	$0.04 (0.03-0.06)	1
Indirect costs	Child care	$0.08 (0.03-0.14)	2	$0.01 (0.00-0.04)	1	$0.04 (0.01-0.06)	1
	Lost income	$4.21 (3.18-5.23)	85	$0.92 (1.70-2.14)	81	$2.64 (2.27-3.00)	83
Total costs		**US$4.95 (US$3.61-6.31)**		**US$2.38 (US$2.00-2.77)**		**US$3.18 (US$2.66-3.71)**	

Table 5.1. presents the user cost adjusted for inflation. Inflation-adjusted costs of accessing HIV testing services were US$4.95 for men, US$2.38 for women, and US$3.18 for the full sample. Cost drivers and all other analyses were not affected by the inflation adjustment.

Finally, user costs were compared against the national poverty line to put the user costs in perspective. The value of a dollar is not the same in every setting. By presenting a user cost of US$3.18 on its own, a reader not familiar with the context may not understand the magnitude of this cost to an average person Malawian. By comparing user costs against the poverty line, magnitude of the dollar value is put in some perspective.

5.3. Sensitivity analysis

As presented earlier, costs of accessing healthcare services can be grouped into direct and indirect costs (227). Direct costs include medical expenditures for diagnosis and treatment and non-healthcare expenses such as transport costs. Estimating direct costs is straightforward as respondents report actual expenses. Indirect expenditures on the other hand, include productivity losses due to an illness or seeking healthcare services (228).

In this chapter I applied reported lost income to capture productivity losses. However, this approach is prone to undervaluing productivity losses for respondents not engaged in formal employment. Literature suggests using the either replacement value or the opportunity cost of unpaid work for those out of the labour market (228). The assumption is to use the economic value of unpaid work on the market by using the minimum wage. Another approach is to use GDP per capita as the economic value of unpaid work.

I conducted a sensitivity analysis of opportunity cost of unpaid work using minimum wage and GDP per capita. Table 5.2. presents the results of the sensitivity analysis.

Table 5. 2: Sensitivity analysis

Costs	As observed		Using minimum wage		Using GDP per capita	
	Men	**Women**	**Men**	**Women**	**Men**	**Women**
Transport	0.25	0.21	0.25	0.21	0.25	0.21
Consultation	0.04	0.04	0.04	0.04	0.04	0.04
Food	0.18	0.17	0.18	0.17	0.18	0.17
Other	0.04	0.03	0.04	0.03	0.04	0.03
Child care	0.04	0.01	0.04	0.01	0.04	0.01
Lost income	2.64	0.92	1.86	1.86	2.89	2.89
Total	**US$3.19**	**US$1.38**	**US$2.41**	**US2.32**	**US$3.44**	**US$3.35**

Using both minimum wage and GDP per capita, women's average estimated lost income was lower than the observed lost income. On the other hand, men's average reported lost income was higher than minimum wage but lower than GDP per capita. This shows that women were more likely to undervalue their lost income than men and thereby, underestimating their cost of seeking testing services. Overall, regardless of the method of measuring lost income applied, lost income was still the highest cost driver demonstrating high opportunity cost to testing. However, caution needs to be taken when interpretating our findings as there is a risk of downward bias of lost income for women.

5.4. Chapter conclusion

User costs represent an important barrier to seeking care, especially in low-and-middle income settings. Distance to facilities, opportunity cost of time, cost of transport, among other costs have been well documented as barriers to testing uptake (48). Community-and home-based distribution of HIVST, in addition to secondary distribution of HIVST brings testing closer to the end users and thereby reducing user costs.

Chapter 6: A descriptive analysis of unit costs of providing HIV testing services in Malawi and integrating HIV self-testing services in public primary care facilities in Southern Africa

This chapter presents a summary of three published papers evaluating costs of providing facility-based HIV testing and HIVST services. As indicated earlier, this thesis research was conducted as part of a wider project evaluating the distribution of HIVST in Southern Africa. I led on all components of the work presented in this chapter. However, some of the work was incorporated in wider STAR Economics Network papers for ease of publication. I have included the paper I led on as was published in this chapter Sande *et al*. (2021) [(229)]and summarised the work I led on in design, data collection and analysis despite not being the first author on those papers. I have also included these papers in appendix 10.1 [Mwenge *et al.* (2017) and Mangenah *et al*. (2019) [(92, 230)).

6.1. Introduction

As countries move towards ending the AIDS epidemic by 2030, there have been efforts to bring innovative testing approaches to the populations left behind. In 2016, WHO recommended HIVST as a complementary approach to reach populations left behind by conventional HIV testing approaches such as facility-based provider HIV testing (50). This chapter is a summary of costing work conducted to inform the implementation of HIVST and to contextualise HIVST by comparing its cost with conventional testing approaches for HIV.

I present a descriptive analysis of costs of providing facility-based provider testing as the conventional approach for HIV testing and community-based distribution of HIVST in Malawi as well as costs of integrating HIVST in public primary care facilities in Malawi, South Africa, Zambia, and Zimbabwe. I had two specific objectives:

i. To determine costs of providing HIV testing services
ii. To determine drivers of these costs

6.2. Methods

In this section, I present a general overview of the methods applied in costing each of the three HIV testing approaches. Additional methodology and implementation details has been presented under each distribution approach.

6.2.1. Cost analysis

Costs were estimated from a provider's perspective. Full costs were estimated using an ingredients-based approach that combined top-down and bottom-up costing approaches. Ingredients-based costing approach involves costing all inputs in a production process (231). The benefit of an ingredients-based approach is that it allows for policymakers and other researchers to validate assumptions, consider if the cost estimates apply to their setting and decide if they can replicate the analysis for their settings (231).

Top-down costing is more aggregate and involves dividing all expenditures involved in providing a service by the number of units produced to determine average costs (182, 184). Bottom-up costing on the other hand, involves observing and measuring inputs from the activity level (182). Bottom-up costing approach is more advantageous as it allows for the identification of inputs that would have been missed from top-down costing such as volunteer time and donated items (182). However, the approach has been argued to potentially under-report inefficiency (232). The limitations of both approaches has necessitated the proposal to combine top-down and bottom-up costing approaches in cost analyses (182, 184). The top-down costing involved expenditure analysis of the implementers' expenditure records to obtain both direct and indirect costs of distributing HIVST.

Table 6.1 presents a combination of bottom-up and top-down costing approaches as applied in this thesis. Costing of facility-based provider testing was through bottom-up costing. This involved collecting and observing resource use at the service provision level. Community-based provision of HIVST was costed using a top-down costing and all costs were obtained from the implementer's expenditure records with a combination of time and motions studies, interviews, and observation used to determine allocation factors.

Finally, costing of the integration of HIVST in public primary care facilities was through a combination of top-down and bottom-up costing approaches. For HIV testing modalities using bottom-up costing, I observed resource use and conducted a series of interviews with providers and facility managers to determine usage. I then applied the economic cost approach described in more detail in the next section to obtain costs.

Table 6. 1: Data sources for costing each HIV testing approach

Cost ingredient		**Facility-based provider testing**	**HIV self-testing integrated in public primary care facilities**
Capital Costs	Training	Interviews with providers	Interviews with providers and implementers' expenditure records
	Sensitisation	N/A	Implementers' expenditure records
	Other start-up	N/A	Implementers' expenditure records
	Building and storage	Observed space used for HIV testing services	Observed space used for HIVST services
	Equipment	Observed equipment used for HIV testing services	Observed equipment used for HIVST services
	Vehicle capital cost	Interviews with providers and facility managers on vehicle use	Implementers' expenditure records
Recurrent Costs	Personnel and per diems	Interviews with providers and time and motion studies	Interviews with providers and time and motion studies
	Supplies	Direct observation, interviews with providers and extraction from pharmacy records	Direct observation and interviews with providers

Test kits	Direct observation and extraction from pharmacy records	Direct observation and implementers' expenditure records
Vehicle operation	Interviews with providers on frequency of delivery of supplies and any other vehicle needs	Implementers' expenditure records and vehicle logbooks
Building operation and maintenance	Interviews with facility managers. extraction from the District Health Office, annualised replacement value where utility bills were not available	Interviews with facility managers, extraction from District Health Office
Recurrent training	N/A	Implementers' expenditure records
Other recurrent costs	Interviews with providers, facility managers and direct observation	Implementers' expenditure records, interviews with providers, facility managers and direct observation
Waste management	Interviews with providers and annualised replacement value of incinerators	Interviews with providers and annualised replacement value of incinerators

The bottom-up and top-down costs were then combined to obtain full costs. The costs were then split based on activities/ingredients but broadly categorised into capital and recurrent.

Capital costs are costs of inputs that have a useful life of more than a year (182, 184, 231). Capital costs include costs of setting-up a project (start-up costs), costs of equipment, renting space and building and storage space among other costs with a longer lifespan (182, 184). Most capital costs are one-time expenses for such items (184). Recurrent costs on the other hand, are costs of inputs whose useful life is less than a year (184). Costs of consumables in the service production process can be considered as recurrent costs.

Since capital costs have a lifespan of more than a year, their value needs to be spread over their useful life to reflect a realistic expectation of the annual value accruing to the intervention or project (184). This is known an annualising or amortisation (183, 184).

There are two main approaches of obtaining the annual value of capital costs: financial costing and economic costing. The difference between financial and economic costs is the way capital costs are annualised. Capital costs have two main components: depreciation and opportunity costs. Depreciation is the fall in value of an item over time due to wear and tear (182). Opportunity cost is the lost opportunity of spending on something else the money that was used to purchase the capital item. Financial costs only account for depreciation in capital items while economic costs account for both depreciation and opportunity cost (183).

Financial costing approach uses straight-line depreciation of capital items which is given as:

$$Financial\ cost = \frac{cost\ of\ a\ capital\ item}{useful\ life}$$ **Equation 6.1**

(183)

This approach assumes that capital items depreciate by the same value every year.

Economic costing approach combines the annual depreciation value with the opportunity cost of the next best alternative opportunity forgone. This opportunity cost is captured using a discount rate. This is estimated as:

$$Economic\ cost = \frac{current\ value\ of\ a\ capital\ item}{annualisation\ factor}$$ **Equation 6.2**

(183)

Where, current value is the replacement value of the capital item. Annualisation factor is determined by combining the useful life of the capital item and discount rate. Here, I used the PMT formula in Ms Excel to determine the economic costs.

The discount rate to be used for annualising capital items should be one recommended in the jurisdiction or to use 3-5% per annum as is frequently used in literature (185). Vassall *et al*. (2017) and WHO (2003) [(182, 231)] also recommended a discount rate of 3% to allow for international comparison. I used a discount rate of 3% in this costing analysis in line with these recommendations.

Useful life of capital items ranged from 3-35 years. Useful life of capital items was obtained in consultation with the implementers. Capital items to be used up within project life such as, project specific training were assumed to have a useful life of 3 years in line with project life. Other equipment where implementers were not able to provide a useful life was assumed to have useful life of 5 years (183). Buildings were assumed to have a lifespan of 35 years.

Cost ingredients

Aside from splitting costs into capital and recurrent, I further split the costs into cost ingredients. Table 6.2. provides a summary of the cost ingredients and their allocation factors. The use of allocation factors was necessary to obtain costs for shared resources such as space, equipment, and personnel.

In addition, the implementers distributed HIVST using a variety of distribution modalities such community-based and workplace. Allocation factors were used to allocate costs across the various HIVST distribution approaches. Finally, some of the implementers were also engaged in research and components of implementation such as monitoring and evaluation. Where resources were shared between the two aspects such as staff time, allocation factors were used to separate research from implementation costs. The decision of allocation factors is often arbitrary although there are various guidelines to help with the process (182-184, 231).

Table 6. 2: Cost ingredients and allocation factors

Cost ingredient*		Facility-based provider testing	Community-based HIV self-testing	HIV self-testing integrated in public primary care facilities
Capital Costs	Training	N/A	% of distributors	% of distributors & direct expenditure
	Sensitisation	N/A	% of communities within the site	Direct expenditure
	Other start-up	Direct observation & facility throughput	N/A	Direct expenditure
	Building and storage	Direct observation & facility throughput for shared space	Direct expenditure	Direct expenditure & space proportion
	Equipment	Direct observation	Direct expenditure	Direct expenditure
	Vehicle capital cost	N/A	Vehicle mileage & distance	Vehicle mileage
Recurrent Costs	Personnel and per diems	Direct observation & % of facility staff for management staff	Direct expenditure, % of distributors & staff interviews for management staff	Direct expenditure & staff proportion
	Supplies	Direct observation & facility throughput	Direct expenditure & % of kits distributed where shared across HIVST modalities	Proportion of kits distributed
	Test kits	Tests conducted	Kits distributed	Kits distributed
	Vehicle operation	Distance	Vehicle mileage & distance	Vehicle mileage and direct expenditure
	Building operation and maintenance	Direct observation and facility throughput for shared space	Direct expenditure	Direct expenditure & space %
	Recurrent training	N/A	% of distributors	Staff proportion
	Other recurrent costs	Facility throughput	% of kits distributed	Direct expenditure
	Waste management	Facility throughput	N/A	N/A

*Mwenge, Sande (230), Mangenah, Mwenge (233), Sande, Matsimela (234)

Adjusting for inflation

The costing studies were conducted and reported over multiple years from 2018 to 2021. The costs were then adjusted for inflation to allow for head-to-head comparison in 2021 US$ (183). Present value of the costs was obtained using equation 6.3:

$$Present\ value = Observed\ value * (1 + \mathrm{P})^{n}$$ **Equation 6.3**

Where:

Present value is the present value of the cost after factoring in inflation

Observed value is the cost as reported in the costing year

P is the average inflation from the costing year to 2021

n is the number of years between the costing year and 2021

(183).

Inflation was estimated using consumer price index with inflation data obtained from the respective Central Bank websites.

Returns to scale

One other important consideration with HIV testing services is the existence of economies of scale. Economies of scale is when average costs fall as production scale increases (235). Observing economies of scale is particularly important to inform scale-up of HIVST by understanding any potential existing technical efficiency to capitalise on. Technical efficiency is the combination of inputs in a way that maximises output (235).

Global health services and interventions are expected to exhibit economies of scale initially before exhibiting diseconomies of scale (182). Understanding and reporting heterogeneity across implementation sites is important to informing cost extrapolation and implementation scale (182). Simply reporting the mean cost of all distribution sites can conceal between site variation in costs (236). I, therefore, explored potential economies of scale by observing unit costs as scale (number of clients testing or kits distributed) increased.

Sensitivity analysis

Finally, I conducted a one-way sensitivity analysis to assess any potential bias and the sensitivity of costs to the various assumptions employed in the analysis. A sensitivity analysis is a process where assumptions employed in an analysis are varied with the aim of observing the impact of these assumptions to the outcomes (185). This process is important to assessing potential bias in the analysis and to identifying areas of uncertainty (184).

There are five main types of sensitivity analyses: one-way/univariate sensitivity analysis, threshold analysis, scenario analysis, multiway analysis and probabilistic sensitivity analysis (185).

A one-way sensitivity analysis looks at the effects of the assumptions on outcomes by varying one parameter at a time. This is different from multiway analysis where multiple parameters are varied at the same time. Threshold analysis on the other hand, varies values of parameters key to the decision (185). For instance, a critical parameter would be the threshold for an incremental cost-effectiveness ratio (237) for an intervention to be acceptable (185). Threshold analysis would involve varying parameters to assess which combinations could cause the cost-effectiveness of the intervention to be above the threshold (185).

Another type of sensitivity analysis is scenario analysis. Under scenario analysis, scenarios are constructed to assess how the outcome behave with each change in scenarios (185). Scenarios also include a base case which is usually the observed case, best and worst cases. This gives an idea of outcomes in the best and worst phases. The final type of sensitivity analysis is probabilistic sensitivity analysis. Under probabilistic sensitivity analysis, distributions of outcomes are drawn from a range of key parameters. This allows for a distribution of an outcome instead of simply point estimates.

The decision of which type of sensitivity analysis to use is dependent on the number of parameters to be varied and degree of uncertainty in the analysis (183). One-way or multiway analyses can be used if there are few parameters containing uncertainty (183).

For this analysis, I chose one-way sensitivity analysis because it is one of the most common forms of sensitivity analyses applied in literature (185) and because most of the parameters were observed with a high degree of certainty. Table 6.3. provides a list of parameters that were varied in the sensitivity analysis. The decision of which parameter to vary was dependent of the list of parameters frequently varied in literature and parameters that were likely to be cost drivers and therefore, a source of concern to budget, policy and implementation.

Table 6. 3: One-way sensitivity analysis variations

Variable[§*]	Variation in sensitivity analysis	Justification
Discount rate	0%	Assuming no opportunity cost
	3% (base)	As frequently used in literature
	12%	Malawi policy rate
Project life years	1 year	If implementation ended earlier than planned
	2 years (base)	Project implementation period
	3 years	Best case if no-cost extension
Useful life of capital items[*]	Half the life years	Assuming misuse of capital items
	Observed	
	Double the life years	Assuming efficient use of capital items
Test kit/letter price	Half the price	Assuming competition and economies of scale at the production level

	Observed price (base)	Government provided price' letter price and kit price during implementation phase
	Double price	Assuming a rise in production and shipping costs
Output: test kits used	Half the number of kits distributed	Assuming a fall in demand for testing
	Observed number of kits distributed (base)	
	Double the number of kits distributed	Assuming increased demand for testing
Personnel costs	Half the unit cost of personnel	Assuming improved efficiency from learning by doing
	Observed (base)	
	Double the unit cost of personnel	Assuming increased costs of personnel
Training	Half cost of training	If implementation was not in a trial setting, training costs may drop
	Observed (base)	
	Double cost of training	Increased scale would be associated with increased training costs
Best case	0% discount rate, 3 years lifespan, half useful life of capital items, half the test kit price and double the number of kits distributed or annual number of tests done in the facility HIV testing model	
Worst case	15% discount rate, 1 year lifespan, double useful life of capital items, double the test kit price and half the number of kits distributed or annual number of tests done in the facility HIV testing model	

*Applicable to facility-based provider testing only as the testing model did not have project life years as useful life of capital items

§used for the facility-based provider testing and the community-based distribution of HIVST and published in Mwenge, Sande (230), Mangenah, Mwenge (233)

6.3. Results

This section presents results of the cost analysis of the three HIV testing approaches. I start by presenting cost results of facility-based provider HIV testing and community-based HIVST in Malawi. Then, I present costs of integrating HIVST in public primary care facilities in four Southern Africa countries.

6.3.1. Costs of facility-based provider HIV testing

This is a detailed presentation of costs of providing HIV testing services in Malawi with the summarised version presented in Mwenge *et al*. (2017) [(230)].

Fifteen out of the 22 public primary healthcare facilities included in the community-based distribution of HIVST CRT were costed using bottom-up costing approach. Top-down costing was not possible for facility-based provider HIV testing as these were all public primary care facilities with bulk of the expenditure happening at the Ministry of Health level and district health office (DHO). Obtaining detailed expenditure data from the Ministry of Health and the DHO was not possible which necessitated bottom-up costing.

I ended up costing 15 of the 22 facilities instead of all 22 facilities due to human resource and project timeline restrictions. There was no random sampling of the 22 facilities to obtain the

15 healthcare facilities included in this cost analysis. Instead, I applied convenience sampling of facilities closest to the district hub. The number of facilities costed in each district was based on the field days allocated in the budget. In the project plan, each district was allocated the number of field days based on the number of facilities in the district with an assumption of 2 days of data collection per facility. However, depending on weather conditions, size, and ease of obtaining data at specific facilities, there were uneven data collection days spent at a facility. This in turn, affected the number of facilities I was able to collect cost data from in each district. There is a possibility that this lack of random sampling of facilities may have introduced a bias in the costs. The final sample was composed of 4 facilities (n=4/8) from Blantyre district, 5 facilities (n=5/7) from Machinga district, 2 facilities (n=2/3) from Mwanza district, and 3 facilities (n=3/4) from Neno district.

Aggregate and unit costs of facility-based provider testing

Table 6.4 provides costs of providing HIV testing services by each testing modality. All costs are reported in 2021 US$. Annual costs of providing HIV testing services ranged from US$6,315 to US$29,458. Number of HIV tests conducted in a period of one year in the facilities ranged from 920 to 8,225 with an average positivity rate of 8% (min-max: 3%-15%). The mean cost per HIV test was US$5.77 (min-max: US$3.46 – US$9.76) with 3,481 as the mean annual tests conducted. The mean cost of identifying an HIV positive patient was US$93.15 (min-max: US$31.01 – 252.61) and the mean number of HIV positive patients identified was 305.

Figure 6.1 presents the key cost drivers. On average, the cost of personnel, test kits and supplies such as stationery were the key cost drivers accounting for 92% of total costs. The cost of personnel alone accounted for 59% of total costs. The cost of managing both clinical and non-clinical wastes from testing was the least cost driver across all testing sites.

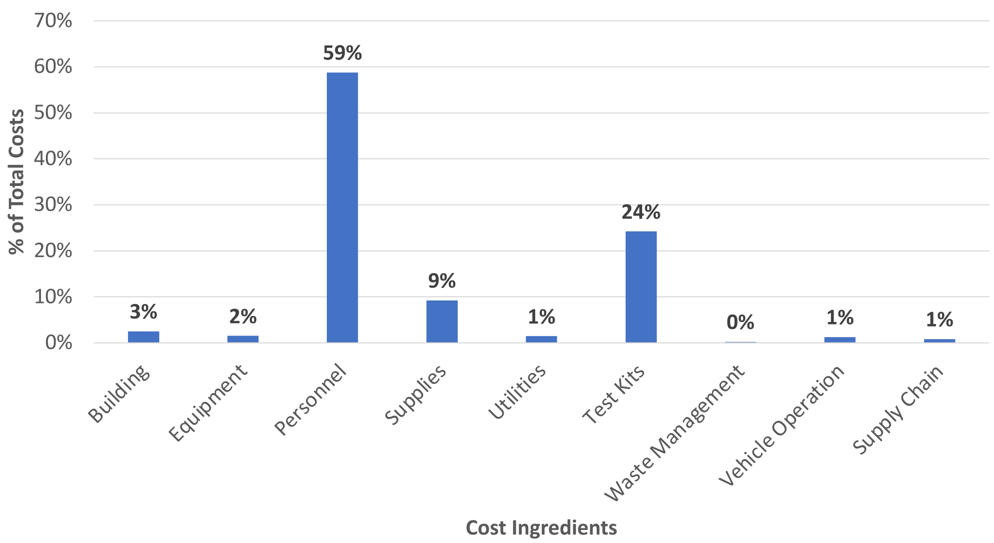

Figure 6. 1: Average cost drivers

Table 6. 4: Costs of providing facility-based provider HIV testing

Cost Ingredient	Aggregate costs (US$)														
	Facility Identification Number														
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Building	294	790	63	746	78	205	271	240	158	255	911	776	769	220	330
Equipment	351	156	127	104	139	284	67	189	101	197	139	286	332	255	259
Personnel	6,698	16,213	8,997	12,300	11,200	9,264	5,877	11,669	10,681	7,407	14,537	8,605	10,160	3,392	10,302
Supplies	945	1,772	1,660	1,733	1,832	1,541	1,068	1,913	1,681	1,286	1,357	1,329	1,374	918	1,238
Utilities	243	464	22	292	42	61	242	389	106	185	184	384	234	133	44
Test Kits	1,537	4,248	5,928	6,073	4,136	5,075	1,367	6,752	5,431	6,684	11,834	5,285	4,263	1,219	3,393
Waste Management	13	37	2	22	2	5	26	23	29	65	65	39	31	27	160
Vehicle Operation	16	77	125	177	36	81	37	109	1,448	425	308	742	76	68	164
Supply Chain	85	159	149	156	165	139	96	172	151	116	122	120	124	83	111
Total Costs	**10,181**	**23,917**	**17,073**	**21,604**	**17,630**	**16,655**	**9,051**	**21,457**	**19,787**	**16,620**	**29,458**	**17,565**	**17,361**	**6,315**	**16,000**
Total tests	1,084	3,064	4,466	4,214	3,086	3,683	927	4,633	3,839	4,797	8,225	3,568	3,167	920	2,538
HIV+ identified	108	230	130	495	121	252	133	602	390	385	950	530	138	25	93
Cost per test	**9.39**	**7.81**	**3.82**	**5.13**	**5.71**	**4.52**	**9.76**	**4.63**	**5.15**	**3.46**	**3.58**	**4.92**	**5.48**	**6.86**	**6.30**
Cost per HIV+ identified	94.27	103.99	131.33	43.64	145.70	66.09	68.05	35.64	50.74	43.17	31.01	33.14	125.80	252.61	172.05

Returns to Scale

Figure 6.2. presents results of the distribution of unit costs with increased testing for all 15 sites included in the cost analysis (returns to scale).

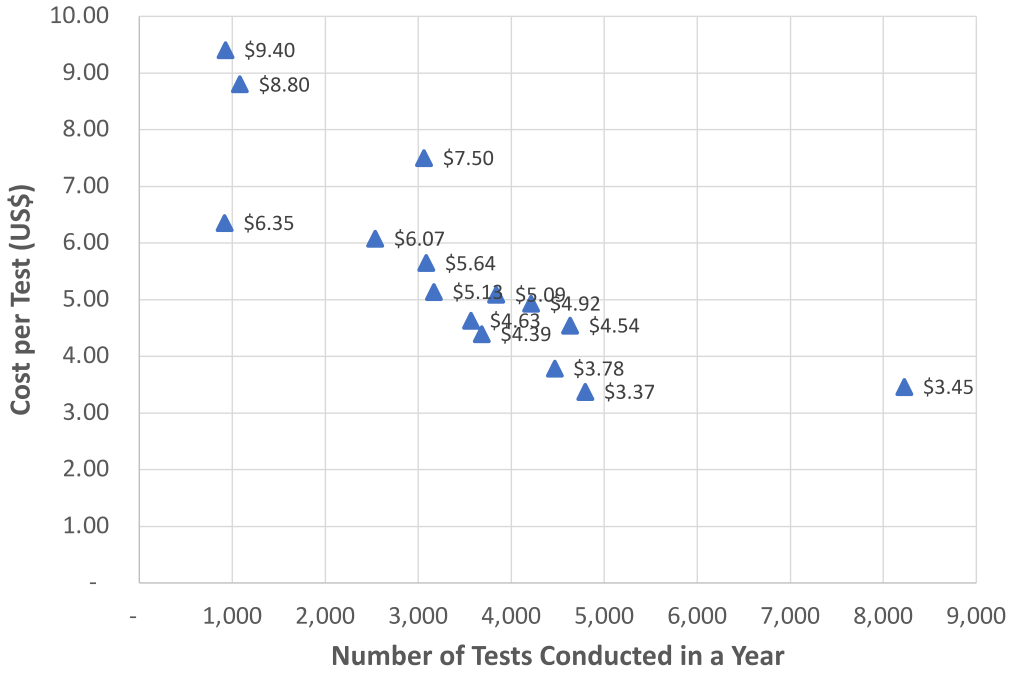

Figure 6. 2: Returns to scale for facility-based provider testing

Unit costs fell with increasing number of HIV tests conducted. The facility with the lowest number of annual tests did not necessarily have the highest unit cost and vice versa. However, on average, there was a negative association between number of annual tests conducted and unit costs, demonstrating increasing returns to scale. As presented in Figure 6.2, facilities with less than 2000 annual tests (this was below the mean annual test kits) were likely to have unit costs above US$6.00 which was higher than the average cost. As annual tests increased unit costs were getting below the mean cost.

There is a potential downward bias in average costs due to the non-random sampling of healthcare facilities included in the analysis. When I compared all 22 facilities (full sample) against the convenience sample in our analysis, the convenience sample on average included larger facilities than if we had included the full sample. The average annual number of HIV testing clients was 2,986 in the full sample against 3,404 in the convenience sample. The difference was 418 (95% CI: (-)1,643 - 806). Our convenience sample also included facilities with on average, a higher HIV positivity rate (8%) than facilities in the full sample (7%). The difference in the average HIV positivity rate was 1.2% (95% CI: (-)1.19% – 1.19%). This inclusion of larger facilities and facilities with higher HIV positivity rate may have led to a downward bias in the average costs in our convenience sample.

Sensitivity analysis

Finally, I conducted a one-way sensitivity analysis to evaluate how unit costs varied with the assumptions employed in our analysis and with a changing implementing environment. A tornado diagram presenting the cost variations is presented in Figure 6.3.

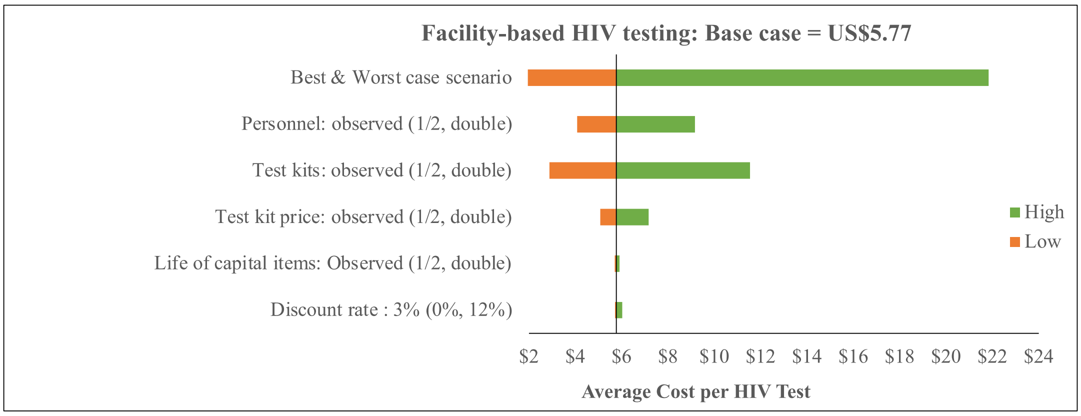

Figure 6. 3: Tornado diagram displaying results of a one-way sensitivity analysis of facility-based provider testing

I observed change in the average unit cost with changing discount rates, lifespan of capital items, test kit price, personnel costs and a combination of all these assumptions and variables in a best- and worst-case scenarios. Unit costs were least sensitive to assumptions on the discount rate and useful life of capital items. Unit costs were, however, more sensitive to changes in the price of test kits and personnel. Overall, the unit costs were most sensitive to a combination of all negative changes such as a rise in test kit prices and a rise in personnel costs, than to positive changes.

6.3.2. Cost of community-based distribution of HIV self-testing

Similar to facility-based provider testing, cost and output data collection of the community-based distribution of HIVST was also up to 12 months of HIVST distribution. Expenditure records from start-up to one year of distribution were obtained from the implementer, PSI. The expenditure records were then used in a step-by-step process to obtain costs of distributing HIVST. Bottom-up costing was employed to obtain allocation factors where expenditures were shared across multiple projects by the same implementer. In addition, PSI distributed HIVST using other distribution modalities other than community-based distribution. The allocation factors were also used to separate costs of community-based HIVST costs from other modalities of HIVST. Costs were aggregated for all 11 communities as expenditure was from and at the central level with no offices in the 11 communities. Tracking costs to the site-level would have involved assumptions that would have affected validity of the costs and introduced bias.

Aggregate and unit costs of community-based distribution of HIV self-testing

Table 6.5. provides aggregate and unit costs for providing community-based HIVST under the PSI implementation in Malawi.

Table 6. 5: Costs of providing community-based HIV self-testing

Cost ingredient			Aggegate Cost (US$)	Unit Cost (US$)
Capital Costs	Start-Up Phase	Training	13,150	0.09
		Sensitisation	67,983	0.45
		Other start-up	126,014	0.83
	Implementation Phase	Building and storage	19,476	0.13
		Equipment	32,578	0.21
		Vehicle	3,676	0.02
Recurrent Costs		Personnel	369,788	2.42
		Supplies	41,395	0.27
		Test kits	486,555	3.19
		Vehicle operation	126,979	0.83
		Building operation	2,563	0.02
		Recurrent training	15,587	0.10
		Other recurrent costs	140,192	0.92
Total			**1,445,934.79**	**9.47**
Total number of communities			11	
Total tests or kits distributed			152,671	

A total of 152,671 HIVST kits were distributed across 11 communities. The total cost of distributing these kits was US$1,445,935 with a cost per kit distributed of US$9.47. The cost of test kits, personnel and other administration costs were key cost drivers accounting for 69% of total costs. Figure 6.4 presents cost drivers of the community-based distribution of HIVST.

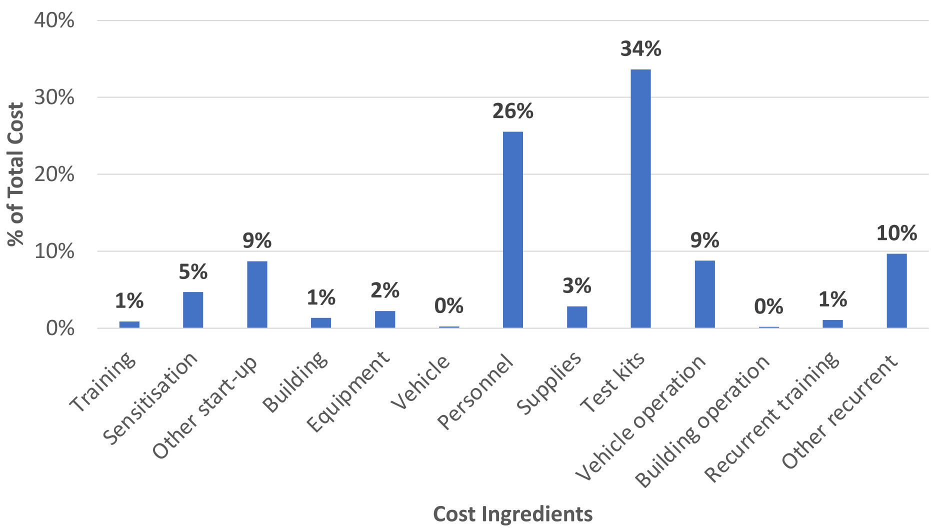

Figure 6. 4: Cost drivers of community-based distribution of HIV self-testing

Sensitivity analysis

A one-way sensitivity analysis of the unit cost of community-based distribution of HIVST showed that the unit costs were more sensitive to number of kits used, the discount rate used and test kit prices. For instance, the unit costs were more sensitive to a halving in the number of kits from 152,671 to 76,336 than a double of the kits distributed from 152,671 to 305,342. When I combined all variable included in the sensitivity analysis, the unit cost was more sensitive to negative changes than positive changes. Thus, a rise in kit price, a fall in number of kits distributed among other variables would have a higher effect on the unit costs than a fall in kit price and an increased number of kits distributed among other variables included in best- and worst-case scenarios. This is presented in Figure 6.5.

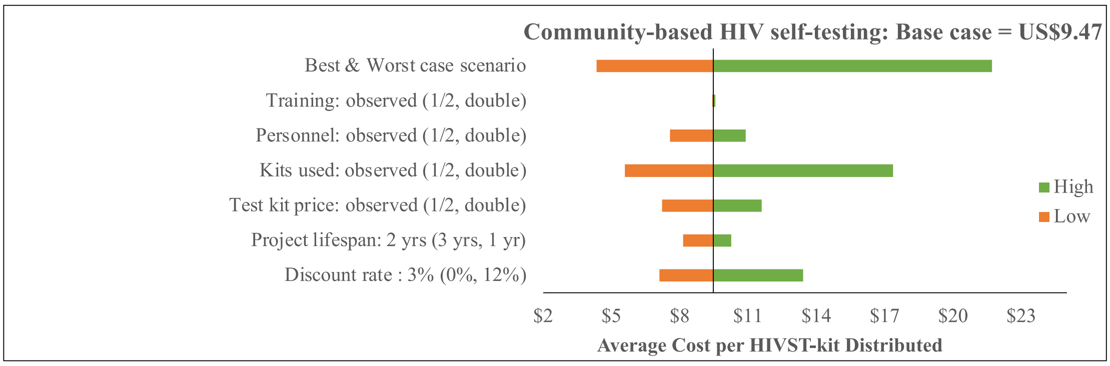

Figure 6. 5: Tornado diagram displaying results of a one-way sensitivity analysis of community-based HIV self-test kits distributed

6.3.3. Costs of integrating HIVST in a trial setting in Malawi

As noted in Chapter 3, the integration of HIVST in Malawi was as part a CRT. The CRT had three trial arms: SoC, HIVST_only and HIVST plus US$10 incentive. SoC involved distributing referral letters to ANC and index clients inviting their sexual contacts to the facilities for testing. HIVST and HIVST plus financial incentive trial arms involved providing an HIVST kit to the ANC and index clients for their sexual contacts' use. Sexual contacts screening positive in the HIVST_only arm were encouraged to present at the clinic for confirmatory testing. All sexual contacts regardless of their HIVST were encouraged to present to the clinic for additional study activities in the HIVST plus financial incentive arm. In this trial arm, sexual contacts presenting to the clinic were given US$10 as a transport reimbursement and reimbursement for their time.

Costing of all three trial arms was incremental to facility-based testing. Table 6.6. provides aggregate and average costs of distributing the letters and HIVST kits in the three trial arms.

Table 6. 6: Costs of integrating HIV self-testing in public primary care facilities

Cost ingredient		Trial arm		
		Standard of Care	**HIV self-testing only**	**HIV self-testing+financial incentive**
Capital Costs	Training	$1,633	$5,072	$6,521
	Sensitisation	$560	$605	$605
	Building and storage	$48	$257	$239
	Equipment	$28	$151	$140
Recurrent Costs	Personnel	$1,919	$3,104	$5,077
	Supplies	$274	$278	$299
	Test kits/letters	$195	$3,705	$3,991
	Vehicle operation	$1,064	$826	$702
	Building operations	$327	$1,705	$1,581
	Other recurrent costs	$54	$55	$59
Total Costs		**$6,102.19**	**$15,756.46**	**$19,213.89**
Total number of facilities		9	9	9
Letters/Kits distributed		1600	1603	1903
Sexual contacts reached (%)		707 (44%)	1261 (79%)	1285 (68%)
HIV positives contacts identified		11	13	54
Cost per letter/kit distributed		**$3.81**	**$9.83**	**$10.10**
Cost per sexual contact reached		**$8.63**	**$12.50**	**$14.95**

The average cost of distributing a letter was US$3.81, while that of distributing an HIVST kit was US$9.83 in the HIVST_only arm and US$10.10 in the HIVST+financial incentive arm. The US$10 incentive was excluded from this analysis as the incentive was only given to the sexual contacts upon presenting to the facilities for follow-on services. Providing HIVST kits allowed for more sexual contacts to be reached than simply providing a referral letter. Forty four percent of sexual contacts were reached using the referral letters against 79% of sexual contacts reached in the HIVST_only arm and 68% reached in the HIVST+financial incentive arm. It was, however, more expensive to reach a sexual contact in the HIVST arms than in SoC. The cost of reaching a sexual contact as US$8.63 in SoC, and US$12.50 and US$14.95 in the HIVST_only and HIVST+financial incentive arms, respectively. The absolute number of HIV positive identified was higher in the HIVST+financial incentive arm (n=54) when compared to SoC (n=11) and HIVST_only trial arms (n=13). The cost of confirming HIV positive sexual contacts was beyond the scope of this work. A detailed discussion of the trial is presented in Choko *et al*. (2021) [(81)].

Across all three trial arms, cost of training and personnel were key cost drivers. In the HIVST arms, cost of the HIVST kits was also an important cost driver. Figure 6.7 presents the cost drivers by trial arm.

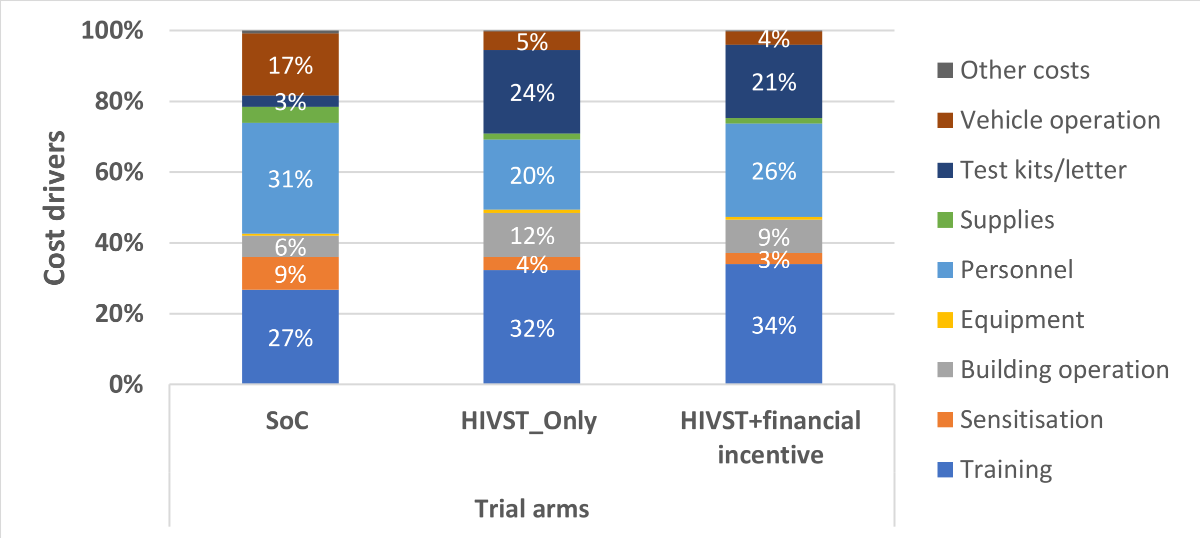

Figure 6. 6: Cost drivers by trial arm

Sensitivity analysis

A one-way sensitivity analysis of the unit cost of the trial arms showed that unit costs were more sensitive to the number of letters and kits distributed, Figure 6.7. This shows the importance of scale in secondary distribution of HIVST. In SoC, the costs were least sensitive to the price of the letters. Across all three arms, the unit costs were least sensitive to an increase in the discount rate. This was not a surprising find as this was an incremental costing implying that there were relatively fewer capital costs included.

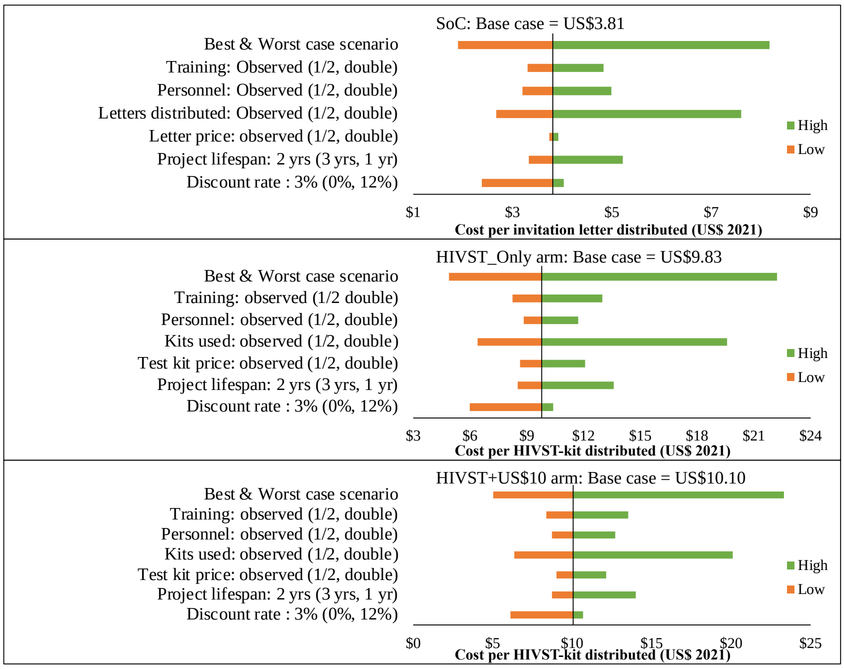

Figure 6. 7: Tornado diagrams displaying one way sensitivity analyses by trial arm

6.3.4. Cost of integrating HIV self-testing in facility-based settings

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First Name(s)	Linda Alinafe		
Surname/Family Name	Sande		
Thesis Title	Impact of HIV self-testing on costs, access and socioeconomic equity in HIV testing in Malawi		
Primary Supervisor	Prof. Fern Terris-Prestholt		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

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When was the work published?	2021		
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Have you retained the copyright for the work?*	No	Was the work subject to academic peer review?	Yes

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Costs of Integrating HIV Self-Testing in Public Health Facilities in Malawi, South Africa, Zambia and Zimbabwe

Authors

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Abstract

Introduction

As countries approach the UNAIDS 95-95-95 targets, there is a need for innovative and cost-saving HIV testing approaches that can increase testing coverage in hard-to-reach populations. The HIV Self-Testing Africa (STAR)-Initiative distributed HIV self-test (HIVST) kits using unincentivized HIV testing counsellors across 31 public facilities in Malawi, South Africa, Zambia, and Zimbabwe. HIVST was distributed either through secondary (partner's use) distribution alone or primary (own use) and secondary distribution approaches.

Methods

We evaluated the costs of adding HIIVST to existing HIV testing from the providers' perspective in the 31 clinics across the four countries between 2018 and 2019. We combined expenditure analysis and bottom-up costing approaches. We also carried out time-and-motion studies on the counsellors to estimate the human resource costs of introducing and demonstrating how to use HIVST for primary and secondary use.

Results

A total of 41,720 kits were distributed during the analysis period, ranging from 1,254 in Zimbabwe to 27,678 in Zambia. The cost per kit distributed through the primary distribution approach was $4.27 in Zambia and $9.24 in Zimbabwe. The cost per kit distributed through the secondary distribution approach ranged from $6.46 in Zambia to $13.40 in South Africa, with a wider variation in the average cost at clinic-level. From the time-and-motion observations, the counsellors spent between 20 - 44% of the observed workday on HIVST. Overall, personnel and test kit costs were the main cost drivers.

Conclusion

The average costs of distributing HIVST kits were comparable across the four countries in our analysis despite wide cost variability within countries. We recommend context-specific exploration of potential efficiency gains from these clinic-level cost variations and demand creation activities to ensure continued affordability at scale.

Costs of Integrating HIV Self-Testing in Public Health Facilities in Malawi, South Africa, Zambia and Zimbabwe

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Background

UNAIDS set the 95-95-95 targets with the first 95 aiming for 95% of people living with HIV (PLHIV) being aware of their status by 2030 (UNAIDS, 2015b). These fast-track targets have contributed to unprecedented progress towards ending the AIDS epidemic, especially in Eastern and Southern Africa, the region most affected by the epidemic (UNAIDS, 2019).

Despite this progress, the region still faces challenges in reaching men and key populations with testing (UNAIDS, 2019). Some of the hindrances to accessing testing include lack of convenient and accessible testing options especially for rural communities, high indirect user costs in accessing testing and privacy concerns associated with their test results (Indravudh et al., 2017; Maheswaran et al., 2016; Sande et al., 2018; UNAIDS, 2017).

HIV self-testing (HIVST), which is the process whereby a person collects their specimen, performs an HIV test, and interprets their own results in private, can increase the number of PLHIV who are aware of their status and initiate treatment (World Health Organization, 2016). HIVST provides an opportunity for discretion and convenience when testing and is highly acceptable among young people, adult men and first time testers (Hatzold et al., 2019; Indravudh et al., 2017; World Health Organization, 2016).

We explore the costs of integrating HIVST into existing HIV testing services in public primary health facilities in Malawi, South Africa, Zambia, and Zimbabwe between 2018 and 2019. Service integration involves joining together different services to maximize technical efficiency through economies of scale and scope, allocative efficiency, and health outcomes (Sweeney et al., 2012; UNAIDS, 2015a). Previous work on integration of HIVST into outpatient services in Malawi reported an increase in outpatient testing when compared to standard of care (SoC) (Dovel et al., 2020).

To our knowledge, this is the first multi-country cost analysis of the integration of HIVST into public health facilities. Such information is essential to designing sustainable and cost-effective models of HIVST as countries approach the UNAIDS 95-95-95 targets. Previous studies reporting costs of distributing HIVST in the region were either on a small scale (Ahmed et al., 2018) or focused on the community-based distribution of HIVST (D'elbée et al., 2020; Maheswaran et al., 2016; Mangenah et al., 2019). These studies reported average full costs (cost per kit distributed) in 2019 US$ of $9.66 and $8.91 for Malawi, $17.70 for Zambia, and $14.91 for Zimbabwe (Maheswaran et al., 2016; Mangenah et al., 2019), and average incremental costs of $15.40 and $14.00 in early and later phases of a community-based distribution of HIVST in Lesotho, respectively (D'elbée et al., 2020). The only other cost analysis of HIVST integration into facility-based testing services was conducted in Malawi and reported average costs of $4.99 (Meyer-Rath et al., 2019).

Methods

Study overview

HIVST distribution was done by unincentivized Department/Ministry of Health (DoH/MoH) staff (HIV testing counsellors) supported by Population Services International (PSI), Society for Family Health, and the Wits Reproductive Health and HIV Institute in Malawi, Zimbabwe, Zambia and South Africa respectively. Unitaid funded the supporting partners and commodities under the Self-Testing Africa (STAR) Initiative. Primary and secondary distribution approaches for HIVST were implemented. Primary distribution of HIVST involved collecting a test kit for one's use on-site, while secondary distribution involved collecting a test kit for use by sexual partners off-site. Table 1 provides a summary of the distribution approaches by country.

Table 1: Integrated distribution of HIV self-test into routine HIV testing services by country

Country	Channel	Model	Target Population
Malawi & South Africa	Secondary distribution only	Antenatal care distribution Index distribution	Sexual partners of pregnant women Sexual partners of HIV positive clients (newly identified or on antiretroviral therapy)
Zambia & Zimbabwe	Primary & secondary distribution	Antenatal care distribution Index distribution Outpatient department	Sexual partners of pregnant women Sexual partners of HIV positive clients (newly identified or on antiretroviral therapy) Clients attending facility outpatient services

Integration was from the first point of encounter with the clinics' waiting area where clients were briefed on HIVST as they waited for their consultations. Willing clients would visit the HIV testing services (HTS) room and opt for either a provider-administered finger prick test or provider assisted oral-fluid based HIVST (which could be immediately confirmed by a facility-based provider in the event of a reactive result). On the other hand, in the secondary distribution channel, willing pregnant women attending antenatal care, where the HIVST kit was offered for the partner at their first visit, or HIV positive clients (newly diagnosed or enrolled in the ART program) were offered kits for use by their sexual partners. The sexual partners were encouraged through the recipient of the HIVST kit to visit the clinic for a confirmatory test if they screened positive. Figures A1-A4 in the appendix give more detailed information on the integration process in each country.

South Africa's HIVST kit distribution and cost analysis was carried out across eight clinics in Gauteng and North West Provinces. In Zambia, distribution and cost analysis took place in two clinics in Lusaka district, while in Zimbabwe, costing was carried out for distribution in two large clinics in Mashonaland East. The Zimbabwe clinics were purposively sampled based on their proximity to Harare which is where the country’s PSI headquarters was located. Malawi's distribution on the other hand, was implemented as a three-arm pragmatic cluster randomized trial in 27 clinics in the Southern region (Choko et al., 2020). The arms comprised SoC, HIVST-only, and HIVST plus financial incentive (HIVST+FI) arms. SoC arm offered the ANC and index clients letters inviting their partners to the clinic for an HIV test. The HIVST-only and the HIVST+FI arms offered HIVST in addition to the invitation letters. In the HIVST-only arm, partners were encouraged to come to the clinic only if they had screened positive. In the HIVST+FI arm, partners were encouraged to come to the clinic regardless of their screening result and were given a US$10 incentive as reimbursement for their time plus transport. We analysed the costs of all three arms.

Ethics Approval

Ethics approvals for the costing work were obtained from research ethics committees of the London School of Hygiene and Tropical Medicine (Ref. # 15408, Ref. # 11738 for Zimbabwe) and the Malawi College of Medicine (P.02/18/2352), Medical Research Council of Zimbabwe (Ref. # MRCZ/A/2038), the Human Research Ethics Committee (Medical) of the University of Witwatersrand (Ref. # M180379), and the Institutional Review Board of Boston University School of Public Health (IRB # H-37713).

Patient and Public Involvement

Patients and/or the public were not involved in the design or recruitment or conduct, or reporting, or dissemination plans of this research.

Cost Analysis

Economic costs of HIVST integration were estimated from the provider's perspective, with data collected between 2018 and 2019 and reported in 2019 US dollars. We converted local currencies to their US$ equivalent based on each country's average exchange rate for 2019 as sourced from the respective countries' Reserve Bank websites[1]. The costing process involved a combination of expenditure analysis in estimating financial costs and a bottom-up costing to identify and value any additional or donated items not included in expenditure records. We focused on HIVST costs alone because the HTS costs in this setting have been extensively studied and reported elsewhere (Meyer-Rath et al., 2019; Mwenge et al., 2017).

The expenditure analysis was used to track actual implementation expenses such as cost of buying the test kits and other supplies, salaries, transportation and storage. And the bottom-up costing was used to identify and value donated items at the facility-level such as equipment and space. At the facility level, we only included economic costs directly related to HIVST distribution, such as the counsellors' time, facility space and equipment, and excluded indirect costs such as overheads, i.e. utilities and facility security.

The costs were categorized into capital and recurrent. Capital costs included project start-up costs, training, sensitization, and equipment. Recurrent costs included operational costs such as personnel and per diems, supplies, and cost of test kits, among other costs. Capital costs

[1] Website links included in the bibliography

were annualized over the life course of the project, i.e., two years. We used a discount rate of 3% as recommended in literature and to facilitate comparison with our earlier work in the same countries (D'elbée et al., 2020; Drummond, Sculpher, Claxton, Stoddart, & Torrance, 2015; Mangenah et al., 2019; Mwenge et al., 2017). We varied this discount rate between 0% and 15% to reflect the range in official rates across the countries.

The implementing partners introduced multiple models of distributing HIVST in addition to the facility integrated model, shared costs between models were allocated based on the assumptions presented in appendix Table A1. The allocation factors for shared costs included the proportion of distributors trained, kits distributed, direct expenditure and vehicle mileage by model, among other variables.

In order to allocate the time of facility staff involved in other activities alongside HIVST distribution, we used different methods. In all countries except Zambia, we undertook time-and-motion studies to estimate provider time for the HIVST process. We could not conduct time-and-motion studies in Zambia due to delays in obtaining ethics clearance within the project implementation phase. There, we retrospectively interviewed the counsellors to understand the proportion of time allocated to HIV testing and HIVST services. We asked the counsellors to estimate the percentage of time allocated to HIV testing services and of this, the percentage allocated to HIVST services. We converted these proportions to equivalent overall HIV testing and HIVST time in minutes based on the counsellors stated working hours.

In South Africa, the initial ethics approval provided for up to three hours of continuous observations of the counsellors, this was later revised to continuous observation of a full working day after ethics amendments. More than half of the observations included in this analysis were conducted during the three-hour observation phase.

We obtained the counsellors' salaries from the facilities and multiplied by the average time obtained from the time-and-motion studies and interviews to estimate the facility-level personnel cost of HIVST. Overall personnel cost combined the facility-level personnel cost and personnel costs at the PSI, Society for Family Health, and the Wits Reproductive Health and HIV Institute central-level offices.

Data collection tools, including the time-and-motion tool, were developed as part of a collaborative process under the STAR-Initiative consortium and standardized across the countries except for Zambia (for the time-and-motion tool only) where could not conduct time-and-motion studies. The observations involved timing and recording on paper forms the counsellors' activities throughout their working day. We used the same tools across all HIVST distribution models including the integrated facility-based distribution. Table 2 presents the activities and their description. The activities were broadly categorized into direct and non-direct patient services, with direct patient services capturing time spent in contact with patients. The direct patient services time was allocated directly to either HIVST or finger prick, while the time spent with non-direct patient services was allocated to HIVST or finger prick testing using direct HIVST or finger prick testing time as a proportion of total direct time as an allocating factor. Observations were done continuously by health economists who were trained on time-and-motion studies.

Table 2: Time-and-motion activity codes

Category	Activity	Activity Description
Direct patient services	HIV testing services	HIV finger prick testing including pre-and post-test counselling
	HIV self-test information	Information about self-testing before/without distribution; code also used if client declined to take test kit
	HIV testing information	Non direct patient services
	Primary HIV self-test distribution	HIV self-testing kit primary distribution
	Secondary HIV self-test distribution	HIV self-testing kit secondary distribution includes pre-test counselling and demonstration on how to self-test
	HIV testing with secondary distribution	HIV testing services that included a secondary distribution of HIV self-testing
	Other direct patient services	Time allocated to services that are not related to HIV testing and HIV self-testing such as provision of family planning methods and antiretroviral treatment initiation
Non-direct patient services	HIV self-test administration	Pre-drive administration such as paperwork
	HIV testing administration	Pre-testing administration such as paperwork
	Driving to site	Driving time for the distributor/counsellor to reach the site from the implementers' office
	Non direct patient services	Any time spent not facing clients such as lunch breaks and waiting for clients

We further explored potential economies of scale by observing the incremental unit costs at facility-level as number of kits distributed increased. Economies of scale are efficiency gains from the increased scale of production achieved by spreading fixed costs over more units of output. Given the cross-sectional nature of this study, we could not observe economies of scale over time for each facility but overall relationship between unit costs and distribution scale within country

Finally, a one-way sensitivity analysis was used to assess uncertainty around the cost estimates. We varied the discount rate from 0%-15%, project life years from 1-3 years, counsellors' time on HIVST by ±50% and personnel costs by ±10%. Additionally, we varied all three parameters together to assess the best- and worst-case scenarios.

Results

HIVST Kits Distributed

A total of 41,720 kits were distributed across 31 clinics in the four countries: 24,553 (59%) kits were distributed through the primary distribution channel (Zambia and Zimbabwe), while 17,167 (41%) were distributed through the secondary distribution channel. In the Malawi trial, 1,603 and 1,903 were distributed through the HIVST-only and HIVST+FI arms, respectively. (Table 2).

Table 3: Number of kits distributed by country

Country	Primary Distribution channel	Secondary Distribution channel
Malawi: HIV self-testing_only arm	-	1,603
Malawi: HIV self-testing+financial incentives	-	1,903
South Africa	-	9,282
Zambia	23,416	4,262
Zimbabwe	1,137	117
Total	**24,553**	**17,167**

Time-and-Motion Studies

We conducted a total of 39 time-and-motion observations across Malawi (n=9), South Africa (n=28) and Zimbabwe (n=2); we interviewed 25 counsellors in Zambia. Across all four countries, only the counsellors working in the HTS section were involved in HIVST distribution. In South Africa, we conducted 19 observations for 3 hours each during the 3 hours of observation protocol phase, and 9 observations for an average of approximately 4 hours per observation during the longer observation protocol phase. We further observed an average of 7 hours per counsellor in Malawi, and the 2 observations in Zimbabwe were for approximately 5 hours each. There is a likely bias in the Malawi and Zimbabwe observations due to the small sample sizes; we have accounted for this by varying the counsellor's time in the sensitivity analysis.

On average, a counsellor spent 32 minutes in South Africa to distribute a kit as presented in Table 4. We could not perform a per kit analysis in Malawi and Zimbabwe due to potential small sample size bias. Overall, the counsellors spent an average of 20 and 44 percent of the observed time on HIVST activities in Malawi and South Africa, respectively. In the two observations in Zimbabwe, the counsellor spent an average of 68 percent of the observed time on HIVST. There was no clear variation across activities between the countries. Aside from HIVST, the counsellors spent a significant proportion of the observed time on finger prick testing and non-direct patient activities. The interviewed counsellors in Zambia reported spending an average of 21 percent of their workday on HIVST.

Table 4: Average observed time per kit distributed in South Africa

Time category	Average time in minutes/Kits distributed		Average across protocols/Kits distributed (n=28)
	3 hours observations (n=19)	**>3 hours observations (n=9)**	
Direct HIV self-testing time	5.58	17.63	11.60
Indirect HIV self-testing time	9.39	31.20	20.30
Total HIVST time (% of total counsellors' time)	14.96 (34%)	48.83 (65%)	31.90 (44%)
Kits distributed	78	27	105

Costs

The costs per kit distributed through the primary distribution channel were $4.27 in Zambia and $9.24 in Zimbabwe. The costs per kit distributed through the secondary distribution channels were $6.46 in Zambia, $8.66 in Malawi, $9.05 in Zimbabwe and $13.40 in South Africa. Table 5 provides a summary of the total costs of distributing HIVST kits across all clinics by country.

Personnel and test kit costs were the key cost drivers across all four countries (Figure 1). Personnel costs ranged from 12% of total costs in Zambia's primary distribution channel to 64% in South Africa. The hourly wage per counsellor was $1.10 in Malawi, $2.99 in Zambia, $3.32, $4.16 in Zimbabwe and $4.25 in South Africa. Test kit costs ranged from 17% of total costs in South Africa to 63% in Zambia's primary distribution channel. Additionally, Malawi had relatively higher training costs accounting for 18% of total costs with the rest of the countries' training costs ranging from 1% in South Africa to 8% in Zimbabwe. We could not completely ascertain why Malawi had higher training costs, though the most plausible explanation may be its unique implementation approach through a clinical trial. The South Africa implementation included a component of mHealth for linking clients screening positive to follow-on care (Botha & Booi, 2016). The cost for the mHealth intervention was $0.27, accounting for 2% of total costs.

Table 5: Total costs of HIV self-test kit distribution by country (2019 US$)

Country	Zambia		Zimbabwe		Malawi	South Africa
Distribution						
	Primary	**Secondary**	**Primary**	**Secondary**	**Secondary**	
Capital costs						
Training	$3,435	$1,118	$807	$83	$5,584	$1,049
Sensitisation	$653	$119	$211	$22	$583	$740
Building & storage	$1,441	$2,771	$191	$17	$233	$886
Equipment	$2,225	$1,311	$77	$8	$136	$1,837
Other start-up costs	-	-	-	-	-	$161
Recurrent costs						
Personnel	$11,685	$6,596	$4,216	$398	$8,511	$79,837
Supplies	$3,472	$167	$714	$74	$891	$9,236
Test kits	$63,223	$11,507	$2,672	$275	$8,975	$20,792
Transport	$1,772	$323	$637	$66	$2,352	$244
Recurrent training	$4,044	$1,600	-	-	-	-
Building operation & maintenance	$3,023	$1,107	$272	$27	$3,009	$7,292
Waste management	$1,052	$169	$30	$19	-	-
mHealth	-	-	-	-	-	$2,492
Other recurrent	$3,929	$756	$681	$70	$105	-
Total	**$99,955**	**$27,544**	**$10,508**	**$1,058**	**$30,379**	**$124,556**
Total Kits distributed	23,416	4,262	1,137	117	3,506	9,282
Clinics/country§	3	3	2	2	18	8
Ave. kits distributed /clinic	7,805	1,421	569	59	195	1,060
Cost/Kit	**$4.27**	**$6.46**	**$9.24**	**$9.05**	**$8.66**	**$13.40**
Clinic-level cost/kit (min-max)	$4.17 – $35.64		N/A		$4.67-$17.40	$4.59 - $132.00

§Primary and Secondary distribution in Zambia and Zimbabwe was done in the same clinics therefore our analysis was conducted in a total of 31 clinics even though we have 36 observations

The country-level average costs conceal a wide variation in average costs by facility, especially in South Africa (Figure 2). The clinic-level average costs in South Africa ranged from $4.59 in a facility that distributed 2,182 kits to $132 in a facility that distributed 103 kits. The clinics with the lowest average costs in South Africa were rural clinics with low distribution volumes implying potential economies of scale to HIVST implementation. This clinic-level cost analysis allowed us to explore other potential economies of scale across the 36 observations included in this analysis, as presented in Figure 2. We observed potential economies of scale in Malawi and South Africa i.e., lower average costs in clinics that distributed a higher number of kits, but not Zambia and Zimbabwe.

Sensitivity Analysis

Figure 3 presents the sensitivity analysis results where we varied the discount rate, project life years, counsellors' time allocated to HIVST and personnel costs. In Malawi, the average cost was most sensitive to project life years, with the average costs rising by 21% when capital costs were assumed to have a lifespan of 1 year. In South Africa and Zimbabwe, the average cost was more sensitive to personnel costs, and in Zambia, to the providers' reported time spent on HIVST. In Zambia for instance, doubling the time spent on HIVST led to a 13% rise in average costs, compared to a 5% rise in South Africa and Zimbabwe. Across Malawi, South Africa and Zimbabwe, the average costs were least sensitive to changes in the discount rate from 0% to a high of 15%.

Discussion

We observed the costs of adding HIVST to existing testing services in public facilities. In Malawi, South Africa, Zambia and Zimbabwe. HIVST was distributed through primary and secondary distribution approaches using unincentivized HIV testing counsellors. Costs per kit distributed were comparable across the countries. However, there was a wide variation in the average costs at the clinic level, driven mainly by the variability of costs in South Africa with the costs at the clinic level varying between \$4.59 and \$132. This study fills a gap in literature by reporting multi-country costs of integrating HIVST in public facilities which is a viable option as countries approach the last milestone of the UNAIDS first 95.

In Zambia and Zimbabwe, the average costs of the integrated distribution observed in this study were lower than the inflation adjusted average costs of community-based distribution of HIVST reported in our earlier work (Mangenah et al., 2019). The average costs of community-based distribution in Zimbabwe and Zambia were two and three times higher than facility incremental costs, respectively (\$14.69 vs \$6.10 in Zimbabwe and \$17.00 vs \$5.37 in Zambia). This is expected as the community-based distribution was a vertical intervention unlike the integrated facility distribution that leveraged on existing economies of scope through shared infrastructure and human resource. It is worth noting that integration of HIV testing services may not always lead to efficiency gains in service delivery as observed elsewhere (C. D. Obure, Guinness, Sweeney, Initiative, & Vassall, 2016) and in the Malawi component of this study where the average costs of the facility and community-based distribution in Malawi were comparable i.e. \$8.66 vs \$8.58.

Furthermore, despite the time-and-motion study raising generalizability concerns due to majority of the observations coming from South Africa, the results still offer insight into time demanded by HIVST from the counsellors. Counsellors spent at least 20 percent of the observed workday on direct and indirect HIVST activities in Malawi and as much as 44 percent of the observed workday on HIVST in South Africa. These results are informative to the time burden on the counsellors introduced by HIVST and have implications for the sustainability of HIVST scale-up. The degree of integration and the counsellors' perception of HIVST are important factors in ensuring sustainability. HIVST needs to be horizontally integrated to ensure that the counsellors perceive it as a part of their routine. A viable alternative is unassisted primary distribution of HIVST which has the potential of reducing staff time commitment especially for heavily understaffed facilities and improving linkage to follow on treatment or prevention services. For secondary distribution, pooled demonstration through for example videos streamed in the waiting areas also has potential of reducing direct patient time for the counsellors.

Additionally, the cost driver analysis demonstrated the importance of personnel and test kits in driving the integration costs. Our previous studies on facility-based HIV testing and community-based HIVST distribution also reported the costs of test kits and personnel as key cost drivers (Mangenah et al., 2019; Mwenge et al., 2017). The significance of personnel costs as a critical cost driver cannot be understated, as demonstrated by the time-and-motion studies. There is an opportunity cost to counsellors' time- an intervention such as HIVST may be taking away time from the provision of other essential healthcare interventions especially in clinics that do not use lay counsellors for HIVST distribution. It is also important to ensure that HIVST is not introduced in facilities as a replacement for finger-prick testing but as an alternative testing option with the aim of expanding choice and supporting any potential efficiency gains (Hatzold et al., 2019).

There are potential economies of scale to HIVST implementation. Average costs were lower in sites with high number of kits distributed due to shared fixed/overhead costs. And outlier clinics in South Africa were rural with low number of HIVST kits distributed. The average costs for such clinics need to be evaluated not relative to the high-volume facilities with low average cost but the counterfactual for such rural areas, no testing for the populations left behind.

Finally, this study has the advantage of being a multi-country costing study on integrating HIVST to existing testing services in 31 public facilities. This gives us a better understanding of the feasibility and cost implications of such an approach across countries. The time-and-motion studies enabled us to understand the time commitments required by unincentivized counsellors in an integrated approach of delivering HIVST in public health facilities. We propose room for efficiency gains at the clinic level, as demonstrated by the heterogeneity in clinic-level costs (Carol Dayo Obure et al., 2012); this could be further explored using data envelopment analysis (C. D. Obure, Jacobs, Guinness, Mayhew, & Vassall, 2016). We also recommend demand creation activities and continued kit price negotiations to ensure the intervention's sustainability and continued affordability, especially at scale-up.

Limitations

There are several limitations to this study. A central limitation is that a substantial sample (58%) of the cost clinics was based on a trial. Despite excluding research costs, there may be higher protocol-induced resource use costs, and uptake, which may not be observed at scale-up.

There is also a likely upward bias in the observed time counsellors spent on HIVST due to Hawthorne effect, whereby individuals change their behaviour under observation (Sackett

Catalogue of Bias Collaboration, E.A., & K., 2017). If the counsellors expected a financial incentive from HIVST integration, there was potential for them to spend more time on HIVST distribution during the observations. Nonetheless, we deem it advantageous to collect the time-and-motion data rather than basing the estimation of personnel resource costs solely on retrospective interviews, which is subject to the same bias but with the added challenge of recall bias.

An additional limitation is our inability to construct an index of integration to assess the complex nature of integration at the facility-level and to understand the sources of heterogeneity in facility-level cost due to lack of data (Mayhew et al., 2016; Sweeney et al., 2012).

Finally, constructing cost functions would have been more informative in exploring potential sources of cost heterogeneity at the facility level. We had few facilities within the countries with even more limited variables collected per facility to fully parameterize a cost function analysis. However, aside from South Africa, the rest of the countries' average costs were more homogenous, suggesting potential uniformity in integrated service delivery.

Conclusion

We conducted a cost analysis of an intervention that integrated HIVST into existing HIV testing services in public facilities in Malawi, South Africa, Zambia, and Zimbabwe. The average cost of integrating HIVST into public facilities ranged from $4.27 to $13.40 per kit distributed between countries. Personnel and cost of test kits were the critical cost drivers. We recommend taking the context into account when integrating HIVST into existing testing services. Finally, where staff time may be a constraint for conventional testing, HIVST may help alleviate this by enabling clients to have unassisted testing.

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Competing Interests

None declared.

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Manuscript Figures

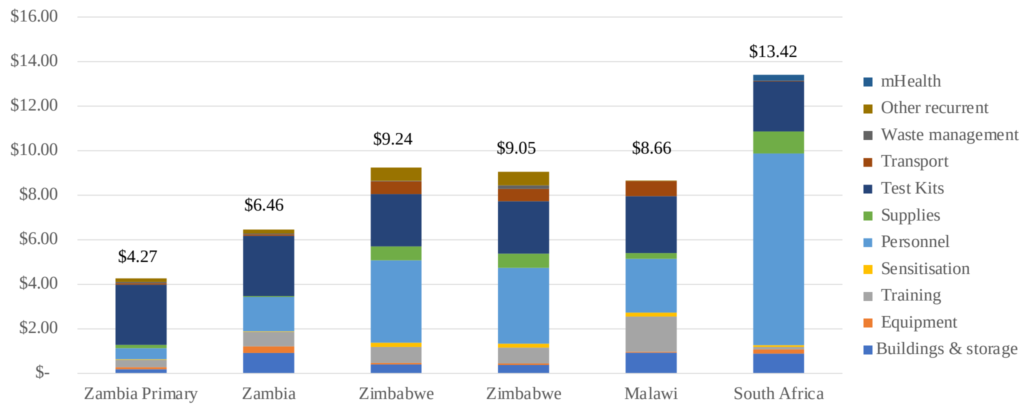

Figure 1: Average costs and cost drivers by country

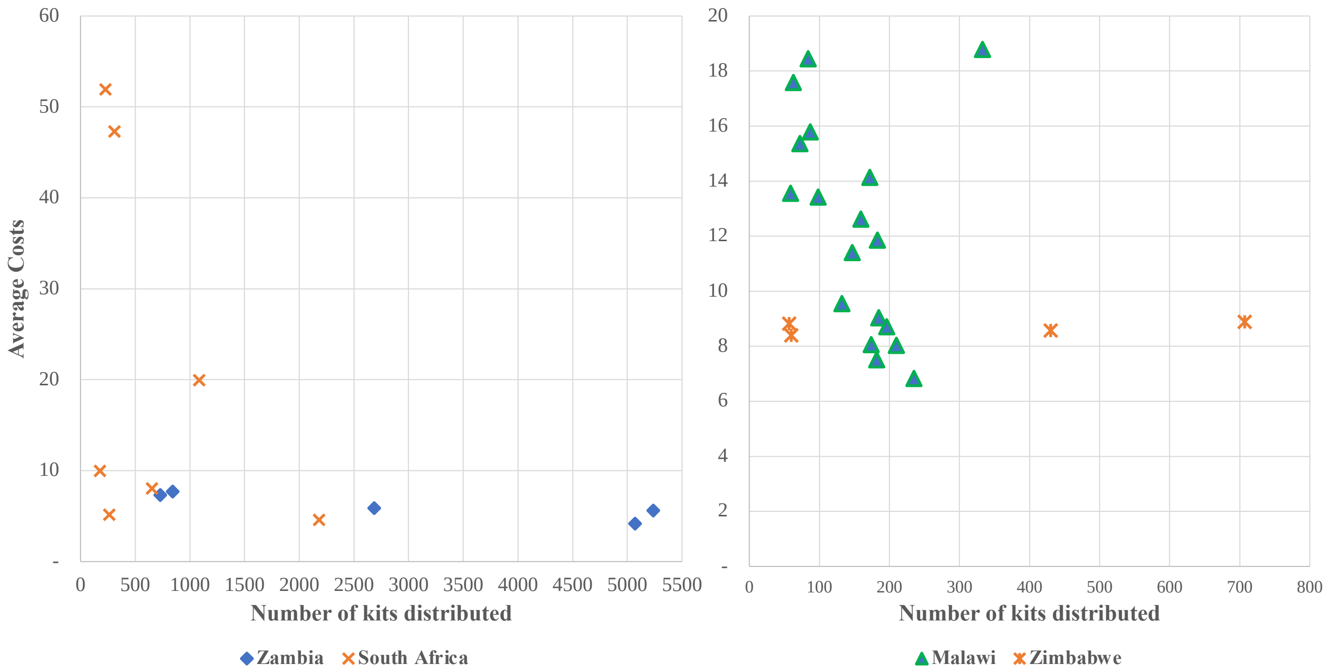

Figure 2: Economies of scale by country

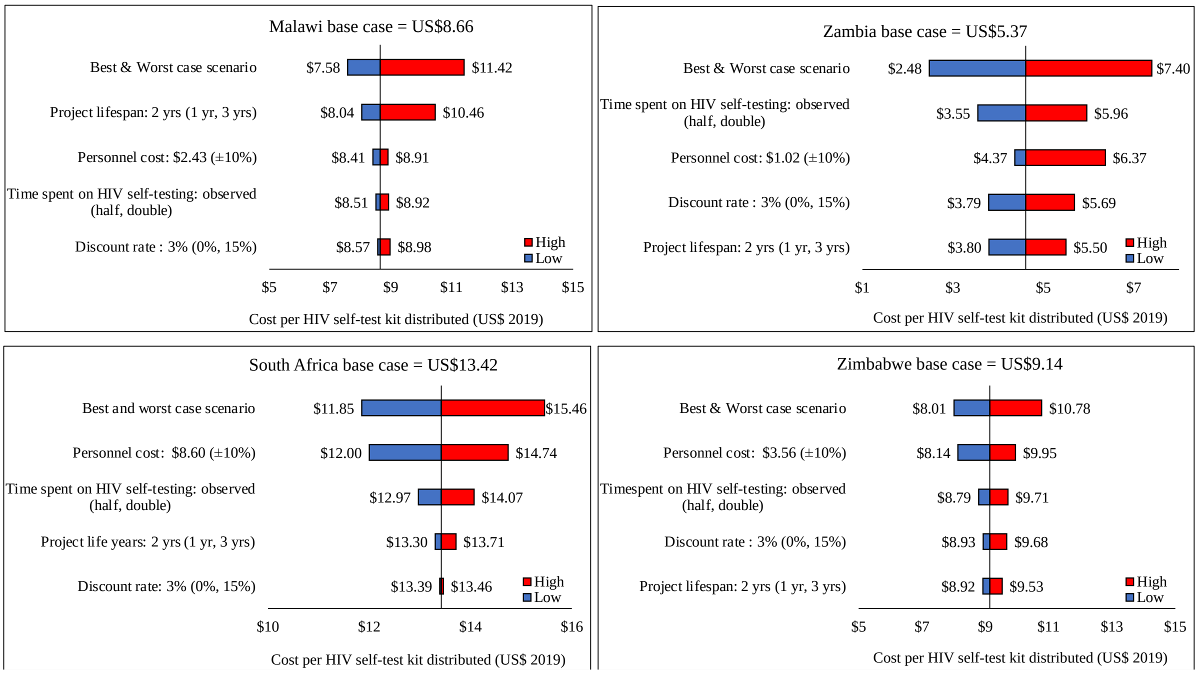

Figure 3: Sensitivity analysis

Table 6. 7: Inflation adjusted costs of integrating HIV self-testing in public primary care facilities

		Zambia		Zimbabwe		Malawi	South Africa
		Primary	Secondary	Primary	Secondary	Secondary	Secondary
Capital Costs	Building & storage	2,228	4,285	266	24	302	996
	Equipment	3,440	2,026	107	11	177	2,054
	Training	5,311	1,729	1,119	115	7,248	1,179
	Sensitization	1,010	184	294	30	757	832
	Other Start-Up	-	-	-	-	-	181
Recurrent Costs	Personnel	18,067	10,198	5,875	555	11,048	89,763
	Supplies	5,369	258	996	102	1,156	10,384
	Test kits	97,752	17,792	3,724	383	11,651	23,377
	Vehicle operation	2,740	499	888	91	3,053	274
	Recurrent training	6,252	2,473	5	-	-	-
	Building operation	4,674	1,712	380	37	3,906	8,199
	Waste management	1,626	262	41	27	-	-
	Other recurrent	6,075	1,169	949	98	136	-
	mHealth	-	-	-	-	-	2,802
	Total	**$154,545.26**	**$42,586.94**	**$14,644.32**	**$1,475.10**	**$39,433.39**	**$140,040.85**
	Kits distributed	23416	4262	1137	117	3506	9282
	Cost per kit distributed	$6.60	$9.99	$12.88	$9.05	$11.25	$15.09

Table 6.6. presents inflation adjusted costs of integrating HIVST in public primary care facilities in public primary care facilities in Malawi, South Africa, Zambia, and Zimbabwe. Inflation adjusted unit costs range from US$6.60 in Zambia's primary distribution of HIVST to US$15.09 in South Africa's secondary distribution of HIVST. Like before adjusting for inflation, primary distribution of HIVST in Zambia has the lowest costs with secondary distribution of the HIVST in South Africa having the highest unit cost of distributing HIVST.

With inflation adjustments, secondary distribution of HIVST in Zimbabwe appears to cost less than secondary distribution of HIVST in Malawi and Zambia. This shows that caution should be taken when conducting a head-to-head comparison of inflation-adjusted costs obtained from multiple settings as the costs may be influenced by monetary policies.

6.4. Chapter discussion

In this chapter, I presented costs of providing HIV testing and HIVST services in Malawi and costs of integrating HIVST in public primary care facilities in four countries in Southern Africa. This is one of the few extensive evaluation of costs of providing HIVST with an additional component of comparing with conventional HIV testing services.

The unit cost of providing HIV testing and HIVST services ranged from US$3.46 in facility-based provider testing in Malawi to US$15.09 in secondary distribution of HIVST in public primary care facilities in South Africa. These costs are comparable to other costing studies that evaluated costs of facility-based testing in Zambia and Zimbabwe (230), costs of community-based testing in Zambia and Zimbabwe (233), costs of integrated and community-based distribution of HIVST in South Africa (64), costs of integrated HIVST distribution in Lesotho (238) and costs of integrated facility-based testing in Malawi (239).

I had expected community-based distribution to be more expensive than any form of facility-based testing due to the absence of shared overheads. Community-based distribution of HIVST was in the initial phase implemented as the only modality of distributing HIVST. This implies that the modality did not benefit from economies of scope arising from shared overheads if there were several interventions or distribution modalities being implemented by the same implementers or distributors. Facility-based testing on the other hand, benefited from shared space and overheads as clinics offered integrated HIV testing services including integration with sexual and reproductive health services.

However, this work showed that the unit cost of community-based distribution was comparable to both primary and secondary distribution of HIVST integrated in primary care facilities. This is likely to be due to the scale of distribution associated with community-based distribution of HIVST as opposed to facility-based integrated HIVST distribution. Community-based testing appears to benefit from economies of scale associated with the degree of distribution. Both secondary and community-based distribution of HIVST is expected to be associated with reduced access costs for the end user. This is because, community-based health service provision is associated with reduced access barriers such as high user costs allowing for higher uptake than facility-based healthcare interventions (7, 8, 15, 55, 59, 119, 240). The limitation with secondary and community-based distribution is the inability to effectively track usage and linkage to care.

In addition, an intervention such as HIVST being distributed free at the point of use is expected to be associated with overuse as moral hazard due to this reduced marginal cost. Moral hazard is the tendency to undertake in inefficient choices when the private marginal cost is low. The concept of moral hazard with the distribution of HIVST has been explored in a later chapter of this thesis. Moral hazard associated with HIVST can lead to wastage of resources as an inefficiency associated with secondary and community-based distribution approaches. This is especially concerning as HIV programmes have already had concerns of over-testing in a context with decreasing global financing resources (241, 242).

However, this wastage can be considered as of social benefit to ensuring that the people left behind are reached with testing. HIV testing must be widely available and within the reach of majority of the population. However, there is a need to balance the extent of over-testing as wastage and ensuring the wide availability of testing. Targeted provision of testing to groups left behind can help ensure that such populations reached with minimal wastage of kits.

The concern for efficient use of test kits is also important because cost of kits and personnel are important cost drivers across all testing models and countries considered in this chapter. The sensitivity analyses further showed the importance of these two variables to the unit costs. Testing approaches that use lay staff and minimal wastage of kits are important to ensuring that testing is affordable. This is especially important as costs of identifying new HIV positive patients are expected to rise as countries reach the first UNAIDS 95 target. Therefore, providing testing using models that have a high positivity rate but minimise provider costs is important for resource allocation. Such models include the secondary distribution of HIVST test kits using sex workers as was demonstrated elsewhere (64).

Finally, this analysis further showed that facility-based provider testing was more affordable than primary and secondary distribution of HIVST. Despite facility based testing being cheaper than HIVST in the community and integrated in facilities, ending AIDS as a public health threat by 2030 requires a move beyond the standard approach to identify PLHIV not currently being reached by conventional testing approaches (21, 243). HIVST has been proven to be effective at reaching first-time testers and young men among other unreached populations (55-57, 244). As noted elsewhere (243), “business as usual is not delivering fast enough”. HIV testing limited to facility-based provider testing will not reach the populations left behind. Additional and novel testing approaches such as targeted HIVST are needed to end the epidemic by 2030 despite costing more than conventional testing.

6.5. Chapter limitations

There are a number of limitations to this work. First, two of the HIVST modalities included in this analysis were implemented as part of randomised trials. This may have led to costs higher than those to be observed at scale-up due to trial protocol influence on implementation.

Second, good practice of economic evaluation requires presenting costs at scale in addition to observed costs (232). However, costs of scale-up was beyond the scope of this work as another costing study under the STAR Economics Network modelled costs of scale-up (245). Cost-effective analyses were also beyond the scope of this PhD and have been explored in other studies under STAR (246, 247), including ongoing work by other PhD students in the project.

Finally, note that the analysis is presenting a head-to-head comparison of a mature programme (facility-based provider testing) against new interventions. Cost of distributing HIVST both at the community or in facility setting may fall as programmes mature and realise efficiency gains from learning by doing (248). In addition, facility-based provider testing did not include start-up costs and so may be considered as incremental costs. Caution should also be taken when interpreting facility-based costs of HIV testing as the lack of random sampling of the costed healthcare facilities may have introduced a downward bias in costs.

6.6. Chapter conclusion

HIVST was recommended by WHO to help reach populations unreached by conventional HIV testing approaches. HIVST being a new intervention in this setting, required a costing study to inform implementation. Cost analyses of facility-based provider testing and a combination of community-based and integrated facility-based distribution of HIVST was conducted in four countries in Southern Africa. Costs of community-based and facility-based testing were comparable. Cost of personnel and test kits were key cost drivers across both conventional testing and HIVST modalities. Affordable approaches to delivering testing such as using more affordable staff cadres such as lay testers, reducing kit wastage and unsupervised testing can help reduce costs.

The next chapter uses some of these costs to evaluate socioeconomic equity in testing uptake and the distribution of subsidies from testing.

Chapter 7: A secondary analysis of socioeconomic equity in HIV testing and over-testing in Malawi: An application of utilisation and benefit incidence analyses

This chapter presents a manuscript under development whose purpose is to evaluate socioeconomic equity in uptake of HIV testing services and subsidies from the same in Malawi.

The initial plan was to use the standard of living index developed in chapter 4 as the measure of SES in this chapter. However, after some delays in my student timelines it was not possible to develop the index in time to be incorporated in the household survey tool used in this chapter. As such, the standard of living index used in this chapter was developed independently by other researchers under the STAR study. There was however, a 63% overlap between indicators used in the standard of living index in this chapter and the index developed in chapter 4.

Overall, our index in chapter 4 had four domains while the one used in this chapter was composed of three domains. In addition, our index was longer containing 16 indicators for the national-level index while the one in this chapter had 10 indicators. Using our index here would have likely improved the precision of the index in distinguishing the socioeconomic quintiles as our index has more dimensions and indicators than the one used in the household survey here. Nevertheless, the index used in this chapter was still useful in categorising the population into socioeconomic quintiles. It reflects the same number of domains as is used in the DHS wealth index and its length is similar to the length of the MPI.

7.1. Introduction

In 2016, the World Health Organization (WHO) recommended HIV self-testing (HIVST) as an innovative way to reach people with HIV testing (50). HIVST is the self-sampling, performing, and interpreting for HIV using either oral fluid or blood (50, 52). HIVST has been shown as particularly effective at reaching undertested populations, including men, young people, first time testers and key populations (50, 54-56, 249). This is because HIVST addresses key access barriers associated with conventional HIV testing such as high opportunity costs coming from missed work, costs; long distances to testing facilities; long lines to access testing; and concerns about confidentiality and stigma (53-59).

This paper seeks to answer four key questions associated with HIV testing: 1) Who in terms of socioeconomic status (SES) is testing and over-testing for HIV? 2) What are the factors driving testing and over-testing for HIV? 3) How are subsidies from HIV testing distributed across socioeconomic groups? 4) Is the distribution of these subsidies equitable? These questions were answered through a secondary analysis of an endline survey evaluating the impact of community-based distribution of HIVST in Malawi.

Our first objective was to understand the socioeconomic distribution of HIV testing and over-testing for HIV in a setting with HIVST. Despite HIVST being available elsewhere as early as 2012 (250), it was not until after the 2016 WHO recommendations that HIVST became more widely available to the general population in Malawi. Uptake of HIVST has been shown to increase with SES and education especially among women (251). In this sense, uptake of HIVST is in line with Everette M. Roger's diffusion of innovation theory and Cesar G. Victora's inverse equity hypothesis (71, 164, 166). These theories argue that new technologies and innovations increasingly reach or are taken up by the richer first before reaching the poorer. Such a situation increases inequity in the early phases of implementation (164). This is particularly concerning in Malawi as HIV testing uptake has been shown to be better among the wealthier and more educated individuals (252, 253) when compared to the poorer and those with low levels of education.

An additional concern with HIVST is the potential for over-testing as a moral hazard. Moral hazard is when a reduction in marginal private cost of care, through for instance subsidies, leads to an increase in use to where its marginal social benefit is less than the marginal social cost (254). This, leads to rates of uptake (HIV testing) in excess of social optimum (255).

Literature on uptake of HIVST has demonstrated concerns of over-testing as PLHIV take up HIVST as a way of checking status change after believing faith healing (47), as an entry point to reengage into HIV treatment after treatment interruptions (256) or to confirm a prior HIV status (67). For instance, a study in in Malawi reported 26% of HIVST reactive participants to have already been on ART (47).

Over-testing has been an increasing concern with HIV programmes necessitating the call for more targeted testing (241, 257, 258). Over-testing leads to inefficient allocation of resources which is particularly concerning in a low resource settings such as Malawi. On the flip side, wider availability of HIVST can normalise testing and help reduce stigma towards testing for HIV.

In this paper, we define over-testing in accordance with WHO guidelines for HIV testing. World Health Organization (2020) [(44)}recommends one to three HIV tests per year for the general population in settings with a generalized epidemic such as Malawi. Testing beyond this is likely to yield little marginal benefit and can be considered as overuse.

We conducted this analysis of the socioeconomic distribution of HIV testing and over-testing for HIV using utilisation incidence analysis. Utilisation incidence analysis is a technique that tracks the use of healthcare services across socioeconomic groupings (259).

Our second objective was to understand the determinants testing and over-testing for HIV in a setting with HIVST. Several studies have explored determinants of HIV testing. Enablers of testing include belonging to a higher socioeconomic group, being female, age especially being younger, education, perceived risk of HIV, having multiple sexual partners, rating one's health both highly and poorly and HIV knowledge (9, 13-15, 19).

Some of the barriers of testing include distance to a testing site, user costs, marital status especially for men and age specifically being older (9, 13, 19, 260). Determinants of HIVST include age, gender, marital status, SES, education level, engagement in unprotected sex and awareness of HIVST through having a family member who has ever tested using HIVST (244). However, little is known about determinants of over-testing for HIV despite concerns about inefficiencies in HIV programme from over-testing.

We conducted a mixed effect multinomial logistic regression analysis to evaluate these determinants of testing and over-testing for HIV. Our choice of multinomial logistic regression was because we wanted to observe if a different set of determinants influence expected testing versus over-testing.

Furthermore, we sought to evaluate the socioeconomic distribution of subsidies from testing for HIV. Uptake and impact of HIVST has been well studied (56, 59, 251, 261). However, not much is known about the distribution of subsidies from HIV testing. We conducted this analysis using benefit incidence analysis (BIA). BIA is an equity evaluation approach that tracks the distribution of subsidies from using health care services across socioeconomic groups (262, 263). Traditionally, BIA was used to evaluate the distribution of public expenditures on social services (264). The approach combines data on healthcare service use and costs of providing the services to estimate subsidies received by users of health services (106, 263, 264). Subsidies in BIA can be considered as indirect transfers from government to individuals dependent on their use of a service (265).

Finally, we sought to understand if the present distribution of subsidies obtained through testing was equitable. We did this by comparing the distribution of the subsidies against need. Understanding the distribution of subsidies from HIV testing against need is important to ensuring efficient and equitable allocation of resources. In addition, the incidence of healthcare subsidies gives an indication of the performance of the healthcare system (263) at reaching the poor.

7.2. Study Setting

Malawi has a high HIV burden with close to a million PLHIV (108). This accounts for 5% of PLHIV in the Eastern and Southern Africa region (108). Progress has been made towards ending the AIDS epidemic as a public health threat by 2030, but some populations such as men and young people are increasingly left behind (108).

Unitaid funded the Self-Testing AfRica (STAR) project which was a multi-country project aimed at catalysing the market for HIVST, generating evidence and creating an enabling environment for scale-up of HIVST (179, 266, 267). STAR was implemented in six southern African countries including Malawi. Under STAR, oral HIVST kits (Oraquick®) were distributed free at the point of use through a combination of facility, community, and workplace distribution modalities.

The parent trial for this study was a cluster randomised trial (CRT) evaluating the impact of community-based distribution of HIVST, trial registration: ClinicalTrials.gov (ref, NCT02718274). For the CRT, 22 public primary care facilities and their catchment areas were randomised 1:1 to standard of care (SoC) and HIVST arms. In SoC, pre-existing HIV testing services were maintained. In the HIVST arm, there was SoC plus door-to-door and on demand distribution of HIVST to residents aged 16 and above (57). The endline household survey showed that testing in the last 12 months (recent testing) was higher in the HIVST arm than SoC. The trial results have been presented in more detail elsewhere (244, 261).

7.3. Data

This paper uses cost data from Mwenge (2017) [(230)] and Mangenah (2019) [(92)]; and individual-level data including testing uptake from the STAR endline household survey. Mwenge (2017) [(230)] evaluated costs of providing HIV testing services in 15 of the 22 primary healthcare facilities included in the STAR CRT. They reported an average cost per person tested in the facilities of US$5.03 (min-max: US$2.96 – 9.24) in 2017 USD (230). Mangenah (2019) [(92)] evaluated costs of providing HIVST in the 11 intervention clusters of the CRT. Mangenah (2019) [(92)] reported cost per HIVST kit distributed of US$8.15 in 2019 USD.

7.4. Methods

7.4.1. Utilisation incidence analysis

To evaluate who in terms of SES is testing for HIV, we conducted a utilisation incidence analysis. This analysis had two components, service utilisation and a measure of SES.

Service utilisation was captured as the number of HIV testing episodes in the last 12 months. This was obtained from the endline household survey.

From the survey, we also obtained information on respondents' last three recent tests. For each of these tests, respondents reported on the type of test, that is, HIVST or facility-based provider test. For respondents with more than three recent tests, we extrapolated the most frequent type of test (of the three recent tests) to the remainder of the reported recent tests.

SES was measured using a multi-dimensional wealth index composed of individual-and household-level characteristics. Individual-level variables included in the wealth index were respondents' gender, income, and engagement in formal employment. Using electricity for lighting was included as a housing characteristic. Household assets were the predominant variables included in the index. For the household assets, we included ownership of a radio, working television set, possession of mobile and landline phones, possession of a refrigerator, sleeping on a bed with a mattress, possession of an automobile and a motorcycle.

We derived the weights of the socioeconomic variables using principal component analysis (199), specifically the Polychoric PCA (268) in Stata. The weights were then used to rank the respondents. We then split the respondents into socioeconomic quintiles. The use of quintiles in grouping populations is common practice when using wealth indices and has been widely used in Demographic Health Surveys (DHS) (198). We then compared the proportion of testing uptake across the socioeconomic quintiles to evaluate incidence of testing.

7.4.2. Determinants of testing and over-testing for HIV

Based on the WHO guidelines explained earlier, we considered 1-3 tests in a year as beneficial level of testing and anything above three as over-testing.

We were interested in evaluating the determinants of testing and over-testing for HIV. We applied a mixed effect multinomial logistic regression to variables presented in Table 7.1. The dependent variable was captured as a nominal variable: 0 - for no testing; 1- necessary testing (1-3 annual HIV tests) and 2- over-testing (more than 3 annual HIV tests).

Table 7. 1: Determinants of testing and over-testing for HIV

Variable	Detail	Justification	References
Age	Continuous variable	Age is likely to influence sexual activeness, knowledge about HIV, and concerns about vertical transmission of HIV for women in the childbearing age	(9, 13)
Age^2	Continuous variable	Age in quadratic form to capture any existing non-linear relationship	
Gender	**Categorical variable** 0: Female 1: Male	Gender is likely to affect demand for testing with women having more opportunities for testing than men	(9)
Socioeconomic status	**Categorical variable** 0: Lowest quintile 1: Second quintile 2: Middle quintile 3: Fourth quintile 4: Highest quintile	SES may predispose individuals to seek care by influencing the affordability and availability dimensions of access	(13, 14)
Education level	**Categorical variable** 0: No formal education 1: Primary education 2: Incomplete secondary 3: Complete secondary or higher	Education may predispose individuals to seek care as they are more aware of health benefits to testing	(9, 13-15)

Literacy	**Categorical variable** 0: Not literate 1: Literate	Especially for HIVST, literacy may influence confidence in using a kit and potentially demand for a kit	
Self-rated health status	**Categorical variable** 0: Poor 1: Fair or Good 2: Very good	Individuals who rate their health as low would seek testing more frequently due to suspicion that they may be HIV+. However, individuals who rated their health as good have also been reported to seek testing more frequently	(269)
Multiple sexual partners	**Categorical variable** 1: Has had sex with more than one steady partner in the last 3 months 0: Otherwise	Proxy for risk behaviour which would increase an individual's HIV risk perception	(9, 13)
Marital status	**Categorical variable** 0: Not married 1: Married or living as married	Married people have been shown to seek testing less especially for men. Married people also tend to consider their partner's status as a proxy for their own. Marital status has however, also been shown to increase the likelihood for testing when compared to individuals who have never been married	(9, 260)
User costs	Continuous variable	User costs may deter testing uptake	(9, 19)

7.4.3. Benefit incidence analysis

BIA was conducted to inform the socioeconomic distribution of subsidies obtained through HIV testing. The analysis was conducted using the following standard steps following guidelines for undertaking BIA (106, 263):

i. Selecting a measure of SES
ii. Ranking the population from poorest to richest using the selected measure of SES
iii. Estimating individual-level utilisation of the health service in question
iv. Estimating individual-level subsidies
v. Splitting the population into socioeconomic quintiles
vi. Aggregating each socioeconomic quintile's share of subsidies
vii. Evaluating each socioeconomic quintile's share of aggregate subsidies against need

Steps 1-3 were already conducted as part of the utilisation incidence analysis. There was, therefore, no need to repeat these steps in the BIA.

Step 4: Estimating individual-level subsidies:

Individual-level subsidies received through undergoing HIV testing were estimated as:

$$S = [(cf * tf) + (cc * tc)]$$ **Equation 1**

Where:

S is the subsidy received by an individual for HIV testing

cf is the unit cost of providing facility-based HIV testing

tf are the number of recent facility-based testing episodes
cc is the unit cost of providing HIVST
tc are the number of recent HIVST episodes

HIV testing in both trial arms was provided free at the point of use which did not necessitate the deduction of any user fees for accessing care.

Each recent testing episode reported in the endline household survey was assigned the corresponding unit cost of providing that service. For facility-based HIV testing, we assigned the corresponding unit cost obtained from Mwenge (2017) [(230)] to each facility-based testing episode depending on the respondent's cluster of residence. We did not have specific unit cost data for seven of the 22 facilities in the CRT. For repondents reporting facility-based HIV testing in these seven clusters, we applied the average unit cost of US$5.03 as the cost of providing an HIV test. For all respondents reporting HIVST, we applied the unit cost of distributing HIVST of US$8.15 from Mangenah (2019) [(92)].

The unit costs were converted to Malawi Kwacha using the reporting year average exchange rate sourced from Reserve Bank of Malawi (2021) [(270)]. Then the unit costs were adjusted for inflation to 2021 Malawi Kwacha using approach recommended by (183)

Finally, we multiplied the unit cost by the number of testing episodes of that type to obtain individual-level subsidy per test type. We then summed the subsidy per test for every individual to obtain total individual-level subsidies.

Step 5: Estimating population-level subsidies and equity
To obtain population-level subsidies, we ranked the population by their SES and split the population into quintiles. Then, individual-level subsidies within each quintile were summed to obtain total subsidies by quintile.

7.4.4. Equity analysis

Step 6: Assessing subsidies against need
This step involved the assessing equity in the distribution of subsidies by comparing each quintile's share of subsidies against need. Need was measured as the proportion of respondents in each quintile not reporting a recent HIV test.

We considered as equality in distribution if there was equal distribution of testing uptake and subsidies across the quintiles. Equitable distribution was when the testing uptake and the distribution of subsidies either favoured the lowest quintile or the group with the highest need. As presented earlier, poorer individuals have lower HIV testing uptake in Malawi. Therefore, an equitable distribution of HIV testing is expected to be biased towards the poorest as they have the greatest need.

Quantifying and presenting inequalities

Inequalities were quantified and presented using bar charts, concentration curves and concentration indices.

A concentration curve is a graph plotting the cumulative distribution of a health outcome such as HIV testing (y-axis) against the cumulative ranking of the population from poorest to richest (x-axis) (106). The curve has a diagonal line known as the line of equality that captures perfect equality in distribution of the health outcome (106). The distribution of the health outcome is interpreted against the line of equality. If the curve lies above the diagonal line, the intervention is considered pro-poor and vice versa.

A summary statistic of the concentration curve is the concentration index. A concentration index ranges of -1 to 1 with a negative value signifying inequality concentrated among the poor and a positive value signifying inequality concentrated among the rich (106). A value of 0 signifies equality in distribution. The further away from 0, the higher the degree of inequality.

7.5. Results

A total of 5,495 respondents were interviewed for the endline household survey: 2,909 (53%) from SoC and 2,586 (47%) from the HIVST arm. Thirty seven percent of the respondents were female. Three percent (185/5,495) of the respondents had incomplete socioeconomic data and were excluded from all analyses requiring socioeconomic variables. Table 7.2 presents a summary of the sample and testing uptake.

Table 7. 2: Sociodemographic variables and testing uptake by trial arm

Descriptive Variable		**Trial Arm**	
		Standard of Care (%)	**HIV Self-Testing arm (%)**
Sample size		2909 (53)	2586 (47)
Female		1,014 (35)	1,015 (39)
Age - median		39 years	37 years
Education	None	599 (21)	511 (20)
	Primary	1902 (65)	1703 (66)
	Secondary or higher	407 (14)	372 (14)
Recent testing		1323 (45)	1727 (67)
Socioeconomic status	Lowest	526 (19)	536 (21)
	Second	551 (20)	511 (20)
	Middle	580 (21)	482 (19)
	Fourth	581 (21)	483 (19)
	Highest	551 (20)	509 (20)
Recent testing by socioeconomic status	Lowest	190 (36)	295 (55)
	Second	292 (53)	360 (70)

	Middle	276 (48)	322 (67)
	Fourth	273 (47)	343 (71)
	Highest	229 (42)	354 (70)
Over-testing		97 (3)	149 (6)
Over-testing by socioeconomic status	Lowest	6 (271)	24 (4)
	Second	19 (3)	33 (6)
	Middle	17 (3)	33 (7)
	Fourth	27 (5)	36 (7)
	Highest	23(4)	21(4)

7.5.1. Utilisation incidence analysis

As indicated earlier, recent testing was higher in the HIVST arm than SoC. This was observed across all socioeconomic quintiles in the HIVST arm when compared to SoC. Across both arms, testing uptake was lowest in the lowest quintile; 36% in SoC and 55% in the HIVST arm. Testing uptake was highest in the second quintile in SoC (53%) and in the fourth quintile in the HIVST arm (71%).

There was a comparable gap in testing uptake between the quintiles reporting the highest and lowest proportion of respondents recently tested across the trial arms. In SoC, there was a 17% gap between the quintiles with the highest and lowest testing uptake. This gap was 16% in the HIVST arm.

When split by gender, recent testing was higher among women than men across both arms. Testing among men in SoC was highest in the second quintile (49%) and lowest in the poorest quintile (28%). This translated to a gap of 20% between the quintiles with the highest and lowest proportion of respondents reporting a recent test. The gap in SoC was larger than that in the HIVST arm. The fourth quintile mong men in the HIVST arm had the highest proportion of respondents reporting a recent test (69%) against 55% in the poorest quintile, translating to a gap of 14%.

When we observed testing among women in SoC, the second and fourth quintiles had the highest proportion of respondents reporting a recent HIV test. Similar to men, the lowest quintile had the least proportion of respondents reporting a recent test (40%). This translated to a gap of 17% in SoC against a gap of 25% in the HIVST arm. The fifth quintile had the highest proportion of respondents reporting a recent test in the HIVST (80%) against 55% in the lowest quintile.

Over-testing was twice as high (6%) in the HIVST arm than SoC (3%). The lowest quintile had the least proportion of respondents reporting over-testing for HIV in SoC, 1%. The lowest and highest quintiles in the HIVST arm had the least proportion of respondents reporting to have over-tested for HIV, 4%. The proportion of respondents reporting to have over-tested by gender in SoC was 4% among women and 3% among men. This proportion was comparable between the genders in the HIVST arm, 6%. Men in the bottom two quintiles in SoC did not report over-testing for HIV against 3% and 8%, respectively among men in the bottom two quintiles in the HIVST arm.

7.5.2. Assessment of equality in testing uptake by trial arm

Figure 7.1. presents concentration curves for recent testing by trial arm. Concentration curves for testing uptake in both arms were clustered around the line of equality showing equality in the distribution of testing. Concentration indices associated with both concentration curves were also clustered around equality 0.01 (95% CI: -0.03 – 0.04) for SoC and 0.04 (95% CI: 0.02 – 0.07) for HIVST arm (Table 7.3). The concentration index of the HIVST arm was significantly different from zero demonstrating slightly higher inequality in the HIVST arm.

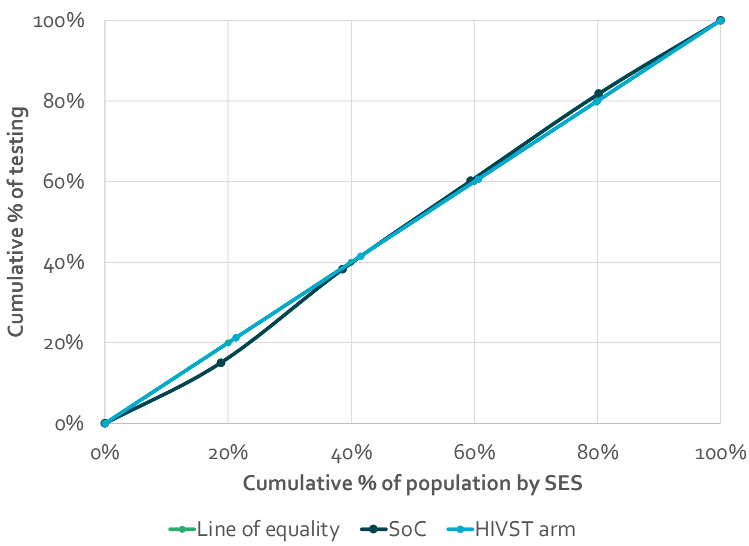

Figure 7. 1: Concentration curves showing recent testing by trial arm

Figure 7.2. presents concentration curves by gender. Concentration curves for men in both trial arms were below the line of equality demonstrating distribution concentrated among the richer. The concentration curve for men in the HIVST arm was slightly further away from the line of equality showing a higher concentration of testing uptake among the richer when compared to SoC. Concentration index (gender analysis results not presented here) for recent testing among men in HIVST arm was 0.02 (95% CI: 0.01 – 0.04) while that of SoC was 0.00 (95% CI: -0.04 – 0.04).

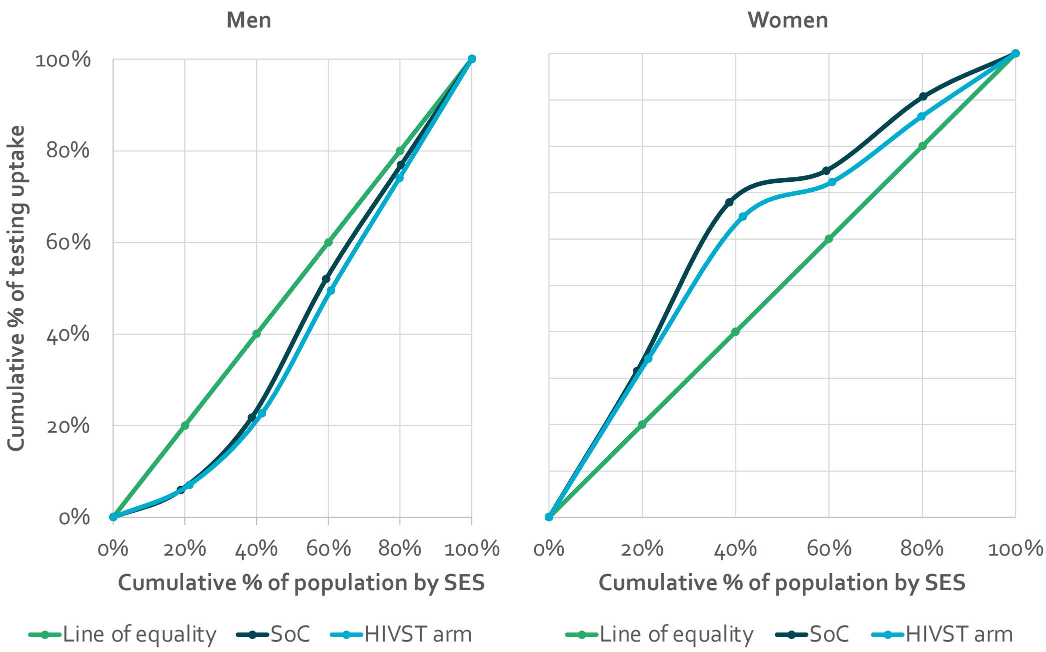

Figure 7. 2: Concentration curves showing the distribution of recent testing by gender

Concentration curves for recent testing among women on the other hand, were above the line of equality in both trial arms demonstrating testing uptake concentrated among the poorer. The concentration curve among women in the HIVST arm was closer to the line of equality than in SoC, demonstrating less degree of pro-poor distribution in the HIVST arm.

Figure 7.3. presents concentration curves for the distribution of over-testing by trial arm. In SoC, over-testing was concentrated among the richer with the concentration curve below and further away from the line of equality. The concentration curve for over-testing in the HIVST was closer to the line of equality demonstrating that everyone regardless of SES had a similar likelihood to over-test in the HIVST arm. Concentration index for over-testing was positive and larger in SoC, 0.17 (95% CI: -0.02 – 0.36) than in the HIVST arm, 0.00 (95% CI: -0.12 – 0.12). This demonstrated a higher degree of inequality in the distribution of over-testing concentrated among the richer in SoC than the HIVST arm.

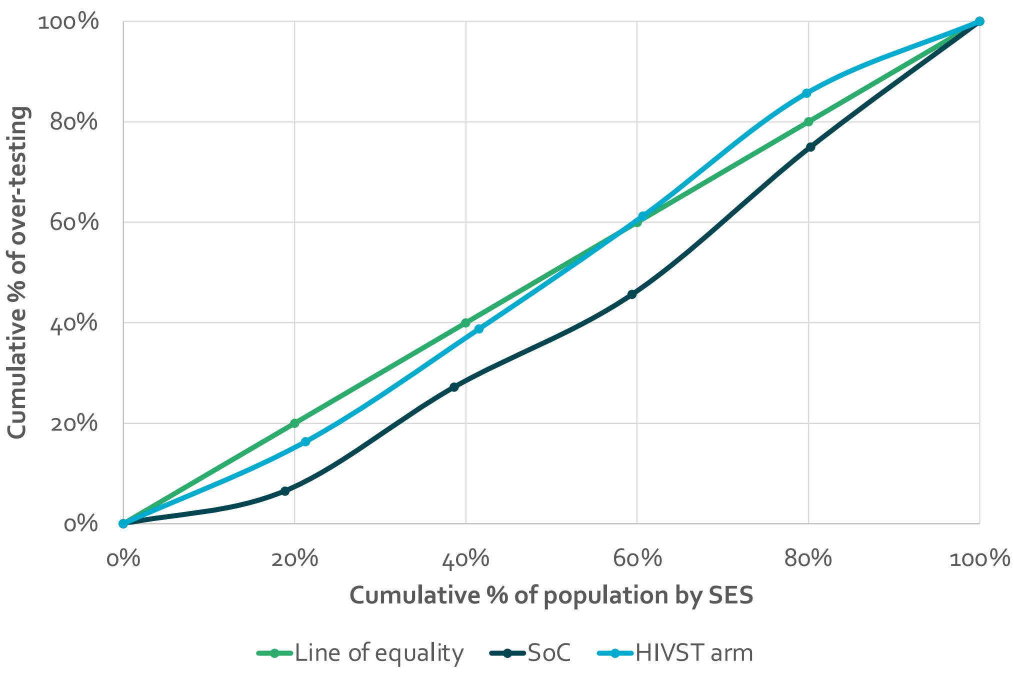

Figure 7. 3: Concentration curves showing the distribution of over-testing by trial arm

Figure 7.4. presents concentration curves of over-testing by trial arm and gender. Concentration curve for over-testing among men in SoC was below and further away from the line of equality. This demonstrated that over-testing among men in SoC was heavily concentrated among the richer. The concentration curve for over-testing for men in the HIVST arm was initially below the line of equality showing a concentration of over-testing among the richer before overlapping with the line of equality. Similar to the full sample analysis, this showed that only the richer men were likely to over-test for HIV in SoC while all men regardless of SES were likely to over-test in the HIVST arm. Concentration index for over-testing among men in SoC [0.28 (95% CI: 0.08 – 0.48)] was larger than that of HIVST arm [-0.07 (95% CI: -0.22 – 0.09)]. This demonstrated a higher concentration of over-testing for HIV among richer men in the SoC than HIVST arm.

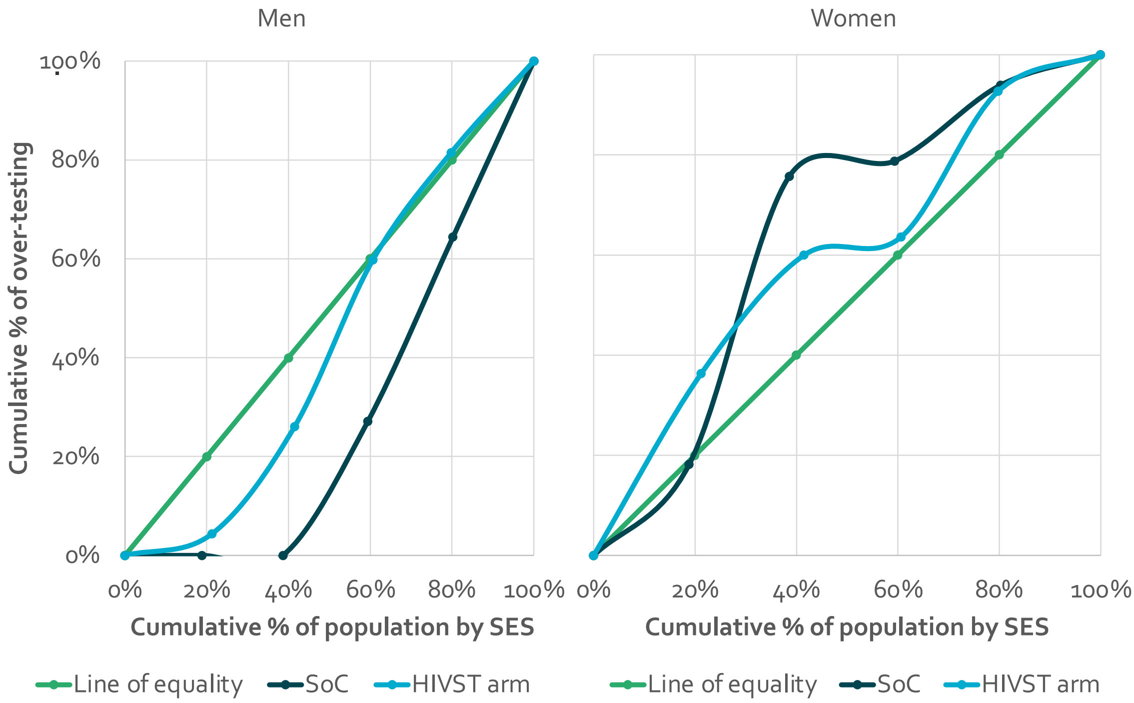

Figure 7. 4: Concentration curves showing the distribution of over-testing by trial arm and gender

Concentration curves for over-testing for women in both trial arms were above the line of equality showing concentration of equality favouring the poorer. It was not clear which curve dominated the other by simply observing the concentration curves. The values of concentration index for women in the HIVST arm was slightly larger [-0.08 (95% CI: -0.20 – 0.36)] than that of SoC [-0.06 (95% CI: -0.07 – 0.18)]. This demonstrated a more propoor distribution of over-testing among women in the HIVST arm when compared to SoC.

Table 7. 3: Concentration indices

Testing uptake	Trial arm	Index Value	95% Confidence Interval		n
Recent testing	Standard of care	0.01	-0.03	0.04	2789
	HIV self-testing arm	0.04	0.02	0.07	2521
Over-testing	Standard of care	0.17	-0.02	0.36	2789
	HIV self-testing arm	0.00	-0.12	0.12	2521
Subsidies	Standard of care	0.01	-0.04	0.06	2789
	HIV self-testing arm	0.07	0.03	0.12	2521

7.5.3. Determinants of testing and over-testing for HIV

We applied a random effects multinomial logistic regression of testing uptake. Table 7.4. presents results of this analysis. Uptake of testing was positively associated with belonging to the HIVST arm, an interaction of trial arm and SES, being married, and user costs. Uptake of testing on the other hand, was negatively associated with increasing age and being male.

Over-testing for HIV was positively associated with belonging to the HIVST arm, SES, being married and increasing user costs.

Table 7. 4: Determinants of testing and over-testing for HIV

Dependent Variable (n=5,306)	Independent Variables	Coefficient	P-Value	95% Confidence Interval
Recent testing	HIVST arm	0.49^{**}	0.027	0.06 - 0.92
	Age	-0.05^{***}	0.003	(-)0.081 - (-)0.02
	Age^2	0.00	0.277	(-)0.00 - 0.001
	Male	-0.37^{***}	0.001	(-)0.59 - (-)0.16
	Wealth Quintile			
	II	0.272	0.295	(-)0.24 - 0.78
	III	0.216	0.392	(-)0.28 - 0.71
	IV	0.110	0.728	(-)0.51 - 0.73
	V	-0.091	0.784	(-)0.75 - 0.56
	HIVST arm*Wealth Quintile			
	HIVST*II	0.30	0.335	(-)0.37 - 0.91
	HIVST*III	0.10	0.742	(-)0.54 - 0.68
	HIVST*IV	0.56^{**}	0.036	0.05 - 1.13
	HIVST*V	0.86^{**}	0.018	0.15 - 1.57
	Education			
	Primary education	0.22	0.309	-0.20 - 0.64
	Incomplete secondary	0.15	0.644	(-)0.47 - 0.76
	Secondary or higher	0.30	0.354	(-)0.34 - 0.94
	Literate	-0.09	0.603	(-)0.45 - 0.26
	Self-rated health			
	Fair or Good	0.04	0.824	(-)0.33 - 0.41
	Very good	-0.06	0.764	(-)0.44 - 0.32
	Multiple sexual partners	-0.04	0.765	(-)0.29 - 0.22
	Married or living as married	0.36^{***}	0.000	0.16 - 0.56
	User costs	2.43^{***}	0.000	1.37 - 3.49
Over-testing	HIVST arm	2.01^{***}	0.001	0.80 - 3.22
	Age	- 0.06	0.107	(-)0.12 - 0.02
	Age^2	0.00	0.653	(-)0.00 - 0.0008
	Male	(-)0.43	0.156	(-)1.03 - 0.17
	Wealth Quintile			
	II	0.96^{*}	0.056	(-)0.02 - 1.94
	III	0.85	0.153	-0.32 - 2.01
	IV	1.32^{**}	0.013	0.28 - 2.36
	V	1.03^{*}	0.098	(-)0.19 - 2.25
	HIVST arm*Wealth Quintile			
	HIVST*II	(-)0.41	0.503	(-)1.61 - 0.79
	HIVST*III	(-)0.54	0.323	(-)1.61 - 0.53
	HIVST*IV	(-)0.63	0.298	(-)1.82 - 0.56
	HIVST*V	(-)0.74	0.327	(-)2.21 - 0.74
	Education			
	Primary education	0.15	0.585	(-).39 - 0.70
	Incomplete secondary	0.44	0.364	(-).51 - 1.30
	Secondary or higher	(-)0.32	0.502	(-)1.24 - 0.61
	Literate	0.11	0.755	(-)0.56 - 0.78
	Self-rated health			

Fair or Good	0.47	0.302	(-)0.42 - 1.36
Very good	0.42	0.483	(-)0.74 - 1.57
Multiple sexual partners	(-)0.06	0.816	(-)0.56 - 0.44
Married or living as married	0.56*	0.038	0.03 - 1.10
User costs	2.43***	0.000	1.32 - 3.55

***Significant at 1% level of significance **Significant at 5% level of significance

*Significant at 10% level of significance

7.5.4. Subsidies through HIV testing

Subsidies were higher in the HIVST arm than in SoC, US$14,255.85 (95% CI: US$13,705.11–14,806.60) versus US$10,253.32 (95% CI: US$9,810.84 – 10,695.79). A t-test comparing mean subsidies received by respondents in each arm showed a statistically significant difference at 1% significance level. This means that on average, respondents in the HIVST arm received higher subsidies than in SoC.

The share of subsidies received in both arms was highest in the fifth wealth quintile and lowest in the first quintile. Across both arms, the highest quintile received 22% of subsidies while the lowest received 17% of subsidies. The difference in mean subsidies received in the lowest and highest quintiles was US$0.47 [95% CI; (0.97) – 0.04] in SoC and US$2.00 [95% CI: (2.68) – (1.33)] in the HIVST arm. These differences were statistically significant at 10% and 1% level of significance in SoC and HIVST arms, respectively.

Subsidies for both men and women were higher in the HIVST arm than SoC. Subsidies from over-testing were twice as high in the HIVST arm than SoC: US$1,768.23 (95% CI: US$1,507.37–2,029.08) versus US$908.05 (95% CI: US$728.18 – 1,087.91). Subsidies from over-testing accounted for 6% and 11% of total subsidies in SoC and the HIVST arm, respectively. The highest quintile in SoC had the highest share of subsidies from over-testing, 36%. This was in comparison to a share of 8% from over-testing in the lowest quintile. In the HIVST arm, the third and fourth quintiles had the highest share of subsidies from over-testing (25% each). The lowest quintile had the least share of subsidies from over-testing, 14%.

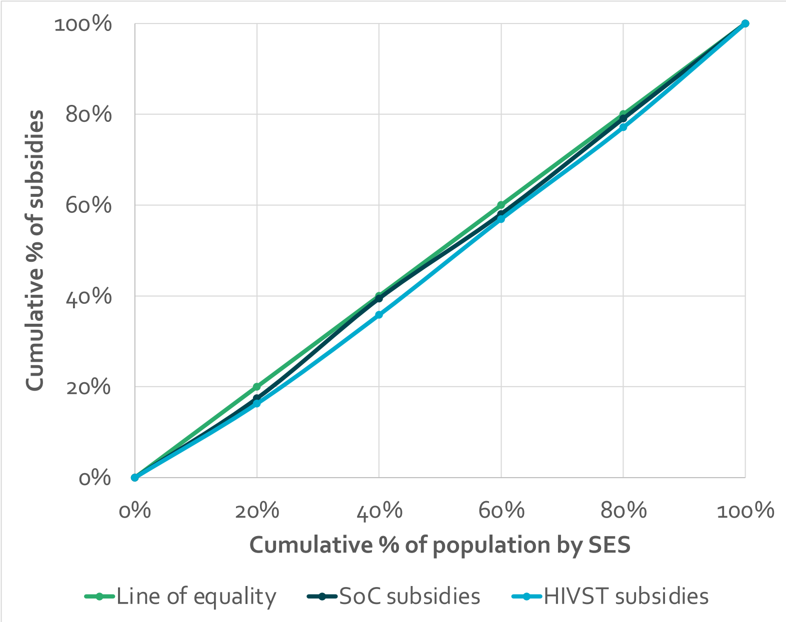

Figure 7. 5: Concentration curves showing the distribution of subsidies across trial arms

Similar to recent testing, concentration curves for subsidies in both SoC and HIVST arms were clustered around the line of equality showing equality in the distribution of subsidies in both arms (Figure 7.5). Concentration index for the distribution of subsidies was larger in the HIVST arm, 0.07 (95% CI: 0.03 – 0.12) than in SoC, 0.01 (95% CI: -0.04 – 0.06).

When this distribution was disaggregated by gender (Figure 7.6), concentration curves for the distribution of subsidies among women were above the line of equality while that of men were below the line of equality. This showed that subsidies from HIV testing were concentrated among the poor for women in both trial arms. It further showed that distribution of subsidies among men was concentrated among the richer for men in both trial arms. The dominating effect between the concentration curves among both men and women in both trial arms was not clear. The concentration index for the distribution of subsidies among men in the HIVST arm was 0.04 (95% CI: -0.01 – 0.10) and 0.02 (95% CI: -0.04 – 0.08). This showed a slightly higher concentration of subsidies among richer men in the HIVST arm than SoC. The concentration index in the distribution of subsidies among women was higher in the HIVST arm, 0.08 (95% CI: 0.02 – 0.15) than among women in SoC, 0.04 (95% CI: -0.05 – 0.13). This demonstrated a higher degree of concentration of subsidies among women in the HIVST arm than SoC.

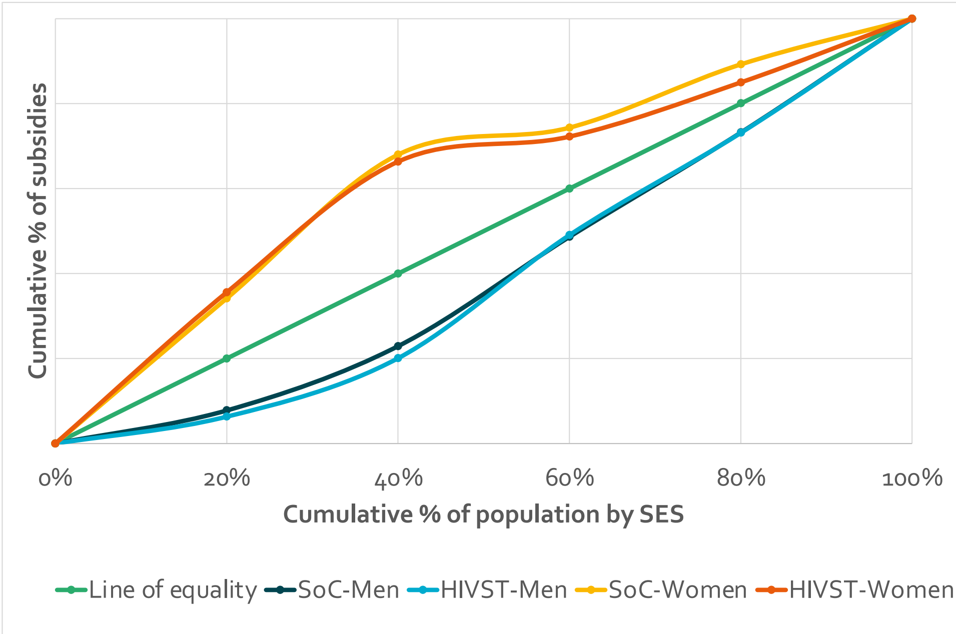

Figure 7. 6: Concentration curves showing the distribution of subsidies across trial arms and gender

7.5.5. Distribution of subsidies against need

Figure 7.7. presents the distribution of subsidies against need (proportion of respondents per quintile not reporting a recent test) per trial arm. Despite the HIVST arm reporting a lower absolute number of respondents not to have recently tested for HIV, the poorest quintile in the HIVST arm was worse-off than the poorest quintile in SoC. Of all respondents reporting not to have recently tested in the HIVST, 28% were in the poorest quintile. This was against 22% in SoC. Despite this, the poorest in the HIVST arm only received 16% of subsidies. This showed a greater degree of inequitable distribution of subsidies in the HIVST arm than SoC.

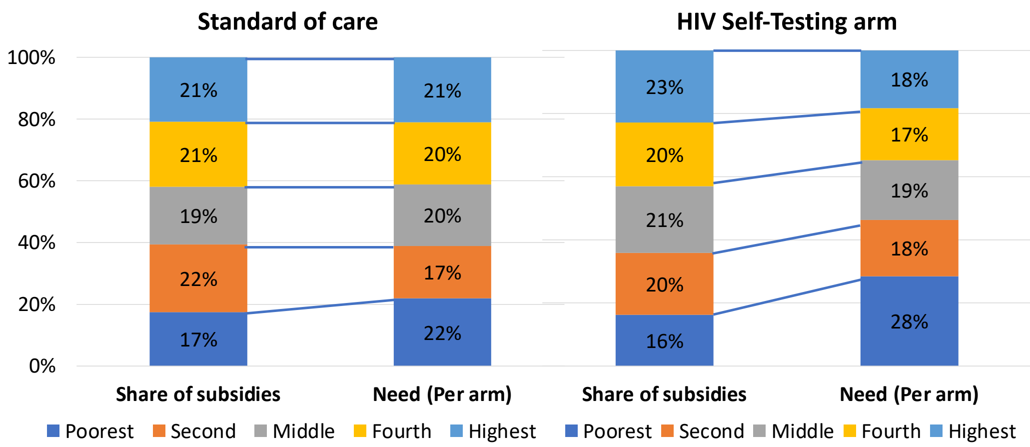

Figure 7. 7: Distribution of subsidies against proportion of respondents not reporting a recent HIV test (need) by trial arm.

7.6. Chapter discussion

This paper was a secondary analysis of the impact of community-based distribution of HIVST on socioeconomic equity in uptake of HIV testing and subsidies obtained through HIV testing in Malawi. Recent testing, over-testing and subsidies obtained through testing for HIV were higher in the HIVST arm than in SoC. Factors influencing uptake of HIV testing included belonging to the HIVST arm, age, gender, effect of the trial arm was also influenced by SES (interacting trial arm and SES), marital status and user costs. Determinants of over-testing for HIV included belonging to the HIVST arm, SES, marital status and user costs.

We had hypothesised that HIVST may be taken up quicker by the richer with the poorer lagging as suggested by the theory of diffusion of innovation and the inverse equity hypothesis (71, 164). Our results suggest that community-based distribution of HIVST may be in line with the theory of diffusion of innovation and the inverse equity hypothesis. HIVST improved testing uptake when compared to SoC. When we focussed on HIVST arm alone (see Table 7.2. and Figure 7.2.), the lowest quintile had the least proportion of respondents reporting a recent test: 55% in the lowest quintile as opposed to 70% in the highest quintile. In addition, the gap between share of subsidies and need was highest in the lowest quintile (12%) demonstrating that the poor were increasing lagging behind the higher socioeconomic quintiles.

A second finding was that full sample analyses concealed gender inequalities in testing uptake and the distribution of subsidies from testing. The full sample concentration curves for the distribution of testing uptake and subsidies for both trial arms were clustered around the line of equality. This is despite the gender analysis showing clear socioeconomic inequality in uptake of testing and distribution of subsidies. It is important for equity evaluations to present disaggregated results by a variable of interest such as age and gender to avoid concealing such disparities.

The gender disaggregated concentration curves further showed an important difference in access to testing between men and women. Women's concentration curves for recent testing, over-testing, and subsidies from testing for HIV were concentrated among the poor regardless of trial arm. This was unlike men's concentration curves where testing was concentrated among the richer. There are two possible explanations for this. First, men in Malawi incur higher user costs to testing than women (58). These user costs could be hindering access especially among poorer men. The other explanation is that women have better access to HIV testing services than men (2, 4-9). Women in reproductive ages access testing through antenatal care services and as they seek childcare (9, 56, 249) among other options. This enables women to have better testing uptake than men.

We propose improved targeting in the provision of HIV testing services favouring the poor and men. This targeted provision of testing was also validated by the analysis of the distribution of subsidies against need. We have demonstrated a mismatch between the distribution of subsidies and the proportion of respondents not reporting a recent test (Figure 7.7). The poorest were left behind across both arms.

Increased targeted testing to the poor can be done through different approaches such as workplace distribution of HIVST. The workplace approach is likely to reach the poor if it includes both formal and informal workplaces. HIVST distribution models have evolved over time to include better targeted approaches than the early community-based distribution model that we have analysed here (55, 64). Additional context specific models should also be considered to ensure people with need for testing are not left behind.

We were also concerned with over-testing as a moral hazard effect from the distribution of HIVST. Over-testing introduces potential waste in the provision of and access to HIV testing services. Significant resources may be going to over-testing and thereby increasing programme costs. For instance, only 6% of the respondents in the HIVST arm had over-tested for HIV but this translated to 11% of total subsidies in the HIVST arm.

An important question with HIVST is if we should be overly concerned about this amount of over-testing. The proportion of over-testers and subsidies in the HIVST arm is comparable with assumptions around wastage used in a cost-effectiveness analysis of HIVST in South Africa where wastage in a fixed-point distribution model of HIVST was assumed to be 11% (246). In addition, this amount of over-testing is lower than rates reported elsewhere (47). As such, the amount of over-testing though demonstrating inefficient allocation of resources is within expected rates with HIVST.

In this paper, we further evaluated determinants of testing and over-testing for HIV. The mixed effects multinomial logistic regression analysis showed that trial arm, age, gender, SES, marital status and user costs are significant determinants of testing and over-testing for HIV. Our analysis is in line with other findings on determinants of testing in the region (9, 13, 15, 45, 56).

We also evaluated the distribution of subsidies from HIV testing. It was not surprising that HIVST arm subsidies were higher than those of SoC. This is because HIVST arm had a higher uptake of testing than Soc in addition to HIVST kits (Oraquick®) costing more than finger-prick testing (Determine™). Subsidies are also a function of frequency of testing. The higher subsidies in the HIVST arm may also show that not only was testing uptake higher in the HIVST arm, but testing was also more frequent than in SoC.

The equity analysis that compared distribution of subsidies against need showed that the poorest individuals in each trial arm were left behind with testing with the degree of inequity greater in the HIVST arm. This implies inequity in the distribution of subsidies which should be addressed to ensure social justice (fairness and justice). With time, we expect the poorest quintile to catchup with the other quintiles but initiatives to improve their testing would speed up thee catching up process.

Finally, the concentration curves for subsidies by gender echoed the gender recent testing concentration curves. Women's concentration curves for subsidies in both arms were pro-poor. Men's concentration curves for subsidies in both arms were pro-rich. We suspect that the pro-poorness in the distribution of subsidies among women was likely due to women accessing testing through antenatal care (ANC). Due to ANC, poor women have been able to access testing unlike men who appear to have an access challenge. Men with higher SES are accessing testing better and more frequently than those of lower SES hence the pro-richness in the distribution of subsidies among men. Ensuring that all men regardless of SES are reached with testing is essential to ending the AIDS epidemic as a public health threat by 2030.

7.7. Chapter limitations

There are a number of limitations to this study. The first is that we were not able to compare socioeconomic equity in testing uptake and over-testing for HIV in the baseline and endline surveys. Different sets of socioeconomic variables were collected during the two surveys making a head-to-head comparison not possible. The set of socioeconomic variables included in the baseline survey did not perform well in differentiating the socioeconomic quintiles. As such, we asked a different set of socioeconomic variables in the endline to be able to distinguish across the socioeconomic quintiles.

There is also a possibility that the improved testing uptake through HIVST distribution may have contributed to improved SES. Residents screening positive for HIV may have sought additional care and were linked to ART allowing them to be more productive. The trial was implemented for only a year and newly initiated PLHIV are often not considered virally suppressed until after six months of uninterrupted treatment. Therefore, such an effect if there, would have only marginally improved SES during the implementation period.

Another limitation is the potential reporting bias introduced by capturing testing uptake using self-report. HIV status or reporting bias may have influenced reporting of HIV testing as well as frequency of testing. Unfortunately, we could not link actual facility-based testing and HIVST distribution data with the survey respondents to allow us to validate the self-report.

In addition, individuals included in this study were from a relatively socioeconomically homogeneous population. We used a short index to measure SES in a group that is homogeneous and thereby potentially affecting our ability to distinguish the poor from non-poor. It is also possible that despite some participants being categorised as belonging to the highest wealth quintile, they may not be very different from the quintiles immediately below them.

An additional limitation with is work is on the definition of moral hazard. We adopted a definition based on HIV testing policies and funders' recommendations. Such a definition may not ably accommodate social gains associated with over-testing as it is more focussed on efficiency that is, resource allocation and private marginal gains. As acknowledged earlier, over-testing may be associated with higher social gains which may be lost when we limit the annual number of HIV tests. However, in a low resource setting such as Malawi it is important to ensure efficient use of resource despite such potential social gains from existing inefficiencies.

The analysis of over-testing was also based on norms for low-risk general population. The population in the survey were broadly general population, which will include a portion of high-risk individuals. We did not collect information on the risk behaviours of respondents over-testing for HIV. As such, we assumed that all over-testing observed was unnecessary and therefore, wastage. However, there may be high risk populations in our sample to whom frequent testing is necessary. Higher rates of over-testing among higher risk individuals is recommended and efficient and cannot be removed in this analysis. Moreover, broadening the target group may have the benefit of reducing testing stigma, that in turn can increase uptake of testing among key and vulnerable populations.

Finally, we used costs of HIV testing with an implicit assumption of head-to-head comparison between HIVST and facility-based testing. However, there is a difference in the maturity and intensity of testing between these two approaches that is likely to influence the costs. The facility-based testing was a mature programme that has gained from learning by doing, economies of scale and scope. HIVST was a new intervention that was implemented as part of a trial. The unit cost of distributing HIVST used in this study is likely to be higher than it would have been if observed when HIVST was scaled-up. There is a caveat to this in that, use of HIVST in early introduction may be higher than in a mature programme, due to novelty use (71, 157). We repeated the analysis using conventional testing unit costs. The amount of subsidies in the HIVST were lower than when we used the HIVST unit costs. However, overall findings in the distribution of subsidies remained unchanged despite the lower monetary value of subsidies.

7.8. Chapter conclusion

This is a first study to concurrently study the impact of freely distributed public health products on equity in uptake, moral hazard and BIA. While free distribution of HIV testing reduces financial barriers of HIV testing across the population, the poorest quintile showed the lowest uptake and the lowest share of subsidies. Excess use, in terms of repeated testing in general populations was relatively highest among those in higher SES strata. While it is critical to maintain free access to HIV testing to link all people to treatment and prevention, a differentiated market, that introduces branded testing targeting the middle classes may show promise for reducing overuse among the better off.

The next chapter relates these findings to the entire thesis work. In chapter 8, I also discuss the other three objectives of the thesis and policy implications of the same.

Chapter 8: Thesis discussion and policy implications

8.1. Introduction

This thesis evaluated the impact of distributing HIVST on costs, uptake, and equity in testing HIV testing. The backbone of the thesis was an efficiency analysis that fed into an equity analysis. This chapter critically assesses the major findings of this thesis, discusses the relevance of these findings to research and policy, presents areas for future research and the main strengths and limitations of this research work. Finally, I also reflect on things I would have done differently with hindsight.

8.2. Major findings

In this section, I present a summary for the major findings of this thesis. The overall aim was to explore efficiency and inequalities in HIV testing services in Southern Africa with an added emphasis on Malawi. This thesis' approach offers an empirical and methodological contribution to the field of economics by demonstrating how economic evaluations can combine efficiency and equity concepts. The combination of the concepts is also useful to policy makers who can address questions of efficiency in resource allocation and determine if the resources are being allocated according to need. Here, I present a summary of the major findings from each of the chapter.

8.2.1. Major findings from Chapter 4: Constructing and validating a standard of living index for low-income settings such as Malawi

In Chapter 4, I developed and validated an index that can be used to measure SES in a low-income setting such as Malawi. I used a publicly available dataset to develop the index and applied the approach used in Demographic Health Surveys.

The main finding from this chapter is that SES can be measured using a multidimensional index that is comparable to other wealth indices such as the DHS wealth index and the MPI. Unlike the DHS wealth index, our index has fewer number of indicators allowing for easier incorporation in epidemiological surveys. Another advantage over the DHS wealth index and which is a similarity to other multidimensional indices such as the MPI is that our index incorporates human capital variables thereby being a better reflection of the multidimensional nature of poverty.

However, unlike how other multidimensional indices are often applied, our index categorises individuals into quintiles as opposed to a binary categorisation (203, 272). This then moves the focus from whether an individual is below or above some threshold to the socioeconomic distribution of the population in the different groups. It also allows for a more nuanced comparison of the population.

In addition, I sought to develop an area-based measure of SES by acknowledging the difference in access to certain services and the interpretation of ownership of certain assets between urban and rural areas. I constructed a short standard of living index for Malawi with an added advantage of national-level, rural and urban indices. This allows researchers working in urban and rural areas, or national level to decide which index to use. The limitation with using an area-based index is that it does not allow for easy comparison between urban and rural residents (207). Study specific objectives should help determine which of the indices to use.

8.2.2. Major findings from Chapter 5: Importance of exploring user costs as a deterrent in uptake of care

In Chapter 5, I explored the affordability dimension of access by evaluating costs of accessing HIV testing services across four districts in Southern Malawi. One of the main findings from this chapter is the magnitude of user costs in these rural communities. Reported costs of accessing HIV testing services were twice as high among men than women.

High costs of seeking care including HIV care even where care is provided free of charge have also been observed in other studies in Malawi (223, 273, 274). Even where services are provided free of charge, the cost of transport and the opportunity cost of time have been shown to affect uptake of HIV care (275).

In our study, indirect costs, especially lost income, were higher than direct costs. This demonstrates the role of opportunity costs in dissuading access to care even in settings where healthcare services are provided free of charge. Higher indirect costs of seeking care when compared to direct costs were also reported in malaria treatment seeking in Ghana (276). A study in an agricultural community in reported higher opportunity cost of seeking care during the rainy season (277). Our study did not explicitly factor for seasonality, but we expect the opportunity cost of seeking testing to also be higher during the rainy season as a large proportion of our study population were engaged in farming both on their own farms and as casual labourers.

Another major finding from this chapter was the importance of the approach of estimating lost income in determining costs. In our sample, men on average reported higher lost income than women. A sensitivity analysis comparing three approaches of estimating lost income demonstrated that women in our sample may have underestimated their lost income. This was expected, as a relatively higher proportion of women in our sample were likely not engaged in formal employment. However, despite the approach of measuring lost income employed, the opportunity cost of time remained as an important cost driver. A similar observation was noted by Su *et al*. (2013) who reported higher indirect costs than direct costs regardless of the method of estimating lost income applied (277).

8.2.3. Major findings from chapter 6: Costs of providing HIV testing services

In chapter 6, I conducted a descriptive analysis of costs of providing HIVST testing services. This was an evaluation of three HIV testing approaches: facility-based provider HIV testing, community-based distribution of HIVST and facility-based integration of primary and secondary distribution of HIVST. Costs were evaluated from a provider's perspective combining bottom-up and top-down costing approaches.

The costs of providing HIV testing services were lowest in facility-based HIV testing in Malawi (US$5.77) and highest in facility-based secondary distribution of HIVST in South Africa (US$15.09). Our findings are in line with costs observed in other studies where secondary distribution of HIVST was the least cost-effective distribution modality (86). Regardless of the HIV testing modality, cost of test kits and personnel were some of the key cost drivers. A similar observation was noted in facility-based testing and community-based distribution of HIVST in Zambia and Zimbabwe (92, 230). Overall, HIVST regardless of distribution modality costed more than facility-based provider testing.

The WHO recommendation for HIVST was to introduce HIVST as a complement to existing testing services. Therefore, national testing guidelines need not implement HIVST as the main testing approach as this may indeed translate to replacing a more affordable approach with a more expensive alternative. HIVST should be implemented as a supplement to reach populations left behind who may not be easily reached by conventional testing approaches. The presentation of costs of three HIVST distribution approaches (community-based, primary, and secondary distribution) shows the versatility of distribution approaches associated with HIVST. There are additional HIVST distribution alternatives (52, 55, 64) available with the three presented here acting as examples of distribution approaches.

The dilemma of rationing HIVST is however being removed. In 2022, the WHO announced a drop in the price of HIVST to US$1.00 in LMICs (278). This price negotiation makes the price of HIVST in most cases as comparable to many HIVST screening tests currently being used in LMICs. This reduced price combined with higher degree of integration of HIVST to existing testing approaches with minimal involvement of facility staff and distribution of HIVST outside of trial and research settings will reduce costs of distributing HIVST even further.

8.2.4. Major findings from chapter 7: Equity evaluation

Chapter 7 explored inequalities and inequities in the distribution of HIV testing and subsides from testing.

The first finding from this chapter is the importance of incorporating equity considerations in decision making. As introduced in chapter 3, there tends to be an emphasis on efficiency in economic evaluations when informing health sector priorities (180). Such economic evaluations do not place an explicit consideration on equity (279). However, as countries approach the last mile in ending AIDS as a public health threat, an emphasis on efficiency alone disregarding equity is likely to be suboptimal. If the poor face high access barriers, it is possible for service provision targets to be met while widening socioeconomic inequalities (275). That is, national-level reports will demonstrate increased uptake of testing but there will still be subgroups of the population (the poorest individuals) not reached with testing.

With regards to HIV/AIDS, there have been increased effort to make services such as ART more widely available (280). However, increased availability alone does not guarantee uptake across all patient spectrum (280). Therefore, efficiency goals alone while important, are not sufficient to ensuring uptake across all patient types. In this thesis, I have shown that despite HIV testing services being provided free of charge, the poor were left behind. Such an observation is important to ensuring improved population/area targeting in service provision.

The second finding of note in this chapter is the importance of exploring inequalities relative to need. There are few studies that explore inequalities relative to need (275). In this thesis I not only evaluated the distribution of testing uptake and subsidies from testing, but also this distribution against need. This allows for an assessment of whether the distribution of benefits from testing was appropriate (281). Such an evaluation is in line with the vertical equity form of the egalitarian goal presented in chapter 2 (99, 101).

An equity evaluation without considering need, implicitly assumes same degree of need across all quintiles (281). This is especially problematic as there is both a social gradient in health, and an inverse relationship between the availability of good medical care and need (136, 138, 139, 160). The existence of a social gradient in health and the inverse care law both demonstrate greater need for healthcare among the poorest groups. Not explicitly considering need in health sector resource allocation may worsen healthcare access among the poorest groups and in turn increase inequalities.

Similar to finding 2 above, is the finding that uptake of HIV testing in the context of HIVST is consistent with the inverse equity hypothesis. The inverse equity hypothesis argues that new health interventions are initially adopted by the wealthier groups before trickling down to the poorer groups (164, 166). This is problematic as the poor often have greater health needs than the richer due to the existence of the social gradient in health, among other reasons (136, 138, 139). Therefore, any degree of inequity in testing uptake facing the poor is not only unfair and unjust, but also a detriment to HIV/AIDS epidemic control.

The inverse equity hypothesis also applied to HIV testing services in another study in Malawi which reported lower use of facility-based testing among the poorest groups (275). There are several reasons for this, including, high financial and non-financial barriers to access that disproportionately affect the poorest groups (275).

With the provision of HIVST, the theory of diffusion of innovation may also explain why the poor were not taking up testing at the rate as the wealthier groups. Information on new technologies passes specific social systems and communication channels (157). There is a possibility that such systems and channels are not effectively reaching the poorest groups. The inverse equity hypothesis, however, is not limited to HIV testing alone. The scale-up of HIV treatment has also raised concerns of the poorest groups being left behind (280).

The final finding from this chapter is the importance of moving beyond a full sample to a subgroup analysis. Here, I showed that full sample analyses can conceal existing inequalities. Observation of recent testing and subsidies from testing for HIV in the full sample showed high socioeconomic equality in the distribution. However, a disaggregation by gender showed that recent testing and subsidies from testing were concentrated among the poor in women but among the richer in men. This shows an access concern among poorer men.

8.3. Contribution to knowledge

This section presents this thesis' key contributions to empirical findings and methods.

Contribution to empirical findings

This thesis contributes knowledge to the need, implementation and scale-up of HIVST in low-and-middle income settings. The first objective of this thesis showed the important role played by direct and indirect user costs in affecting uptake of testing. It may be easy to make a sweeping generalisation that men may not be interested in testing. Men face uptake barriers different from women including higher user costs. This finding contributes to knowledge on targeting approaches for men and implementation of such targeting initiatives. Testing initiatives targeting men would need to factor in the opportunity cost to seeking care.

Objectives one and two together show the importance of conducting cost evaluations alongside implementation. The user cost analysis not only strengthened the case for HIVST but also informed the providers on how much user costs would be offset if HIVST is scaled-up.

The provider cost analyses further contextualise the costs of HIVST by comparing HIVST with conventional testing. Furthermore, these costs can be and have been incorporated into modelling work to evaluate cost-effectiveness [(246)] and econometric work [(245)] to model scale-up implications of HIVST.

As noted in chapter 2, most studies tend to conduct modelling studies to inform resource allocation. There is an extensive number of studies exploring cost-effectiveness of HIVST such as Cambiano *et al*. (2015), Cambiano *et al.* (2019), Jamieson *et al.* (2019), Maheswaran *et al*. (2018), and Okoboi *et al*. (2021) [(85-89)]. Despite the significance of modelling and cost-effectiveness studies in resource allocation, they have limited use for policy makers interested in costs of scaling-up an intervention (282). In this thesis, I present an extensive evaluation of costs of providing HIV testing services that not only can feed into cost-effectiveness studies, but also be used by policy makers to inform scale-up- of HIVST services.

Finally, the equity chapter provides an analysis that is often not explicitly measured in public health interventions. In low-resource settings the focus is usually on efficiency of resource allocation (180). Equity concerns are also important and need not to be forgotten.

Contribution to methods

There are several contributions to methods that can be derived from this work. First, in collaboration with STAR Economics Network, I conducted extensive costing work. Costing interventions in LMICs is methodologically challenging and requires extensive field data collection and assumptions (232, 283). I presented detailed information on the data collected and their sources, assumptions made, and allocation factors used. This provides a useful template for researchers seeking to conduct cost analyses in LMICs to use.

Secondly, I demonstrated how an index of SES can be derived from existing data. The standard of living index constructed in this thesis will allow for a more practical alternative for researchers in Malawi. This approach can also be adopted and adapted by other researchers needing to generate a standard of living index for their setting. The approach uses inbuilt Stata® commands such that the researchers would not need to write their own codes. The approach can also be adapted to other user languages other than Stata® for researchers using other analysis software.

The use of BIA to one sector or disease is not frequent. Often BIA is applied to a wide range of healthcare services to track subsidies across the sector. Here, I have demonstrated that BIA can be used for a disease-specific area to show any existing inequalities in the distribution.

In addition, the equity analysis combined efficiency and equity concepts. This is not widely applied in the field of economics. Most economics work explore efficiency and equity concerns separately and not combined as I explored in this thesis. I further explored resource allocation relative to need. This, as demonstrated earlier is also a unique methodological approach that is not frequently explored. Such a combined approach is not only useful for resource allocation, but also important for evaluating the appropriateness of how those resources have been allocated.

8.4. Limitations of the thesis

There are some limitations to this thesis. Additional limitations have already been acknowledged in the specific chapters. The main limitation is on the choice of a measure of SES used in the equity evaluation. As indicated earlier, the use of a wealth index as a measure of SES was developed for practical reasons. In low-income settings such as rural Malawi, the population is highly homogeneous such that different socioeconomic groups may not be very different in reality. There is a possibility of misclassifying individuals with a wealth index when such individuals are not very different socioeconomically in practice.

The choice of using a wealth index as the measure of SES in this thesis also introduces a limitation with the generalisability of the findings outside of Malawi although the methods can be applied in other settings. A wealth index is context specific and may not be transferrable to other settings. This is different from for instance using an income-or consumption-based measure that can be converted to the international equivalent such as international dollars or the international poverty line. Another challenge with a wealth index is that it needs updating over time. This limitation also applies to the standard living index constructed in this thesis: it will require updating over time.

Furthermore, risk scores such as the standard of living index developed in this thesis tend to perform well on the derivation dataset but may not perform well elsewhere. Our inability to externally validate the index introduces a limitation in its applicability. The index performed reasonably well with IHS4 dataset but may not perform as well in other settings in Malawi. Therefore, caution needs to be taken when adopting the index to other studies. However, the high correlation of our standard of living index with the DHS wealth index shows that any misclassification may not be very far from frequently used and validated existing indices.

In addition, the development of the standard of living index was based on the DHS wealth index. The DHS wealth index was constructed based on convenience using a set of variables available in the DHS dataset. Our standard of living index could have benefitted from an additional set of indicators that were available in the IHS4 but not available in DHS datasets. However, we were interested in including indicators that were easy to collect and had been validated in the context. The DHS wealth index in this sense fitted that requirement.

Another limitation with the approach I took in this thesis is the use of self-reported user costs obtained retrospectively. It is possible that the user costs in this study may have suffered from recall bias leading to both under-and-overestimation of costs. Despite user costs being important and a potential access barrier, they are in magnitude lower than costs of hospitalisation where for instance, households had to borrow money or sell off assets to pay for treatment. Respondents would be better able to recall the larger costs for hospitalisation than for accessing testing. This is, however, likely to be at random such that any potentially overestimated costs may have been offset by the underestimated costs.

In addition, there may be a systematic bias in reporting user costs especially lost income based on gender. With men in the setting more likely to be engaged in paid employment than women, men may value their lost time higher and have a readily available cost of such time based on their lost earnings as they sought testing. An alternative to handling lost income would be imputing all respondents with US$0.00 opportunity cost value with minimum wage or GDP per capita. However, I decided not to use this approach as I would introduce an additional bias since we did not have a way of distinguishing respondents with US$0.00 opportunity cost value from those who did not know how to value or undervalued their time. To reduce such reporting bias, data collectors were trained and encouraged to probe the respondents when asking about the user costs.

Another limitation is the use of assumptions in estimating costs of providing HIV testing services. Cost and resource use data in LMICs are not readily available necessitating the use of assumptions in such analyses. Despite the inclusion of sensitivity analyses, some costs may have been affected by the assumptions applied. There has been increased work in LMICs of developing guidance organisations of the nature of the National Institute for Health and Care Excellence in the NHS UK. Such developments will entail readily available cost and tariffs for LMICs to ensure fewer assumptions associated with cost evaluations in the settings are required.

In the BIA, there was a potential bias introduced to over-testers by extrapolating their most frequent test to the remainder of their annual tests. Ideally, we should have asked the respondents to give detailed information on all their testing episodes in the preceding 12 months. This, however, would have excessively lengthened the questionnaire and required more interview time. We, therefore, only obtained data on the most recent three testing episodes and extrapolated these data to the remainder of testing episodes. Such an extrapolation may have over-estimated subsidies accruing to late adopters who also happened to be frequent testers. Such respondents may have tested using HIVST in months preceding the endline survey as this was after substantial time of HIVST distribution, while they had tested in the primary care facilities all the other previous times. Our analysis will describe all their other testing episodes as HIVST and overestimate the subsidies they received. However, late adopters make up only 16 percent of all adopters (71) and only a subset of this proportion would also be over-testers.

Finally, in the endline survey we obtained the number of testing episodes but not location of each episode. This means that we knew who had tested for HIV in the preceding 12 months, the type of test for the most recent three tests but we did not know where they had tested especially for facility-based testing. I assumed that respondents reporting facility-based testing tested within their vicinity. As such, I imputed cost of providing testing from that facility as the subsidy received by the respondent for testing for HIV. This means such individuals may have received a subsidy different from the one allocated to them in this study. As I had indicated in chapter 1, people accessing facility-based provider testing may have concerns about privacy and may not test within their vicinity (48). However, given that a large proportion of the clusters in the STAR CBDA trial were rural and that distance and transport costs are an important access barrier for rural dwellers (148, 218, 222), it is likely that majority of the respondents tested at their nearest facility.

8.5. Strengths of thesis approach

One of the key strengths of this thesis is the detailed cost analysis conducted to inform the distribution of HIVST. Costs of providing HIVST were explored for both community and facility-based approaches and for some, across multiple countries. Rarely are cost evaluations for new interventions in LMICs conducted in such detail and at such a scale. This analysis presents implementers in the settings and funders an opportunity to have a broader picture of cost implications of HIVST. It also allows for a comparison with conventional testing. By using ingredients-based costing, we offer Ministries of Health and implementers an opportunity to dissect the costs and decide on alterations that can be done to the distribution approaches to reduce provider costs.

Furthermore, a combination of distribution approaches in both trial and non-trial implementation settings also ensured that we have a better understanding of costs of HIVST. Despite a higher proportion of the costed sites belonging to the trial distribution, I present costs from both controlled and less controlled implementation setups.

Another strength of this thesis is the equity analysis. Implementation focus tend to be on efficiency with cost-effectiveness analyses accompanying the implementation. Demonstrating socioeconomic equity of a new intervention as I have presented in this thesis is a strength that should not be ignored. It allows for the understanding if resources are reaching people with the greatest need. As countries approach UNAIDS 95 targets, there are increasing calls for leaving no one behind. An investigation of impact of HIVST on equity allows for more deliberate implementation of HIVST to ensure that inequalities are not worsened and that there is minimal wastage.

The use of BIA itself is not common as the approach requires multiple data including cost and utilisation data which may not be easily available (106, 263). However, the approach allows for a unique opportunity of tracking who gains from healthcare investments. The equity evaluation in a trial setup also gave us a good opportunity to have both cost and uptake data for the BIA. An additional strength relating to the trial setup is that we were able to conduct a rigorous evaluation of the socioeconomic distribution of uptake and subsidies from testing between the trial arms.

In this thesis I was also able to evaluate over-use associated with HIVST. There have been concerns about over-testing for HIV especially with HIVST. Here, I was able to show who, in terms of gender and SES, is over-testing for HIV. This allows Ministries of Health to target the distribution of HIVST with the aim of reducing overuse and ensure improved efficiency in resource allocation.

Finally, I constructed both an area-specific (urban or rural) and a national-level standard of living index. The area-specific index allows for researchers to decide which index to use based on the population they are interested in. Researchers interested in the rural population may use the rural standard of living index while researchers working with both rural and urban populations may use the national-level standard of living index.

8.6. Implications for research

In this section, I discuss future research areas to be considered.

First, conducting the cost evaluation included in this thesis was tasking and required substantial fieldwork. Such efforts are repeated across multiple diseases. Future work would be beneficial to many health economists working in Malawi by compiling such existing costs and across multiple diseases for easy access of cost data. This is in additional to conducting additional costing work for other diseases responsible for the highest disease burden in the country.

As indicated earlier, these findings have been incorporated in broader work evaluating cost-effectiveness and scale-up of HIVST. This work has been useful and informative but there remains a gap on optimal mix of HIVST. National and international HIV guidelines have increasingly incorporated HIVST. There remains a gap in understanding an optimal mix of HIVST with conventional testing approach. As I have shown here, HIVST is prone to overuse. As such, its distribution should ensure minimal room for overuse. We do not know what this mix should be for different countries to minimise wastage. Future research and modelling work should inform such decisions.

Finally, I also developed and validated a standard of living index. As noted earlier, the index would require external validation beyond the derivation dataset. Future research work on measuring SES in Malawi should focus on using this index to different diseases and settings. This will inform the generalisability and performance of the index beyond the derivation data.

8.7. Implications for policy

The main theoretical framework driving this thesis was that not all uptake of innovation is optimal and equitable uptake. Some interventions and new technologies are prone to overuse and may be associated with increasing inequalities. Ministries of Health need to be aware of such implications and recommend population-wide uptake of new interventions with caution. Equity evaluations should be given as much priority as cost-effectiveness evaluations.

The socioeconomic equity evaluation has further shown the multidimensionality of access. Despite HIVST and conventional HIV testing being available free at the point of use, the poorest are still lagging behind other socioeconomic groups. This demonstrates that availability is not equal to access. Policy should explicitly consider and target such populations to ensure their uptake of testing.

Finally, the societal cost analysis presents an important trade-off. Costs of distributing HIVST across the various modalities are higher than the conventional testing approaches. With the fall in price of HIVST kits and the increased degree of integration of HIVST to conventional approaches, costs of distributing HIVST are expected to be lower than those reported in this thesis. Despite this expected fall in provider costs of HIVST, costs of distributing HIVST may still be higher than facility-based provider testing. The trade-off is that HIVST has the advantage of reaching populations left behind by conventional testing approaches. Such populations are likely to have high user costs. Reaching such populations is expected to cost more than the easier to reach populations such as pregnant women. With HIVST, Ministries of Health will incur higher provider costs that offset user costs. A decision should be made on each country's willingness to pay to reach the populations left behind. That is, how much of these user costs would Ministries of Health be willing to offset.

8.8. Reflections

In hindsight, there are several things I would have done differently during this PhD research work. The first would have been better aligning my PhD objectives with the wider STAR timelines. Objective 3 on constructing and validating a standard of living index could have greatly benefitted from being externally validated in the STAR endline household survey. However, my student timelines were not well aligned with the umbrella project timelines such that it was not possible to incorporate the index to the STAR endline survey.

Secondly, implementation of HIVST in Malawi was as part of two CRTs. In the CBDA CRT, I incorporated socioeconomic questions such that I was able to conduct the equity analysis. I did not however, include such questions in the trial evaluating the secondary distribution of HIV in public primary care clinics. Adding a similar set of questions to this trial would have allowed for a comparison on socioeconomic equity in the two trials hence a richer analysis.

Finally, in the user cost analysis I was not able to differentiate between zero costs because there were no costs incurred and zero costs because the respondent undervalued their time. Perhaps adding additional questions with predetermined costs would have been more useful to such respondents.

As with many other research projects, this work was affected by the COVID-19 pandemic and the resulting travel restrictions and lockdowns. Other components of this work beyond the cost of integrating HIVST in public primary care facilities were initially planned to be multi-country analyses. However, the COVID-19 pandemic, travel bans and lockdowns that resulted delayed data collection and budgets such that it was not possible to collect the data within the PhD timelines.

8.9. Thesis Conclusion

In this thesis I set out to evaluate the impact of distributing HIVST on costs, uptake, and equity in access to testing and distribution of subsidies from testing. Despite facility-based provider testing costing less than HIVST modalities, HIV testers especially men incur significant user costs that act as a potential access barrier. HIVST testing can help reach such groups with testing. Implementation of HIVST should be tailored in a way that recognises the context and will not increase or introduce unnecessary socioeconomic inequalities.

9.0. References

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10.0. Appendix

10.1. Appendix A: Non-first author papers associated with this thesis

Paper 1: Mwenge, Sande (230)

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RESEARCH ARTICLE

Costs of facility-based HIV testing in Malawi, Zambia and Zimbabwe

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Abstract

Background

Providing HIV testing at health facilities remains the most common approach to ensuring access to HIV treatment and prevention services for the millions of undiagnosed HIV-infected individuals in sub-Saharan Africa. We sought to explore the costs of providing these services across three southern African countries with high HIV burden.

Methods

Primary costing studies were undertaken in 54 health facilities providing HIV testing services (HTS) in Malawi, Zambia and Zimbabwe. Routinely collected monitoring and evaluation data for the health facilities were extracted to estimate the costs per individual tested and costs per HIV-positive individual identified. Costs are presented in 2016 US dollars. Sensitivity analysis explored key drivers of costs.

Results

Health facilities were testing on average 2290 individuals annually, albeit with wide variations. The mean cost per individual tested was US$5.03.9 in Malawi, US$4.24 in Zambia and US $8.79 in Zimbabwe. The mean cost per HIV-positive individual identified was US$79.58, US $73.63 and US$178.92 in Malawi, Zambia and Zimbabwe respectively. Both cost estimates were sensitive to scale of testing, facility staffing levels and the costs of HIV test kits.

Conclusions

Health facility based HIV testing remains an essential service to meet HIV universal access goals. The low costs and potential for economies of scale suggests an opportunity for further

Competing interests: The authors have declared that no competing interests exist.

scale-up. However low uptake in many settings suggests that demand creation or alternative testing models may be needed to achieve economies of scale and reach populations less willing to attend facility based services.

Introduction

Over 35 million people are living with HIV, the majority in sub-Saharan Africa [1]. In particular, HIV prevalence stands at 10.6%, 12.3% and 14.6% among individuals aged 15–64 in Malawi, 15–59 in Zambia and 15–64 in Zimbabwe, respectively [2–5]. Timely initiation of antiretroviral treatment (ART) has the potential to ensure those infected can lead healthy lives, potentially living as long as uninfected individuals in the region [6], and reduces the probability for further sexual and vertical transmission through suppressed viral load [3, 7]. Despite efforts to increase access to ART in the region, millions continue to die [1], while those who do start treatment do so late [8]. Achieving universal and timely access to ART relies on ensuring those who are infected with the virus are aware of their status [9].

In the last decade Southern Africa has seen significant scale up of HIV testing services (HTS). In Zambia, this has led to the proportion of 15-49-year-olds who have tested and received their HIV test result in the previous 12 months increasing from 19% of women and 12% of men in 2007 to 70% of women and 63% of men in 2015 [3]. According to the Malawi Population-Based HIV Impact Assessment (MPHIA), 76% of women and 67% of men aged 15–64 who are living with HIV know their HIV status [10]. In Zimbabwe, 71% of women and 70% of men aged between 15 and 64 who are living with HIV know their HIV status [4]. Conversely, though national statistics group all HTS indicators together, it is known that the scope of HTS has expanded beyond facility based activities [11]. For example community based HTS has been said to increase number of individuals with known HIV status and improve HIV knowledge in general [12–15]. This has mainly been achieved by increasing the availability of health facility-based HTS [16, 17].

Moreover countries have adopted the 2015 World Health Organisation (WHO) guidelines, which recommend immediate ART for all HIV-positive adults and children [18], and are aiming to achieve the UNAIDS 90-90-90 target (i.e. by 2020 90% of all people living with HIV should know their HIV status, 90% of all individuals with diagnosed HIV infection will receive sustained ART, and 90% of all individuals receiving ART will have viral suppression [19]. Clearly meeting these goals requires further scale-up and better targeting of HTS. Understanding the costs of delivering HTS is critical to ensure efficient use of resources and improve planning and budgeting. However, information on HTS costs remains sparse in the region, and where available, estimates show wide variation in costs per person tested ranging from US$5 to US$50 [20, 21].

This paper presents the costs of health provider delivered facility-based HTS in Malawi, Zambia and Zimbabwe and explores cost drivers and economies of scale. In addition, cost estimates presented in this paper will inform the cost-effectiveness analysis of HIVST implementation in the HIV-Self Testing AfRica (STAR) project.

Methods

Setting

In 2016 UNITAID commissioned STAR project to assess the feasibility, acceptability and the potential health impact of distributing HIV self-test kits in Malawi, Zambia and Zimbabwe.

We undertook a cost analysis of facility-based HTS services provided at 54 health facilities serving the STAR study populations in Malawi (15), Zambia (10) and Zimbabwe (29). Health facilities included both primary and secondary care facilities.

In the STAR project community-based distribution of HIVST is being evaluated in Malawi, Zambia and Zimbabwe. In these countries, communities were selected for the purposes of the main implementation evaluation being undertaken. Briefly, communities were selected in collaboration with the countries' Ministry of Health. The selected communities had to be served by a local government health facility providing HIV care, with no alternative HIV care facility nearby. Preference was given to communities with high HIV prevalence. For this costing study, in Malawi and Zimbabwe all health facilities included in the impact evaluation were included while in Zambia 12 facilities were randomly selected. Data collection occurred prior to HIVST implementation.

In Malawi, all 15 facilities were rural primary health clinics located in Blantyre, Machinga, Mwanza and Neno districts. In Zambia, there were two peri-urban and eight rural primary health clinics located in four districts, Ndola, Kapiri Mposhi, Choma and Lusaka. In Zimbabwe, all 29 health facilities evaluated were in rural areas including one mission hospital, one mine hospital, two district government hospitals, and 25 rural primary health clinics. There were between one and six HIV testing staff full-time equivalents (FTEs) working at each health facility in the three countries. For Zambia, unlike Malawi and Zimbabwe, HIV testing staff included a mix of paid and volunteer counselors. Table 1 presents a detailed description of study sites.

At all health facilities individuals may voluntarily attend the health facility to request HIV testing or may be referred to the HTS service because they are unwell, pregnant or have an illness that warrants HIV testing (e.g. Tuberculosis). In all three countries, HIV testing is performed using finger-prick rapid diagnostic test (RDT) kits and follows standard serial testing algorithms where those who test positive on the first RDT undergo confirmatory testing using a different RDT kit [22]. In each of the countries, a different RDT kit is used for the confirmatory testing. For those found to have discordant test results on serial testing are an immediate

Table 1. Sample overview and facility description.

Characteristic	Description	Malawi	Zambia	Zimbabwe
Number of districts	Number of districts	4	3	6
Number of sites	Sample size	15	10	29
Type of facility	Primary health clinic (Hospital)	15 (0)	10 (0)	27 (3)
Population	Mean catchment population at sampled facilities (median; range[$])	27,439 (19,172; 5,500–82,581)	18,266 (15,223; 7673–50,094)	3,196 (3,088; 549–6,699)
Location	Rural (urban/peri-urban)	15 (0)	8 (2)	29 (0)
Personnel	Mean HTS* FTEs[&] per facility (median; range[$])	2 (2; 1–4)	6 (6; 2–10)	5 (4; 2–11)
	Mean HTS FTEs per 10,000 population (median, Range)	16 (13; 5–35)	31 (31; 13–53)	68 (52; 24–184)
	Mean Paid counsellors per facility (median; range[$])	2 (2; 1–4)	1 (1; 0–5)	5 (4; 2–11)
	Mean Volunteers per facility (median; range[$])	-	4 (4; 2–7)	-
National HIV prevalence (%) [2–5]	Adults 15 to 49 years	9.1	12.3	14.6

FTE = Full time Equivalent.

[&]HTS = HIV testing services.

[$]Range is presented in terms of minimum—maximum.

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parallel repeat test is done on both testing is done on both tests. For those found to have discordant test results on serial testing an immediate parallel repeat test is done. If both test 1 and test 2 are reactive results are reported positive; if both are non-reactive, results are reported negative. If the results from parallel testing are discordant, clients are advised to repeat HIV test after 4 weeks in Malawi and 14 days in Zambia and Zimbabwe. All those who test HIV-negative are advised to re-test in three months. A detailed description of the national HIV testing algorithms in the three countries is provided in the Supplemental figures S1–S3 Figs. HTS department is a unit in the facility with a physical space where all HTS data within the facility are aggregated. HIV testing is done by trained counselors, either employed or volunteers, at the facility. Counselors may also be placed in different locations within the facility (e.g. Antenatal clinic) to perform HIV testing.

Cost data collection

The study was undertaken from the health providers' perspective to estimate the costs of routine provider delivered facility-based HTS and understand key determinants of these costs. Full annual financial and economic costs were estimated. Financial costs represent all expenditures for resources used in the intervention, while economic costs capture the full value of all resources used, including valuation of donated goods or services, here the opportunity cost of volunteer counsellors' time [23]. Volunteer time was valued as a product of the number of hours that volunteers spent on doing HTS activities and the average stipend rate which non-government organizations (NGOs) pay volunteers for providing similar activities in Zambia. Annual resource use data were sequentially and retrospectively collected with end dates rolling between June 2016 and April 2017, depending on the date of the data collection visit. Costs were adjusted to 2016 United States dollars (US$) using the average exchange rates, ZMK722.99 for Malawi, ZMW10.03 for Zambia and US$1 for Zimbabwe, over the period of the costing [24] and deflators [25].

Standardised costing methods were developed collaboratively by economists across the three countries to ensure consistency of data collection and analysis. We employed both ingredients based (bottom up) costing and top-down costing where we apportioned costs stepwise to their respective cost centers [10, 26]. Types, quantities and unit costs of cost items were collected through interviews, expenditure and outcome review at facility and district levels. Where unit costs were not present in the expenditure records, market prices were used. See S1 Table for details of the allocation of each cost item. Capital costs included: buildings, equipment and vehicles whilst recurrent costs captured personnel, HIV testing commodities, general supplies, facility level operations including transportation and waste management. Capital costs were annualised and discounted at a 3% rate in accordance with WHO guidelines [27]. Overhead costs were considered at two levels; facility overhead which included all the costs that are needed to ensure the overall running of the facility, and HTS centre-specific costs, which are the costs of running the HTS department where HIV-related activities are conducted. Due to difference in financial reporting system across the three countries overhead costs were allocated differently in each country, particularly costs related to health systems management (Above-facility administration, supervision & mentorship) and facility administration. Supply chain costs were apportioned using allocation factors from literature [28]. See supplemental table S1 Table for details.

Outputs and allocation factor data collection

Alongside cost data collection we collected data on the catchment population, number of outpatient department (OPD) visits, number of staff, number of HTS visits and number of HIV-positive results, through reviewing facility registers. Data sources were facility registers and heath information aggregation forms. These data were also used in the allocation of overhead and shared costs.

Data analysis

Total annual costs of running HTS at each facility and the respective unit costs were estimated by dividing the total facility costs by the annual number of people tested and the number of HIV-positive individuals identified. Descriptive statistical analysis was performed to calculate mean and median (with the minimum and maximum ranges) for unit costs per HIV test and HIV-positive identified for each country. To explore potential drivers of costs descriptively, Pearson correlations were calculated. A univariate sensitivity analysis was undertaken to understand the impact of HIV test kit price and staff time on the unit costs. The impact of price on unit costs was explored by applying the lowest and highest observed test kit prices across the three countries. The impact of staffing was explored by considering variation in staffing in a +/-20% range to; (a) cope with increased testing demand; (b) explore impact of introduction of community-based HIV testing or HIV self-testing requiring fewer facility based counsellors. We also assessed the impact of the size of facility on the unit costs in Zimbabwe, where the costing sample included both clinics and hospitals. All facilities from Malawi and Zambia were clinics; we only had a clinic-hospital mix in Zimbabwe (3 rural hospitals out of 29 facilities). In our analysis facility size is defined by the catchment population and HTS department by the number of annual HTS visits.

Ethics

Ethical approvals for the project were secured from the appropriate research review boards. This included the London School of Hygiene and Tropical Medicine (LSHTM) Ethics Committee, Malawi National Health Sciences Research Committee, University of Zambia Biomedical Research Ethics Committee, Medical Research Council of Zimbabwe (MRCZ) and University College London Ethics Committee. The STAR trials are registered under the Clinical Trials Network (ClinicalTrials.gov) under registration numbers NCT02793804; NCT02718274; Pan African clinical trials registry (Zimbabwe) PACTR201607001701788.

Results

HTS output summary

The mean number of HIV tests conducted per clinic during the 12-month costing period was 2,359 with 3,404, 3,161 and 1,542 in Malawi, Zambia and Zimbabwe, respectively (Table 2). The mean HIV prevalence amongst those who accessed HIV testing at the health facilities was 7% (9% for Malawi, 9% for Zambia, and 6% for Zimbabwe). While the annual number of HTS visits was significantly associated with the size of the health facility catchment population when pooling across the three countries ($R^2 = 0.53$, N = 53, $P<0.000$), when estimated at the country level the correlation only remained significant in Malawi (($R^2 = 0.55$, N = 15, $P<0.002$) and Zambia ($R^2 = 0.76$, N = 10, P = 0.001) but no longer in Zimbabwe ($R^2 = 0.030$, N = 28, $P<0.379$).

Fig 1 shows the number of HTS visits each month for all the health facilities sampled in the three countries. In Malawi, the majority of the health facilities appears to have experienced gradual increases in number of HTS visits over the study period. In Zambia, the number of HTS visits every month appears relatively constant over the year, with two clinics experiencing

Table 2. Test kit prices and average (mean; median) annual facility HTS outputs.

	Malawi	Zambia	Zimbabwe
Test kit price[^] First	Determine $1.00 Unigold $1.00	Determine $1.00-$1.20 Unigold $1.60	Determine $1.07 First response $0.71
HIV tests	3404 (3461; 835–7953)	2789 (2338; 852–6957)	1542 (1132; 368–5735)
HIV+ identified (median; range*)	304 (230;25–950)	251; (120; 48–907)	93; (63; 12–409)
Facility HIV+ reactivity rate	9% (8%; 3%-16%)	9% (7%; 2%-16%)	6% (6%; (1%-14%)

*Range is presented in terms of minimum—maximum

^Test kit prices were derived from national laboratory and medical supplies procurement catalogues from each country complimented by discussion with key stakeholder

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a peak in visits in July and August. In Zimbabwe, many of the health facilities experienced significant fluctuation in monthly HTS visits.

The mean annual number of HIV testing episodes per HTS staff FTE was 1132 (519–2075) in Malawi, 597 (238–1257) in Zambia and 895 (237–2285) in Zimbabwe. Country-level analysis did show the number of HTS staff was strongly correlated with the size of the facility catchment population in Zambia, though not in Malawi and Zimbabwe. Cross-country analysis shows that there was no significant relationship between the number of HIV counsellors employed at each health facility and the facility catchment population ($R^2 = 0.01$, N = 53, P = 0.4039). At country-level, the results showed that the correlation was significant in Zambia, but not in Malawi and Zimbabwe. Overall, there was no correlation between the number of HIV counsellors employed and the number of HIV testing episodes ($R^2 = 0.01$, N = 54, P = 0.53).

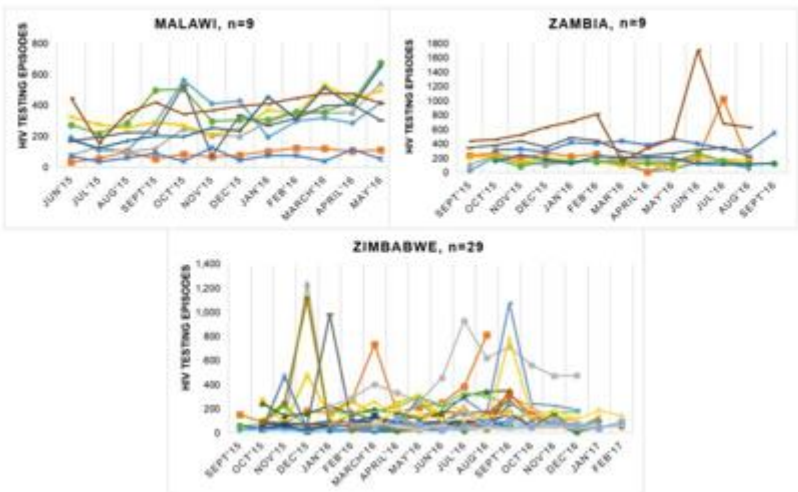

Fig 1. Monthly HTS visits by facility*. *monthly service statistics were not available for all clinics.

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Table 3. Total and mean economic costs (minimum-maximum).

Cost item	Malawi (US$)			Zambia (US$)			Zimbabwe (US$)		
	Total annual costs	**Cost per test performed**	**Cost per HIV+**	**Total annual costs**	**Cost per test performed**	**Cost per HIV+**	**Total annual costs**	**Cost per test performed**	**Cost per HIV+**
Capital costs									
Buildings and storage	347 (54–777)	0.13 (0.01–0.28)	1.9 (0.34–7.52)	133 (59–254)	0.07 (0.02–0.21)	0.97 (0.17–1.87)	190 (32–514)	0.22 (0.01–1.40)	4.62 (0.44–24.47)
Equipment	169 (57–300)	0.08 (0.01–0.28)	1.43 (0.12–8.70)	160 (41–391)	0.1 (0.01–0.46)	1.44 (0.06–3.35)	108 (38–304)	0.11 (0.01–0.45)	2.36 (0.15–11.16)
Vehicles	-	-	-	91 (21–249)	0.06 (0.01–0.26)	0.69 (0.04–1.86)	22 (0–633)	0.01 (0.00–18)	0.06 (0.00–1.77)
Other	-	-	-	43 (29–61)	0.02 (0.01–0.05)	0.39 (0.04–1.24)	-	-	-
Total capital cost	*517 (162–938)*	*0.2 (0.04–0.51)*	*3.33 (0.61–16.22)*	*428 (211–844)*	*0.24 (0.05–1.00)*	*3.49 (0.32–697)*	*320 (72–1,095)*	*0.33 (0.03–1.85)*	*7.04 (0.66–32.36)*
Recurrent costs		-	-						
Personnel	8,375 (2,893–13,828)	2.97 (1.35–6.00)	46.57 (13.05–115.72)	6,678 (1,373–32,665)	2.05 (0.51–4.70)	36.83 (5.82–115.76)	7,670 (3,141–34,398)	6.69 (1.85–118.88)	131 (26.36–313)
Supplies—test kits	3,713 (912–9,064)	1.19 (1.13–1.26)	19.16 (8.51–41.58)	3421 (1,128–8,692)	1.22 (1.14–1.35)	21.34 (8.21–46.39)	1826 (439–6,747)	1.2 (1.12–1.29)	28.71 (9.39–84.61)
Supplies	1,231 (783–1,632)	0.46 (0.79–1.09)	7.83 (1.22–31.32)	450 (163–596)	0.21 (0.08–0.58)	3.32 (0.62–5.95)	441 (130–2,032)	0.38 (0.09–2.9)	7.82 (1.61–31.27)
Supply chain	111 (70–147)	0.04 (0.01–0.10)	0.7 (0.11–2.82)	307 (101–779)	0.11 (0.10–00.12)	1.91 (0.76–4.16)	203 (63–676)	0.14 (0.03–0.34)	3.22 (0.41–9.26)
Operation & maintenance	393 (67–1325)	0.36 (0.06–1.22)	3.64 (0.62–12.27)	751 (210–1,427)	0.42 (0.05–1.14)	6.85 (0.32–13.71	56 (0.00–682)	0.1 (0.00–01.15)	0.7 (0.00–8.42)
Recurrent training	-	-	-	-	-	-	-	-	-
Waste management	31 (2–136)	0.01 (0.00–0.05)	0.24 (0.01–1.46)	2 (1–4)	-	0.02 (0.00–0.07)	2.01 (0.38–7.32)	-	0.06 (0.00–0.43)
Total recurrent costs	*14304 (4,4981–24228)*	*4.85 (2.96–890)*	*76.24 (25.50–199.22)*	*11,609 (4,440–43,071)*	*4 (2.34–6.19)*	*70 (16.30–184.39)*	*10198 (4198–4162)*	*8.46 (3.33–20.68)*	*171.88 (41-97-426.05)*
Total cost / unit cost	**14,822 (5,386–25,124)**	**4.92 (2.95–8.33)**	**79.58 (26.45–215.44)**	**11,652 (4,486–43,106)**	**4.24 (2.49–6.24)**	**73.63 (16.62–191.35)**	**10,517 (4,476–38,514)**	**8.79 (3.38–21.51)**	**178.92 (43.81–442.43)**

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Total HTS costs

S2 Table presents resource utilization for key recurrent supplies. The total annual economic costs for the health facilities sampled in the three countries are shown in Table 3, financial costs are presented in Supplemental Table S3 Table. The median total annual costs were US $14,822 (range: US$5,386-US$25,124) for Malawi, US$8,797 (range: US$4,486-US$43,106) for Zambia and US$8,774 (range: US$4,476-US$38,514) for Zimbabwe. In the three countries,

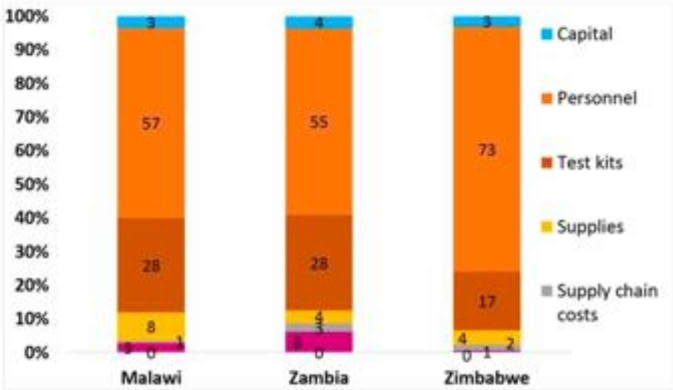

Fig 2. Input shares by country (%).

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salaries for personnel accounted for 57%, 55% and 73% of the total annual cost in Malawi, Zambia and Zimbabwe, respectively (Fig 2). The variation in costs across the countries was significantly correlated with variation in staffing levels (P = 0.04 for Malawi, P = 0.04 for Zambia, and P<0.01 for Zimbabwe); some facilities relied heavily on volunteer/ lay providers (mainly in Zambia) whereas others tended to employ highly trained and paid staff. The cost of the HIV RDT kit and supplies accounted for 28% in Malawi, 28% in Zambia and 17% in Zimbabwe of the total annual cost. Capital costs accounted for approximately 4% of the total annual cost for Zambia, and 3% for Malawi and Zimbabwe.

Unit costs

The median costs per individual tested for HIV in Malawi, Zambia and Zimbabwe were US $4.56, US$3.96, US$6.25, respectively. The median cost per HIV-positive individual identified were US$58.044 for Malawi, US$54.33 for Zambia and US$141.67 for Zimbabwe. Average unit costs are reported in Table 3.

To identify the presence of economies of scale, Fig 3 shows the cost per individual tested and cost per HIV-positive individual identified by the annual number of HIV testing episodes performed at the health facility and the annual number of HIV-positive individuals identified at each of the health facilities, respectively. The cost per individual tested for HIV was lower at health facilities that were testing more individuals. Likewise, the cost per HIV-positive individual identified was lower at health facilities that were identifying more HIV-positive individuals.

Sensitivity analysis

When varied the prices of HIV test kits from the observed prices for each country (base prices) to the observed minimum price (US$1.00 for Determine in Malawi and US$0.71 in Zimbabwe, both the mean cost per individual tested for HIV and mean cost per HIV-positive individual identified changed by 13% for Malawi, 11% for Zambia and 18% for Zimbabwe. When test kit prices were set at the observed maximum prices (US$1.10 for Determine and US$1.60 for Uni-Gold in Zambia), the mean cost per individual tested for HIV changed by 11% for Malawi, 9%

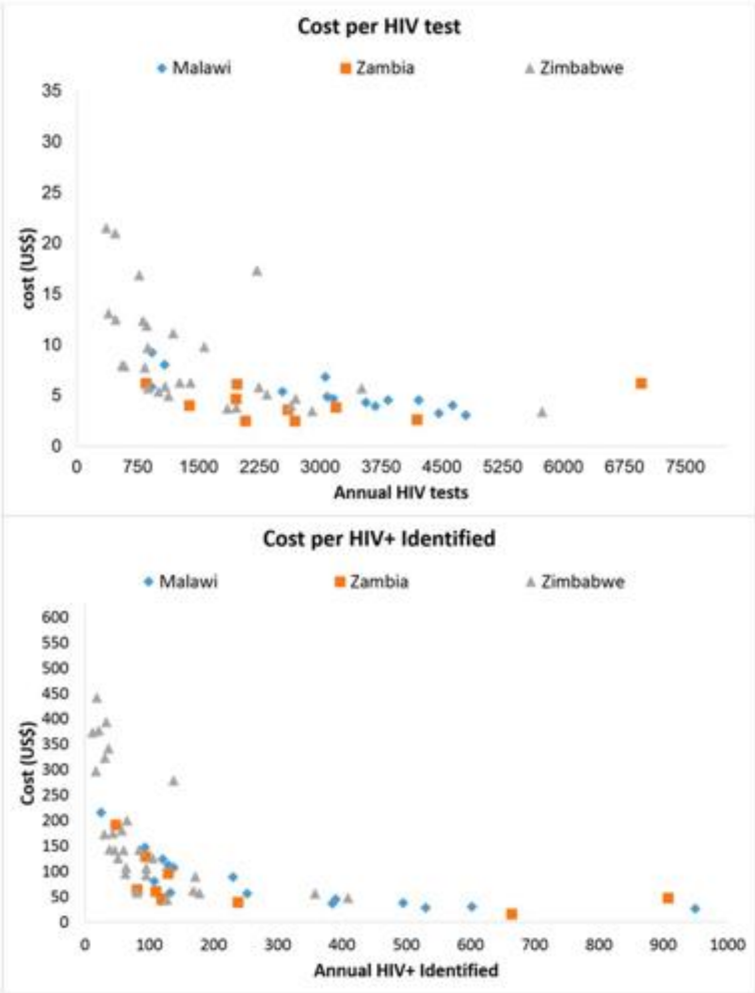

Fig 3. Economies of scale.

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for Zambia and 13% for Zimbabwe. The mean cost per HIV-positive individual identified changed increased by the same magnitude for each country.

When we set personnel costs were set at 20% lower than actually observed, both the mean cost per individual tested for HIV and mean cost per HIV-positive individual identified reduced by 13% for Malawi, 11% for Zambia and 18% for Zimbabwe. When personnel costs were 20% higher than that observed, the mean cost per individual tested for HIV increased by

Table 4. Sensitivity analysis results.

Parameter	Malawi (US$)		Zambia (US$)		Zimbabwe (US$)	
	Per HIV test	Per HIV+	Per HIV test	Per HIV+	Per HIV test	Per HIV+
Base case	5.05	79.58	4.24	73.63	8.79	178.92
HIV Test kit Prices						
Observed low prices (Determine = US$0.87; UniGold = US$0.71)	5.02	75.93	3.88	67.44	8.70	176.91
Observed Higher prices (Determine = US$1.10; UniGold = US$1.60)	5.22	82.05	4.24	73.63	8.93	181.88
Personnel costs						
20% reduction	4.45	70.27	3.83	66.26	7.45	152.68
20% increase	5.64	88.90	4.65	80.99	10.13	205.25

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11% for Malawi, 9% for Zambia and 13% for Zimbabwe. The mean cost per HIV-positive individual identified increased by 10% for Malawi, 9% for Zambia and 13% for Zimbabwe. Only Zimbabwe included hospitals in the costing. When these were excluded, mean cost per individual tested for HIV ranged from US$8.79 to US$7.65, and mean cost per HIV-positive individual identified dropped from US$178.92 to US$150.40. Table 4 shows details of outcomes from sensitivity analysis.

Discussion

Health facility-based HIV testing remains the most common approach for individuals to learn their HIV status. Ensuring that 90% of all people living with HIV in sub-Saharan Africa know their HIV status by 2020 may require further scale-up of facility-based HTS. We found that the costs of delivering these HTS services in three southern African countries could be as low as US$3 per individual tested, especially in health facilities that were seeing a larger number of individuals.

The mean provider costs of facility-based HTS were similar in Malawi and Zambia and higher in Zimbabwe, ranging from US$4.24 to US$8.79 per person tested. Our findings are

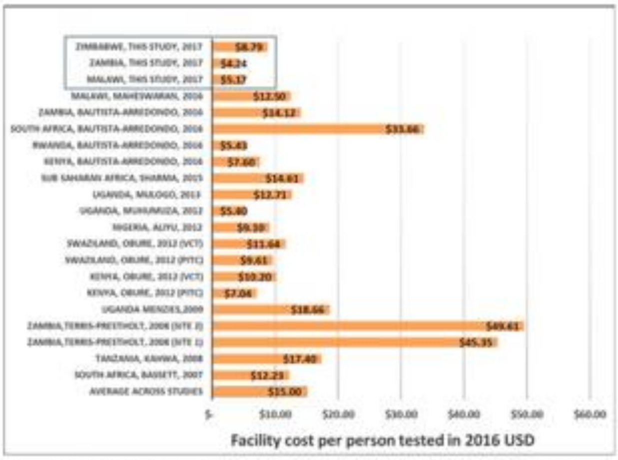

Fig 4. Comparison of cost per person tested for HIV in health facility in sub-Saharan Africa.

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fairly consistent with previous studies that estimated costs to test for and identify individuals with HIV at health facilities in the region (Fig 4) [29–39]. A facility-based costing study conducted in Malawi in 2014, with capital, overhead, staff salaries, consumables and equipment costs reported in 2014 prices, showed a higher cost of US$12.50 per person tested when adjusted to 2016 prices [40]. Notably, this estimate included costs of staff training, and service monitoring and evaluation, which was not observed in our study.

Previous studies in Zambia and South Africa, conducted between 2011 and 2012 with costs reported in 2013, estimated costs of US$14.12 and US$33.66 per person tested (in 2016 prices), respectively. Staff salaries were the main cost driver in South Africa [31]. The average economic costs were also estimated in 2009 for Kenya and Swaziland, with costs per person tested ranging from US$10.20 to US$11.64 for voluntary counselling and testing (VCT), and US$7.04 to US$9.61 (in 2016 prices) for provider initiated testing and counselling (PITC) [37]. These recent studies show large decreases as compared to cost estimates from the early years of HTS introduction (2001), costs reported in 2007, of which US$49.61 and US$45.35 (in 2016 prices) are reported costs per person tested [39]. It is important to note that, during early years of HTS introduction, HTS were delivered at high costs. HTS delivery was also surrounded by a lot of challenges (e.g. stigma, lack of confidentiality, fewer testing facilities) which required a lot of effort to create user demand [41–43]. Common across facility costing studies of HTS are the large contribution of human resources, training, test kits and consumables as drivers of costs.

We found considerable variation in cost estimates within and between countries and over time as the approach to and intensity of HTS evolved. Unit costs were especially low in larger health facilities that were seeing more individuals. These facilities often also provided a broader range of services. This suggests potential economies of scale, where inputs are more efficiently used due to fixed costs being spread across more outputs, and/or economies of scope, where fixed costs are spread across more services, both leading to lower unit costs. We did not find a strong relationship with the number of HIV counsellors working at the health facility and the number of individuals undergoing HIV testing. It is possible health facilities with greater numbers of HIV counselors are seeing fewer individuals for HIV testing during the time period of this study because past HIV testing was high and therefore fewer individuals in the community are unaware of their current HIV status. Conversely it is also possible that the demand for HIV testing amongst those served by these better staffed facilities, or the size of the facilities' catchment population are low. However, the findings suggests that existing HTS in health facilities could be seeing more individuals for HIV testing without needing additional resources except the consumables needed to perform the HIV test. We found that the monthly number of HTS episodes at health facilities in Malawi gradually increased over the study period. This may reflect the recent introduction of test and treat, where HIV treatment is initiated immediately upon an HIV-positive test result [18]. Conversely, we found major fluctuation in the monthly number of HTS episodes at health facilities in Zimbabwe. This could be due to supply issues, e.g. HIV test kit stock outs. Alternatively, demand side variation, for example anecdotal evidence suggests peaks in rural HTS around the Christmas period and subject to weather conditions, that may universally affect people presenting for HTS.

Observed cost variation across countries and facilities presents a room for HTS innovations as well as an opportunity to assess the additional resources and approaches needed to achieve the UNAIDS 90-90-90 targets. For example, engaging communities through outreach programmes may complement facility-based HIV testing in settings with low demand [44]. Personnel costs accounted for a significant component of the total provider costs of facility-based HTS. There have been suggestions that the counselling process could be optimised [45], enabling counsellors to see more individuals or facilities to be staffed by fewer personnel. Alternatively, providing HIVST kits to health facility attendees, allowing them to perform and interpret their own test result, potentially in the privacy of their own homes or within private areas within facilities and discuss their results with healthcare providers. This approach could also reduce personnel needs at facilities or allow busy health facilities to meet HTS demand. HIVST has the additional benefit of high acceptability especially amongst men [46]. However, recognition of other potential bottle necks should be considered weighing the benefits of introducing new technological innovations because low output may also be caused by supply challenges such as stock-outs, which new test technology may or may not alleviate.

The cost per HIV-positive individual identified in our study ranged from as low as US$17 to as high as US$442. HIV testing and anti-retroviral treatment (ART) has been available in these three countries for over a decade, with recent estimates suggesting more than half of people living with HIV (PLHV) in the region are receiving treatment [1]. As there are fewer and fewer numbers of PLHV unaware of the infection, the cost per HIV-positive individual identified by HTS will continue to increase over time. In order to achieve the UNAIDS 90-90-90 targets this cost estimate should not inform decisions to fund or not fund HTS services, but may still provide useful insight into which HTS services are effective. It is important to note that we found approximately one in ten attendees of facility-based HTS in these three southern African countries to be HIV-positive. This confirms the fact that the three countries have made tremendous progress towards the 1st 90 of the USIAD 90-90-90 target [3, 4, 10], leading to having most of the people with known HIV status, and the remaining population comprising of 'hard-to-reach people who may not want to test. Our study shows similar HIV reactivity rate (6–8%) across the three countries despite having quite different national HIV prevalence. This could be attributed to the fact that most of our facilities were rural with low population density and more importantly HIV prevention and treatment activities are widely provided in these communities with notable impact [3, 4, 10]. Health facilities continue to provide an important route for individuals to learn their HIV status.

A major limitation of our findings is the different financial reporting systems used in the three countries that made it challenging to standardise the allocation of central overhead costs. Another challenge in our data collection was that, as in other similar studies, we faced poor record keeping in the facilities; missing information and inconsistency in financial reporting across facilities. Additionally, by not including costs borne by patients and their carers for accessing testing, this does not give a true reflection of the economic burden of HIV testing. Measurement of patients' costs can be essential for social planning as it gives insight into costs borne by individuals, households and society as a whole and can identify barriers to accessing HIV testing. However, an analysis of patient costs of accessing HTS in the same setting is underway. Thus, future research should consider direct and indirect costs of treatment from, at least, the provider and patient perspective as well as the long-term disability due to illness. This perspective can complement the provider's perspective taken in this study.

Facility-based HIV testing services remains an effective approach to identifying undiagnosed HIV-positive individuals and can be an affordable approach to reaching the first 90. There are potential opportunities to improve their efficiency, which would need to be complemented by approaches to address demand side constraints to have a beneficial impact.

Supporting information

S1 Fig. Malawian HIV testing algorithm.
(TIF)

S2 Fig. Zambian HIV testing algorithm.
(TIF)

S3 Fig. Zimbabwe HIV testing algorithm for children above 18 months, adolescents and adults.
(TIF)

S1 Table. Cost allocation factors.
(DOCX)

S2 Table. Resource utilization of key HTS key supplies.
(DOCX)

S3 Table. Financial cost: Mean (min-max).
(DOCX)

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RESEARCH ARTICLE

Economic cost analysis of door-to-door community-based distribution of HIV self-test kits in Malawi, Zambia and Zimbabwe

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Abstract

Introduction: HIV self-testing (HIVST) is recommended by the World Health Organization in addition to other testing modalities to increase uptake of HIV testing, particularly among harder-to-reach populations. This study provides the first empirical evidence of the costs of door-to-door community-based HIVST distribution in Malawi, Zambia and Zimbabwe.

Methods: HIVST kits were distributed door-to-door in 71 sites across Malawi, Zambia and Zimbabwe from June 2016 to May 2017. Programme expenditures, supplemented by on-site observation and monitoring and evaluation data were used to estimate total economic and unit costs of HIVST distribution, by input and site. Inputs were categorized into start-up, capital and recurrent costs. Sensitivity and scenario analyses were performed to assess the impact of key parameters on unit costs.

Results: In total, 152,671, 103,589 and 93,459 HIVST kits were distributed in Malawi, Zambia and Zimbabwe over 12, 11 and 10 months respectively. Across these countries, 43% to 51% of HIVST kits were distributed to men. The average cost per HIVST kit distributed was US$8.15, US$16.42 and US$13.84 in Malawi, Zambia and Zimbabwe, respectively, with pronounced intersite variation within countries driven largely by site-level fixed costs. Site-level recurrent costs were 70% to 92% of full costs and 20% to 62% higher than routine HIV testing services (HTS) costs. Personnel costs contributed from 26% to 52% of total costs across countries reflecting differences in remuneration approaches and country GDP.

Conclusions: These early door-to-door community HIVST distribution programmes show large potential, both for reaching untested populations and for substantial economies of scale as HIVST programmes scale-up and mature. From a societal perspective, the costs of HIVST appear similar to conventional HTS, with the higher providers' costs substantially offsetting user costs. Future approaches to minimizing cost and/or maximize testing coverage could include unpaid door-to-door community-led distribution to reach end-users and integrating HIVST into routine clinical services via direct or secondary distribution strategies with lower fixed costs.

Keywords: HIV self-testing; costs and cost analysis; community; Malawi; Zambia; Zimbabwe

Additional Supporting Information may be found online in the Supporting information tab for this article.

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1 | INTRODUCTION

In East and Southern Africa, freely available HIV services have led to a 42% reduction in AIDS-related deaths between 2010 and 2016. Despite such gains, 24% of people living with HIV (PLWH) remain undiagnosed [1]. UNAIDS has set global targets for 90% of PLWH to know their status, 90% of known HIV-positive individuals, to be on ART and 90% of those on antiretroviral therapy (ART) to have their viral load suppressed by 2020 [2]. To surpass and sustain high levels of awareness of HIV status, greater efforts are needed to ensure that HIV testing reaches those individuals who have not yet been tested for HIV. This, however, is likely to require more significant financial investments, innovative approaches and new technologies, including HIV self-testing (HIVST).

HIVST is defined as a process where a person collects his/her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting,

Table 1. Key setting characteristics

	Malawi	Zambia	Zimbabwe	Source
National HIV prevalence among adults 15 to 59 years (%)	10.0	12.0	14.6	[8–10]
Number of districts	4	4	8	[11]
Number of sites	11	16	44	[11]
Catchment population of sites: mean (range)	27,439 (5500 to 82,581)	18,266 (7673 to 50,094)	3196 (549 to 6699)	[11]
Location: rural (urban or peri-urban)	11 (0)	16 (8)	44 (0)	[11]
Scale of current HTS – based on facility HTS in same communities and period	16,921	27,888	44,727	[16]
Men attendance at HTS – based on facility HTS – % men	34	37	26	[8–10]
Health facility HTS cost per person tested in US$: mean (range)	$5.03 ($2.96 to $9.24)	$4.24 ($2.49 to $6.24)	$8.79 ($3.38 to $21.51)	[16]

HTS, HIV testing services.

either alone or with someone they trust. The World Health Organization recommends HIVST to reach the "at risk" and "untested" populations including men as a complement to current conventional testing approaches, including facility-based and targeted community outreach-based testing [1,3-5]. The cost of HIVST kits has declined in some settings, with the OraQuick® HIV self-test now costing US$2 per kit in 50 low- and middle-income countries [6]. However, at US$2, it is around twice the price of standard HIV rapid diagnostic tests currently used for HIV testing in Africa [7]. Although HIVST kit price may be higher, impact analyses show that it can have an important public health benefit and offer value for money if implemented as a complement to current testing approaches [4,5].

The HIV Self-Testing AfRica (STAR) project has delivered over one million HIVST kits in Malawi, Zambia and Zimbabwe between 2016 and 2017 through a combination of distribution approaches, including facility-based distribution at outpatient departments, within voluntary medical male circumcision (VMMC) services and in the community. This study presents the costs of the model that uses community-based distribution agents (CBDAs) to deliver HIVST either at people's homes or within the community setting, hereafter "the CBDA model," to generate evidence to inform the scale-up of cost-effective HIV testing services (HTS).

2 | METHODS

2.1 | Setting, intervention and evaluation

Table 1 presents key setting characteristics across countries. In short, the adult HIV prevalence rates in Malawi, Zambia and Zimbabwe were approximately 10.0%, 12.0% and 14.6% respectively [8-10]. While Malawi and Zimbabwe CBDA model sites were exclusively rural, a third of Zambia sites were peri-urban or urban. Malawian and Zambian distribution sites were fewer and each served large populations, while Zimbabwe delivered kits to a larger number of smaller communities. This difference in site size is also reflected in the unit costs of conventional facility-based testing, with higher costs in the smaller facilities in Zimbabwe. It is also notable that men contribute only 26% to 37% of HTS clients in these facilities.

In the CBDA model, all individuals aged ≥16 years who were present in the homestead at the time of CBDAs' home visit were eligible for self-testing. Testing was done by the self-tester themselves after kit use demonstration and information on test result interpretation and linkage to follow-on care by the CBDAs. CBDAs provided a self-referral card to all testers to facilitate linkage to the local health facility for confirmatory testing and care for individuals with reactive HIVST results. In some cases, CBDAs were present during the self-test to provide reassurance and support if testers requested their presence or assistance. Table 2 presents the characteristics of the CBDA model implemented across countries. Narrative descriptions of the models can be found in Data S1. The impact of the CBDA model on uptake of HIV testing and ART is being evaluated in three cluster-randomized trials (CRTs). Detailed methodology of these CRTs is published elsewhere [11].

2.2 | Costing methods

We estimated the full economic cost of delivering HIVST within the CBDA model from the providers perspective, following international costing guidelines [12]. This included start-up and training costs, prior to the first HIVST kit distributed. Annual costs were estimated, with implementation costs collected between June 2016 and May 2017, depending on country implementation timelines. Start-up, training and all other capital costs were annualized using a 3% discount rate. All costs were converted to 2017 US dollars using average annual exchange rates and the dollar inflation rate [13-15].

This top-down costing collated all financial expenditures and categorized each line item by input type and distribution model. Inputs were allocated to distribution sites following predefined allocation factors, based on project monitoring and evaluation (M&E) data, including the percentage of kits distributed, percentage of distributors based in each site, distance from central office and percentage of direct expenditures, which is a weighted average of the preceding

Table 2. Overview of door-to-door community-based HIVST delivery models

	Malawi	Zambia	Zimbabwe
Type of cadre used for distribution of HIVST kits	• Trained CBDAs • Some with prior experience distributing other reproductive health products for PSI	• Trained facility and CBDAs • Recruited from communities with prior links to respective health facilities	• Trained CBDAs • Information on HIVST and linkage to post-test services
Mode of distribution	• Door-to-door community-based distribution • PSI field teams-maintained stocks	• Door-to-door distribution by CBDA's within communities and households • Facility-based distributors-maintained stocks for CBDAs	• Campaign-style door-to-door community distribution to households for four to six weeks • PSI field teams-maintained stocks
Services offered to HIV self-test clients	• Introduction and demonstration of HIVST kit use (including interpretation of results) • CBDAs typically revisited clients a few days after dropping off the kit to: o enquire whether it had been used, o pick up the used kit o disclosed non-reactive HIVST: referral to VMMC o disclosed reactive HIVST: referral to linkage to HIV care	• Introduction and demonstration of HIVST kit use (including interpretation of results) • CBDAs typically revisited clients a few days after dropping off the kit to: o enquire whether it had been used o pick up the used kit o disclosed non-reactive HIVST: referral to VMMC o disclosed reactive HIVST: referral to linkage to HIV care	• Introduction and demonstration of HIVST kit use (including interpretation of results) • Follow-on services by PSI-Zimbabwe mobile outreach teams at one to two weeks post HIVST kit distribution o confirmatory HTS plus o family planning o blood pressure checks and CD4 count when available o clients alerted to linkages to government health facilities
Used HIVST kit returns	• Specially designed and locked drop-boxes to return used self-test kits located: o at all intervention sites	• Specially designed and locked drop-boxes were used to return used self-test kits, located: o at each facility and o local community public areas	• Specially designed and locked drop-boxes, located: o at CBDA's homestead o each health facility o local community public areas
CBDA reimbursement	• Per HIVST kit distributed US$0.15 (MWK 100)	• Monthly US$78 (ZMW 750) independent of performance.Later changed to: • Per HIVST distributed US$0.52 (ZMW 5) and per used HIVST kit returned US$0.21 (ZMW 2)	• Per ward campaign (four to six weeks) US$50 with a maximum of 100 kits per distributor • Per HIVST client linking to any PSI outreach service: $0.20 in half of the evaluation clusters

HIVST, HIV self-testing; CBDA, community-based distribution agent; PSI, Population Services International; MWK, Malawi Kwacha; ZMW, Zambian Kwacha.

allocation factors. Table S1 presents how each allocation factor was applied to input type. Further detail of the definitions of project phase and inputs can be found in Data S2.

To estimate economic costs, the expenditure analysis was complemented by a valuation of all other resources used in the CBDA model. Observations of distribution in each site strengthened the economists' understanding of the intervention and allowed for collection of data on donated goods and services. As a vertical model, these were relatively limited, and include a value for district or health facility storage contributed by the public health system. During the life of the project, the price of HIVST kits dropped from nearly $4 per kit to $2 per kit. The latter was imputed in place of the higher observed prices as it was considered the relevant kit price for any decision-making building upon this analysis. Total costs, total kits distributed and average cost per kit distributed were estimated at the country level, and for each country, at the site level. The latter provides a range of average costs by site and allows for identification of economies of scale.

2.3 | Sensitivity analysis

We undertook a series of one-way sensitivity analyses to assess the impact of key cost assumptions on the unit cost per HIVST kit distributed. We varied the discount rate used to annualize costs from the base case of 3% to 0% and 15% to capture the impact of not discounting or using a higher local central bank discount rate. Prevailing discount rates during the study period were 15% in Malawi, 12.5% in Zambia and 7% in Zimbabwe [13-15]. We further evaluated the impact of applying alternative allocation factors that is swapping % of kits distributed and % of CBDAs per site. We varied annualization (economic life years) time frames: training & sensitization was varied between one and three years (base case is two years) and project start-up life between 2.5 and 7.5 years (base case is five years) to assess impact if the project goes on for shorter or longer than assumed.

2.4 | Scenario analysis

In anticipation of planned programme scale-up by respective country ministries of health, we conducted scenario analysis varying salaries ±10% to assess the impact of integration into public health services, and variation in kit distribution by ±10%. We also modelled the impact of HIVST kit price between the observed average kit price (US$3.40), a recent Bill and Melinda Gates Foundation subsidized price (US$2) and a hypothetical price approximately equal to current rapid finger prick test price (US $1) [16]. Finally, we estimated a best- and worst-case scenario, the point where all the parameters yield the lowest/highest unit cost per kit distributed. To generate estimates that are comparable with the costs of ongoing facility HTS in the same communities in Malawi, Zambia and Zimbabwe [16], we also present costs without above site-level costs and start-up.

2.5 | Ethics

The study did not involve patient-level data collection; we did, however, obtain permission from ministries of health in the three countries to collate data from administrative, M&E records at facility level for cost allocation. Ethical approvals for the parent study were obtained from the Medical Research Council of Zimbabwe, Malawi College of Medicine Research Ethics Committee, University of Zambia Biomedical Research Ethics Committee, London School of Hygiene and Tropical Medicine Ethics Committee and University College London Ethics Committee. The trials are registered under the Clinical Trials Network (ClinicalTrials.gov) under registration numbers NCT02793804; NCT02718274; Pan African clinical trials registry PACTR201607001701788 for Malawi, Zambia and Zimbabwe.

3 | RESULTS

3.1 | Community-based distribution model programme outcomes

During the costing period, 152,671, 103,589 and 93,459 HIVST kits were distributed in Malawi, Zambia and Zimbabwe against the approximate targets of 62,500, 416,294 and 224,116 through a total of 138, 139 and 1009 CBDAs respectively. The average number of HIVST kits distributed was 12,538 (range: 4556 to 42,134) across 11 sites in Malawi, 7206 (range: 1758 to 20,450) across 16 sites in Zambia and 2124 (range: 319 to 4201) across 44 sites in Zimbabwe, where distribution was intentionally restricted by campaign duration (Table S2). Nearly half (49%, 51% and 43%, respectively) of the HIVST kits were distributed to men.

3.2 | Total HIVST costs and cost composition

Table 3 summarizes the findings of the cost analysis. The total distribution costs were calculated as US$1,243,940.66, US $1,700,730.45 and US$1,293,135.00 in Malawi, Zambia and Zimbabwe respectively. Capital costs accounted for 3%, 4% and 2% of the total costs with start-up costs accounting for 15%, 10% and 6% in Malawi, Zambia and Zimbabwe respectively. Within recurrent costs, personnel costs accounted for a significant portion of total costs, at 26%, 52% and 42% of costs in Malawi, Zambia and Zimbabwe respectively. Although the price of kits was centrally negotiated and thus the same across countries, kits contributed to the largest portion of total costs in Malawi (34%) and the second largest proportion in both Zambia and Zimbabwe (14% and 17% respectively).

3.3 | Unit costs

The country-level costs per HIVST kit distributed were US$8.15 for Malawi, US$16.42 for Zambia and US$13.84 in Zimbabwe. The cost per HIVST kit distributed across the sites ranged from US$7.20 to US$17.04 in Malawi, US$7.90 to U$50.00 in Zambia and from US$10.19 to US$54.44 in Zimbabwe. Figure 1 shows the unit cost per HIVST kit distributed plotted against the scale of HIVST kits across the three countries. Unit costs were generally lower at sites that were distributing a larger number of self-test kits, suggesting a spreading of fixed costs across variable numbers of kits. When above site-level and start-up costs are removed our estimates were comparable to the facility HTS unit costs estimated in the same communities [16]: US$6.67, US $10.42 and US$10.18 for the CBDA model, compared with facility HTS unit costs of $5.03 ($2.96 to $9.24), $4.24 ($2.49 to $6.24) and $8.79 ($3.38 to $21.51) in Malawi, Zambia and Zimbabwe respectively.

3.4 | Sensitivity and scenario analysis

Figures 2a,b,c show results from the univariate sensitivity and scenario analyses by country. Our unit costs per HIVST kit distributed remained robust when key cost parameters were varied. Varying life of start-up training and sensitization between one and three years resulted in costs of US$7.85 and US $16.42 versus US$9.07 and US$15.05 in Malawi and Zambia respectively. For Zimbabwe, however, there was no change to the base case cost of US$13.84 as training and sensitization costs were classified as recurrent due to the sequential and short-term nature of distribution across the eight districts, requiring training of CBDA who distribute for just four to six weeks. Varying life of start-up life or development phase between 2.5 and 7.5 years resulted in costs of US$8.23, US $15.40 and US$14.42 compared to US$8.13, US$14.28 and US $13.63 in Malawi, Zambia and Zimbabwe respectively.

Varying HIVST kit price between US$1 and US$3.40 yielded costs of US$6.44, US$15.15 and US$12.25 versus US $8.87, US$17.60 and US$14.99 in Malawi, Zambia and Zimbabwe respectively. Varying salaries by ±10% yielded costs of US$7.94, US$15.57 and US$13.24 versus US$8.37, US$17.27 and US$14.43 respectively. Varying kit quantity by ±10%

Table 3. HIV self-test kit distribution cost breakdown and key cost contributors (in 2017 US$)

	Malawi Kits distributed: 152,671 12 months: June 2016 to May 2017		Zambia Kits distributed: 103,589 11 months: July 2016 to May 2017		Zimbabwe kits distributed: 93,459 10 months: August 2016 to May 2017	
Input type	**Intervention cost**	**%**	**Intervention cost**	**%**	**Intervention cost**	**%**
Start-up						
Training	$11,313.34	1%	$31,000.73	2%	$3,149.10	0%
Sensitization	$58,485.72	5%	$58,306.80	3%	$2,694.30	0%
Start-up other	$108,409.87	9%	$84,745.15	5%	$75,942.83	6%
Capital costs						
Building and storage						
Central	$16,755.33	1%	$54,077.43	3%	$3,266.62	0%
Warehouse	$–	–	$–	–	$–	–
Site level	$–	–	$–	–	$–	–
Equipment						
Central equipment	$28,026.91	2%	$13,597.20	1%	$14,759.28	1%
Site level	$–	–	$–	–	$7,621.29	1%
Vehicles and bicycles	$3,162.38	0%	$–	–	$–	–
Other capital	$–	–	$–	–	$35.14	0%
Total costs (capital and start-up)	$226,153	18%	$241,727	14%	$107,468	8%
Recurrent costs						
Personnel	$318,129.23	26%	$880,688.56	52%	$555,187.86	42%
HIV self-test kits	$418,584.61	34%	$237,303.53	14%	$219,627.52	17%
Supplies						
T-shirts, bags, flipcharts	$35,611.73	3%	$78,569.63	5%	$67,757.98	5%
Other supplies	$–	–	$–	–	$142,543.96	11%
Vehicle operation, maintenance and transport	$109,240.41	9%	$148,117.37	9%	$57,396.14	4%
Building operation/maintenance						
Central	$2,204.87	0%	$19,416.76	1%	$18,602.17	1%
Warehouse	$–	–	$–	–	$13,141.39	1%
Site level	$–	–	$–	–	$–	–
Recurrent training	$13,409.18	1%	$19,235.49	1%	$90,440.92	7%
Waste management	$–	–	$–	–	$554.89	0%
Other recurrent	$120,607.08	10%	$75,671.83	4%	$20,414.02	2%
Total costs (recurrent)	$1,017,787	82%	$1,459,003	86%	$1,185,667	92%
Total CBDA HIVST costs	$1,243,940	100%	$1,700,730	100%	$1,293,135	100%
Cost per kit distributed	$8.15		$16.42		$13.84	

Note that totals have been rounded to the nearest US$.
HIVST, HIV self-testing; CBDA, community-based distribution agent.

yielded costs of US$7.41, US$15.63 and US$12.83 versus US $9.06, US$17.60 and US$15.07 respectively. The best-case scenario was US$6.14, US$13.99 and US$12.32 per kit distributed, whereas the worst-case scenario was US$10.27, US $20.12 and US$21.85 per kit distributed.

4 | DISCUSSION

This is the first published study to present costs of door-to-door CBDA delivery of HIVST kits in Malawi, Zambia and Zimbabwe. Costs ranged from as low as US$7.20 at a very large distribution site where CBDA distribution of HIVST kits was integrated with the delivery of other health products, to US$54.55 with campaign-style delivery in a very small community in Zimbabwe that would otherwise not have access to testing. Staff costs contributed a substantial portion of the costs highlighting potential opportunities for lower cost models from reconfiguring distribution to rely on unpaid volunteers within door-to-door community-led distribution models. Additionally, economies of scale can clearly be optimized. In this analysis, we showed how unit costs fall as the number of

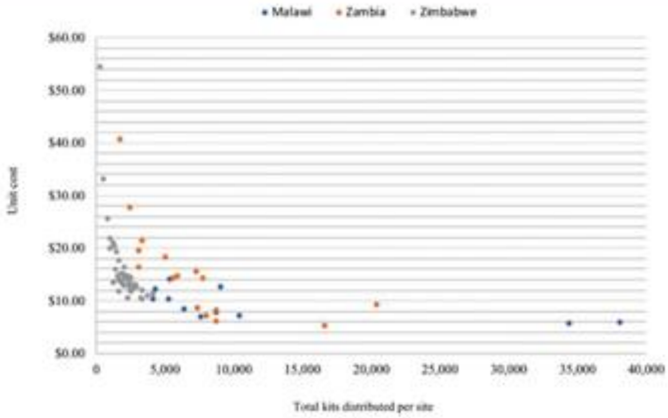

Figure 1. HIV self-testing (HIVST) costs per HIVST kit distributed by site and quantity in 2017 US$.

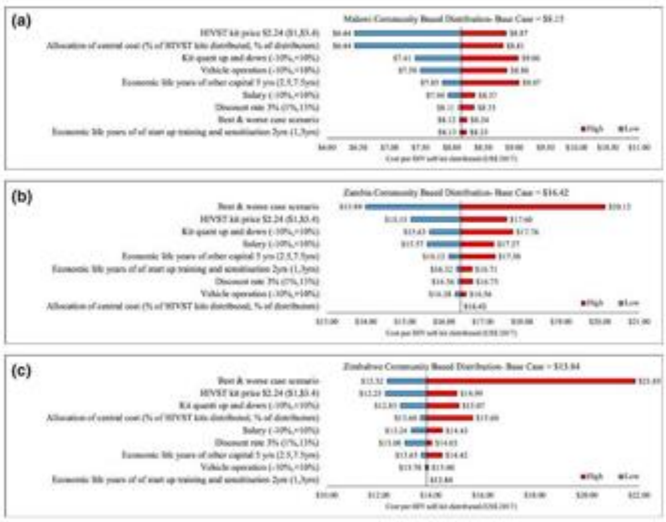

Figure 2. (a, b, c) Tornado diagrams of findings from deterministic sensitivity analysis (univariate and scenario analyses) in Malawi, Zambia and Zimbabwe.

kits distributed increases. As all modes of testing are scaled up and testing coverage increases, it will be critical to target populations efficiently, with special focus on communities underserved by facility-based HTS.

Although costs are presented from a provider's perspective, door-to-door community HIVST distribution relieves users from substantial direct and indirect costs of attending health facilities. A study in these same communities in Malawi showed the mean costs of accessing HIV testing among women and men as US$1.83 and US$3.81, respectively, with men reporting significantly higher opportunity costs (i.e. lost income) [17]. Community HIVST distribution reduces these costs to nearly zero, as kits are delivered in the home with no waiting times. We can, therefore, estimate the societal costs of facility-based HIV testing in Malawi as US$6.86 for women and US$8.84 for men (the user costs reported above and the provider costs as reported by Mwenge et al. [16]). This is comparable with our observed HIVST societal costs (excluding start-up and above service level costs: US$6.67) in Malawi. Thus, HIVST may provide for unmet testing needs among remotely or never-tested individuals, or others with high user costs of accessing facility-based testing.

HIVST costs reflected across all three countries are not dissimilar to those reported previously in Malawi ($8.78 in 2016 US$) [18]. We also found the cost of door-to-door community HIVST distribution to be comparable to standard community-based HIV testing in sub-Saharan Africa (range: US$7.37 to US $36.93) [19,20]. While we did find that CBDA delivered HIVST under this early demonstration and research programmes were more costly than facility-based HIV testing [16,18], we also found HIVST reached many more individuals. During the period of this costing study, health facilities serving the study communities provided HIV testing to approximately 17,000, 28,000 and 45,000 people, while the HIVST service distributed approximately 152,671, 104,000 and 94,000 kits in Malawi, Zambia and Zimbabwe respectively. Importantly, half of the HIVST kits were distributed to men, while only 26% to 37% of facility HIV testing clients were men [8-10], the population group primarily contributing to the HIV testing gap.

We anticipate potential for substantial economies of scale as HIVST programmes scale-up and mature. The door-to-door community HIVST distribution model costed for this current study was implemented by a non-governmental organization, under a research protocol, using paid and incentivized CBDAs and delivered to predominantly rural communities with no previous knowledge of, or experience with, HIVST. Interventions delivered in a research context tend to be associated with higher costs, as the primary objective is achieving effectiveness. Large-scale implementation through door-to-door community-led HIVST distribution with ordinarily paid government providers or community residents is likely to be significantly less costly. There are additional potential costs savings. First, we found costs were lower in high kit distribution sites suggesting economies of scale and ability to deliver at lower costs in more densely populated communities. Second, 10% to 20% of the costs were start-up and initial capital costs, which would decrease as services mature. Third, as general populations and providers gain a better understanding of HIVST as a screening technology, we would expect less intense need for CBDAs (and therefore, less intense need for training workshops) and community sensitization activities.

Additionally, CBDAs could incorporate HIVST delivery into other health service activities thereby delivering cost savings to providers through economies of scope in services delivered by the CBDAs. Finally, as the HIVST market grows, technology advances and newer manufacturers enter, the price of HIVST kits will likely fall to prices comparable to blood-based kits currently used in health facilities and in-person support requirements could, in theory, could become cheaper than provider-supervised testing. In this case, HIVST could save costs and allow providers to focus on confirmatory testing and strengthening linkage to ART [21,22]. To identify this, it will be important to take a full system costing approach. Such data have been collated and will be analysed jointly to inform cost-effectiveness modelling.

From a research perspective, the wide cost variations highlight the importance of evaluating costs across a variety of settings in order to generate means and confidence intervals. Future analyses of these data may generate useful insights into efficiency and provide key inputs into modelled cost-effectiveness analyses. It would also be important to expand conventional sensitivity analyses to assess unit costs when these observed ranges are included or when unit costs are incorporated as a function of scale. Furthermore, considering that our analysis only shows the costs of implementing CBDA model for a non-governmental perspective and that these costs can vary if the kits were distributed differently, an important next research question will be to explore the costs of possible HIVST distribution modalities such as secondary distribution and social marketing models among others.

4.1 | Limitations

The findings of our cost analyses are limited to unit costs per kit distributed as the private nature of the HIVST did not allow us to estimate the costs of identifying new HIV-positive individuals or those HIV-positive individuals linked to treatment through HIVST. In addition, our results are borne out of a research trial setting and may not truly reflect a real-world situation: for example, site fixed transport costs are likely higher due to the distances between the trial communities, while in routine scale-up, all communities would receive HIVST kits and transport would be shared across far higher scale.

Additionally, as HIVST was a new product, distribution was conservative, restricting the numbers of kits that each CBDA could distribute in Zimbabwe, and so constraining opportunities to operate at larger scale. Consequently, costs were likely higher than future routine implementation. The benefits of HIVST distribution may also be restricted by test performance characteristics such as sensitivity, specificity and ability of the user to read the test as well as rates of linkage to care. An important consideration would be the optimal, setting-specific incentive structure for door-to-door community-based distribution of the kits. It is important to highlight that for purposes of this analyses authors had not collated and analysed data on self-test kit utilization. However, previous work has not only shown high uptake of HIVST but also high levels of kit utilization by recipients [4]. Key strengths of this cost analysis are the estimation of costs across seventy-one sites in three Southern African countries. The costing teams used standardized costing guidelines and collaboratively analysed data ensuring consistency of methods across countries and application of a range of sensitivity and scenario analyses exploring the impact of our assumptions.

4.2 | Implications

Countries keen to achieve impact and meet the global testing and treatment targets will likely need to invest in a mixture of HIV testing approaches, including door-to-door community delivered HIVST targeted at populations with financial or other barriers to obtaining HIV testing in health services, that is people living in settings with high undiagnosed HIV or remote communities, and groups such as men and adolescents. Reducing costs during short-term scale-up and implementation of this model should focus on economies of scope and scale and ensure efficiencies in personnel and transportation costs. Alternative cost-minimization approaches also need to be explored for acceptability, impact and affordability, aiming to provide affordable access to HIVST nationally, for example integrating HIVST within the existing facility and community health services, secondary distribution from facilities including partner delivered and peer-network approaches.

5 | CONCLUSIONS

Staff costs were a substantial cost contributor highlighting the potential for lower cost models if distribution relied on unpaid volunteers within door-to-door community-led distribution models.

Economies of scale can also be optimized with our costs showing reductions when kits are distributed in higher numbers. Across all three countries, our HIVST cost estimates were not dissimilar to previous door-to-door community-based HIVST and standard community-based HIV testing models costed in sub-Saharan Africa. Although the costs of CBDA delivered HIVST were higher than facility-based HIV testing the evidence shows HIVST reaches many more individuals. A significant portion (almost half) of HIVST kits were distributed to men (key contributors to the HIV testing gap) compared to only 26% to 37% for facility HIV testing.

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COMPETING INTERESTS

The authors have no conflicts of interest to declare.

AUTHORS' CONTRIBUTIONS

CM, LM, LS, NA, MD, HM and FTP conceptualized and designed the study. CM, LM, LS, NA, PC, TC and SK collected and facilitated the collection of data. CM, LM, LS, NA, PC, TC, SK, MD, JJO, HM and FTP analysed and interpreted the data. CM, LM, LS, NA, MD, PC, TC, SK, JJO, MM, MN, RC, PI, ELS, MNE, GN, OM, KH, CJ, HA, ELC, FC, HM and FTP drafted the manuscript and revised it critically. MM, MN, RC, PI, ELS, MNE, GN, OM, KH, CJ, HA, ELC, FC, HM and FTP supervised the study and facilitated the acquisition of the cost data. All co-authors approved the final version to be published.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Table S1: Cost allocation factors across the interventions by cost input type.

Table S2: Site-level total and unit costs of HIVST and facility-based testing.

Data S1: Narrative description of the CBDA models across countries.

Data S2: Definitions of cost category and cost inputs and allocation factors.

10.2. Appendix C: Data collection tools

Appendix C1: Relevant Individual demographic questions

Individual - sociodemographics

To be completed by all individuals consenting to participate within the household

I would now like to ask you information about yourself.

Question No.	Construct	Variable	Wording of question	Data entry	Skips	Ranges for continuous variables	Hint
A02	Sex	respsex	(Interviewer to indicate)	1 Male 2 Female			
A03	Date of birth	respdob	What is your date of birth?	Select for Day Month Year	If respdob is known, skip to edu	[TODAY'S DATE-16 YEARS]-[TOMORROW'S DATE-99 YEARS]	
A04	Age in years	respageyrs	How old are you?	Number		16-99	
A05	Educational attainment	edu	What was the highest level of education that you have completed?	1 No formal schooling; 2 Primary incomplete or complete 3 Secondary incomplete 4 Secondary complete 5 Tertiary or higher 9 Decline to answer			
A06	Literacy	literate	Can you read a newspaper or letter?	Y-N-DTA		If edu is 4 or 5, literate should be yes	

A07	Employment status	salary	Are you employed for a wage salary, commission or any formal payment in kind excluding casual labour, for anyone who is not a member of your household?	Y-N-DTA	If no, skip to A09		
A08	Wage income	wage	In a month, how much do you earn for wage/salary and commission before taxes?	Number		1-??, 9999999	Enter 9999999 for decline to answer
A09	Allowance income	allow	In a month, how much do you usually receive in allowances or gratuities, including in-kind payments such as uniform, housing, food and transport that were not included in the salary you just reported?	Number		0-??, 9999999	Estimate cash value of any in-kind payments received Enter 9999999 for decline to answer Enter 0 if no payments were received
A10	Business income	businessinc	In a month, how much average profit do you earn on business enterprises that give you constant earnings?	Number		0-??, 9999999	Sum up the average profits for all enterprises owned Enter 9999999 for

							decline to answer Enter 0 if no payments were received
A11	Informal income wage	informalwage	In a month, how much do you earn from informal income sources aside from those listed above?	Number		0-??, 9999999	Enter 9999999 for decline to answer Enter 0 if no payments were received

Appendix C2: Testing Uptake

Question No.	Variable name	Construct	Wording of question	Data type	Skips	Ranges	Hint	Notes
B01	evertest	Ever tested for HIV	Have you ever been tested for HIV?	Y-N-DTA	If yes, skip to yrtestcount			
B02	thoughttest	Thought about testing	Have you ever thought about testing for HIV?	Y-N-DTA				
B03	whynottest_X	Why not tested?	What best describes why you haven' t tested for HIV?	A I am not at risk of being HIV positive or contracting HIV infection - Y-N-DTA B. I don't want to know my HIV status - Y-N-DTA C. I am afraid of testing positive or dying after HIV positive results - Y-N-DTA D. I am afraid of stigma and discrimination related to HIV testing - Y-N-DTA [COMMENT: ?? I AM AFRAID OTHER PEOPLE WILL JUDGE ME OR TREAT ME POORLY IF I TEST FOR HIV??] E. I don’t feel sick enough to test for HIV - Y-N-DTA F. HIV testing is not a dignified or important thing to do at my age - Y-N-DTA G. I am too young to test or not yet sexually active - Y-N-DTA [COMMENT: DON'T KNOW ABOUT THIS - WOULDN'T THEY JUST PUT ANSWER A]		If decline to answer for one choice, must have decline to answer for all choices		Read out - revised categories for endline

				H. My partner won’t let me test or may blame me for bringing HIV into this relationship - Y-N-DTA [COMMENT: THE SECOND PART IS QUITE SPECIFIC. MAYBE INSTEAD: MY PARTNER WON'T LET ME TEST OR I AM AFRAID OF THE CONSEQUENCES OF TESTING ON MY RELATIONSHIP I. My family member(s) won’t let me test - Y-N-DTA [COMMENT: COULD WORD SIMILAR TO THE SUGGESTED ANSWER FOR THE PARTNER QUESTION] J. It is too expensive for me to visit the facility, or the facility is too far away - Y-N-DTA K. I cannot take time off work to go test - Y-N-DTA [COMMENT: COMBINE WITH ANSWER BELOW: IT IS DIFFICULT FOR ME TO TAKE TIME OUT OF THE DAY TO GO TEST] L. It will take too much time to test - Y-N-DTA [COMMENT: TAKE THIS ANSWER OUT WITH SUGGESTED MODIFICATION ABOVE] M. Health facilities offer poor quality HTC services - Y-N-DTA [COMMENT: COMBINE WITH ANSWER BELOW: MY NEAREST HEALTH FACILITY OFFERS				

				POOR TESTING SERVICES, INCLUDING SHORTAGES OF STAFF AND TESTS] N. Health facilities lack testing materials - Y-N-DTA [COMMENT: TAKE THIS ANSWER OUT WITH SUGGESTED MODIFICATION ABOVE] O. I think my TEST results will not be confidential or I don't want to be tested by someone who knows me - Y-N-DTA P. I don't like the attitude of the health care providers - Y-N-DTA Q. Other reason - Y-N-DTA				
B04	knowfac	Know of facility	Do you know any facilities offering HIV testing and counselling to people who live around here?	Y-N-DTA	If no or DTA, skip to thoughttest			Note that following non-user questions are from WHO generic tools
B05	faceasy	How easy to reach facility	If you wanted to go, how easy or difficult would it be for you to go the health facility from your home?	1 Very easy 2 Somewhat easy 3 Somewhat difficult 4 Very difficult 9 Decline to answer				
B06	offeredtest	Had test offered	Have you ever had an HIV test offered to you when you were at a health	Y-N-DTA	Go to heardselftest			End of non-user section

			facility or in your home?					
B07	yrtestcount	Testing in last twelve months	In the last 12 months, that is before [TODAY'S DATE-12 MONTHS], how many times have you tested for HIV?	Number	If 88 or 99, skip to testdate_1	0-15, 88, 99	If you had a test to confirm earlier results, this should be counted separately Enter 88 for don't know or 99 for decline to answer	
B08	lifetestcount	Lifetime test count	In total, how many HIV tests have you had in your lifetime?	Number		1-50 (value must be greater than yrtestcount), 88, 99	If you had a test to confirm earlier results, this should be counted separately Enter 88 for don't know or 99 for decline to answer	

B09	testdate_1	Dates of last three tests	What was the date of your most recent HIV test?	MY		[TODAY'S DATE]-[TODAY'S DATE-12 MONTHS] based on yrtestcount, otherwise [TOMORROW'S DATE-12 MONTHS]-[DATE OF BIRTH]	For dates prior to 2015, indicate only the year.	
B10	testdate_2	Dates of last three tests	What was the date of your second-most recent HIV test?	MY	If lifetestcount=1, 1 count If lifetestcount=2, 2 count If lifetestcount>=3, 3 count If lifetestcount=88 or 99 & yrtestcount=1, 1 field If lifetestcount=88 or 99 & yrtestcount=2, 2 count If lifetestcount=88 or 99 & yrtestcount>=3, 3 count If yrtestcount=88 or 99, 1 field	[TODAY'S DATE]-[TODAY'S DATE-12 MONTHS] based on yrtestcount, otherwise [TOMORROW'S DATE-12 MONTHS]-[DATE OF BIRTH]	For dates prior to 2015, indicate only the year.	

B11	testdate_3	Dates of last three tests	What was the date of your third-most recent HIV test?	MY	If lifetestcount=1, 1 count If lifetestcount=2, 2 count If lifetestcount>=3, 3 count If lifetestcount=88 or 99 & yrtestcount=1, 1 field If lifetestcount=88 or 99 & yrtestcount=2, 2 count If lifetestcount=88 or 99 & yrtestcount>=3, 3 count If yrtestcount=88 or 99, 1 field	[TODAY'S DATE]-[TODAY'S DATE-12 MONTHS] based on yrtestcount, otherwise [TOMORROW'S DATE-12 MONTHS]-[DATE OF BIRTH]	For dates prior to 2015, indicate only the year.	
B12	heardselftest	Heard of self-testing	Have you heard about HIV self-testing as a method for testing for HIV? [Definition if needed from WHO technical report: HIV self-testing is a process whereby a person who wants to know	YN	If no and evertest=yes, skip to knowresults. If no and evertest=no or DTA, skip to knowfollowup			

			his or her HIV status collects a specimen, performs a test, and interprets the test result in private.]					
B13	howheard_*	How heard of HIV self-testing	Where did you hear about HIV self testing?	Check all that apply: A. community-based distributor B. friend or family member C. other community member D. healthcare provider E. VMMC mobilizer F. Tunza/New Start counselor G. Workplace peer educator H. Targeted outreach communication I. Community drama J. National events (VCT day, national health week & World AIDS Day) K. Print media: leaflet/brochure L. Other media: whatsapp/Facebook M. Other person or event N. Decline to answer	If evertest=no or DTA, go to knowfollowup	If decline to answer for one choice, must have decline to answer for all choices		PHS to review with colleagues
B14	selftestever	Self test ever	Have you ever used a self-test to test for HIV?	Y-N-DTA	If no or DTA, skip to knowfollowup			
B15	selftest12mos	Self test within past 12 months	Within the past 12 months, have you used a self-test to test for HIV?	Y-N-DTA				

B16	knowfollowup	Awareness of follow-up - HIV care	If you were to test positive , do you know how to access appropriate follow-up services?	YN			Follow-up services include care and treatment services, including ART and confirmative testing for those testing positive.	Note that there is a similar question on VMMC in the VMMC section

Appendix C3: Costs of testing Uptake

To be completed by SELECTED individuals ONLY

For each of last three tests

(Note that past year time is reflected in IPV questions)

Costs questions are in blue rows and should be asked only of the first test if this test occurred within the past 12 months

Prompt [OUTSIDE LOOP]: Now I would like to ask you more about your last [3] HIV tests. If you have had a test to confirm earlier results, I want you to tell me about each test separately.

Prompt [INSIDE LOOP]: For these sets of questions, I would like to ask you about your [last/second-to-last/third-to-last] test on [testdate_1]

Question No.	Variable name	Construct	Wording of question	Data type	Skips	Ranges	Hint	Notes
C01	testloc_X	Location of test	Where did you have your [last/second-to-last/third-to-last] HIV test?	1 Health facility (not ANC) 2 ANC centre 3 VCT centre 4 HTC in the community (ie. Mobile VCT) 5 Self-test at the health facility 6 Self-test at home or in the community				In the community = not at a facility/not at home. Note that respondents will have already answered this for the first test in the indiv-testing questions and could be skipped or preanswered?

C02	testinit_X	Initiation of test	Who initiated the test?	1 Own initiative: I approached the provider or or distributor about testing 2 Partner initiative: My partner approached me about testing. 3 Offered by health worker or community volunteer (CBDA): A provider or health worker approached me and suggested testing 4 VMMC: A VMMC mobilizer approached me to test 5 Other person: Another person (not a health worker, VMMC mobilizer, or partner) approached me and suggested testing 6 Decline to answer	If testdate_X< 12 months & selftest12mos=no, skip to C07 If selftestever= no, skip to C07			Split first item into own then partner (done)
C03	selftest_X	Self-test	Was this test a self-test?	Y-N-DTA	If no or DTA, skip to discusspart_X			Two sets of questions on partner tests based on self-test/not self test - this is potentially confusing

								for data analysis
C04	selftestsource_X	Self-test - where from	Who did you obtain the self-test from?	1 CBDA 2 VMMC mobilizer 3 Health care worker 4 Partner 5 Parent 6 Sibling 7 Other family member 8 Friend 9 Chief 10 Employer 11 Teacher 12 Religious leader 13 Other 99 Decline to answer				
C05	selftestalone_X	Self-test - anyone present?	Was anyone else with you when you self-tested?	Y-N-DTA	If no, skip to testdur or knowres_X			

C06	selftestpresent_X	Self-test - who present?	Who was with you when you performed the self-test?	(Check all that apply) A CBDA - Y-N-DTA B Health care worker - Y-N-DTA C Partner - Y-N-DTA D Parent - Y-N-DTA E Other family member - Y-N-DTA F Friend - Y-N-DTA G Chief - Y-N-DTA H Employer - Y-N-DTA I Teacher - Y-N-DTA J Religious leader - Y-N-DTA K Other - Y-N-DTA		If decline to answer for one choice, must have decline to answer for all choices			Added HCW to options
C07	discusspart_X	Discussion with partner	Did you discuss testing with your partner before you tested?	Y-N-N/A-DTA	If no or N/A or DTA, skip to testdur If no or N/A or DTAand not selected for extended survey or not the most recent test that occurred within past 12 months, skip to knowres_X	If testinit_X= 2 or selftestsource=4 or seltestpresent_X_C=yes, then discusspart_X should probably be yes			

C08	testpart_X	Testing with partner	Did you test at the same time as when your partner also tested?	Y-N-N/A-DTA	If not selected for extended survey and not the most recent test that occurred within past 12 months, skip to knowres_X			Note rewording to differentiate between testing with partner present and testing while partner tested
C09	testpart_X	Testing with partner	Did you test with your partner in your [LAST/SECOND/THIRD TO-LAST] HIV test?	YN	Valid for non-self-tests only			Note - there is a question about partner testing in the short testing section adminstered to everyone. Reordered questions so testing with partner and self-testing with partner both before costs

C10	testdur	Costs - duration	**[Prompt for costs questions:] Now, I would like to ask you about the incurred costs from your last HIV test ?** How long did it take to have your test? Including travelling to the facility waiting to be tested and waiting for your results?	Select Minutes Hours	Only ask if selected for extended survey and the most recent test that occurred within past 12 months	Minutes: 0-59 Hours: 1-12	Enter 99 for decline to answer	
C11	testvisitreas	Costs - reason for travel	Was this visit to the [LOCATION OF TEST] primarily to be tested for HIV?	Y-N-DTA	Only ask if selected for extended survey and the most recent test that occurred within past 12 months			Note that [LOCATION OF TEST] will be gathered earlier in the questionnaire
C12	testtrans	Costs - transit mode	How did you get to the [LOCATION OF TEST] ?	1 Walked 2 Took own bicycle 3 Took public transport 4 Used own car or motorcycle 5 Took taxi (bicycle or car) 6 Other	If 1 or 2, skip to C14 If C01=5, skip to C13 Only ask if selected for extended survey and the most recent test that occurred within past 12 months			

C13	costtrans	Costs - transit costs	How much did you pay to get to [LOCATION OF TEST] and back home?	Number	Only ask if selected for extended survey and the most recent test that occurred within past 12 months	1-25,000	Enter 888888 for don't know and 999999 for decline to answer	
C14	consultfee	Costs - consultation	Did you have to pay any fees to take the HIV test? This includes consultation, registration, the test kit, and health passport.	Y-N-DTA	Skip if selftest_X=yes If no or DTA, skip to C16 Only ask if selected for extended survey and the most recent test that occurred within past 12 months			

C15	costconsult	Costs - consultation costs	How much in fees did you pay to take the HIV test?	Number	Skip if selftest_X=yes Only ask if selected for extended survey and the most recent test that occurred within past 12 months	1-25,000	Enter 888888 for don't know and 999999 for decline to answer	
C16	childcare	Costs - child care	Did you have to pay for anyone to cover your regular duties while getting the HIV test? This includes to take care of your children, supervise your shop, or perform your agricultural activities.	Y-N-DTA	If no or DTA, skip to C17 Only ask if selected for extended survey and the most recent test that occurred within past 12 months			
C17	costchildcare	Costs - child care costs	How much did you pay for someone to cover your regular duties?	Number	Only ask if selected for extended survey and the most recent test that occurred within past 12 months	1-25,000	Enter 888888 for don't know and 999999 for	

							decline to answer	
C18	food	Costs - food	Did you have to purchase food outside the home because of your HIV test?	Y-N-DTA	If no or DTA, skip to C20 Only ask if selected for extended survey and the most recent test that occurred within past 12 months			
C19	costfood	Costs - food costs	How much did you pay for food?	Number	Only ask if selected for extended survey and the most recent test that occurred within past 12 months	1-25,000	Enter 888888 for don't know and 999999 for decline to answer	

C20	other	Costs - other	Did you have any other incurred costs related to your last HIV test?	Y-N-DTA	If no or DTA, skip to C22 Only ask if selected for extended survey and the most recent test that occurred within past 12 months			
C21	costother	Costs - other costs	If yes, how much did you pay?	Number	Only ask if selected for extended survey and the most recent test that occurred within past 12 months	1-25,000	Enter 888888 for don't know and 999999 for decline to answer	
C22	costworklost	Costs - how much earned	How much would you have earned during the time you took off to get tested for HIV?	Number	Only ask if selected for extended survey and the most recent test that occurred within past 12 months	0-??	Enter 888888 for don't know and 999999 for	Note: if in kind, need prompt to obtain value

							decli ne to answ er	
C23	costsource	Costs - source	Who primarily provided the money to support the costs of accessing the test?	1 Myself 2 My partner 3 Myself and my partner jointly 4 Family 5 Friend 6 Employer 7 Other 9 Decline to answer	Only ask if selected for extended survey and the most recent test that occurred within past 12 months			

10.3. Appendix D: Ethics approvals

CERTIFICATE OF ETHICS APPROVAL

This is to certify that the College of Medicine Research and Ethics Committee (COMREC) has reviewed and approved a study entitled:

P.01/16/1861 – HIV self-testing Africa (STAR) Malawi: General population – A duster randomized trial of providing HIV and self-testing kits through community-based distribution agents by Dr. Nicola Desmond

On 29th February 2016

As you proceed with the implementation of your study, we would like you to adhere to international ethical guidelines, national guidelines and all requirements by COMREC as indicated on the next page

[redacted]

Approved by
College of Medicine
29 FEB 2016
(COMREC)
Research and Ethics Committee

29/02/2016
Date

Observational / Interventions Research Ethics Committee

Prof Liz Corbett
Professor of Clinical Epidemiology
Department of Clinical Research (CRD)
LSHTM

19 April 2016

Dear Prof Liz Corbett ,

Study Title: HIV Self-Testing AfRica (STAR) Malawi: General Population

LSHTM ethics ref: 10566

Thank you for your application for the above research, which has now been considered by the Interventions Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	Malawi CVs	13/01/2016	1
Protocol / Proposal	Gen pop - questionnaires	19/01/2016	1
Information Sheet	Gen pop - updated consent and info 27 Jan	27/01/2016	2
Sponsor Letter	QA786_HIVST_Sponsor Confirmation	27/01/2016	1
Protocol / Proposal	STAR Malawi - General Population V2.0	24/02/2016	2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

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LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

Ms LINDA SANDE

LSHTM

31 October 2018

Dear Linda,

Study Title: Does HIV self-testing improve socioeconomic equity in access to HIV testing in Malawi and Zambia?

LSHTM ethics ref: 15465

Thank you for your application for the above research, which has now been considered by the Observational Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Consent form	PS04A-Participant Information Sheet, Household Survey V2.0	27/04/2015	2.0
Local Approval	STAR UNZA REC Impact Amendment approval Letter 20150606	06/06/2015	1.1
Local Approval	COMREC Gen pop	29/02/2016	1.0
Local Approval	STAR General Population April 2016 - LSHTM Approval	19/04/2016	1.0
Local Approval	LSHTM_amend	20/09/2016	1.0
Consent form	hh survey ICF v1.0_23-08-17	23/08/2017	1.0
Consent form	PS.CL.01B - Consent Form, Acceptability and Feasibility of Community-led HIVST-Mw,Zm	30/11/2017	1.0
Consent form	PS04F - Assent Form V1.0-Mw.Zm	30/11/2017	1.0
Investigator CV	Neuman BBSRC CV Aug 2018	31/08/2018	1.0
Investigator CV	Linda Sande CV-30-09-18	30/09/2018	1.0
Investigator CV	Dr Maheswaran_Full_CV_Sept_2018	30/09/2018	1.0
Investigator CV	E_Corbett_Biosketch 2018. Current.	30/09/2018	1.0
Protocol / Proposal	Socioeconomic equity in acess to HIV testing in Malawi and Zambia Protocol_V1.1	18/10/2018	1.1
Investigator CV	Terris-Prestholt CV Oct 2018	21/10/2018	1.0

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk