Cost-effectiveness analysis of HIV self-testing among key populations in Côte d'Ivoire, Mali, and Senegal

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Abstract

Background: Despite global efforts to End AIDS, HIV still poses a significant public health challenge in Western Africa. Its burden disproportionately affects key populations (KP), which includes men who have sex with men (MSM), female sex workers (FSW) and their clients, and people who use drugs, among others. HIV self-testing (HIVST) is a promising strategy to improve HIV testing rates and reduce the undiagnosed fraction of people living with HIV (PLHIV). It could help achieve the UNAIDS 95-95-95 goals of 95% knowledge of status among PLHIV. The community-led ATLAS programme implemented and promoted HIVST in three West African countries over 2019-2021, distributing over 350,000 kits, focussing on KP and secondary distribution to their partners and relatives.

Objectives: My thesis aims to evaluate the cost-effectiveness of the ATLAS HIVST programme and of its potential scale-up in Côte d'Ivoire, Mali, and Senegal. To achieve this, I:

1) Evaluated the incremental costs and affordability of the ATLAS HIVST programme and of HIVST scale-up scenarios in Côte d'Ivoire, Mali, and Senegal,
2) Examined the cost-effectiveness of HIVST scenarios and assess the sensitivity of these estimates to various assumptions,
3) Compared the incremental cost-effectiveness ratios from my thesis to previously published estimates.

Methods: The epidemiological impact of HIVST was assessed using a previously developed and calibrated compartmental model of sexual HIV transmission dynamics that reflects testing behaviours, including HIVST. I considered the distribution of HIVST to two KP groups and their partners: FSW and MSM. I compared the cost-effectiveness of two main scenarios against a counterfactual one (without HIVST) over a 20-year horizon (2020-2039). The first scenario corresponds to the observed ATLAS programme (ATLAS-only) and the second one to a hypothetical national scale-up version of ATLAS (ATLAS scale-up). I evaluated the effectiveness of HIVST using the number of disability-adjusted life-years (DALY) averted by each modeled scenarios in the three countries. Scenarios were compared using incremental cost-effectiveness ratios (ICER). Costing was performed using a healthcare provider's

perspective, costs were discounted at 4%, and standardized to $USD 2020. The 90% uncertainty intervals for the ICER are calculated by resampling the epidemiological outcomes from the model and costs from triangular distributions using 10 000 Monte-Carlo simulations.

Results: The ATLAS-only scenario averted a small number of new HIV infections but was nevertheless highly cost-effective, even under low willingness-to-pay thresholds. The ICERs are below $130 per DALY averted for all three countries. When considering the scale-up of the program, substantial epidemiological impacts were achieved. The ICERs for the scale-up scenario were $199 (90%UI: $122 to $338) per DALY averted in Côte d'Ivoire, $224 (90%UI: $118 to $415) in Mali, and $61 (90%UI: $18 to $128) in Senegal. Even over a shorter 10-year time horizon, the programmes were still very cost-effective, with ICERs for all countries below $330 per DALY averted for ATLAS-only scenario, and below $510 per DALY averted for ATLAS scale-up.

Conclusion: HIVST programmes in West Africa, where KP are important to overall transmission dynamics, have the potential to be highly cost-effective. These findings support the integration of HIVST within HIV testing services as an additional modality that can reach undiagnosed people living with HIV.

Résumé

Contexte: Malgré les efforts mondiaux pour mettre fin au SIDA, le VIH demeure un défi majeur pour la santé publique en Afrique de l'Ouest. Dans cette région, le fardeau de la maladie affecte disproportionnellement les populations clés (PC). Les PC comprennent les hommes ayant des rapports sexuels avec d'autres hommes (HSH), les travailleuses du sexe (TS) et leurs clients, ainsi que les consommateurs de drogues. L'auto-dépistage VIH (ADVIH) est une stratégie prometteuse pour améliorer les taux de dépistage du VIH et réduire la proportion de personnes vivant avec le VIH (PVVIH) non diagnostiquées. Ceci pourrait faciliter l'atteinte du premier objectif « 95-95-95 » de l'ONUSIDA qui vise à ce que 95% des PVVIH connaissent leur statut sérologique. Le programme communautaire ATLAS a mis en œuvre et promu l'ADVIH dans trois pays d'Afrique de l'Ouest de 2019 à 2021, distribuant plus de 350 000 kits, en se concentrant sur les PC et la distribution secondaire à leurs partenaires et proches.

Objectifs: Mon mémoire vise à évaluer le rapport coût-efficacité du programme ATLAS et de son potentiel de mise à l'échelle en Côte d'Ivoire, au Mali et au Sénégal. Pour ce faire, j'ai :

1) Évalué les coûts incrémentaux et l'accessibilité financière du programme ATLAS ADVIH et des scénarios d'expansion de l'ADVIH en Côte d'Ivoire, au Mali et au Sénégal,
2) Examiné le rapport coût-efficacité de scénarios de ADVIH et évalué la sensibilité de ces estimations à diverses hypothèses,
3) Comparé les ratios de coût-efficacité incrémentiels de mon mémoire aux estimations précédemment publiées.

Méthodes: L'impact épidémiologique des ADVH a été estimé à partir des résultats d'un modèle dynamique à compartiments, développé et calibré précédemment, de la transmission sexuelle du VIH qui reflète les comportements de dépistage, y compris l'ADVIH. J'ai pris en compte la distribution de l'ADVIH à deux groupes de PC et leurs partenaires: les TS et les HSH. J'ai comparé le rapport coût-efficacité de deux scénarios principaux à un scénario de référence sans ADVIH sur un horizon temporel de 20 ans (2020-2039). Le premier scénario correspond au programme ATLAS (ATLAS-uniquement) et à un scénario hypothétique de mise à l'échelle nationale des ADVIH (ATLAS-mise-à-l'échelle). J'ai évalué l'efficacité de l'ADVIH en

utilisant le nombre d'années de vie corrigées de l'incapacité (AVCI) évitées. Les scénarios ont été comparés à l'aide de ratios coût-efficacité incrémentiels (RCEI). L'évaluation des coûts a été réalisée du point de vue du prestataire de soins de santé, les coûts ont été actualisés à 4% et standardisés en $USD 2020. Les intervalles d'incertitude à 90% des RCEI ont été calculées en rééchantillonnant les impacts épidémiologiques du modèle et les coûts à partir de distributions triangulaires à l'aide de 10 000 simulations de Monte-Carlo.

Résultats : Le scénario ATLAS uniquement a évité un petit nombre de nouvelles infections par le VIH mais était néanmoins très rentable, même avec de faibles seuils de volonté de payer. Les RCEI sont inférieurs à 130 $ par AVCI évitée pour les trois pays. Lorsque l'on considère l'expansion du programme, un impact épidémiologique considérable a été atteint. Les RCEI pour le scénario mise à l'échelle étaient de 199$ (90%UI: 122$ à 338$) par AVCI évitée en Côte d'Ivoire, 224$ (90%UI: 118$ à 415$) au Mali et 61$ (90%UI: 18$ à 128$) au Sénégal. Même sur un horizon temporel plus court de 10 ans, les programmes sont toujours très rentables, avec des RCEI inférieurs à 330$ par AVCI évitée dans les trois pays pour le scénario ATLAS uniquement, et inférieurs à 510$ par AVCI évitée pour le programme ATLAS mise à l'échelle.

Conclusion: Les programmes ADVIH en Afrique de l'Ouest, où les PC sont importantes aux dynamiques de transmission, ont le potentiel d'être hautement rentables. Ces résultats soutiennent l'intégration de l'ADVIH dans les services de dépistage du VIH comme une modalité supplémentaire pouvant atteindre les personnes vivant avec le VIH non diagnostiquées.

Preface

This thesis focuses on the ATLAS ("*Auto-test VIH, libre d'accéder à la connaissance de son statut*") community-led HIV self-testing (HIVST) programme that distributed kits to key populations (KP), primarily female sex workers (FSW), and men who have sex with men (MSM). I focused on the economic implication of ATLAS in three Western African countries: Côte d'Ivoire, Mali, and Senegal.

The thesis is organized as follows. In the Introduction, I present the scope of this research, specifically the distribution of HIVST to KP, within the broader context of the HIV/AIDS epidemic in sub-Saharan Africa (SSA). In Chapter 1, I present literature reviews on the role of KP in HIV transmission in SSA, HIV testing services (HTS) and HIVST, and the evidence base related to economic evaluations of HIVST. In Chapter 2, I describe the objectives of this thesis. Chapter 3 provides a detailed description of the methodology used to conduct this research. Chapter 4 presents the economic evaluation and the findings in the form of a manuscript. In Chapter 5, I discuss the importance of these findings in the broader context of alternative testing modalities, community-led HIV response, and HTS among KP. Finally, I conclude my thesis by providing some final statements in Chapter 6.

This thesis has been prepared according to the guidelines for a manuscript-based thesis. My work has been submitted for publication:

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Contributions of authors

IJL, RS, MCB, JL, MD, FTP, OKZ, AV, ASF, and MMG contributed to the formulation of the research question and conceptualized the study. RS, NS, MMG, and MCB worked on the development of the HIV model of HIV transmission. IJL performed the review of HVIST economic evaluations studies among key populations. IJL used model outputs to estimate the epidemiolocal impacts (infections averted, deaths prevented, years life lost, and year of life lived with disability) of HIV self-testing (HIVST) and contributed to the elaboration of model scenarios. IJL developed the computing infrastructure to estimate the fully loaded costs, including cost functions, of different HIVST scale-up scenarios. IJL performed the cost-effectiveness analyses and developed the Monte Carlo simulations required to estimate the uncertainty. All authors contributed to interpreting results and critically reviewed the manuscript presented in Chapters 4. IJL drafted the manuscript in Chapter 4, and all authors revised them for important intellectual content. This thesis was written by IJL.

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List of Abbreviations

ART	Antiretroviral therapy
ATLAS	Auto-Test VIH, Libre d'Accéder à la connaissance de son Statut
CFSW	Clients of female sex workers
CI	Confidence interval
CSO	Civil society organizations
DALY	Disability-adjusted life-years
FSW	Female sex workers
HIVST	HIV self-testing
HTS	HIV testing services
ICER	Incremental cost-effectiveness ratio
KP	Key populations
MSM	Men who have sex with men
PLHIV	People living with HIV
PWUD	People who use drugs
PWID	People who inject drugs
SSA	Sub-Saharan Africa
STAR	HIV Self-Testing Africa
STI	Sexually transmitted infection
SW	Sex worker
UI	Uncertainty interval
UNAIDS	Joint United Nation Programme on HIV/AIDS
WHO	World Health Organization
WTP	Willingness-to-pay

Introduction

HIV epidemics, key populations, and HIV testing

Approximately 39 million people were living with HIV (PLHIV) around the globe in 2022, including 37.5 million adults and 1.5 million children [1]. An estimated 67% of PLHIV live in sub-Saharan Africa. The Western and Central Africa region shares the third highest burden of HIV, with more than 5 million PLHIV, the majority of them being members of key populations (KP) whose unmet prevention needs make them at higher HIV acquisition and transmission risks [2]. The *Joint United Nations Programs on HIV/AIDS* (UNAIDS) has put forward the 95-95-95 targets to "End AIDS" and "End inequalities" by 2030. The 95-95-95 targets aims for 95% of PLHIV to know their status, 95% of people who know their status to receive treatment, and 95% of people on treatment to have a suppressed viral load [3]. Gaps in HIV testing services remains and these hinder progress of achieving the first 95% target of status awareness, and consequently, the affects the whole prevention and treatment cascade.

Members of KP include female sex workers (FSW), men who have sex with men (MSM), people who inject drugs (PWID), among others. They share a disproportionately high HIV burden and, globally, they accounted for 74% of new HIV acquisitions in 2022 [2,4]. KP are often subject to sexual violence, stigma, and criminalisation due to the sociocultural context, which renders their access to testing and treatment services difficult [5]. The proportion of KP aware of their HIV positive status is lower than that of the general population [6,7]. As a result, many members of KP remain undiagnosed, cannot access treatment, and do not achieve a suppressed viral load. The latter is causing unnecessary ill-health and result in onward HIV transmission as individuals with suppressed viral load are not infectious [8]. Closing the HIV testing gaps and strengthening the treatment and care cascade for KP could greatly benefit the progress towards epidemic control.

HIV self-test (HIVST) offers a promising solution to address these challenges. The privacy offered by HIVST allows individuals to overcome potential social barriers and fear of judgment, making it a convenient and empowering option for those who may be reluctant to use traditional facility-based testing. HIV Self-Testing Africa (STAR) was the first pilot project promoting HIVST in Africa. STAR demonstrated the potential of HIVST as a cost-effective tool to increase status

awareness and linkage to treatment in Eastern Africa where the prevalence of undiagnosed HIV is high (>3%) [9]. However, no study has been conducted in Western or Central Africa regarding the cost-effectiveness of HIVST. HIV epidemics in Western and Central Africa are epidemiologically distinct from those in Eastern Africa, with lower population HIV prevalence and greater importance of key populations to overall transmission dynamics. In 2019, the ATLAS project (*Auto Test VIH, Libre d'Accéder à la connaissance de son Statut*) was initiated to promote and implement HIVST in three Western Africa countries: Côte d'Ivoire, Mali, and Senegal. Over the 3-year implementation period, this community-led project collaborated with local government and organizations to distribute HIVST to KP, their sexual partners, and PLHIV and other sexually transmitted infections (STI) patients.

Objectives

This thesis aims to determine the costs and cost-effectiveness of HIVST in Western Africa. Using detailed data from the ATLAS project, I evaluated the cost-effectiveness of the HIVST programme in Côte d'Ivoire, Mali, and Senegal and examined the economic implications of the scale-up of such programs.

Chapter 1 – Literature review

This chapter first reviews the status of HIV epidemics and the importance of KP in West Africa. It will specifically examine the challenges of diagnosing female sex workers (FSW), men who have sex with men (MSM), and their sexual partners. Then, it will be followed by a review of HIVST as a novel diagnostics tool and its potential benefits and harms. Lastly, it presents the use of HIVST on improving the status knowledge awareness.

1.1 Key populations and HIV epidemics

1.1.1 Definition of key population

The definition of key populations (KP) involves two main components: an increased risk of acquiring or transmitting a certain disease or condition, and limited access to health services due to legal or societal barriers that results in unmet prevention needs. This definition acknowledges the interplay of biomedical, behavioral, and structural factors that increase vulnerability among these groups. The identification of KP is not exclusive to HIV/AIDS and applies to other infectious pathogens.

In the HIV context, the World Health Organization (WHO) defined KP as "*groups who, due to specific higher-risk behaviors, are at increased risk of HIV, irrespective of the epidemic type or local context*". MSM, sex workers (including female, male, and transgender adults), people who inject drugs (PWID), transgender people, and prisoners are commonly recognized as KP as they are affected by HIV across all countries and epidemics typologies [10]. Both MSM and FSW are more likely to have multiple sexual partners, engage in condomless sex, and be subjected to physical and sexual violence [10]. They also often face social stigma and criminalization of their work and/or sexual behaviours which deter them from seeking HIV services [11].

1.1.2 Prevalence and incidence of HIV

In Western and Central Africa, HIV epidemics affect KP disproportionately. The regional prevalence in the overall population was 1.1% (15+ years old) in 2022. Yet, the prevalence of HIV was 7.5% among FSW, 8.0% among MSM, 3.7% among PWID, 21.9% among transgender people, and 2.8% among people in prison in this same region for that year [12]. Specifically for Côte

d'Ivoire, the prevalence of HIV in 2020 was 4.8% among FSW and 7.7% among MSM, compared to the national prevalence of 2.1% in the same year [13,14]. In Mali, 8.7% of FSW were living with HIV in 2019, in comparison to 1.1% in the overall general population (both male and female) [15,16]. A survey conducted Bamako, Mali in 2014 suggested a prevalence of 13.7% (95% CI: 9.2-18.1%) among MSM [17]. In Senegal, 27.6% of MSM are living with HIV [18].

The number of new HIV acquisitions in Western and Central Africa has been reduced by 43% between 2010 and 2021 [2]. In 2022, 74% of new HIV infections occurred among members of KP and their sex partners in Western and Central Africa. Further breakdown by subgroups suggests that 24% of new HIV infections were acquired by FSW, 28% by clients of FSW, 28% by the sex partners of all KP, 18% by MSM, 2% by transgender women, and 2% by PWID [2]. Meanwhile, sex workers (SW; both male and female) only constitute 0.60% of the population (15+ years), MSM 0.64%, and PWID 0.05% [13]. Moreover, in a modelling study on the contribution of new transmissions by KP in Senegal, unprotected sex between MSM were estimated to contribute 64% of new cumulative HIV acquisitions (95%CI: 37-79%) from 2005 to 2015. Meanwhile, for the same time period, the population attributable fraction (PAF) of transactional sex towards HIV transmission is lower at 14% (95%CI: 5-35%) in Senegal [19]. In Côte d'Ivoire, sex between men contribute 45% (95%CI: 21-51%) of HIV infections and commercial sex 20% (95% CI: 8-40%), from 2005 to 2015. The PAF is also projected to rise to 51% and 64% from 2015 to 2025 for MSM and FSW, respectively [20]. The stark contrast between the size of the KP and their contribution to new HIV infections highlights the importance of prioritising KP in the response to reduce HIV transmission in the region.

1.1.3 Knowledge of HIV status among key populations

Knowledge of status among members of KP varies across regional settings. In 2020, the global average for knowledge of HIV status among male and female SW was 67%, 66% among MSM, and 62% among PWID [21]. In the sub-Saharan African region, knowledge of status among MSM was estimated to be 51% (95%CI: 30-72%) in 2020, with MSM in Western and Central Africa being the least likely to know their status at 44% (95%CI: 9-79%) [7]. In Western Africa, knowledge of status among MSM living with HIV is estimated to be 20% (95% CI: 13-29%) [7].

In a small cross-sectional study conducted in Ouagadougou, Burkina Faso, only 3 of the 46 FSW living with HIV reported being aware of their status [22].

1.1.4 Current testing and prevention strategies and testing gap among key populations

The status neutral approach to HIV testing services (HTS), first proposed in 2018, aims to link those living with HIV to antiretroviral therapy (ART) and those at risk of HIV acquisition to the appropriate prevention services [23,24]. It differs from the traditional case-finding approach by not solely focusing on individuals living with HIV [25]. Prevention services for those at risk of HIV acquisition include condom provision (male and female), prevention of mother-to-child transmission, pre-exposure prophylaxis, post-exposure prophylaxis, voluntary male medical circumcision, sexually transmitted infection screening and treatment, and needle and syringe programmes [26]. The status-neutral approach also serves as the re-entry point to treatment and prevention services for those who have fell out of HIV care.

Despite the continuous effort to increase HIV testing uptake, HIV testing rates among KP remain sub-optimal, creating a "testing gap". Previously, KP had to rely on laboratory-based serological testing, whether through facility-based testing or being offered services through community-based testing. Although community-based activities (e.g., mobile outreach, door-to-door services) could benefit KP, their uptake of HTS is still lower than that of the general population [27]. Specifically, social barriers deter KP from HTS due to concerns related to breach in of confidentiality, biases and prejudices held by healthcare workers, and lack of sensitivity towards KP's unique needs [28,29]. Numerous structural barriers, such as police harassment and criminalisation. further impede KP's access to traditional HTS [30,31].

1.2 HIV self-test

1.2.1 Overview of HIV self-testing

HIV self-test (HIVST) is a rapid diagnostics tool where the users collect their own samples, perform the test, and interpret their result either by themselves or with the assistance of a healthcare worker in a private setting [32]. Currently, HIVST is available in two forms: a blood-based test and an oral fluid-based test. They are considered third generation HIV test, which only detects HIV

antibodies and has a median window period of 1 to 3 months, compared to fourth generation tests which can detect both HIV antibodies and antigens, and has a slightly shorter window period of 18 days [33,34]. The blood-based test requires the user to collect a capillary blood-sample, usually from a finger prick. The blood is then applied to the test trip to detect the presence of any HIV-antibodies. The oral fluid-based test functions by the same principle, but only requires a sample of oral fluid, usually from the gum line. The oral fluid-based tests are less sensitive than the blood-based test. A systematic review found the real world sensitivity of the oral fluid-based test to range between 66.7% to 100% and the specificity between 94.7% to 100% [35].

In December 2016, WHO published a strong recommendation for HIVST, citing the efficiency and wide acceptability of HIVST [36]. HIVST can be used as a tool to reach populations that are otherwise not able to be tested through traditional facility-based HTS, such as KP and rural populations. It also echoes the status-neutral approach of HTS, acting as a triage test to link both those tested positive and negative to appropriate additional testing and care, as well as prevention and counselling services through referral by community peer educators [37-39].

Nevertheless, there are limitations to the usage of HIVST. It does not replace the conventional testing methods in providing a definitive positive diagnosis. Those with a reactive HIVST are still required to confirm their HIV status through facility-based testing. For those already on ART, HIVST is not recommended as it may incur a false-negative test result due to viral suppression [37]. Moreover, the user may misinterpret the test result by themselves. The rates of correct interpretation are both 84% for blood-based tests and 84% for oral fluid-based tests [40]. Lastly, due to the nature of HIVST, it may be hard to track individuals after usage of the test kit, delaying linkage to treatment and other care services [41,42]. Within sub-Saharan Africa, the main barriers are the affordability of test kits, perceived unreliability of test results, and fear of a positive test result [43].

1.2.2 Acceptability and usage of HIVST

The acceptability of HIVST among adults aged 15-49 years old is high (81%-100%), and the oral fluid-based kit is preferred over conventional testing methods in both high- and low-income countries [27,44]. Although, in four studies evaluating the acceptability in sub-Saharan Africa, the acceptability of HIVST within programmes targeting both men and women varies

between 22% to 94%. Meanwhile, the acceptability of HIVST is higher among programmes focusing on men only (70-94%) [44]. Studies suggested that the high acceptability of HIVST is attributable to the privacy it offers, the convenience of usage, and particular for oral fluid-based tests, the non-invasive nature [32,42,45,46]. The benefit of privacy is more often reported in studies reporting unsupervised approach compared to supervised approach [46]. In Western Africa, HIVST received high acceptability by FSW, MSM, and PWID. Members of KP are willing to actively redistribute HIVST as an acceptable means to protect both themselves and their clients and/or sexual partners. However, some KP also cited fear of their sexual partner's reaction as the main barrier to secondary distribution [47]. This echoed one of the initial concerns related to the distribution of HIVST related to the coercive testing of sexual partners and a potential greater risk of violence if the test is reactive [48-50].

Aside from the wide acceptability and preferences, HIVST was found to double uptake of HIV testing (risk ratio [RR]=2.09; 95%CI: 1.69-2.58) in the general population. The linkage to care and treatment is similar (RR=0.95; 95% CI: 0.79-1.13) compared to the standard testing services [51]. Within KP, HIVST increased testing uptake by 1.45 times (RR=1.45; 95%CI: 1.20-1.75). For MSM specifically, the availability of HIVST increased the testing frequency by 2.56 times (95%CI: 1.24-3.88), compared to standard testing services that were offered as usual [52].

1.3 Existing HIVST programmes in Africa

There have been two programmes promoting and implementing the use of HIVST in Africa: the HIV Self-Testing Africa Initiative (STAR), and the ATLAS (*Auto Test VIH, Libre d'Accéder à la connaissance de son Statut*) programme. The STAR initiative was funded and launched in 2015 by *Unitaid* as a five-year project to develop the market for HIVST in Eastern and Southern African countries. The initiative aimed to establishing the evidence for the acceptability and feasibility of scale-up, creating guidelines and regulatory frameworks, and developing a sustainable market for HIVST [53]. STAR initiative involved a variety of delivery models, including clinic-based distribution, secondary distribution to sexual partners, workplace distribution, and community outreach. The initiative is designed to reach individuals with low testing uptake and limited access to testing services, namely FSW, MSM, young people, and adult men aged 15-49 years old [54].

The ATLAS programme was created and funded in 2019 by Unitaid and implemented with 21 civil society organization (CSO) partners through the coordination of Solthis and the *Institut de recherche pour le développement* (IRD), to promote the use of HIVST as a HIV-testing option for members of KP and their sexual partners in Côte d'Ivoire, Mali, and Senegal to implement and promote HIVST [44,55,56]. In collaboration with local governmental and community partners, HIVST kits were distributed by peer educators to KP, people living with HIV and other STI patients, and subsequently, through secondary distribution reaching, the clients and/or sexual partners of these populations [57]. The ATLAS programme aimed to describe, analyse, and understand the economic, social, and epidemiological effects of the introduction of HIVST to Western Africa, in order to better inform policy-makers [57]. Recent published studies from ATLAS have already outlined the qualitative benefits of peer-driven HIVST distribution in expanding the coverage of HTS, as well as the barriers the programmes need to overcome [47,58].

1.4 Impact, cost-effectiveness, and knowledge gaps

HIVST was shown to deliver medium-sized epidemiological impacts in terms of HIV infections prevented in sub-Saharan Africa. In a modelling study of the STAR programme (Eastern and Southern Africa), HIVST distribution through FSW channels was estimated to avert 330 to 340 deaths per year, and 1 430 to 1 520 infections per year, over the course of 50 years across the adult populations in Zambia, Zimbabwe, Malawi, and Lesotho [9]. The impact of the ATLAS programme (Western Africa) was also modeled and three years of HIVST distribution through the FSW and MSM channels was projected to avert a median of 1 794 infections and 591 HIV-related deaths across all three countries combined (Côte d'Ivoire, Mali, and Senegal) over a 20-year time horizon. Meanwhile, nationally-scaled HIVST distribution campaigns through FSW and MSM channels could avert a median total of 105 031 new infections, and 7 390 HIV-related deaths in all three countries combined [59].

1.4.1 Cost-effectiveness of HIVST

Cost-effectiveness analyses of HIVST have been conducted in many settings across the globe. In a nation-wide randomized controlled trial targeting MSM in the United States spanning 12 months, the incremental cost-effectiveness ratio (ICER) was estimated to be $134 583 USD 2016 per transmission averted, and $74 476 per QALY gained [60]. However, compared to the

high income and lower HIV prevalence settings, the ICER is significantly lower in sub-Saharan Africa. The main characteristics of reviewed cost-effectiveness analyses conducted in sub-Saharan Africa are shown in Table 1. A 3-month community-led HIVST campaign targeting the general adult population was estimated to cost $985 to $1 312 per person confirmed positive, excluding those on ART, or those previously tested positive, respectively [61]. Meanwhile, another non-randomised experimental study focusing on MSM in Uganda suggested that the 3-month peer-driven HIVST distribution initiative costed $147 per person confirmed positive [62]. In the non-randomised STAR study with a 3-year time horizon, HIVST distribution at KP hotspots costed $697 per positive case confirmed, while the FSW distribution channel costed $59 per positive case confirmed [55]. In the longer-term STAR modelling study, the ICER for FSW HIVST distribution channel was estimated to be $120 USD 2016 per DALY averted over a 20-year time horizon [9]. Although there lacks a cost-effectiveness analysis for HIVST distribution prioritizing KP in Western Africa, an ATLAS costing study estimated the average cost and scale-up costs of HIVST in Côte d'Ivoire, Mali, and Senegal for each category of KP. The average observed costs per HIVST kit distributed were $15 for FSW, $23 for MSM, and $80 for PWUD. Meanwhile, the average costs per kit distributed after program scale-up were $11 for FSW, $16 for MSM, and $32 for PWUD, due to economies of scale [63].

Table 1. Characteristics of the cost-effectiveness of HIV-self testing (HIVST) programmes in Africa.

Study	Country	Currency	Study design	Study population & Distribution method	Time Horizon	ICER
Jamieson *et al.* [56]	South Africa	USD 2019	Modelling study	Six HIVST distribution modalities.	20 years	Per infection averted: cost-saving to $14 688 Per life years saved: cost-saving to $4 162 Per AIDS-death averted: cost-saving to $147 396
Cambiano *et al.* [9]	South Africa	USD 2016	Modelling study	FSW, young people (15-24 years), adult men (25-49 years), community-based distribution.	50 years	FSW: $50-120 per DALY averted. Young people: $680-2 000 per DALY averted. Adult men: $520 – 880 per DALY averted.
Matsimela *et al.* [55]	South Africa	USD 2018	Non-randomised experimental study	11 distribution models. Including KP hotspots distribution and FSW health programme.	3 years	KP Hotspot: $697 per new case confirmed, $861 per new ART initiation. FSW: $59 per new positive case confirmed, $112 per new ART initiation.
Maheswaran *et al.* [64]	Malawi	USD 2014	Modelling study	General population, community-based distribution in combination with facility HIV testing and counselling.	20 years	$253.90 (95%CI: 201.71-342.02) per QALY gained, using 2015 WHO ART guidelines.
Indravudh *et al.* [61]	South Africa	USD 2018	Cluster-randomised trial	Village residents aged 15 years or older, community-led distribution.	3 months	$1 312 per person tested positive, excluding previously diagnosed individuals. $985 per person tested positive, excluding individuals on ART.
Okoboi *et al.* [62]	Uganda	USD 2018	Non-randomised experimental study	MSM, civil society organisation-led peer delivery.	3 months	$147 per new positive case confirmed.

All ICERs were estimated from the provider's perspective.
ART: Anti-retroviral treatment; CI: Credible interval; ICER: Incremental cost-effectiveness ratio; FSW: Female sex workers; MSM: Men who have sex with men

1.4.2 Knowledge gaps

KP-focused HIVST programmes are generally shown to be cost-effective with good case-finding rates. Given the importance of KP to HIV epidemics in Western and Central Africa, countries in the region could benefit from KP-focused HIVST distribution programmes. However, limited economic evaluations of HIVST have so far been conducted in Western and Central Africa. Importantly, several factors could influence cost-effectiveness of HIVST distribution programme in the region. These factors include the prevalence of undiagnosed HIV infections, the degree of test substitution (replacing conventional facility-based tests with self-tests instead of increasing testing coverage), the rate of linkage to confirmatory testing post-HIVST, the eventual linkage to care after a confirmed diagnosis, as well as the externalities (or indirect effects) that HIVST could have on onward transmission. Secondly, although existing model-based estimates of the population-level impact of ATLAS suggest modest health benefits, the cost-effectiveness of these programmes has not been demonstrated. Cost-effectiveness estimates are important for priority settings and resources allocations. They can inform policymakers on the economic feasibility of HIVST distribution programmes targeting KP at a national level in Western Africa. To address these questions, this thesis leverages data from the ATLAS programme, covering regional KP in three Western African countries, as described in the following chapters.

Chapter 2 Study objectives

The aim of my thesis is to evaluate the cost-effectiveness of the ATLAS programme in Côte d'Ivoire, Mali, and Senegal. Such an economic evaluation can help decision makers understand the value and population-level contribution of KP-specific HIVST programmes to HIV transmission. This was achieved through three specific objectives:

1. Evaluate the incremental costs and affordability of the ATLAS HIVST programme and of HIVST scale-up scenarios in Côte d'Ivoire, Mali, and Senegal.
2. Examine the cost-effectiveness of those scenarios and assess the sensitivity of these estimates to various assumptions.
3. Compare the incremental cost-effectiveness ratios from this thesis to previously published estimates.

Chapter 3 Methodology

3.1 ATLAS programme

The ATLAS (*Auto Test VIH, Libre d'Accéder à la connaissance de son Statut*) programme was created and funded in 2019 by Unitaid and the *Institut de recherche pour le développement* (IRD) and implemented with CSO partners through *Solthis*. The objective of ATLAS was to promote the use of HIVST as an HIV testing option for members of KP and their sexual partners in Côte d'Ivoire, Mali, and Senegal [44,55,56]. In collaboration with local governmental and community partners, HIVST kits were distributed by peer educators to KP, their sexual partners, as well as people living with HIV and other STI patients for secondary distribution to their sexual partners [57]. A previous costing study estimated the average costs and scale-up costs of integrating the programme into CSO in these countries [63]. In addition, the population-level epidemiological impact of ATLAS has previously been explored through mathematical modeling [65]. However, the cost-effectiveness of the programme has not been assessed yet.

The programme ran from late-2019 to mid-2022, collaborating with a total of 21 CSO (10 in Côte d'Ivoire, 3 in Senegal, and 8 in Mali) [66]. The programme considered two distribution strategies: a large-scale community-led distribution and a smaller-scale health facility-based distribution [67]. In total, 397 367 kits were distributed in Côte d'Ivoire, Mali, and Senegal, out of which 64% were distributed through FSW-based activities, 24% through MSM-based, and 12% to PWUD, indexing testing, and STI channels.

The kits were distributed through peer educators in community-led campaigns organized by CSO partners, who instructed members of KP on the usage and interpretation of the tests through training sessions, brochures, and shareable video support in French and local languages [68]. Members of KP were also instructed on how to seek confirmational testing after receiving a positive test result through a hotline or peer educator. Each primary user received multiple kits for their own use, and further secondary distribution to their sexual partners and/or relatives.

Around 85% of the total HIVST kits distributed by ATLAS in the three countries over 2019-2021 were dispensed to either MSM or FSW. HIVST distributed through other channels (e.g., PWUD and other STI patients) were not included in this model since they accounted for a small

(~12%) percentage of total kits distributed. According to STAR data, 80% of the distributed tests were used [69]. An ATLAS survey suggested that 50% of individuals with a reactive HIVST result would seek additional confirmatory testing and, if confirmed HIV-positive, will be linked to ART treatment. Typically, there is a 2-month gap between a reactive HIVST result and a follow-up confirmatory testing for those seeking it and 1 month from confirmatory testing to ART initiation [65,69,70]. Finally, HIVST can lead to test substitution (i.e., people who would have tested using conventional HIV testing using HIVST instead) which would limit increases in testing coverage. Analyses of programmatic data in Côte d'Ivoire and Senegal allowed me to consider the percentage of substitution of conventional tests by HIVST: 20% in Côte d'Ivoire, 30% in Mali, and 40% in Senegal [66]. Based on information provided by the manufacturer, the sensitivity and specificity of the OraQuick HIVST are assumed to be 92% and 99%, respectively [66,71].

Interview surveys suggested that key stakeholders believed that HIVST could increase testing uptake due to its anonymous nature which can protect KP's identity, and remove geographical barriers that may hinder access to facility-based HTS [72]. Meanwhile, another ATLAS survey focused on the population within the ATLAS region of intervention in Côte d'Ivoire also reported interests and positive attitudes for freely-available HIVST kits [73]. Through a telephone survey conducted during ATLAS' implementation, 30% of the self-testers were reached through secondary distribution and 41% of all the self-testers reported being tested for the first time. Nearly all (99%) reported no difficulty in using the test or interpreting the result. The participation was higher in MSM-based distribution channels, compared to other channels [74]. An ecological study comparing ATLAS health districts with those without ATLAS found that HIVST had a positive impact on both access to testing and positive diagnoses, while having a possible effect on substitution for conventional tests [66].

3.2 Economic evaluations

Economic evaluation is one of the most important tools in health economics to determine which intervention can maximise the health benefits with limited financial resources. An economic evaluation measures the cost and the outcome of interventions and evaluate the allocative efficiency. Allocative efficiency involves the distribution of economic resources to maximise the health benefits, such that the limited funds, tangible assets, and intangible resources are optimally deployed. There are two common approaches to an economic evaluation that compares different

interventions: cost-effectiveness analysis, and cost-benefit analysis. There are several components to be considered when conducting an economic evaluation: the target outcome of the intervention, the time horizon, and the perspective of cost-estimates (i.e., society versus health provider).

3.2.1 Cost-effectiveness analysis

Cost-effectiveness analysis is the most common form of economic evaluation of health interventions. The cost-effectiveness is usually expressed as the incremental cost-effectiveness ratio (ICER) which is the ratio of the incremental cost of the programme of interest, in contrast to a baseline scenario, divided by the difference of the health outcome of choice between the programme of interest and the baseline scenario. ICER represents the additional cost per additional health benefit [75].

Traditional cost-effectiveness analysis often uses outcome measures such as number of infections averted, or number of deaths averted. These outcomes are limited to comparison between interventions with similar targets, such as reduction of mortality [76]. However, since the development of the concept of disability-adjusted life-years (DALY), and quality-adjusted life-years (QALY), cost-effectiveness analyses can consider a wider range of comparisons, across different interventions and health conditions. Cost-effectiveness analyses using specifically either DALY or QALY as outcome measurements are also called cost-utility analysis. DALY is a measurement of disease burden which combines years of life lost (one year of life of lost equals to one DALY) and years of life lived with disability (each year lived with a condition is multiplied by the disability weight of said condition) [77]. Meanwhile, QALY represents the quality of life lived, where each year of perfect health lived equals to one QALY, and each year lived with the condition is multiplied by a utility value that is assigned to the condition determined through questionnaires. These utility outcomes are more comprehensive, combining both morbidity and mortality. Nevertheless, cost-effectiveness analyses often fail to capture the societal benefits. It only considers the health consequences produced by the intervention.

3.2.2 Cost-benefit analysis

Cost-benefit analysis shares similarities with cost-effectiveness analysis as it also assesses the worthiness of an intervention and can inform decision-making. However, cost-benefit analyses

capture better the overall consequences of an intervention in monetary terms on the society in general. A net benefit value is calculated by subtracting the total cost from the total benefits. Alternatively, a benefit-cost ratio can also be produced. The total benefit is not restricted to the direct monetary gain, but also encompasses the positive and negative externalities such as increased productivity, reduced burden on the healthcare system, environmental benefits, and social welfare benefits. These benefits have to be assigned monetary values, which can be difficult to assess objectively, especially for intangible or non-market benefits such as productivity and human life. A cost-benefit analysis is best conducted when the research interest lies in determining the effect on the general society by implementing an intervention.

3.3 HIV self-testing scenarios

In this thesis, three scenarios are modelled over a 20-year time horizon: 1) the scenario without any HIVST distribution (counterfactual), 2) the factual ATLAS scenario (ATLAS-only), and 3) a hypothetical version of ATLAS that would achieve national scale-up and coverage (ATLAS-scale-up).

The counterfactual scenario assumed that no HIVST are being distributed. The rate of conventional HIV testing and linkage to care follows the current trend. The factual ATLAS-only scenario reflected the actual impact achieved between 2019 and 2021 by the implementation of the ATLAS programme, and the projected impact of the 3-year distribution over a 20-year time horizon. The ATLAS scale-up scenario simulated the situation where the ATLAS programme would be expanded from regional to national distribution. The programme undergoes a scale-up period from 2022 to 2024, where the number of distributed HIVST would increase until 2025. By 2025, the model assumed that 95% of MSM or FSW without HIV, and untreated MSM or FSW living with HIV, would receive 2 kits per year, either for their own use or redistribution, in line with the WHO HIV testing recommendations [23]. The proportion of test kits redistributed is assumed to be the same as the factual ATLAS scenario.

3.4 Health impacts of ATLAS over the long term

Mathematical modelling has become a helpful too to orient public health decision-making, especially for infectious diseases [78]. Traditional clinical trials are limited by the recruitment

process, time constraints, and funding restrictions. It is often impossible or unethical to conduct an experimental trial and impose multiple interventions on the same population in order to estimate their combined impacts. Moreover, mathematical model allows for the assessment of long-term consequences over a time horizon of 10, or 20 years, which is otherwise impractical to perform using empirical data.

The long-term impact of HIVST on HIV transmission was explored using a transmission dynamics model previously described by Silhol and colleagues [79]. Briefly, this is a deterministic compartmental model of sexual HIV transmission that developed and calibrated to country- and KP-specific epidemiological and behavioural data, as well as ATLAS data and the published literature. Model parameterization and calibrations were carried out separately for Côte d'Ivoire, Mali, and Senegal for the period 1980-2020.

The models represent an open population divided into eight risk categories: FSW, clients of FSW, MSM who have relationships with both men and women or exclusively with men, those who patronize female sex workers, non-KP females with either low or intermediate risk based on their yearly partners, and non-KP males similarly categorized by their annual partners. The population was segmented into four age groups: 15-19, 20-24, 25-49, and 50-59 years old. Individuals enter the sexually active stage by the age of 15 and exit either by the age of 59 or by death due to HIV infection or other unrelated causes. In the absence of treatment, PLHIV progress through four infection stages: acute infection, untreated HIV infection (>200 CD4 cells per μL), untreated AIDS ($\leq$200 CD4 cells per μL), and treated HIV. Once diagnosed at an age- and group-specific time-varying testing rates, PLHIV can be linked to and receive antiretroviral treatment (ART) to achieve viral suppression. The model was fitted to empirical local estimates of HIV prevalence, the proportion ever tested for HIV, the proportion diagnosed, the proportion on ART, the proportion virally suppressed, as well as national data on the number of conventional tests performed over 2015-2019 and the fraction of tests which were positive [80].

The primary effectiveness outcome for this analysis was the number of disability-adjusted life years (DALY) averted over 20 years (2019-2039). DALYs combine years of life lost (YLL) and years of life living with disability due to infection (YLD). YLL was calculated from the number of deaths in each age category times the country-specific life expectancy at the age of death [81]. YLD was calculated using the disability weight by disease stage and the number of

people in each HIV infection stage during the corresponding year [82]. The DALYs were calculated for each year and summed over 20 years. The formula used for the DALY calculation is shown below [83]:

$$\text{YLL} = \sum_{a} D_a \times e_a$$

$$\text{YLD} = \sum_{i} P_i \times DW_i$$

$$\text{DALY} = \sum_{t=2020}^{2039} YLL_t + YLD_t$$

where a is the subscript for the age group, i is the disease stage, and t is the calendar year; D_a is the number of deaths at age a; e_a is the remaining life expectancy at age a; P_i is the number of people living with HIV; and DW_i is the disability weight associated with the disease stage.

Secondary outcomes included the number of new HIV acquisitions averted and the number of AIDS-related deaths prevented.

3.5 Costs

The costs of the programme are estimated from the provider's perspective over a 20-year time horizon, using an ingredient approach. This approach uses granular resource usage data from observed or modelled usage to estimate the total cost of the program [84]. The unit cost of HIVST was informed through micro-costing studies conducted as a part of the ATLAS initiative which used on-site time-in-motion technique. This technique employs observers to systematically record the duration and sequence of each intervention-related personnel activity [63]. Time-in-motion studies offer precision and accuracy of cost estimates by capturing real-world activities. The costs are discounted at 4%, following the rate used by the Central Bank of Western Africa States [85].

In this thesis, the accounted programme costs do not equal the total expenditure of the ministries of health regarding HIV testing, counselling, treatment, and prevention. Instead, I only account for the costs that may change due to the implementation and/or scale-up of the ATLAS programme (i.e., the incremental cost of HIVST). I will subsequently refer to this as the total accounted cost. The total accounted cost is composed of the cost of conventional testing (for both

KP and the general population), the cost of HIVST (through FSW- and MSM-channel distribution), the cost of confirmational testing after a reactive HIVST result, and the cost of ART (for both KP and the general population). The composition of each cost category is presented in Table 2. The average fully-loaded cost for each HIVST kit used was estimated separately for FSW and MSM channels, with regards to the difference in percentage of secondary distribution. The total accounted cost for each scenario in each country is obtained by the summation of all the cost categories together. And the incremental cost is obtained through subtracting the total accounted cost of the counterfactual base case scenario from that of either the ATLAS-only or ATLAS scale-up scenario.

Table 2. Composition of cost categories used for the calculation of total accounted costs.

Cost categories	**Populations**	**Source country, year**	**Composition**
Conventional testing	General population	Côte d'Ivoire, 2015	Training, outreach, counselling, personnel, and test kits [86]
	FSW	Côte d'Ivoire, 2013	
	MSM	Côte d'Ivoire, 2013	
HIV self-testing	FSW	Côte d'Ivoire, 2020 Mali, 2020 Senegal,2020	Capital cost, personnel, transportation, storage, training, sensitisation, equipment, overhead administration, and test kits [63]
	MSM		
Confirmational testing	General population	Côte d'Ivoire, 2015	Same as conventional testing
	FSW	Côte d'Ivoire, 2013	
	MSM	Côte d'Ivoire, 2013	
Anti-retroviral therapy	General population, FSW, and MSM	Côte d'Ivoire, 2015	Personnel, distribution, medical assays, and medication [86] *Assuming 90% of individual taking first line ART while 10% are taking second line ART [87]

FSW: female sex workers; MSM: men who have sex with men.

3.5.1 Cost function

To account for the reduction in costs derived from potential economy of scale in the ATLAS scale-up scenario, I used a cost function to estimate the scaled-up average unit cost of HIVST [63]. The costs were categorized into fixed costs that stay constant and variable costs that change with scale (i.e., number of HIVST distributed). The total annual cost at scale for HIVST distribution is obtained by multiplying the scale of each variable resource by their respective unit costs and summing the total variable costs with the fixed costs. The scale-up process was assumed to take place from 2022 to 2024 following each country's reported HIVST volume targets, during which HIVST distribution would increase annually until 2025, when it will have reached full scale. The average cost at scale per HIVST kit (A_{pct}) for population *p* in country *c* in year *t* is calculated by dividing the total annual cost at scale (T_{pct}) by the number of HIVST distributed in that year and country (N_{pct}). The total annual cost at scale (T_{pct}) is a function of the fixed costs (F_{pct}), variable costs (V_{pct}), and price per HIVST kits distributed (P_{pc}).

$$A_{pct} = \frac{T_{pct}}{N_{pct}}$$

$$T_{pct} = F_{pct} + V_{pct} + \left(P_{pc} \times N_{pct}\right)$$

3.5.2 Cost-effectiveness acceptability curve

Cost-effectiveness acceptability curves (CEAC) represent the probability that an intervention is cost-effective compared to the base case scenario, over a range of potential WTP thresholds. The x-axis of the CEAC represents different values of willingness-to-pay (WTP) thresholds, which represent the provider's willingness to pay for the intervention for each additional gain of health benefits. Meanwhile the y-axis represents the probability that the intervention is cost-effective at each of those threshold values. In this thesis, the curve represents the change in the proportion of ICERs that are below each threshold in the 10 000 Monte Carlo simulations.

3.5.3 Threshold and willingness-to-pay

To assess the cost-effectiveness of an intervention, the ICER is often compared against a certain threshold value. The approach in this thesis aligns with the *WHO CHOICE* guideline that suggests using a generalized-CEA approach, which is to compare the different intervention scenarios against a hypothetical reference case. The guideline also advised against the use of a generic threshold, such as often cited time threshold that correspond to three-times-GDP per capita rule. These generic thresholds can lead to decision-making disparities between high-income countries and low- and middle-income countries even for interventions with similar ICER [88]. In this thesis, I used two WTP thresholds to assess the potential cost-effectiveness of the ATLAS initiative and its subsequent scale-up program. These thresholds are country-specific and adapted to a multitude of factors, including income level, health system, and external factors outside the healthcare focus. In this thesis, two WTP are used based on their category of income level: $155 USD 2022 for Mali and $488 for Côte d'Ivoire and Senegal. These thresholds are calculated based on per capita health expenditures and healthy life expectancy [89].

3.6 Monte-Carlo simulations

Monte-Carlo simulations were used to obtain the 90% uncertainty interval of the ICER. The simulation combined the modelled uncertainty of the impact of HIVST on health outcomes (i.e., DALY, number of new infections, and number of AIDS-related deaths) by sampling from the posterior distribution of model outputs. Meanwhile, each cost was assigned a triangular probability distribution, as shown in Table 3, to address the uncertainty in costs. The median, minimum and maximum values are derived from the previous ATLAS costing study [20]. The distributions of costs were sampled 10 000 times to simulate a wide range of possible scenarios. By doing so, the simulations provided a distribution of potential cost-effectiveness outcomes. A 90% uncertainty interval was taken for each ICER.

3.6.1 Sensitivity analysis

I included both the undiscounted (in the main analysis) and discounted effectiveness outcomes (at 4% in the sensitivity analysis, in line with the discount rate on costs) [88]. Discounting for the costs is usually justified since it takes into account the opportunity cost of the

resources used in the intervention that can be otherwise invested in other health policies or even other economic sectors [90]. However, there have been debates regarding whether to discount health outcomes. The argument for discounting states that the choice is based on positive time preference, which implies that the society values immediate benefits over delayed ones [91]. However, the health outcomes were not discounted in the main analysis of this thesis because discounting of future health gains implies that the healthy lives at present are worth more than healthy lives in the future. It devalues the beneficial outcomes of preventative interventions and may bias health policies decisions [92,93].

I also conducted sensitivity analyses to evaluate the effect of key assumptions in the scenarios: lower linkage to confirmational testing and care following a reactive self-test (25% instead of 50%), no substitution of conventional tests by HIVST (0% instead of 20%), lower usage of distributed HIVST (50% instead of 80%), higher ART price per person per year ($254 instead of $216), using real-world sensitivity for the HIVST (87.5% instead of 92%), and $1 unit cost of HIVST at scale-up (instead of $2.87 for Côte d'Ivoire, and $3.36 for Mali and Senegal). These sensitivity analyses help to inform the robustness of ICER based on the changes in the assumptions.

The code to replicate all the analyses is available at: https://github.com/inga-l/atlas

3.7 Literature search strategy

To compare the estimates with previously published literature, I conducted a scoping review for the economic evaluations of HIVST distribution programmes in sub-Saharan Africa. The literature search for the scoping review for this topic and literature review chapter was conducted on the OVID database, using the databases: Medline and Embase. The specific search strategy is described in Appendix 1 – Additional methods for the search strategy.

Chapter 4 Study results

This manuscript addresses all three objectives mentioned in Chapter 2 of my thesis. It examines the impact and the cost-effectiveness of the HIVST distribution to KP within the ATLAS project and the scale-up scenario of ATLAS in Côte d'Ivoire, Mali, and Senegal and assess the sensitivity of these estimates to various assumptions and compared the results to previously published estimates. This study used the mathematical model and programme data from the ATLAS project. This manuscript is currently under editing.

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Cost-effectiveness analysis of community led HIV self-testing among key populations in Côte d'Ivoire, Mali, and Senegal

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Keywords: HIV-self testing, key population, community-led delivery, HIV testing services, diagnosis, cost-effectiveness, cost function.

Abstract

Introduction: HIV self-testing (HIVST) is a promising strategy to improve diagnosis coverage among key populations (KP). The ATLAS program implemented HIVST in three West African countries over 2019-2022, distributing over 380,000 kits up until 2021, with a focus on community-led distribution by KP to their peers and subsequent secondary distribution to their partners and clients. We aim to evaluate the cost-effectiveness of HIVST in Côte d'Ivoire, Mali, and Senegal.

Methods: A HIV transmission dynamics model was adapted and calibrated to country-specific epidemiological data, and used to predict the impact of HIVST. We considered the distribution of HIVST among two KP –female sex workers (FSW), and men who have sex with men (MSM)– and their sexual partners and clients. We compared the cost-effectiveness of two scenarios against a counterfactual without HIVST over a 20-year horizon (2019-2039). The ATLAS-only scenario mimicked the 2-year implemented ATLAS program whereas the ATLAS-scale-up scenario achieved 95% coverage of HIVST distribution among FSW and MSW by 2025 onward. HIVST effectiveness was measured as the number of disability-adjusted life-years (DALY) averted. Scenarios were compared using incremental cost-effectiveness ratios (ICER). Costing was performed using a healthcare provider's perspective. Costs were discounted at 4%, converted to $USD 2022, and estimated using a cost-function to accommodate economies of scale.

Results: The ATLAS-only scenario averted a small number of new HIV infections over twenty years: 289 in Côte d'Ivoire (90% uncertainty interval: 158-478), 393 in Mali (183-758), and 273 in Senegal (126-705). However, it was highly cost-effective, even at low willingness-to-pay thresholds. The median ICER was below $120 per DALY averted for each country. Scaling-up the ATLAS program would also be cost-effective, and substantial epidemiological impacts would be achieved. The ICER for the scale-up scenario were $199 ($122-$338) per DALY averted in Côte d'Ivoire, $224 ($118-$415) in Mali, and $61 ($18-$128) in Senegal.

Conclusion: Community-led HIVST programs in West Africa, where KP are important to overall transmission dynamics, have the potential to be highly cost-effective. These findings support the scale up of community-led HIVST to reach population otherwise may not access conventional testing services.

Introduction

Closing the diagnosis gaps among people living with HIV (PLHIV) is central for countries to achieve the 95-95-95 targets set by the *Joint United Nations Programs on HIV/AIDS* (UNAIDS) to "End AIDS" [1]. Increasing diagnosis coverage requires the use of acceptable and effective HIV testing strategies. HIV self-testing (HIVST) allows individuals to test for HIV on their own by collecting a sample (blood or oral), performing the test, and interpreting the result either in private or with a healthcare worker. In Eastern Africa, the HIV Self-Test AfRica (STAR) project demonstrated that community based and community led distribution of HIVST was efficient and cost-effective if the prevalence of undiagnosed HIV is higher than 3% [2]. The privacy offered by HIVST makes it an acceptable testing modality by members of key populations (KPs) [3]. The common definition of KPs include female sex workers (FSW), gay, bisexual, and other men who have sex with men (MSM), and people who use drugs (PWUD) [4]. Although clients and sexual partners of KP are not included within the KP definition, they are also vulnerable to HIV transmission dynamics [5-7]. However, no studies have been conducted on the cost-effectiveness of community-led distribution of HIVST in Western or Central Africa [8]. In this region, members of KP are disproportionally affected by HIV: 74% of new HIV acquisitions were estimated to occur among KP, their clients and sexual partners in Western and Central Africa in 2021 [9,10].

Current HIV testing services (HTS) in West Africa mainly rely on laboratory testing which requires KP to receive the test and results either at a health facility or from community outreach workers [11]. Such conventional HTS may exclude members of KP, their clients, and sexual partners because stigmatization of their sexual behaviours, identities, and social status can create barriers to testing. There are also opportunity cost associated with those using conventional HTS. Gaps in diagnosis coverage among KPs and their sexual partners and clients means that additional testing modalities and approaches are needed, complementing traditional HTS [12,13]. The UNAIDS Global AIDS Strategy recommended that community organizations to be integrated as key partners into national AIDS plans to expand the coverage of HTS. The strategy aimed to increase to 60% of HIV prevention and advocacy programmes and 30% of testing and treatment services to be delivered by community-led organizations [14,15].

In 2018, the ATLAS program (*Auto Test VIH, Libre d'Accéder à la connaissance de son Statut*) was launched to implement and promote HIVST in Côte d'Ivoire, Mali, and Senegal [16-18]. Since mid-2019, in collaboration with local governmental and civil society organizations

(CSO), HIVST kits were distributed by peer educators to KPs (FSWs, MSM and PWUD) [19]. All distribution channels integrated secondary distribution for partners, clients, and relatives of primary contacts. A previous economic evaluation estimated the average costs and scale-up costs of integrating the program into CSO in these countries [20]. In addition, the population-level epidemiological impact of ATLAS has previously been explored through mathematical modeling [21]. In this study, we evaluate the cost-effectiveness of the community-based MSM and FSW components of the ATLAS program and of scaling-up this program in Côte d'Ivoire, Mali, and Senegal. Importantly, cost functions are incorporated to accurately reflect the change in unit costs as a function of programme scale –something that is rarely addressed [15,22,23]. Although there have been previous studies on community-led HIVST distribution in the general population in sub-Saharan Africa, to our knowledge, this is the first cost-effectiveness analysis of community-led HIVST by KP [24,25].

Methodology

The ATLAS Program

The protocol for the ATLAS program has been described elsewhere [19]. Briefly, the ATLAS program was funded by Unitaid, and was coordinated by Solthis, an international non-governmental organization, and IRD, a French research institute. It was implemented with 21 CSO partners (10 in Côte d'Ivoire, 3 in Senegal, and 8 in Mali) to promote the use of HIVST as an option for members of KP and their sexual partners in Côte d'Ivoire, Mali, and Senegal. OraQuick HIV Self-Test® kits were distributed to FSW, MSM, PWUD, partners of PLHIV, patients of STI clinics from July 2019 to December 2021. Two distribution strategies were considered: large-scale community-based distribution and smaller-scale health facility-based distribution [26]. Peer educators instructed members of KP on how to use the kit, how to interpret the results, and how to seek confirmational testing after a reactive result through a hotline or peer educators. Two to three kits were distributed to primary users for further secondary distribution to their partners and relatives. In total, over 380,000 kits were distributed in Côte d'Ivoire, Mali and Senegal, out of which 64% were distributed through FSW-based activities, 24% through MSM-based, and 12% to PWUD, indexing testing, and STI channels.

Mathematical modeling of the epidemiological impact

The long-term impact of HIVST on HIV was explored using a HIV transmission dynamics model, described elsewhere [27]. Briefly, a deterministic compartmental model of sexual HIV transmission was developed, parameterized, and calibrated for each country using local behavioural, epidemiological, intervention KP data, country surveys, ATLAS data, program data, and published literature. The modelled population is stratified into four age groups (15-19, 20-24, 25-49, 50-59) and eight risk groups: FSW, clients of FSW, MSM reporting both female and male sex partners (MSMW), MSM having male partners exclusively (MSME), and low-risk (0-1 partner per year for females, and 0-2 partners per year for males) and intermediate-risk (>1 partner per year for females, and >2 partners per year for males) non-KP heterosexual male and females. PLHIV progress through four infection stages: acute infection, untreated HIV infection (>500, 350-500, 200- 349, and >200 CD4 cells per μL), untreated AIDS (≤200 CD4 cells per μL), and treated HIV [28]. Once diagnosed at an age- and group specific time-varying testing rates, PLHIV can be linked to and receive antiretroviral treatment (ART) to achieve viral suppression. The model was fitted to empirical local estimates of HIV prevalence, the proportion ever tested for HIV, the proportion diagnosed, the proportion on ART, the proportion virally suppressed, as well as national data on the number of conventional tests performed over 2015-2019 and the fraction of tests which were positive [29].

Around 88% of HIVST kits distributed by ATLAS in all three countries over 2019-2021 were dispensed through activities focused on MSM or FSW. Tests distributed through other channels (index testing, PWUD and other STI patients) were not included in this model since they accounted for a small (~12%) proportion of all kits. According to STAR data, 80% of the distributed tests kits were used [30]. An anonymous phone-based ATLAS survey suggested that 50% of individuals with a reactive HIVST result proceed to confirmatory testing and, if confirmed HIV-positive, will be linked to care [31,32]. We assumed an average time from a reactive HIVST to confirmatory testing (among those seeking it) was 2 months and the time from confirmatory testing to ART initiation was 1 month [21,27,30,33]. Finally, HIVST can lead to test substitution (i.e., people using HIVST in lieu of conventional tests) which would limit increases in testing coverage. Analyses from programmatic data in Côte d'Ivoire and Senegal suggested that substitution of conventional tests by HIVST may have occurred at 20% for Côte d'Ivoire, 40% for

Senegal, and 30% is assumed for Mali [34]. HIVST sensitivity and specificity were assumed to be 92% and 99%, based on manufacturer data [32,35].

The primary effectiveness outcome for this analysis was the number of disability-adjusted life years (DALY) averted over twenty years (2019-2039). DALYs combine years of life lost (YLL) and years of life lived with disability (YLD). YLL was calculated from the number of deaths in each age category times the country-specific life expectancy at the age of death (shown in Table 1A) [36]. YLD was calculated using the disability weight by disease stage (Table 1B) and the number of people in each HIV stage during the corresponding year [28]. Secondary outcomes included the cumulative number of new HIV acquisitions prevented and the number of AIDS-related deaths averted. We included both the undiscounted (in the main analysis) and discounted effectiveness outcomes (at 4% in the sensitivity analysis) [37].

Table 1. Assumptions to derive the disability-adjusted life-years.

A) Life expectancy (in years) by country and age group [36]

	15-19 years old	20-24 years old	25-49 years old	50 years or older
Côte d'Ivoire	46.65	42.41	30.60	18.04
Mali	49.94	45.75	33.40	19.22
Senegal	53.92	35.80	30.60	20.83

B) Disability weight according to HIV progression and treatment status (larger weights indicate more severe disability) [28]

	Acute infection	Untreated chronic HIV	Untreated AIDS	Treated HIV
Disability weight	0.012	0.274	0.582	0.078

HIV self-testing scenarios: ATLAS-only and ATLAS-scale-up

Two main intervention scenarios were compared to a counterfactual without any HIVST over a 20-year time horizon (Table 2). The first scenario corresponds to the observed 2-year implementation of HIVST (2019-2021) through only FSW and MSM channels (ATLAS-only scenario). It assumes no HIVST distribution from the start of 2022. The ATLAS-scale-up scenario assumes the same distribution of HIVST from 2019-2021 as in the ATLAS-only scenario, but then scales up the distribution to cover more KP from 2022-2024 and holding HIVST distribution

constant from 2025 onward, with secondary distribution. At scale, an average of two HIVST kits were distributed each year, in line with WHO recommendations, to 95% of either "eligible/indicated" MSM and FSW [38].

Table 2. Description of counterfactual, ATLAS-only, and ATLAS-scale-up scenarios, and main assumptions, used to evaluate the cost-effectiveness of HIV self-test kits in Côte d'Ivoire, Mali, and Senegal over 2019-2039.

Scenario	Description	Assumptions and references
Counterfactual	Scenario without any HIVST distribution.	• Maintaining current probability of HIV testing across different age groups through conventional modalities. • Proportion of individual virally suppressed on ART will reach 85-95% by 2030.
ATLAS-only	ATLAS HIVST distribution (2019-2021)	• HIVST kits are distributed through community led MSM and FSW channels with secondary distribution. • 159,770, 130,145, and 45,890 kits are distributed between Q3 2019 to Q4 2021 in Côte d'Ivoire, Mali, and Senegal, respectively [19]. • Secondary distribution and profile of HIVST users informed by phone surveys [32,33]. • Number of tests distributed over 2019-2021 are informed by the programmatic data by channel and age. • 80% of HIVST kits are used [30]. • 50% of reactive HIVST are followed by a confirmation test [33]. • Average delay between reactive HIVST and confirmatory testing of 2 months (among those seeking confirmatory testing). • One-month delay between confirmatory testing and linkage to ART initiation (among those confirmed HIV-positive) [33]. • 20% (Côte d'Ivoire), 30% (Mali), and 40% (Senegal) substitution of conventional HIV testing among users of HIVST [32]. • HIVST has 92% sensitivity and 99% specificity [35].
ATLAS-scale-up	Same as ATLAS-only but national scale-up	• Same as above • 95% of FSW and MSM without HIV or untreated people living with HIV in each country will receive 2 HIVST per year from 2025, regardless of status awareness while retaining the same probability of usage [21]. • Assumed a constant % of kits distributed secondarily by FSW (53%) and by MSM (9%) over 2019-2039 (ATLAS phone survey). • Reduced distribution cost of HIVST at scale-up (details presented in Table 3)

Abbreviations: HIVST, HIV self-tests; ART, antiretroviral therapy; KP, key population; MSM, men who have sex with men; FSW, female sex workers.

Costing and cost-effectiveness analyses

The economic costs of the ATLAS program were estimated from the provider's perspective (i.e., the Ministries of Health of Côte d'Ivoire, Senegal, and Mali), using an ingredient-based

approach [20]. Micro-costing studies were conducted as part of ATLAS, using on-site time-in-motion approaches, and these informed our costing [20]. We conducted an incremental cost analysis where only additional resources required to introduce HIVST to the pre-existing healthcare infrastructure and community outreach were accounted. The costing analysis followed a top-down approach, and each line of expenditure is categorized into start-up, capital, and recurrent costs. The accounted costs were classified into three broad categories: 1) HIVST for KP, 2) conventional HIV testing services for both KP and the remaining population, and 3) ART to all PLHIV.

The average fully loaded cost of one HIVST kit used was calculated separately for FSW and MSM channels, considering their differences in secondary distribution (Table 3). The average unit cost per HIVST distributed accounts for the capital costs, cost of the kit, personnel, transportation, storage, training, sensitization, equipment, and overhead administration [20]. The average unit cost of a conventional test was sourced from previously published literature and includes training, outreach, counselling, personnel, and the tests themselves [39]. The average unit cost of a confirmatory test for HIVST was assumed to be the same as a conventional test. The annual unit cost of ART includes personnel, distribution, medical assays, and medications [39]. The ART cost used in this analysis is a weighted average cost, assuming 90% of individuals are taking first-line ART while 10% are taking second-line ART [40]. All three countries were assumed to adopt the same cost of conventional tests and cost of ART as Côte d'Ivoire. Each component total cost was calculated by multiplying the average resource unit cost by the amount of each resource used, as estimated by the mathematical model. The total accounted costs for the scenario were obtained by summing all the component costs.

To account for the reduction of costs due to the scale up of HIVST distribution, we used a cost function to estimate the scaled-up average unit cost of HIVST as follows [20]. The costs were categorized into fixed costs and variable costs that change with scale (i.e., number of HIVST distributed). The scale-up process was assumed to take place from 2022-2024 following countries' reported HIVST volume targets, during which HIVST distribution would increase each year until it reaches full scale in 2025. The average cost at scale per HIVST kit (A_{pct}) for population p in country c in year t was calculated by dividing the total annual cost at scale (T_{pct}) by the number of HIVST distributed in that year and country (N_{pct}). The total annual cost at scale (T_{pct}) was a function of the fixed costs (F_{pct}), variable costs (V_{pct}), and price per HIVST kits distributed (P_{pc}).

$$A_{pct} = \frac{T_{pct}}{N_{pct}}$$

$$T_{pct} = F_{pct} + V_{pct} + \left(P_{pc} \times N_{pct}\right)$$

The incremental cost-effectiveness ratios (ICER) were obtained through dividing the difference in cost between each scenario by their difference in health outcomes (DALY averted, number of new infections averted, or number of AIDS-related deaths averted). All costs were standardized to the value of USD in 2022 and discounted at 4%, in line with the rate used by the Central Bank of Western Africa States [41,42]. Cost-effectiveness acceptability curves were obtained by plotting the proportion of Monte-Carlo simulations of a scenario being cost-effective under country-specific threshold values for willingness to pay (WTP): $155 for Mali, and $488 for Côte d'Ivoire and Senegal [43]. The methodology and results are presented according to the CHEERS guidelines for health economic evaluation (Table S4) [44].

Uncertainty analyses

The median and 90% uncertainty interval of the ICERs were derived by combining uncertainty in the modeled effectiveness outcomes (e.g., DALYs, HIV acquisitions), which is obtained by sampling the posterior distribution of model parameters, with cost uncertainty through Monte-Carlo sampling from a uniform plausible range of cost (from a triangular distribution; Table 3 and Table S1).

Sensitivity analyses

We conducted a sensitivity analysis to evaluate the effect of key assumptions: higher average unit price of ART, discounting costs at 0% instead of 4%, lower fraction of HIVST kits used (50% instead of 80%), lower proportion of conventional HIV tests substituted (none instead of 20%-40%), lower proportion of confirmatory testing and linkage to care following a reactive HIVST (30% instead of 50%), lower sensitivity of HIVST (87.5% instead of 92%), and WHO-negotiated $1 unit price for HIVST (instead of $2.57 for Côte d'Ivoire and $3.36 for Mali and Senegal) [45].

Ethics consideration

No participant consent was required for this analysis. The ATLAS project was launched in mid-2019 and ended in mid-2022 and its protocol has been approved by the WHO Ethical Research Committee, the Côte d'Ivoire National Ethics Committee for Life Sciences and Health, the Ethics

Committee of the Faculty of Medicine and Pharmacy of the University of Bamako, Mali, and the National Ethics Committee for Health Research of Senegal.

Table 3. Average unit costs ($USD 2022) used to obtain the annual total accounted costs in Côte d'Ivoire, Mali, and Senegal.

		Côte d'Ivoire	Mali	Senegal
Conventional Testing [39]	Female sex workers	19.12	Adopting the same costs as Côte d'Ivoire	
	Men who have sex with men	24.72		
	Remaining population	9.06		
HIVST at start-up 2019-2021 [20]	Female sex workers	14.28	17.36	18.61
	Men who have sex with men	16.61	30.05	29.33
HIVST during scale-up period [20]	Female sex worker 2022	11.12	11.56	14.50
	Men who have sex with men 2022	11.01	19.64	26.44
	Female sex worker 2023	9.59	10.71	13.83
	Men who have sex with men 2023	9.59	18.06	24.63
	Female sex worker 2024	9.16	10.45	13.63
	Men who have sex with men 2024	9.27	17.57	24.30
HIVST at full scale 2025 onward [20]	Female sex workers	6.54	11.99	14.17
	Men who have sex with men	11.99	19.62	26.16
ART * [39]	All populations – first line	196.20	Adopting the same costs as Côte d'Ivoire	
	All populations – second line	394.58		

*per person per year
Abbreviations: ART, antiretroviral treatment; HIVST, HIV self-tests.
Uncertainties around these median costs, used in our sensitivity analysis, are shown in Table S1.

Results

Effectiveness of HIVST

Compared to the counterfactual no-HIVST scenario, the ATLAS-only scenario was estimated to avert a median of 289 (90% uncertainty interval: 158-478) HIV infections in Côte d'Ivoire, 393 (90%UI: 183-758) in Mali, and 273 (90%UI: 126-705) in Senegal. In terms of reduction in disease burden, the ATLAS-only scenario would avert 16,900 (90%UI: 10,400-22,600) DALYs in Côte d'Ivoire, 19,100 (90%UI: 9,500-36,500) in Mali and 11,700 (90%UI: 5,500-24,300) in Senegal from 2019-2039 (Table 4).

In the ATLAS-scale-up scenario, a median of 2,243 (90%UI: 1,335–3,440) infections were averted in Côte d'Ivoire, 1,566 (90%UI: 969–3,428) in Mali, and 3,005 (90%UI: 1,374–5,370) in Senegal. The same scenario will also result in 112,400 (90%UI: 72,100-176,700) DALY averted in Côte d'Ivoire, 70,200 (90%UI: 35,500-122,400) in Mali, and 92,300 (90%UI: 51,700-152,700) in Senegal over the same 20-year period (Table 4).

HIV self-testing program costs

From 2019-2039, the total discounted median cost of the ATLAS-only scenario accounted for in this analysis was estimated to be $380M (90%UI: 204M-656M), $100M (90%UI: 81M-125M), and $201M (90%UI: 168M-236M) for Côte d'Ivoire, Mali, and Senegal, respectively. In the ATLAS-only scenario over the 20-year time horizon, most of the accounted costs in this analysis were attributed to conventional testing (median of 92.1% for all three countries) and ART (median proportion 7.6% for all three countries), whereas costs associated with HIVST and confirmatory testing during the ATLAS program accounted for less than 1% of the total cost (Table S2a-c).

Due to economies of scale in the ATLAS scale-up scenario, the average unit cost per HIVST was lower in 2025 compared to the start of the program. The total program cost for Côte d'Ivoire, Mali, and Senegal was calculated to be $382M (90%UI: 207M-657M), 102M (90% UI: 83M-127M), and $202M (90%UI: 168M-238M), respectively over 20 years. In this scenario, the largest portion of the cost was attributed to conventional testing (between 87% to 90% of the total cost), ART following at 7.1% to 7.2%, and HIVST accounting for between 2.7% to 5.4% (Table S2d-f).

Table 4. Total use of HIVST, accounted costs, and health outcomes from 2019 to 2039

A) Côte d'Ivoire

		ATLAS only Scenario	ATLAS Scale-Up Scenario
Resources (90% UI)	HIVST kits distributed	159,970	6,326,000 (4,613,000 - 7,678,000)
Total accounted costs ($USD2022) (90% UI)		$379,244,000 ($204,424,000 - $656,453,000)	$381 662,000 ($207,090,000 - $656,960,000)
Outcomes (90% UI)	Deaths averted	505 (314 - 679)	3,379 (2,155 – 5,315)
	Infections averted	289 (158 - 478)	2,243 (1,335 - 3,440)
	DALY averted	16,900 (10,400 - 22,600)	112,400 (72,100 - 176,700)

B) Mali

		ATLAS only Scenario	ATLAS Scale-Up Scenario
Resources (90% UI)	Kits distributed	130,145	1,728,000 (1,421,000 - 2,304,000)
Total accounted costs ($USD2022) (90% UI)		$100,451,000 ($81,485,000 - $125,075,000)	$102,300,000 ($83,349,000 - $126,876,000)
Outcomes (90% UI)	Deaths averted	530 (261 - 979)	1,936 (969 - 3,428)
	Infections averted	393 (183 - 758)	1,566 (668 - 3,164)
	DALY averted	19,100 (9,500 - 36,500)	70,200 (35,500 - 122,400)

C) Senegal

		ATLAS only Scenario	ATLAS Scale-Up Scenario
Resources (90% UI)	Kits distributed	45,890	1,793,000 (1,369,000 - 2,368,000)
Total accounted costs ($USD2022) (90% UI)		$201,331,000 ($167,698,000 - $235,985,000)	$201,828,000 ($168,178,000 - $237,576,000)
Outcomes (90% UI)	Deaths averted	344 (165 - 721)	2,729 (1489 - 4611)
	Infections averted	273 (126 - 705)	3005 (1374 - 5370)
	DALY averted	11,700 (5,500 - 24,300)	92,300 (51,700 - 152,700)

Abbreviations: UI, Uncertainty interval; DALY, disability-adjusted life years.
All costs are discounted at 4% and outcomes at 0%.

Cost-effectiveness

The median ICERs of the ATLAS-only scenario were estimated to be $126 (90%UI: $88 - $210) in Côte d'Ivoire, $92 (90%UI: $46-$191) in Mali, and $27 (90%UI: $11-$58) in Senegal per DALY averted over 2019-2039 (Table 5A). For the ATLAS-scale-up, the ICERs were $217 (90%UI: $133-$368) in Côte d'Ivoire, $244 (90%UI: $129-$452) in Mali, and $66 (90%UI: $20-$140) in Senegal per DALY averted (Table 5B). The ICERs per infection and death averted are presented in Table 5. HIVST remained cost-effective when considering shorter time horizons (Table S3).

Table 5. Incremental cost-effectiveness ratios of HIV self-testing scenarios in Côte d'Ivoire, Mali, and Senegal over 2019 to 2039.

A) ATLAS-only scenario

	Côte d'Ivoire	Mali	Senegal
$ per DALY averted (90%UI)	126 (88 - 210)	92 (46 - 191)	27 (11 - 58)
$ per infection prevented (90%UI)	7,380 (4,140 - 13,350)	4,390 (1,920 - 9,920)	1,950 (409 - 5,290)
$ per death averted (90%UI)	4,210 (2,950 - 7,000)	3,320 (1,670 - 6,950)	1,570 (451 - 3,930)

B) ATLAS scale-up scenario

	Côte d'Ivoire	Mali	Senegal
$ per DALY averted (90%UI)	217 (133 - 368)	244 (129 - 452)	66 (20 - 140)
$ per infection prevented (90%UI)	10,880 (6,060 - 20,400)	10,710 (4,830 - 25,000)	2,080 (512 - 5,260)
$ per death averted (90%UI)	7,250 (4,460 - 12,330)	8,910 (4,790 - 16,610)	2,250 (647 - 4,740)

Abbreviations: UI, uncertainty interval; DALY, disability-adjusted life years
All currencies are expressed in $USD 2022

Cost-effectiveness acceptability curves allowed us to visualize the proportion of simulations that met a predefined willingness to pay (WTP) threshold (Figure 1). The $155 threshold for low-income countries yielded a probability of the ATLAS-only scenario to be cost-effective at 100%, 91%, and 99% for Côte d'Ivoire, Mali, and Senegal, respectively. Meanwhile, using a $488 threshold for medium-low-income countries, the probabilities of the ATLAS-only

and ATLAS-scale-up scenarios being cost-effective were 100% and over 97%, respectively, for all three countries.

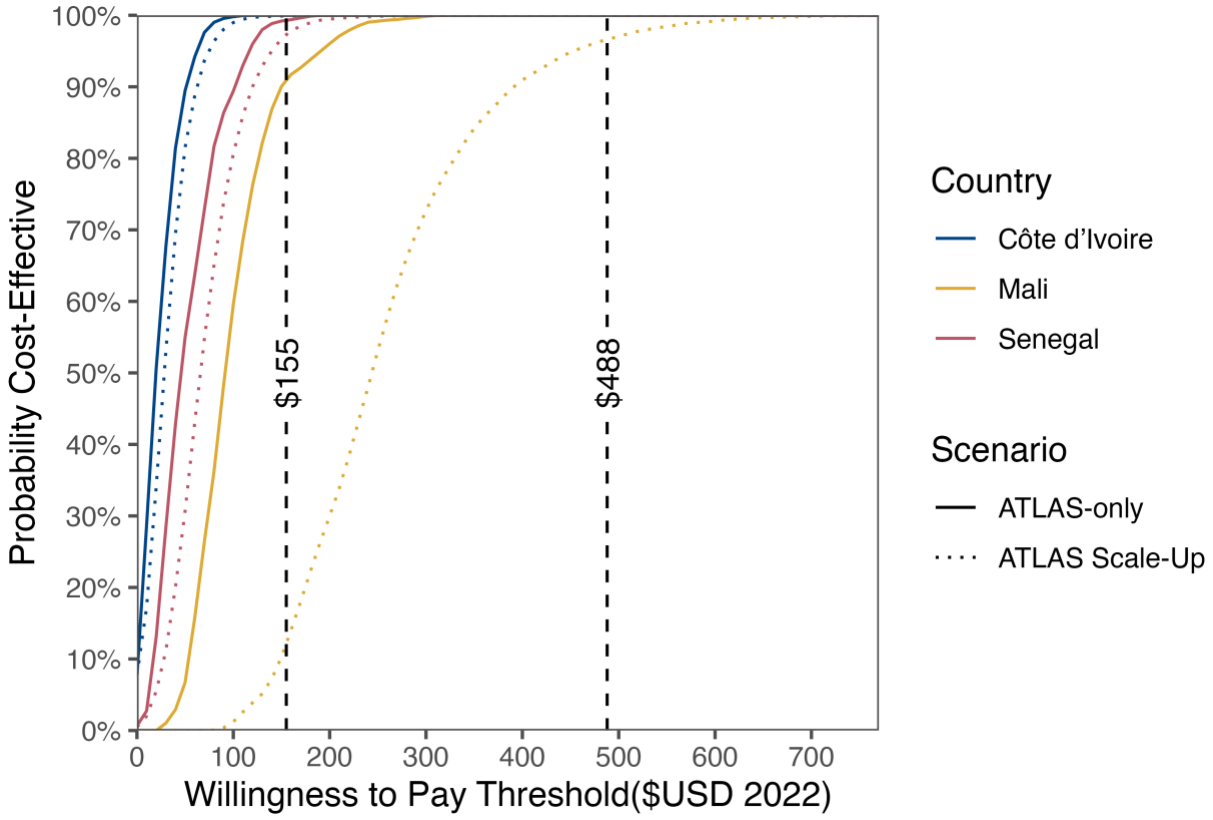

Figure 1. Cost-effectiveness acceptability curves for ATLAS-only (solid lines) and ATLAS-scale-up (dotted lines) scenarios over 20 years. The vertical dashed lines correspond to the country-specific thresholds ($155 for Mali, and $488 for Côte d'Ivoire and Senegal). The curves represent the proportion of the simulations that are below a specific willingness to pay threshold.

Sensitivity analysis

The ICER of the ATLAS-only and scale-up scenarios for Côte d'Ivoire was sensitive to lower linkage to confirmational testing and care, and lower usage (Table 6a). The ICER for Mali remained robust except for scenarios assuming a lower linkage to care, which has large uncertainty interval for both the ATLAS-only and scale-up scenario (Table 6b). The same effect was observed in Senegal for lower linkage while a 0% discount rate on costs increased the ICER.

Table 6. Sensitivity analysis of ICERs of the primary outcome ($USD 2022/DALY averted)

A) Côte d'Ivoire

	ATLAS-only (90% UI)	ATLAS Scaled-up (90% UI)
Main scenario	126	217
25% linkage to care and confirmational test following a reactive self-test (vs 50%)	374 (235 - 691)	413 (246 - 729)
0% substitution of conventional tests by HIVST (vs 20%)	Cost-saving	Cost-saving
50% usage of distributed HIVST (vs 80%)	218 (158 - 350)	346 (221 - 590)
ART price of $233 per year (vs $198 per year)	Cost-saving	Cost-saving
0% discount rate on cost (vs 4%)	131 (89 - 221)	326 (198 - 560)
4% discount rate on impact (vs 0%)	180 (125 - 298)	348 (213 - 592)
87.5% sensitivity (vs 92%)	135 (94 - 224)	225 (138 - 383)
$1 unit cost of HIVST at scale-up (vs. $2.87)	N/A	Cost-saving

B) Mali

	ATLAS-only	ATLAS Scaled-up
Main scenario	92	244
25% linkage to care and confirmational test following a reactive self-test (vs 50%)	448 (-3,822 - 6,270)	673 (303 - 2,689)
0% substitution of conventional tests by HIVST (vs 30%)	60 (33 - 109)	183 (100 - 315)
50% usage of distributed HIVST (vs 80%)	183 (90 - 407)	371 (198 - 738)
ART price of $233 per year (vs $198 per year)	87 (41 - 197)	241 (124 - 449)
0% discount rate on cost (vs 4%)	131 (89 - 221)	326 (198 - 560)
0% discount rate on impact (vs 0%)	137 (70 - 289)	395 (210 - 737)
87.5% sensitivity (vs 92%)	99 (49 - 210)	255 (134 - 481)
$1 unit cost of HIVST at scale-up (vs. $3.36)	N/A	211 (110 - 396)

C) Senegal

	ATLAS-only	ATLAS Scaled-up
Main scenario	27	66
25% linkage to care and confirmational test following a reactive self-test (vs 50%)	184 (-882 - 2,579)	103 (36 - 222)
0% substitution of conventional tests by HIVST (vs 40%)	29 (10 - 64)	61 (17 - 129)
50% usage of distributed HIVST (vs 80%)	117 (43 - 267)	110 (54 - 218)
ART price of $233 per year (vs $198 per year)	35 (-8.2 - 105)	57 (3.9 - 131)
0% discount rate on cost (vs 4%)	131 (89 - 221)	326 (198 - 560)
0% discount rate on impact (vs 0%)	69 (20 - 172)	110 (32 - 232)
87.5% sensitivity (vs 92%)	51 (15 - 131)	67 (20 - 142)
$1 unit cost of HIVST at scale-up (vs. $3.36)	N/A	40 (-5 - 102)

Abbreviations: ICER, incremental cost-effectiveness ratio; HIVST, DALY, disability adjusted life-years; HIV self-tests; ART, antiretroviral therapy.

Discussion

The ATLAS program distributed a relatively small numbers of HIVST kits to FSW, MSM, and their clients and partners and its epidemiological impact in terms of DALY averted was consequently modest. However, our cost-effectiveness analysis suggests HIVST distribution through community-led KP channels, including secondary distribution, can be highly cost-effective. This holds true for WTP thresholds as low as $155 per DALY averted over a 20-year time horizon. Moreover, when considering the national scale-up of the ATLAS program, where 95% of MSM and FSW would receive 2 HIVST per year, our evaluation also revealed that it is likely to be cost-effective [38].

The strategic focus on diagnoses and treatment of members of KP living with HIV has the potential to generate indirect benefits for the whole population [6]. In our modeled populations, most undiagnosed HIV infections are among males and KP, particularly in Mali, where over 25% of undiagnosed infections are within FSW and their clients, and Senegal, where KP account for around 60% of the total undiagnosed infections [46]. A modelling study in SSA suggested that prioritizing community-led KP prevention strategies could avert 3.7 million more infections than the status quo in 2015, over a 15-year timeframe [47]. This underscores the significance of tailoring interventions to the needs of KP to close the diagnosis gap. Stigmatization and criminalization limit access to HIV testing for KP [48]. In comparison to conventional testing, HIVST offers more privacy and convenience to its users and can easily integrate into a community-led distribution strategy. HIVST has demonstrated its general acceptability among KP in several countries [49]. Even with a short implementation period of three years, ATLAS programme achieved progress in terms of DALY averted through community-led distribution of HIVST to KP.

It was possible to incorporate economies of scale into our mathematical modelling, using a simple cost function. When considering the economic implications of KP-focused HIVST distribution programs, the average loaded unit cost of HIVST accounted for a low proportion of overall program costs, even with relatively high percentage of substitution (up to 40% in Senegal). Our average costs per kit distributed in the ATLAS scale-up scenario are comparable with the findings of other studies from South Africa [16,50,51]. Community-led testing-service is an affordable option for HIVST distribution. With WHO announcing new US$1 price per blood-based HIVST kit in July 2022, if the characteristics are similar to the oral fluid-based assumed in our

analysis, the cost of the program will be further reduced, rendering the scale-up of the ATLAS program even more cost-effective [52].

Compared to previous economic analyses in SSA, our ICERs per infection averted are higher over shorter terms: ranging from $41 400 to $166,000 over a 3-year time horizon (Table S3). For instance, a cost-effectiveness analysis on HIVST peer distribution among MSM conducted in Uganda in 2018 calculated an intermediary ICER of $6,253 per transmission averted [53]. The difference between the prevalence of undiagnosed HIV, the shorter term ICERs could be mainly attributed to the disparity between the costing method, the scale of the HIVST distribution program, and the length of the time horizon.

Using DALYs averted in the cost-effectiveness analysis is more appropriate as it captures both the morbidity and mortality prevention benefits. The cost-effectiveness analysis of the STAR program in Eastern and Southern Africa, where the epidemic is less concentrated among KP than in the three ATLAS countries, reported a similar ICER for FSW HIVST distribution channel of $120 per DALY averted (USD 2016) over a 20-year time horizon [2]. In a similar study based in South Africa, the FSW distribution modality was cost-saving, while the MSM channel had a median ICER of $20 (USD 2017) per life years saved, over 20 years [50].

Our results should be interpreted considering some limitations. First, the mathematical model used to project the epidemiological impacts of HIVST relies on several assumptions, especially regarding the characteristics of secondary distribution. Because HIVST cannot be tracked, the profiles of secondary users were characterized using a phone surveys, informing model assumptions. However, efforts were made to enhance the model's accuracy by using several data streams collected during the ATLAS program's implementation. Another limitation is that we only considered FSW-based and MSM-based channels and have not modelled the other smaller distribution channels, because of data gaps among these other populations and their small proportion of kits received. Finally, we evaluated the cost from the healthcare provider's perspective. As a result, societal benefits, such as improved productivity, savings on social welfare services, and other broader impacts, were not fully captured in the analysis.

Strengths of this study included the large number of qualitative, economic, programmatic and survey data that were collected as part of the ATLAS program [20,32,34]. This allowed us to obtain setting- and population-specific information on cost of key elements of the programs as well as key information informing the mathematical model. Second, we estimated the

epidemiological impact using comprehensive reviews of country-specific epidemiological data and a transmission-dynamic model, which allowed us to project plausible long-term impacts over a 20-year timeframe taking into consideration uncertainties in parameter assumptions. Third, by modelling three countries, our analysis reflected the influence of epidemic contexts within the same region (e.g., the prevalence of HIV is around 0.4% but more concentrated among MSM and FSW in Senegal, whereas Côte d'Ivoire has a prevalence of 1.8% with many infections occurring among non-KP) [54,55]. We explored the scalability of the ATLAS program over a 20-year time horizon, assessing the cost-effectiveness of the program at a larger scale. Finally, very few analyses have investigated the cost-effectiveness of a community-led response, which can inform the feasibility and achievement of the 2025 targets for a scaled-up response at a national level.

Conclusion

Overall, the ATLAS program suggests that community-led distribution of HIVST can bring significant improvements in HIV status awareness, reduce new infections and deaths, and improve resource allocation. By strategically prioritizing KP and their sexual partners and clients, the program offers a comprehensive approach to address the complex challenges of HIV prevention and care. HIVST's high cost-effectiveness in all three Western African countries suggests that, despite an apparently modest epidemiological impact, it should be considered by national control programs as an affordable complementary strategy to serve groups with insufficient access to current HIV testing services.

Competing interests

The authors have no conflicts of interest that are directly relevant to the content of this article.

Author's contributions

IJL, RS, MCB, JL, MD, FTP, OKZ, AV, ASF, and MMG contributed to the formulation of the research question and conceptualized the study. NS reviewed and analysed ATLAS program data. RS, NS, MMG, and MCB worked on the development of the HIV model of HIV transmission. IJL performed the cost-effectiveness analysis on the simulations, based on inputs from MD, FTP, KB, and MT. FTP and MD advised on developing the cost-function. IL drafted the manuscript. All authors critically revised it for important intellectual content, and gave final approval of the version to be published.

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Data Availability Statement

The code to replicate the cost-effectiveness analyses is available on Github (https://github.com/inga-l/atlas)

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Supplementary Materials

Table S1. Cost assumption and distributions inputs ($USD 2022)

a) Côte d'Ivoire			
	Mode	Minimum	Maximum
Female sex workers			
Conventional tests	19.12	14.28	47.31
HIV self-tests start-up (2019-2021)	14.50	12.97	18.20
HIVST scale up (2022)	11.09	10.39	11.77
HIVST scale-up (2023)	9.60	8.96	10.25
HIVST scale up (2024)	9.15	8.50	9.79
HIVST scaled-up (2025 onward)	9.67	7.68	14.26
Men who have sex with men			
Conventional tests	24.72	16.52	30.80
HIV self-tests start-up (2019-2021)	16.68	15.15	20.93
HIVST scale up (2022)	11.00	10.05	11.96
HIVST scale-up (2023)	9.65	8.72	10.56
HIVST scale up (2024)	9.25	8.33	10.18
HIVST scaled-up (2025 onward)	6.25	5.38	8.00
General population			
Conventional tests	9.06	8.36	43.84
ART – First line and second line *	216.26	111.87	253.53

b) Mali			
Female sex workers			
Conventional tests	19.12	14.28	47.31
HIV self-tests start-up (2019-2021)	17.44	15.70	18.31
HIVST scale up (2022)	11.56	10.61	12.54
HIVST scale-up (2023)	10.71	9.81	11.62
HIVST scale up (2024)	10.45	9.56	11.35
HIVST scaled-up (2025 onward)	18.54	12.37	23.85
Men who have sex with men			
Conventional tests	24.72	16.52	30.80
HIV self-tests start-up (2019-2021)	30.52	27.80	31.94
HIVST scale up (2022)	19.64	18.34	20.93
HIVST scale-up (2023)	18.06	16.82	19.30
HIVST scale up (2024)	17.57	16.34	18.80
HIVST scaled-up (2025 onward)	18.43	13.84	26.33
General population			
Conventional tests	9.06	8.36	43.84
ART – First line and second line *	216.26	111.87	253.53

c) Senegal			
Female sex workers			
Conventional tests	19.12	14.28	47.31
HIV self-tests start-up (2019-2021)	18.64	18.20	20.71
HIVST scale up (2022)	14.50	13.54	15.47
HIVST scale-up (2023)	13.83	12.94	14.74

HIVST scale up (2024)	13.63	12.72	14.52
HIVST scaled-up (2025 onward)	8.19	6.77	9.28
Men who have sex with men			
Conventional tests	24.72	16.52	30.80
HIV self-tests start-up (2019-2021)	29.43	28.45	32.92
HIVST scale up (2022)	26.44	24.56	28.33
HIVST scale-up (2023)	24.63	23.12	26.16
HIVST scale up (2024)	24.30	22.70	25.89
HIVST scaled-up (2025 onward)	16.02	9.10	23.69
General population			
Conventional tests	9.06	8.36	43.84
ART – First line and second line *	216.26	111.87	253.53

* ART: Anti-retroviral treatment; the cost of ART is assumed to be the same for general population, female sex workers, and men who have sex with men.

DALY calculation equations

Years of Life Lost: YLL Years of Life with Disability: YLD

YLL = LE in age group – age at time of death

YLD = Sum (Disease stage * Years at disease stage * Disability weight of disease stage)

DALY = YLL + YLD

Table S2. Cost breakdown over 20 years in ATLAS-only and ATLAS scale-up scenarios

a) Cote d'Ivoire - ATLAS-only scenario		
	Median amount distributed	Percentage of total cost
Conventional tests for general population	79,816,222	92.17%
Conventional tests for FSW	5,757,704	
Conventional tests for MSM	1,150,498	
Self-tests for FSW	105,907	0.1829%
Self-tests for MSM	53,864	
ART for FSW, MSM & general population	1,980,153	7.635%
Confirmational tests for FSW	1,097	0.0081%
Confirmational tests for MSM	974	

b) Mali - ATLAS-only scenario		
Conventional tests for general population	9,029,644	92.11%
Conventional tests for FSW	426,259	
Conventional tests for MSM	42,335	
Self-tests for FSW	109,265	0.2460%
Self-tests for MSM	20 881	
ART for FSW, MSM &General population	242,776	7.630%
Confirmational tests for FSW	1,174	0.0081%
Confirmational tests for MSM	536	

c) Senegal - ATLAS-only scenario		
Conventional tests for general population	25,940 795	92.09%
Conventional tests for FSW	773,291	
Conventional tests for MSM	116,610	
Self-tests for FSW	29,890	0.2624%
Self-tests for MSM	16,000	

ART for FSW, MSM &General population	293,621	7.629%
Confirmational tests for FSW	218	0.0081%
Confirmational tests for MSM	1,128	

d) Cote d'Ivoire - ATLAS scale-up scenario		
Conventional tests for general population	79768648	89.81%
Conventional tests for FSW	5571483	
Conventional tests for MSM	799,330	
Self-tests for FSW	3,128,897	2.782%
Self-tests for MSM	3,128,452	
ART for FSW, MSM & general population	1,973,361	7.282%
Confirmational tests for FSW	19,020	0.123%
Confirmational tests for MSM	19,119	

e) Mali - ATLAS scale-up scenario		
Conventional tests for general population	8,979,537	87.42%
Conventional tests for FSW	238,018	
Conventional tests for MSM	6,430	
Self-tests for FSW	1,167,602	5.391%
Self-tests for MSM	577,556	
ART for FSW, MSM &General population	240 735	7.083%
Confirmational tests for FSW	7,543	0.120%
Confirmational tests for MSM	4,690	

f) Senegal - ATLAS scale-up scenario		
Conventional tests for general population	25,867,593	89.03%
Conventional tests for FSW	519,854	
Conventional tests for MSM	27,045	
Self-tests for FSW	1,008,346	3.646%
Self-tests for MSM	671,024	
ART for FSW, MSM &General population	192,529	7.218%
Confirmational tests for FSW	5,189	0.122%
Confirmational tests for MSM	23,298	

FSW: Female sex workers; MSM: Men who have sex with men; ART: Anti-retroviral treatment

Table S3. Incremental Cost-Effectiveness ratio with alternative time horizons ($USD 2022)

a) Côte d'Ivoire

Time horizon	Outcome	ATLAS-Only Scenario (90% UI)	ATLAS Scale-Up Scenario (90% UI)
10 Years (2019 - 2029)	per DALY averted	$359 ($250 - $558)	$548 ($335 - $921)
	per new infection averted	$18,600 ($11,100 - $33,000)	$256,00 ($15,000 - $47,000)
	per death averted	$12,300 ($8570 - $19,200)	$19,000 $(11,600 - $32,800)
3 Years (2019 - 2021)	per DALY averted	$3,570 ($2,210 - $7,900)	
	per new infection averted	$181,000 ($96,400 - $339,000)	N/A
	per death averted	$134,000 ($80,400 - $371,000)	

DALY: Disability-adjusted life years; N/A: Not applicable

b) Mali

Time horizon	Outcome	ATLAS-Only Scenario (90% UI)	ATLAS Scale-Up Scenario (90% UI)
10 Years (2019 - 2029)	per DALY averted	$298 ($158 - $617)	$512 ($299 - $973)
	per new infection averted	$11,300 ($5,490 - $ 26,100)	$18,300 ($9,100 - $41,300)
	per death averted	$11,200 ($5,930 - $23,400)	$19,800 $11,200, $37,400)
3 Years (2019 - 2021)	per DALY averted	$5,460 ($2,390 - $15,400)	
	per new infection averted	$145,000 ($68,200 - $318,000)	N/A
	per death averted	$244,000 ($100,000 - $921,000)	

DALY: Disability-adjusted life years; N/A: Not applicable

c) Senegal

Time horizon	Outcome	ATLAS-Only Scenario (90% UI)	ATLAS Scale-Up Scenario (90% UI)
10 Years (2019 - 2029)	per DALY averted	$147 ($68 - $327)	$220 ($110 - $427)

	per new infection averted	$4,670 ($1,790 - $11,300)	$5,420 $(2,390 - $12,000)
	per death averted	$5,170 ($2,370 - $11,300)	$7,780 ($3,880 - $15,200)
3 Years (2019 - 2021)	per DALY averted	$2,640 ($1,190 - $7,000)	
	per new infection averted	$45,100 ($21,300 - $94,100)	N/A
	per death averted	$109,000 ($46,700 - $427,000)	

DALY: Disability-adjusted life years; N/A: Not applicable

Table S4. CHEERS 2022 Checklist

Topic	No.	Item	Location where item is reported
Title			
	1	Identify the study as an economic evaluation and specify the interventions being compared.	Title, Page 1
Abstract			
	2	Provide a structured summary that highlights context, key methods, results, and alternative analyses.	Abstract, Page 1
Introduction			
Background and objectives	3	Give the context for the study, the study question, and its practical relevance for decision making in policy or practice.	Introduction
Methods			
Health economic analysis plan	4	Indicate whether a health economic analysis plan was developed and where available.	Methods
Study population	5	Describe characteristics of the study population (such as age range, demographics, socioeconomic, or clinical characteristics).	Methods
Setting and location	6	Provide relevant contextual information that may influence findings.	Methods
Comparators	7	Describe the interventions or strategies being compared and why chosen.	Methods
Perspective	8	State the perspective(s) adopted by the study and why chosen.	Methods
Time horizon	9	State the time horizon for the study and why appropriate.	Methods
Discount rate	10	Report the discount rate(s) and reason chosen.	Methods

Topic	No.	Item	Location where item is reported
Selection of outcomes	11	Describe what outcomes were used as the measure(s) of benefit(s) and harm(s).	Methods
Measurement of outcomes	12	Describe how outcomes used to capture benefit(s) and harm(s) were measured.	Methods
Valuation of outcomes	13	Describe the population and methods used to measure and value outcomes.	Supplementary
Measurement and valuation of resources and costs	14	Describe how costs were valued.	Methods
Currency, price date, and conversion	15	Report the dates of the estimated resource quantities and unit costs, plus the currency and year of conversion.	Methods
Rationale and description of model	16	If modelling is used, describe in detail and why used. Report if the model is publicly available and where it can be accessed.	Methods
Analytics and assumptions	17	Describe any methods for analyzing or statistically transforming data, any extrapolation methods, and approaches for validating any model used.	Methods
Characterizing heterogeneity	18	Describe any methods used for estimating how the results of the study vary for subgroups.	Methods
Characterizing distributional effects	19	Describe how impacts are distributed across different individuals or adjustments made to reflect priority populations.	N/A
Characterizing uncertainty	20	Describe methods to characterize any sources of uncertainty in the analysis.	Methods
Approach to engagement with patients and others affected by the study	21	Describe any approaches to engage patients or service recipients, the general public, communities, or stakeholders (such as clinicians or payers) in the design of the study.	Composition of the ATLAS team

Topic	No.	Item	Location where item is reported
Results			
Study parameters	22	Report all analytic inputs (such as values, ranges, references) including uncertainty or distributional assumptions.	Methods and supplementary
Summary of main results	23	Report the mean values for the main categories of costs and outcomes of interest and summarise them in the most appropriate overall measure.	Results
Effect of uncertainty	24	Describe how uncertainty about analytic judgments, inputs, or projections affect findings. Report the effect of choice of discount rate and time horizon, if applicable.	Results
Effect of engagement with patients and others affected by the study	25	Report on any difference patient/service recipient, general public, community, or stakeholder involvement made to the approach or findings of the study	N/A
Discussion			
Study findings, limitations, generalisability, and current knowledge	26	Report key findings, limitations, ethical or equity considerations not captured, and how these could affect patients, policy, or practice.	Discussion
Other relevant information			
Source of funding	27	Describe how the study was funded and any role of the funder in the identification, design, conduct, and reporting of the analysis	End of manuscript
Conflicts of interest	28	Report authors conflicts of interest according to journal or International Committee of Medical Journal Editors requirements.	None declared

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Chapter 5 Discussion

This thesis provides insights into the epidemiological and economic implications of community-led HIVST distributions to KP by characterizing the incremental cost-effectiveness ratio of the ATLAS program. The analysis sheds light on the affordability and the longer-term financial viability of HIVST distribution to KP in Côte d'Ivoire, Mali, and Senegal by exploring economic impacts of the HIVST scale-up scenarios.

5.1 Main findings

My results showed the programme would achieve a moderate impact with regards to the primary (i.e., disability-adjusted life years; DALY) and secondary outcomes (i.e., infection averted and deaths presented). The ATLAS programme would avert 16 900 DALY in Côte d'Ivoire, 19 100 in Mali, and 11 700 in Senegal over the course of 20 years. Meanwhile, over the same time horizon, the scaled-up ATLAS programme would avert 112 400 DALY in Côte d'Ivoire, 70 200 in Mali, and 92 300 in Senegal. These findings suggest that HIVST can reduce transmission through increased diagnoses among KPs and linkage to prevention or treatment for those taking the test. These estimates add on to our current knowledge about the impacts of HIVST distribution in sub-Saharan Africa and emphasize the importance of integrating HIVST to HTS to expand testing and diagnosis coverage. HIVST has the potential to serve those who may otherwise be unreachable through conventional testing services and mitigating the diagnostics gap between KP and the general population.

The manuscript also offers evidence of the cost-effectiveness of the community-led distribution of HIVST through KP channels, and the feasibility of its subsequent scale-up. The estimated median ICER of the ATLAS programme for all three countries were below $130 for each DALY averted over 20 years, which is below the $155 WTP-threshold for low-income countries. Meanwhile, the scaled-up ATLAS programme will produce a median ICER of $217 per DALY averted in Côte d'Ivoire, $244 in Mali, and $66 in Senegal, over the 20-year timeframe. Using the WTP threshold of $488, the scaled-up scenario would be over 98% cost-effective for all countries. The high probability of cost-effectiveness for ICER accentuates the merits of community-driven strategies for HIV testing. Moreover, HIVST only accounts for less than 0.3%

of the total accounted cost in ATLAS-only scenarios and less than 5.4% in ATLAS scale-up scenarios in all three countries. The findings show that HIVST accounts for a small proportion of the total costs, and the programme is affordable. Finally, my thesis gives insights into the potential of broadening community-led HIVST distribution to KPs at larger scales, and ultimately achieve the UNAIDS objective of having 60% of the HIV prevention and advocacy services provided by community-led programmes [94].

5.2 Strengths and limitations

A standout strength of this this is its encompassing multi-country analysis. By concurrently examining Côte d'Ivoire, Mali, and Senegal, the study affords insights into the generalizability, applicability, and robustness of its findings in Western and Central Africa. Moreover, the use of a mathematical model allowed for long term predictions, over 10- and 20-year time horizons, which are important to take into account. Furthermore, by using a cost-function, I considered the economy of scale, identifying the relationship between the scale of distribution and its associated costs. Few cost-effectiveness analyses have so far done so despite new strong recommendations to include these in economic evaluations.

Nevertheless, several limitations should be acknowledged when interpreting these results. First, the analyses relied on several assumptions related to HIVST and its secondary distribution. While efforts were made to base these assumptions on the best available data, they are still subject to uncertainty. Second, the cost data utilized for conventional testing and ART could benefit from being more specific to the individual countries. Variability in economic conditions, healthcare infrastructures, and population health profiles mean that the approach in this thesis might not fully capture country-specific nuances. While a regional overview offers broad insights, nation-specific data would provide a more detailed understanding of the economic implications of the ATLAS HIVST program. Third, while the use of a willingness-to-pay threshold offers a tangible benchmark, it inherently reflects individuals' or society's ability to pay, rather than the actual value of the health outcome. Consequently, it may not always align with ethical considerations or with the true societal value of an intervention, especially in settings with economic disparities. Lastly, the cost-effectiveness analysis was conducted from a provider's perspective. While this offers valuable insights into the economic implications for healthcare systems and organizations, it does

not fully capture the societal benefits and externalities that might arise from the program. Important factors like improved quality of life for individuals, decreased societal stigma, or broader economic benefits –which are very challenging to accurately quantify– might not be adequately represented in the manuscript.

5.3 Areas for future research

The study's findings pave the way for several directions of future research. Firstly, there's a need for further programme monitoring. As HIVST is being scaled-up, monitoring systems should be implemented to routinely assess the programme effectiveness. Moreover, subsequent studies can also venture into the optimization of HIVST distribution. With a foundational understanding of broader economic implications, the next step is refining the resource allocation to distribution channels and modalities to maximize outreach and cost-effectiveness. By weaving community-led HIVST distribution into a broader network of prevention services, testing regimes, and interventions, key stakeholders could enhance the overarching HIV response.

Chapter 6 Conclusions

The ATLAS programme of community-led HIVST distribution to KP had demonstrated moderate impact but also notable cost-effectiveness when compared to the scenario without any HIVST distribution. The findings illustrate the benefits of HIVST distribution through KP channels, which accelerates towards the overarching goal of decreasing HIV incidence and can lead to a potential reduction in HIV financing in the long term. Additionally, the distribution of HIVST serve as a catalyst in addressing structural determinants of HIV transmission. By mitigating social barriers to access HTS, HIVST can help to further reduce health disparities. These results can inform key stakeholders on the economic implications of using HIVST distribution to expand HTS coverage and bridging diagnostic gaps between KP and the general population. While these results are encouraging, they also emphasize the importance of continuous and meticulous monitoring of the ATLAS program. Moreover, further research is required to optimise the resource allocation for the various community-led KP distribution channels to reach the maximum cost-effectiveness.

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Appendix 1 – Additional methods for the search strategy

Search terms for sub-Saharan Africa has been adapted from S. M. Campbell's hedge terms. Below is the search strategy used for the literature search:

Medline [95]:
exp Africa/ or (Africa* or Angola or Benin or Botswana or "Burkina Faso" or Burundi or "Cabo Verde" or "Cape Verde" or Cameroon or Central African Republic or Chad or Comoros or Congo or "Cote d'Ivoire" or "Ivory Coast" or Djibouti or "Equatorial Guinea" or Eritrea or Eswatini or Ethiopia or Gabon or Gambia or Ghana or Guinea or "Guinea-Bissau" or Kenya or Lesotho or Liberia or Madagascar or Malawi or Mali or Mauritius or Mozambique or Namibia or Niger or Nigeria or "Nile Valley" or Rwanda or "Sao Tome" or Principe or Senegal or Seychelles or "Sierra Leone" or Somalia or "South Africa" or "Sub Saharan" or Tanzania or Togo or Uganda or Zambia or Zimbabwe).mp.

Embase [96]:
exp Africa/ or (Africa* OR Angola OR Benin OR Botswana OR "Burkina Faso" OR Burundi OR "Cabo Verde" OR "Cape Verde" OR Cameroon OR Central African Republic OR Chad OR Comoros OR Congo OR "Cote d'Ivoire" OR "Ivory Coast" OR Djibouti OR "Equatorial Guinea" OR Eritrea OR Eswatini OR Ethiopia OR Gabon OR Gambia OR Ghana OR Guinea OR "Guinea-Bissau" OR Kenya OR Lesotho OR Liberia OR Madagascar OR Malawi OR Mali OR Mauritania OR Mauritius OR Mozambique OR Namibia OR Niger OR Nigeria OR "Nile Valley" or Rwanda OR "Sao Tome" OR Principe OR Senegal OR Seychelles OR "Sierra Leone" OR Somalia OR "South Africa" OR "Sub Saharan" or Sudan OR Tanzania OR Togo OR Uganda OR Zambia OR Zimbabwe)

Search terms for HIV/AIDS has been adapted from Y. Mizuno 2018[97]:

MEDLINE:
* = focus MeSH term / = MeSH term
adj = adjacency search
ti = title ab = abstract
$ = truncation
HIV or AIDS MeSH and keywords
1. *HIV infections/
2. *AIDS/
3. *HIV Seropositivity/
4. *AIDS Serodiagnosis/
5. HIV infect$.ti,ab
6. HIV positiv$.ti,ab
7. HIV care.ti,ab
8. (HIV adj4 incidence).ti,ab
9. (HIV adj4 prevent$).ti,ab
10. (HIV adj4 risk$).ti,ab
11. (HIV adj4 prevalen$).ti,ab
12. (HIV adj4 new$ infect$).ti,ab
13. (HIV adj4 new$ diagnos$).ti,ab
14. (HIV adj4 transm$).ti,ab
15. (living adj4 HIV).ti,ab
16. (living adj4 (AIDS not hearing)).ti,ab
17. or/1-16

EMBASE:
* = focus indexing term / = indexing term
adj = adjacency search
ti = title ab = abstract
$ = truncation
HIV or AIDS indexing and keywords
1. *Human Immunodeficiency Virus Infection/
2. *Acquired Immune Deficiency Syndrome/

3. *Serodiagnosis/
4. HIV infect$.ti,ab
5. HIV positiv$.ti,ab
6. HIV care.ti,ab
7. (HIV adj4 incidence).ti,ab
8. (HIV adj4 prevent$).ti,ab
9. (HIV adj4 risk$).ti,ab
10. (HIV adj4 prevalen$).ti,ab
11. (HIV adj4 new$ infect$).ti,ab
12. (HIV adj4 new$ diagnos$).ti,ab
13. (HIV adj4 transm$).ti,ab
14. (living adj4 HIV).ti,ab
15. (living adj4 (AIDS not hearing)).ti,ab
16. or/1-15

Search term for Health Economic Analysis/Cost-effectiveness analysis:

MEDLINE:

1. Economics/
2. exp "Costs and Cost Analysis"/
3. Economics, Nursing/
4. Economics, Medical/
5. Economics, Pharmaceutical/
6. exp Economics, Hospital/
7. Economics, Dental/
8. exp "Fees and Charges"/
9. exp Budgets/
10. budget*.ti,ab,kf.
11. (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.
12. (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2
13. (cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.
14. (value adj2 (money or monetary)).ti,ab,kf.
15. exp models, economic/
16. economic model*.ab,kf.
17. markov chains/
18. markov.ti,ab,kf.
19. monte carlo method/
20. monte carlo.ti,ab,kf.
21. exp Decision Theory/
22. (decision* adj2 (tree* or analy* or model*)).ti,ab,kf.
23. or/1-22
24. "Value of Life"/
25. Quality of Life/
26. quality of life.ti,kf.
27. ((instrument or instruments) adj3 quality of life).ab.
28. Quality-Adjusted Life Years/
29. quality adjusted life.ti,ab,kf.
30. (qaly* or qald* or qale* or qtime* or life year or life years).ti,ab,kf.
31. disability adjusted life.ti,ab,kf.
32. daly*.ti,ab,kf.
33. (sf36 or sf 36 or short form 36 or shortform 36 or short form36 or shortform36 or sf thirtysix or sfthirtysix or sfthirty six or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).ti,ab,kf.
34. (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six or shortform6 or short form6).ti,ab,kf.

35. (sf8 or sf 8 or sf eight or sfeight or shortform 8 or shortform 8 or shortform8 or short form8 or shortform eight or short form eight).ti,ab,kf.
36. (sf12 or sf 12 or short form 12 or shortform 12 or short form12 or shortform12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab,kf.
37. (sf16 or sf 16 or short form 16 or shortform 16 or short form16 or shortform16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab,kf.
38. (sf20 or sf 20 or short form 20 or shortform 20 or short form20 or shortform20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab,kf.
39. (hql or hqol or h qol or hrqol or hr qol).ti,ab,kf.
40. (hye or hyes).ti,ab,kf.
41. (health* adj2 year* adj2 equivalent*).ti,ab,kf.
42. (pqol or qls).ti,ab,kf.
43. (quality of wellbeing or quality of well being or index of wellbeing or index of well being or qwb).ti,ab,kf.
44. nottingham health profile*.ti,ab,kf.
45. sickness impact profile.ti,ab,kf.
46. exp health status indicators/
47. (health adj3 (utilit* or status)).ti,ab,kf.
48. (utilit* adj3 (valu* or measur* or health or life or estimat* or elicit* or disease or score* or weight)).ti,ab,kf.
49. (preference* adj3 (valu* or measur* or health or life or estimat* or elicit* or disease or score* or instrument or instruments)).ti,ab,kf.
50. disutilit*.ti,ab,kf.
51. rosser.ti,ab,kf.
52. willingness to pay.ti,ab,kf.
53. standard gamble*.ti,ab,kf.
54. (time trade off or time tradeoff).ti,ab,kf.
55. tto.ti,ab,kf.
56. (hui or hui1 or hui2 or hui3).ti,ab,kf.
57. (eq or euroqol or euro qol or eq5d or eq 5d or euroqual or euro qual).ti,ab,kf.
58. duke health profile.ti,ab,kf.
59. functional status questionnaire.ti,ab,kf.
60. dartmouth coop functional health assessment*.ti,ab,kf.
61. or/24-60
62. 23 or 61

EMBASE:
Same keywords, limits used as per MEDLINE search

Search terms for HIV self-test
EMBASE/MEDLINE:

1. self evaluation/ and HIV test/
2. HIV test*.mp.
3. self test*.mp.
4. 1 or 3
5. exp Human immunodeficiency virus infection/

6. (hiv or human immune* vir* or human immune* deficiency vir*).mp.

5 or 6