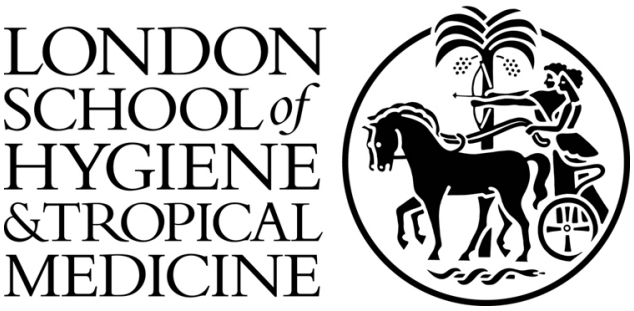

Investigating Men's Preferences for HIV Self-Testing and Linkage: Exploring Strategies for Policy Impact

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Thesis submitted in fulfilment of the requirement for the award of the degree of Doctor of Philosophy (PhD) of the University of London

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Declaration of own work

I, Cheryl Johnson, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis' I have read and understood the School's definition of plagiarism and cheating given in the Research Degrees Handbook.

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Thesis Abstract

There has been a substantial scale-up of HIV testing, yet 15% of people with HIV are still unaware of their status. Recent reports suggest many of those unreached are men, particularly those over 30 years of age, in sub-Saharan Africa. HIV self-testing (HIVST) has been proposed as one approach for reaching men who are hesitant or unable to access existing services. Despite this potential, concerns about lay people's ability to self-test and link to care, as well as possible social harm, remain. This PhD investigates preferences for, and linkage following, HIVST, among men, as well as harms and benefits that emerge, to inform policy and implementation. This PhD is made up of the following pieces of work.

First, a systematic review was conducted on the effectiveness of HIVST compared to standard HIV testing. Five randomised controlled trials (RCTs) were identified out of 638 citations; all were among men. The review found that compared to standard HIV testing, HIVST: doubled testing uptake (RR = 2.12; 95% CI: 1.51, 2.98), nearly doubled testing frequency (Rate ratio = 1.88; 95% CI: 1.17; 3.01) and doubled the likelihood of an HIV-positive diagnosis (RR = 2.02; 95% CI: 0.37, 10.76, 5.32). Linkage appeared suboptimal in one RCT, but data was limited and of very low-quality. There was no indication of harm attributable to HIVST. This paper was published in the Journal of the International AIDS Society in 2017. I used these results to inform development of guidelines from the World Health Organization.

Second, cross-sectional analysis of data was conducted using 31 385 survey respondents from two of the first Demographic and Health Surveys to include HIVST questions (Malawi and Zimbabwe 2015-16). This work highlighted that nearly one-third of men had never tested and that HIVST awareness and experience was low, 12.6% and 1.2% respectively. Analysis of willingness to self-test was limited by data availability to Zimbabwean men but showed highest willingness to self-test among men at high HIV-related sexual risk (aOR = 3.74; 95%CI: 1.39–10.03). Effect modification was observed between HIV-related sexual risk and socioeconomic variables with multivariable analysis showing that high-risk men were more likely than low-risk men to be willingness to self-test if they were wealthier, unemployed, rural and tested before. These data can be used to investigate future impact of HIVST as programmes scale up. This paper was published in the BMC Public Health in 2020.

Third, a formative qualitative study explored the potential for HIVST to be part of a broader strategy for engaging midlife-older Malawians in HIV testing, prevention and care. The study applied a life-course theoretical framework to understand how age is enacted socially and its implications on HIV testing and sexual risk behaviours in men and women. Adults over 30 years

of age were considered “respectable”, beyond sexual risk taking and infidelity; and therefore, perceived as invulnerable to HIV. Thus, HIV testing was stigmatized as a threat to social status. Given this, self-testing was preferred to conventional alternatives, with older men wanting to access HIVST through fixed community collection points, workplaces or bus depots. Partner-delivered HIVST was also desired. This paper was published in the BMC Public Health in 2021.

Fourth, a discrete choice experiment (DCE) was nested within a six-armed adaptive cluster-randomised trial using secondary HIVST distribution to male partners of pregnant women in Blantyre, Malawi, to provide proxy preferences on the feasibility of financial incentives. Overall, 602 pregnant women were surveyed about their partner’s preference for linkage interventions for anti-retroviral therapy (ART) or voluntary male medical circumcision (VMMC) following HIVST or standard HIV testing. Analysis using a multinomial logit model indicated that, according to women, men would prefer US$3, not US$10, for linking to ART (US$3: $\beta = 0.087$, $p<0.10$ vs US$10: -0.228, $p<0.01$). The latent class analysis revealed that for linkage to ART, women were split between those with significant preferences for standard testing (37.1%), those preferring HIVST plus US$3 (28.4%), those preferring a lottery (26.2%), and those feeling partners would never link (8.2%). For VMMC, the latent class analysis, found women to be either optimistic (77.0%) or those pessimistic (23.0%) their partners would link regardless of intervention. In qualitative interviews with 75 women, most were too unsure to guess their partner’s views, others considered their partner either very unlikely, or very likely, to link regardless of incentive. Concern with what men would do with the cash incentive was expressed. Findings contrasted with the parent study which showed a strong effect of incentives on men’s linkage, with US$10 outperforming US$3 financial incentives and lottery prizes ineffective. The paper is currently in preparation for submission to BMC Infectious Diseases.

This PhD project supports HIVST as an important tool for reaching African men who may not otherwise test. HIVST implementation and linkage interventions, particularly for midlife-older men, need to factor in social and cultural norms, including attitudes among their female partners. The approach followed here, combining a systematic review, population survey, qualitative study, and DCE, provides insight into how valuable HIVST is for reaching men, and the importance of strategies that will reach midlife-older men and are accepted by female partners. As the largest gap in absolute diagnoses in sub-Saharan Africa continues to be among 35–49-year-old men, these findings are of critical importance and have been used to inform policy development globally and nationally, as countries scale-up HIVST and work toward achieving the “first 95” – diagnosis of 95% of all people with HIV by 2025.

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Abbreviations and acronyms

ACASI	audio computer assisted self-interview
AHI	acute HIV infection
ANC	antenatal clinic
AIDS	acquired immunodeficiency syndrome
aOR	adjusted odds ratio
ART	antiretroviral treatment
ARV	antiretroviral drugs
CAI	condomless anal intercourse
CBD	community-based distributors
CD4 cells	CD4+ subtype of T-lymphocytes
CI	confidence Interval
COMREC	College of Medicine Research and Ethics Committee
COREQ	consolidated criteria for reporting qualitative research
COVID-19	severe acute respiratory syndrome coronavirus-2
CROI	Conference on Retroviruses and Opportunistic Infections
DCE	discrete choice experiment
DHS	Demographic Health Surveys
EIA	enzyme immunoassays
EMBASE	Excerpta Medica dataBASE
FGD	focus group discussion
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GRADE	grading of recommendations, assessment, development, and evaluation
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HIVST	HIV self-testing
HTS	HIV testing services
IAC	International AIDS Conference
IAS	International AIDS Society
IDI	in-depth interview
IgA	HIV immunoglobin A
IgG	HIV immunoglobin G
IgM	HIV immunoglobin M

IPV	intimate partner violence
IRB	International review board
LCM	latent class model
LMIC	low- and middle-income countries
LSHTM	London School of Hygiene and Tropical Medicine
LSTM	Liverpool School of Tropical Medicine
MAMS	multi-arm multi-stage
MEDLINE	Medical Literature Analysis and Retrieval System Online
M-H	mantel-haenszel method
MLW	Malawi Liverpool Wellcome Trust Clinical Research Programme
MNL	multinomial logit model
MSM	men who have sex with men
MWK	Malawian Kwacha
NA	not applicable
NAT	nucleic acid amplification
OR	odds ratio
PEPFAR	Presidents Emergency Plan for AIDS Relief
PhD	Doctor of Philosophy
PITC	provider-initiated testing and counselling
PLHIV	people living with HIV
PMTCT	prevention of mother to child transmission
PrEP	pre-exposure prophylaxis
PRISMA	preferred reporting items for systematic reviews and meta-analyses
PSI	Population Services International
Q	quote
RCT	randomised controlled trial
RDT	rapid diagnostic tests
RNA	ribonucleic acid
RR	relative risks
SARS-CoV-2	severe acute respiratory syndrome coronavirus-2
SD	standard deviation
SMS	short messaging service
SOC	standard of care
STAR	Self-Test Africa

STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
US$	US dollars
VCT	voluntary testing and counselling
VMMC	voluntary male medical circumcision
WHO	World Health Organization

1.0 Introduction

1.1 Aims

This research aims to understand gaps in HIV testing, and how HIV self-testing (HIVST) could be used to contribute to closing these gaps, among men in sub-Saharan Africa. In particular, this research focuses on how preferences for self-testing and linkage to prevention and treatment can be used to increase the impact of HIVST implementation and to inform future HIVST policies and strategies focused on men. The overarching research question for this thesis was: how should HIVST be optimized for future implementation so that access to affordable and acceptable HIV testing, with timely linkage to care and prevention are improved for men in sub-Saharan Africa?

1.2 Objectives

The specific objectives were to:

1. synthesise the effectiveness of HIVST in randomised controlled trials (RCTs) among men;
2. assess gaps in HIV testing and willingness to consider HIVST among men in sub-Saharan Africa;
3. explore perceptions of HIV testing and HIVST among middle-aged and older African men; and
4. identify ways to optimise future secondary distribution of HIVST through antenatal clinics by incorporating both male and female linkage preferences.

1.3 Structure of thesis

This thesis is comprised of manuscripts and peer-reviewed articles in their published form or as prepared for submission. Four articles were written, three of which were published and one which was under peer review at the time of writing this thesis. The main chapters are structured around these articles and accompanied by a cover letter and a short introduction. Tables and figures for these articles are located at the end of each chapter, along with references and additional appendices or supplemental information.

The remainder of this chapter describes the overarching research question and methodological approaches used to address research questions in this thesis. This chapter also describes my role in each piece of work presented in this thesis, and the collaborations that I formed during my PhD work.

Chapter 2 provides background to the thesis. The chapter outlines HIV infection and diagnosis and then discusses the evolution of the HIV response and HIV testing services (HTS). This is followed by a discussion of masculine norms and how they affect men's engagement in HIV testing and health services more broadly. Then, there is a summary describing HIVST and linkage to HIV prevention and care interventions. The chapter closes with a discussion of why efforts to increase demand for health services are needed, particularly for men.

Chapter 3 presents a systematic review I conducted on RCTs on the effects of HIVST on the uptake and frequency of HIV testing services, as well as linkage to care and other social harms and benefits. This work was done to characterise the effectiveness of self-testing particularly for reaching men and to inform WHO guidelines. It was the first review of its kind to assess potential effectiveness of HIV self-testing. The primary research question for this study was: should HIVST be offered as an additional HIV testing approach? The findings led to the following study which examined levels of awareness, use, and willingness to self-test for HIV in sub-Saharan Africa. This work was published in the Journal of the International AIDS Society in 2017.

Chapter 4 presents a cross-sectional data analysis I conducted using two of the first Demographic and Health Surveys to include HIVST questions (Malawi and Zimbabwe) two large population-based surveys in Malawi and Zimbabwe from 2015-16). The survey analysis provided information on the awareness, use and future willingness to self-test among men with HIV-related risks, and identified gaps in testing for future prioritisation. These surveys were the first in Africa to incorporate standard questions on HIVST into national surveys. The primary research question for this study was: what was the prevailing level of awareness, use and willingness to self-test for HIV in Malawi and Zimbabwe? The findings led to the following study which examined the effects of age-gender norms on HIV testing and self-testing, as well as sexual risk-behaviours, among midlife-older Malawians. This work was published in BMC Public Health in 2020.

Chapter 5 presents formative qualitative research I conducted using 12 in-depth interviews and five focus group discussions among urban and rural Malawians aged 30-74. Here, I applied the

life-course framework to understand how age-gender norms and social positions affected HIV-risk perception and willingness to access HIV testing, and to highlight how HIVST could be used to better reach midlife-older age groups who may not otherwise test. The primary research question for this study was: how do individual age and gender norms affect sexual risk perceptions and HIV testing and self-testing behaviours? The findings led to the following study which examined how effective and feasible financial incentives are to support linkage to HIV prevention and treatment following secondary HIVST distribution from pregnant women to their male partners. This work was published in BMC Public Health in 2021.

Chapter 6 presents findings from a discrete choice experiment and a qualitative sub-study that I conducted. Here, I collected preferences by proxy were collected among pregnant women to understand how to optimise linkage interventions for their male partners following HIVST. This study was nested in a six-arm adaptive multi-arm multi-stage (MAMS) cluster randomised trial. The primary research question for this study was: how effective and feasible are financial incentives that support linkage to prevention and care following secondary distribution of HIVST from pregnant women to their male partners? This work is submitted and under-review at a peer-reviewed journal.

Chapter 7 provides an overall discussion of the thesis, followed by key strengths and limitations, recommendations and conclusions.

Given the timeliness of the question and topic, several related research dissemination activities were undertaken and are presented in Appendix 8.3.

This work has had global, regional and national impact. First, it has been utilised by WHO to develop the first normative guidance on HIVST and subsequent implementation guidance and updates. Through this work I have been able to work closely with national governments and donor agencies to allocate additional resources toward HIVST. Second, this work has been utilised at a regional level to support HIVST priorities, policies and implementation across sub-Saharan Africa. Third, the Malawian Ministry of Health has become a leader in HIVST and has taken onboard concepts from this research. I have engaged in local meetings with stakeholders in Malawi to guide HIVST implementation and scale-up. Lastly, I have applied lessons learned from this research to self-testing approaches in other disease areas including leading development of guidance on self-testing for hepatitis C virus (HCV) and severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2).

1.4 Problem conception and scientific approach

The focus of this thesis and PhD evolved from my work as part of the Self-Testing Africa (STAR) Consortium and the World Health Organization (WHO). My involvement in STAR began in 2013 when I supported WHO in writing a meeting report for the first international consultation on HIVST. This report mapped out research gaps and led to my role managing a special issue on HIVST with AIDS and Behaviour. At this time, I was invited to collaborate on a Unitaid proposal with the London School of Hygiene and Tropical Medicine.

Following a successful letter of intent, in November 2013, I attended a London-based workshop which focused on developing the research and implementation plan for the Unitaid grant proposal. The research was to be led by Professor Liz Corbett who had started working on HIVST through a health worker survey in 2007 and subsequent implementation studies in Malawi since 2009. At this workshop, I took on a role to lead WHO's involvement in STAR, with a focus on evidence-based policy development and coordination with WHO prequalification and supporting regulation and registration of HIVST products in low- and middle-income countries. Prior to joining the STAR Consortium, I had led exploratory work on HIVST within the U.S. Agency for International Development and had seen the strong acceptability and interest in HIVST. The potential for HIVST to reach those hesitant or unable to access existing services was clear, and important evidence and policy gaps needed to be urgently filled.

The first phase of the STAR Consortium was successfully funded from 2015 to 2017 and implementation lead Dr Karin Hatzold from Population Services International (PSI) joined. During the end of the first phase in 2016, I participated in a phase 2 grant development workshop where we mapped out priority research gaps which remained. As I reviewed available testing data, I observed that many programmes were struggling to reach men and that HIVST could be a potential strategy to increase access to HIV testing, prevention and care. During my initial systematic review to support the 2016 WHO guideline development process, I identified that secondary distribution of HIVST to male partners of pregnant women was a highly effective strategy that should be prioritised for sub-Saharan Africa. However, there were still concerns about linkage to care and potential social harm.

In summary, my guiding research questions were:

1. Is HIVST, in RCTs among men, a safe and effective way to increase uptake of HIV testing and onward prevention and treatment services?

2. What gaps in HIV testing remain among men in sub-Saharan Africa?
3. What are men's perceptions of and preferences for HIV testing, HIVST and linkage services?
4. How do we use both male and female preferences to design effective, acceptable and feasible strategies for secondary distribution of HIVST through antenatal clinics?

I spent the first year of my PhD studying statistical designs and completing short courses related to discrete choice experiments and decision analysis. I also focused on completing a systematic review on HIVST which included available evidence from RCTs. The next step was to conduct the population-based survey data analysis to assess key gaps in and preferences for HIV testing and HIVST. This allowed me to identify the importance of focusing on midlife-older men and the importance of applying a life-course theoretical framework toward my qualitative research. The qualitative research then gave insight into HIV-risk perceptions, as well as preferences and views following HIVST implementation. The subsequent discrete choice experiment identified male partner preferences by proxy after asking pregnant women to select which linkage to care strategy their partner would prefer. The additional qualitative component also identified women's rationale and potential concerns for different linkage interventions.

I was able to combine qualitative and quantitative research methods due to my MA in Applied Anthropology and Certificate of Public Health obtained from Georgia State University, as well as my participation in online and other short courses through London School of Hygiene & Tropical Medicine and University College of London. I also participated in learning workshops led by Professor Fern Terris-Prestholt which focused on specific economic evaluation and discrete choice experiment methods as part of the STAR Consortium.

1.5 My role

I led all the work that is included in this thesis. I conceived the overall approach to addressing the research questions before seeking input from my supervisors. The supervisors then advised me on the appropriate collaborators to include for specific components of the research project. For example, Dr Melissa Neuman was contacted to collaborate on statistical analysis of the population-based surveys, Dr Nicola Desmond was contacted to collaborate on qualitative methods and Professor Fern Terris-Prestholt and Dr Marc D'Elbee provided support on the statistical design for the discrete choice experiment. I obtained all information and approvals from Demographic Health Survey (DHS) to access survey datasets and analysed the surveys

according to the data and materials provided. I also contributed to writing sections and amendments to larger protocols and obtained locally approved ethics from the College of Medicine Research and Ethics Committee (COMREC) for two studies. Both studies were nested within larger studies linked to the broader STAR Consortium. Once ethical approval was obtained, I finalised data collection tools and standard operating procedures.

I was involved in designing and piloting data collection tools. The data were managed at the Data Department of Malawi Liverpool Wellcome Trust Clinical Research Programme with my involvement. For the qualitative studies, I reviewed translated transcripts and then coded and analysed the data. I worked closely with a native speaker and qualitative specialists Drs Moses Kumwenda and Nicola Desmond. For the discrete choice experiment, I worked closely with Dr Augustine Choko who was the principal investigator of the parent study in which this protocol was nested.

I wrote Stata do-files to clean the quantitative data before analysis in Stata and N-logit as appropriate. I wrote the first drafts of all manuscripts and was responsible for revisions and final submission to a peer-reviewed journal.

1.6 Collaborations

Collaboration that was utilised through the preparation of this thesis:

1. Professors Liz Corbett and Fern Terris-Prestholt (London School of Hygiene and Tropical Medicine)
2. Drs Melissa Neuman and Marc D'Elbee (London School of Hygiene and Tropical Medicine)
3. Drs Augustine Choko and Moses Kumwenda (Malawi Liverpool Wellcome Trust)
4. Drs Nicola Desmond and Peter MacPherson (Liverpool School of Tropical Medicine)
5. Dr Rachel Baggaley (World Health Organization)
6. The STAR Consortium

1.7 Ethical considerations

Ethical approvals were obtained from the College of Medicine Research and Ethics Committee (COMREC) and the London School of Hygiene and Tropical Medicine. No participants were enrolled until ethical approval was provided in writing. All participants had to provide consent either in the form of a thumb print or in writing.

1.8 Funding

I am grateful to Unitaid and the STAR Consortium for supporting parts of my PhD by providing funding for including research studies and field work. Grant number: NCT02718274.

2.0 Background

2.1 HIV infection and diagnosis

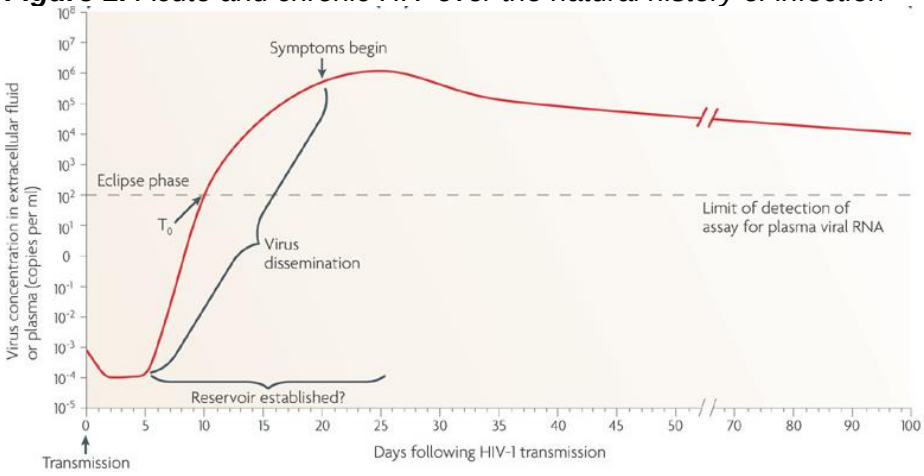
Forty years ago, the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) was identified [1] and would become one of the world's biggest health challenges. At least 40.1 million lives have been lost to HIV/AIDS to date, and HIV/AIDS continues to be the number one cause of death among women in Africa [2, 3].

HIV, the agent that causes AIDS, is a retrovirus [4] and blood-borne pathogen that is a transmitted through blood, semen, rectal and vaginal fluids, and breast milk [5]. HIV is primarily transmitted through sex, injecting drug use or mother-to-child transmission during pregnancy or the breastfeeding period [5]. Heterosexual transmission has been a predominant mode of transmission in Africa [6], particularly between midlife-older men and adolescent girls and young women in southern Africa [7, 8].

HIV-1 transmission starts with high viral production of HIV ribonucleic acid (RNA) that leads to viremia, followed by production of HIV-1 infected proteins (e.g. p24 antigen) and an antibody response appearing with gp41 and HIV immunoglobin M (IgM), followed by HIV immunoglobin G (IgG) and immunoglobin A (IgA) [9, 10]. Within the first 10 days of transmission, often called the "eclipse period", HIV is established in tissue at exposure sites and HIV viral RNA is increasing but not yet detectable in plasma (see Figure 1) [10]. HIV then disseminates to the lymph nodes and rapidly proliferates resulting in high viral RNA production and depletion of CD4+ subtype of T-lymphocytes (CD4 cells) [10, 11]. At this point, the eclipse period has ended and HIV RNA can be detected in plasma using nucleic acid amplification (NAT) testing (see Fig 2) [12].

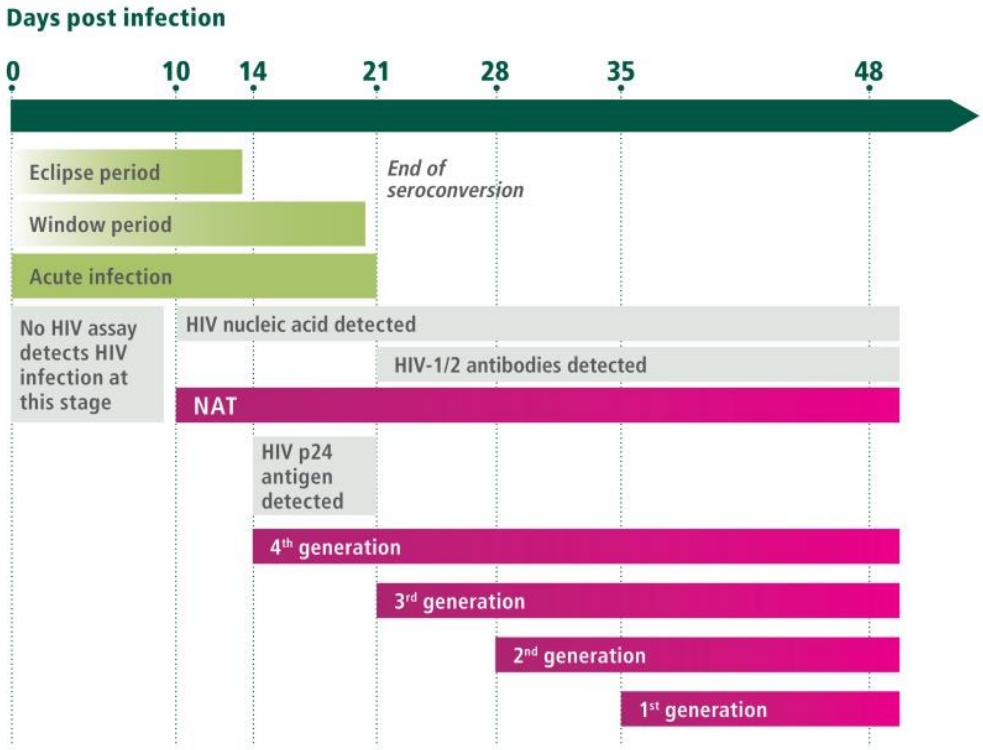
Within 14 days of transmission, viral replication increases and causes high-levels of viremia, and the HIV antibody response and HIV viral capsid (core) p24 protein production increases, marking a period of high-level of infectiousness and the appearance of clinical symptoms [11]. At this point, an acute HIV infection (AHI) can be detected using either NAT testing or fourth generation assays which detect HIV p24 antigen and HIV-1 antibodies. After 21 days when peak viremia is reached and the HIV-1 antibody response increases, however, viral HIV RNA declines and p24 antigen is no longer detectable in blood [12]. This marks the end of the AHI period and beginning of chronic HIV infection where there may not be clinical symptoms (see Figure1).

Figure 1: *Acute and chronic HIV over the natural history of infection*



Source: McMichaels, 2010 [10]

Figure 2: *Detecting HIV-infection with various formats and generations of in vitro diagnostics over the natural history of infection*



Source: WHO, 2015 [13]

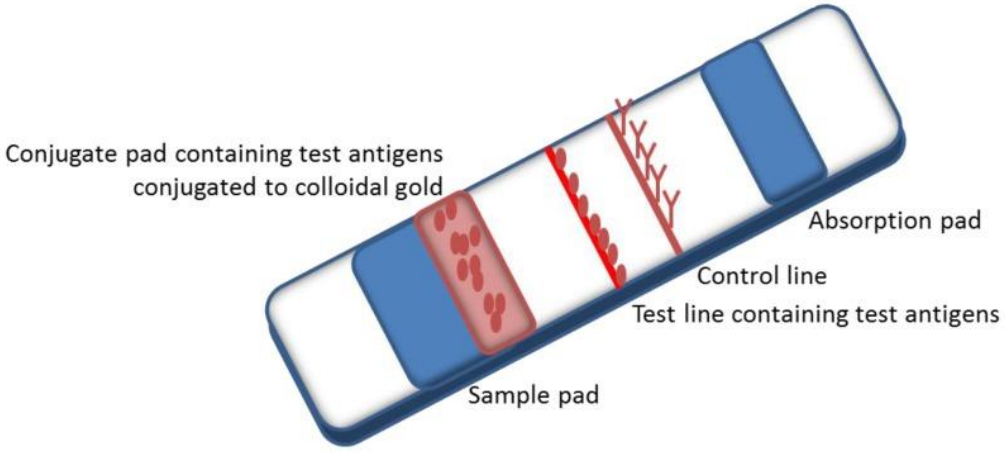
Due to the immune response at this stage, HIV-1 antibodies which have developed, will be detected by serology assays. HIV serology assays used are generally enzyme immunoassays (EIAs) or rapid diagnostic tests (RDTs) which detect HIV-1 antibodies in gp41, HIV IgM and IgG

[14]. Third generation serology assays (using both IgM and IgG) will be able to detect HIV antibodies 21 days from transmission, followed by second and first generation serology assays (using only IgG) which detect HIV antibodies around 28 and 35 days from transmission (see Fig 1.1a) [14, 15]. HIV-1 antibodies will persist and, if HIV is untreated, CD4 cells will continue to deplete causing an individual's immune response to deteriorate and the development of AIDS [12].

Because HIV infections result in persistent antibodies, serology testing has become the primary way to provide an accurate diagnosis. Early on, the World Health Organization (WHO) issued guidance to ensure high quality testing in low- and middle-income countries (LMICs) promoted the use of RDTs and set the standard for all HIV serology assays to have at least 99% sensitivity and 98% specificity and to be used within a testing algorithm that achieved a 99% positive predictive value of greater [12].

HIV RDTs broadly include assays which are either lateral-flow (immunochromatographic) or vertical-flow (immunofiltration) and can use either oral fluid or fingerprick/whole blood specimens. The most common HIV RDTs in use are lateral-flow (see Figure 3) and use fingerprick/whole blood specimens.

Figure 3: *Representation of a typical immunochromatographic HIV RDT*



Source: WHO, 2015 [13]

Because of the wide availability and affordability of HIV RDTs globally (less than US$1), as well as innovations and scale-up of antiretroviral (ARV) drugs, HIV testing services (HTS) reach more people, deliver same day diagnoses and provide immediate referrals for treatment or prevention in either community or facility settings [12, 16]. HIV RDTs have also made it possible

to introduce self-testing for HIV (HIVST), which use these same simple assays to enable individuals to learn their status themselves alongside instructions and support tools [12].

HTS programmes across LMICs, particularly in Africa, generally rely exclusively on RDTs [17]. Since WHO first recommended HIVST in 2016 [18], there are six WHO prequalified products available for procurement [19] and 98 countries have national policies supporting HIVST [20]. Globally, HIVST scale-up has been significant in east and southern Africa [21], with more than half of all countries in the region reporting both policies and implementation [22].

2.2 Global HIV response and HTS evolution

In the last four decades, there has been tremendous progress in the global HIV response, particularly for HTS programmes. HIV testing was one of the first HIV interventions in all countries, starting in 1985 with testing which was limited to blood screening and specialty laboratories [23]. Two years later, ARV drugs for HIV treatment were developed, however, access was highly limited due to costs, and both testing and treatment in LMICs would remain limited for many years [24].

In the late-1980s and early-1990s, there were efforts to make testing more widely available through the establishment of “voluntary testing and counselling (VCT)” sites that delivered free and confidential testing [12, 25, 26]. The first VCT sites focused on delivering pre- and post-test counselling for all testers, emphasising prevention and risk reduction for newly diagnosed PLHIV [25, 26]. VCT models in LMICs were moderately successful [27], but benefits were limited due to the lack of treatment access, no vaccine, poor knowledge and awareness, as well as high levels of stigma toward testing and PLHIV more broadly [28].

As a result of these many challenges, in 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), hosted by WHO, was formed to direct international investment and funding toward countries in greatest need [29]. With increased funding available, in 2003, the WHO and Joint United Nations Programme on HIV/AIDS (UNAIDS), launched the “3-by-5” initiative to put 3 million PLHIV on treatment by 2005 [30] and the United States formed the President’s Emergency Programme for HIV/AIDS Relief (PEPFAR) [26]. Along with national governments, these initiatives, led to rapid expansion of HIV testing and treatment. Notably, ART was scaled-up across LMICs, including the start of prevention of mother-to-child transmission (PMTCT) programmes which provided ARV drugs to pregnant and breastfeeding mothers to stop onward

transmission to their children [31, 32]. With treatment scale-up, HTS became far more beneficial. HTS was scaled-up using affordable HIV RDTs and same-day diagnosis and referral to care became the standard [26].

Despite these gains, HTS remained a critical gap. By 2005, WHO estimated that only 12% of all people who wanted an HIV test had access, and in Africa, where HIV burden was highest, surveys estimated only 10% of PLHIV had been diagnosed [32]. Strategic efforts were needed to expand access to and uptake of HIV testing, alongside scale-up of treatment and prevention services. The following innovations and policy shifts led to substantial progress in diagnosing PLHIV.

First, HIV testing was routinely offered to all patients in health facilities in east and southern Africa where HIV burden was highest (termed, provider-initiated testing and counselling (PITC)) [31, 33-35]. Early successes, particularly integrating HIV testing into antenatal clinics (ANC) [36], began to have an impact [37] resulting in more than a five-fold increase in testing coverage between 2004 and 2013 [38, 39]. Second, in addition to VCT sites, HIV testing expanded through a range of community outreach models focused on reaching those that may be hesitant or unable to access health facilities, such as workplaces [40], door-to-door [41], and mobile vans [42]. Community-based HTS not only reached PLHIV who did not know their status, but reached PLHIV earlier in the disease stage compared with facility-based HTS [42]. Third, couples and index-partner testing scale-up was shown to have an impact on prevention among serodiscordant couples (i.e. one HIV-positive partner and one HIV-negative partner) [43] and to efficiently identify a high number of PLHIV in need of treatment [44, 45]. Additional efforts have been successful extending these services to high-risk groups and key populations using social network approaches which promote testing to peers [46]. Fourth, HIVST increased access to and uptake of testing among those who may not otherwise test; enabling individuals to access kits more feely and to test when and where they want [21, 47, 48]. Since early 2020, HIVST have also provided an important way to maintain essential testing services in settings disrupted by severe acute respiratory syndrome coronavirus-2 (SARS-CoV- 2/COVID-19) [49, 50].

Global advances in prevention also had a substantial impact on controlling the HIV/AIDS epidemic. Due to the high HIV burden in sub-Saharan Africa, voluntary male medical circumcision (VMMC), which more than halves HIV acquisition risk among men [51], became an early priority. As a result, in 2017, WHO estimated VMMC had averted 230,000 new HIV

infections and anticipated more than a million would be averted by 2030 [52]. Despite substantial progress, however, only three African countries were on track to achieve their target of 80% coverage [53]. Harm reduction approaches, including needle and syringe programmes and opioid substitution therapy, have been shown to reduce HIV transmission among people who inject drugs [54, 55]. Despite the high efficacy and cost-effectiveness of these programmes, policy barriers have played a role in hindering scale-up and implementation in many settings [56].

Following the evidence that ART could help prevent HIV acquisition [57-60] and that PLHIV who are on ART and are virally suppressed cannot transmit to their partners [61, 62], it has become a priority to rapidly offer and initiate treatment and to update counselling messages to make patients aware of this benefit [12, 16]. Yet, knowledge and dissemination of this information has been slow, and gaps in communication remain [63, 64]. According to a 2020 survey, only a third of PLHIV had discussed information related to how viral suppression on ART prevents transmission to partners [64].

Building off the evidence on the preventive benefits of ART to prevent HIV acquisition, pre-exposure prophylaxis (PrEP) (the use of oral ARV drugs among people who are HIV negative) has been shown to significantly decrease risk of HIV acquisition [65]. Further innovations have continued to increase access to PrEP, such as event-driven PrEP for men who have sex with men [66], the dapivirine vaginal ring for women [67] and long-acting injectable cabotegravir for prevention [68, 69]. There are also innovations in service delivery to promote access, including simplified and differentiated PrEP service delivery [70]. For example, HIVST has been used to support PrEP initiation, re-initiation and continuation as a way to reduce clinic visits and promote effective PrEP use [71].

HTS is now integrated within all HIV prevention programmes, as both a way to link people who are HIV negative to the most relevant options and as part of routine monitoring for those who remain at high ongoing risk of HIV acquisition [72], such as young women in east and southern Africa, and serodiscordant couples and key populations worldwide [12]. These innovations have marked substantial progress in the scale-up of HIV prevention, testing and treatment services. It is now estimated that out of more than 38.4 million PLHIV, 85% know their status, 75% are on treatment and 68% are virally suppressed and unable to transmit the virus to sexual partners

[3]. Gaps remain however with approximately 1.5 million new HIV infections every year and 5.9 million PLHIV still undiagnosed [2].

Despite high HIV testing and treatment coverage, HIV incidence remains high in pregnant and breastfeeding women in sub-Saharan Africa, and is highest among women in known serodiscordant partnerships [73]. Such high rates continue to be linked to undiagnosed and untreated HIV infections among men [7]. Within sub-Saharan Africa overall, men with HIV, aged 35–49 years, continue to represent the largest the largest gap in undiagnosed HIV [74] and, subsequently, have low ART coverage and viral suppression [75]. Trends suggest new infections are rising with older male age groups [76], and PopART, a large universal testing and treatment study in South Africa and Zambia, reported the greatest transmission occurred among 25-39 year old men [77]. Innovative HTS approaches are needed to reach men if global 95-95-95 targets and low HIV incidence are to be achieved by 2025 [78].

2.3 Masculinity and HIV testing, prevention and treatment services

Cultural views, attitudes, values and micro and macro social structures of male gender norms and roles, e.g. hegemonic masculinity, influence behaviour, social status, and perpetuate inequalities that impact the HIV epidemic and an individual's access to and uptake of HIV testing, prevention and treatment services [79, 80].

In the context of HIV, norms of 'masculinity' have been shown to contribute to men's willingness to engage in 'risk-taking' behaviour, as well as their unwillingness to access health services [81-83]. As reported by Santana et al., traditional ideas of masculine gender roles are associated with young men's likelihood to engage in condomless sex and intimate partner violence (IPV) [84]. Traditional views of men's gender role as "breadwinner", together with structural factors including tangible loss of work opportunities, resources and transportation costs, can also hinder men from accessing health services. As shown by Sande et al., the cost for men to access facility-based HIV testing in Malawi is higher than for women, primarily due to the loss of more work opportunities and higher daily wages [85]. Choko et al. reports that this real loss of resources, as well as men's perception of the economic and social cost of not being seen as a "provider", can create stress and anxiety and ultimately prevent men from testing and linking to care [86]. Traditional concepts of gender norms, such as the "tough man", can cause men to see HIV as a threat to their manhood and as a result not seek or access HIV services [87-92].

This unwillingness to utilise health services is also closely linked to concerns about stigma, discrimination, and privacy [86-89], as men do not want to be seen as weak for accessing care.

Such norms among men, driven by hegemonic masculinity, may also undermine women's health and health-seeking behaviour [91, 93]. Men may inflict harm on their female partners who are seeking HIV testing, prevention and treatment services, through controlling behaviours, including economic, emotional, psychosocial or physical violence. For instance, in Malawi, men reported that they felt more entitled to pressuring their partners to test, whereas women used less direct ways to encourage their partner to test [94]. In South Africa, men exhibited controlling behaviours and had strong negative reactions to women's requests to test as a couple or use condoms; and in some cases, men withheld financial support or accused their female partner of bringing HIV into the relationship [93].

Discordant relationships, where one partner is HIV-positive and the other is HIV-negative, may also be prone to breakdown [95, 96], particularly couples with few resources and an HIV-positive female partner [95]. Fear of being identified as the positive partner in a discordant relationship presents a barrier to partner notification and testing services, as many fear that by disclosing their status they will be blamed or abandoned for bringing HIV into the relationship [97]. Thus, it is rare for couples in east and southern Africa to engage in the health system together [98]. Additionally, evidence suggests women diagnosed with HIV [99], and/or women with an HIV-positive male partner [100], are at increased risk of IPV. As a result, women may be less likely to disclose to their male partners or invite their partner for HIV testing [101], even when aware that they and their partners may be at high risk.

These gender norms are not only internalised by men and women, but also in the health system. Many health services and systems are built around women and children, with men often perceiving health facilities to be spaces for women and children [86]. This is apparent in the context of the global HIV response, as the implementation and scale-up of testing and treatment services in many settings has focused on ANC/PMTCT progrmmes, with few large-scale programmes offering multiple male-friendly entry points [102]. Out of concern for possible social harm, many programmes have also been reluctant to offer partner HIV testing and/or partner notification services [44].

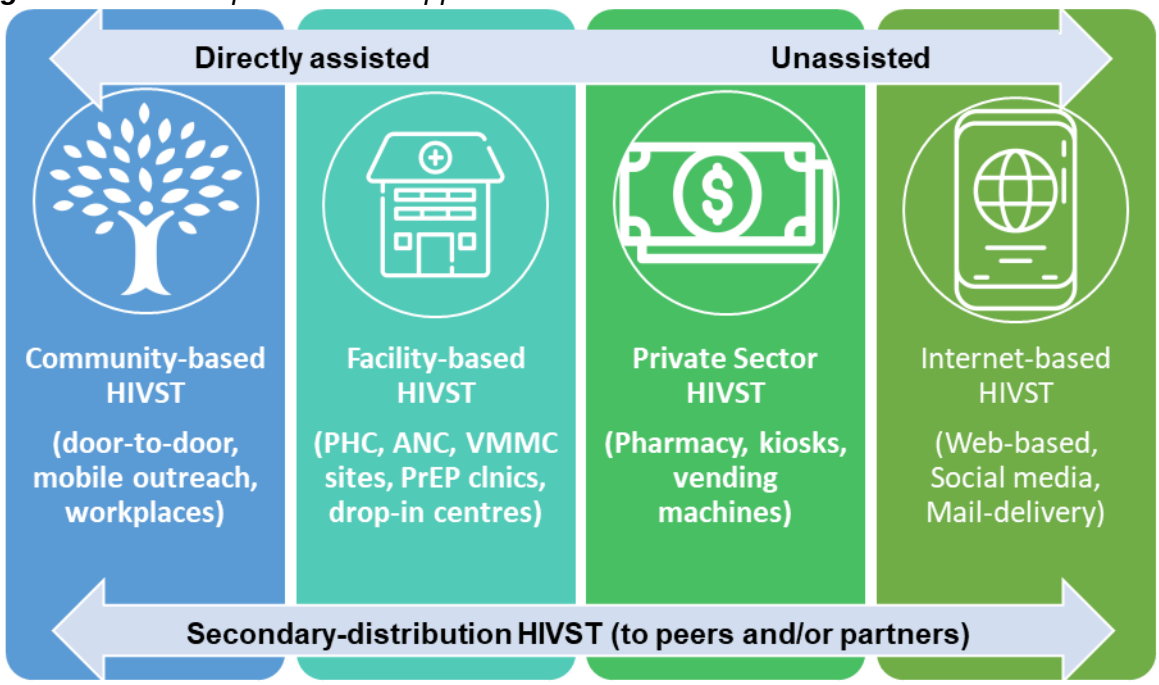
2.4 HIV self-testing

The focus of my thesis is on men's preferences for HIVST, including linkage to both prevention and treatment services, to inform the development of person-centred self-testing policies and implementation.

In 2016, WHO first recommended HIVST, an approach whereby a person collects their specimen (oral fluid or fingerstick/whole blood), performs the test and interprets the results themselves or with someone they trust [18]. As with all HIV testing, a single test cannot provide a positive diagnosis. Further testing using the full national algorithm is needed to provide a definitive positive diagnosis and before starting ART. HIV negative results are more definitive because of a high negative predictive; however as with all HIV testing, those with recent exposure or at high ongoing HIV-risk are encouraged to access prevention services and to retest.

HIVST has been demonstrated to be a safe, acceptable and effective way to increase access to and both uptake and frequency of HIV testing [12, 18, 103]. HIVST is particularly appealing as a more discreet option for populations who may be hesitant or unable to easily access other testing options, such as men, young people and key populations [21, 104, 105]. There are a number of ways in which HIVST can be implemented (see Figure 4), including community-led distribution door-to-door [106], mobile outreach [21], Internet and mail order [107], pick-up through facilities [21], as well as secondary distribution where kits are offered to others by peers or partners [108-112]. The availability of support tools that can optimise accuracy and onward linkage to prevention and care are important for all forms of HIVST distribution. While instructions for use or videos may be sufficient for many self-testers [113], direct assistance from a community health worker or peer, including brief in-person demonstrations on how to self-test and interpret the results, can be helpful for some users [114].

Figure 4: *HIVST implementation approaches*

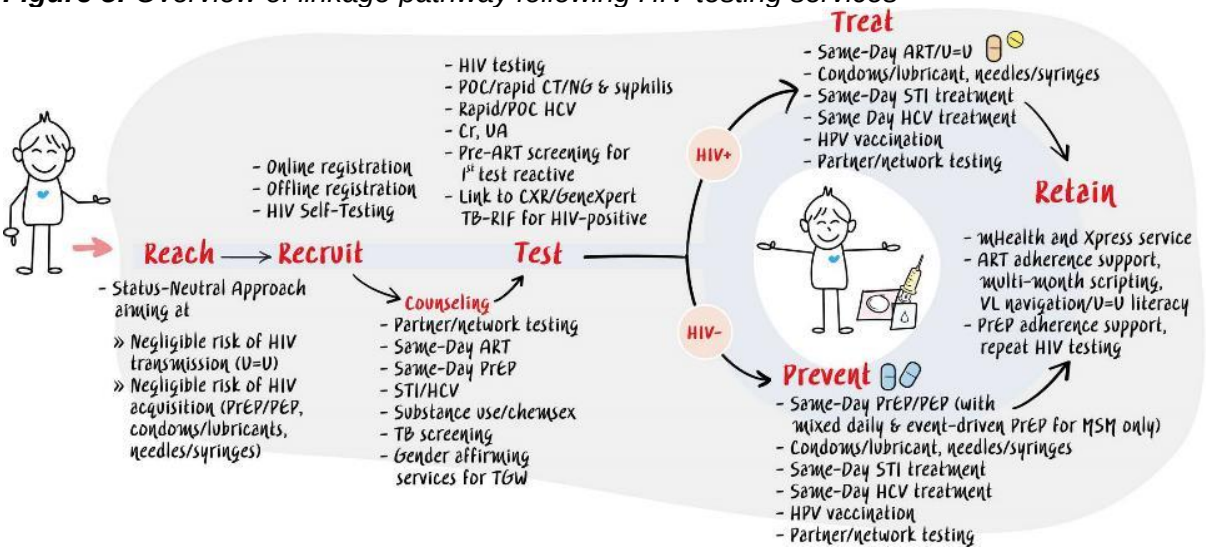


Secondary distribution of HIVST, where a person who receives a kit offers it to their social, sexual or drug injecting partners, has emerged as a highly effective strategy [48] particularly for reaching male partners of pregnant women in Africa [108, 112, 115, 116]. Four trials from Africa have showed that secondary distribution of HIVST to male partners of pregnant women at ANC increased overall testing rates among men [108, 112, 115, 116] and two found an increase in couples testing overall [112, 116]. Despite these benefits, men who do not receive the same support options may struggle to correctly self-test and some women may have concerns or challenges offering a kit to their partner. According to a recent study in Malawi, secondary distribution of HIVST to male partners of pregnant women reported lower sensitivity and more reports of false-negative results than previous door-to-door distribution with offer of direct assistance (89.7% vs 97.9%) [108, 117]. Though reports of social harm following HIVST are rare [118], some women have concerns that offering an HIVST kit to their partner could lead to potential break-ups, arguments and other IPV [108, 112, 115, 116]. While men report HIVST is highly acceptable and that they would link to care after a reactive result, many also had concerns that men didn't have enough awareness about HIVST or education and information on how to access or use kits [119].

2.5 Linkage to HIV prevention and treatment

Linkage to HIV prevention and treatment services is a critical component for all HIV testing services and approaches. Services are often integrated and include follow-up to support retention in care and effective prevention programming (Figure 5).

Figure 5: *Overview of linkage pathway following HIV testing services*



Source : Vannakit et al. 2020 [120]

Linkage after any HIV testing approach outside health facilities can be challenging [121]. A systematic review focused on community-based testing in sub-Saharan Africa found that following home-based, mobile outreach and other forms of community-based HIV testing, linkage to care for newly diagnosed PLHIV ranged from 26-37% [122]. Further, many PLHIV disengage after diagnosis and over the course of lifelong treatment and need interventions and support to re-engage in care [123]. HIV testing, including HIVST, can be an important entry point for PLHIV needing to re-engage in care and to access support service [124-128]. Opportunities to link to prevention are often missed as well [129], with suboptimal referrals to and uptake of VMMC among men in east and southern Africa [130].

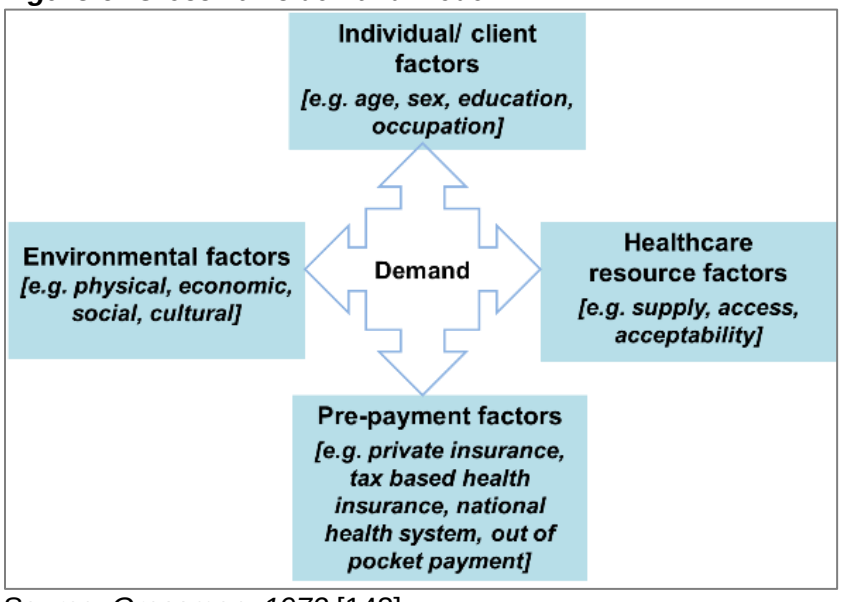
While linkage to care following HIVST has been comparable to other testing approaches in RCTs [48] and can have a positive effect on ART initiations [131], additional interventions and support tools can further enhance linkage. RCTs comparing HIVST with and without linkage support have shown the use of peer navigators [132], home-based ART initiation [133] and provider-incentives [134] can increase linkage to care following HIVST. User preferences for support after HIVST vary with some preferring incentives, home visits, phone calls, or text

messages to facilitate linkage to HIV care [135, 136]. Interventions to facilitate linkage to VMMC among men have had variable impact, however, effective strategies include economic compensation [137] and active referral and follow-up [137] from mobile and home-based outreach.

2.6 Driving demand for HIV services

There are many drivers that influence individual demand for healthcare services. One's demand for health services is shaped by individual, environmental, healthcare resource and macro pre-payment factors (see Figure 6). Individual factors are particularly critical to understanding demand for health services. According to consumer choice and utilities theories [138-140], individuals, will make rational choices and select the service with the optimal set of attributes levels which bring them the greatest satisfaction. In the context of HTS, services will be selected based on user preferences for the following: type of provider, location of service, and price to users. However, additional factors, such as masculine norms detailed above, can also directly and indirectly reduce one's ability [141] and likelihood of accessing health services [142].

Figure 6: *Grossman's demand model*



Source: Grossman, 1972 [143]

To address these challenges, incorporating user preferences into the design of services and additional demand generation interventions is critical. Despite the importance of reaching men to achieve global 95-95-95 goals, there are few national policies and resources dedicated to closing the gap among 35–49-year-old men with the greatest absolute number of HIV diagnoses

across sub-Saharan Africa [74]. Because of the complexity of implementing and scaling-up services that will reach men, further research is needed to better inform service delivery models, priorities, and national policies around whether to offer and how to offer incentives to improve and sustain public health impact.

My thesis investigates ways in which HIVST can be optimised for reaching midlife-older men in Malawi by incorporating preferences for service delivery and linkage to care to inform policy development and implementation. Since starting my PhD, HIVST has become more widely used, but implementation still lags and is small scale as policies lack specificity on how best to use HIVST to reach midlife-older men. In this PhD, I characterise the impact of HIVST among men and identify important preferences and gaps among men and their female partners.

References

1. CDC. Pneumocystis pneumonia--Los Angeles. MMWR Morb Mortal Wkly Rep. 1981;30(21):250-2.
2. UNAIDS. Global commitments, local action: After 40 years of AIDS, charting a course to end the pandemic. Geneva: Joint United Nations Programme on HIV/AIDS; 2021. Available from: https://www.unaids.org/sites/default/files/media_asset/global-commitments-local-action_en.pdf.
3. UNAIDS. UNAIDS Global AIDS Update — Confronting inequalities — Lessons for pandemic responses from 40 years of AIDS. Geneva: Joint United Nations Programme on HIV/AIDS; 2022. Available from: https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update.
4. Barre-Sinoussi F, Chermann JC, Rey F, Nugeyre MT, Chamaret S, Gruest J, Dauguet C, Axler-Blin C, Vezinet-Brun F, Rouzioux C, Rozenbaum W, Montagnier L. Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). Science. 1983;220(4599):868.
5. Hladik F, McElrath MJ. Setting the stage: host invasion by HIV. Nat Rev Immunol. 2008;8(6):447-57.
6. Gouws E, Cuchi P. Focusing the HIV response through estimating the major modes of HIV transmission: a multi-country analysis. Sex Transm Dis. 2012;88(Suppl 2):i76.

7. Akullian A, Bershteyn A, Klein D, Vandormael A, Bärnighausen T, Tanser F. Sexual partnership age pairings and risk of HIV acquisition in rural South Africa. AIDS. 2017;31(12):1755-64.
8. de Oliveira T, Kharsany AB, Gräf T, Cawood C, Khanyile D, Grobler A, Puren A, Madurai S, Baxter C, Karim QA, Karim SS. Transmission networks and risk of HIV infection in KwaZulu-Natal, South Africa: a community-wide phylogenetic study. Lancet HIV. 2017;4(1):e41-e50.
9. Tomaras GD, Haynes BF. HIV-1-specific antibody responses during acute and chronic HIV-1 infection. Curr Opin HIV AIDS. 2009;4(5):373-9.
10. McMichael A, Borrow P, Tomaras G, Goonetilleke N, Haynes B. The immune response during acute HIV-1 infection: clues for vaccine development. Nat Rev Immunol 2010;10(1):11-23.
11. Cohen MS, Gay CL, Busch MP, Hecht FM. The detection of acute HIV infection. J Infect Dis. 2010;202(S2):S270-S7.
12. WHO. Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2019.
13. WHO. Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2015.
14. Rosenberg NE, Pilcher CD, Busch MP, Cohen MS. How can we better identify early HIV infections? Curr Opin HIV AIDS. 2015;10(1):61-8.
15. WHO. Annex 7: Diagnostics for HIV diagnosis: Consolidated Guidelines on HIV Testing Services: 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection. Geneva: World Health Organization; 2015.
16. WHO. Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring. Geneva: World Health Organization; 2021.
17. Fonner VA, Sands A, Figueroa C, Baggaley R, Quinn C, Jamil MS, Johnson C. Country adherence to WHO recommendations to improve the quality of HIV diagnosis: a global policy review. BMJ Glob Health. 2020;5(5):e001939.
18. WHO. Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2016.
19. WHO. New US$ 1 price for HIV self-tests Geneva: World Health Organization; 2022 [cited 2022 12 August]. Available from: https://www.who.int/news/item/27-07-2022-new-1-dollar-price-for-hiv-self-tests.

20. WHO. WHO HIV policy adoption and implementation status in countries. Geneva: World Health Organization; 2022. Available from: https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/who-hiv-policy-adoption-and-implementation-status-in-countries.pdf?sfvrsn=bb35e6ae_6.

21. Hatzold K, Gudukeya S, Mutseta MN, Chilongosi R, Nalubamba M, Nkhoma C, Munkombwe H, Munjoma M, Mkandawire P, Mabhunu V, Smith G, Madidi N, Ahmed H, Kambeu T, Stankard P, Johnson CC, Corbett EL. HIV self-testing: breaking the barriers to uptake of testing among men and adolescents in sub-Saharan Africa, experiences from STAR demonstration projects in Malawi, Zambia and Zimbabwe. J Int AIDS Soc. 2019;22(Suppl 1):e25244.

22. UNAIDS, WHO. Laws and policy database. 2019.

23. Alexander T, Pasetti M. Human immunodeficiency virus diagnostic testing: 30 years of evolution. Clinical and Vaccine Immunology. 2016;23(4):249-53.

24. Forsythe SS, McGreevey W, Whiteside A, Shah M, Cohen J, Hecht R, Bollinger LA, Kinghorn A. Twenty years of antiretroviral therapy for people living with HIV: global costs, health achievements, economic benefits. Health Aff. 2019;38(7):1163-72.

25. Marum E, Taegtmeyer M, Chebet K. Scale-up of voluntary HIV counseling and testing in Kenya. JAMA. 2006;295:859-62.

26. Marum E, Taegtmeyer M, Parekh B, Mugo N, Lembariti S, Phiri M, Moore J, Cheng AS. "What took you so long?" The impact of PEPFAR on the expansion of HIV testing and counseling services in Africa. J Acquir Immune Defic Syndr. 2012;60(S3):S63-9.

27. Denison JA, O'Reilly KR, Schmid GP, Kennedy CE, Sweat MD. HIV voluntary counseling and testing and behavioral risk reduction in developing countries: a meta-analysis, 1990–2005. AIDS Behav. 2008;12(3):363-73.

28. Unitaid, WHO, STAR. Knowing your status–then and now: realizing the potential of HIV self-testing. Geneva: Unitaid; 2018.

29. SDC. The Global Fund to Fight AIDS, Tuberculosis and Malaria – Global Fund: Swiss Agency for Development and Cooperation; [cited 2021 24 June]. Available from: https://www.dfae.admin.ch/deza/en/home/partnerships-mandates/partnerships-multilateral-organisations/weitere-organisationen-netzwerke/gfatm.html.

30. WHO, UNAIDS. Treating 3 million by 2005: Making it happen, the WHO strategy. Geneva: World Health Organization; 2003. Available from: https://www.who.int/3by5/publications/documents/en/3by5StrategyMakingItHappen.pdf?ua=1.

31. WHO. Provider-initiated HIV testing and counselling in health facilities. Geneva: World Health Organization; 2007.

32. WHO. Towards universal access by 2010: How WHO is working with countries to scale-up HIV prevention, treatment, care and support. Geneva: World Health Organization; 2006.

33. Kamya M, Wanyenze R, Namale A. Routine HIV testing: the right not to know versus the rights to care, treatment and prevention. Bull World Health Organ. 2007;85(B).

34. Steen T, Seipone K, Gomez Fde L, Anderson M, Kejelepula M, Keapoletswe K, et al A. Two and a half years of routine HIV testing in Botswana. J Acquir Immune Defic Syndr. 2007;44(484-8).

35. De Cock K, Bunnell R, Mermin J. Unfinished Business — expanding HIV testing in developing countries. N Eng J Med. 2006;354(400-2).

36. Hensen B, Baggaley R, Wong VJ, Grabbe KL, Shaffer N, Lo YR, Hargreaves J. Universal voluntary HIV testing in antenatal care settings: a review of the contribution of provider-initiated testing & counselling. Trop Med Int Health. 2012;17(1):59-70.

37. Kennedy CE, Fonner VA, Sweat MD, Okero FA, Baggaley R, O'Reilly KR. Provider-initiated HIV testing and counseling in low- and middle-income countries: a systematic review. AIDS Behav. 2013;17(5):1571-90.

38. WHO. HIV/AIDS programme highlights 2008-2009. Geneva: World Health Organization; 2009.

39. WHO. Global update on the health sector response to HIV. Geneva: World Health Organization; 2014.

40. Corbett EL, Makamure B, Cheung YB, Dauya E, Matambo R, Bandason T, Munyati SS, Mason PR, Butterworth AE, Hayes RJ. HIV incidence during a cluster-randomized trial of two strategies providing voluntary counselling and testing at the workplace, Zimbabwe. AIDS. 2007;21(4):483-9.

41. Geoffroy E, Schell E, Jere J, Khozomba N. Going door-to-door to reach men and young people with HIV testing services to achieve the 90-90-90 treatment targets. Public Health Action. 2017;7(2):95-9.

42. Suthar AB, Ford N, Bachanas PJ, Wong VJ, Rajan JS, Saltzman AK, Ajose O, Fakoya AO, Granich RM, Negussie EK, Baggaley RC. Towards universal voluntary HIV testing and counselling: A systematic review and meta-analysis of community-based approaches. PloS Med. 2013;10(8):e1001496.

43. WHO. Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples: recommendations for a public health approach. Geneva: World Health Organization; 2012.
44. Dalal S, Johnson C, Fonner V, Kennedy CE, Siegfried N, Figueroa C, Baggaley R. Improving HIV test uptake and case finding with assisted partner notification services. AIDS. 2017;31(13):1867-76.
45. WHO. WHO recommends social network-based HIV testing approaches for key populations as part of partner services package. Geneva: World Health Organization; 2019. Available from: https://www.who.int/publications/i/item/WHO-CDS-HIV-19.32.
46. Witzel TC, Eshun-Wilson I, Jamil MS, Tilouche N, Figueroa C, Johnson CC, Reid D, Baggaley R, Siegfried N, Burns FM, Rodger AJ, Weatherburn P. Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis. BMC Med. 2020;18(1):381.
47. Eshun-Wilson I, Jamil MS, Witzel TC, Glidded DV, Johnson C, Trouneau NL, Ford N, McGee K, Kemp C, Baral S, Schwartz S, Geng EH. A systematic review and network meta-analyses to assess the effectiveness of human immunodeficiency virus (HIV) self-testing distribution strategies. Clin Infect Dis. 2021.
48. PSI. Considerations for hiv self-testing in the context of the COVID-19 pandemic and its response: an operational update. Washington DC: Population Services International; 2020.
49. WHO. Assessment of HIV testing services and antiretroviral therapy service disruptions in the context of COVID-19: Lessons learned and way forward in sub-Saharan Africa. Geneva: World Health Organization; 2021. Available from: https://www.who.int/publications/i/item/9789240039599.
50. Lei JH, Liu LR, Wei Q, Yan SB, Yang L, Song TR, Yuan HC, Lv X, Han P. Circumcision status and risk of HIV acquisition during heterosexual intercourse for both males and females: a meta-analysis. PloS One. 2015;10(5):e0125436.
51. WHO. Voluntary medical male circumcision for HIV prevention. Geneva: World Health Organization; 2018. Available from: https://www.who.int/hiv/pub/malecircumcision/vmmc-progress-brief-2018/en/.
52. Cork MA, Wilson KF, Perkins S, Collison ML, Deshpande A, Eaton JW, Earl L, Haeuser E, Justman JE, Kinyoki DK, Mayala BK, Mosser JF, Murray CJL, Nkengasong JN, Piot P, Sartorius B, Schaeffer LE, Serfes AL, Sligar A, Steuben KM, Tanser FC, VanderHeide JD, Yang M, Wabiri N, Hay SI, Dwyer-Lindgren L. Mapping male circumcision for HIV prevention efforts in sub-Saharan Africa. BMC Med. 2020;18(1):189.

53. Aspinall EJ, Nambiar D, Goldberg DJ, Hickman M, Weir A, Van Velzen E, Palmateer N, Doyle JS, Hellard ME, Hutchinson SJ. Are needle and syringe programmes associated with a reduction in HIV transmission among people who inject drugs: A systematic review and meta-analysis. Int J Epidemiol. 2014;43(1):235-48.

54. MacArthur GJ, Minozzi S, Martin N, Vickerman P, Deren S, Bruneau J, Degenhardt L, Hickman M. Opiate substitution treatment and HIV transmission in people who inject drugs: Systematic review and meta-analysis. BMJ. 2012;345:e5945.

55. DeBeck K, Cheng T, Montaner JS, Beyrer C, Elliott R, Sherman S, Wood E, Baral S. HIV and the criminalisation of drug use among people who inject drugs: A systematic review. Lancet HIV. 2017;4(8):e357-e74.

56. Attia S, Egger M, Müller M, Zwahlen M, Low N. Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. AIDS. 2009;23(11):1397-404.

57. Melo M, Santos B, De Cassia Lira R, Varella IS, Turella M, Rocha TM, Nielsen-Saines K. Sexual transmission of HIV-1 among serodiscordant couples in Porto Alegre, southern Brazil. Sex Transm Dis. 2008;35(11):912-5.

58. Castilla J, Del Romero J, Hernando V, Marincovich B, García S, Rodríguez C. Effectiveness of highly active antiretroviral therapy in reducing heterosexual transmission of HIV. J Acquir Immune Defic Syndr. 2005;40(1):96-101.

59. Quinn TC, Wawer MJ, Sewankambo N, Serwadda D, Li C, Wabwire-Mangen F, Meehan MO, Lutalo T, Gray RH. Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. N Engl J Med. 2000;342(13):921-9.

60. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, Hakim JG, Kumwenda J, Grinsztejn B, Pilotto JHS, Godbole SV, Mehendale S, Chariyalertsak S, Santos BR, Mayer KH, Hoffman IF, Eshleman SH, Piwowar-Manning E, Wang L, Makhema J, Mills LA, de Bruyn G, Sanne I, Eron J, Gallant J, Havlir D, Swindells S, Ribaudo H, Elharrar V, Burns D, Taha TE, Nielsen-Saines K, Celentano D, Essex M, Fleming TR. Prevention of HIV-1 infection with early antiretroviral therapy. N Eng J Med. 2011;365(6):493-505.

61. Rodger AJ, Cambiano V, Bruun T, Vernazza P, Collins S, Degen O, Corbelli GM, Estrada V, Geretti AM, Beloukas A, Raben D, Coll P, Antinori A, Nwokolo N, Rieger A, Prins JM, Blaxhult A, Weber R, Van Eeden A, Brockmeyer NH, Clarke A, Del Romero Guerrero J, Raffi F, Bogner JR, Wandeler G, Gerstoft J, Gutiérrez F, Brinkman K, Kitchen M, Ostergaard L, Leon A, Ristola M, Jessen H, Stellbrink HJ, Phillips AN, Lundgren J. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive

antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet. 2019;393(10189):2428-38.

62. Ngure K, Ongolly F, Dolla A, Awour M, Mugwanya KK, Irungu E, Mugo N, Bukusi EA, Morton J, Odoyo J, Wamoni E, Barnabee G, Peebles K, O'Malley G, Baeten JM. "I just believe there is a risk" understanding of undetectable equals untransmissible (U = U) among health providers and HIV-negative partners in serodiscordant relationships in Kenya. J Int AIDS Soc. 2020;23(3):e25466.

63. Okoli C, Van de Velde N, Richman B, Allan B, Castellanos E, Young B, Brough G, Eremin A, Corbelli GM, Mc Britton M, Hardy WD, de los Rios P. Undetectable equals untransmittable (U = U): awareness and associations with health outcomes among people living with HIV in 25 countries. Sex Transm Dis. 2021;97(1):18.

64. Chou R, Evans C, Hoverman A, Sun C, Dana T, Bougatsos C, Grusing S, Korthuis PT. Preexposure prophylaxis for the prevention of HIV infection: evidence report and systematic review for the US preventive services task force. JAMA. 2019;321(22):2214-30.

65. Parienti J-J. On-demand PrEP efficacy: forgiveness or timely dosing. Lancet HIV. 2020;7(2):e79-e80.

66. Nel A, van Niekerk N, Van Baelen B, Malherbe M, Mans W, Carter A, Steytler J, van der Ryst E, Craig C, Louw C, Gwetu T, Mabude Z, Kotze P, Moraba R, Tempelman H, Gill K, Kusemererwa S, Bekker L-G, Devlin B, Rosenberg Z. Safety, adherence, and HIV-1 seroconversion among women using the dapivirine vaginal ring (DREAM): an open-label, extension study. Lancet HIV. 2021;8(2):e77-e86.

67. Clement ME, Kofron R, Landovitz RJ. Long-acting injectable cabotegravir for the prevention of HIV infection. Curr Opin HIV AIDS. 2020;15(1):19-26.

68. WHO. Guidelines on long-acting injectable cabotegravir for HIV prevention. Geneva: World Health Organization; 2022. Available from: https://www.who.int/publications/i/item/9789240054097.

69. WHO. Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Geneva: World Health Organization; 2022. Available from: https://www.who.int/publications/i/item/9789240053694.

70. Kiptinness C, Kuo AP, Reedy AM, Johnson CC, Ngure K, Wagner AD, Ortblad KF. Examining the use of HIV self-testing to support PrEP delivery: A systematic literature review. Curr HIV/AIDS Rep. 2022.

71. McNairy ML, El-Sadr WM. A paradigm shift: focus on the HIV prevention continuum. Clin Infect Dis. 2014;59(S1):S12-S5.

72. Graybill LA, Kasaro M, Freeborn K, Walker JS, Poole C, Powers KA, Mollan KR, Rosenberg NE, Vermund SH, Mutale W, Chi BH. Incident HIV among pregnant and breast-feeding women in sub-Saharan Africa: a systematic review and meta-analysis. AIDS. 2020;34(5).

73. Giguère K, Eaton JW, Marsh K, Johnson LF, Johnson CC, Ehui E, Jahn A, Wanyeki I, Mbofana F, Bakiono F, Mahy M, Maheu-Giroux M. Trends in knowledge of HIV status and efficiency of HIV testing services in sub-Saharan Africa, 2000-2020: a modelling study using survey and HIV testing programme data. Lancet HIV. 2021;8(5):e284-e93.

74. Cornell M, Majola M, Johnson LF, Dubula-Majola V. HIV services in sub-Saharan Africa: the greatest gap is men. Lancet. 2021;397(10290):2130-2.

75. Akullian A, Vandormael A, Miller JC, Bershteyn A, Wenger E, Cuadros D, Gareta D, Bärnighausen T, Herbst K, Tanser F. Large age shifts in HIV-1 incidence patterns in KwaZulu-Natal, South Africa. Proceedings of the National Academy of Sciences. 2021;118(28):e2013164118.

76. Fraser C. New data and findings including phylogenetic analysis. International AIDS Conference; 29 Jul - 2 Aug 2022;Montreal, Canada.

77. UNAIDS. Understanding fast-track: accelerating action to end the AIDS epidemic by 2030. Geneva: Joint United Nations Programme for HIV/AIDS; 2015. Available from: https://www.unaids.org/sites/default/files/media_asset/201506_JC2743_Understanding_FastTrack_en.pdf.

78. Dunkle KL, Jewkes R. Effective HIV prevention requires gender-transformative work with men. Sex Transm Infect. 2007;83(3):173-4.

79. Griffith DM, Gilbert KL, Bruce MA, Thorpe RJ. Masculinity in Men's Health: Barrier or Portal to Healthcare? In: Heidelbaugh JJ, editor. Men's Health in Primary Care. Cham: Springer International Publishing; 2016. p. 19-31.

80. Creighton G, Oliffe JL. Theorising masculinities and men's health: A brief history with a view to practice. Health Sociology Review. 2010;19(4):409-18.

81. Robertson S. Theories of masculinities and health-seeking practices. "Nowhere Man" Men's Health Seminar;Belfast, Ireland: Nowhere Man Press; 2008.

82. Thorpe RJ, Jr., Wilson-Frederick SM, Bowie JV, Coa K, Clay OJ, LaVeist TA, Whitfield KE. Health behaviors and all-cause mortality in African American men. Am J Mens Health. 2013;7(4 Suppl):8s-18s.

83. Santana MC, Raj A, Decker MR, La Marche A, Silverman JG. Masculine gender roles associated with increased sexual risk and intimate partner violence perpetration among young adult men. J Urban Health. 2006;83(4):575-85.

84. Sande L, Mangenah C, Mwenge L, Neuman M, Indravundh P, d'Elbee M, Johnson C, Hatzold K, Corbett E, Terris-Prestholt F. A gender analysis of HIV testing user costs among rural communities in Malawi. INTEREST; May 2017; Lilongwe, Malawi.

85. Choko AT, Kumwenda MK, Johnson CC, Sakala DW, Chikalipo MC, Fielding K, Chikovore J, Desmond N, Corbett EL. Acceptability of woman-delivered HIV self-testing to the male partner, and additional interventions: a qualitative study of antenatal care participants in Malawi. J Int AIDS Soc. 2017;20(1):21610.

86. Hensen B, Taoka S, Lewis J, Weiss H, Hargreaves J. Systematic review of strategies to increase men's HIV-testing in sub-Saharan Africa. AIDS. 2014;28(14):2133-45.

87. Indravudh P, Henson B, OtteimKampe E, Kumwenda M, Simwinga M, Desmond N, Johnson C, Hatzold K, Ayles H, Corbett E, Neuman M, (STAR) UPS-TA. Masculinity and uptake of HIV testing: validity of the conformity to masculine norms inventory-22 in Malawi and Zambia 9th International AIDS Society Conference; 23-26 July 2017;Paris, France;.

88. O'Brien R, Hunt K, Hart G. 'It's caveman stuff, but that is to a certain extent how guys still operate': men's accounts of masculinity and help seeking. Soc Sci Med. 2005;61(3):503-16.

89. Skovdal M, Campbell C, Madanhire C, Mupambireyi Z, Nyamukapa C, Gregson S. Masculinity as a barrier to men's use of HIV services in Zimbabwe. Global Health. 2011;7(1):13.

90. Skovdal M, Campbell C, Nyamukapa C, Gregson S. When masculinity interferes with women's treatment of HIV infection: a qualitative study about adherence to antiretroviral therapy in Zimbabwe. J Int AIDS Soc. 2011;14(1):29.

91. Siu GE, Seeley J, Wight D. Dividuality, masculine respectability and reputation: how masculinity affects men's uptake of HIV treatment in rural eastern Uganda. Soc Sci Med. 2013;89:45-52.

92. Chikovore J, Gillespie N, McGrath N, Orne-Gliemann J, Zuma T, on behalf of the ATSG. Men, masculinity, and engagement with treatment as prevention in KwaZulu-Natal, South Africa. AIDS Care. 2016;28(Suppl 3):74-82.

93. Kumwenda M, Munthali A, Phiri M, Mwale D, Gutteberg T, MacPherson E, Theobald S, Corbett L, Desmond N. Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. AIDS Behav. 2014;18(Suppl 4):S396-404.
94. Mackelprang RD, Bosire R, Guthrie BL, Choi RY, Liu A, Gatuguta A, Rositch AF, Kiarie JN, Farquhar C. High rates of relationship dissolution among heterosexual HIV-serodiscordant couples in Kenya. AIDS Behav. 2014;18(1):189-93.
95. Payne C, Nakyanjo N, Ddaaki W, Hutchinson N, Burke V, Nalugoda F, Kennedy C. HIV partner notification values and preferences in Rakai, Uganda: A qualitative study. Ann Glob Health.83(1):162.
96. Wamoyi J, Renju J, Moshabela M, McLean E, Nyato D, Mbata D, Bonnington O, Seeley J, Church K, Zaba B, Wringe A. Understanding the relationship between couple dynamics and engagement with HIV care services: insights from a qualitative study in Eastern and Southern Africa. Sex Transm Infect. 2017;93(Suppl 3).
97. Mulrenan C, Colombini M, Howard N, Kikuvi J, Mayhew SH. Exploring risk of experiencing intimate partner violence after HIV infection: A qualitative study among women with HIV attending postnatal services in Swaziland. BMJ Open. 2015;5(5).
98. Jewkes R, Sikweyiya Y, Morrell R, Dunkle K. The Relationship between intimate partner violence, rape and HIV amongst South African men: A cross-sectional study. PloS One. 2011;6(9):e24256.
99. Schaffer EM, Agot K, Thirumurthy H. The association between intimate partner violence and women's distribution and use of HIV self-tests with male partners: Evidence from a Cohort Study in Kenya. J Acquir Immune Defic Syndr. 2017.
100. Johnson CC, Kennedy C, Fonner V, Siegfried N, Figueroa C, Dalal S, Sands A, Baggaley R. Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis. J Int AIDS Soc. 2017;20(1):21594-.
101. Figueroa C, Johnson C, Verster A, Baggaley Rl. Attitudes and acceptability on HIV self-testing among key populations: a literature review. AIDS Behav. 2015;19(11):1949-65.
102. Indravudh PP, Sibanda EL, d'Elbée M, Kumwenda MK, Ringwald B, Maringwa G, Simwinga M, Nyirenda LJ, Johnson CC, Hatzold K, Terris-Prestholt F, Taegtmeyer M. 'I will choose when to test, where I want to test': investigating young people's preferences for HIV self-testing in Malawi and Zimbabwe. AIDS. 2017;31(Suppl 3):S203-s12.
103. Indravudh PP, Fielding K, Kumwenda MK, Nzawa R, Chilongosi R, Desmond N, Nyirenda R, Neuman M, Johnson CC, Baggaley R, Hatzold K, Terris-Prestholt F, Corbett EL.

Effect of community-led delivery of HIV self-testing on HIV testing and antiretroviral therapy initiation in Malawi: A cluster-randomised trial. PloS Med. 2021;18(5):e1003608.

104. MacGowan RJ, Chavez PR, Borkowf CB, Owen SM, Purcell DW, Mermin JH, Sullivan PS. Effect of internet-distributed HIV self-tests on HIV diagnosis and behavioral outcomes in men who have sex with men: a randomized clinical trial. JAMA Int Med. 2020;180(1):117-25.

105. Choko AT, Fielding K, Johnson CC, Kumwenda MK, Chilongosi R, Baggaley RC, Nyirenda R, Sande LA, Desmond N, Hatzold K, Neuman M, Corbett EL. Partner-delivered HIV self-test kits with and without financial incentives in antenatal care and index patients with HIV in Malawi: a three-arm, cluster-randomised controlled trial. Lancet Glob Health. 2021;9(7):e977-e88.

106. Amstutz A, Lejone TI, Khesa L, Muhairwe J, Bresser M, Vanobberghen F, Kopo M, Kao M, Nsakala BL, Tlali K, Klimkait T, Battegay M, Labhardt ND, Glass TR. Home-based oral self-testing for absent and declining individuals during a door-to-door HIV testing campaign in rural Lesotho (HOSENG): a cluster-randomised trial. Lancet HIV. 2020;7(11):e752-e61.

107. Hensen B, Schaap AJ, Mulubwa C, Floyd S, Shanaube K, Phiri MM, Bond V, Bwalya C, Simwinga M, Fidler S, Hayes R, Mwinga A, Ayles H. Who accepts and who uses community-based secondary distribution hiv self-testing (HIVST) kits? findings from the intervention arm of a cluster-randomized trial of HIVST distribution nested in four HPTN 071 (PopART) communities in Zambia. J Acquir Immune Defic Syndr. 2020;84(4).

108. Choko AT, Nanfuka M, Birungi J, Taasi G, Kisembo P, Helleringer S. A pilot trial of the peer-based distribution of HIV self-test kits among fishermen in Bulisa, Uganda. PloS One. 2018;13(11):e0208191.

109. Gichangi A, Wambua J, Mutwiwa S, Njogu R, Bazant E, Wamicwe J, Wafula R, Vrana CJ, Stevens DR, Mudany M, Korte JE. Impact of HIV self-test distribution to male partners of ANC clients: results of a randomized controlled trial in Kenya. J Acquir Immune Defic Syndr. 2018;79(4):467-73.

110. Figueroa C, Johnson C, Ford N, Sands A, Dalal S, Meurant R, Prat I, Hatzold K, Urassa W, Baggaley R. Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis. Lancet HIV. 2018;5(6):e277-e90.

111. Simwinga M, Kumwenda MK, Dacombe RJ, Kayira L, Muzumara A, Johnson CC, Indravudh P, Sibanda EL, Nyirenda L, Hatzold K, Corbett EL, Ayles H, Taegtmeyer M. Ability to understand and correctly follow HIV self-test kit instructions for use: applying the cognitive interview technique in Malawi and Zambia. J Int AIDS Soc. 2019;22(S1):e25253.

112. Choko AT, Corbett EL, Stallard N, Maheswaran H, Lepine A, Johnson CC, Sakala D, Kalua T, Kumwenda M, Hayes R, Fielding K. HIV self-testing alone or with additional interventions, including financial incentives, and linkage to care or prevention among male partners of antenatal care clinic attendees in Malawi: An adaptive multi-arm, multi-stage cluster randomised trial. PloS Med. 2019;16(1):e1002719.

113. Masters SH, Agot K, Obonyo B, Napierala Mavedzenge S, Maman S, Thirumurthy H. Promoting partner testing and couples testing through secondary distribution of HIV self-tests: A randomized clinical trial. PloS Med. 2016;13(11):e1002166.

114. Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S, Gaydos CA, Makombe SD, Chunda T, Squire SB, French N, Mwapasa V, Corbett EL. The uptake and accuracy of oral kits for HIV self-testing in high hiv prevalence setting: a cross-sectional feasibility study in Blantyre, Malawi. PloS Med. 2011;8(10):e1001102.

115. Kumwenda MK, Johnson CC, Choko AT, Lora W, Sibande W, Sakala D, Indravudh P, Chilongosi R, Baggaley RC, Nyirenda R, Taegtmeyer M, Hatzold K, Desmond N, Corbett EL. Exploring social harms during distribution of HIV self-testing kits using mixed-methods approaches in Malawi. J Int AIDS Soc. 2019;22(S1):e25251.

116. Hlongwa M, Mashamba-Thompson T, Makhunga S, Murararaneza C, Hlongwana K. Men's perspectives on HIV self-testing in sub-Saharan Africa: A systematic review and meta-synthesis. BMC Public Health. 2020;20(1):66.

117. Vannakit R, Janyam S, Linjongrat D, Chanlearn P, Sittikarn S, Pengnonyang S, Janamnuaysook R, Termvanich K, Ramautarsing R, Phanuphak N, Phanuphak P. Give the community the tools and they will help finish the job: key population-led health services for ending AIDS in Thailand. Journal of the International AIDS Society. 2020;23(6):e25535.

118. Wong VW, Wong GL, Chim AM, Cheng TF, Cheung SW, Lai CM, Szeto KJ, Tsang S, Wu SH, Yan KK, Hui AY, Yiu DC, Wu BB, Cheung D, Chung CS, Lai CW, Chan HL. Targeted hepatitis C screening among ex-injection drug users in the community. J Gastroenterol Hepatol. 2014;29(1):116-20.

119. Sharma M, Ying R, Tarr G, Barnabas R. Systematic review and meta-analysis of community and facility-based HIV testing to address linkage to care gaps in sub-Saharan Africa. Nature. 2015;528(7580):S77-85.

120. Mirzazadeh A, Eshun-Wilson I, Thompson RR, Bonyani A, Kahn JG, Baral SD, Schwartz S, Rutherford G, Geng EH. Interventions to reengage people living with HIV who are lost to follow-up from HIV treatment programs: A systematic review and meta-analysis. PloS Med. 2022;19(3):e1003940.

121. Ehrenkranz P, Rosen S, Boulle A, Eaton JW, Ford N, Fox MP, Grimsrud A, Rice BD, Sikazwe I, Holmes CB. The revolving door of HIV care: Revising the service delivery cascade to achieve the UNAIDS 95-95-95 goals. PloS Med. 2021;18(5):e1003651.

122. Angotti N, Bula A, Gaydosh L, Kimchi EZ, Thornton RL, Yeatman SE. Increasing the acceptability of HIV counseling and testing with three C's: convenience, confidentiality and credibility. Soc Sci Med. 2009;68(12):2263-70.

123. Franse CB, Kayigamba FR, Bakker MI, Mugisha V, Bagiruwigize E, Mitchell KR, Asiimwe A, Schim van der Loeff MF. Linkage to HIV care before and after the introduction of provider-initiated testing and counselling in six Rwandan health facilities. AIDS Care. 2017;29(3):326-34.

124. Fuente-Soro L, Lopez-Varela E, Augusto O, Sacoor C, Nhacolo A, Honwana N, Karajeanes E, Vaz P, Naniche D. Monitoring progress towards the first UNAIDS target: understanding the impact of people living with HIV who re-test during HIV-testing campaigns in rural Mozambique. J Int AIDS Soc. 2018;21(4):e25095.

125. Moore HA, Metcalf CA, Cassidy T, Hacking D, Shroufi A, Steele SJ, Duran LT, Ellman T. Investigating the addition of oral HIV self-tests among populations with high testing coverage - Do they add value? Lessons from a study in Khayelitsha, South Africa. PloS One. 2019;14(5):e0215454.

126. Rapaport SF, Peer AD, Viswasam N, Hahn E, Ryan S, Turpin G, Lyons CE, Baral S, Hansoti B. Implementing HIV prevention in sub-Saharan Africa: A systematic review of interventions targeting systems, communities, and individuals. AIDS Behav. 2022.

127. Choko AT, Candfield S, Maheswaran H, Lepine A, Corbett EL, Fielding K. The effect of demand-side financial incentives for increasing linkage into HIV treatment and voluntary medical male circumcision: A systematic review and meta-analysis of randomised controlled trials in low- and middle-income countries. PloS One. 2018;13(11):e0207263.

128. Neuman M, Fielding KL, Ayles H, Cowan FM, Hensen B, Indravudh PP, Johnson C, Sibanda EL, Hatzold K, Corbett EL. ART initiations following community-based distribution of HIV self-tests: meta-analysis and meta-regression of STAR Initiative data. BMJ Global Health. 2021;6(Suppl 4):e004986.

129. Nichols B, Cele R, Chasela C, Siwale Z, Lungu A, Long L, Moyo C, Rosen S, Chilengi R. Cost and impact of community-based, assisted HIV self-testing amongst youth in Zambia. Conference on Retroviruses and Opportunistic infections; 4-7 March 2019;Seattle, WA, USA.

130. MacPherson P, Lalloo DG, Webb EL, Maheswaran H, Choko AT, Makombe SD, Butterworth AE, van Oosterhout JJ, Desmond N, Thindwa D, Squire SB, Hayes RJ, Corbett EL.

Effect of optional home initiation of HIV care following HIV self-testing on antiretroviral therapy initiation among adults in Malawi: A randomized clinical trial. JAMA. 2014;312(4):372-9.

131. Sibanda E, Neuman M, Tumushime M, Hatzold K, Watadzaushe C, M; M, Dirawo J, Napierala S, Ncube G, Taegtmeyer M, Johnson C, Fielding K, Weiss H, Corbett E, Cowan F. Linkage to care after HIV self-testing in Zimbabwe: a cluster-randomised trial. Conference on Retroviruses and Opportunistic Infections; 4-6 March 2018;Boston, MA, USA.

132. Chipungu J, Bosomprah S, Zanolini A, Thimurthy H, Chilengi R, Sharma A, Holmes CB. Understanding linkage to care with HIV self-test approach in Lusaka, Zambia - a mixed method approach. PloS One. 2017;12(11):e0187998.

133. Choko AT, Kumwenda MK, Johnson CC, Sakala DW, Chikalipo MC, Fielding K, Chikovore J, Desmond N, Corbett EL. Acceptability of woman-delivered HIV self-testing to the male partner, and additional interventions: a qualitative study of antenatal care participants in Malawi. J Int AIDS Soc. 2017;20(1):21610-.

134. Kennedy CE, Yeh PT, Atkins K, Fonner VA, Sweat MD, O'Reilly KR, Rutherford GW, Baggaley R, Samuelson J. Economic compensation interventions to increase uptake of voluntary medical male circumcision for HIV prevention: A systematic review and meta-analysis. PloS One. 2020;15(1):e0227623-e.

135. Lancaster KJ. A new approach to consumer theory. J Polit Econ. 1966;74(2):132-57.

136. Hendler R. Lancaster's new approach to consumer demand and its limitations. Amer Econ Rev. 1975;65(1):194-9.

137. Vass C, Rigby D, Payne K. The Role of Qualitative Research Methods in Discrete Choice Experiments. Med Decis Making. 2017;37(3):298-313.

138. Caplin A, Leahy J. The supply of information by a concerned expert. Econ Journ. 2004;114(497):487-505.

139. Marteau T, Ashcroft R, Oliver A. Using financial incentives to achieve healthy behaviour. BMJ. 2009;338(7701).

140. Grossman M. On the concept of health capital and the demand for health. J Polit Econ. 1972;80.

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	1603327	**Title**	Ms
First Name(s)	Cheryl		
Surname/Family Name	Johnson		
Thesis Title	Investigating Men's Preferences for HIV Self-Testing and Linkage: Exploring Strategies for Policy Impact		
Primary Supervisor	Professor Liz Corbett		

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

SECTION B – Paper already published

Where was the work published?	Journal of the International AIDS Society		
When was the work published?	May 2017		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	No		
Have you retained the copyright for the work?*	**No**	Was the work subject to academic peer review?	**Yes**

*If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the of a systematic review and drafted the protocol, outcomes of interest and search terms in coordination with the WHO guideline development group. I led the review including searches, extraction and completed meta-analysis with support from my co-authors. After running the intial search and review, I then updated the review through March 2017. I led analysis and interpretation, and I drafted and wrote the manuscript.

SECTION E

Student Signature	Cheryl Johnson [redacted]
Date	13 August 2022

Supervisor Signature	Liz Corbett [redacted]
Date	13/08/2022

3.0 Systematic review

3.1 Introduction

A systematic review was undertaken to examine the existing evidence regarding the effectiveness of HIVST on the following outcomes: uptake of HIV testing, frequency of HIV testing, identification of people with HIV (positivity) among those tested, linkage to care, social harm and risk behaviour. The systematic review adhered to Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to inform normative guideline development processes. Five RCTs were identified and included in the review. Key findings were that there was moderate quality evidence that HIVST doubled uptake and frequency of HIV testing compared to facility-based testing services. Uptake of HIVST increased partner testing in two RCTs. Linkage following HIVST appeared suboptimal, but evidence was very low-quality evidence with only one study reported on this outcome and no studies reported on linkage to prevention methods.

Tables and figures are at the end. All supplemental material is in Appendix 1 and 2.

This review was submitted to the Journal of the International AIDS Society in January 2017 and was then updated and resubmitted in March 2017. It is described as published below.

3.2 Systematic review paper

Title: Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis

Authors: Cheryl C Johnson[a*], Caitlin Kennedy[b], Virginia Fonner[c], Nandi Siegfried[a,d], Carmen Figueroa[a], Shona Dalal[a], Anita Sands[e], and Rachel Baggaley[a]

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Abstract

Introduction: HIV self-testing (HIVST) is a discreet and convenient way to reach people with HIV who do not know their status, including many who may not otherwise test. To inform World Health Organization (WHO) guidance, we assessed the effect of HIVST on uptake and frequency of testing, as well as identification of HIV-positive persons, linkage to care, social harm, and risk behaviour.

Methods: We systematically searched for studies comparing HIVST to standard HIV testing until 1 June 2016. Meta-analyses of studies reporting comparable outcomes were conducted using a random-effects model for relative risks (RR) and 95% confidence intervals. The quality of evidence was evaluated using GRADE.

Results: After screening 638 citations, we identified five randomized controlled trials (RCTs) comparing HIVST to standard HIV testing services among 4,145 total participants from four countries. All offered free oral-fluid rapid tests for HIVST and were among men. Meta-analysis of three RCTs showed HIVST doubled uptake of testing among men (RR = 2.12; 95% CI: 1.51, 2.98). Meta-analysis of two RCTs among men who have sex with men showed frequency of testing nearly doubled (Rate ratio = 1.88; 95% CI: 1.17; 3.01), resulting in two more tests in a 12–15-month period (Mean difference = 2.13; 95% CI: 1.59, 2.66). Meta-analysis of two RCTs showed HIVST also doubled the likelihood of an HIV-positive diagnosis (RR = 2.02; 95% CI: 0.37, 10.76, 5.32). Across all RCTs, there was no indication of harm attributable to HIVST and potential increases in risk-taking behaviour appeared to be minimal.

Conclusions: HIVST is associated with increased uptake and frequency of testing in RCTs. Such increases, particularly among those at risk who may not otherwise test, will likely identify more HIV-positive individuals as compared to standard testing services alone. However, further research on how to support linkage to confirmatory testing, prevention, treatment and care services is needed. WHO now recommends HIVST as an additional HIV testing approach.

Keywords: HIV/AIDS, HIV test, HIV self-test, public health

Introduction

Global scale-up of HIV testing services (HTS) has been significant. From 2010 to 2014, more than 600 million people received HTS in 122 low- and middle-income countries [1]. This expansion has been made possible through the widespread introduction of provider-initiated testing and counselling and an array of community-based approaches which are now considered the standard of care [2]. Despite this, approximately 40% of all HIV infections are undiagnosed worldwide [3] and countries are seeking ways to increase the number of people who know their HIV status to achieve the first of the United Nation's 90-90-90 HIV testing and treatment goals – diagnosis of 90% of all people with HIV by 2020 [4].

HIV self-testing (HIVST) has been proposed as an approach to reach people who are not accessing existing HTS, such as men, young people, and key populations (i.e. people who inject drugs, men who have sex with men, sex workers, and transgender people). HIVST refers specifically to a process in which a person collects his or her specimen (oral fluid or blood) and performs a test and interprets the result, often in private or with someone they trust [2].

Several observational studies [5–17] and systematic reviews [18–21] have shown HIVST can be performed accurately and is an acceptable and feasible testing approach in a variety of contexts; including among populations at ongoing HIV risk and those who may not otherwise test. As a discreet, convenient and empowering approach, many well-documented barriers to standard HTS, such as long-lines, services offered at inconvenient times, fear of stigma and lack of confidentiality [22], can be addressed by HIVST [18,23–26].

To assess the potential effects of HIVST compared to standard HTS, that is, facility- or community-based approaches, we conducted a systematic review. Our objective was to assess the effects of HIVST on uptake and frequency of HIV testing, diagnosis of people with HIV, linkage to prevention and care, risk behaviour, social harm or other adverse events, compared to standard HTS. Review findings were then used to help determine whether HIVST should be recommended as an additional HTS approach in WHO guidelines.

Methods

This review followed guidance from the Cochrane Collaboration [27] and the PRISMA statement for the reporting of systematic reviews and meta-analyses. The review protocol and the full quality assessment are available in Appendix 1–2 (Supplemental material).

Search strategy and inclusion criteria

We searched five electronic databases PubMed, CINAHL, PsycINFO, Sociological Abstracts, and EMBASE through 1 June 2016 for peer-reviewed articles. We also searched the following conference databases for abstracts: International AIDS Conference (IAC), International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention (IAS), and Conference on Retroviruses and Opportunistic Infections (CROI). IAC and IAS conference abstracts were searched for all available years (2001–2015). For CROI, only recent conferences (2014–2016) were searched as past conferences were inaccessible. Secondary reference searching was conducted on all studies included in the review as well as on previously published reviews. We also contacted experts to identify additional studies, specifically abstracts being presented at the 2016 IAC, and reviewed databases listing ongoing RCTs through clinicaltrials.gov, WHO International Clinical Trials Registry Platform, and Pan African Clinical Trials Registry.

The search strategy was adapted for entry into all computer databases using key terms “HIV”, “self-test”, and “home test” (Appendix 1 (Supplemental material)). To search HIV-related conference abstracts, only terms for self-testing were used because search functions were limited. No language or geographic limitations were placed on the search.

Two reviewers (CK and VF) screened studies. The first reviewer identified study titles and abstracts meeting the inclusion criteria. The second reviewer evaluated the application of screening criteria and approved selected studies. Disagreements between reviewers were resolved through discussion and consensus. CJ, VF, CK also contacted all authors of studies included in the review to collect additional information about each study.

To be included, studies needed to directly compare HIVST to HTS by a provider in either a facility or community setting (defined as standard HTS) and report on one or more of the following outcomes: (1) uptake of HIV testing (e.g. the number of participants who tested for HIV in the study period); (2) frequency of HIV testing (e.g. the number of times a participant tested for HIV in the study period); (3) social harm/adverse events (defined as any undesirable experience, or intended or unintended harm associated with HIV self-testing); (4) HIV positivity (e.g. the proportion of people with a reactive self-test who received confirmatory HTS and were diagnosed HIV positive); (5) proportion of people linked to confirmatory testing, clinical assessment or treatment and/or measurement of CD4 or viral load among those diagnosed HIV positive; (6) linkage to prevention services following nonreactive self-test result; or (7) sexual risk behaviour (measured as report of condomless sex, sexual transmitted infections (STIs) or

number of sexual partners). Additionally, we also searched for the full-text publication of any abstract included in the review as of 15 March 2017 to check for updates to previous reports.

Data analysis

Data were extracted independently by four reviewers using standardized extraction forms. Risk of bias was assessed according to guidance by the Cochrane Collaboration and determined by CK, VF, NS, and CJ [27]. Where multiple studies reported the same or comparable outcomes, meta-analyses were conducted using random-effects models to combine relative risks for dichotomous data, mean differences for continuous data, or rate ratios for frequency data, with 95% confidence intervals using REVMAN 5.3.5.

Quality assessment

GRADE methodology was used to assess and appraise the quality of evidence for each outcome across all studies, and included an evaluation of the risk of bias, imprecision, indirectness, and inconsistency, and other considerations including publication bias [28] (Appendix 2 (Supplemental material)).

Results

The searches yielded 638 citations, which after screening resulted in five eligible RCTs (Fig. 1).

Study characteristics

All five RCTs were published between 2015 and 2017. Three were full-text manuscripts [29–31], one of which was in press [31,32], and two were conference abstracts [33,34]. These studies included a total of 4,145 individuals (range: 230–2523). The largest study was among 1410 pregnant women and 1113 of their locatable male partners in Kenya [33]. All RCTs reported outcomes among men: two took place in Kenya where women delivered HIVST to their male partners [30,33] and the remainder were among men who have sex with men (MSM) in Australia [29], Hong Kong SAR [31,32], and the United States [34]. Table 1 summarizes the study characteristics.

All studies offered free oral HIVST kits with the manufacturer's instructions for use, but differed in terms of the number of kits and the level of assistance provided. In order to encourage quarterly testing, in the United States and Australia, MSM had continuous access to HIVST kits

[29,34], and in Australia, participants received four HIVST kits at enrolment. In Kenya, women were provided with two HIVST kits at enrolment (one for them and one for their male partner) [30,33]. In Hong Kong SAR, MSM were provided with only one HIVST kit at enrolment [31,32].

HIVST can be delivered with direct assistance, such as an in-person demonstration on how to self-test, or unassisted using either manufacture instructions for use alone. In addition, other support tools such as telephone hotlines, videos or messaging services may also be provided [2]. Two RCTs [29,31,32] provided unassisted HIVST, but in addition to the test kit participants had access an informational video; and one RCT, also provided motivational interviewing via telephone and counselling through online live-chat services [31,32]. The remainder provided an in-person demonstration on how to self-test (direct assistance) [30,33,34]; two of which provided women a demonstration so they could show their male partners how to self-test [30,33].

Uptake of HIV testing

Three RCTs [30–33] reported on uptake of HIV testing (Table 2). A meta-analysis showed moderate-quality evidence that HIVST doubled the uptake of HIV testing compared to standard HTS (RR = 2.12; 95% CI: 1.51, 2.98; Tau2 = 0.08; Chi2 = 32.88, df = 2 (p = 0.001; I2 = 94%)) (Figure 2). The high level of statistical heterogeneity was driven by the Gichangi and colleagues RCT [33], which measured uptake among men who had accepted some form of HIV testing and did not include those who declined testing. Since the estimate of effects was beneficial for all three RCTs, we did not downgrade for inconsistency. Two RCTs [30,33], where women delivered HIVST to their male partners, also reported HIVST increased uptake of couples testing compared to standard HTS, with moderate-quality evidence (Table 2).

There was low-quality evidence that HIVST resulted in greater HIV testing uptake among young MSM in Hong Kong SAR (18–25 years of age), including both recent and non-recent testers compared to standard HTS (Young MSM: RR = 1.79; 95% CI: 1.43, 2.24; Recent testers: RR = 1.75; 95% CI: 1.46, 2.08; Non-recent testers: RR = 2.22; 95% CI: 1.61; 3.08) [31,32]. In this same study, MSM who reported condomless anal intercourse at baseline were more likely to test if they were in the HIVST group compared to if they were in the standard testing group (RR = 1.75; 95% CI: 1.26, 1.81) [31,32].

Frequency of HIV testing

Two RCTs [29,34] in this review, both among MSM, reported on the frequency of HIV testing. Meta-analysis showed there was low-quality evidence that HIVST nearly doubled testing frequency compared to facility-based testing (Rate ratio = 1.88; 95% CI: 1.17; 3.01; Tau2 = 0.11, Chi2 = 23.33, df = 1 (p < 0.0001), I2 = 96%) (Figure 3) and resulted in two more HIV tests in a 12–15-month period than those receiving standard facility-based HTS (Mean difference = 2.13; 95% CI: 1.59, 2.66; Tau2 = 0.10; Chi2 = 2.37, df = 1 (p = 0·12), I2 = 58%) (Figure 4) [29,34]. In Australia, there was very low-quality evidence that HIVST substantially increased the frequency of testing among non-recent testers compared to standard facility-based HIV testing at 12 months (Rate ratio = 5.54; 95% CI: 3.15, 9.74) [29] (Table 3).

HIV positivity

Two RCTs [30,34] reported on HIV positivity following HIV testing. Meta-analysis showed there was very low-quality evidence that HIVST doubled the likelihood of an HIV-positive diagnosis compared to those using standard testing alone (RR = 2.02; 95% CI: 0.37, 10.76, 5.32) (Figure 5).

Linkage to care

One RCT in Kenya [30], with very low-quality evidence, reported on linkage to care. In the study, women reported that 25% (n = 2/8) of their male partners in the HIVST group linked to confirmatory testing at 3-month follow-up. Following confirmatory testing, both men were reportedly confirmed HIV positive and then linked to care. In the control group, women reported that all four male partners who were diagnosed HIV positive linked to care.

Risk behaviour

Two RCTs [31,32,34] reported on risk-taking behaviours. In the United States, there was very low-quality evidence showing that MSM in the HIVST group did not increase condomless anal intercourse compared to those undergoing facility-based HTS (RR = 0.94: 95% CI: 0.55, 1.61) [34]. In this same study, there was very low-quality evidence that men in the HIVST group acquired fewer STIs than those in the standard HTS group (RR = 0.42; 95% CI: 1.15, 1.15) [34]. However, among MSM in Hong Kong SAR, there was very low-quality evidence that those in

the HIVST group were more likely to report condomless anal intercourse (RR = 1.43: 95% CI: 0.98, 2.08) at 6-month follow-up than those in the standard HTS group.

Social harm

One RCT [30] with very low-quality evidence reported on social harm following HIVST or standard facility-based HTS. In this trial, there were reports of a single harm in each group among two HIV-negative participants, 1/297 (0.34%) in the HIVST group and 1/303 (0.33%) in the control group, both relating to verbal and/or physical intimate-partner violence (IPV). In the HIVST group, the harm was not directly related to HIVST as the female participant reported violence occurred as a result of agreeing to participate in the study without consulting her husband. At enrolment neither participant reported experiencing IPV in the past 12 months, and the RCT used IPV screening tools and excluded women reporting risk of IPV [30].

Discussion

Standard HTS approaches are essential and serve many people, but current approaches continue to miss a substantial number of people with HIV and those at high ongoing risk. This systematic review and meta-analysis finds there is moderate quality evidence that HIVST can increase the uptake of HIV testing and low-quality evidence that HIVST increases the frequency of HIV testing. This evidence is limited to MSM and male partners of pregnant and post-partum women in sub-Saharan Africa. However, these findings on increased uptake are consistent with the results of implementation studies from Kenya [13,35], Lesotho [17], Malawi [36,37], and Zimbabwe [38] which have been conducted among other populations known to have poor testing coverage, including men, young people and the households of people newly diagnosed with HIV, but do not directly compare with standard facility-based HTS.

Such increases in HIV testing uptake and frequency have important public health implications, if they can be achieved at a population level and reach those with undiagnosed HIV infection and at ongoing risk. As shown by two RCTs in this review [30,34] and reports from several other studies [12,15,31,36,39,40], increased testing due to HIVST can identify a greater or equivalent proportion of HIV infections as many existing HTS approaches. Sustained increases in HIV testing among men and other higher-risk populations, facilitated by HIVST, could identify a greater number of infections, and at an early stage in their infection [41], and result in earlier

diagnosis and initiation of treatment and reduce HIV-related mortality. This is a particular priority for men, as they have greater HIV-related mortality than their female peers [42].

Limited information on linkage to care was identified in this review. Of the two RCTs reporting, one found that 72% (n = 396) of the male partners of women who received an HIVST kit said they accessed further testing to confirm their result [33]. This outcome, however, could not be directly compared with standard testing. In the other [30], while linkage following a reactive self-test appeared lower than those diagnosed in the standard group, few HIV-positive test results (n = 8) were reported. Additionally, this low level of linkage may be due to under-reporting and the possibility that some men already knew their HIV-positive status and were in care.

There are approaches following HIVST known to facilitate linkage to treatment, such as the offer of home-based ART initiation which resulted in a three-fold increase in linkage to care following HIVST in Malawi [43]. While results from a cluster-randomized trial in Malawi and a cohort study in Kenya suggest linkage to care following HIVST can be comparable to current national linkage rates [15,36], efforts to shorten the time between diagnosis and enrolment in care and improve overall linkage rates are needed. Further research is needed to identify ways to enhance linkage following HIVST; particularly for key populations, who may be less likely to link to services due to restrictive laws and policies.

Results from three RCTs [29,31,32,34] reporting on risk behaviours suggest HIVST did not increase risk-taking behaviour among MSM. While one RCT reported very low-quality evidence that HIVST could increase and having multiple sex partners among MSM in [31,32], results were not statistically significant. Additionally, data collected at baseline suggested high-risk MSM may be more likely to take up HIVST than standard HTS; and a sub-analysis among MSM who took up any testing across both arms found no effect on (RR = 0.81, 95% CI: 0.57, 1.75) and a minimal effect in reducing multiple male sex partners (RR = 0.72, 95% CI > 0.54, 0.95) [31,32]. Thus, while HIVST may not directly increase risk behaviours, there is some uncertainty and it is important that messages which reinforce the importance of using effective HIV prevention methods, such as condoms, are provided.

Only a single IPV event [30], which was not directly related to HIVST, was identified in this review of RCTs. Such findings are consistent with those reported by a review assessing harm resulting from self-testing for various conditions and diseases [44], an observational study in the United States among MSM [45], and a 2-year cluster-randomized trial [36] and parallel

longitudinal qualitative study [24,46] in Malawi, which reported no cases of physical violence, self-harm or suicide and few cases of “coercion”.

In Malawi, the majority of those reporting “coercion” were men who also stated they were highly satisfied with HIVST (92%, 130/141) and would recommend it to others [36]. Qualitative findings from this same study also indicated that most users consider HIVST to be empowering, but some couples (n = 2/17) felt “pressure” to self-test by their partner and said serodiscordant HIVST results were challenging [24,46]. In contrast, a cohort study among 265 HIV-negative pregnant and post-partum women and female sex workers in Kenya reported two cases of IPV among post-partum women who distributed HIVST to their male partner and two cases of physical violence among female sex workers who distributed HIVST to their clients [15]. It is unclear if these cases were attributable to HIVST, as 41% of women in the study reported experiencing violence in the preceding 12 months [15]. These findings suggest that not all testing approaches are appropriate for all contexts, and caution is still needed in vulnerable populations. In order to guide safe HIVST implementation, programmes will need to consult populations at a risk of abuse. Additionally, HIVST may not be an appropriate or safe approach for all populations. It is important that information on where and how to access other HTS approaches, including community-based options, continues to be provided.

Strengths and limitations

While other reviews on HIVST have assessed accuracy, feasibility and acceptability [18–21], this review is the first to directly compare HIVST to standard HTS and to systematically assess the effect of HIVST on uptake and frequency of testing, diagnosis of HIV-positive persons, linkage to care, risk behaviour and potential social harm. Additional strengths of this review include its ability to identify the latest evidence in both published and grey literature, its adherence to the PRISMA and Cochrane reporting standards and its consultation with global experts when defining the outcomes of interest to ensure finding would be relevant to the implementation and delivery of HTS (Appendix 2 (Supplemental material)).

The review and RCTs included, however, also have several limitations. Few studies which directly compared HIVST to standard HTS were identified in the review, and meta-analyses were only able to be performed among a small number of RCTs which had comparable outcomes. RCTs identified focused on male partners of women in antenatal or post-partum care and MSM, including sub-groups of recent and non-recent testers and young MSM. Other populations were not evaluated.

All RCTs compared HIVST to facility-based HTS. None compared HIVST to other community-based HTS approaches. Testing behaviour was assessed through self-report in all five RCTs and the potential for detection bias cannot be disregarded. However, self-reported data was validated with clinical records in two RCTs [29,32]. Two studies in this review were conference abstracts. However, we were able to contact all authors directly and obtain additional information, including full study protocols, which addressed some reporting gaps (Appendix 2 (Supplemental material)).

Conclusions

This review found greater uptake of and frequency of HIV testing associated with HIVST compared to standard HTS. Risk-taking behaviour did not appear to increase due to HIVST, nor was HIVST associated with harm. Based on the findings of this review, and additional information reviewed at an expert meeting, WHO now recommends HIVST be offered as an additional HTS approach. Countries should make HIVST available and determine how to use this approach to fill gaps in testing coverage and reach those at risk who are not accessing existing HTS. Further assessment of different service delivery models and strategies to facilitate linkage, cost-effectiveness and the pathway to create supportive policies will be needed to maximize the potential of introducing HIVST.

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Competing interests

We declare not competing interests. The authors alone are responsible for the views expressed in this article and they do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated.

To access the supplementary material to this article please see Supplementary Files under Article Tools online.

Disclaimer

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication. The authors alone are responsible for the views expressed in this article and they do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated.

References

1. World Health Organization (WHO). Factsheet to the WHO consolidated guidelines on HIV testing services. Geneva: WHO; 2015.
2. World Health Organization (WHO). Consolidated guidelines on HIV testing services. Geneva: WHO; 2015.
3. UNAIDS. Prevention gap report. Geneva: Joint United Nations Programme on HIV/AIDS; 2016.
4. Fast-track - ending the AIDS epidemic by 2030. Geneva: UNAIDS; 2014.

5. Bustamante MJ, Konda KA, Joseph Davey D, Leon SR, Calvo GM, Salvatierra J, et al. HIV self-testing in Peru: questionable availability, high acceptability but potential low linkage to care among men who have sex with men and transgender women. Int J STD & AIDS. 2017;28(2):133–10.
6. Cowan F. Designing safe, acceptable and appropriate HIVST interventions for female sex workers. Presented at: 21st International AIDS Conference; 2016. July 18–22; Durban, South Africa.
7. De La Fuente L, Rosales-Statkus ME, Hoyos J, Pulido J, Santos S, Bravo MJ, et al. Are participants in a street-based HIV testing program able to perform their own rapid test and interpret the results?. Plos One. 2012;7(10):e46555.
8. Green K, Thu H. In the hands of the community: accelerating key population-led HIV lay and self-testing in Viet Nam. Presented at: 21st International AIDS Conference; 2016. July 18–22; Durban, South Africa.
9. Grinsztejn B, De Boni R. Ahora e Agora: HIVST to reach men who have sex with men (MSM) in Brazil. Presented at: 21st International AIDS Conference; 2016. July 18–22; Durban, South Africa.
10. Lippman SA, Moran ME, Ventura A, Castillo LS, Buchbinder S, Treves-Kagan S, et al. Home HIV testing among transgender women in San Francisco: a pilot feasibility and acceptability study. AIDS and Behav. 2017;20(4):928–38.
11. Marley G, Kang D, Wilson EC, Huang T, Qian Y, Li X, et al. Introducing rapid oral-fluid HIV testing among high risk populations in Shandong, China: feasibility and challenges. BMC Public Health. 2014;14:422.
12. Medline A, Huang E, Marlin R, Young S, Kwok J, Klausner J. Using Grindr™, a social-media–based application, to increase HIV self testing among high-risk men who have sex with men in Los Angeles, California, 2014. Presented at: Conference on Retroviruses and Opportunistic Infections; 2015. February 23–26; Seattle, WA.
13. Ngure K, Heffron R, Mugo N, Irungu E, Njuguna N, Mwaniki L. Uptake of HIV self-testing among people receiving PrEP in Kenya. Presented at: Research for HIV Prevention Conference; 2014. Oct 30–Nov 3; Cape Town, South Africa.
14. Sarkar A, Mburu G, Behara J, Sharma P, Mishra S, Mehra S. Feasibility of supervised self-testing using an oral fluid-based HIV rapid testing method. Presented at: 8th International AIDS Society Conference; 2015. July 19–22; Vancouver, Canada.
15. Thirumurthy H, Masters S, Mavedzenge S, Maman S, Omanga E, Agot K. Promoting male partner HIV testing and safer sexual decision making through secondary distribution of

self-tests by HIV-negative female sex workers and women receiving antenatal and post-partum care in Kenya: a cohort study. Lancet HIV. 2016;3(6):e266–e74.
16. Wang XF, Wu ZY, Tang ZZ, Nong QX, Li YQ. Promoting HIV testing with home self-test kit among men who have sex with men in China: a feasibility study. Lancet. 2015;386:68.
17. Zerbe AV, DiCarlo AL, Mantell JE, Remien RH, Morris DD, Frederix K, et al. Acceptability and uptake of home-based HIV self-testing in Lesotho. Top Antivir Med. 2015;23:509–10.
18. Figueroa C, Johnson C, Verster A, Baggaley R. Attitudes and acceptability on HIV self-testing among key populations: a literature review. AIDS Behav. 2015;19(11):1949–65.
19. Figueroa C, Johnson C, Verster A, Dalal S, Baggaley R. Systematic review on HIV self-testing (HIVST) performance and accuracy of results. Presented at: 21st International AIDS Conference; 2016. July 18–22; Durban, South Africa.
20. Krause J, Subklew-Sehume F, Kenyon C, Coelebunders R. Acceptability of HIV self-testing: a systematic literature review. BMC Public Health. 2013;13:735.
21. Pant Pai N, Sharma J, Shivkumar S, Pillay S, Vadnais C, Joseph L, et al. Supervised and unsupervised self-testing for HIV in high- and low-risk populations: A systematic review. Plos Med. 2013;10(4):e1001414.
22. Siedner MJ, Ng CK, Bassett IV, Katz IT, Bangsberg DR, Tsai AC. Trends in CD4 count at presentation to care and treatment initiation in sub-Saharan Africa, 2002-2013: a meta-analysis. Clin Inf Dis. 2015;60(7):1120–27.
23. Martinez Perez G, Cox V, Ellman T, Moore A, Patten G, Shroufi A, et al. 'I know that i do have HIV but nobody saw me': oral HIV self-testing in an informal settlement in South Africa. Plos One. 2016;11(4):e0152653.
24. Kumwenda M, Munthali A, Phiri M, Mwale D, Gutteberg T, MacPherson E, et al. Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. AIDS Behav. 2014;18(Suppl 4):S396–404.
25. Nkuna E, Nyazema N. HIV self-testing, self-stigma and HAART treatment at the university of Limpopo: health sciences students' opinion and perspectives. Open AIDS J. 2016;10:78–82.
26. Brown W 3rd, Carballo-Dieguez A, John RM, Schnall R. Information, motivation, and behavioral skills of high-risk young adults to use the HIV self-test. AIDS Behav. 2016;20:2000–09.

27. Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from http://www.handbook.cochrane.org.
28. Guyatt GH, Oxman AD, Montori V, Vist G, Kunz R, Brozek J, et al. GRADE guidelines: 5. Rating the quality of evidence–publication bias. J Clin Epidemiol. 2011;64(12):1277–82.
29. Jamil MS, Prestage G, Fairley CK, Grulich AE, Smith KS, Chen M, et al. Effect of availability of HIV self-testing on HIV testing frequency in gay and bisexual men at high risk of infection (FORTH): a waiting-list randomised controlled trial. Lancet HIV. 2017;S2352-3018(17)30023-1.
30. Masters SH, Agot K, Obonyo B, Napierala Mavedzenge S, Maman S, Thirumurthy H. Promoting partner testing and couples testing through secondary distribution of HIV self-tests: A randomized clinical trial. Plos Med. 2016;13(11):e1002166.
31. Wang Z, Lau J, Ip M, Ho S, Phoenix K, Latkin CA, et al. A randomized control trial evaluating efficacy of promoting home-based HIV self-testing with online counseling on increasing HIV testing among men who have sex with men. In Press.
32. Wang Z, Lau J, Ip M, Ho S. A randomized controlled trial evaluating the efficacy of promoting HIV self-testing and online real-time counseling on increasing HIV testing among men who have sex with men in Hong Kong. Presented at: International Congress of Behavioral Medicine; 2016. December 7–10; Melbourne, Australia.
33. Gichangi A, Wambua J, Gohole A, Mutwiwa S, Njogu R, Bazant E, et al. Provision of oral HIV self-test kits triples uptake of HIV testing among male partners of antenatal care clients: results of a randomized trial in Kenya. Presented at: 21st International AIDS Conference; 2016. July 18–22; Durban, South Africa.
34. Katz D, Golden M, Hughes J, Farquhar C, Stekler J. HIV self-testing increases HIV testing frequency among high-risk men who have sex with men: a randomized controlled trial. Presented at: 8th International AIDS Society Conference; 2015. July 19–22; Vancouver, Canada.
35. Mugo P, Micheni M, Shangala J, Hussein M, Graham S, Rinke De Wit T, et al. Uptake and acceptability of oral HIV self-testing among community pharmacy clients in Kenya: A feasibility study. Plos One. 2017;12(1):e0170868.
36. Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, Sambakunsi R, et al. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: A community-based prospective study. Plos Med. 2015;12(9):e1001873.

37. Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S, Gaydos CA, et al. The uptake and accuracy of oral kits for HIV self-testing in high HIV prevalence setting: A cross-sectional feasibility study in Blantyre, Malawi. Plos Med. 2011;8(10):e1001102.
38. Sibanda E, Mutseta M, Hatzold K, Gudukeya S, Dhliwayo A, Lopez C, et al. Community-based distribution of HIV self-test kits: results from a pilot of door-to-door distribution of HIV self-test kits in one rural Zimbabwean community. Presented at: 21st International AIDS Society; 2016. July 18–22; Durban, South Africa.
39. Katz D, Golden M, Cassell D, Stekler J. Monitoring the population-level impact of HIV self-testing through HIV surveillance and partner services. Presented at: National HIV Prevention Conference; 2015. December 6–9; Atlanta, USA.
40. Katz D, Golden M, Farquhar C, Stekler J. HIV self-test distribution via STI partner services to reach untested men who have sex with men. Presented at: National HIV Prevention Conference; 2015. December 6–9; Atlanta, USA.
41. Guy RJ, Prestage GP, Grulich A, Holt M, Conway DP, Jamil MS, et al. Potential public health benefits of HIV testing occurring at home in Australia. Med J Aust. 2015;202(10):529–31.
42. Bor J, Rosen S, Chimbindi N, Haber N, Herbst K, Mutevedzi T, et al. Mass HIV treatment and sex disparities in life expectancy: demographic surveillance in rural. Plos Med. 2015;12(11):e1001905.
43. MacPherson P, Lalloo DG, Webb EL, Maheswaran H, Choko AT, Makombe SD, et al. Effect of optional home initiation of HIV care following HIV self-testing on antiretroviral therapy initiation among adults in Malawi: a randomized clinical trial. J Am Med Assoc. 2014;312(4):372–79.
44. Brown A, Djimeu E, Cameron D. A review of the evidence of harm from self-tests. AIDS Behav. 2014;18(Suppl 4):S445–9.
45. Carballo-Dieguez A, Frasca T, Balan I, Ibitoye M, Dolezal C. Use of a rapid HIV home test to screen potential sexual partners prevents HIV exposure in a high-risk sample of MSM. AIDS Behav. 2012;16(7):1753–60.
46. Lora W, Chipeta E, Desmond N. Understanding coercion in the context of semi-supervised HIV self-testing in urban Blantyre, Malawi. Presented at: 21st International AIDS Conference; 2016. July 18–22; Durban, South Africa.

3.3 Tables and figures

Figure 1: *Study selection*

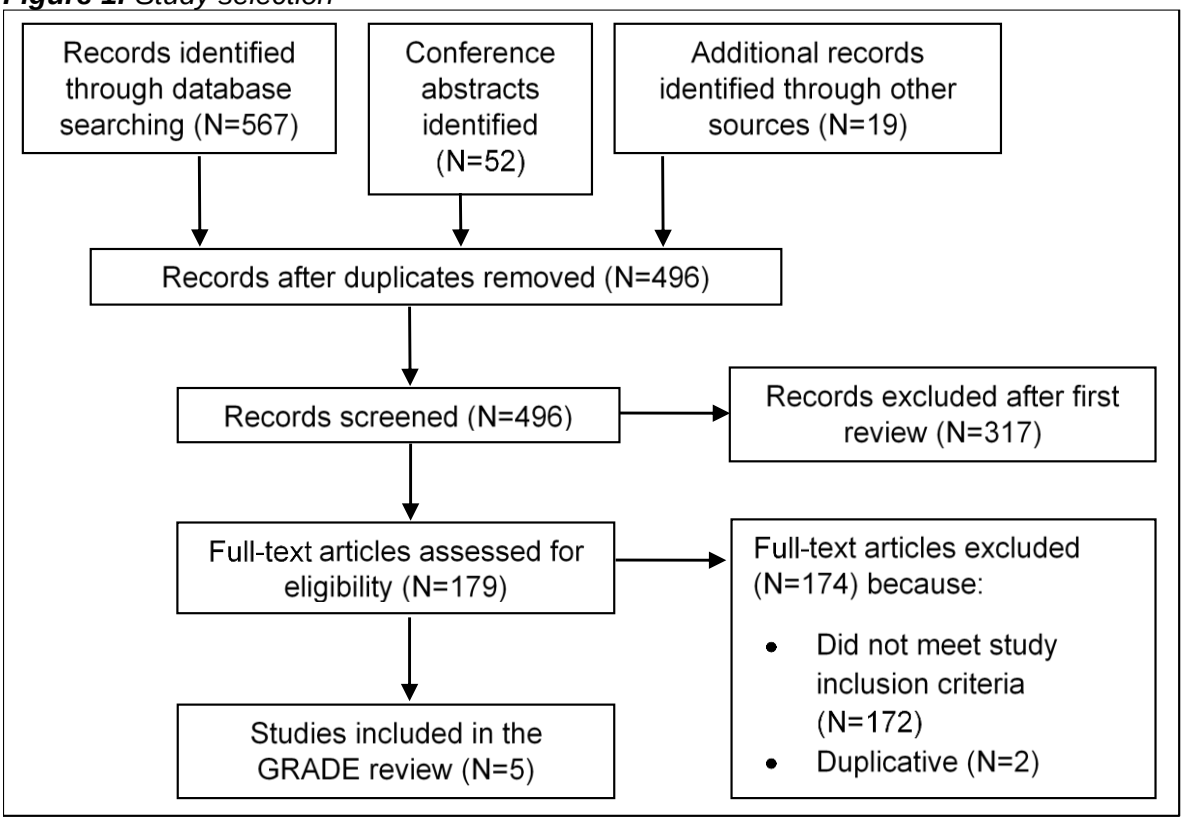


Table 1: *Summary of included study characteristics (n = 5)*

Author and location	Population	Study design and intervention	Test kit	Type of support
Gichangi et al., 2016 [33] Kenya	Pregnant women (n = 1410); Male partners of pregnant women (n = 1113) Pregnant women (>18 years of age) attending their first antenatal clinic visit who believed they were not at risk of IPV and had a male partner with unknown or HIV-negative status.	RCT: Women randomized (1:3) to one of three groups: (1) receive 2 HIVST kits and encouragement to distribute a kit to their male partner (intervention); (2) receive standard letter to invite male partner for HIV testing alone or as a couple at clinic (standard of care); or (3) receive a referral card stating importance of male partner testing in prevention-of-mother-to-child-transmission (control). Follow-up was completed at the end of the study at three months.	OraQuick	Directly Assisted: Provided women an HIVST kit which included instructions-for-use, a demonstration on how to use the HIVST kit and interpret the results correctly. Also provided instruction on how to encourage their male partner to test and how to handle their partners in case of a positive result.
Jamil et al., 2017 [29] Australia	High-risk MSM (n = 362) HIV-negative men >18 years of age who could speak or write in the English language reporting >5 partners and CAI in past 3-months.	RCT: Men were randomized (1:1) to either free HIVST or standard facility-based testing. Men in the HIVST group received 4 kits; participants could request up to 12-kits per year free of charge. Kits were picked up at study site or mailed to participants. In both groups, men completed a tablet-based questionnaire at enrolment and subsequent online surveys every 3 months. Participants who did not respond were sent reminders by phone call, SMS or email. Study was completed at 12 months.	OraQuick	Unassisted: Provided HIVST kit with manufacturer instructions, as well as a video link and 24 hr hotline. HIVST kits were also labelled with stickers with local information and resources to access support and for emergencies

Author and location	Population	Study design and intervention	Test kit	Type of support
Katz et al., 2015 [34] USA	High-risk MSM (n = 230) HIV-negative men >18 years of age who could speak English and had a stable home or mailing address reporting >1 event of CAI with partners of discordant or unknown HIV status, a STI, methamphetamine/popper use, or ≥10 male oral or anal sex partners in the past year	RCT: Men were randomized (1:1) to free HIVST or to standard facility-based testing. All participants were told quarterly HIV testing is recommended, informed about acute HIV infection, given a calendar marked with test dates and were offered reminders to test. All participants were asked to complete quarterly online surveys. Those in the standard care group, completed questionnaires reporting the date and location of HIV testing, reasons for testing, and interval sexual history and substance use. Those in the HIVST group were given a HIVST kit and could receive kits on site or by mail upon request. Men in the HIVST group had unlimited access to HIVST kits, but could not receive more than 1-kit per month. Study was completed at 15 months.	OraQuick	Directly Assisted: Provided HIVST kit with manufacturer instructions and a face-to-face demonstration on how to use the test and included pre-test information, and post-test counselling materials were also provided in-person Also provided a list of local HIV/AIDS and related resources and condoms, and a 24-hr telephone hotline for counselling and technical support
Masters et al., 2016 [30] Kenya	Pregnant or post-partum women (n = 600) Women (18–39 years of age) presenting at post-partum or antenatal care who had a male partner with unknown or known HIV-negative status and did not report being at risk of IPV.	RCT: Women were randomized (1:1) to (1) receive two HIVST kits and encouragement to distribute a kit to their male partner or (2) to receive referral vouchers inviting their male partner for HIV testing alone or as a couple. In both groups, women were provided messages to encourage their male partner to test for HIV. Follow-up was sought every month and at the end of the study at three months.	OraQuick	Directly Assisted: Provided women an HIVST kit with manufacturer instructions and an in-person demonstration on how to use the HIVST kit correctly. Women also received instruction on how to encourage their male partner to test.

Author and location	Population	Study design and intervention	Test kit	Type of support
Wang et al., 2016 [31,32] Hong Kong SAR, China	MSM (n = 430) Chinese-speaking HIV-negative men > 18 years of age who had not tested for HIV in the past 6-months and had access to online live-chat applications in Hong Kong with no intention to move in the next 6-months.	RCT: Men were randomized (1:1) to (1) HIVST including a free test kit by mail, a video promoting testing, an instructional video on HIVST, HIVST motivational interviewing by phone, and online live-chat pre- and post-testing counselling or (2) to standard HIV testing including a video promoting testing and encouragement to test for HIV. Three surveys were also conducted at baseline, midline at 6-months the study end. Those completing all three surveys received a supermarket coupon in the mail worth HK$50 (US$8).	OraQuick	Unassisted: Provided HIVST kit with manufacturer instructions, plus access to motivational interviewing by telephone and pre- and post-test counselling by nurses through live online chat systems (e.g. Line, Whats App, Skype) who also observed individuals self-testing.

IPV: intimate partner violence; RCT: randomized controlled trial; HIVST: HIV self-test; CAI: condomless anal intercourse; STI: sexually transmitted infections; MSM: men who have sex with men; SMS: short messaging service

Table 2: *Summary of select study outcomes (n = 5)*

			Uptake of overall HIV testing				Uptake of couples HIV testing				Mean test frequency		HIV positivity (%)	
Author /Year	**Country**	**Population**	**Standard HTS**	**n (%)**	**HIVST**	**n (%)**	**Standard HTS**	**n (%)**	**HIVST**	**n (%)**	**Standard HTS**	**HIVST**	**Standard HTS**	**HIVST**
Gichangi et al., 2016 [33]	Kenya	Male partners of pregnant women	471	132 (28)	472	373 (79)	471	106 (22.5)	472	323 (68.4)	N/A	N/A	N/A	N/A
Wang et al., 2016 [31,32]	Hong Kong SAR, China	MSM	215	109 (50.6)	215	193 (89.7)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Masters et al., 2016 [30]	Kenya	Male partners of pregnant women	303	148 (48.8)	297	258 (86.7)	303	95 (31.3)	297	214 (72)	N/A	N/A	4 (1.32)	8 (2.7)
Katz et al., 2015 [34]	United States	MSM	114	N/A	116	N/A	N/A	N/A	N/A	N/A	3.5	5.3	2(1·8)	4 (3.4)

			Uptake of overall HIV testing				Uptake of couples HIV testing				Mean test frequency		HIV positivity (%)	
Author /Year	**Country**	**Population**	**Standard HTS**	**n (%)**	**HIVST**	**n (%)**	**Standard HTS**	**n (%)**	**HIVST**	**n (%)**	**Standard HTS**	**HIVST**	**Standard HTS**	**HIVST**
Jamil et al., 2017 [29]	Australia	MSM	165	N/A	178	N/A	N/A	N/A	N/A	N/A	1.9	4.0	N/A	N/A

HIVST: HIV self-test; HTS: HIV testing services; MSM: men who have sex with men; NA: not applicable.

Table 3: *Summary of study outcomes on uptake and frequency of HIV testing among recent and non-recent testers among men who have sex with men (n = 2)*

		Standard HIV testing			HIVST		
Author, Year & Country	**Population**	**Standard HTS**	**% Uptake**	**Mean Test Frequency**	**HIVST**	**% Uptake**	**Mean Test Frequency**
Wang et al., 2016 **Hong Kong SAR, China**	MSM Recent tester (> 4 tests in 3 years)	30	22(73·3)	NA	24	23(95·8)	NA
	MSM Non-recent tester (1-3 tests in 3 years)	114	61(53·5)	NA	121	113(93·4)	NA
	MSM Non-recent tester (0 tests in 3 years)	71	26(36·6)	NA	70	57(81·4)	NA
Jamil et al., 2017 **Australia**	MSM Recent tester (tested ≤ 2 years)	141	NA	2·1	148	NA	4·2
	MSM Non-recent tester (tested > 2 years)	24	NA	0·7	30	NA	2·9

HIVST: HIV self-testing; HTS: HIV testing services; MSM: men who have sex with men

Figure 2: *Uptake of HIV testing over three and six month periods among male partners of pregnant women and men who have sex with men.*

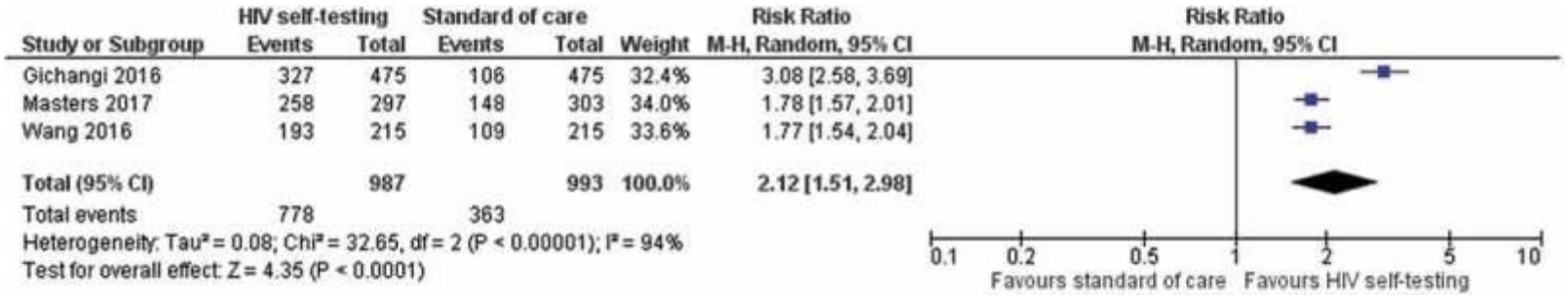


Figure 3: *Rate ratio of frequency of testing in a 12–15-month period among men who have sex with men.*

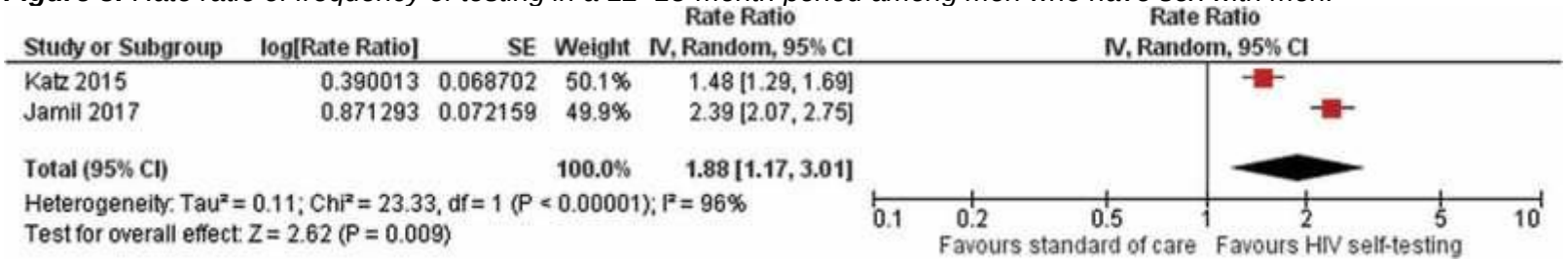


Figure 4: *Frequency of HIV testing measured by the mean number of tests in a 12–15-month period among men who have sex with men.*

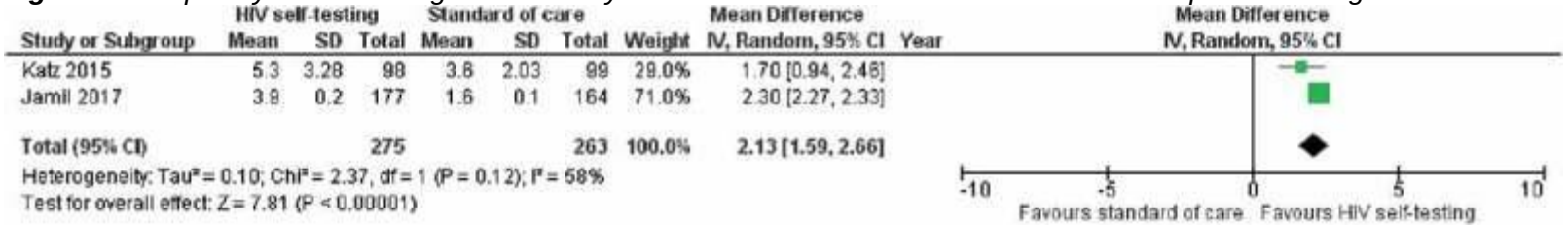
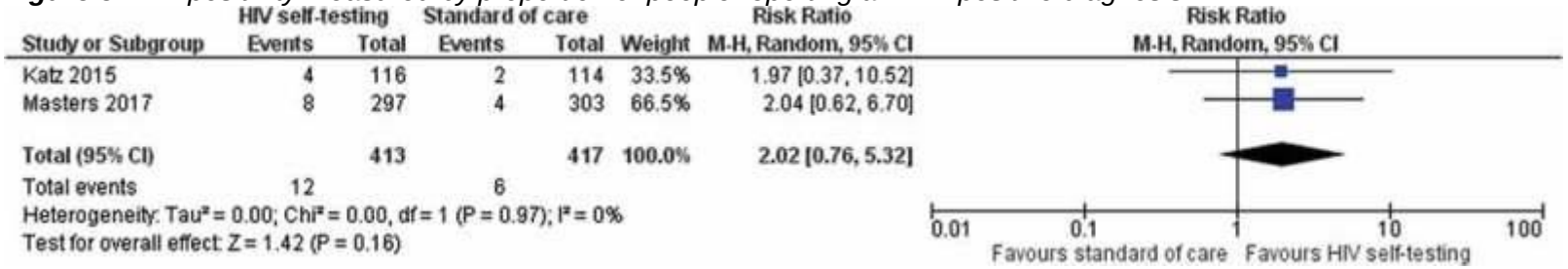


Figure 5: *HIV positivity measured by proportion of people reporting an HIV-positive diagnosis.*



3.4 Supplementary information

Appendix 1. *HIV self-testing: systematic review protocol*

Background

In July 2015, WHO published the first Consolidated Guidelines on HIV testing services. These guidelines outline the critical elements and recommendations essential for HIV testing services. Within these guidelines HIV self-testing was mentioned and outlined, but not fully recommended. Further guidance on HIV self-testing is planned for December 1 2016. In order to develop this guidance various systematic reviews of available evidence on HIV self-testing will be needed.

Definition

HIV self-testing is a process where a person who wants to know his or her HIV status uses a kit to collect a specimen, performs a test (generally a rapid diagnostic test or RDT), and interprets the test results; while self-testing cannot provide a diagnosis, and reactive test results must be confirmed by health workers through national HIV testing algorithms, the privacy afforded by self-testing may encourage more people to learn their HIV status. Self-testing programs can differ by the support available around self-testing, distribution mechanisms of test kits, and linkages to diagnostic testing and HIV services. There are also questions surrounding how HIV self-testing will be used and experienced by different users in different settings and in different social and relationship contexts.

PICO question

Should HIV self-testing be offered as an additional approach to deliver HIV testing services?

P: Populations receiving HIV testing services

I: HIV testing services that include self-testing

C: HIV testing services that do not include self-testing

O: Listed below

Primary Outcomes

(1) Uptake of HIV testing services that include self-testing (proportion of those offered HIV self-testing who accepted and completed self-test, also report the proportion of first-time testers who were offered HIV self-testing who accepted and completed self-test and reported no prior HIV test)

(2) Frequency of HIV testing (compare frequency of self-testers to frequency of standard testers, adjust comparison for reports among groups where re-testing at least annually is recommended)
(3) Social harm/adverse events (e.g., device-related issues, coercion, violence [including intimate-partner violence, violence from family members or community members, etc.], psycho-social harm, self-harm, suicide, stigma, discrimination, frequency of STI screening)

Secondary Outcomes

(4) Proportion of people who self-tested diagnosed HIV-positive (adjusted to exclude people aware of their HIV serostatus and on antiretroviral therapy (ART))
(5) Measurement of CD4 or viral load (comparing measurements of those with reactive self-test result and HIV-positive diagnosis by a healthcare provider to measurements of those diagnosed by healthcare provider at baseline or standard HIV testing services arm)
(6) Linkage to clinical assessment or ART following a reactive self-test result and HIV-positive diagnosis by a healthcare provider (among people who have a reactive HIV test result, percentage who reach this next stage of triage)
(7) Linkage to prevention visit after nonreactive test result (among people who have a nonreactive test result, percentage who reach prevention service, e.g. contraception, condoms, needle and syringe programmes, opiod substitution therapy, voluntary male medical circumcision, pre-exposure prophylaxis and post-exposure prophylaxis)
(8) Sexual risk behaviour (condom use/condomless sex/unprotected sex, STI, point-of-sex testing and number of sexual partners)

Inclusion criteria

To be included in the review, an article must meet the following criteria:

1) Study design that compares people who received HTS using self-testing to people who received HTS through another modality, or to no intervention (no HTS)
2) Measured one or more of the primary or secondary outcomes listed above
3) Published in a peer-reviewed journal or conference abstract

Stratifications

All outcomes will be stratified and presented by the following categories:

- Supervised (defined as direct support through in-person demonstration of how to perform self-test and follow-up support, counselling, referral and linkage to care)

- Unsupervised (defined as indirect support through video, instructions for use, package inserts, hotline or other information which provides counselling, support, referral and linkage to care)
- General populations (all adults)
- Adolescents and young people (ages 10-14, 15-19, and 15-24)
- Sex/Gender (males and females)
- Key populations (defined as men who have sex with men, sex workers, transgender people, people who inject drugs and people in prisons or closed settings)
- Past HIV testing frequency (particularly for the outcome of frequency of HIV testing)
- Partner type (ex: social harms from primary versus non-primary partners, test distribution to different types of partners, etc.)

No restrictions will be placed based on location of the intervention. No language restrictions will be used on the search. Articles in languages other than English will be translated where necessary.

Following the GRADE approach, if direct evidence for this PICO question is limited or non-existent, indirect evidence will be used instead, but downgraded for indirectness. Similarly, if evidence from randomized controlled trials is limited, evidence from non-randomized but controlled studies will be used instead, but also downgraded per the GRADE system. Finally, if evidence from peer-reviewed studies or conference abstracts is not available, the search will be broadened to include other grey literature (such as program evaluations that have not undergone peer review).

Search strategy

The following electronic databases will be searched through the search date of April 1, 2016 (and updated with a new search as of June 1, 2016: PubMed, CINAHL, Sociological Abstracts, PsycINFO, and EMBASE. Secondary reference searching will also be conducted on all studies included in the review. Further, selected experts in the field will be contacted to identify additional articles not identified through other search methods. We will also search for ongoing RCTs through clinicaltrials.gov, the WHO ICTRP, PACTR, and the Australian New Zealand Clinical Trials Registry.

We will also search the following conferences for relevant conference abstracts: International AIDS Conference (IAC), Conference on HIV Pathogenesis, Treatment, and Prevention (IAS), and Conference on Retroviruses and Opportunistic Infections (CROI). The IAC and IAS conference abstracts will be searched for all available years. For CROI, only the most recent conferences (2014, 2015 and 2016) will be searched as past conferences are inaccessible.

Search terms

The following search strategy will be adapted for entry into all computer databases. These search terms will be used both for the main systematic review (PICO question) and for the values and preferences review.

(HIV [tiab] OR “human immunodeficiency virus” [tiab]) AND (self-test [tiab] OR "self-testing" [tiab] OR “home-based test" [tiab] OR "home-based testing" [tiab] OR "home test" [tiab] OR "home testing" [tiab])

Only terms for self-testing will be used to search conference abstracts because all conference being searched are HIV-related and search functions are limited.

Screening abstracts

Titles, abstracts, citation information, and descriptor terms of citations identified through the search strategy will be screened by a member of the senior study staff. Full text articles will be obtained of all selected abstracts and two independent reviewers will assess all full-text articles for eligibility to determine final study selection. Differences will be resolved through consensus.

Citations identified through computer database searching will be initially screened into the following categories:

> **Yes** – Used when the article appears to meet the inclusion criteria for the primary review (PICO question).
>
> **Pull to check** – Used when the article may or may not meet the inclusion criteria, and the full text of the article must be reviewed before final decision about inclusion can be made.
>
> **No** – Used when the article clearly does not meet the inclusion criteria for the review and no further consideration is necessary.
>
> **Values and Preferences** – Used when the article does not meet the inclusion criteria for the main review (PICO question), but does meet criteria for the values and preferences review (described below).

Data extraction and management

Data will be extracted independently by two reviewers using standardized data extraction forms. Differences in data extraction will be resolved through consensus and referral to a senior study team member from WHO when necessary.

The following information will be gathered from each included study:

- Study identification: Author(s); type of citation; year of publication

- Study description: Study objectives; location; population characteristics; description of the type of HIV testing (for both self-testing and other testing arms); description of any additional intervention components; study design; sample size; follow-up periods and loss to follow-up
- Outcomes: Analytic approach; outcome measures; comparison groups; effect sizes; confidence intervals; significance levels; conclusions; limitations

For randomized trials, risk of bias will be assessed using the Cochrane Collaboration's tool for assessing risk of bias (Cochrane Handbook, chapter 8.5 – Higgins & Green, 2011). This tool assesses random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias) blinding of outcome assessment (detection bias), incomplete outcome data addressed (attrition bias), incomplete outcome data, and selective reporting (reporting bias). Methodological components of the studies will be assessed and classified as high or low risk of bias. For non-randomized trials but comparative studies, study rigor will be assessed using the Evidence Project 8-item checklist for intervention evaluations.

Data analysis

Data will be analysed according to coding categories and outcomes. Where there are multiple studies reporting the same outcome, meta-analysis will be conducted using random-effects models to combine odds ratios with the program Comprehensive Meta-Analysis (CMA). Data will be summarized in GRADE tables, summary of finding tables, and risk/benefit tables.

Values and preferences review

The same search terms will be used to search and screen for studies to be included in the values and preferences review. Studies will be included in this review if they present primary data examining people's preferences regarding self-testing. We will focus on studies examining the values and preferences of people who have used or potentially would use self-testing themselves, but we will also include studies examining the values and preferences of providers and other stakeholders. These studies can be qualitative or quantitative in nature, but must present primary data collection – think pieces and review articles will not be included. Values and preferences literature will be summarized qualitatively and will be organized by study design and methodology, location, and

population. We will also consider values and preferences around self-testing related to different partner types.

References

Higgins, J.P.T., & Green, S. (2011). *Cochrane Handbook for Systematic Reviews of Interventions.* Version 5.1.0. Available from: http://www.cochrane-handbook.org/. Accessed on: June 10, 2011.

Appendix 2. *Quality assessment for systematic review on HIV self-testing*

GRADE Methodology

All outcomes were selected based on relevance to the intervention and its implementation, which was determined in consultation with the WHO guideline development group (GDG). Using an electronic survey the GDG rated the outcomes on a scale of 1-9 to determine the critical outcomes (1 – 3 NOT IMPORTANT; 4 – 6 IMPORTANT; 7 – 9 CRITICAL).

All outcomes deemed critical were included in evidence profiles and influenced decision-making to determine the quality of evidence and strength of recommendation.

Table A2.1. *GDG ranking relative importance of study outcomes*

Outcome		Relative importance	Comment
1	Frequency of sexually transmitted infection (STI) screening	4	Important
2	Frequency of HIV testing	6	Important
3	Coercion	6	Important
4	Intimate-partner violence (IPV)	6	Important
5	Violence from family/community	6	Important
6	Psycho-social harm	6	Important
7	Stigma	6	Important
8	Discrimination	6	Important
9	Measurement of CD4 or viral load	6	Important
10	Number or proportion of STIs	6	Important
11	Number of sexual partners	6	Important
12	Point-of-sex testing	6	Important
13	Condom use/condomless sex	6	Important
14	HIV RDT/HIVST kit device-related issues	7	Critical
15	Self-harm	7	Critical
16	Linkage to prevention	7	Critical
17	Uptake of HIV testing	8	Critical
18	Suicide	8	Critical
19	Proportion of diagnosed HIV-positive	8	Critical
20	Linkage to further testing, clinical assessment or ART	9	Critical

Table A2.2. *GRADE table and quality assessment by study outcome*

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**HIV self-testing**	**Standard of care**	**Relative (95% CI)**	**Absolute**		
Uptake of HIV testing (follow-up at up to 6 months) (assessed with: meta-analysis using number randomised as denominators)												
3[1]	randomised trials	serious[2]	no serious inconsistency[3]	no serious indirectness[4]	no serious imprecision	none	777/987 (78.7%)	363/993 (36.6%)	RR 2.12 (1.51 to 2.98)	409 more per 1000 (from 186 more to 724 more)	⊕⊕⊕O MODERATE	CRITICAL
Uptake of HIV testing in male partners of women in antenatal care (follow-up at 3 months) (assessed with: meta-analysis using number of women randomised as denominator)												
2[5]	randomised trials	serious[6]	no serious inconsistency[7]	no serious indirectness	no serious imprecision	none	584/772 (75.6%)	254/778 (32.6%)	RR 2.33 (1.31 to 4.14)	434 more per 1000 (from 101 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL
Uptake of HIV testing among men who have sex with men (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	none[11]	193/215 (89.8%)	109/215 (50.7%)	RR 1.77 (1.54 to 2.04)	390 more per 1000 (from 274 more to 527 more)	⊕⊕⊕O MODERATE	CRITICAL
Uptake of HIV testing among 18 -25 years (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	67/72 (93.1%)	40/77 (51.9%)	RR 1.79 (1.43 to 2.24)	410 more per 1000 (from 223 more to 644 more)	⊕⊕OO LOW	CRITICAL
Uptake of HIV testing among age 26+ (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	126/143 (88.1%)	69/138 (50%)	RR 1.76 (1.48 to 2.1)	380 more per 1000 (from 240 more to 550 more)	⊕⊕OO LOW	CRITICAL
Uptake of HIV testing among most recent testers: > 4 tests in past 3 years (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	23/24 (95.8%)	22/30 (73.3%)	RR 1.31 (1.04 to 1.65)	227 more per 1000 (from 29 more to 477 more)	⊕⊕OO LOW	CRITICAL
Uptake of HIV testing among recent testers: 1 - 3 tests in past 3 years (follow-up at 6 months)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	HIV self-testing	Standard of care	Relative (95% CI)	Absolute		
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	113/121 (93.4%)	61/114 (53.5%)	RR 1.75 (1.46 to 2.08)	401 more per 1000 (from 246 more to 578 more)	⊕⊕OO LOW	CRITICAL
Uptake of HIV testing among non-recent testers: 0 tests in past 3 years (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	57/70 (81.4%)	26/71 (36.6%)	RR 2.22 (1.61 to 3.08)	447 more per 1000 (from 223 more to 762 more)	⊕⊕OO LOW	CRITICAL
HIV positivity (assessed with: confirmed HIV-positive diagnosis following HIV testing)												
2[13]	randomised trials	serious[14]	no serious inconsistency	no serious indirectness	very serious[15]	none	12/413 (2.9%)	6/417 (1.4%)	RR 2.02 (0.76 to 5.32)	15 more per 1000 (from 3 fewer to 62 more)	⊕OOO VERY LOW	CRITICAL
Frequency of HIV testing (range from 12 - 15 months) (Better indicated by higher values)												
2[16]	randomised trials	serious[9]	no serious inconsistency	no serious indirectness	serious[17]	none	275	263	-	MD 2.13 higher (1.59 to 2.66 higher)[18]	⊕⊕OO LOW	IMPORTANT
Frequency of HIV testing Risk Ratios (range from 12 - 15 months) (Better indicated by higher values)												
2[16]	randomised trials	serious[9]	no serious inconsistency	no serious indirectness	serious[17]	none	275	263	-	Rate Ratio 1.88 higher (1.17 to 3.01 higher)	⊕⊕OO LOW	IMPORTANT
Frequency of HIV testing among recent testers (tested =< 2 years) (follow-up 12 - 15 months; Better indicated by higher values)												
1[19]	randomised trials	serious[9]	no serious inconsistency[11]	no serious indirectness	no serious imprecision[20]	reporting bias[12]	147	140	-	Rate Ratio 2.23 higher (1.93 to 2.58 higher)	⊕⊕OO LOW	IMPORTANT
Frequency of HIV testing among non-recent testers (tested > 2 years) (follow-up 12 - 15 months; Better indicated by higher values)												
1[19]	randomised trials	serious[9]	no serious inconsistency[11]	no serious indirectness	serious	reporting bias[12]	30	24	-	Rate Ratio 5.54 higher (3.15 to 9.74 higher)	⊕OOO VERY LOW	IMPORTANT
STI diagnosis												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**HIV self-testing**	**Standard of care**	**Relative (95% CI)**	**Absolute**		
1[21]	randomised trials	serious[22]	no serious inconsistency[10]	no serious indirectness	serious[23]	reporting bias[24]	5/116 (4.3%)	12/114 (10.5%)	RR 0.41 (0.15 to 1.13)	62 fewer per 1000 (from 89 fewer to 14 more)	⊕OOO VERY LOW	IMPORTANT
Condomless sex (follow-up 6 months; assessed with non-concordant condomless anal intercourse)												
1[8]	randomised trials	serious[25]	no serious inconsistency	no serious indirectness	serious[26]	reporting bias[24]	53/215 (24.7%)	37/215 (17.2%)	RR 1.43 (0.98 to 2.08)	74 more per 1000 (from 3 fewer to 186 more)	⊕OOO VERY LOW	IMPORTANT
Condomless sex (follow-up 9 months; assessed with non-concordant condomless anal intercourse)												
1[21]	randomised trials	serious[25]	no serious inconsistency[10]	no serious indirectness	serious[27]	reporting bias[24]	21/116 (18.1%)	22/114 (19.3%)	RR 0.94 (0.55 to 1.61)	12 fewer per 1000 (from 87 fewer to 118 more)	⊕OOO VERY LOW	IMPORTANT
Condomless sex (follow-up 15 months; assessed with non-concordant condomless anal intercourse)												
1[21]	randomised trials	serious[25]	no serious inconsistency[10]	no serious indirectness	serious[27]	reporting bias[24]	28/116 (24.1%)	24/114 (21.1%)	RR 1.15 (0.71 to 1.85)	32 more per 1000 (from 61 fewer to 179 more)	⊕OOO VERY LOW	IMPORTANT
Adverse events												
1[28]	randomised trials	serious[25]	no serious inconsistency[10]	no serious indirectness	very serious[27]	reporting bias[24]	1/297 (0.34%)	1/303 (0.33%)	RR 1.02 (0.06 to 16.24)[29]	0 more per 1000 (from 3 fewer to 50 more)	⊕OOO VERY LOW	IMPORTANT

[1] Masters et al., 2017: Male partners of women attending antenatal and postpartum care in Kenya; Gichangi et al., 2016: Male partners of women attending antenatal care in Kenya; and Wang et al., 2016: Men who have sex with men in Hong King SAR of the People's Republic of China

[2] Risk of Bias: We down-graded once. The outcome of HIV testing was based on self-report in two trials and the risk of detection bias cannot be excluded. In Wang 2016 self-report of testing was validated against clinical records. Performance bias may be operational across trials as neither providers nor participants were blinded.

[3] Inconsistency: We did not downgrade for inconsistency despite a high statistical heterogeneity (Heterogeneity: $Tau^2 = 0.08$; $Chi^2 = 32.88$, df = 2 ($P < 0.00001$); $I^2 = 94\%$). This heterogeneity was driven by the Gichangi trial which we were unable to explain. However the effects were beneficial across all trials and hence we did not downgrade.

[4] Indirectness: We did not down-grade for indirectness but note that two trials (Gichangi and Masters) were conducted as couples testing trials (female participants were given HIVST kits to give to or self-test with their male partners) and Wang which randomized men who have sex with men presenting with no HIV testing in the previous 6 months to HIVST or control.

[5] Masters et al., 2017: Male partners of women attending antenatal and postpartum care in Kenya; Gichangi et al., 2016: Male partners of women attending antenatal care in Kenya

[6] Risk of Bias: We down-graded once. The outcome of HIV testing was based on self-report in two trials and the risk of detection bias cannot be excluded. Performance bias may be operational across trials as neither providers nor participants were blinded.
[7] Inconsistency: We did not downgrade for inconsistency despite a high statistical heterogeneity ($Chi^2 = 28.16$, df = 1 ($P < 0.00001$); $I^2 = 96\%$ This heterogeneity was driven by the Gichangi trial which we were not able to explain. However the effects were beneficial across all trials and hence we did not downgrade.
[8] Wang et al., 2016: Men who have sex with men in Hong Kong, SAR
[9] Risk of bias: We down-graded once for risk of bias. The outcome of HIV testing was validated but performance bias cannot be excluded as neither the participants nor the providers could be blinded.
[10] Inconsistency cannot be appraised in a single study.
[11] These results are from a single trial only and generalizability to other settings among men who have sex with men may be limited. However, the beneficial effects are supported by trials in women attending antenatal and postpartum care services (Gichangi and Masters),
[12] These results are from a sub-group of a single trial and should be viewed with caution.
[13] Katz et al., 2015: Men who have sex with men in the United States; Masters et al., 2017: Male partners of women attending antenatal care in Kenya.
[14] Risk of bias: We down-graded once. The HIV diagnosis would be validated but the risk of performance bias cannot be excluded given that providers and participants could not be blinded in either study.
[15] Imprecision: The event rate is very low and the confidence interval is very wide.
[16] Jamil et al., 2015: Men who have sex with men in Australia; and Katz et al., 2015: Men who have sex with men in the United States
[17] Imprecision: Down-graded once as the confidence interval is wide.
[18] Standard deviations were calculated from the 95% confidence interval provided.
[19] Jamil et al., 2015: Men who have sex with men in Australia
[20] Imprecision: The confidence interval is not wide, but the results are from a sub-group and should be viewed with caution.
[21] Katz et al., 2015: Men who have sex with men in the United States
[22] Risk of bias: We downgraded once. The STI diagnosis would be validated but the risk of performance bias cannot be excluded given that providers and participants could not be blinded.
[23] Imprecision: We down-graded once. The event rate is very low in both groups. The estimate crosses both the line of no effect and appreciable benefit.
[24] These results are from a single trial only.
[25] Risk of Bias: We down-graded once. The outcome was by self-report and performance bias could not be excluded due to a lack of blinding.
[26] Imprecision: We down-graded once. The event rate is very low in both groups and the confidence interval is wide.
[27] Imprecision: We down-graded once. The event rate is very low in both groups
[28] Masters et al., 2017: Women attending antenatal and postpartum care in Kenya
[29] The adverse event in the HIVST arm was not actually related to HIVST per se. A participant in the intervention arm reported experiencing verbal/physical abuse from her husband because she agreed to participate in the study without consulting him. She left the home for a period of about three weeks, after which she returned home. When a Research Assistant communicated with the participant at a two-month follow-up, the participant reported that all was well between her and her husband. One participant from the control arm also reported (IPV. Neither participant experienced IPV in the 12 months prior to the intervention. (Additional data provided by authors via email.)

Figure A2.1. *Cochrane Collaboration Risk of Bias Assessment, by study*

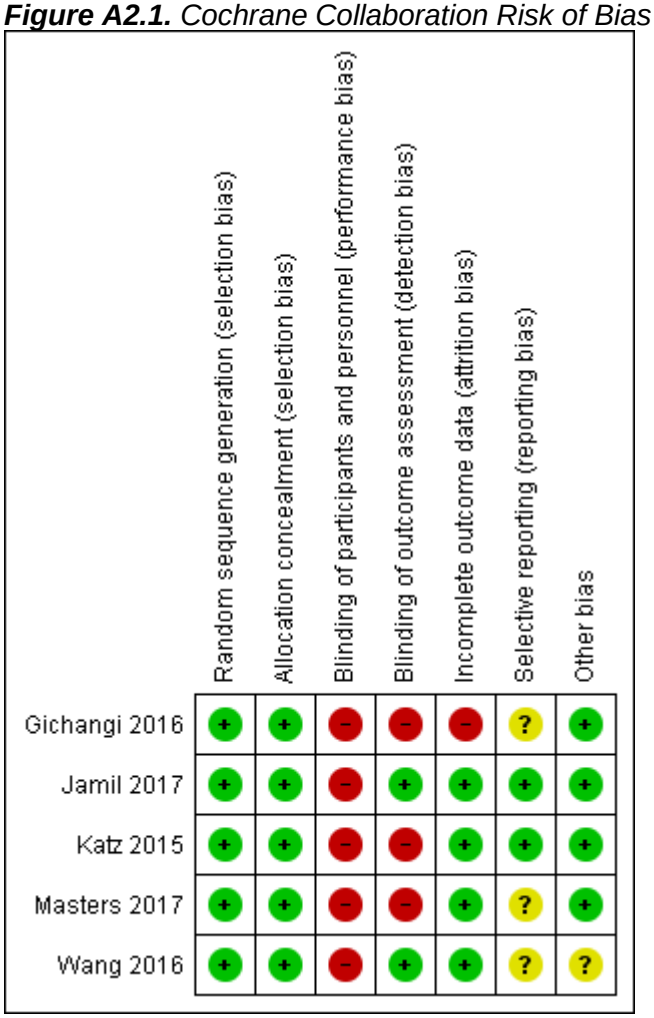


Table A2.3. *Cochrane risk of bias of all included studies (n=5)*

Author / Year	Jamil et al., 2017
Random sequence generation (selection bias)	**Low-risk** Computer-generated randomisation codes, arms were stratified by frequency of testing (recent and non-recent testers)
Allocation concealment (selection bias)	**Low-risk** Allocation was concealed using sealed opaque envelopes which were handled by a research assistant not associated with the trial.
Blinding of participants and personnel (performance bias)	**High-risk** It was reported that given the nature of the intervention, it is not feasible to blind the recruitment staff and participants to their study arm allocation. Although participants were not blinded to study arm allocated, it seems unlikely this would have affected study results.
Blinding of outcome assessment (detection bias)	**Low-risk** It was reported that the statistician analysing RCT data was blinded to the study arms **Primary outcome: mean number of HIV tests per person over 12 months.** Secondary outcomes: mean number of STI (chlamydia, gonorrhea, syphilis) tests per person; reasons for HIV testing; and the acceptability of HIVST. Data was provided by self-report. All episodes of HIV and STI testing during the follow-up period for each participant were manually extracted from the patient management systems at their respective recruitment sites by a data manager blinded to study arm allocation. If participants reported HIV/STI testing at clinics other than their recruitment site, those clinics were contacted to obtain records of all episodes of HIV and STI testing during the follow-up period. Only facility-based tests with a valid clinic record were included in HIV/STI testing frequency. If a participant reported using more self-testing kits than had been provided according to dispensing logs, the difference was deducted from the self-testing frequency.
Incomplete outcome data addressed (attrition bias)	**Low-risk** It was reported that retention was high across both study arms (98% in HIVST group and 92% in standard of care group). Investigators reported using an intent-to-treat analysis at 12 months.
Selective reporting (reporting bias)	**Low-risk** Study reported on all outcomes stated in the study protocol, with the exception of the second phase of the study which will offer all those in the facility-based HTS arm HIVST for 12-months.
Other bias	**Low-risk** None identified or noted.

Author / Year	Katz et al., 2015
Random sequence generation (selection bias)	**Low-risk** Computer-generated random number and using blocks of random size. Randomization did not result in complete balance between study arms.
Allocation concealment (selection bias)	**Low-risk** Block sizes were not disclosed to study staff involved in recruitment, enrolment, group assignment, or other participant interaction to ensure concealment. The randomization schedule will be performed by the study statistician, and group assignment will be enclosed in sequentially numbered, sealed envelopes by university staff not involved in the study. Participants will be asked to open the next envelope in sequence and read the group assignment to study staff.
Blinding of participants and personnel (performance bias)	**High-risk** It was reported that given the nature of the intervention, it is not feasible to blind the recruitment staff and participants.
Blinding of outcome assessment (detection bias)	**High-risk** **Primary outcome: HIV testing frequency over 15 months – if self-report then high risk for this outcome**. Secondary outcomes: self-reported sexual risk behaviors over 6, 9, 12 and 15 months of follow-up; bacterial STI infections at 15 months (syphilis, gonorrhea, and chlamydial infection). Study relied on self-report of all outcomes by study participants.
Incomplete outcome data addressed (attrition bias)	**Low-risk** It was reported that retention was high across both study arms (84% (98/116) in HIVST group and 87% (99/114) in standard of care group. Investigators reported using an intent-to-treat analysis at 15 months.
Selective reporting (reporting bias)	**Low-risk** Study reported on all outcomes stated in the study protocol.
Other bias	**Low-risk** None identified or noted.

Author / Year	Gichangi et al., 2016
Random sequence generation (selection bias)	**Low-risk** The study had three arms into which participants were randomly assigned. Each study arm was allocated a different colour: Arm 1 was yellow colour, arm two green and arm three blue. Coloured stickers amounting to each facility's sample size were labelled and put in envelopes, sealed and completely mixed up.
Allocation concealment (selection bias)	**Low-risk** Once study participants were consented, they were asked to pick an envelope and open. The research assistant checked the label colour to determine which study arm the respondent fell into.
Blinding of participants and personnel (performance bias)	**High-risk** Study staff was not blinded to knowing the study group to which each participant was randomized and participants knew what they were being offered although the study did not explain to them about the group they belonged to and what each other group was getting.
Blinding of outcome assessment (detection bias)	**High-risk** **Primary outcome**: male partner HIV testing, by any means, within 3-months after ANC client enrollment. Relied on self-reported outcomes by female participants and male participants who tested for HIV in any of the study arms. Used kappa statistic to compare variation between responses between male and female participants.
Incomplete outcome data addressed (attrition bias)	**High-risk** It was reported that retention of female participants was high across all study arms: 86% (408/471) arm 1; 83% (387/467) arm 2; 89% (422/475) HIVST intervention arm. Male partner follow-up was also high 80% (375/471) arm 1; 76% (362/475) arm 2; 84% (396/475) HIVST intervention arm; both study arms. Investigators reported using an intent-to-treat analysis at 3-months.
Selective reporting (reporting bias)	**Uncertain-risk** Study reported on primary outcomes stated, but study protocol was not available for full review
Other bias	**Low risk** **None identified or noted**

Author / Year	Masters et al., 2016
Random sequence generation (selection bias)	**Low-risk** Computer-generated random number and using block size of 20
Allocation concealment (selection bias)	**Low-risk** Assignment contained in sealed envelopes that were then presented to participants by research assistants
Blinding of participants and personnel (performance bias)	**High-risk** Not blinded. After randomization it was not possible to blind given the nature of the intervention and the comparison groups.
Blinding of outcome assessment (detection bias)	**High-risk** **Primary outcome:** women's report of whether their partner had an HIV test within 3-months of enrollment. **Secondary outcomes**: discussed HIV testing with partner; couples testing; learned partner's HIV status; report of IPV. **Additional outcomes:** sexual behaviour and decision making (such as condom use); adverse reaction to a positive or discordant test result. Study primarily relied on self-reported of outcomes from women of male partners who self-tested. Confirmatory testing following HIVST was validated by tracking number of referral vouchers at study facilities.
Incomplete outcome data addressed (attrition bias)	**Low-risk** It was reported that retention was high across both study arms. Follow-up was completed for 95% of study participants (570/600) and was high in both HIVST group 96% and 94% in comparison group. Investigators reported using an intent-to-treat analysis at 3-months.
Selective reporting (reporting bias)	**Unclear-risk** Study reported on nearly all outcomes in the protocol with the exception of those in the intervention group who received confirmatory HIV testing; and sexual behaviour and decision-making outcomes.
Other bias	**Low-risk** None identified or noted.

Author / Year	Wang et al., 2016
Random sequence generation (selection bias)	**Low-risk** Participants were recruited by convenient sampling and then randomly allocated into the intervention group and the control group by having sealed opaque envelops drawn by the research assistant. Block randomization with block size of eight was used.
Allocation concealment (selection bias)	**Low-risk** Participants were randomly allocated into the intervention group and the control group by having sealed opaque envelops drawn by the research assistant.
Blinding of participants and personnel (performance bias)	**High-risk** The allocation was not blinded to participants and personnel.
Blinding of outcome assessment (detection bias)	**Low-risk** **Primary outcome:** proportion increase in HIV testing over 6-months. Validation of self-reported data was conducted using clinical records. Other outcomes, including participant characteristics collected at baseline, were only measured by self-report. **Secondary outcome:** condomless anal intercourse with men at 6-months and report of multiple male partnerships at 6-months.
Incomplete outcome data addressed (attrition bias)	**Low-risk** A total of 857 prospective participants were approached (online: 493, venues: 347, and referral: 17). Out of 583 eligible MSM being invited (online: 224; venues: 347; referral: 17), 153 (26.2%) declined to participate in the study; 430 (73.8%) provided verbal informed consent and complete the baseline survey and the intervention (online: 194; venues: 219; referral: 17). Following enrollment, it was reported that retention was high across both study arms 86.5% in HIVST group and 85.1% for control group. Investigators reported using an intent-to-treat analysis at 6-months.
Selective reporting (reporting bias)	**Uncertain-risk** Full Study protocol was not available for full review of all study outcomes.
Other bias	**Unclear-risk** Health promotion was limited to MSM who had access to online face-to-face communication tools.

Table A1.4 *PRISMA checklist*

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Title page, Abstract, 3
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-23
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	4, Appendix 1
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-11, Appendix 2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	3-4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	4 Appendix 1
Study selection	9	State the process for selecting studies (i.e. screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4-5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5 Appendix 2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	4-5
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	5, Appendix 2
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	5 Appendix 2
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A

Section/topic	#	Checklist item	Reported on page #
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	5-6 Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6-11 Table 1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Appendix 2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Figure 2 –pg 12 Figure 3a-pg 15 Figure 3b-pg 16 Figure 4- pg 17 Appendix 2
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	12-17
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Appendix 2
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	12, 16-17
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	19-22
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	22-23
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	23-24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	24

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	1603327	**Title**	Ms
First Name(s)	Cheryl		
Surname/Family Name	Johnson		
Thesis Title	Investigating Men's Preferences for HIV Self-Testing and Linkage: Exploring Strategies for Policy Impact		
Primary Supervisor	Professor Liz Corbett		

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

SECTION B – Paper already published

Where was the work published?	BMC Public Health		
When was the work published?	May 2020		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	No		
Have you retained the copyright for the work?*	**No**	Was the work subject to academic peer review?	**Yes**

*If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	With colleagues in WHO I conceived the research question, wrote the protocol and USAID, I motivated the inclusion of and helped draft questions on HIV self-testing to be included in the DHS HIV questionnaire HIV self-testing (optional) module from 2016 onwards https://dhsprogram.com/data/Guide-to-DHS-Statistics/Self-Testing_for_HIV.htm. For this paper, I built on that, conceived the research questions and obtained the DHS datasets from Malawi and Zimbabwe. I wrote a statistical analysis plan with Prof Corbett and then led the data analysis and interpretation. I drafted and wrote the first draft of the manuscript.

SECTION E

Student Signature	Cheryl Johnson [redacted]
Date	13 August 2022

Supervisor Signature	Liz Corbett [redacted]
Date	13 August 2022

4.0 Cross-sectional survey data analysis

4.1 Introduction

Cross-sectional survey data analysis was undertaken to investigate sociodemographic factors and sexual risk behaviours associated with previously testing for HIV, and past use, awareness of, and future willingness to self-test. Responses from the first cross-sectional Demographic and Health Surveys to include HIVST questions in Malawi and Zimbabwe were pooled and analysed using univariable and multivariable logistic regression. Key findings were that many Malawian and Zimbabwean men had never tested for HIV and that HIVST awareness and experience was very low. Willingness to self-test was high among Zimbabwean men, especially older men with moderate-to-high HIV-related sexual risk.

Tables and figures are at the end. All supplemental material is located in Appendix 1.

This data analysis was submitted to BMC Public Health in January 2020 and published in May 2020. It is described as published below.

4.2 Cross-sectional survey data analysis paper

Title: Use and awareness of and willingness to self-test for HIV: an analysis of cross-sectional population-based surveys in Malawi and Zimbabwe

Authors: Cheryl Johnson[1,2*], Melissa Neuman[3], Peter MacPherson[4,5], Augustine Choko[2,4], Caitlin Quinn[1], Vincent J. Wong[6], Karin Hatzold[7], Rose Nyrienda[8], Getrude Ncube[9], Rachel Baggaley[1], Fern Terris-Prestholt[10] and Elizabeth L. Corbett[2,4]

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Abstract

Background: Many southern African countries are nearing the global goal of diagnosing 90% of people with HIV by 2020. In 2016, 84 and 86% of people with HIV knew their status in Malawi and Zimbabwe, respectively. However, gaps remain, particularly among men. We investigated awareness and use of, and willingness to self-test for HIV and explored sociodemographic associations before large-scale implementation.

Methods: We pooled responses from two of the first cross-sectional Demographic and Health Surveys to include HIV self-testing (HIVST) questions in Malawi and Zimbabwe in 2015–16. We investigated sociodemographic factors and sexual risk behaviours associated with previously testing for HIV, and past use, awareness of, and future willingness to self-test using univariable and multivariable logistic regression, adjusting for the sample design and limiting analysis to participants with a completed questionnaire and valid HIV test result. We restricted analysis of willingness to self-test to Zimbabwean men, as women and Malawians were not systematically asked this question.

Results: Of 31,385 individuals, 31.2% of men had never tested compared with 16.5% of women ($p < 0.001$). For men, the likelihood of having ever tested increased with age. Past use and awareness of HIVST was very low, 1.2 and 12.6%, respectively. Awareness was lower among women than men (9.1% vs 15.3%, adjusted odds ratio [aOR] = 1.55; 95% confidence interval [CI]: 1.37–1.75), and at younger ages, and lower education and literacy levels. Willingness to self-test among Zimbabwean men was high (84.5%), with greater willingness associated with having previously tested for HIV, being at high sexual risk (highest willingness [aOR = 3.74; 95%CI: 1.39–10.03, $p < 0.009$]), and being ≥25 years old. Wealthier men had greater awareness

of HIVST than poorer men ($p < 0.001$). The highest willingness to self-test (aOR = 3.74; 95%CI: 1.39–10.03, $p < 0.009$) was among men at high HIV-related sexual risk.

Conclusions: In 2015–16, many Malawian and Zimbabwean men had never tested for HIV. Despite low awareness and minimal HIVST experience, willingness to self-test was high among Zimbabwean men, especially older men with moderate-to-high HIV-related sexual risk. These data provide a valuable baseline against which to investigate population-level uptake of HIVST as programmes scale up. Programmes introducing, or planning to introduce, HIVST should consider including relevant questions in population-based surveys.

Background

Both Malawi and Zimbabwe have made tremendous progress toward the “first 90” global target of diagnosing 90% of people with HIV. In 2016, estimates showed that 84% of people with HIV in Malawi and 86% in Zimbabwe were aware of their status [1]. By end-2018, 90% of all people with HIV had been diagnosed: 940000 and 1.3 million people in Malawi and Zimbabwe, respectively [1]. As a result, reaching the remaining people with HIV who do not know their status is becoming costly and challenging, with national programmes reporting declining numbers of people with HIV diagnosed through HIV testing services [2, 3]. Global and national priorities now include defining sustainable approaches that maintain these high rates of testing coverage, while reaching individuals and groups still in need of HIV testing, prevention and treatment.

Across southern Africa, men are less well served by HIV programmes than women, less likely to have ever tested [4] and more likely to develop advanced HIV disease, reflecting late diagnosis and/or treatment initiation [5]. Men have fewer opportunities for HIV testing compared to women, as well as social–cultural, economic and systemic barriers that reduce access to and uptake of services [6, 7].

HIV self-testing (HIVST) is recommended by the World Health Organization (WHO) [2] and is a key intervention for reaching populations who may not test otherwise, particularly men [8]. Results from multiple evaluations show that HIVST has a high uptake, can increase the population coverage of HIV testing, and has high safety and acceptability globally [9, 10]. As of July 2019, this recommendation has been taken up globally, with nearly 7 million HIVST kits procured by major donors, and 77 countries reporting that they have an HIVST policy, 38 of which are fully implementing self-testing [11, 12].

Both Malawi and Zimbabwe were early adopters of self-testing, with pilot studies starting between 2010 and 2015 [13, 14]. These pilots were then followed by the development of national policies and initiation of large-scale implementation in mid-2015 under the STAR (Self-Test AfRica) Initiative [15]. Since then, multiple evaluations of HIVST in each country have shown community- and facility-based HIVST, as well as partner-delivered HIVST, to be feasible and effective ways of reaching first-time testers, men, young people, as well as partners of people with HIV [10, 16,17,18,19]. Recent mathematical modelling suggests that HIVST can also be cost-effective with appropriate targeting of men in southern Africa among other priority groups [20, 21].

As both countries move toward broader scale up of self-testing, we used Demographic and Health Survey (DHS) data from 2015 to 16 to analyse population-level awareness and use of, and willingness to self-test prior to large-scale implementation [22, 23]. These questions were initially optional additions to the DHS questionnaire in 2015. As such, the objective of this study was to provide a point of comparison with future evaluations post national scale up, as well as to inform future implementation of HIVST. We assessed early implementation of HIVST questions in population-based surveys, and associations with awareness and use of, and future willingness to, self-test.

Methods

We obtained population-based survey data from the 2015–16 Malawi and Zimbabwe DHS with standard permissions from DHS and ICF International [22, 23]. These provide data from a representative sample of men (15–54 years) and women of reproductive age (15–49 years) living in Malawi and Zimbabwe, with linked laboratory HIV test results. We limited our analysis to participants who had completed interviewer-administered questionnaires, provided blood specimens for HIV testing, and had a valid result from this HIV test.

Our main outcomes of interest were self-reported by survey respondents: ever testing for HIV, awareness and use of HIVST, and willingness to self-test in the future. Willingness to self-test was asked only in Zimbabwe, and included only in the male questionnaire. The complete survey questionnaires are accessible on the DHS website: https://dhsprogram.com/.

Independent variables

The choice of independent covariates was informed by the literature on factors influencing testing for HIV and adaptation of the simplified hierarchical framework for HIV testing (including self-testing) among men in sub-Saharan Africa (see Fig. 1). We also pre-specified a stratified analysis by HIV testing history to explore differences in awareness and use of, and willingness to, self-test for HIV.

Independent variables used in the analysis included country (i.e. Malawi or Zimbabwe), sex (i.e. male or female), household wealth (i.e. measured by standard quintiles), age (i.e. measured by five-year age bands from 15 to 45 years and 45+ years), education (i.e. measured by secondary education or lower), literacy (i.e. ability to read, or not read, a full sentence), employment (i.e. actively working in the past 7 days), marital status (i.e. married or cohabiting), and HIV status reported during the survey (i.e. HIV-positive or HIV-negative). A three-category HIV-related sexual risk variable was defined from reported sexual activity (i.e. measured by sexual activity, or inactivity, in the past 4 weeks), and the following high-risk exposures in the previous 12 months: multiple (i.e. ≥2) partners; any paid sex (asked to men); having received gifts, cash or other compensation in exchange for sex (asked to women); and having a sexually transmitted infection (STI). Individuals with one or more of these risk variables were classified as “high-risk”. The remaining respondents reporting no other risk exposures were classified as “moderate risk” if sexually active in the past 4 weeks and “low-risk” if reporting no sexually activity in the past 4 weeks.

Data analysis

We used Stata version 11 for analysis (College Station, Texas). We set standard country-specific sampling and cluster weights provided by DHS using the survey (svy) commands. We excluded participants with missing data for outcomes or independent variables from the analysis.

As independent variables were all categorical, we reported baseline characteristics as proportions. We selected variables for inclusion in multivariable models by the putative causal framework (Fig. 1), and by investigating effect modification and collinearity. Univariable and multivariable analyses used logistic regression. We calculated p-values across age, wealth and HIV-related sexual risk using the Wald test.

We investigated associations between independent and outcome variables using univariable odds ratios (ORs) with 95% confidence intervals (CI). Before multivariable analysis, we explored confounding and collinearity between independent variables by investigating associations between variables for all those with significant associations with any given outcomes. We explored potential effect modification [24] using stratified analyses by sex, HIV status, previous HIV testing history and HIV-related sexual risk category.

Results

Baseline characteristics

We included 31,385 survey respondents reporting on HIV testing history: 14,911 and 16,474 records from Malawi and Zimbabwe, and 14,027 and 17,358 among men and women, respectively (Table 1). Of these, a total of 24,683 individuals were asked about HIVST, and 6702 (21.4%, n = 31,385) not asked. An additional 15 individuals (0.06%, n = 24,683) asked about HIVST had missing data related to questions on sexual activity used to determine HIV-related sexual risk.

A total of 78.6% and 75.4% of people reported ever having tested for HIV in Zimbabwe and Malawi, respectively ($p < 0.001$). More women compared to men (83.5% vs 68.8%; $p < 0.001$), and more urban compared to rural residents (79.9% vs 75.9%; $p < 0.001$) had tested previously. A larger proportion of those never tested were 15–24 years compared to those who were ≥ 25 years (see Table 1).

The proportion of people who had ever self-tested was 1.2% and similar in both countries. However, while overall 12.6% had awareness of HIVST, it was greater in Zimbabwe compared to Malawi (14.5% vs 11.4%; $p < 0.001$) and among men compared to women (15.3% vs 9.1%; $p < 0.001$) (Table 1). Among the respondents, those with greater awareness of self-testing were ≥ 30 years of age (≥30 years: 21.1% vs < 30 years: 9.1%; $p < 0.001$), wealthier (richest: 22.8% vs poorest: 6.4%; $p < 0.001$) and those with higher education levels (at least secondary education: 17.8% vs primary education or less: 7.5%; $p < 0.001$) than those aged < 30 years, those who were poorer and had lower education levels. Willingness to self-test could be assessed only among 7372 Zimbabwean men (48 men had missing data on willingness), as only men were asked about willingness to self-test, and this question was not included in the Malawi DHS questionnaire.

Most Zimbabwean men (84.5%) were willing to self-test (Supplementary Table S1 includes baseline characteristics of Zimbabwean men on willingness to self-test, 2015–16). Men aged ≥25 years reported greater willingness to self-test than men aged < 25 years (88.7% vs 78.8%; p < 0.001). High-risk men also reported greater willingness to self-test than low-risk men (78.8% vs 63.5%; p < 0.001). Most men willing to self-test had tested in the past 12 months (88.5%). However, 86.4% of the men who had not tested for HIV in the previous two or more years were also willing to self-test.

Ever testing for HIV

Age, HIV status and HIV-related sexual risk appeared to modify effects in the multivariable analysis across a number of variables (Table 2). Collinearity affected the results of multivariable analysis, notably between age and HIV-related sexual risk, marital status and HIV-related sexual risk, age and education level, and education level and literacy.

Use and awareness of self-testing

A complete analysis of ever self-testing is shown in supplementary Table S2. Table 3 provides outcomes from the univariable and multivariable analyses for awareness of HIV self-testing.

In the multivariable analysis, men aged 30–34 years had greater odds of past self-testing use compared to younger men (age 15–19 years) (aOR = 2.89; 95%CI: 1.47–5.68, p < 0.002) (TableS2). Across wealth quintiles, being wealthier was also associated with previous self-testing (p < 0.001), with the wealthiest individuals having the greatest odds of past self-testing (aOR for richest vs poorest = 3.59; 95%CI: 1.79–7.18, p < 0.001).

In the multivariable analysis, respondents in Malawi and those from a rural setting were less likely to be aware of HIVST compared with Zimbabweans and urban participants (Table 3). However, the following variables were significantly associated with being aware of HIVST: being male (male vs female: aOR = 1.55; 95%CI: 1.37–1.75, p < 0.001), aged 15–19 years (when compared with those aged 25–29 years: aOR = 1.76; 95%CI: 1.43–2.17, p < 0.001 and aged 35–39 years: aOR = 1.69; 95%CI: 1.34–2.12, p < 0.001), wealthier (wealthiest vs poorest: aOR = 3.03; 95%CI: 2.46–3.73, p < 0.001), having employment (actively working vs not actively working: aOR = 1.25; 95%CI: 1.12–1.42, p < 0.001), being literate (literate vs illiterate:

aOR = 1.17; 95%CI: 1.01–1.36, p < 0.035) and having previously tested for HIV (ever tested vs never tested: aOR = 1.89; 95%CI: 1.65–2.17, p < 0.001).

Willingness to self-test among Zimbabwean men

The relationship between willingness to test and socioeconomic variables (wealth and actively working) and HIV status substantially differed according to both high and low HIV-related sexual risk (Table 4): see, for example, univariable OR for HIV status and employment. Thus, we adapted our planned multivariable analysis to account for effect modification between HIV-related sexual risk categorization and socioeconomic variables. On multivariable analysis, men with high HIV-related sexual risk behaviours were more likely than low-risk men to express willingness to self-test if they were also from higher socioeconomic quintiles, not working, in rural settings and had tested previously (interaction terms: socioeconomic status, p = 0.066; rural residence, p = 0.071; employment p = 0.003; literacy, p = 0.225; married, p = 0.401; aware of self-test, p = 0.605; previous testing, p = 0.001; and HIV status p = 0.162).

On multivariable analysis of men at high HIV-related sexual risk, willingness to self-test increased with age (p = 0.030), with the strongest association for those aged 35–39 years compared to those aged 15–19 years (aOR = 4.87; 95%CI: 2.14–11.07, p < 0.001). Similarly, willingness to self-test among men with high HIV-related sexual risk increased in rural settings (rural vs urban: aOR = 3.56, 95%CI: 1.61–7.90, p = 0.002) and with greater wealth quintiles (wealthiest vs least wealthy: aOR = 3.74, 95%CI: 1.39–10.53, p = 0.009).

While actively working men with high HIV-related risk were less willing to self-test (actively working vs not actively working: aOR: 0.57, 95%CI: 0.34–0.95, p = 0.030), actively working low-risk men were more willing to self-test than when not actively working (aOR 1.41; 95%CI: 1.13–1.77, p = 0.003). The association with previous testing and willingness to test was also more pronounced for low-risk men (ever tested vs never tested: aOR 1.48; 95%CI: 1.18–1.85, p < 0.001) than high-risk men (ever tested vs never tested: aOR 1.20; 95%CI: 0.76–1.90, p = 0.435), while associations with age (p = 0.106) and wealth (p = 0.102) were less pronounced than for high-risk men (Table 4, described above).

We additionally conducted a stratified analysis to investigate whether willingness to self-test varied by past HIV-testing behaviour (i.e. previously tested or not) (see supplementary Table S3). Patterns of willingness to self-test were similar for the 2437/7372 (33.1%) men who had never previously tested as for those with at least one past HIV test, with greater willingness in older men.

Discussion

The main findings from this analysis of 2015–16 survey data captured immediately before HIVST implementation in Malawi and Zimbabwe were that awareness and lifetime use of self-testing were low, with 12.6% of respondents being aware of self-testing and 1.2% having ever self-tested for HIV. Willingness to self-test was high, although this question was asked only of male Zimbabweans, with 84.5% respondents reporting themselves willing, including 30.4% of all previously untested men. Self-testing appeared to appeal most strongly to older men and those with high-to-moderate HIV-related sexual risk. The highest willingness to self-test was in men aged 35–39 years and those in rural settings, where having never previously tested for HIV was more common than in urban settings. Factors independently associated with greater awareness of HIVST included men, urban residence, and literacy; with many of these same factors also associated with having tested for HIV at least once in this analysis of 2015–16 data. Poorer and unemployed individuals were less likely to be aware of self-testing.

Despite significant gains and scale up of HIV testing in both Malawi and Zimbabwe, men continue to be missed [1, 2]. According to recent “first 90” estimates in sub-Saharan Africa, the absolute number of men with HIV aged ≥25 years are much less likely to know their HIV-positive status than women overall and younger men [25]. As the median age of all people with HIV continues to increase [26], identifying and scaling-up strategies that appeal to older age groups will be needed, especially older men and those at high risk. Greater efforts are needed to roll out evidence-based HIVST approaches to reaching men, such as through health facilities and secondary distribution from female partners attending antenatal care in high HIV-burden settings, or through networks of other high-risk sexual, drug injecting or social contacts, including those with HIV [9, 16, 27, 28].

Considering the high willingness to self-test in high-risk men in rural areas, additional community outreach strategies may be needed. HIVST in workplaces and through faith-based organizations should also be considered, as early programmatic data suggest it may be particularly useful for reaching older men [29]. However, more focused programmatic efforts and communication strategies for workplace HIVST may be needed, as in contrast to low-risk men, high-risk men who were working were less willing to self-test. Further evaluation is needed to understand the utility of HIVST through formal and informal workplace programmes and how

well they can reach high-risk men. It will be important to assess differences in HIVST awareness, use and willingness among older and higher-risk men in future surveys.

The importance of high willingness to self-test among older Zimbabwean men, including those with higher risk factors, should not be underestimated. This challenges perceptions that men may not want to test or are afraid to test for HIV and underscores the importance of providing more opportunities and HIV testing options that are acceptable to men. As reported in a recent analysis among never tested men in sub-Saharan Africa, nearly all those offered HIV testing in the survey accepted it and learnt their results [4].

Since these surveys, HIVST, alongside conventional testing, has been rapidly scaled up, notably so for Malawi and Zimbabwe. Between May 2015 and July 2017, the STAR Initiative alone distributed 172,830 and 265,091 HIVST kits in Malawi and Zimbabwe, respectively [10]. Following publication of the WHO guidelines and WHO prequalification of four HIVST products, as well as multiple large-scale implementation studies [2, 30], volumes continue to increase annually, with latest estimates suggesting that between 2017 and 2020, with existing donor support, both countries will have procured at least 4 million self-testing kits [12].

High willingness to self-test in Malawi and Zimbabwe has also been underscored by the observed high uptake in community-based HIVST interventions. Uptake by 45–75% was reported by end-line surveys between 2016 and 2019 in three population-level cluster randomized trials in rural communities [18, 19, 31]. In 2017, a survey following community-based HIVST kit distribution in rural Zimbabwe, with or without supply-side financial incentives for post-test linkage, showed that 81.7% of residents were aware of self-testing and 55.8% had self-tested [18]. Two trials of community distribution of HIVST kits in rural Malawi showed high uptake of HIVST, with significant increase in ever testing for HIV in men and adolescents [19, 31]. Even in the standard-of-care arms, 31.5% of participants in the 2016–17 trial and 32.3% in the 2018–19 trial, respectively, were aware of HIVST [18, 19, 31].

These are substantial increases compared to the low awareness and use of self-testing in the 2015–16 DHS, and highlight the broader impact on awareness from large implementation science studies, such as the STAR Initiative. In 2015–16, HIVST was limited to small pilot studies in each country, as national and international policies were still under development and there were no nationally registered or WHO-prequalified products available [32].

As HIVST continues to expand globally, monitoring overall HIVST use, and awareness of and willingness to test will contribute to a better understanding of the reach and impact of HIVST. Ideally, the extent to which social determinants such as urban residence, literacy and affluence dictate awareness of HIVST will diminish with more comprehensive distribution strategies such as those through community outreach, health facilities, by sexual partners and in other venues such as workplaces and private sector pharmacies. Population-based surveys, like the DHS, will then provide an important source of information for countries implementing HIVST, as well as those planning to add HIVST as part of existing HIV testing services. Together with routine programmatic data and special studies, population-based surveys that have included questions on HIVST can then provide a meaningful baseline and point of comparison for future analyses and important insights for future implementation.

Although Malawi and Zimbabwe have scaled up HIV testing and have now achieved the first “90”, gaps remain, particularly among men. Efforts are on to reach the first “95” by 2030 – diagnosing 95% of all people with HIV – which is the new goal. As a result, strategies for diagnosing the shrinking number of people with HIV who do not know their status are becoming more challenging and also less cost-effective unless targeted toward specific populations and settings with lower knowledge of status among people with HIV [3]. Maintaining the high testing coverage and knowledge of status achieved will not be inexpensive and HIVST is likely to play a role in sustaining services and potentially reducing costs. Furthermore, HIVST also addresses patient costs of accessing services and equity concerns, which also need to be considered, especially as programmes get closer to the national goals.

Programmes will need to carefully evaluate how they can both maintain essential HIV testing services in facilities, while also deploying highly focused and effective outreach with limited resources. Strategies such as offering HIVST through specific channels among priority populations, or through periodic and geographically targeted community outreach (such as every 5 years), may be more cost-effective and affordable as more people with HIV learn their status and new infections decline [20].

Limitations

This study has many strengths, such as its large sample size and that it is one of the first to provide an assessment of HIVST use and awareness of, and willingness to, self-test in two

early-adopter African countries prior to wide-scale implementation. As such, it provides insight into the progress and changes made since HIVST has been rolled out, serving as an example for countries monitoring HIVST implementation and scale up. Pooling results, however, may have limited the ability to analyse some differences between countries.

As a cross-sectional survey using self-reported information, there may be reporting bias due to social desirability [33]. Previous studies have highlighted challenges with collecting self-reported data, particularly related to sexual risk behaviours and HIV testing history [34, 35]. Thus, it is possible that there may be differences between what people reported and their actual behaviour. Given that HIVST was relatively new during the surveys, it is possible that willingness may also change as more people have experience self-testing. Additionally, few respondents reported awareness of and past self-testing, which may introduce bias and affect the reliability of the results. It will be important to assess awareness and use of self-testing, as well as willingness to self-test in the future, following broader implementation and scale up.

Like many population-based surveys, the respondents included were limited to women 15–49 years old and men 15–54 years old. Efforts will be needed to consider older populations, particularly as the median age of people with HIV increases. Also, given that we included two of the first countries to include questions on HIVST, there were discrepancies in implementation, such that not all those surveyed were asked about self-testing, and willingness to self-test could not be assessed in Malawians or Zimbabwean women. Willingness to self-test may be similar or different among women and among Malawians, and it will be important to ensure that their replies to these questions are included in future surveys.

Conclusions

Even in 2019, the percentage of people who had never tested for HIV remained above target for Malawian and Zimbabwean men aged ≥25 years [25]. Reaching these men will be critical to achieving the 2030 goals and maintaining low HIV incidence. Despite low awareness and previous use of HIVST among 2015–16 DHS respondents, willingness to self-test was high, especially among older Zimbabwean men with high sexual risk. Reaching these groups is a priority for HIV testing, prevention and care services as we move towards HIV elimination. Social determinants – notably urban residence, paid employment, literacy and wealth – had a pronounced impact on awareness of HIVST in 2015–16, a time that preceded programmatic implementation.

These data provide a valuable baseline against which to investigate population-level HIVST uptake and equity as programmes scale up. Countries conducting population-based surveys, especially those where HIVST is being used or is soon to be introduced, should consider including questions to assess knowledge and awareness of, and willingness to self-test, with the aim of providing baseline data, and to better understand the potential impact of HIVST over time and across and within countries.

Availability of data and materials

We obtained required permissions from DHS and accessed data from the DHS website. All data and materials used in this analysis are available through the DHS programme: https://dhsprogram.com/.

References

1. UNAIDS. Communities at the Centre. Geneva: Joint United Nations Programme on HIV/AIDS; 2019.
2. WHO. Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2019.
3. Phillips AN, Cambiano V, Nakagawa F, Bansi-Matharu L, Wilson D, Jani I, et al. Cost-per-diagnosis as a metric for monitoring cost-effectiveness of HIV testing programmes in low-income settings in southern Africa: health economic and modelling analysis. J Int AIDS Soc. 2019;22(7):e25325.
4. Quinn C, Kadengye DT, Johnson CC, Baggaley R, Dalal S. Who are the missing men? Characterising men who never tested for HIV from population-based surveys in six sub-Saharan African countries. J Int AIDS Soc. 2019;22(10):e25398.
5. Chihana ML, Huerga H, Van Cutsem G, Ellman T, Goemaere E, Wanjala S, et al. Distribution of advanced HIV disease from three high HIV prevalence settings in sub-Saharan Africa: a secondary analysis data from three population-based cross-sectional surveys in Eshowe (South Africa), Ndhiwa (Kenya) and Chiradzulu (Malawi). Glob Health Action. 2019;12(1):1679472.
6. Hawkes S, Buse K. Gender and global health: evidence, policy, and inconvenient truths. Lancet. 2013;381(9879):1783–7.

7. Baker P, Dworkin SL, Tong S, Banks I, Shand T, Yamey G. The men's health gap: Men must be included in the global health equity agenda. Bull World Health Organ. 2014;92(8):618–20.
8. Johnson CC, Kennedy C, Fonner V, Siegfried N, Figueroa C, Dalal S, et al. Examining the effects of HIV self-testing compared to standard HIV testing services: A systematic review and meta-analysis. J Int AIDS Soc. 2017;20(1):21594.
9. Jamil M, Wilson I, Witzel C, Figueroa C, Barr-Dichiara M, Rodgers A, et al. Should HIV self-testing be offered as an HIV testing approach? ICASA; 2–7 December 2019; Kigali, Rwanda. Abstract: THPEC104, https://www.professionalabstracts.com/icasa2019/iplanner/#/presentation/2504. Accessed 16 May 2020.
10. Hatzold K, Gudukeya S, Mutseta M, Chilongosi R, Nalubamba M, Nkhoma C, et al. HIV self-testing: breaking the barriers to uptake of testing among men and adolescents in sub-Saharan Africa, experiences from STAR demonstration projects in Malawi, Zambia and Zimbabwe. J Int AIDS Soc. 2019;22(Suppl 1):e25244.
11. UNAIDS. UNAIDS laws and policies Geneva: Joint United Nations Programme on HIV/AIDS and World Health Organization; 2019. Available from: http://lawsandpolicies.unaids.org/. Accessed 2020 3 Jan.
12. WHO. WHO HIV self-testing need and demand forecast, 2019–2025. Geneva: World Health Organization; 2019.
13. Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S, Gaydos CA, et al. The uptake and accuracy of oral kits for HIV self-testing in high HIV prevalence setting: a cross-sectional feasibility study in Blantyre, Malawi. PloS Med. 2011;8(10):e1001102.
14. Mavengere Y, Sibanda E, Hatzold K, Cowan F, Mugurungi O, Mavedzenge S. Can 'late-read' of self-test devices be used as a quality assurance measure?: results of a pilot HIV self-test project in Zimbabwe. 21st International AIDS conference; 18–22 July 2016; Durban, South Africa. Abstract: TUPEE636; http://programme.aids2016.org/Abstract/Abstract/4171. Accessed 16 May 2020.
15. Neuman M, Indravudh P, Chilongosi R, d'Elbée M, Desmond N, Fielding K, et al. The effectiveness and cost-effectiveness of community-based lay distribution of HIV self-tests in increasing uptake of HIV testing among adults in rural Malawi and rural and peri-urban Zambia: protocol for STAR (self-testing for Africa) cluster randomized evaluations. BMC Public Health. 2018;18(1):1234.

16. Choko AT, Corbett EL, Stallard N, Maheswaran H, Lepine A, Johnson CC, et al. HIV self-testing alone or with additional interventions, including financial incentives, and linkage to care or prevention among male partners of antenatal care clinic attendees in Malawi: an adaptive multi-arm, multi-stage cluster randomised trial. PloS Med. 2019;2019(1):e1002719.
17. Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, Sambakunsi R, et al. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: a community-based prospective study. PloS Med. 2015;12(9):e1001873.
18. Sibanda E, Neuman M, Tumushime M, Hatzold K, Watadzaushe C, Mutseta M, et al. Linkage to care after HIV self-testing in Zimbabwe: a cluster-randomised trial. Conference on opportunistic infections and retroviruses; 3–6 Mar 2018; Boston, USA.
19. Indravudh P, Fielding K, Kumwenda M, Nzawa R, Chilongosi R, Desmond N, et al. Community-led delivery of HIV self-testing targeting adolescents and men in rural Malawi: a cluster-randomised trial. 10th International AIDS society conference; 21–24 July 2019; Mexico City, Mexico. Abstract: MOSY0105LB; http://programme.ias2019.org/Abstract/Abstract/4874. Accessed 16 May 2020.
20. Cambiano V, Johnson CC, Hatzold K, Terris-Prestholt F, Maheswaran H, Thirumurthy H, et al. The impact and cost-effectiveness of community-based HIV self-testing in sub-Saharan Africa: a health economic and modelling analysis. J Int AIDS Soc. 2019;22(Suppl 1):e25243.
21. Johnson LF, van Rensburg C, Govathson C, Meyer-Rath G. Optimal HIV testing strategies for South Africa: a model-based evaluation of population-level impact and cost-effectiveness. Sci Rep. 2019;9(1):12621.
22. NOS and ICF. Malawi Demographic and Health Survey 2015–16. Zomba, Malawi: National Statistical Office and ICF; 2017.
23. Zimbabwe National Statistics Agency and ICF International. Zimbabwe Demographic and Health Survey 2015. Final report. Zimbabwe National Statistics Agency and ICF International: Rockville, Maryland, USA; 2016.
24. Corrani P, Olsen M, Pedersen L, Dekkers O, Vandenbroucke J. Effect modification, interaction and mediation: an overview of theoretical insights of clinical investigators. Clin Epidemiol. 2017;9:331–8.
25. Giguère K, Eaton J, Marsh K, Stannah J, Maheu-Giroux M. “First 90” estimates: where are the gaps? ICASA; 2–7 Dec 2019; Kigali, Rwanda.
26. UNAIDS. UNAIDS estimates, average age of people living with HIV. Geneva: Joint United Nations Programme on HIV/AIDS; 2019.

27. Offorjebe O, Shaba F, Balakasi K, Nyrienda M, Hoffman R, Dovel K, et al. Partner-delivered HIV self-testing increases the perceived acceptability of index partner testing among HIV-positive clients in Malawi. 22nd International AIDS Conference; 23–27 July 2018; Amsterdam, Netherlands. Abstract: WEPEE683; http://programme.aids2018.org/Abstract/Abstract/5275. Accessed 16 May 2020.
28. Dovel K, Shaba F, Offorjebe OA, Balakasi K, Nyirenda M, Phiri K, et al. Effect of facility-based HIV self-testing on uptake of testing among outpatients in Malawi: a cluster-randomised trial. Lancet Glob Health. 2020;8(2):e276–e87.
29. WHO and ILO. HIV self-testing at the workplace. Geneva: International Labour Organization; World Health Organization; 2018.
30. Wong V, Jenkins E, Ford N, Ingold H. To thine own test be true: HIV self-testing and the global reach for the undiagnosed. J Int AIDS Soc. 2019;22(Suppl 1):e25256.
31. Indravudh P, Fielding K, Neuman M, Chilongosi R, Mkandawire P, Nyondo E, et al. Increasing knowledge of HIV status and demand for antiretroviral therapy using community-based HIV self-testing in rural communities: a cluster randomised trial in Malawi. 22nd International AIDS conference; 25–27 July 2018; Amsterdam, Netherlands. Abstract: THPDC0103; http://programme.aids2018.org/Abstract/Abstract/7310. Accessed 16 May 2020.
32. WHO and Unitaid. Landscape for HIV rapid diagnostic tests for HIV self-testing. Geneva: Unitaid and World Health Organization; 2015.
33. Fisher R. Social desirability bias and the validity of indirect questioning. J Consum Res. 1993;20(2):303–15.
34. Rentsch CT, Reniers G, Machemba R, Slaymaker E, Marston M, Wringe A, et al. Non-disclosure of HIV testing history in population-based surveys: implications for estimating a UNAIDS 90-90-90 target. Glob Health Action. 2018;11(1):1553470.
35. Slaymaker E. A critique of international indicators of sexual risk behaviour. Sex Transm Infect. 2004;80(Suppl 2):ii13–21.

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Ethics approval and consent to participate

All DHS and data collection procedures were approved by the ICF Institutional Review Board (IRB), as well as in the country of research. In Zimbabwe, the survey protocol and biomarker collection including HIV testing procedures were reviewed and approved by the Medical Research Council of Zimbabwe (MRCZ), the Institutional Review Board of ICF International, and the Centers for Disease Control and Prevention (CDC) in Atlanta. In Malawi, the survey protocol, including biomarker collection and HIV testing procedures were reviewed and approved by the National Health Sciences Research Committee in Malawi and the ICF Institutional Review Board. Participation was voluntary, and all individuals provided verbal informed consent according to approved survey protocols. This article features a secondary analysis of publicly available DHS data which does not require further ethics approval. Details on ethical procedures are provided in the annexes to DHS reports and on the DHS website: https://dhsprogram.com/What-We-Do/Protecting-the-Privacy-of-DHS-Survey-Respondents.cfm.

Competing interests

The authors have no competing interests. The contents in this article are those of the authors and do not necessarily reflect the view of the World Health Organization or the U.S. President's Emergency Plan for AIDS Relief, the U.S. Agency for International Development or the U.S. Government.

4.3 Tables and figures

Figure 1: *Mechanisms affecting HIV testing uptake in adults (aged 15+ years) in southern Africa, by age, gender, and sexual risk behaviour*

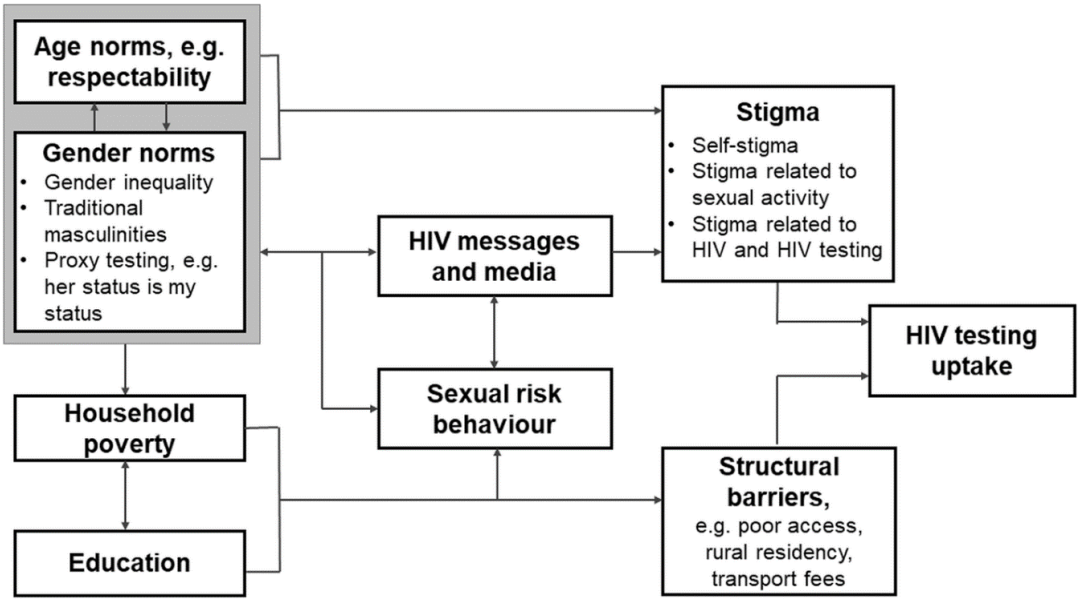

Table 1: *Baseline characteristics in Malawi and Zimbabwe, 2015–16*

Variables[a]	Ever tested (*N* = 31,385)[b]			Ever self-test (*N* = 24,683)[b]			Aware self-test (*N* = 24,683)[b]		
	N	%	*p*-value[§]	*N*	%	*p*-value[§]	*N*	%	*p*-value[§]
Total population	24,148	76.9		287	1.2		3118	12.6	
Country			< 0.001			< 0.001			< 0.001
Malawi	11,726	75.4		141	1.0		1671	11.4	
Zimbabwe	12,422	78.6		146	1.5		1447	14.5	
Sex			< 0.001			0.008			< 0.001
Female	14,500	83.5		103	1.0		983	9.1	
Male	9648	68.8		184	1.3		2135	15.3	
Residence			< 0.001			< 0.001			< 0.001
Urban	7951	79.9		151	2.1		1516	21.2	
Rural	16,197	75.9		136	0.8		1602	9.1	
Age group (years)			< 0.001			< 0.001			< 0.001
15–19	3252	44.8		30	0.5		437	7.0	

Variables[a]	Ever tested (*N* = 31,385)[b]			Ever self-test (*N* = 24,683)[b]			Aware self-test (*N* = 24,683)[b]		
	N	%	*p*-value[§]	*N*	%	*p*-value[§]	*N*	%	*p*-value[§]
20–24	4703	80.7		42	0.9		562	12.1	
25–29	4337	90.3		59	1.6		580	16.0	
30–34	4070	91.1		55	1.7		497	15.2	
35–39	3247	89.2		42	1.5		426	15.7	
40–44	2446	87.4		35	1.7		303	15.0	
45+	2093	80.8		24	1.1		313	14.7	
Wealth			< 0.001			< 0.001			< 0.001
Poorest	3697	76.4		18	0.5		246	6.4	
Poorer	4029	75.8		38	0.9		336	7.8	
Middle	4252	75.3		26	0.6		279	8.3	
Rich	5594	77.6		56	0.9		669	12.2	
Richest	6576	78.5		149	2.3		1488	22.8	
HIV status			< 0.001			0.108			0.029
HIV negative	20,646	75.0		249	1.1		2760	12.5	
HIV positive	2570	90.6		38	1.5		358	10.4	
Marital status			< 0.001			0.005			< 0.001
Single	7595	58.9		99	0.9		1175	11.2	
Married or cohabiting	16,553	89.5		188	1.3		1943	13.7	
Employment			< 0.001			0.033			< 0.001
Not actively working	8719	70.1		85	1.0		823	9.4	
Actively working	15,429	81.4		202	1.3		2295	14.4	
Education			< 0.001			< 0.001			< 0.001
≤ Primary	10,617	74.8		70	0.6		927	7.5	
≥ Secondary	13,531	78.7		217	1.8		2191	17.8	
Literacy			< 0.001			< 0.001			< 0.001
Illiterate	5211	73.5		44	0.7		488	8.0	

Variables[a]	Ever tested (*N* = 31,385)[b]			Ever self-test (*N* = 24,683)[b]			Aware self-test (*N* = 24,683)[b]		
	N	**%**	***p*-value[§]**	***N***	**%**	***p*-value[§]**	***N***	**%**	***p*-value[§]**
Literate	18,937	77.9		243	1.3		2630	14.2	
Sexually active			< 0.001			< 0.001			< 0.001
Sexually inactive	9064	64.0		107	1.5		1225	17.7	
Active in past 4 weeks	15,053	87.6		180	1.5		1890	14.2	
HIV-related risk[c]			< 0.001			< 0.001			< 0.001
Low risk	8457	63.5		94	0.9		1102	10.3	
Moderate risk	13,092	88.7		134	1.2		1497	13.6	
High risk	2570	78.8		59	2.0		516	17.2	

[a]Ever tested refers to people surveyed on HIV testing history who reported that they previously tested for HIV before the survey. Overall, 31,385 people were asked about their HIV testing history and 24,148 responded that they had tested previously. Ever self-tested refers to people surveyed on HIV self-testing who reported that they had previously self-tested. Overall, 24,683 people were asked whether they had self-tested and 287 reported that they had self-tested previously. Aware of self-testing refers to people surveyed who reported that they were aware of HIV self-testing. Overall, 24,683 people were asked whether they were aware of self-testing and 3118 reported that they were aware of self-testing

[b]Out of 31,385 people surveyed, 31,348 were included as 37 people were missing information on sexual activity and HIV-related risk. Not all participants were systematically surveyed on self-testing questions. Out of 31,385 people surveyed, 24,683 were asked about self-testing, resulting in a smaller sample size. Among these were 15 people reporting on self-testing who did not provide information on sexual activity and HIV risk. Population size asked about ever testing for HIV: 31347 (HIV risk/sexual activity). Population size asked about awareness or ever self-testing for HIV: 24668 (HIV risk/sexual activity)

[c]HIV risk as defined in this analysis includes reported sexual activity in the past four weeks, and the following high-risk exposures in the previous 12 months: multiple (i.e. ≥2) partners, any paid sex (asked to men), having received gifts, cash or other compensation in exchange for sex (asked to women), and having a sexually transmitted infection (STI). Individuals with any “high-risk” exposures were classified as “high-risk”, with the remaining respondents classified as “low risk” if reporting no sexually activity in the past four weeks, and as “moderate risk” otherwise

[§]*P*-value based on cluster-adjusted chi-squared test

Table 2: *Univariable and multivariable associations between sociodemographic factors and ever testing for HIV in Malawi and Zimbabwe, 2015–16*

Variables	Univariable (weighted) *N* = 24,683[a]		Multivariable (weighted) *N* = 24,668[a]	
	OR	95% CI and *p*-value	aOR	95% CI and *p*-value
Country				
Zimbabwe	1		1	
Malawi	0.76	0.67–0.87	0.82	0.70–0.94
Sex				
Female	1		1	
Male	1.73	1.54–1.92	1.55	1.37–1.75
Age				
15–19	1	$p < 0.001$[§]	1	$p < 0.001$[§]
20–24	1.79	1.50–2.12	1.35	1.12–1.62
25–29	2.52	2.11–3.00	1.76	1.43–2.17
30–34	2.44	2.02–2.94	1.66	1.32–2.08
35–39	2.46	2.04–2.97	1.69	1.34–2.12
40–44	2.09	1.70–2.55	1.45	1.14–1.86
45+	2.00	1.64–2.46	1.31	1.04–1.66
Residence				
Urban	1		1	
Rural	0.33	0.29–0.39	0.64	0.55–0.77
Ever tested				
No	1		1	
Yes	2.18	1.94–2.45	1.89	1.65–2.17
HIV status				
HIV negative	1		1	
HIV positive	1.12	0.95–1.31	0.89	0.75–1.06
Marital status				
Single	1		1	

Variables	Univariable (weighted) *N* = 24,683[a]		Multivariable (weighted) *N* = 24,668[a]	
	OR	95% CI and *p*-value	aOR	95% CI and *p*-value
Married or cohabiting	1.26	1.13–1.39	[b]	[b]
Wealth				
Poorest	1	$p < 0.001$[§]	1	$p < 0.001$[§]
Poor	1.26	1.04–1.53	1.24	1.02–1.51
Middle	1.26	1.03–1.53	1.25	1.02–1.53
Rich	1.87	1.53–2.28	1.49	1.20–1.84
Richest	4.30	3.54–5.22	3.03	2.46–3.73
Employment				
Not actively working	1		1	
Actively working	1.63	1.47–1.82	1.25	1.12–1.42
Education				
≤ Primary	1		1	
≥ Secondary education	2.69	2.38–3.04	[b]	[b]
Literacy				
Illiterate	1		1	
Literate	1.84	1.59–2.12	1.17	1.01–1.36
HIV risk[c]				
Low risk	1	$p < 0.001$[§]	1	$p < 0.518$
Moderate risk	1.37	1.24–1.53	1.03	0.90–1.17
High risk	1.75	1.51–2.03	1.10	0.93–1.31

[a] Both samples were weighted based on standard Demographic and Health Survey weights; Strata = 56; PSU = 1256. Not all participants were systematically surveyed on self-testing questions. Out of 31,385 people surveyed, 24,683 were asked about self-testing, resulting in a smaller sample size. Among those reporting on HIV self-testing, 15 did not provide information on sexual activity and HIV risk. Population size asked about awareness or ever self-testing for HIV: 24668 (HIV risk), 24,668 (sexual activity)

[b] Represents variables that were not included in the multivariable analysis due to identified collinearity

[c] HIV risk as defined in this analysis includes reported sexual activity in the past four weeks, and the following high-risk exposures in the previous 12 months: multiple (i.e. ≥2) partners, any paid sex (asked to men), having received gifts, cash or other compensation in exchange for sex (asked to women), and

having a sexually transmitted infection (STI). Individuals with any “high-risk” exposures were classified as “high-risk”, with the remaining respondents classified as “low risk” if reporting no sexually activity in the past four weeks, and as “moderate risk” otherwise

[§]*P*-value based on the Wald test. *P*-values for variables with more than two categories are shown

Table 3: *Univariable and multivariable associations between sociodemographic factors and awareness of HIV self-testing in Malawi and Zimbabwe, 2015–16*

Variables	**Univariable (weighted)** ***N* = 24,683**[a]		**Multivariable (weighted)** ***N* = 24,668**[a]	
	OR	**95% CI and *p*-value**	**aOR**	**95% CI and *p*-value**
Country				
Zimbabwe	1		1	
Malawi	0.76	0.67–0.87	0.82	0.70–0.94
Sex				
Female	1		1	
Male	1.73	1.54–1.92	1.55	1.37–1.75
Age				
15–19	1	$p < 0.001$[§]	1	$p < 0.001$[§]
20–24	1.79	1.50–2.12	1.35	1.12–1.62
25–29	2.52	2.11–3.00	1.76	1.43–2.17
30–34	2.44	2.02–2.94	1.66	1.32–2.08
35–39	2.46	2.04–2.97	1.69	1.34–2.12
40–44	2.09	1.70–2.55	1.45	1.14–1.86
45+	2.00	1.64–2.46	1.31	1.04–1.66
Residence				
Urban	1		1	
Rural	0.33	0.29–0.39	0.64	0.55–0.77
Ever tested				
No	1		1	
Yes	2.18	1.94–2.45	1.89	1.65–2.17
HIV status				

Variables	Univariable (weighted) *N* = 24,683[a]		Multivariable (weighted) *N* = 24,668[a]	
	OR	95% CI and *p*-value	aOR	95% CI and *p*-value
HIV negative	1		1	
HIV positive	1.12	0.95–1.31	0.89	0.75–1.06
Marital status				
Single	1		1	
Married or cohabiting	1.26	1.13–1.39	[b]	[b]
Wealth				
Poorest	1	$p < 0.001$[§]	1	$p < 0.001$[§]
Poor	1.26	1.04–1.53	1.24	1.02–1.51
Middle	1.26	1.03–1.53	1.25	1.02–1.53
Rich	1.87	1.53–2.28	1.49	1.20–1.84
Richest	4.30	3.54–5.22	3.03	2.46–3.73
Employment				
Not actively working	1		1	
Actively working	1.63	1.47–1.82	1.25	1.12–1.42
Education				
≤ Primary	1		1	
≥ Secondary education	2.69	2.38–3.04	[b]	[b]
Literacy				
Illiterate	1		1	
Literate	1.84	1.59–2.12	1.17	1.01–1.36
HIV risk[c]				
Low risk	1	$p < 0.001$[§]	1	$p < 0.518$
Moderate risk	1.37	1.24–1.53	1.03	0.90–1.17
High risk	1.75	1.51–2.03	1.10	0.93–1.31

[a] Both samples were weighted based on standard Demographic and Health Survey weights; Strata = 56; PSU = 1256. Not all participants were systematically surveyed on self-testing questions. Out of 31,385

people surveyed, 24,683 were asked about self-testing, resulting in a smaller sample size. Among those reporting on HIV self-testing, 15 did not provide information on sexual activity and HIV risk. Population size asked about awareness or ever self-testing for HIV: 24668 (HIV risk), 24,668 (sexual activity)

[b] Represents variables that were not included in the multivariable analysis due to identified collinearity

[c] HIV risk as defined in this analysis includes reported sexual activity in the past four weeks, and the following high-risk exposures in the previous 12 months: multiple (i.e. ≥2) partners, any paid sex (asked to men), having received gifts, cash or other compensation in exchange for sex (asked to women), and having a sexually transmitted infection (STI). Individuals with any “high-risk” exposures were classified as “high-risk”, with the remaining respondents classified as “low risk” if reporting no sexually activity in the past four weeks, and as “moderate risk” otherwise

[§]*P*-value based on the Wald test. *P*-values for variables with more than two categories are shown

Table 4: *Univariable and multivariable associations between sociodemographic factors and willingness to self-test among men in Zimbabwe, by those at low, moderate and high HIV-related risk, 2015–16*

Variables	Univariable (weighted)						Multivariable (weighted)					
	Having low risk (*n* = 3142)[a]		Having moderate risk (*n* = 2988)[a]		Having high risk (*n* = 1241)[a]		Having low risk (*n* = 3142)[a]		Having moderate risk (*n* = 2988)[a]		Having high risk (*n* = 1241)[a]	
	OR	95% CI and *p*-value	OR	95% CI and *p*-value	OR	95% CI and *p*-value	aOR	95% CI and *p*-value	aOR	95% CI and *p*-value	aOR	95% CI and *p*-value
Age (years)												
15–19	1	$p < 0.001$[§]	1	$p = 0.063$[§]	1	$p = 0.028$[§]	1	$p = 0.106$[§]	1	$p = 0.343$[§]	1	$p = 0.030$[§]
20–24	1.78	1.37–2.30	1.49	0.70–3.23	2.44	1.21–4.92	1.47	1.11–1.92	1.31	0.60–2.85	2.71	1.32–5.57
25–29	2.00	1.36–2.96	2.43	1.18–4.99	2.09	0.99–4.41	1.50	1.00–2.27	1.89	0.90–3.95	2.66	1.23–5.75
30–34	2.01	1.11–3.63	2.52	1.24–5.09	2.86	1.35–6.05	1.44	0.79–2.64	1.98	0.96–4.07	3.82	1.82–8.00
35–39	1.69	0.96–2.99	2.31	1.10–4.85	3.77	1.75–9.14	1.17	0.65–2.10	1.92	0.91–4.07	4.87	2.14–11.07
40–44	1.82	0.88–3.78	2.52	1.16–5.44	2.21	0.95–5.16	1.27	0.59–2.72	2.09	0.96–4.59	3.02	1.18–7.71
45+	1.61	0.93–2.81	1.70	0.87–3.33	1.94	0.93–4.07	1.05	0.56–1.95	1.44	0.72–2.88	2.46	1.09–5.54
Residence												
Urban	1		1		1		1		1		1	
Rural	0.81	0.64–1.02	1.18	0.89–1.55	1.33	0.86–2.06	0.71	0.49–1.03	1.14	0.74–1.76	3.56	1.61–7.90
Wealth												
Poorest	1	$p = 0.128$[§]	1	$p = 0.113$[§]	1	$p = 0.981$[§]	1	$p = 0.102$[§]	1	$p = 0.260$[§]	1	$p = 0.080$[§]
Poor	1.04	0.75–1.45	1.87	1.13–3.09	1.16	0.58–2.30	1.02	0.74–1.41	1.72	1.02–2.91	1.27	0.64–2.50

Variables	Univariable (weighted)						Multivariable (weighted)					
	Having low risk (*n* = 3142)[a]		Having moderate risk (*n* = 2988)[a]		Having high risk (*n* = 1241)[a]		Having low risk (*n* = 3142)[a]		Having moderate risk (*n* = 2988)[a]		Having high risk (*n* = 1241)[a]	
	OR	95% CI and *p*-value	OR	95% CI and *p*-value	OR	95% CI and *p*-value	aOR	95% CI and *p*-value	aOR	95% CI and *p*-value	aOR	95% CI and *p*-value
Middle	0.97	1.00–1.90	1.27	0.85–1.88	0.96	0.49–1.89	0.98	0.71–1.35	1.20	0.78–1.84	1.04	0.51–2.10
Rich	1.38	0.70–1.34	1.12	0.71–1.77	1.03	0.52–2.05	1.04	0.73–1.47	1.03	0.60–1.77	2.64	1.07–6.53
Richest	1.02	0.74–1.42	1.12	0.75–1.67	1.10	0.57–2.12	0.65	0.42–1.02	1.02	0.54–1.94	3.74	1.39–10.03
Employment												
Not actively working	1		1		1		1		1		1	
Actively working	1.64	1.35–1.99	1.19	0.86–1.63	0.72	0.44–1.18	1.41	1.13–1.77	1.12	0.78–1.61	0.57	0.34–0.95
HIV status												
HIV negative	1		1		1		1		1		1	
HIV positive	1.82	1.19–2.79	0.94	0.56–1.59	0.76	0.43–1.35	1.41	0.87–2.30	0.84	0.49–1.42	0.67	0.37–1.21
Marital status												
Single	1		1		1		1		1		1	
Married or cohabiting	0.59	0.40–89	0.72	0.47–1.10	0.72	0.49–1.06	[b]	[b]	[b]	[b]	[b]	[b]
Education												
≤ Primary	1		1		1		1		1		1	

Variables	Univariable (weighted)						Multivariable (weighted)					
	Having low risk (*n* = 3142)[a]		Having moderate risk (*n* = 2988)[a]		Having high risk (*n* = 1241)[a]		Having low risk (*n* = 3142)[a]		Having moderate risk (*n* = 2988)[a]		Having high risk (*n* = 1241)[a]	
	OR	95% CI and *p*-value	OR	95% CI and *p*-value	OR	95% CI and *p*-value	aOR	95% CI and *p*-value	aOR	95% CI and *p*-value	aOR	95% CI and *p*-value
≥ Secondary	1.52	1.22–1.89	1.20	0.91–1.58	1.19	0.77–1.86	[b]	[b]	[b]	[b]	[b]	[b]
Literacy												
Illiterate	1		1		1		1		1		1	
Literate	1.23	0.98–1.55	1.66	1.18–2.32	1.36	0.83–2.22	1.16	0.91–1.48	1.55	1.07–2.25	1.32	0.78–2.23
Ever tested												
No	1		1		1		1		1		1	
Yes	1.74	1.40–2.15	2.00	1.47–2.72	1.40	0.88–2.20	1.48	1.18–1.85	1.87	1.37–2.55	1.20	0.76–1.90
Aware of self-test												
No	1		1		1		1		1		1	
Yes	1.35	0.95–1.92	0.96	0.69–1.34	1.00	0.56–1.78	1.09	0.76–1.55	0.94	0.66–1.33	0.89	0.50–1.60

[a] Weighted analysis using standard Demographic and Health Survey (DHS) sample weights: Sample size = 7041.0867; Strata = 19; PSU = 400. Out of 7420 men surveyed, 7372 reported on willingness to self-test. Forty-eight men did not respond and one did not provide information on sexual activity (HIV risk). Sexual activity was not reported by one respondent and could not be used in the HIV risk variable. These variables have a total sample size of 7371

[b] Represents variables that were not included in the multivariable analysis due to identified collinearity

[c] HIV risk as defined in this analysis includes reported sexual activity in the past four weeks, and the following high-risk exposures in the previous 12 months: multiple (i.e. ≥2) partners, any paid sex (asked to men), having received gifts, cash or other compensation in exchange for sex (asked to women), and having a sexually transmitted infection (STI). Individuals with any “high-risk” exposure were classified as “high-risk”, with the remaining respondents classified as “low risk” if reporting no sexually activity in the past four weeks, and as “moderate risk” otherwise

[§] *P*-value based on the Wald test. *P*-values for variables with more than two categories are shown

4.4 Supplementary information

Appendix 1. *Supplementary tables*

Table S1. *Baseline characteristics of men in Zimbabwe reporting on willingness to self-test, 2015-16*

Variables	Willing to self-test (N=7372)*		
	n	% willing	p-value§
Population	6 232	84.5	
Age group (yrs)			<0.001
15-19	1 388	74.6	
20-24	1 043	85.1	
25-29	882	87.7	
30-34	881	90.2	
35-39	715	89.8	
40-44	615	90.2	
45+	708	85.8	
Residence			0.179
Urban	2 466	85.2	
Rural	3 766	84.1	
Wealth quintile			0.068
Poorest	898	83.1	
Poor	1 020	84.9	
Middle	1 119	82.8	
Richest	1 560	86.2	
Richest	1 635	84.7	
Marital status			<0.001
Single	2 877	79.8	
Married or cohabiting	3 355	89.1	
Employment			<0.001
Not currently working	2 035	79.8	
Actively working	4 197	87.0	
Education			<0.001
≥Primary	1 391	81.0	
≥Secondary	4 841	85.6	
Literacy			<0.001
Being illiterate	919	85.5	
Being literate	5 313	79.4	
HIV status			0.018
HIV negative	5 460	84.2	
HIV positive	772	87.2	
Sexually active**			<0.001
Not sexually active	2 727	79.5	
Active in last 4-weeks	3 505	89.0	
Circumcision**			0.019
Uncircumcised	5 247	85.0	
Circumcised	990	82.4	
HIV-related risk***			<0.001
Low-risk	2 477	78.8	
Moderate-risk	2 668	89.3	
High-risk	1 087	87.6	
Ever tested for HIV			<0.001

Variables	Willing to self-test (N=7372)*		
	n	% willing	p-value§
No	1 895	77.8	
Yes	4 337	87.9	
Last HIV test (months)**			0.114
< 12 months	3 016	88.5	
≥ 12 months	390	86.5	
≥ 24 months	917	86.4	
Aware of HIV self-testing			0.010
No	5 165	84.1	
Yes	1 067	87.0	
Ever self-tested for HIV			0.001
No	6 116	84.3	
Yes	116	95.9	

***** Weighted analysis using standard Demographic and Health Survey (DHS) sample weights: Sample size = 7041.0867; Strata = 19; PSU=400. Willingness to self-test refers to people surveyed who reported they were willing to self-test in the future. Out of 7420 men surveyed, 7372 reported on willingness to self-test. 48 men did not respond and 1 not provide information on sexual activity (HIV risk). Sexual activity was not reported by 1 respondent and could not be used in HIV risk variable. These variables have a total sample size of 7371.

**Sexual activity and HIV risk reported by 7371 people, as 1 person did not provide information on sexual activity and risk. Month of last test was reported by 4920 people, as not all those surveyed had tested previously.

****** HIV risk is defined in this analysis includes reported sexual activity in the past four weeks, and the following high-risk exposures in the previous 12 months: multiple (i.e. ≥2) partners, any paid sex (asked to men), having received gifts, cash or other compensation in exchange for sex (asked to women), and having a sexually transmitted infection (STI). Individuals with any “high-risk” exposures were classified as “high-risk”, with the remaining respondents classified as “low risk” if reporting no sexually activity in the past four weeks, and as “moderate risk” otherwise.

§ P-value based on cluster-adjusted chi-squared test.

Table S2. *Univariable and multivariable associations between sociodemographic factors and ever-self-testing for HIV in Malawi and Zimbabwe, 2015-16*

Variables	Univariable (weighted) n=24 683*		Multivariable (weighted) n=24 668*	
	Odds ratio	95% CI and p-value	Odds ratio	95% CI and p-value
Country				
Zimbabwe	1		1	
Malawi	0.74	0.53-1.04	0.81	0.53-1.24
Sex				
Female	1		1	
Male	1.27	0.93-1.74	1.05	0.75-1.46
Age				
15-19	1	p<0.002§	1	p<0.017§
20-24	1.86	1.10-3.15	1.75	0.98-3.10
25-29	2.66	1.62-4.38	2.47	1.43-4.27
30-34	3.15	1.76-5.63	2.89	1.47-5.68
35-39	2.70	1.47-4.94	2.50	1.22-5.10
40-44	2.47	1.37-4.47	2.35	1.19-4.66
45+	1.56	0.82-3.00	1.41	0.69-2.91
Residence				
Urban	1		1	
Rural	0.36	0.25-0.50	0.76	0.45-1.27
HIV status				
HIV negative	1		1	
HIV positive	1.27	0.83-1.95	1.03	0.66-1.62
Marital status				
Single	1		1	
Married or cohabiting	1.23	0.88-1.73	**	**
Wealth				
Poorest	1	p<0.001§	1	p<0.001§
Poor	1.82	0.94-3.52	1.81	0.94-3.49
Middle	1.21	0.59-2.49	1.22	0.60-2.50
Rich	2.11	1.12-3.96	1.74	0.90-3.38
Richest	4.79	2.59-8.85	3.59	1.79-7.18
Employment				
Not actively working	1		1	
Actively working	1.31	0.95-1.80	0.99	0.70-1.44
Education				
≤Primary	1		1	
≥ Secondary	3.08	2.20-4.32	**	**
Literacy				
Being illiterate	1		1	
Being literate	2.05	1.35-3.09	1.37	0.91-2.08
HIV-related risk* **				
Low-risk	1	p<0.004§	1	p<0.178§
Moderate-risk	1.35	0.96-1.93	1.06	0.74-1.52
High-risk	2.20	1.36-3.57	1.61	0.96-2.71

* Both samples were weighted based on standard DHS weights; Strata = 56; PSU=1 256. Not all participants were systematically surveyed on self-testing questions. Out of 31 385 participants, 24 683 were asked about HIV self-testing, resulting in smaller sample size. Among those reporting on HIV self-

testing, 15 did not provide information on sexual activity and HIV risk. Population size asked about awareness or ever self-testing for HIV: 24 668 (HIV risk), 24 668 (sexual activity).

**Represents variables which were not included in the multivariable analysis due to identified collinearity.

*** HIV risk is defined in this analysis includes reported sexual activity in the past four weeks, and the following high-risk exposures in the previous 12 months: multiple (i.e. ≥2) partners, any paid sex (asked to men), having received gifts, cash or other compensation in exchange for sex (asked to women), and having a sexually transmitted infection (STI). Individuals with any "high-risk" exposures were classified as "high-risk", with the remaining respondents classified as "low risk" if reporting no sexually activity in the past four weeks, and as "moderate risk" otherwise.

§ P-value based on Wald test. P-values for variables with more than two categories are shown.

Table S3. *Univariable and multivariable associations between sociodemographic factors and willingness to self-test among men in Zimbabwe, by testing history, 2015-16*

Variables	Univariable (weighted)				Multivariable (weighted)			
	Ever tested (n=4 934)*		Never tested (n=2 437)*		Ever tested (n=4 934)*		Never tested (n=2 437)*	
	OR	95% CI and p-value	OR	95% CI and p-value	aOR	95% CI and p-value	aOR	95% CI and p-value
Age								
15-19	**1**	p<0.001§	**1**	p<0.001§	**1**	p<0.004§	**1**	p<0.003§
20-24	1.76	1.32-2-36	1.70	1.27-2.28	1.60	1.17-2.18	1.53	1.13-2.09
25-29	2.01	1.46-2.77	2.47	1.59-3.83	1.63	1.15-2.32	2.03	1.27-3.23
30-34	2.59	1.80-3.73	2.25	1.40-3.60	1.99	1.35-2.96	1.66	0.94-2.93
35-39	2.32	1.80-3.73	2.76	1.61-4.73	1.80	1.20-2.72	2.06	1.13-3.75
40-44	2.53	1.72-3.72	1.96	1.04-3.71	2.04	1.34-3.10	1.47	0.70-3.09
45+	2.08	1.49-2.92	1.27	0.85-1.87	1.71	1.18-2.48	0.93	0.58-1.51
Residence								
Urban	1		1		1		1	
Rural	1.05	0.83-1.34	0.95	0.73-1.24	1.08	0.73-1.60	0.99	0.61-1.62
Wealth								
Poorest	**1**	p<0.745§	**1**	p<0.551§	**1**	p<0.724§	**1**	p<0.751§
Poor	1.20	0.83-1.74	1.16	0.83-1.64	1.22	0.84-1.76	1.20	0.92-1.55
Middle	1.00	0.71-1.42	0.94	0.69-1.27	1.06	0.74-1.51	1.02	0.75-1.40
Rich	1.11	0.74-1.66	1.21	0.84-1.76	1.09	0.72-1.63	1.17	0.80-1.72
Richest	0.99	0.70-1.39	0.96	0.67-1.37	0.92	0.56-1.50	0.97	0.55-1.73
Employment								
Not actively working	1		1		1		1	
Actively working	1.51	1.24-1.83	1.58	1.29-1.94	1.14	0.91-1.42	1.20	0.94-1.53
Education								
≤Primary					1		1	
≥ Secondary	1.28	1.00-1.64	1.16	0.95-1.42	**	**	**	**
Literacy								
Being illiterate	1		1		1		1	
Being literate	1.39	1.06-1.83	1.17	0.91-1.50	1.42	1.06-1.90	1.19	0.92-1.55
HIV status								

Variables	Univariable (weighted)				Multivariable (weighted)			
	Ever tested (n=4 934)*		Never tested (n=2 437)*		Ever tested (n=4 934)*		Never tested (n=2 437)*	
HIV negative	1		1		1		1	
HIV positive	0.93	0.64-1.35	2.26	1.29-3.97	0.79	0.55-1.14	1.83	1.03-3.24
Marital status								
Single	1		1		1		1	
Married or cohabiting	1.84	1.48-2.29	1.61	1.25-2.07	**	**	**	**
HIV-related risk* **								
Low-risk	1	p<0.001§	1	p<0.001§	1	p<0.505§	1	p<0.250§
Moderate-risk	1.91	1.52-2.41	1.66	1.26-2.18	1.40	1.07-1.82	1.17	0.81-1.79
High-risk	1.58	1.18-2.11	1.97	1.31-2.95	1.42	0.90-1.67	1.39	0.93-2.17
Aware self-test								
No	1		1		1		1	
Yes	1.17	0.87-1.57	0.96	0.66-1.41	1.11	0.82-1.52	0.79	0.56-1.18

**Weighted analysis using standard DHS sample weights; Strata = 19; PSU=400. Out of 7 420 men surveyed, 7 372 reported on willingness to self-test. 48 respondents did not respond to this question on willingness. Because 1 person did not provide information on sexual activity and sexual risk resulting in sample size 7 321 for both HIV risk.

**Represents variables which were not included in the multivariable analysis due to identified collinearity.

***HIV risk is defined in this analysis includes reported sexual activity in the past four weeks, and the following high-risk exposures in the previous 12 months: multiple (i.e. ≥2) partners, any paid sex (asked to men), having received gifts, cash or other compensation in exchange for sex (asked to women), and having a sexually transmitted infection (STI). Individuals with any “high-risk” exposures were classified as “high-risk”, with the remaining respondents classified as “low risk” if reporting no sexually activity in the past four weeks, and as “moderate risk” otherwise.

§ P-value based on Wald test. P-values for variables with more than two categories are shown.

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	1603327	**Title**	Ms
First Name(s)	Cheryl		
Surname/Family Name	Johnson		
Thesis Title	Investigating Men's Preferences for HIV Self-Testing and Linkage: Exploring Strategies for Policy Impact		
Primary Supervisor	Professor Liz Corbett		

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

SECTION B – Paper already published

Where was the work published?	BMC Public Health		
When was the work published?	April 2021		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	No		
Have you retained the copyright for the work?*	**No**	Was the work subject to academic peer review?	**Yes**

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	For this paper, I picked up a problem that had been partly explored by Prof Corbett and Moses Kumwenda (my coauthor) in 2013, in response to the observation that older adults in Blantyre, Malawi, appeared to be reluctant to self-test for HIV. Using that starting point - and knowing that older adults were also likely to be relatively hard to reach with self-testing in rural Malawi (as this pattern is seen throughout Africa). I added to the 2013 interviews and focus group discussion with additional prospective data collection in the Unitaid "STAR" studies. I have had previous Anthropology training, and worked closely with Drs Moses Kumwenda and Nicola Desmond to refine the data collection tools, interview guides and purposive selection frameworks. Dr Kumwenda was responsible for data collection, and supervised the interviews, translation and transcription in both study phases. I combined the transcripts and used Thematic content and framework analysis with a common coding framework. I identified the "life course theory" used to underpin the final coding, analysis and theoretical framework. I led on the data analysis, coding and interpretation. I wrote the first draft of the manuscript.

SECTION E

Student Signature	Cheryl Johnson	[redacted]
Date	13 August 2022	

Supervisor Signature	Liz Corbett	[redacted]
Date	13 August 2022	

5.0 Qualitative study

5.1 Introduction

Qualitative research was undertaken to explore how age is enacted socially and its implications on HIV testing and sexual risk behaviours. I explore the potential for HIV self-testing (HIVST) to be part of a broader strategy for engaging midlife-older adults in HIV testing, prevention and care. I used a life course approach and thematic analysis to identify recurrent themes and variations. Midlife-older adults (30–74 years of age) associated their age with respectability and identified HIV as "a disease of youth" that would not affect them, with age protecting them against infidelity and sexual risk-taking. HIV testing was felt to be stigmatizing, challenging age norms, threatening social status, and implying "lack of wisdom". HIVST which has often been highlighted as a tool for reaching young people, identified as a potentially valuable tool for engaging midlife-older age groups who may not otherwise test.

Tables and figures are at the end. All supplemental material is located in Appendix 1.

This data analysis was submitted to BMC Public Health in April 2020 and published in April 2021. It is described as published below.

5.2 Qualitative study paper

Title: 'Too old to test?': A life course approach to HIV-related risk and self-testing among midlife-older adults in Malawi

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Abstract

Background: Despite the aging HIV epidemic, increasing age can be associated with hesitancy to test. Addressing this gap is a critical policy concern and highlights the urgent need to identify the underlying factors, to improve knowledge of HIV-related risks as well as uptake of HIV testing and prevention services, in midlife-older adults.

Methods: We conducted five focus group discussions and 12 in-depth interviews between April 2013 and November 2016 among rural and urban Malawian midlife-older (≥30 years) men and women. Using a life-course theoretical framework we explored how age is enacted socially and its implications on HIV testing and sexual risk behaviours. We also explore the potential for HIV self-testing (HIVST) to be part of a broader strategy for engaging midlife-older adults in HIV testing, prevention and care. Thematic analysis was used to identify recurrent themes and variations.

Results: Midlife-older adults (30–74 years of age) associated their age with respectability and identified HIV as “a disease of youth” that would not affect them, with age protecting them against infidelity and sexual risk-taking. HIV testing was felt to be stigmatizing, challenging age norms, threatening social status, and implying “lack of wisdom”. These norms drove self-testing preferences at home or other locations deemed age and gender appropriate. Awareness of the potential for long-standing undiagnosed HIV to be carried forward from past relationships was minimal, as was understanding of treatment-as-prevention. These norms led to HIV testing being perceived as a threat to status by older adults, contributing to low levels of recent HIV testing compared to younger adults.

Conclusions: Characteristics associated with age-gender norms and social position encourage self-testing but drive poor HIV-risk perception and unacceptability of conventional HIV testing in midlife-older adults. There is an urgent need to provide targeted messages and services more appropriate to midlife-older adults in sub-Saharan Africa. HIVST which has often been

highlighted as a tool for reaching young people, may be a valuable tool for engaging midlife-older age groups who may not otherwise test.

Background

Aging among people living with HIV (PLHIV) has attracted significant interest in recent years. While treatment scale-up has resulted in better quality and longer life, numbers of new infections are not declining, and indeed are increasing in older (> 50 years) adults [1]. In sub-Saharan Africa, HIV prevalence among older men and undiagnosed infections are on the rise: in 2015, 50% of new HIV infections among men in sub-Saharan Africa were in 30–49 year olds [2, 3]. With the median age of PLHIV increasing every year [2], by 2030 approximately 73% of PLHIV will be over 50 years [4] with the vast majority in sub-Saharan Africa.

Low levels of recent HIV testing in midlife-older populations, generally ≥30 years of age, stand in contrast with the changing epidemic in southern Africa. In east and southern Africa – where 85% of all PLHIV are now aware of their status [1] – many midlife-older adults, especially men, have still never tested or not tested recently [5]. Late diagnosis and initiation of treatment is common among midlife-older men, who prescribe to traditional views of masculinity and age which view accessing HIV services, including testing, as a threat to their position in community and family life [6, 7]. This trend among midlife-older men may also contribute to new infections in younger women in southern Africa where intergenerational relationships have been considered a key driver of the HIV epidemic [8]. For midlife-older women, some of whom no longer need antenatal or family planning services, access to and uptake of HIV testing declines considerably [9]. Declining concerns about unwanted pregnancy, together with minimal public awareness of changes in the demographics of the HIV epidemic [10, 11], may lead to greater willingness to engage in condomless sex with existing or new partners of unknown HIV status [12,13,14].

Despite increasing HIV prevalence, risk perception and perceived susceptibility to HIV is believed to be low in midlife-older age groups [9, 15, 16]. Age-targeted health education and behaviour change campaigns in southern Africa remain focused on adolescents and young people (15–24 years) and have yet to be adapted for other age groups. As a result, in urban Malawi, only 42.8 and 66.7% of over-40-year-old men and women participated in the first year of community-based HIV self-testing (HIVST) distribution in 2012–13 and had an HIV

prevalence of 22.5%. In contrast, during this same period, 89.3 and 100% of adolescent boys and girls aged 16–19 years participated with a lower HIV prevalence of 2.5% [17]. Since then, Malawi has scaled-up HIVST and youth continue to be a priority [18].

Poor knowledge of their HIV risk and hesitancy to access HIV testing in the context of high prevalence and incidence among midlife-older men and women undermine global efforts to achieve and maintain low HIV incidence by 2030. Addressing this gap is a critical policy concern and highlights the urgent need to identify the underlying factors, to improve knowledge of HIV-related risks as well as uptake of HIV testing and prevention services, in midlife-older adults.

Theoretical framework

The life-course comprises the set of socially defined events and roles individuals enact over time [19]. Within the life-course, in addition to chronological age, aging is socially and historically constructed by different life events, experiences, and social expectations which shape individual behaviours, perceptions and attitudes [20, 21]. These age constructs inform how individuals enact and cultures express “age” through different life stages, such as adulthood, midlife and elderhood, and their meaning in society [20, 22,23,24]. Within these constructs culturally-dominant ideals of achievement, respectability and status contribute to shared age-related identities [25]. Diversity of experiences informed by gender, power, class, place and time also influence and define multiple and continuous expressions of age within and across cultures [26,27,28].

Studies in southern Africa have begun to apply life-course approaches to understanding HIV among older adults [9, 16, 29,30,31,32,33,34,35]. Findings have highlighted how age norms can make accessing HIV prevention, testing and care challenging. This is often due to concerns about loss of respect and age-related stigma and discrimination reflecting experiences from earlier times when treatment was not widely available. Age norms can also be gendered by traditional masculinities reducing HIV testing and ART initiation among older men [7], or increased household and community responsibilities becoming a barrier to health services, including HIV testing, among older women [12, 22, 29].

The vast majority of studies continue to focus on aging as it relates to trends in HIV epidemiology, risk factors and issues following an HIV-positive diagnosis [10, 11, 15, 29, 36].

Framing the discussion around the life-course [19], while also considering age and gender [20, 25], contributes to the literature by examining the gendered construction of 'respectable' midlife-older age adult life in southern Africa, and how it influences perceptions of HIV-related risk and both conventional HIV testing and self-testing in urban and rural Malawi.

Here we explore perceptions of HIV risk and HIV testing among midlife-older men and women living in rural and urban Malawi following the introduction of HIVST. Drawing on theories of life-course [20, 21] and performance of self in society [24], we use qualitative methods to understand how social age is enacted and implications for HIV testing and sexual risk behaviours among midlife-older Malawians. We also explore the potential for HIVST to be part of a broader strategy for engaging midlife-older adults in HIV testing, prevention and care.

Methods

This qualitative study was nested in two cluster-randomised trials of community-based HIVST, one (ISCTN02004005) in three high-density townships of Ndirande, Likhubula and Chilomoni in urban Blantyre and one (NCT02718274) in Manyenje and Nkoka villages in rural Blantyre, Malawi. Results, including uptake of HIVST by age and sex have been described elsewhere [17, 18, 37]. Briefly, volunteers from intervention communities were trained as community-based distributors (CBDs) responsible for providing HIVST to their neighbours [17, 38]. Distributors provided residents with pre-test information, including a demonstration on how to use an oral HIVST kit (OraQuick HIV Self-Test, OraSure Technologies, LLC, Bethlehem, PA, USA). Community members could self-test with a CBD or take a kit home to test later. All self-testers were informed by CBDs that they needed to confirm reactive results and where to access treatment. Disclosure of self-test results was not required, though many shared results with CBDs [17, 18, 37].

Five focus group discussions (FGDs) (n = 48) and 12 in-depth interviews (IDIs) were conducted between April 2013 and November 2016 in five HIVST intervention areas. Community residents were eligible for FGDs if 35 years or older, and IDIs if over 30 years. FGD and IDI participants were recruited prospectively, by liaising with CBDs. Participants were only engaged once for approximately 1 h and were provided transport and refreshments. FGDs included: two with both men and women cluster residents, two with women only, and one with community distributors only. FGDs ranged from 8 to 12 participants, including 48 participants in total. IDIs were limited to community members who had self-tested (Table 1).

Community FGDs and IDIs explored personal experiences and community perceptions, including aspects of the life-course, such as: age and gender norms, social positions, as well as knowledge of HIV and treatment, risk perception, stigma, social harm, self-testing, relationships with distributors, and perceptions of barriers to testing. The distributor FGD explored their experiences offering HIVST to middle-aged and older community members, and perceived barriers to testing. Topic and interview guides are publicly available on the London School of Hygiene and Tropical Medicine (LSHTM) website [39]. All participants in IDIs and FGDs were assured that information shared was confidential and identifiable information would not be shared. FGD participants were requested to maintain confidentiality related to discussion. All participants were anonymized and identifying information was de-linked using a unique study code prior to review and analysis. Unique participant study codes were only made accessible to the research team.

FGDs and IDIs were conducted in the local language (Chichewa) by three male field workers experienced in qualitative methods (MK, MP, and LK) and audio recorded. One field worker led each FGD and IDI. All field workers were trained, participated in development of interview guides and had extensive experience working in the community as qualitative researchers and were native speakers. All recordings were transcribed into Chichewa and then translated into English by trained personnel. Electronic data was stored in password protected servers (RedCap) and password protected computers. Paper-based data was kept in a locked cabinet which was only accessible to the research team.

Thematic content and framework analysis were conducted on FGD and IDI transcripts using a common coding framework developed under the STAR Initiative for data sorting and indexing. Transcripts were first read (CJ, JM, MK) and grouped by themes and then triangulated across participants by age, gender, HIV status and setting (urban or rural). Transcripts were read and re-read in English and Chichewa, then coded themes were jointly re-reviewed to ensure consistency (CJ, MK). Following which, themes were extracted and used to refine the framework iteratively and inform the analysis that was software assisted by NVIVO 12 (QSR International Pty Ltd.). Study findings, from Self-Testing Africa (STAR) and HitTB, were then disseminated to local communities and the ministry of health. Individual participants, however, did not review results.

Ethical approval was obtained from LSHTM, and Malawi College of Medicine and Research and Ethics Committee (COMREC) (P011/10/1020). According to COMREC approved procedures, all participants were informed about the study and goals to evaluate HIVST. All literate participants provided written informed consent and all illiterate participants provided verbal witnessed informed consent and a thumb print. The study and presentation of results followed COREQ guidelines.

Results

Community residents participating in the study were aged 30–74 years. Additional characteristics and key FGDs and IDIs quotes are summarised in Tables 1 and 2 in addition to select quotes which highlight key themes. Data presented, and findings were consistent. Supplementary information includes full summary of participant quotes (S1).

The main themes, using a life-course framework, identified that there were stages of elderhood, with midlife-older age beginning around 30 to 35 years but mostly defined by respectable behaviour (e.g. low sexual activity, fidelity), attributes (e.g. wisdom) and life events (e.g. marriage, number of children) (see Fig. 1). Exploration of perceptions on HIV risk and HIV testing revealed views on respectable behaviour and age drove midlife-older adults to associate HIV with youth, but this reflected lack of knowledge and awareness of their own age-specific risks, including that HIV could have been acquired earlier and in previous relationships. The risk of sexual transmission at older ages was ignored: instead, there was a strong focus on non-sexual modes of transmission, implicitly considered more socially acceptable.

Because of their age, participants felt HIV testing could undermine their respectability, their roles and relationships in family and community life, and that health workers may stigmatize them if diagnosed with HIV. Learning one’s HIV-positive status later in life was considered stressful and deemed unhelpful, particularly as knowledge of the full benefits of ART and its role in preventing further transmission among those virally suppressed was very limited. As a result, midlife-older adults often considered conventional HIV testing unacceptable. Conversely, HIVST was highly preferable, for its convenience and privacy, especially through door-to-door distribution, though there were differences by age and sex.

Figure 1 illustrates emerging themes within a life course approach with variation by age and gender among ‘respectable midlife-older adults’ in urban and rural Malawi.

Defining age and midlife-older adulthood

Participants drew from a range of norms and attributes to define elderhood and the start of midlife-older age in Malawi. While some focused on chronological age, with midlife-older age starting between 30 and 35 years, most defined this period by attributes and experiences [20], including the start of declining health or loss of strength, increased wisdom, respectable behaviour, major life events and increased responsibilities (e.g. marriage, parenthood). Because of this, many acknowledged that youth could be treated as “older”, based on marriage and through being compliant and respectable. Whereas those engaged in ‘bad’ or ‘unwise’ behaviours were considered “childish” at any age (Table 2, quotes (Q) 1–3).

> The one who is looked at as an old person, is the one who follows the advice that he has been given, because when an old person is told something he follows the rules. The one whom we consider as a young person, is the one who doesn’t follow the advice that people give him. – Community resident, 35-49 years, urban, FGD

Participants voiced disapproval however when life events challenged life-course norms, such as older men leaving families and children, or pregnancy among young girls and older women.

Midlife social positions and sexuality

Gender roles and responsibilities continued to follow traditional heteronormative dichotomies of men as head-of-household and women caring for the household and community. With age, both midlife-older adults, especially women, were expected to become more responsible, with diminishing sexual activity and infidelity. Being faithful and trustworthy was considered important for both genders, although most commonly described as a ‘mature’ female trait.

Older participants described themselves as ‘less sexually active’, more likely to be married, and less likely to have many partners. Indeed, having a ‘highly active sex drive’ in later life was considered socially unacceptable (Q4).

> How could an elderly person like this be found with a disease like this? It should have happened to the youth because they are the ones who ‘run faster’ (are more active sexually). – Community resident, 35-49 years, urban, IDI

Risk perceptions in relation to modes of HIV transmission

Men and women felt that only youth were affected by HIV, and midlife-older adults were at low risk (Q7). Sexual risk was discussed purely in the context of current behaviour, without acknowledging that a recent HIV diagnosis could reflect infection acquired years earlier.

> When an old person is looking at a young person, he thinks that a young person has [HIV] in his body. But when a young person is looking at an old person he is 100% sure that this old person does not have any [HIV] in his body. – Community resident, 35-49 years, urban, FGD

Infidelity by oneself or one's partner was an acknowledged risk for acquiring HIV within both urban and rural communities. Few participants however were willing to acknowledge this as a risk within their own relationship. Men spoke more frequently and openly about infidelity, including hinting of doubts about their partner, but still rated themselves as being at low risk. The exception was when a partner was known to be HIV-positive or was known to have had an affair with someone known to be HIV-positive (Q10).

> [Interviewer: You had any perception of risk of HIV then, before found positive with self-testing?] Yes, because my husband had a relationship with a woman who was HIV positive and she was on ARVs … My husband doesn't stop his immoral behaviour. – Community resident, 35-49 years, rural, IDI

While sexual transmission of HIV was acknowledged, midlife-older adults strongly emphasised non-sexual modes of transmission as a reason for older adults to worry about HIV and to consider HIV-testing. This reflected stated age norms of sexual inactivity, marriage, fidelity and respectability assigned to those considered older. Women in both rural and urban areas expressed concern about acquiring HIV through caring for the sick and bathing the dead. Routinely sharing items was another concern cited by both men and women, and including beard shavers, razors, soap and needles used for removing thorns. For CBDs, emphasising non-sexual routes of transmission provided a socially acceptable way of promoting HIVST amongst midlife-older adults, avoiding detailed discussions about sex which made participants less comfortable (Q11).

> We explain to them that one can contract the virus through different ways. It might be that you helped a certain person, or maybe you used something sharp, and from

> nowhere you can easily contract the virus. Because of that, they say ‘I think that you are explaining well’ and you will find that they get tested. –CBD, < 35 years, urban, FGD

Consequences of HIV testing and diagnosis in later life

Midlife-older adults considered themselves to be more subject to HIV stigma and at greater risk of losing social standing than younger people if diagnosed with HIV, or even if seen to be testing. They anticipated being considered ‘childish’, mocked and laughed at if diagnosed HIV-positive, and that their diagnosis would be interpreted as a ‘lack of wisdom’ and sexual impropriety (Q14–16).

> We look at those old people who contract HIV as if they lack wisdom. – Community resident, 35-49 years, urban, FGD

The extent to which these concerns were justifiable, and from what age, however, was unclear: for instance, neither of the two married women in their 30s who disclosed that they were diagnosed with HIV through self-testing experienced any negative reactions (Q24–25).

Awareness of HIV was considered psychologically stressful, with some older adults considering themselves to be “already finished” with little to gain from learning their HIV status. ART was considered beneficial to health by all, although sometimes difficult to access. And there was little evidence of awareness of treatment-as-prevention, with newly diagnosed participants instead stating intent to use condoms or practice sexual abstinence with their spouse (Q17; Q19).

> Some older people say ‘I have already grown up – what is remaining here is just dying. Why should I go to test? Even if they will mend [treat] me, what will that do for me?’ – Community resident, 50+ years, urban, FGD

> Since that incident happened [both diagnosed with HIV], the community health worker came and gave us condoms. That’s what we are using now. We are using condoms, apart from that we usually having sex once per week or two weeks. – Community resident, 35-49 years, rural, IDI

In this context, testing for HIV was considered stigmatizing for older adults as there was widespread belief that wanting to test would be interpreted as evidence of recent infidelity or sexual risk-taking and that testing HIV-positive would only be harmful. The need for complete confidentiality was stressed for the act of testing, as well as the results, with caution expressed even for home-based or community programmes visible to family and neighbours even though

participants recognised that those testing HIV-positive would inevitably lose all confidentiality as soon as they were seen to be attending their local ART clinic.

Experiences and concerns relating to self-testing

Community-based HIVST, with support and guidance from a CBD and the option to give a kit to a partner, was considered to have many advantages for midlife-older adults, addressing their concerns by providing confidentiality and stigma, as well as convenience. Older participants desired more support compared to younger participants while self-testing, which was confirmed by CBDs (Q26–28).

> Old people prefer different things. Those who have reached 45 to 70 years are the ones who test in our presence so that we should help them in reading the results, and so you can explain the instructions to them properly. – CBD, 35-49 years, urban, FGD

Being able to give an HIVST kit to a partner or self-test with a spouse, having decided and received information and counselling together, was considered advantageous by midlife-older adults (Q29–32).

> I found myself to be HIV positive together with my husband. [Before] we had plans to go for testing, so we took self-testing together as an advantage to us, [and] we accepted the results … There is benefit because it [self-testing] will bring trust and love to each other. – Community resident, 35-49 years, rural, IDI

Neither gender, however, liked the idea of having a self-test kit imposed on them by their partner via “secondary distribution”, reflecting themes of HIV testing undermining social position, as well as questioning one’s elderhood by doubting their fidelity.

Concerns about risks posed to the community by HIVST were negligible for all age-groups, with anticipated benefits considered to outweigh harms. No social harm was reported by participants who all previously self-tested, including two women who disclosed that they were diagnosed with HIV through self-testing.

Future service delivery preferences for self-testing

Many urban participants considered younger CBDs inappropriate for older community members, being unable to discuss personal issues and unlikely to be persuasive (Q33; Q35). However,

older participants in rural settings prioritized trustworthiness over age or sex of distributors (Q34).

> [Interviewer: Who should distribute self-test kits in terms of age and sex?] Anyone, as long as the person is trustworthy. – Community resident, 35-49 years, urban, IDI

This reinforced views that chronological age alone is not important, but that respectable behaviours and experience can also define what is considered “older”.

Acceptable alternatives to door-to-door distribution varied by age and gender, with women in their 30s suggesting outreach linked to antenatal and family-planning clinics, older women suggesting health facilities, and older men preferring fixed community collection points, workplaces or bus depots. These preferences aligned closely with perceptions of what was deemed age-gender appropriate.

Views on linkage post-HIVST did not appear to vary by age or gender, but some participants strongly preferred face-to-face post-test support. Following HIVST, having accompaniment from a relative or health worker or a referral slip (as in the study) was considered useful. Few other tools and approaches to support linkage were suggested.

Discussion

Our study has applied the life course approach [20] to understand how midlife-older age (≥30 years) is defined and culturally expressed by Malawians not only as chronological age, but through social and gender norms and attributes which focus on what is considered respectable behaviour. These norms, coupled with limited awareness of the changes in the HIV epidemic, including high HIV prevalence in their age-group and treatment as prevention, result in low HIV-risk perception among older men and women in Malawi. Such findings support previous studies that have highlighted barriers and challenges with reaching older populations with HIV testing, prevention and treatment services in southern Africa [12, 22, 29].

Age norms defining midlife-older adulthood drove views that conventional HIV testing later in life is disreputable and unacceptable, implying infidelity, sexual risk-taking and a lack of wisdom that, if discovered, would threaten social position in family and community life. Socioemotional selectivity [40] was observed among older adults who highlighted concerns about stigmatising reactions, and that an HIV-positive diagnosis was too stressful and unhelpful. Awareness of the potential for long-standing undiagnosed HIV to be carried forward from past relationships was

minimal, as was understanding of treatment-as-prevention. These norms led to HIV testing being perceived as a threat to status by older-adults, and likely drives the low levels of recent HIV testing in midlife-older adults [10, 15], as well as lower uptake of early introduction of HIVST in Malawi [17], compared to younger adults.

There is urgent need to communicate the changing epidemiology of HIV, and provide supportive HIV testing and prevention efforts, to midlife-older African adults, given their substantial underappreciation of personal risks, especially among + 35 year old men where HIV prevalence and new infections now exceeds younger age groups [1, 3]. Communicating the importance of condom use later in life, as well as how being on ART and maintaining viral suppression prevents transmission to sexual partners should be prioritized.

Older participants expressed marked preference for access to HIVST over other testing modalities, similar to younger age groups [17, 18, 41]. HIVST delivered at home, with an additional kit for a partner was generally acceptable among midlife-older adults, addressing concerns about being seen testing; though support in the testing process was needed.

Age and gender norms of what is ‘respectable’ for midlife and older adults emerged as key issues affecting HIV risk perceptions, knowledge and acceptability of HIV testing services. As previously reported [9, 16, 42, 43], the role and responsibility of women increased with age, including expectations of fidelity, being a caregiver and keeping the family healthy and HIV-negative. These preconceptions led many older men and women in established relationships to perceive their HIV risk to be low. Middle-aged and older adults strongly held the view that only young people could be affected because ‘mature adults’ were less sexually active, less susceptible to infidelity and had fewer partners.

This belief starkly contrasts with current epidemiological data [3, 31], but reflects cultural expectations of midlife and older Malawians, as well as gendered views of HIV, and early experiences and messages dating back to when HIV was first recognized in African societies [44] at which time HIV services and messages focused on reaching women and young people because of elevated risk. Such focus may have inadvertently reinforced views of low risk perception among older age groups, especially men, and undermined messages on the importance of testing and HIV prevention more broadly. These views, as well as limited knowledge of the full benefits of ART, emerged as key drivers of the concerns about potential stigma and social consequences of accessing HIV testing among older adults. The evidence on how to deliver effective HIV interventions and messages for older adults is limited [23, 45].

Further implementation research is needed to identify and scale-up messages and methods that effectively address sexual risk behaviour and HIV-related risks amongst midlife-older adults.

Our findings support HIVST as a useful tool for reaching midlife-older adults. The very same gender and social norms that drove low-risk perception and poor acceptability of HIV testing among mature adults, also drive preferences for self-testing. The feeling that testing at health facilities was too stigmatizing, costly and time consuming for older adults mirrored their stated preferences for self-testing because of its discretion and ease. While there was some variation, older adults preferred door-to-door HIVST, with an extra kit for a partner. Distribution by older providers, or those considered respectable, was often preferred. Acceptable HIVST kit access points varied by age and gender, defaulting to social positions and settings deemed gender appropriate (i.e. discreet collection points or workplace for older men and clinics for older women). Given the COVID-19 context, offering HIVST for midlife-older adults may also be increasingly advantageous to decongest health facilities and maintain essential services for those with potential risk factors that might lead to more serious disease in older populations.

Partner self-testing was viewed positively by all participants. Having an established social role and relationship was linked to this view, as well as having few concerns about harm in midlife-older adults. However, while individuals were inclined to give a self-test to a spouse, none stated they wanted to receive a kit from their partner. These findings further reinforce earlier reports showing both preference for giving a partner a kit [42], while receiving a kit is undesirable [46]. Considering continued reports of acceptability and high uptake of partner self-testing among men and women [47, 48], the lack of a stated preferences for receiving a kit from a partner is likely associated with socioemotional selectivity [27, 40] and avoiding undesirable relationship concerns, such as infidelity.

Future programmes should consider these preferences, and social and cultural norms of midlife-older adults, when planning HIVST, as well as broader HIV testing, implementation. Greater efforts however are still needed to reorient how age norms affect HIV risk and testing. Strategies including use of older providers and community workers who can provide support and instructions on how to self-test should be considered, as well as ambassadors who can align HIV prevention and testing behaviours with increasing respectability, health and responsibility among those who are older, and integrating HIV testing for older age groups as part of testing for non-communicable diseases [9, 16]. Information and counselling messages on the full benefits of treatment, particularly treatment as prevention are critical and may reduce some of the fear and stress of an HIV-positive diagnosis which inhibits testing later in life. Additional

outreach strategies using traditional media, e.g. newspaper, radios, and village networks may be important as opposed to social media and other technologies being utilised to reach young people.

Our study has several limitations. First, although our study aimed to include a range of adults aged over 30 years, Malawi has a young population, with only 4 and 20%, respectively, aged over 50 and 35 years, as is reflected in our median age of participants of 41 years [49]. This does mean that our findings primarily concern social norms amongst middle-aged rather than older-aged Malawians and may not generalise to countries with markedly different population age-structures. Second, our findings under-represent the views of those who declined HIVST, many of whom may have been older. Third, we conducted qualitative studies within the context of broader cluster-randomised trials that primarily delivered door-to-door HIVST. Therefore, preferences on HIVST may have included more general preferences for door-to-door and community-based HIV testing. Fourth, because more women were recruited into the study, and that there was not a male only FGD, the views of men may be under-represented. Lastly, it is possible that a young male data collection team (age < 35 years) may have influenced the quality of data collected especially from women and older participants. However, the experience of the team and support from senior qualitative researchers (ND) helped overcome this challenge.

Conclusions

Age and gender norms are important drivers of HIV risk perception and HIV testing uptake during midlife-older adulthood. Using the life-course approach we highlight how age and gender norms contribute to poor uptake of conventional HIV testing by middle-aged or older individuals, as well as preferences for future self-testing in Malawi. With changes in HIV epidemiology, the increasing ease of access to ART and new HIV testing options (such as HIVST), there is an urgent need to provide targeted messages and services more appropriate to this age-group in sub-Saharan Africa. These messages need to include information on HIV risk and the importance of condoms later in life, as well as education on the benefits of ART including that PLHIV on ART who maintain viral suppression will not transmit HIV to their partners.

Despite concerns that HIV testing in facilities would be viewed as disreputable and undermine the current and future social status of midlife-older adults, HIVST appeared to provide a safe and acceptable alternative for mature adults to test, without challenging social age or gender

expectations. While door-to-door, with an extra kit for a partner and support for the self-testing, continues to be preferred by middle-aged and older adults, additional service delivery approaches were considered age-gender appropriate (i.e. clinics for women, discreet community collection points and workplaces for men). Future programmes should consider these preferences as they plan HIV testing services, including HIVST scale-up, among midlife and older adults.

Availability of data and materials

As agreed in the LSHTM, and Malawi College of Medicine and Research and Ethics Committee (COMREC) ethics approval and research protocol, qualitative interview transcripts and the corresponding anonymised NVivo file are only visible to the direct research team, and are not publicly available.

References

1. UNAIDS. Communities at the Centre. Geneva: Joint United Nations Programme on HIV/AIDS; 2019.
2. UNAIDS. The life-cycle approach to HIV: get on the fast-track finding solutions for everyone at every stage of life. Geneva: Joint United Nations Programme on HIV/AIDS; 2016.
3. Giguère K, Eaton J, Marsh K, Johnson L, Johnson C, Ehui E, Jahn A, et al. Trends in knowledge of HIV status and efficiency of HIV testing services in sub-Saharan Africa (2000-2020): a modelling study of survey and HIV testing program data. Lancet HIV. 2021. https://doi.org/10.1016/S2352-3018(20)30315-5.
4. Smit M, Brinkman K, Geerlings S, Smit C, Thyagarajan K, van Sighem A, et al. Future challenges for clinical care of an ageing population infected with HIV: a modelling study. Lancet Infect Dis. 2015;15(7):810–8. https://doi.org/10.1016/S1473-3099(15)00056-0.
5. Mhlongo S, Dietrich J, Otwombe KN, Robertson G, Coates TJ, Gray G. Factors associated with not testing for HIV and consistent condom use among men in Soweto. South Africa PloS One. 2013;8(5):e62637. https://doi.org/10.1371/journal.pone.0062637.
6. Jacques-Avino C, Garcia de Olalla P, Gonzalez Antelo A, Fernandez Quevedo M, Romani O, Cayla JA. The theory of masculinity in studies on HIV. A systematic review. Glob Public Health. 2019;14(5):601-20. https://doi.org/10.1080/17441692.2018.1493133.

7. Siu GE, Seeley J, Wight D. Dividuality, masculine respectability and reputation: how masculinity affects men's uptake of HIV treatment in rural eastern Uganda. Soc Sci Med. 2013;89:45–52. https://doi.org/10.1016/j.socscimed.2013.04.025.

8. Topazian HM, Stoner MCD, Edwards JK, Kahn K, Gómez-Olivé FX, Twine R, Hughes JP, Cohen MS, Pettifor A. Variations in HIV risk by young women's age and partner age-disparity in rural South Africa (HPTN 068). J Acquir Immune Defic Syndr. 2020 Apr 1;83(4):350–6. https://doi.org/10.1097/QAI.0000000000002270.

9. Schatz E, Knight L. “I was referred from the other side”: Gender and HIV testing among older South Africans living with HIV. PloS One. 2018;13(4):e0196158.

10. Vollmer S, Harttgen K, Alfven T, Padayachy J, Ghys P, Bärnighausen T. The HIV epidemic in sub-Saharan Africa is aging: evidence from the demographic and health surveys in sub-Saharan Africa. AIDS Behav. 2017;21(1):101-13. https://doi.org/10.1007/s10461-016-1591-7.

11. Rosenberg MS, Gómez-Olivé FX, Rohr JK, Houle BC, Kabudula CW, Wagner RG, Salomon JA, Kahn K, Berkman LF, Tollman SM, Bärnighausen T. Sexual behaviors and HIV status: a population-based study among older adults in rural South Africa. J Acquir Immun Defic. 2017;74(1):e9–e17. https://doi.org/10.1097/QAI.0000000000001173.

12. Jacobs RJ, Kane MN. HIV-related stigma in midlife and older women. Soc Work Health Care. 2010;49(1):68–89. https://doi.org/10.1080/00981380903018140.

13. Orel NA, Spence M, Steele J. Getting the message out to older adults: effective HIV health education risk reduction publications. J Appl Gerontol. 2005;24(5):490–508. https://doi.org/10.1177/0733464805279155.

14. Lindau ST, Leitsch SA, Lundberg KL, Jerome J. Older women's attitudes, behavior, and communication about sex and HIV: a community-based study. J Women's Health. 2006;15(6):747–53. https://doi.org/10.1089/jwh.2006.15.747.

15. Maes CA, Louis M. Knowledge of AIDS, perceived risk of AIDS, and at–risk sexual behaviors among older adults. J Am Acad Nurse Pract. 2003;15(11):509–16. https://doi.org/10.1111/j.1745-7599.2003.tb00340.x.

16. Schatz E, Houle B, Mojola S, Angotti N, Williams J. How to “live a good life”: aging and HIV testing in rural South Africa. J Aging Health. 2018;31(4):709–32. https://doi.org/10.1177/0898264317751945.

17. Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, Sambakunsi R, Mdolo A, Makombe SD, Desmond N, Hayes R, Maheswaran H, Corbett EL. Uptake, accuracy, safety,

and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: a community-based prospective study. PloS Med. 2015;12(9):e1001873. https://doi.org/10.1371/journal.pmed.1001873.

18. Hatzold K, Gudukeya S, Mutseta M, et al. HIV self-testing: breaking the barriers to uptake of testing among men and adolescents in sub-Saharan Africa, experiences from STAR demonstration projects in Malawi, Zambia and Zimbabwe. J Int AIDS Soc. 2019;22(S1):e25244. https://doi.org/10.1002/jia2.25244.

19. Elder GH, Johnson MK, Crosnoe R. The emergence and development of life course theory. In: Mortimer JT, Shanahan MJ, editors. Handbook of the life course. Boston, MA: Springer US; 2003. p. 3–19. https://doi.org/10.1007/978-0-306-48247-2_1.

20. Alwin DF. Integrating varieties of life course concepts. J Gerontol B Psychol Sci Soc Sci. 2012;67B(2):206–20. https://doi.org/10.1093/geronb/gbr146.

21. Elder GH, Rockwell RC. The life-course and human development: an ecological perspective. Int J Behav Dev. 1979;2(1):1-21. https://doi.org/10.1177/016502547900200101.

22. Makoni S, Stroeken K. Aging in Africa. New York: Routledge; 2002.

23. Fry PS. Major social theories of aging and their implications for counseling concepts and practice: a critical review. Couns Psychol. 1992;20(2):246-329.https://doi.org/10.1177/0011000092202002.

24. Goffman E. The presentation of self in everyday life. New York: Doubleday; 1959.

25. Riley MW, Johnson M, Foner A, Clausen JA, Cohn R, Hess B, et al. Aging and society, volume 3: a sociology of age stratification: Russell Sage Foundation; 1972.

26. France A, Roberts S. The problem of social generations: a critique of the new emerging orthodoxy in youth studies. J Youth Stud. 2015;18(2):215–30. https://doi.org/10.1080/13676261.2014.944122.

27. Fung HH. Aging in culture. Gerontologist. 2013;53(3):369-77. https://doi.org/10.1093/geront/gnt024.

28. Harling G, Morris KA, Manderson L, Perkins JM, Berkman LF. Age and gender differences in social network composition and social support among older rural south Africans: findings from the HAALSI study. J Gerontol B Psychol Sci Soc Sci. 2020;75(1):148–59. https://doi.org/10.1093/geronb/gby013.

29. Schatz E, Seeley J. Gender, ageing and carework in east and southern Africa: a review. Glob Public Health. 2015;10(10):1185–200. https://doi.org/10.1080/17441692.2015.1035664.

30. Emlet CA. “You’re awfully old to have this disease”: experiences of stigma and ageism in adults 50 years and older living with HIV/AIDS. Gerontologist. 2006;46(6):781–90. https://doi.org/10.1093/geront/46.6.781.

31. Houle B, Mojola SA, Angotti N, Schatz E, Gómez-Olivé FX, Clark SJ, Williams JR, Kabudula C, Tollman S, Menken J. Sexual behavior and HIV risk across the life course in rural South Africa: trends and comparisons. AIDS Care. 2018;30(11):1435–43. https://doi.org/10.1080/09540121.2018.1468008.

32. Mojola SA, Williams J, Angotti N, Gomez-Olive FX. HIV after 40 in rural South Africa: a life course approach to HIV vulnerability among middle aged and older adults. Soc Sci Med. 2015 Oct;143:204–12. https://doi.org/10.1016/j.socscimed.2015.08.023.

33. Soomro N, Fitzgerald G, Seeley J, Schatz E, Nachega JB, Negin J. Comparison of antiretroviral therapy adherence among HIV-infected older adults with younger adults in Africa: systematic review and meta-analysis. AIDS Behav. 2019;23(2):445–58. https://doi.org/10.1007/s10461-018-2196-0.

34. Negin J, Cumming RG. HIV infection in older adults in sub-Saharan Africa: extrapolating prevalence from existing data. Bull World Health Organ. 2010;88(11):847–53. https://doi.org/10.2471/BLT.10.076349.

35. Negin J, Nemser B, Cumming R, Lelerai E, Ben Amor Y, Pronyk P. HIV attitudes, awareness and testing among older adults in Africa. AIDS Behav. 2012;16(1):63–8. https://doi.org/10.1007/s10461-011-9994-y.

36. Kuteesa MO, Wright S, Seeley J, Mugisha J, Kinyanda E, Kakembo F, Mwesigwa R, Scholten F. Experiences of HIV-related stigma among HIV-positive older persons in Uganda--a mixed methods analysis. SAHARA J. 2014;11(1):126–37. https://doi.org/10.1080/17290376.2014.938103.

37. Indravudh P, Fielding K, Neuman M, Chilongosi R, Mkandawire P, Nyondo E, et al. Increasing knowledge of HIV status and demand for ART using community-based HIV self-testing in rural communities: a cluster randomised trial in Malawi. Amsterdam: 22nd International AIDS Conference; 2018.

38. Neuman M, Indravudh P, Chilongosi R, d'Elbée M, Desmond N, Fielding K, Hensen B, Johnson C, Mkandawire P, Mwinga A, Nalubamba M, Ncube G, Nyirenda L, Nyrienda R, Kampe EOI, Taegtmeyer M, Terris-Prestholt F, Weiss HA, Hatzold K, Ayles H, Corbett EL. The effectiveness and cost-effectiveness of community-based lay distribution of HIV self-tests in increasing uptake of HIV testing among adults in rural Malawi and rural and peri-urban Zambia:

protocol for STAR (self-testing for Africa) cluster randomized evaluations. BMC Public Health. 2018;18(1):1234. https://doi.org/10.1186/s12889-018-6120-3.

39. LSHTM, STAR. STAR HIV self-testing Africa initiative – research London. UK: London School of Hygiene and Tropical Medicine; 2015. [2 Jan 2020]. Available from: http://hivstar.lshtm.ac.uk/protocols/

40. Carstensen LL, Fung HH, Charles ST. Socioemotional selectivity theory and the regulation of emotion in the second half of life. Motiv Emot. 2003;27(2):103–23. https://doi.org/10.1023/A:1024569803230.

41. Indravudh PP, Sibanda EL, d'Elbée M, et al. 'I will choose when to test, where I want to test': investigating young people's preferences for HIV self-testing in Malawi and Zimbabwe. AIDS. 2017;31(S3):S203–S12. https://doi.org/10.1097/QAD.0000000000001516.

42. Choko A, Kumwenda M, Johnson C, et al. Acceptability of woman-delivered HIV self-testing to the male partner: a qualitative study of antenatal clinic-linked participants in Blantyre. Malawi J Int AIDS Soc. 2017;20(1):21610. https://doi.org/10.7448/IAS.20.1.21610.

43. Kumwenda M, Corbett E, Chikovore J, et al. Discordance, disclosure and normative gender roles: barriers to couple testing within a community-level HIV self-testing intervention in urban Blantyre. Malawi AIDS Behav. 2019;22:2491–9.

44. Udvardy M, Cattell M. Gender, aging and power in sub-Saharan Africa: challenges and puzzles. J Cross Cult Gerontol. 1992;7(4):275–88. https://doi.org/10.1007/BF01848695.

45. Negin J, Rozea A, Martiniuk AL. HIV behavioural interventions targeted towards older adults: a systematic review. BMC Public Health. 2014;14(1):507. https://doi.org/10.1186/1471-2458-14-507.

46. d'Elbée M, Indravudh PP, Mwenge L, Kumwenda MM, Simwinga M, Choko AT, Hensen B, Neuman M, Ong JJ, Sibanda EL, Johnson CC, Hatzold K, Cowan FM, Ayles H, Corbett EL, Terris-Prestholt F. Preferences for linkage to HIV care services following a reactive self-test: discrete choice experiments in Malawi and Zambia. AIDS. 2018;32(14):2043–9. https://doi.org/10.1097/QAD.0000000000001918.

47. Choko AT, Corbett EL, Stallard N, et al. HIV self-testing alone or with additional interventions, including financial incentives, and linkage to care or prevention among male partners of antenatal care clinic attendees in Malawi: an adaptive multi-arm, multi-stage cluster randomised trial. PloS Med. 2019;2019(1):e1002719.

48. Jamil M, Wilson I, Witzel C, Figueroa C, Barr-Dichiara M, Rodgers A, et al. Should HIV self-testing be offered as an HIV testing approach? Kigali: ICASA; 2019.

49. NOS ICF. Malawi demographic health survey 2015–16. Zomba, Malawi, and Rockville. Maryland: NSO and ICF; 2017.

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Ethics approval and consent to participate

All data collection procedures were approved by LSHTM, and Malawi College of Medicine and Research and Ethics Committee (COMREC) (P011/10/1020). According to COMREC approved procedures, all literate participants provided witnessed written informed consent and all literate participants provided or witnessed verbal informed consent. Witnessed verbal consent procedures included a research assistant reading information contained in the study information sheet to both the participant and witness. If a potential research participant showed willingness to participate, we were required to obtain a thumbprint from the participant and a signature from a participant’s witness.

Competing interests

The authors declare that they have no conflict of interest. The contents in this article are those of the authors and do not necessarily reflect the view of the World Health Organization.

5.3 Tables and figures

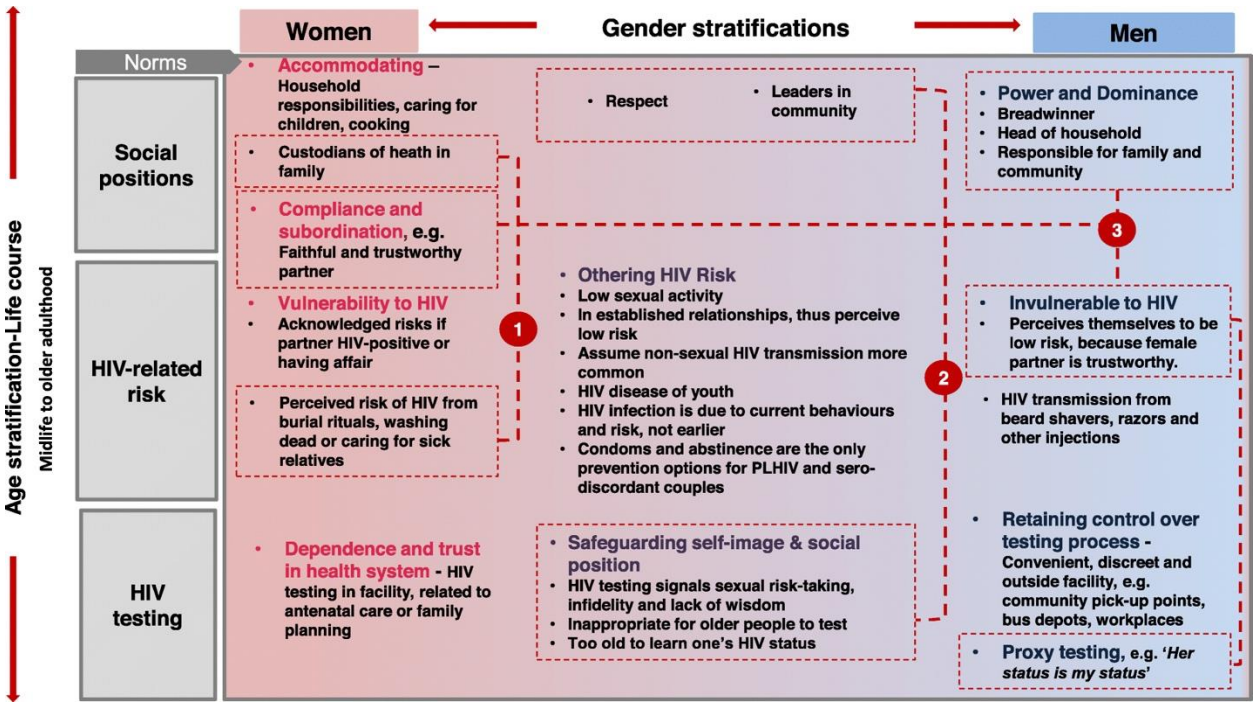
Table 1: *Demographic characteristics of community residents and distributors*

	FGD (*n* = 4)	CBD FGD (*n* = 1)	IDI (*n* = 12)
	# of participants, n = 37	***# of participants, n = 11***	***# of participants, n = 12***
Sex			
Male	9	6	6
Female	28	5	6
Age (years)			
Median age	39 years (range:35–74)	33 years (range: 24–61)	35 years (range: 31–64)
< 35	0	7	5
35–49	34	3	5
50+	2	1	2
Unknown	1	0	0
Education			
Adult literacy	1	0	0
Primary incomplete or complete	15	0	7
Secondary school complete	0	9	2
Some secondary education	21	2	3
Marital Status			
Married or living as married	23	*	10
Widowed, separated or divorced	14	*	1
Never married	0	*	1
HIV status			
HIV positive	9	*	2
HIV negative	24	*	10
Unknown	4	*	0
Ever tested			

Yes	20	*	8
No	5	*	4
Unknown	12	*	0
Self-tested			
Yes	32	*	12
No	5	*	0

FGD Focus group discussion, *CBD* Community-based distributor, *IDI* In-depth Interview

Figure 1: *Example of perceptions of social positions, HIV-related risk and HIV testing by social age and gender among 'respectable' midlife-older adults in urban and rural Malawi.*



This figure is illustrative using three examples of age stratification-life course variation by gender among midlife-older adults in urban and rural Malawi: (1) Social positions of older women as custodians of health in the family is related to women's representation of HIV risk, such as caring for sick relatives and burial rituals which are considered their responsibility and so, represent a 'respectable' risk that can be acknowledged openly; (2) Social positions of respect and being leaders in the community relates to midlife-older adults perceptions that testing is inappropriate for their age this HIV risks resulting in the "othering" of HIV-related risk behaviours as those which are contrary to characteristics of midlife-older adults; and (3) Social positions among older women as faithful and trustworthy relates to men's views that they are low risk, and because of their lack of knowledge about HIV serodiscordancy among couples, they do not think they need HIV testing.

5.4 Supplementary information

Appendix 1. *Supplementary table*

Table S1: *Detailed summary of participant quotes from focus group discussions and in-depth interviews across the life course*

Key themes	#	Participant quote	Participant characteristics
Defining age and midlife-older adulthood			
Age as chronological	1a*	[A old person] is over 35 years. A person who is 34 years and below is not [old]…[Because] when you can see that one is 35 years may also have a family. 20 years is not married…[and in a] youthful stage…	Community resident, 35-49 years, urban, Focus group discussion (FGD)
	2	In my community old people…their age range starts from 30 [years] going up.	Community resident, 35-49 years, urban, FGD
	3	I think there are various stages of being elderly. Someone with 36 years of age -- we call them elderly.	Community resident, 35-49 years, urban, FGD
Age as health	4	A youth doesn't have diseases like elderly people.	Community resident, 35-49 years, urban, FGD
	5	The youths have much strength and they do any work they can do, so for us the old ones who are 35 years going up, it's like the strength decreases as we grow.	Community resident, 35-49 years, urban, FGD
Age as wisdom	6	Because he is older he [is] able to advise children on what to do.	Community resident, 35-49 years, urban, FGD
	7	A person can be older but if he has nothing then he is a kid…That is why we say wisdom nowadays is the wisdom that uses money	Community resident, 35-49 years, urban, FGD
	8	*[Interviewer: Who are usually in positions such as members of parliament or chairmen?]* [Those] positions do not look at whether this person is young or old, but the experience…and how that person is. Some can be old but they can fail to look after the village. So even a youth can hold a big position in the village.	Community resident, 50+ years, urban, FGD
Age as life events	1b*	[A old person] is over 35 years. A person who is 34 years and below is not [old]…[Because] when you can see that one is 35 years may also have a family. 20 years is not married…[and in a] youthful stage…	Community resident, 35-49 years, urban, FGD

Key themes	#	Participant quote	Participant characteristics
	9	I have started a motherly life, so I can now be doing this and that; all that I was doing in the past was childish	Community resident, 35-49 years, urban, FGD
	10	…In the past a person who is 40 years was able to give birth to maybe 15 children.	Community resident, 35-49 years, urban, FGD
	11	…it is not wise…your children giving birth and [that] you are also giving birth.	Community resident, 35-49 years, urban, FGD
	12	If you find a [young girl] you find that in her childish ways she gets pregnant…and delivers a child.	Community resident, 50+ years, urban, FGD
Age as responsibility	13	The elderly person is the one who has the responsibility in the family because for example at 40 years that means he has a lot of children…the one who is working is the same elderly person…because there are not many children who have been educated and they are working	Community resident, 35-49 years, urban, FGD
	14	The one who takes up responsibilities is an old woman.	Community resident, 35-49 years, urban, FGD
Age as behaviour	15	If your behaviour is not good…even a child thinks you are also a child. While if a little child gives himself respect, some people also respect him as if he is older.	Community resident, 35-49 years, urban, FGD
	16	The one who is looked at as an old person, is the one who follows the advice that he has been given, because when an old person is told something he follows the rules. The one whom we consider as a young person, is the one who doesn't follow the advice that people give him.	Community resident, 35-49 years, urban, FGD
	17	We know a young person [by] their behaviour…it's like a prodigal life. They drink a lot, smoke chamba, fornication is becoming rampant in the young ones.	Community resident, 35-49 years, urban, FGD
Gender roles and norms			
Head of household	18	In terms of my home, I always make sure that whenever there is a problem in the family such as shortage of food or insufficient clothing, I should solve it. I may not deal with it wholly, but at least I try my level best. Further to that, I also participate in the development endeavors of our community that needs the participation of men…The obligations of a man in a family [is] to ensure that the household has enough food, buying clothes for the children but also living in an appropriate environment.	Community resident, 35-49 years, rural, IDI

Key themes	#	Participant quote	Participant characteristics
	19	The first thing is to find money, and the second thing is when you find that money you should build a house and buy home necessities. Even people will appreciate that "yes, this man is doing his job as a man". But if you can't find money, there is food scarcity [for] your family because there is no money. There might be poverty at your family.	Community resident, 50+ years, rural, FGD
Taking care of children and household	20	There are many responsibilities. She has to look for food and also cultivating the fields. Even if she is not the one tilling the ground, she must play a supervisory role to the work in the field…She must make sure her household members are eating a well-balanced diet from all the six groups.	Community resident, <35 years, rural, in-depth interview (IDI)
	21	[Being a woman, it might be dressing and the way she talks…[When it comes to taking care of her own health or the family's health], she should have a hardworking spirit at work or at business and be independent.	Community resident, 35-49 years, rural, IDI
Fidelity and trust	22	[Being a woman means] behaviour as well, as a woman doesn't need to go around with other men apart from her own husband.	Community resident, 35-49 years, rural, IDI
	23	Being a man, it means you are a man. I can say that, you would have sexual feelings to other women, but it just takes the person's mind [to decide] whether to go for it or not, [and not just thinking] that you are a man, [who] can do anything.	Community resident, 50+ years, rural, FGD
Social expectations and standing			
HIV is a 'disease of youth'	24	How could an elderly person like this be found with a disease like this? It should have happened to the youth because they are the ones who 'run faster' (are more active sexually)	Community resident, 35-49 years, urban, IDI
	25	[Older people] think there is no reason to go for testing because in their time there was no HIV. HIV is a disease for people who were born after the year 1985. They think the disease is not part of them as they were born and grew up before the disease was discovered.	Community-based distributor (CBD), 35-49 years, urban, FGD
	26	We older people know that this disease is very dangerous - maybe we know that more than the youths do. We have learnt that message through examples, looking after people who have died because of 'running around'. We are really afraid of it. We have responsibilities and if we go, we know the care in our homes will be decreased. We tell the children 'you have to be careful because you will contract diseases'. But the youth are not afraid of it.	Community resident, 35-49 years, urban, FGD
	27	When an old person is looking at a young person, he thinks that a young person has [HIV] in his body. But when a young person is looking at an old person he is 100% sure that this old person does not have any [HIV] in his body	Community resident, 35-49 years, urban, FGD
	28	Most people think AIDS is a disease for the youth, because old people are the ones who give advice. If they are giving advice to the youth and then they should also contract the	Community resident, 35-49

Key themes	#	Participant quote	Participant characteristics
		virus, it becomes surprising. It makes people ask a lot of questions.	years, urban, FGD
HIV-related risk perceptions			
Infidelity and trust	29	No I don't have concerns, even though I am not in marriage but I have a partner and I have trust in her.	Community resident, <35 years, rural, IDI
	30	You can say this is my wife and we are loving each other without knowing that you are thinking differently.	Community resident, 50+ years, rural, IDI
	31	*[Interviewer: You had any perception of risk of HIV then before found positive with self-testing?]* Yes, because my husband had a relationship with a woman who was HIV positive and she was on ARVs…My husband doesn't stop his immoral behaviour.	Community resident, 35-49 years, rural, IDI
	32	I had the intention to go for testing after noting the results of my husband [his results showed he was HIV positive]. So the results prompted me to have the desire to test as well.	Community resident, 35-49 years, rural, IDI
Social acceptability of HIV testing			
Social and self-stigma	33	We explain to them that one can contract the virus through different ways. It might be that you helped a certain person, or maybe you used something sharp, and from nowhere you can easily contract the virus. Because of that, they say 'I think that you are explaining well' and you will find that they get tested.	Community-based distributor (CBD), <35 years, urban, FGD
	34	…I always have fear with barbershops that cant we get HIV? I just think that because everyone use the same [shaving] machine.	Community resident, 50+ years, rural, FGD
	35	…I used bath soaps, so maybe through that I can have a concern [HIV risk].	Community resident, 50+ years, rural, IDI
	36	If you go for HIV-testing people say you doubt yourself. They talk a lot saying there is something making you go for testing. They don't look at it as if it's just your decision, or it is because you listened to the counselling, or that you wish yourself a better future. They think that maybe you have been sleeping around or maybe you are getting sick.	Community resident, 35-49 years, urban, FGD
	37	[Testing] is done quickly when you go to the hospital, and it is better as there are no people there, and everything ends in the room between yourself and the doctor. While at home, you do the testing in front of a lot of children. When a child is there he may be saying 'counsellors came and they have conducted a test on my mother'. Then somebody could ask 'what were they testing her for?', and the child could exclaim 'AIDS!'. So you see, that means my neighbours will know that I did the testing with the counsellors.	Community resident, 35-49 years, urban, FGD

Key themes	#	Participant quote	Participant characteristics
	38	Some older people ask us what will happen if they are found with the virus - will they receive the drugs right here at home or from the hospital? They say some people feel ashamed to go to the hospital and receive drugs, as there will be a queue for such things.	CBD, <35 years, urban, FGD
	39	If an old person has been found with the virus, people tend to wonder saying “aah how come?” because it’s like a young person is the one who is very active in sexual activities. So how has this old man contracted the virus? We look at those old people who contract HIV as if they lack wisdom.	Community resident, 35-49 years, urban, FGD
Perceptions and experiences self-testing			
Disadvantages of HIV testing	40	The issue of transport cannot be ruled out because the money to be used for transport could as well be used in the home for other basic needs as such I would rather not go and use the money feed the family.	Community resident, 35-49 years, rural, IDI
Recommend self-testing	41	*[Interviewer: Would you recommend self-test to your friends or family?]* Very much. If an opportunity emerges that you want to test them, or they want to test themselves and I am around, I would definitely encourage them to use the apparatus because it is very good	Community resident, 35-49 years, rural, IDI
	42	Yes, I would recommend because the procedure is simple.	Community resident, <35 years, rural, FGD
Benefits of reactive self-test	43	Aah, I don’t see any problems. I think there are only benefits because some people are not comfortable to go to the health facility for testing. So it is easier for them to use this method and know their status…Well, [when testing HIV-positive with self-test], I just accepted and admitted it…If I live in denial and be anxious it won’t solve anything. I had to accept and follow the counselling	Community resident, <35 years, rural, FGD
	44	The test kit is a very good thing because you are able to read the results yourself instantly. I believed the [positive] results….There is benefit because it [self-testing] will bring trust and love to each other.	Community resident, 35-49 years, rural, IDI
Ease of use and time saving	45	It was very simple to self-test, I just followed the instructions and managed to test myself….I would recommend self-testing because we save time instead of going to HTC [HIV testing and counselling] we do it ourselves at home. When you think about time and cost, is better to use self-testing because you will do it while at home. Self-test and you don’t waste your time, while at HTC you need to travel and spend money for transport and you will be tested by the doctor.	Community resident, <35 years, rural, IDI
	46	[Self-testing] at home - you can do that within fifteen minutes while you are doing other things at home, while testing at a facility it can take you over an hour.	Community resident, <35 years, rural, IDI
Preferences for support			

Key themes	#	Participant quote	Participant characteristics
Support during self-testing	47	The counselling regarding the kit itself would be to highlight how the apparatus works or how we can use it. After knowing how it works, then we would be able to use it. The only assistance I would want is advice regarding how to properly use the kit.	Community resident, 35-49 years, rural, IDI
	48	The counsellor should provide counselling only, not monitoring the person.	Community resident, 35-49 years, rural, IDI
	49	[Without guidance and supervision] it [would] be difficult because you don't even know how to open the pack. For other people they can be easily to understand, while others it may be difficult for them, so to others might bring confusion.	Community resident, 50+ years, rural, FGD
	50	Old people prefer different things. Those who have reached 45 to 70 years are the ones who test in our presence so that we should help them in reading the results, and so you can explain the instructions to them properly. But people who are 28 to 40 years like to test by themselves because they know that may be their behaviour was not right at a certain time, and they know it wouldn't be a problem to go to the hospital themselves.	CBD, 35-49 years, urban, FGD
Preferences kit distribution of self-test kits			
Expectations of CBDs	51	Old people are stubborn to hear any advice from children. They don't believe these children. They look at themselves as old people who have more wisdom. So, if a young counsellor goes to such a person, will they listen to him?	Community resident, 35-49 years, urban, FGD
	52	*[Interviewer: Who should distribute self-test kits in terms of age and sex?]* Anyone, as long as the person is trustworthy	Community resident, 35-49 years, urban, IDI
	53	…Maybe your child will be conducting a test on me. I am an old person.	Community resident, 50+ years, urban, FGD
Home-based distribution	54	The best distribution is like what happened last time, because many people were received. So if they can continue to distribute on the same way [door-to-door], I believe many people will know their HIV status. I think if they pass through the Village head man, people will not go but they should reach them through door to door.	Community resident, 50+ years, rural, FGD
	55	At our village headman's residence because we have [outreach family planning clinic] every month, so that place would be easy for everyone to get the self-testing kit.	Community resident, <35 years, rural, IDI
Facility-based distribution	56	[HIV self-tests should be distributed] in all our nearest health centres like Zingwangwa, Mpemba and Pensulo.	Community resident, <35 years, rural, IDI
	57	[Self-tests] should be at the hospital, may be at K1.000.00 as a price.	Community resident, 35-49 years, rural, IDI

Key themes	#	Participant quote	Participant characteristics
Other: Community collection points, workplace, bus depots	58	Create a collection point [for men] at the same chief's compound.	Community resident, 35-49 years, rural, IDI
	59	The place could be somewhere closer to us so that we do not need to spend money on transport in order to reach the place. Finding a good place which we feel that this place is close to us and that even the people around there can easily access it.	Community resident. 35-49 years, rural, IDI
	60	It needs to be distributed especially in the companies, bus depot and other areas that are largely men available.	Community resident, <35 years, rural, IDI
Pre- and post-test support			
Phone or in-person	61	Through phone can be the best way, because through a letter the person might be illiterate so that would be difficult to understand.	Community resident, 50+ years, rural, FGD
	62	I don't think there should be anything to worry about because the message can be delivered anyhow [by phone or in-person], even at a public rally. There you are not targeting one person but a group of people which has gathered there.	Community resident, <35 years, rural, IDI
	63	Some people do not have access to phones, so the best way is face to face.	Community resident, <35 years, rural, IDI
Partner self-testing			
Family and couples counselling	64	The best counselling should be provided as a couple, because they will remind each other if one has forgotten.	Community resident, 50+ years, rural, IDI
	65	Counselling given to a family as a whole is good because it gives an opportunity for everyone to hear for himself… Especially [for] me and my wife	Community resident, 35-49 years, rural, IDI
Give kit to partner	66	Yes, I would be very glad because me and my wife are one. So if that could be the arrangement I believe she would be very glad to, because from the very beginning she was the one who was encouraging me to go for blood testing. With this kit, my wife would also be able to test herself.	Community resident, 35-49 years, rural, IDI
	67	I found myself to be HIV positive together with my husband. [Before] we had plans to go for testing, so we took self-testing together as an advantage to us, [and] we accepted the results…There is benefit because it [self-testing] will bring trust and love to each other.	Community resident, 35-49 years, rural, IDI
Perceived benefits of treatment			
Fatalism	68	Some people say they are already dead when they test HIV positive, instead of start to receive ARVs.	Community resident, 50+ years, rural, IDI
	69	Some older people say 'I have already grown up – what is remaining here is just dying. Why should I go to test? Even if they will mend me, what will that do for me?'	Community resident, 50+ years, urban, FGD

Key themes	#	Participant quote	Participant characteristics
Condom use and abstinence	70	Since that incident happened [both diagnosed with HIV], the community health worker came and gave us condoms. That's what we are using now. We are using condoms, apart from that we usually having sex once per week or two weeks.	Community resident, 35-49 years, rural, IDI
	71	Yes, we use [condoms]…We will continue. As for this unborn baby, [I am protecting it through] the treatment I am receiving.	Community resident, <35 years, rural, IDI
Linkage to care			
Accompaniment or assistance	72	Relatives can help you to link with support and care services by confirming to doctors that indeed you are HIV positive.	Community resident, 50+ years, rural, IDI
	73	The person can be assisted if there is a health worker nearby.	Community resident, <35 years, rural, IDI
Referrals, including letters or slips	74	I will need to get a letter [referral slip] from your organization to show at the hospital, that can be better.	Community resident, 35-49 years, rural, IDI
Incentives	75	After counselling the person advised them to go to the service centre to receive medication, maize flour, cooking oil and other things.	Community resident, 50+ years, rural, FGD
Social harms			
No concerns, just benefits	76	There would be no risks apart from benefits for everyone who will know his/her HIV status.	Community resident, 50+ years, rural, FGD
	77	No that cannot happen because whoever go for self-testing that means has made a decision.	Community resident, 35-49 years, rural IDI
	78	Aah, I don't see any problems. I think there are only benefits…There isn't any threat.	Community resident, <35 years, rural, IDI
Re-use of self-test kits	79	Those self-testing kits needs to be taken care of and kept on safe place to avoid reuse of the kits.	Community resident, <35 years, rural, IDI
Not disclosing reactive results	80	The problem might be if you found HIV positive and haven't disclosed to health workers that might be a problem.	Community resident, <35 years, rural, IDI
Harming self or others	81	To me what I envisage as a threat to this program mainly relates to when people know their results. Some people if found positive may take it as the end of their life and decide to infect as many people as possible so that they are not alone with the virus. The only way to prevent that is to ensure that a person is properly counselled before the testing and that he understands that whatever results that may come out, should not cause him to get confused and start misbehaving.	Community resident, 35-49 years, rural, FGD

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	1603327	**Title**	Ms
First Name(s)	Cheryl		
Surname/Family Name	Johnson		
Thesis Title	Investigating Men's Preferences for HIV Self-Testing and Linkage for Policy Impact		
Primary Supervisor	Professor Liz Corbett		

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

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	No		
Have you retained the copyright for the work?*	**No**	Was the work subject to academic peer review?	**Yes**

*If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	BMC Infectious Diseases
Please list the paper's authors in the intended authorship order:	Johnson C, Choko A, D'Elbee M, Sakala D, Kumwenda M, Hatzold K, Nyrienda R, Taegtmeyer M, Desmond N, Baggaley R, Fielding K, Corbett E, Terris-Prestholt F
Stage of publication	**Not yet submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the idea of investigating whether a DCE "by-proxy" (pregnant women reporting on their male partner's preferences) would correspond with trial data on service uptake from Dr Choko's PhD (PASTAL) randomised trial. I visited Malawi to discuss my needs with Dr Choko, and designed a DCE with Drs d'Elbee and Terris-Prestholt. I worked with Dr Choko to integrate the DCE into the data collection of his PASTAL trial. I designed the final DCE questions, choices and images. Dr Choko supervised the data collection. I led data cleaning, analysis and interpretation, having attended a short course on DCE design and analysis in London. I drafted and wrote the first draft of the manuscript.

SECTION E

Student Signature	Cheryl Johnson [redacted]
Date	3 September 2022

Supervisor Signature	Liz Corbett [redacted]
Date	3 September 2022

6.0 Partner preferences by proxy

6.1 Introduction

A mixed methods study, that includes a DCE and qualitative interviews, was undertaken within a six-arm cluster randomised trial evaluating the impact of linkage interventions for men following HIVST distribution through pregnant women in Blantyre, Malawi. The DCE explored partner preferences by proxy, i.e. women were asked about their male partner's preferences for linking to support following HIVST, to explore the impact of financial incentives to support linkage following secondary HIVST distribution. Overall, women felt their partners needed support to link to care and prevention. For linking to VMMC, women were comprised of two groups: those who were pessimistic that their male partners would link and those who were optimistic their partners would link regardless of intervention. Unexpectedly, preferences were higher for the use of US$3 over US$10 financial incentives for linkage to ART. For linking to ART, women were comprised of four groups, those favouring HIVST plus a US$3 financial incentive, those favouring standard testing, those favouring a cash lottery prize, and those pessimistic their partners would link to ART regardless of intervention.

Results of the parent trial, however, showed a strong effect of incentives on men's linkage, with US$10 outperforming US$3 for ART and VMMC, while lottery prizes were ineffective. In qualitative interviews, women expressed concern about the use of cash incentives and felt their partner's views and religious beliefs, as well as inflexible health services, were key reasons for not linking. Women's views remain critical as they need to be engaged to deliver HIVST kits to their partners. The paper is in preparation for submission to BMC Infectious Diseases.

Tables and figures are at the end. All supplemental material is in Appendix 1.

6.2 Discrete choice experiment paper

Title: Do women know what men want?: A discrete choice experiment assessing partner preferences by proxy for linkage following HIV self-testing within an adaptive multi-arm, multi-stage cluster randomised trial in Malawi

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Abstract

Background: HIV self-testing (HIVST) has been demonstrated to be a safe, acceptable and effective way to reach people who may not otherwise test, particularly through secondary HIVST distribution to male partners of pregnant women. Previous studies have highlighted challenges with linkage to care among men, particularly following secondary distribution, and reported that financial incentives can increase linkage rates. Here we explore preferences by proxy to understand the feasibility of financial incentives to support linkage following secondary HIVST distribution in Blantyre, Malawi.

Methods: A mixed methods study including a discrete choice experiment (DCE) was undertaken within a cluster randomised trial evaluating the impact of linkage interventions for anti-retroviral therapy (ART) and voluntary male medical circumcision (VMMC) among men following HIVST distribution through pregnant women in Blantyre, Malawi. Women were asked to provide preferences by proxy and to select linkage interventions that their male partner would prefer, including a phone call, US$3 incentive, US$10 incentive, lottery, or no intervention. Data were analysed using multinomial logit (MNL) and latent class (LCM) models. Qualitative interviews were conducted among a sub-set of women following the DCE to understand their responses.

Results: Overall, 602 women completed the DCE. The MNL analysis indicated that, according to women, men would be against no linkage support (ART: β= -1.472, p<0.01; VMMC: β= -0.457, p<0.01), but would prefer US$3, not US$10, for ART initiation (US$3: β= 0.087, p<0.10 vs US$10: -0.228, p<0.01). For linking to ART, analysis using LCM indicated that women were split between those with significant preferences for standard testing (37.1%), those preferring HIVST plus US$3 (28.4%), those preferring a lottery (26.2%), and those feeling partners would never link (8.2%). For linking to VMMC, analysis using LCM found women to be either optimistic (77.0%) or pessimistic (23.0%) partners would link, regardless of intervention. In qualitative interviews with 75 women, most were too unsure to guess their partner's views, others considered their partner either very unlikely, or very likely, to link regardless of incentive. Concern with what men would do with the cash incentive was expressed. Findings contrasted with the parent study which showed a strong effect of incentives on men's linkage, with US$10 outperforming US$3 for ART and lottery prizes ineffective for VMMC.

Conclusions: Women, and preferences by proxy, were generally unable to predict their male partners linkage preferences when compared with the parent trial, likely due to the challenge of differentiating women's own preferences from those of her partner, specifically related to concerns about their male partners receiving larger financial incentives. Women's views remain critical as they need to be engaged to deliver HIVST kits to their partners.

Key words: HIV self-test; incentives; linkage; men

Background

There has been substantial progress in the scale-up of HIV prevention, testing and treatment services globally, particularly in east and southern Africa. In the sub-region, it is now estimated that 90% of people with HIV know their status, 78% of people with HIV are on anti-retroviral therapy (ART), and 73% of people with HIV are virally suppressed. Despite these gains, gaps remain particularly among men with HIV who have substantially lower knowledge of their status (88%), ART coverage (74%) and viral suppression (69%) compared to the wider population [1].

Recent estimates indicate that men with HIV, aged 35–49 years [2], have the largest absolute number of undiagnosed HIV in sub-Saharan Africa, and this therefore contributes to both low ART coverage and viral suppression [3]. Studies of transmission dynamics in the region have also pointed toward critical gaps in HIV prevention coverage, particularly insufficient implementation of voluntary male medical circumcision (VMMC) among young men, as a key driver of new infections [4]. As a result, new HIV infections are not only high among women in the region but are also rising among midlife and older male age groups [5, 6]. Innovative HIV testing and linkage approaches are needed to reach men if global 95-95-95 targets and low HIV incidence is to be achieved by 2025 [7].

HIV self-testing (HIVST) is recommended by the World Health Organization [8] and has been shown to be a safe and effective approach for reaching men, especially through secondary distribution channels such as partners [9-11]. While studies have shown HIVST achieves linkage to care similar to other testing approaches [9, 11, 12], and that HIVST can increase ART initiation overall [9, 13], enhanced methods to support specific populations like men may be needed. This may be particularly important for secondary HIVST distribution approaches where the people being reached are often those who are not connected to the health system. Several linkage interventions after HIVST have been effective at increasing linkage to care, such as home-based ART initiation [14], peer navigators [15], small supplier incentives [16] and conditional financial incentives [17, 18]. Additionally, community campaigns have been shown to increase ART initiations overall, both temporarily [16] and in the long-term [19]. However, strategies to support linkage to prevention following HIVST have largely been mixed, with trials showing enhanced demand creation did not increase VMMC uptake among young men in Zimbabwe [20] and that neither peer-navigators nor incentives increased linkage to pre-exposure prophylaxis (PrEP) or ART in young people in South Africa [21]. Only one trial using fixed financial incentives following HIVST effectively increased VMMC uptake in Malawi [17].

Despite this evidence, few countries have adopted enhanced linkage strategies following HIVST due to resource limitations and challenges with targeting the interventions appropriately. Financial incentives in particular have not been widely used programmatically in low- and middle-income countries because of concerns about unintended consequences, misuse and how they may impact future service delivery across the health system, equity and universal health coverage.

Discrete choice experiments (DCEs) have been useful in understanding individual preferences for HIVST across different settings and lessons learned have highlighted that HIVST is desirable. A recent systematic review found across studies individuals generally prefer HIVST to be: low cost or free to access, and include pre-test support, educational information and post-test counselling [22]. In Malawi and Zimbabwe, a DCE exploring preferences for linkage to further testing and ART after a reactive self-test result had similar findings but suggested that for linkage individuals desired short waiting times and conveniently located services the most, and may not strongly value active linkage support following HIVST [23].

Here we present results from a discrete choice experiment (DCE) which was nested within a six-arm cluster randomised trial evaluating the impact of linkage interventions for men following HIVST distribution through pregnant women in Blantyre, Malawi. DCEs are a valuable way to measure user preferences [24], particularly when there is limited data and interventions are complex. For example, secondary distribution of HIVST requires engagement from both women and men. Preferences by proxy were collected to understand the potential feasibility of financial incentives to support linkage following secondary HIVST distribution, in a setting where directly interviewing husbands was not possible.

Methods

The DCE was nested within a six-arm adaptive multi-arm, multi-stage, cluster randomised trial using secondary HIVST distribution to male partners through pregnant women presenting at antenatal care in Blantyre, Malawi [25, 26]. The trial took place between 8 August 2016 and 30 June 2017, and randomised women to either the standard of care (SOC; standard offered through a clinic invitation letter for male partners) or 1 of 5 intervention arms: two HIVST kits with no linkage intervention for partners; two HIVST kits with US$3 conditional fixed financial incentive for partners; two HIVST kits with US$10 conditional fixed financial incentive for

partners; two HIVST kits and a 10% chance of receiving US$30 in a lottery for partners; and two HIVST kits and a phone call reminders for partners. Male partner uptake of HIVST and linkage to both ART and VMMC were assessed. A full description of the trial design and results is published elsewhere [25, 26]. The DCE design is presented in the supplementary material.

The DCE was administered during the trial period between 26 October 2016 and 30 June 2017 either at study enrolment or at the 28-day follow-up visit at Ndirande, Bangwe, and Zingwangwa primary health clinics. The questionnaires were programmed onto electronic tablets and administered by trained study staff who surveyed women. An additional paper-based card was also made available at study sites. Participant information regarding women and their male partners were captured as part of trial enrolment and at subsequent follow-up visits, including age, relationship status, education-level, employment status, testing history and general health. To administer the DCE, staff explained each attribute and level. Individuals were asked to evaluate four linkage to ART scenarios and four linkage to VMMC scenarios. Each scenario presented standard testing or HIVST with the following linkage interventions: US$3 financial incentive, US$10 financial incentive, cash prize lottery, and a phone call reminder. The opt out alternative was described as “My partner would not link to ART” or “My partner would not link to VMMC”. Women who reported their male partner was already circumcised were automatically opted out of VMMC linkage questions because during the pilot it caused confusion and most women did not think they could answer. An example of the pictorial representation of a scenario presented to pregnant women is provided in the supplementary information (Fig. S1).

Demographic data collected by the parent trial was merged with the DCE survey results. Multinomial logit (MNL) models and latent class models (LCM) estimated the effect of the attributes on choice made between the sets of alternatives. The output coefficients of these models illustrated the level of preference and overall utility of the proxy preferences for each attribute level (i.e. what women believed their male partners would most prefer and not prefer). We tested for heterogeneity and model fit using a likelihood ratio test and Akaike’s information criterion (AIC). To examine heterogeneity within proxy preferences, we tested the effects of sociodemographic factors using age, literacy, general health and marital status. We also assessed how well the DCE predictions aligned with the parent trial results using the following formula: p=exp(u)/sum exp(U) to assess predicted choices, then ranked and visually assessed the probabilities across interventions. Data were shaped in Microsoft Excel and Stata version 11 (College Station, Texas) and then analysed in Nlogit 5 software [27].

A qualitative sub-study was conducted asking women about their choices after the DCE survey, particularly women who opted out of, or opted into, all options presented. Data was coded and analysed in Microsoft Excel.

Results

Participant characteristics

Participant characteristics are presented in Table 1. In total, out of 2,349 women who enrolled and participated in the parent trial, 628 women were surveyed, 95.8% (602) provided complete responses and 99.3% (598/602) provided full information about their male partner.

Education levels were high among men and women, 92.8% and 93.6% respectively. Men, however, were more likely to be working than women (unemployed: 3.7% vs 63.6%). Nearly all (96.8%) women indicated this was not their first test in their current pregnancy and more than one-third of male partners had not tested previously. Very few women had self-tested previously and partner HIV testing was uncommon, with only two women indicating that they previously tested with a partner. Most women also reported that their male partners were already circumcised (72.4%). Similarly high levels of circumcision were also reported in the trial population (out of 630 HIV negative men, 64.8% were already circumcised) [17].

Average preferences by proxy for linkage to ART

Results from the MNL model indicated that, according to women, men would be against most interventions, particularly the use of a US$10 financial incentive for ART (β= -0.228, $p<0.01$) or HIVST alone (β= -0.160, $p<0.01$) (Fig. 1). Women also strongly felt men would prefer standard testing when there was no linkage support. The only intervention women moderately thought men would prefer was the use of US$3 financial incentive ART (β=0.087, $p<0.10$) (Fig. 1). Overall, 19.8% (119/602) of women opted out at least once, of which 36 women (5.1%) always opted out.

When compared to the parent trial, these results differed substantially, with the least preferred option from the DCE (HIVST plus a US$10 financial incentive) being the most effective among men in the trial (Table 2). Women did identify that the use of US$3 financial incentives would be effective, and despite being outperformed by US$10 financial incentives in the trial, it was still effective and led to a three-fold increase in men's linkage to ART [17] (Fig. 2).

LCM analysis of partner preferences by proxy for ART linkage

The LCM analysis identified heterogeneity among women and what they thought male partners would prefer for linkage to ART. Figure 3 presents results of the LCM analysis by class.

In the DCE survey, 28.4% belonged to Class 1 “pro-HIVST”. This group strongly favoured self-testing overall regardless of linkage strategies (β=6.904, p<0.01). This group also preferred the use of US$3 financial incentives (β=1.317, p=0.10), but were averse to other linkage strategies particularly the lottery (β=-3.623, p<0.05). Preferences for a US$3 financial incentive over other options might have been indicative of their preference for self-testing as this small incentive was the same value of transportation to the clinic to access further testing and ART. This contrasted with Class 2 “moderate-risk takers” where 26.2% of respondents belonged. This was the only group where individuals favoured the lottery (β=0.402, p<0.05), but who were too conservative to desire the use of high value US$10 financial incentives (β=-0.596, p<0.01). Class 3 “ART pessimists” where 8.2% belonged, were more likely to opt out (β=3.259, p<0.01) and generally did not think any linkage interventions would be successful. Class 4 is where 37.1% of respondents belonged, “the traditionalists”. This group strongly favoured standard testing, and disliked HIVST (β=-7.198, p<0.05), the use of US$10 financial incentives (β=-1.951, p<0.10) and phone call reminders (β=-1.399, p<0.10). Analysis of sociodemographic factors found that women in Class 1 and 3 were more likely to be married and women in Class 3 were less likely to have good health (supplementary information, Table S2).

Average preferences by proxy for linkage to VMMC

Results from the MNL model indicated that, according to women, men would prefer a linkage intervention for VMMC (Fig. 4). Overall, 33.5% (56/167) women opted out at least once and 28 of these women (16.8%) always opted out.

When comparing uptake of interventions in the parent trial among men with circumcision appointments, these results differed substantially. While not statistically significant, in the DCE, women appeared to slightly favour a cash lottery prize or HIVST alone to support linkage to VMMC. In the trial, however, HIVST alone was insufficient, and the lottery was ineffective and confusing to men (Table 3). There was very little alignment between what men selected in the trial and what their female partners thought they would select.

LCM analysis of partner preferences by proxy for VMMC linkage

The LCM analysis identified heterogeneity among women and what they thought male partners would prefer for linkage to VMMC. Figure 5 presents results of the LCM analysis by class.

In the DCE survey, Class 1 is where 77.0% of respondents belonged, “VMMC optimists”. This group was less likely to opt out (β=-2.483, p<0.01) and seemed to think their male partner may link regardless of intervention and that additional support may not have a substantial impact. However, Class 2, where 23.0% of the respondent belonged, were “VMMC pessimists”. This group was more likely to opt out of choices (β=-3.313, p<0.01) and had little hope that their partner would link to VMMC. While not statistically significant, there was a signal that this group felt there were substantial barriers hindering VMMC linkage as they were more supportive of the use of US$3 and US$10 financial incentives. Analysis of sociodemographic factors found that women in Class 1 were more likely to have good to excellent health, which may have caused them to be more optimistic about their partners willingness to link. Other variables, such as women’s age, literacy and marital status, did not appear to affect classes (supplementary information, Table S4).

Qualitative findings

Overall, 75/602 (12.5%) of women in the study participated in the qualitative sub-study with the providers sharing their views after the survey. Supplementary information (Table S5) provides further information on the qualitative study participant characteristics.

Approximately half of women indicated they were unsure about the survey and hesitant to guess their partner’s views. Many also noted it took time to understand the survey after initial confusion. During the interview some participants told study staff that they were already having trouble in the relationship, and this made them unsure of their choices. In one case, a woman indicated she was not confident in her choices because her partner recently denied the pregnancy and stopped coming to the house.

Women also indicated that they opted out of choices because they felt their partner would not link regardless of intervention choices. Some felt that HIV testing was the key barrier to linkage, indicating that their partner had previously refused, or that they would be resistant to a specific

testing approach because it was not trustworthy or inconvenient. Women were divided in their views on whether their male partner would prefer standard testing and self-testing.

> ‘[He] refuses to test, doesn’t want to’
> – Female participant, 28 years of age, Bangwe Clinic

> ‘[He] refuses self-testing because his friend who is a doctor told him he has no idea about self-test kits’ – Female participant, 24 years of age, Bangwe Clinic

For others, barriers hindering their partners from linking were broader and related to their partners having deeper concerns about accessing any health service. Religious beliefs were also felt to be a key reason men would not go to a clinic or use medication. Some also reported that their partner worked outside of the city and not having more flexible or mobile services was a barrier. Women generally felt their partners would be most resistant to VMMC regardless of the incentives because they were too busy, often due to their work or the time services were available, were afraid or that they had already made the choice not to be circumcised.

> ‘The man refuses circumcision…and he always says that if found positive he cannot take medication.’ – Female participant, 22 years of age, Bangwe Clinic

> ‘[He] is apostolic and doesn’t take medication, he doesn’t go to the hospital according to his beliefs’ – Female participant, 30 years of age, Bangwe Clinic

> ‘He wants circumcision, but he is a driver and always busy’ – Female participant, 20 years of age, Bangwe Clinic

> ‘He cannot do circumcision, he is always so afraid’ – Female participant, 32 years of age, Bangwe Clinic

Some indicated that instead of interventions, such as financial incentives, alternative service delivery would be more effective such as offering services at different times and on the weekends and providing follow-up after the pregnancy period.

> ‘Always free weekends only. He can only do the circumcision on the weekends.’
> – Female, 19 years of age, Bangwe Clinic

‘He will do it [circumcision] after the birth, but not now.’ – Female, 18 years of age, Bangwe Clinic

Many women also felt all options could work and encourage men to link, as it supported their engagement in the pregnancy. Some women appeared to be open to incentives particularly of lower value equivalent to transportation (US$3), others however, felt these additional interventions were unnecessary, particularly for ART, and had concerns about their partners receiving money. Women tended to think that an HIV diagnosis alone would provide sufficient motivation for their partner to link to care and go to the clinic.

‘This encourages men to take part in [care] during the pregnancy’
– Female, 28 years of age, Ndirande Clinic

‘He is usually busy and would complain about transport [for VMMC]…[For ART], my husband would want an incentive, he would complain to just come here at least the transport [money] would encourage him’ – Female, 21 years of age, Zingwangwa Clinic

‘[My] husband [has] no problem in taking medication, even without being given money.’
– Female, 20 years of age, Bangwe Clinic

‘The man cannot come if he hears that we are giving money to participants’
– Female, 20 years of age, Zingwangwa Clinic

‘[My] husband will understand and if he [is] found positive he will come for treatment.’
–Female, 27 years of age, Zingwangwa Clinic

Discussion

The main findings from this DCE evaluating proxy preferences elicited from women regarding their male partners’ need for linkage support for VMMC and ART were that women did not accurately predict the strong effect of financial incentives on timely linkage by their male partner, as shown by results in the six-armed adaptive parent trial. Most women were hesitant to support any fixed financial incentives, especially the higher (US$10) incentive for either linkage to ART or linkage to VMMC, whereas this was the most effective linking strategy in the parent trial. Only

women who thought their partners would strongly prefer HIVST were in favour of using a US$3 financial incentive for linkage to ART. This was likely because women justified the incentive, equivalent to the costs of transportation to the clinic, because HIVST requires a clinic visit to confirm an HIV positive diagnosis in addition to ART initiation. Qualitative interviews suggested that women may have felt conflicted, feeling pessimistic about the viability of financial incentives, and worried about how their partner would spend the funds. Only some women were open to lower value incentives (US$3) or a cash prize lottery to support linkage to ART. Further, women generally did not feel that additional support would substantially help their partners link to VMMC. This was one of the first studies to investigate DCE preferences by proxy alongside a trial that was able to inform the accuracy of these predictions. As such, the approach and main findings, that Malawian women were unable to separate their own concerns about financial incentives from their perception of their partner's preferences, has a broader relevance to other researchers beyond HIV testing and linkage.

Our DCE results contrasted with findings from the parent study showing that incentives strongly affect men's linkage, with US$10 outperforming US$3 for ART and VMMC while lottery prizes were ineffective [17]. Thus, preferences by proxy appear to not have accurately predicted male partner choices: instead, proxy preferences revealed women's preferences and their own views on what male partners should or should not receive. Women's negative views on financial incentives for male partners likely affected responses and predictions. While preferences by proxy methodologies cannot replace methods to gather individual preferences, they may have complementary utility for designing interventions involving partners, families and households. Future studies investigating preferences by proxy should also collect direct preferences from the primary recipients of prospective interventions.

Financial incentives successfully increased linkage of men to VMMC and ART in the parent trial [17]. These findings confirmed previous studies that rely on behavioural economics theories whereby financial incentives provide an immediate benefit and 'nudge' individuals to change behaviours, as well as compensate individuals for costs, such as those incurred by transportation or lost wages due to accessing health services [28, 29]. The effectiveness of financial incentives, however, can vary substantially based on the context and intervention type. For instance, while financial incentives can more than double the uptake of standard HIV testing [30], delivery of HIVST kits to the home may have such high acceptability that additional incentives become futile [17] or may miss the intended population of those with undiagnosed

HIV [8]. In the context of linkage to ART, the impact of financial incentives has been more mixed, with a recent systematic review finding increases in ART adherence and continuity of care, but no effect on linkage to ART, ART initiation or viral suppression [30]. Such variations could be because financial incentives have been largely framed as compensation, and less often as part of 'nudging' interventions designed to change behaviour. Future research should focus more on coupling financial incentives with other nudging interventions such as default settings, temptation bundles, and gamification [31]. Performance in settings with lower coverage of HIV testing and ART may also differ from settings, such as Malawi, where coverage is high and efforts are being made to focus on men and not a broader population. Implementation research on how to effectively target financial incentives toward specific groups without exacerbating equity issues is needed.

In the context of VMMC, direct financial incentives have consistently been important for supporting linkage to this one-time procedure [25, 32], with higher value incentives (US$15) being most effective in the short-term compared to lower-value incentives (US$2.5) [33]. However, the overall impact and effect on absolute differences may be too small to justify the investment [34]. In this study, women were divided into two groups those that were pessimistic that any intervention would enable their partner to link to VMMC and those more optimistic who did not think their partner needed a linkage intervention. Over 70% of male partners were already circumcised in the parent trial [17], suggesting that those unreached may have more complex barriers hindering access to VMMC . Further research is needed into how to adapt service delivery and provide linkage options that may be beneficial to the family more broadly, viable for programmatic implementation, and effective at encouraging male partners to consider VMMC in the context of secondary HIVST distribution from pregnant women.

Pregnant women may view high value financial incentives negatively because of undesirable relationship concerns, such as infidelity and alcohol use, and how money may affect power dynamics and their future child's HIV risk. In Malawi, a qualitative study indicated such concerns finding that high value incentives, such as those for US$10, were perceived to be excessive and encourage misuse or could promote multiple sexual partnerships or incentivize increasing family size [35]. To avoid the risk of social harm in the context of couples testing, small household goods have been used instead of cash incentives which caused concern in Zimbabwe [36].

Given the economic pressures of pregnancy, women may be less amenable to resources being allocated to their male partner instead of to the family. Additionally, because women are responsible for providing HIVST kits, information and support to their male partners, through secondary HIVST distribution methods, they may be frustrated that they are not compensated or encouraged with similar incentives. While there is substantial research demonstrating the impact of financial incentives on individual behaviours, such as HIV testing uptake and linkage to care, less is known about the impact on partner and family dynamics. Future implementation research is needed to design linkage strategies which are effective and acceptable to both men and women, such as family incentive structures that could benefit both male and female partners. This will likely be important for the long-term sustainability of secondary HIVST distribution approaches as programmes scale-up. In this context, results of a larger pragmatic trial with three arms (standard testing versus secondary distribution of HIVST versus secondary distribution of HIVST plus a US$10 linkage incentive) may be insightful [37]. This trial from Malawi was a direct follow-on from the parent trial that this DCE was nested into [17], and found that pregnant women from 27 antenatal clinics were less likely to participate and deliver HIVST kits to their male partners if they were in the financial incentive arm (US$10 to support male partner linkage) than those in the HIVST-only arm [37]. This potentially confirms our study findings that in the context of secondary HIVST distribution to male partners, financial incentives may not be sustainable and could lead to suboptimal implementation rates in the longer-term.

Although this study focused on linkage preferences, women revealed that there are deeper issues reducing men's engagement in HIV testing, prevention and care which are also important to address. Providing differentiated service delivery is recommended by WHO and critical to successful programming [8], but access and implementation often varies widely at country-level [38]. It is important to design services that will overcome existing barriers to services and that will enhance male engagement. Our findings that work and suboptimal clinic hours are barriers that hinder men's access to care align with other studies, and suggest that male-friendly strategies, such as offering ART in convenient locations and providing weekend hours, are important [39]. Partnership with employers to provide workplace HIVST, prevention and care are also highly effective and can be useful particularly for men who are highly mobile and live and work away from home [40, 41].

Accurate messaging at the community-level and engagement with faith leaders is important to addressing myths and mistrust. Efforts to increase men's HIV knowledge and awareness also

remains important, as studies show there is often poor understanding of serodiscordancy and poor awareness that those taking ART and achieving viral suppression cannot transmit to their partners [42]. Lastly, enhancing male engagement is likely not a one-time intervention, but will require follow-up. For those not ready to link, it is critical to continue encouraging male partner engagement including in the post-partum and breast-feeding period both for individual health and efforts to eliminate mother-to-child transmission.

This study was one of the first to compare preferences by proxy with trial outcomes and had the strengths of being conducted in a setting with real-world HIVST implementation and having a mixed-methods design which included qualitative interviews. This helped ground the study and provided greater insight into stated preferences provided by women. Our study had several limitations, however. First, although our study aimed to include more women randomised to the parent study, only half (n=308/602) of the women completing the survey were randomised. This was because enrolment in the trial took place in a busy clinic setting with limited staff, and not all those presenting could be surveyed and/or enrolled in the trial. Because of this we only included a sample of trial participants and were unable to fully assess male partner characteristics and individual choices. As a result, our findings may not fully represent women and men in the trial. Second, more than 70% of the women in our study indicated their male partner was already circumcised. Because of this a smaller number of women were able to answer questions asking about their male partners linkage preference. During piloting, we attempted to include these participants, however it caused confusion at sites and women were generally unable or unwilling to answer. As a result, data collected and analysed regarding linkage to VMMC was limited. Third, the qualitative sub-study indicated that women had some initial challenges with the survey and had difficulty guessing what their partner would choose. This suggests that obtaining preferences by proxy can be challenging to collect and interpret.

Conclusion

In this early investigation of DCE preferences by proxy, women were generally unable to predict their male partners linkage preferences following secondary HIVST distribution when compared with the parent trial. However, findings revealed hidden preferences among women and their concerns about their male partners receiving financial incentives. They also identified women's views that deeper issues were hindering men's linkage, including mistrust, religious beliefs and

inflexible service delivery options. Women's views remain critical as they need to be engaged to deliver HIVST kits to their partners.

Availability of data and materials

Primary data files from the parent trial are available at https://datacompass.lshtm.ac.uk/923/. As agreed in the LSHTM, and Malawi College of Medicine and Research and Ethics Committee (COMREC) ethics approval and research protocol, qualitative interview transcripts and the corresponding anonymised file are only visible to the direct research team and are not publicly available.

References

1. UNAIDS. Global commitments, local action: After 40 years of AIDS, charting a course to end the pandemic. Geneva: Joint United Nations Programme on HIV/AIDS; 2021. Available from: https://www.unaids.org/sites/default/files/media_asset/global-commitments-local-action_en.pdf.
2. Giguère K, Eaton JW, Marsh K, Johnson LF, Johnson CC, Ehui E, Jahn A, Wanyeki I, Mbofana F, Bakiono F, Mahy M, Maheu-Giroux M. Trends in knowledge of HIV status and efficiency of HIV testing services in sub-Saharan Africa, 2000-2020: a modelling study using survey and HIV testing programme data. Lancet HIV. 2021;8(5):e284-e93.
3. Cornell M, Majola M, Johnson LF, Dubula-Majola V. HIV services in sub-Saharan Africa: the greatest gap is men. Lancet. 2021;397(10290):2130-2.
4. de Oliveira T, Kharsany AB, Gräf T, Cawood C, Khanyile D, Grobler A, Puren A, Madurai S, Baxter C, Karim QA, Karim SS. Transmission networks and risk of HIV infection in KwaZulu-Natal, South Africa: a community-wide phylogenetic study. Lancet HIV. 2017;4(1):e41-e50.
5. Akullian A, Vandormael A, Miller JC, Bershteyn A, Wenger E, Cuadros D, Gareta D, Bärnighausen T, Herbst K, Tanser F. Large age shifts in HIV-1 incidence patterns in KwaZulu-Natal, South Africa. Proceedings of the National Academy of Sciences. 2021;118(28):e2013164118.
6. Fraser C. New data and findings including phylogenetic analysis. International AIDS Conference; 29 Jul - 2 Aug 2022;Montreal, Canada.
7. UNAIDS. Understanding fast-track: accelerating action to end the AIDS epidemic by 2030. Geneva: Joint United Nations Programme for HIV/AIDS; 2015. Available from:

https://www.unaids.org/sites/default/files/media_asset/201506_JC2743_Understanding_FastTrack_en.pdf.

8. WHO. Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2019.

9. Jamil MS, Eshun-Wilson I, Witzel TC, Siegfried N, Figueroa C, Chitembo L, Msimanga-Radebe B, Pasha MS, Hatzold K, Corbett E, Barr-DiChiara M, Rodger AJ, Weatherburn P, Geng E, Baggaley R, Johnson C. Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis. eClinicalMedicine. 2021;38.

10. Johnson CC, Kennedy C, Fonner V, Siegfried N, Figueroa C, Dalal S, Sands A, Baggaley R. Examining the effects of HIV self-testing compared to standard HIV testing services: A systematic review and meta-analysis. J Int AIDS Soc. 2017;20(1):21594-.

11. Eshun-Wilson I, Jamil MS, Witzel TC, Glidded DV, Johnson C, Trouneau NL, Ford N, McGee K, Kemp C, Baral S, Schwartz S, Geng EH. A systematic review and network meta-analyses to assess the effectiveness of human immunodeficiency virus (HIV) self-testing distribution strategies. Clin Infect Dis. 2021.

12. Witzel TC, Eshun-Wilson I, Jamil MS, Tilouche N, Figueroa C, Johnson CC, Reid D, Baggaley R, Siegfried N, Burns FM, Rodger AJ, Weatherburn P. Comparing the effects of HIV self-testing to standard HIV testing for key populations: A systematic review and meta-analysis. BMC Med. 2020;18(1):381.

13. Neuman M, Fielding KL, Ayles H, Cowan FM, Hensen B, Indravudh PP, Johnson C, Sibanda EL, Hatzold K, Corbett EL. ART initiations following community-based distribution of HIV self-tests: meta-analysis and meta-regression of STAR Initiative data. BMJ Global Health. 2021;6(Suppl 4):e004986.

14. MacPherson P, Lalloo DG, Webb EL, Maheswaran H, Choko AT, Makombe SD, Butterworth AE, van Oosterhout JJ, Desmond N, Thindwa D, Squire SB, Hayes RJ, Corbett EL. Effect of optional home initiation of HIV care following HIV self-testing on antiretroviral therapy initiation among adults in Malawi: A randomized clinical trial. JAMA. 2014;312(4):372-9.

15. Nichols B, Cele R, Chasela C, Siwale Z, Lungu A, Long L, Moyo C, Rosen S, Chilengi R. Cost and impact of community-based, assisted HIV self-testing amongst youth in Zambia. Conference on Retroviruses and Opportunistic infections; 4-7 March 2019;Seattle, WA, USA.

16. Sibanda EL, Neuman M, Tumushime M, Mangenah C, Hatzold K, Watadzaushe C, Mutseta MN, Dirawo J, Napierala S, Ncube G, Terris-Prestholt F, Taegtmeyer M, Johnson C, Fielding KL, Weiss HA, Corbett E, Cowan FM. Community-based HIV self-testing: a cluster-

randomised trial of supply-side financial incentives and time-trend analysis of linkage to antiretroviral therapy in Zimbabwe. BMJ Global Health. 2021;6(Suppl 4):e003866.

17. Choko AT, Corbett EL, Stallard N, Maheswaran H, Lepine A, Johnson CC, Sakala D, Kalua T, Kumwenda M, Hayes R, Fielding K. HIV self-testing alone or with additional interventions, including financial incentives, and linkage to care or prevention among male partners of antenatal care clinic attendees in Malawi: An adaptive multi-arm, multi-stage cluster randomised trial. PLOS Med. 2019;16(1):e1002719.

18. Zhou Y, Lu Y, Ni Y, Wu D, He X, Ong JJ, Tucker JD, Sylvia SY, Jing F, Li X, Huang S, Shen G, Xu C, Xiong Y, Sha Y, Cheng M, Xu J, Jiang H, Dai W, Huang L, Zou F, Wang C, Yang B, Mei W, Tang W. Monetary incentives and peer referral in promoting secondary distribution of HIV self-testing among men who have sex with men in China: A randomized controlled trial. PLoS Med. 2022;19(2):e1003928.

19. Indravudh PP, Fielding K, Kumwenda MK, Nzawa R, Chilongosi R, Desmond N, Nyirenda R, Neuman M, Johnson CC, Baggaley R, Hatzold K, Terris-Prestholt F, Corbett EL. Effect of community-led delivery of HIV self-testing on HIV testing and antiretroviral therapy initiation in Malawi: A cluster-randomised trial. PLOS Med. 2021;18(5):e1003608.

20. Mavhu W, Neuman M, Hatzold K, Buzuzi S, Maringwa G, Chabata ST, Mangenah C, Taruberekera N, Madidi N, Munjoma M, Ncube G, Xaba S, Mugurungi O, Johnson CC, Corbett EL, Weiss HA, Fielding K, Cowan FM. Innovative demand creation strategies to increase voluntary medical male circumcision uptake: a pragmatic randomised controlled trial in Zimbabwe. BMJ Global Health. 2021;6(Suppl 4):e006141.

21. Shahmanesh M, Mthiyane TN, Herbsst C, Neuman M, Adeagbo O, Mee P, Chimbindi N, Smit T, Okesola N, Harling G, McGrath N, Sherr L, Seeley J, Subedar H, Johnson C, Hatzold K, Terris-Prestholt F, Cowan FM, Corbett EL. Effect of peer-distributed HIV self-test kits on demand for biomedical HIV prevention in rural KwaZulu-Natal, South Africa: a three-armed cluster-randomised trial comparing social networks versus direct delivery. BMJ Global Health. 2021;6(Suppl 4):e004574.

22. Sharma M, Ong JJ, Celum C, Terris-Prestholt F. Heterogeneity in individual preferences for HIV testing: A systematic literature review of discrete choice experiments. EClinicalMedicine. 2020;29-30:100653.

23. d'Elbée M, Indravudh PP, Mwenge L, Kumwenda MM, Simwinga M, Choko AT, Hensen B, Neuman M, Ong JJ, Sibanda EL, Johnson CC, Hatzold K, Cowan FM, Ayles H, Corbett EL, Terris-Prestholt F. Preferences for linkage to HIV care services following a reactive self-test: discrete choice experiments in Malawi and Zambia. AIDS. 2018;32(14):2043-9.

24. Lancsar E, Louviere J. Conducting discrete choice experiments to inform healthcare decision making: A user's guide. Pharmacoeconomics. 2008;26(8):661-77.

25. Choko AT, Candfield S, Maheswaran H, Lepine A, Corbett EL, Fielding K. The effect of demand-side financial incentives for increasing linkage into HIV treatment and voluntary medical male circumcision: A systematic review and meta-analysis of randomised controlled trials in low- and middle-income countries. PLoS One. 2018;13(11):e0207263.

26. Choko AT, Fielding K, Stallard N, Maheswaran H, Lepine A, Desmond N, Kumwenda MK, Corbett EL. Investigating interventions to increase uptake of HIV testing and linkage into care or prevention for male partners of pregnant women in antenatal clinics in Blantyre, Malawi: study protocol for a cluster randomised trial. Trials. 2017;18(1):349.

27. Greene W. Nlogit 5 Econometric software.

28. Bassett IV, Wilson D, Taaffe J, Freedberg KA. Financial incentives to improve progression through the HIV treatment cascade. Current Opinion in HIV and AIDS. 2015;10(6).

29. Taaffe JE, Longosz AF, Wilson D. The impact of cash transfers on livelihoods, education, health and HIV – what's the evidence? Development Policy Review. 2017;35(5):601-19.

30. Krishnamoorthy Y, Rehman T, Sakthivel M. Effectiveness of Financial Incentives in Achieving UNAID Fast-Track 90-90-90 and 95-95-95 Target of HIV Care Continuum: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. AIDS Behav. 2021;25(3):814-25.

31. Tran S, Smith L, El-Den S, Carter S. The Use of Gamification and Incentives in Mobile Health Apps to Improve Medication Adherence: Scoping Review. JMIR Mhealth Uhealth. 2022;10(2):e30671.

32. Kennedy CE, Yeh PT, Atkins K, Fonner VA, Sweat MD, O'Reilly KR, Rutherford GW, Baggaley R, Samuelson J. Economic compensation interventions to increase uptake of voluntary medical male circumcision for HIV prevention: A systematic review and meta-analysis. PloS One. 2020;15(1):e0227623-e.

33. Thirumurthy H, Masters S, Rao S, Bronson M, Lanham M, Omanga E, Et A, L P. Effect of providing conditional economic compensation on uptake of voluntary medical male circumcision in Kenya: A randomized clinical trial. JAMA. 2014;312(7):703–11.

34. Carrasco MA, Grund JM, Davis SM, Ridzon R, Mattingly M, Wilkinson J, Kasdan B, Kiggundu V, Njeuhmeli E. Systematic review of the effect of economic compensation and

incentives on uptake of voluntary medical male circumcision among men in sub-Saharan Africa. AIDS Care. 2018;30(9):1071-82.

35. Choko AT, Kumwenda MK, Johnson CC, Sakala DW, Chikalipo MC, Fielding K, Chikovore J, Desmond N, Corbett EL. Acceptability of woman-delivered HIV self-testing to the male partner, and additional interventions: a qualitative study of antenatal care participants in Malawi. J Int AIDS Soc. 2017;20(1):21610.

36. Sibanda EL, Tumushime M, Mufuka J, Mavedzenge SN, Gudukeya S, Bautista-Arredondo S, Hatzold K, Thirumurthy H, McCoy SI, Padian N, Copas A, Cowan FM. Effect of non-monetary incentives on uptake of couples' counselling and testing among clients attending mobile HIV services in rural Zimbabwe: A cluster-randomised trial. The Lancet Global Health. 2017;5(9):e907-e15.

37. Choko AT, Fielding K, Johnson CC, Kumwenda MK, Chilongosi R, Baggaley RC, Nyirenda R, Sande LA, Desmond N, Hatzold K, Neuman M, Corbett EL. Partner-delivered HIV self-test kits with and without financial incentives in antenatal care and index patients with HIV in Malawi: A three-arm, cluster-randomised controlled trial. Lancet Glob Health. 2021;9(7):e977-e88.

38. WHO. WHO HIV policy adoption and implementation status in countries. Geneva: World Health Organization; 2022. Available from: https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/who-hiv-policy-adoption-and-implementation-status-in-countries.pdf?sfvrsn=bb35e6ae_6.

39. Nyondo-Mipando AL, Kapesa LS, Salimu S, Kazuma T, Mwapasa V. "Dispense antiretrovirals daily!" restructuring the delivery of HIV services to optimize antiretroviral initiation among men in Malawi. PloS One. 2021;16(2):e0247409.

40. Corbett EL, Makamure B, Cheung YB, Dauya E, Matambo R, Bandason T, Munyati SS, Mason PR, Butterworth AE, Hayes RJ. HIV incidence during a cluster-randomized trial of two strategies providing voluntary counselling and testing at the workplace, Zimbabwe. AIDS. 2007;21(4):483-9.

41. WHO, ILO. HIV self-testing at workplaces: approaches to implementation and sustainable financing. Geneva: World Health Organization; 2022.

42. Johnson C, Kumwenda M, Meghji J, Choko AT, Phiri M, Hatzold K, Baggaley R, Taegtmeyer M, Terris-Prestholt F, Desmond N, Corbett EL. ‘Too old to test?’: A life course approach to HIV-related risk and self-testing among midlife-older adults in Malawi. BMC Public Health. 2021;21(1):650.

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Ethical approval and consent to participate

All data collection procedures were approved by LSHTM, and Malawi College of Medicine and Research and Ethics Committee (COMREC) (P011/10/1020). According to COMREC approved procedures, all literate participants provided witnessed written informed consent and all literate participants provided or witnessed verbal informed consent. Witnessed verbal consent procedures included a research assistant reading information contained in the study information sheet to both the participant and witness. If a potential research participant showed willingness to participate, we were required to obtain a thumbprint from the participant and a signature from a participant's witness.

Competing interests

The authors declare that they have no conflict of interest. The contents in this article are those of the authors and do not necessarily reflect the view of the World Health Organization.

6.3 Tables and figures

Table 1: *Participant characteristics*

Variables	**Clinic of enrolment (n=598)***						
	Ndirande (n=132)		**Bangwe (n=252)**		**Zingwangwa (n=214)**		
	N	***%***	***N***	***%***	***N***	***%***	***p-value***
Study arm	10.0	7.6	8.0	3.2	16.0	7.5	
Standard HTS only	2.0	1.5	23.0	9.1	30.0	14.0	
HIVST only	6.0	4.5	17.0	6.7	8.0	3.7	
HIVST+US$3	14.0	10.6	28.0	11.1	35.0	16.4	
HIVST+US$10	11.0	8.3	17.0	6.7	3.0	1.4	
HIVST+Lottery	24.0	18.2	26.0	10.3	13.0	6.1	
HIVST+Phone call	65.0	49.2	133.0	52.8	109.0	50.9	
							p<0.001
Female age group (years) *Median:* 24 yrs (18-43)							
18-22	44.0	33.3	106.0	42.1	98.0	45.8	
23-27	46.0	34.8	79.0	31.3	55.0	25.7	
28-32	33.0	25.0	42.0	16.7	36.0	16.8	
33-37	8.0	6.1	21.0	8.3	20.0	9.3	
38-42	1.0	0.8	4.0	1.6	4.0	1.9	
43+	0.0	0.0	0.0	0.0	1.0	0.5	
							p=0.22
Male partner age group (years)							
Median: 30 yrs (18-62)							
18-22	14.0	10.6	35.0	13.9	30.0	14.0	
23-27	31.0	23.5	69.0	27.4	49.0	22.9	
28-32	35.0	26.5	70.0	27.8	63.0	29.4	
33-37	34.0	25.8	48.0	19.0	42.0	19.6	
38-42	14.0	10.6	23.0	9.1	25.0	11.7	
43+	4.0	3.0	7.0	2.8	5.0	2.3	
							p=0.79
Partner age difference (years) *Median:* 4 yrs (0-25)							
<5	58.0	43.9	140.0	55.6	96.0	44.9	
5-9	52.0	39.4	79.0	31.3	93.0	43.5	
10-14	18.0	13.6	24.0	9.5	24.0	11.2	
15+	4.0	3.0	9.0	3.6	1.0	0.5	p=0.02
Marital status							
Married	125.0	94.7	237.0	94.0	198.0	92.5	
Polygamous marriage	0.0	0.0	11.0	4.4	6.0	2.8	
Living together as if married	0.0	0.0	1.0	0.4	1.0	0.5	
Never married	1.0	0.8	3.0	1.2	4.0	1.9	

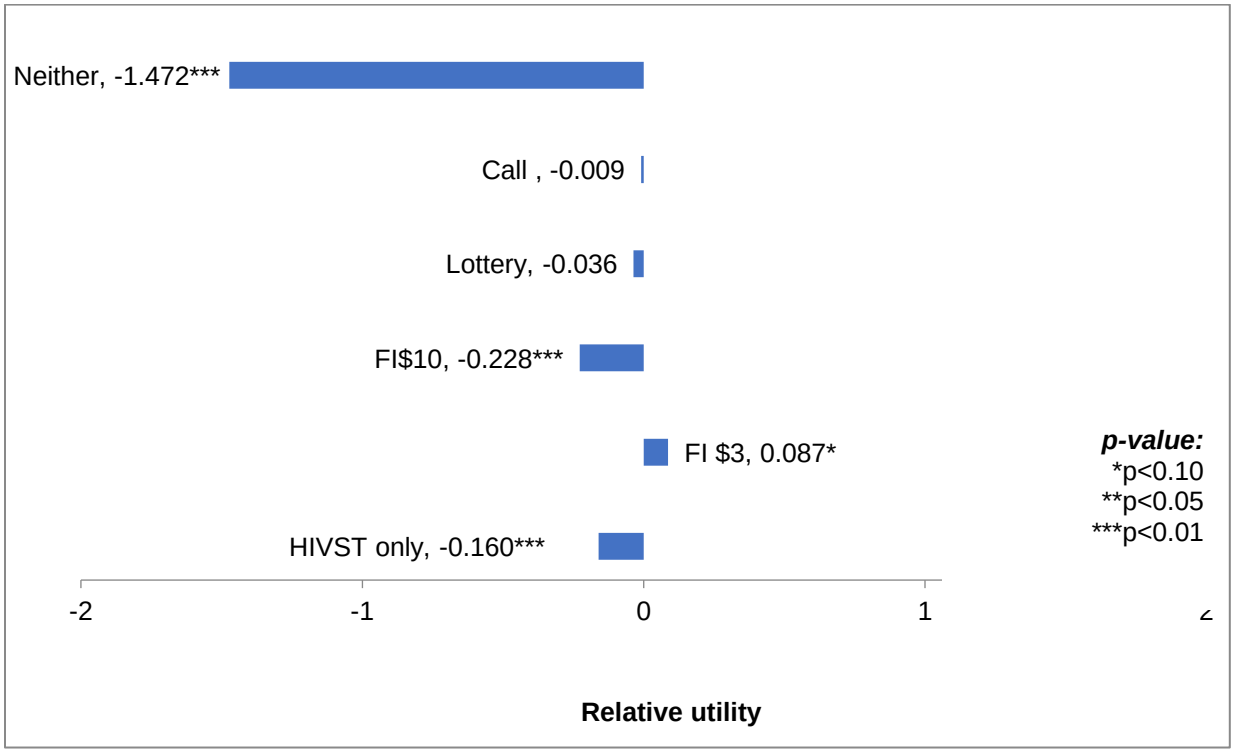
Variables	Clinic of enrolment (n=598)*						
	Ndirande (n=132)		Bangwe (n=252)		Zingwangwa (n=214)		
Widow	0.0	0.0	0.0	0.0	0.0	0.0	
Separated	0.0	0.0	0.0	0.0	0.0	0.0	
Divorced	0.0	0.0	0.0	0.0	0.0	0.0	
Married but not living together	6.0	4.5	0.0	0.0	5.0	2.3	
							p=0.03
Female education level							
No school	0.0	0.0	0.0	0.0	0.0	0.0	
Primary school	4.0	3.0	10.0	4.0	6.0	2.8	
Secondary school no MSCE	51.0	38.6	132.0	52.4	97.0	45.3	
Secondary school with MSCE	44.0	33.3	89.0	35.3	80.0	37.4	
Higher	31.0	23.5	16.0	6.3	20.0	9.3	
Other	2.0	1.5	5.0	2.0	11.0	5.1	
							p<0.001
Male partner education level							
No school	0.0	0.0	0.0	0.0	0.0	0.0	
Primary school	0.0	0.0	4.0	1.6	2.0	0.9	
Secondary school no MSCE	19.0	14.4	72.0	28.6	49.0	22.9	
Secondary school with MSCE	49.0	37.1	94.0	37.3	70.0	32.7	
Higher	57.0	43.2	70.0	27.8	75.0	35.0	
Other	7.0	5.3	12.0	4.8	18.0	8.4	
							p=0.01
Female occupation							
Paid employee	12.0	9.1	21.0	8.3	18.0	8.4	
Paid domestic worker	1.0	0.8	8.0	3.2	4.0	1.9	
Self-employed	31.0	23.5	53.0	21.0	53.0	24.8	
Unemployed	88.0	66.7	167.0	66.3	136.0	63.6	
Other	0.0	0.0	3.0	1.2	3.0	1.4	
							p=0.75
Male partner occupation							
Paid employee	82.0	62.1	128.0	50.8	121.0	0.6	
Paid domestic worker	3.0	2.3	29.0	11.5	21.0	0.1	
Self-employed	41.0	31.1	71.0	28.2	57.0	0.3	
Unemployed	2.0	1.5	11.0	4.4	9.0	0.0	
Other	4.0	3.0	13.0	5.2	6.0	0.0	
							p=0.06
Female general health							
Excellent	101.0	76.5	53.0	21.0	72.0	33.6	
Good	25.0	18.9	190.0	75.4	134.0	62.6	
Fair	5.0	3.8	7.0	2.8	8.0	3.7	
Poor	1.0	0.8	2.0	0.8	0.0	0.0	
							p<0.001

Variables	Clinic of enrolment (n=598)*						
	Ndirande (n=132)		Bangwe (n=252)		Zingwangwa (n=214)		
Ever tested in pregnancy							
Yes	126.0	95.5	248.0	98.4	205.0	95.8	
No	6.0	4.5	4.0	1.6	9.0	4.2	
							p=0.17
Ever tested with partner							
Yes	0.0	0.0	0.0	0.0	0.0	0.0	
No	132.0	100.0	252.0	100.0	214.0	100.0	
							p<0.001
Ever self-tested							
Yes	11.0	8.3	5.0	2.0	9.0	4.2	
No	121.0	91.7	237.0	98.0	205.0	95.8	
							P=0.01
Male partner ever tested							
Yes	71.0	53.8	155.0	61.5	134.0	62.6	
No	61.0	46.2	97.0	38.5	80.0	37.4	
							p=0.23
Male partner tested in last 12 months*							
Yes	41.0	57.7	59.0	38.1	66.0	49.3	
No	30.0	42.3	96.0	61.9	68.0	50.7	
							p=0.012

Yrs: Years; HIVST: HIV self-test; MSCE: Malawi School Certificate of Education

*Clinic enrolment refers to people surveyed as part of the DCE. Overall, 602 completed the DCE and of these 598 provided complete data including about their male partner. The six participants with incomplete data only provided initial information because they opted not to participate in the parent trial after completing the DCE (n=3), and the others (n=3) were ineligible. Additionally, 166 women indicated that their male partner had tested previously and thus only those women provided information on whether their partner had tested in last 12-months.

Figure 1: *DCE preferences by proxy for male partner linkage to ART*



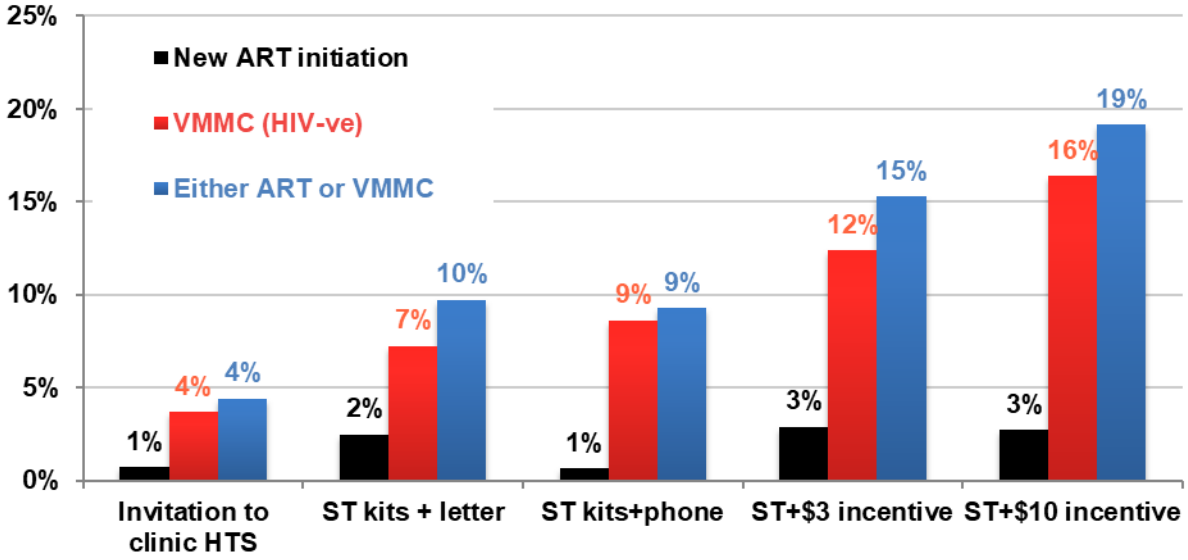
HIVST: HIV self-test; FI $10: US$10 financial incentive; FI $3: US$3 financial incentive. *0.10, **0.05, ***0.01 level of significance with p-value. Log Likelihood function: -2299.24. AIC: 4618.5; AIC/N: 1.92. Chi squared: 28.34; Number of participants: 602; Observations: 2408.

Table 2: *Alignment between the DCE predictions and the parent trial results, linkage to ART*

	Predictions: Overall DCE Linkage to ART (n=602)				**PASTAL Trial Results by Arm (n=2, 349)**		
Choice	Co-efficient	EXP	Predicted choices (%)	Rank	Started ART	Actual choices (%)	Rank
FI $3	0.087	1.091	22.15%	1	10	23.8%	2
Phone call	-0.009	0.991	20.13%	2	2	4.8%	5
Lottery	-0.036	0.965	19.59%	3	4	9.5%	4
HIVST only	-0.160	0.852	17.30%	4	10	23.8%	3
FI $10	-0.228	0.796	16.17%	5	13	31.0%	1
Neither (SoC)	-1.472	0.229	4.66%	6	3	7.1%	6
Total	-1.818	4.924			42		

DCE: discrete choice experiment; ART: anti-retroviral therapy; EXP: exponent; PASTAL: Partner-provided self-testing and linkage (parent trial); HIVST: HIV self-test; SOC: standard of care; HTS: HIV testing services; $3: US$3 financial incentive; $10: US$10 financial incentive. Includes 2408 observations among 602 women.

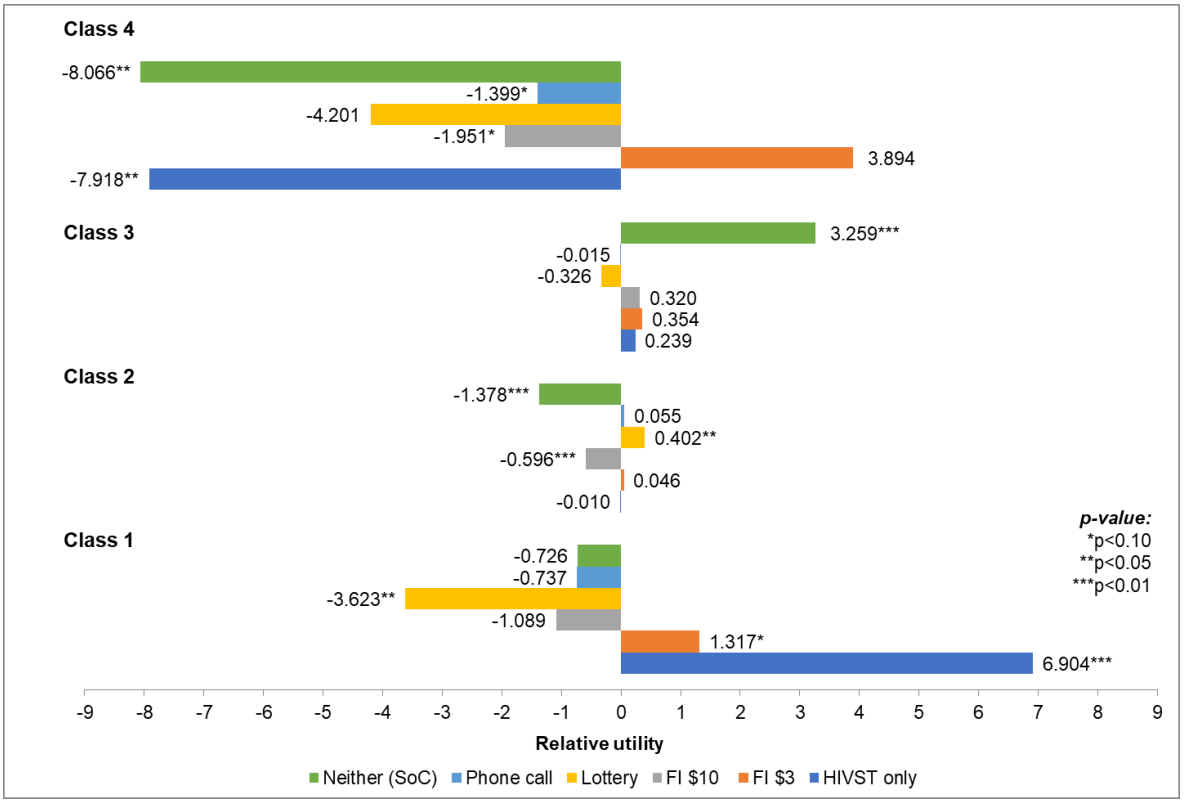
Figure 2: *Percentage of all male partners linking to HIV care or prevention in the parent trial*



HIV-ve: HIV negative; HTS: HIV testing services ST: HIV self-test; ART: antiretroviral therapy; VMMC: voluntary male medical circumcision. Results show the proportion of male partners starting ART or being circumcised: both stages. Intention to treat analysis used including all eligible women. Assumes 1:1 for women and their male partner.

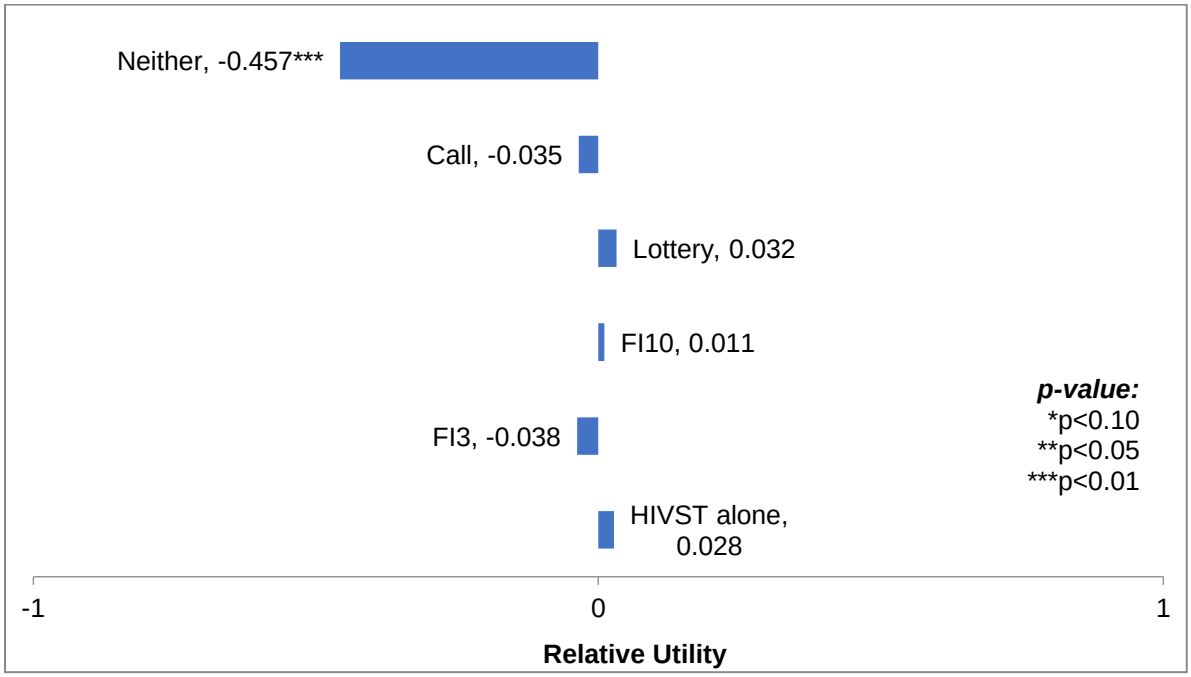
Source: Choko et al 2019 [17].

Figure 3: *DCE preferences by proxy for male partner linkage to ART, latent class analysis*



SoC: standard of care; ART: anti-retroviral therapy; PASTAL: Partner-provided self-testing and linkage (parent trial); HIVST: HIV self-test; SOC: standard of care; FI $3: US$3 financial incentive; FI $10: US$10 financial incentive. Includes 2408 observations among 602 women. Log likelihood function: -1554.919; Log Likelihood ratio: 1489.981; Restricted log likelihood -2645.458; Chi squared: 2181.079; McFadden Pseudo R-squared: 0.412; AIC: 3163.80; AIC/N: 1.314. *0.10, **0.05, ***0.01 level of significance with p-value.

Figure 4: *DCE preferences by proxy for male partner linkage to VMMC*



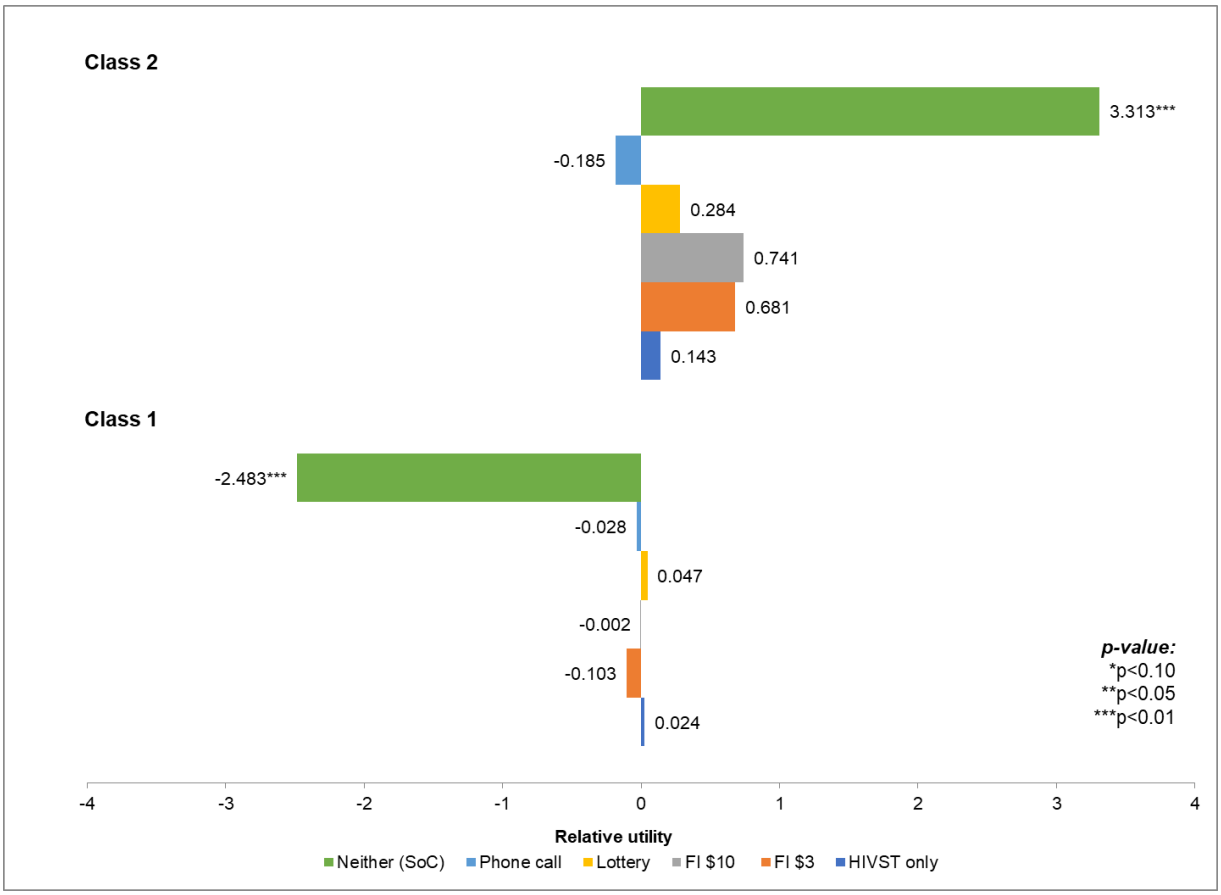
HIVST: HIV self-test; $10: US$10 financial incentive; $3: US$3 financial incentive. *0.10, **0.05, ***0.01 level of significance with p-value. Log Likelihood function: -714.78. AIC: 1449.60; AIC/N: 2.17. Chi squared: 9.15; Number of participants: 167; Observations: 668.

Table 3: *Alignment between the DCE predictions and the parent trial results, linkage to VMMC*

	Predictions: Overall DCE Linkage to VMMC (n=167)				PASTAL Trial Results by Arm (n=2, 349)		
Choice	Co-efficient	EXP	Predicted choices (%)	Rank	Circumcised	Actual choice (%)	Rank
Lottery	0.032	1.033	18.33%	1	3	2.22%	6
HIVST only	0.028	1.028	18.25%	2	17	12.59%	4
FI10	0.011	1.011	17.94%	3	55	40.74%	1
FI3	-0.038	0.963	17.10%	4	29	21.48%	2
Call	-0.035	0.966	17.14%	5	20	14.81%	3
Neither	-0.457	0.633	11.24%	6	11	8.15%	5
Total	-0.459	5.634			135		

DCE: discrete choice experiment; VMMC: voluntary male medical circumcision; PASTAL: Partner-provided self-testing and linkage (parent trial); HIVST: HIV self-test; SOC: standard of care; HTS: HIV testing services; $3: US$3 financial incentive; $10: US$10 financial incentive. Includes 668 observations among 167 women reporting their male partner was not circumcised.

Figure 5: DCE preferences by proxy for male partner linkage to VMMC, latent class analysis



SoC: standard of care; ART: anti-retroviral therapy; PASTAL: Partner-provided self-testing and linkage (parent trial); HIVST: HIV self-test; SOC: standard of care; FI $3: US$3 financial incentive; FI $10: US$10 financial incentive. Includes 668 observations among 167 women. Log likelihood function: -568.683; Restricted log likelihood -733.873; Log Likelihood ratio: 300.785; Chi squared: 330.379; McFadden Pseudo R-squared: 0.225; AIC: 1163.40; AIC/N: 1.742. *0.10, **0.05, ***0.01 level of significance with p-value.

6.4 Supplementary information

Appendix 1. *Design of the discrete choice experiment (DCE)*

The design of the DCE was developed from formative qualitative research [35] and the design of the parent cluster randomised trial [17] in Blantyre, Malawi. Within the STAR Consortium an economics team was established and supported and shared DCE results across Malawi, Zambia and Zimbabwe. We drew lessons from these studies and their efforts to validate the images. Figure S1 shows an example scenario.

We enabled individuals to choose between HIV self-testing and standard testing when selecting their preferred linkage option. The final attribute levels included in the study were:

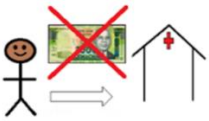
1. Financial incentive 2 000 Malawian Kwacha (MWK) (US$3) (value of transportation)
2. Financial incentive 7 000 MWK (US$10)
3. Phone call reminder
4. Cash prize lottery with 10% chance to win 19,500 MWK (US$30)
5. Testing alone no linkage option
6. Opt out of all options

Overall, participants were asked to select from three choice sets eight times, four regarding linkage to ART and four regarding linkage to VMMC.

Figure S1. *Sample choice task*

What do you think your male partner would prefer to link to care?

Please choice between alternative 1 [verbally describe scenario], Alternative 2 [verbally describe scenario], or neither of them

Attribute	Alternative 1	Alternative 2	Opt out
HIV testing	 *Kudziyeza wekha HIV*	 Kayezedwe ka HIV kwa nthawi zonse ka kuchipatala	**Neither of these options**
Financial incentive	**7,000 MWK**  $10: MWK 7,000	 Popanda Kupatsidwa ndalama	
Phone reminder	 Inde	 Ayi	

*Choice scenario administered by the interviewers to pregnant women using an electronic tablet in primary care clinic. English versions of the DCE questions are shown here but were translated and administered in the local language (Chichewa)

Table S1. *Partner preferences by proxy on male partner linkage to anti-retroviral therapy (ART), multinomial logit (Model 1) and latent class model (Model 2)*

Multinomial logit model (Model 1)			
Attributes	**Coefficient**	**SE**	**SD**
HIVST only	*-0.160****	*0.044*	*1.080*
FI $3	*0.087**	*0.051*	*1.251*
FI $10	*-0.228****	*0.051*	*1.251*
Lottery	*-0.036*	*0.051*	*1.251*
Phone call	*-0.009*	*0.292*	*7.164*
Neither (SoC)	*-1.472****	*0.068*	*1.668*
Model fit statistics			
Log Likelihood function	-2299.909		
Chi squared	26.989		
AIC	4611.80		
AIC/N	1.915		
Participants	602		
Observations	2408		

Latent class, random parameters interactions (Model 2)								
Attribute	***Class 1***		***Class 2***		***Class 3***		***Class 4***	
	Coefficient	***SE***	***Coefficient***	***SE***	***Coefficient***	***SE***	***Coefficient***	***SE***
HIVST only	*6.904****	*2.340*	*-0.010*	*0.131*	*0.239*	*0.633*	*-7.918*	*4.001*
FI $3	*1.317**	*0.692*	*0.046*	*0.138*	*0.354*	*0.472*	*3.894*	*2.578*
FI $10	*-1.089*	*0.695*	*-0.596*	*0.117*	*0.320*	*0.456*	*-1.951*	*1.169*
Lottery	*-3.623*	*1.700*	*0.402*	*0.174*	*-0.326*	*0.619*	*-4.201*	*2.724*
Phone call	*-0.737*	*0.605*	*0.055*	*0.055*	*-0.015*	*0.301*	*-1.399*	*0.753*
Neither (SoC)	*-0.726*	*0.864*	*-1.378*	*0.191*	*3.259*	*0.655*	*-8.066*	*3.478*
Class membership probability	*0.284****		*0.262****		*0.082****		*0.371****	
Model fit statistics								
Log Likelihood function	1554.919							
Restricted log likelihood	-2645.458							
Log Likelihood Ratio	7709.656							
Chi squared	2181.079							

McFadden Pseudo R-squared	0.412
AIC	3163.80
AIC/N	1.314
Participants	602
Observations	2408

HIVST: HIV self-test; HTS: HIV testing services; SoC: Standard of care; FI $10: US$10 financial incentive; FI $3: US$3 financial incentive; AIC: Akaike information criterion. *0.10, **0.05, ***0.01 level of significance with p-value.

Table S2. *Partner preferences by proxy on male partner linkage to anti-retroviral therapy (ART), latent classes model (Model 3) with sociodemographic factors effects (Model 4)*

Latent class, random parameters interactions (Model 3)								
Attributes	***Class 1***		***Class 2***		***Class 3***		***Class 4***	
	Coeff	***SE***	***Coeff***	***SE***	***Coeff***	***SE***	***Coeff***	***SE***
HIVST only	*6.793***	*2.375*	*-0.013*	*0.133*	*-7.963**	*4.178*	*0.149*	*0.643*
FI $3	*1.297**	*0.689*	*0.011*	*0.137*	*3.890*	*2.644*	*0.396*	*0.471*
FI $10	*-1.112*	*0.677*	*-0.585****	*0.120*	*-1.968*	*1.254*	*0.296*	*0.456*
Lottery	*-3.569***	*1.712*	*0.413***	*0.178*	*-4.223*	*2.801*	*-0.445*	*0.651*
Phone call	*-0.765*	*0.598*	*0.067*	*0.099*	*-1.412**	*0.752*	*-0.075*	*0.303*
Neither (SoC)	*-0.830*	*0.855*	*-1.388****	*0.203*	*-8.073*	*3.482*	*3.147****	*0.645*
Latent class, random parameters interactions (Model 4)								
Sociodemographic variables	***Class 1***		***Class 2***		***Class 3***		***Class 4***	
	Coeff	***SE***	***Coeff***	***SE***	***Coeff***	***SE***	***Coeff***	***SE***
Women's age	*0.149*	*0.204*	*0.047*	*0.217*	*-0.115*	*0.206*	*0.0*	*0.0*
Women's literacy	*-0.429*	*0.515*	*-0.139*	*0.550*	*0.312*	*0.547*	*0.0*	*0.0*
Women's health	*-0.254*	*0.204*	*-0.345*	*0.291*	*-1.095****	*0.281*	*0.0*	*0.0*
Married	*1.808***	*0.917*	*1.412*	*0.943*	*2.174***	*0.970*	*0.0*	*0.0*
Model fit statistics								
Log Likelihood function	*-1532.862*							
Restricted log likelihood	*-2645.458*							
Log Likelihood ratio	*1534.094*							
McFadden Pseudo R-squared	*0.421*							
Chi squared	*2225.192*							
AIC	*3143.70*							
AIC/N	*1.306*							
Participants	*602*							

Observations	*2408*

Coeff: Coefficient; HIVST: HIV self-test; HTS: HIV testing services; SoC: Standard of care; FI $10: US$10 financial incentive; FI $3: US$3 financial incentive; AIC: Akaike information criterion. *0.10, **0.05, ***0.01 level of significance with p-value.

Table S3. *Partner preferences by proxy on male partner linkage to voluntary male medical circumcision (VMMC), multinomial logit (Model 1) and latent class model (Model 2)*

Multinomial logit model (Model 1)			
Attribute	**Coefficient**	**SE**	**SD**
HIVST only	*0.028*	*0.089*	*1.150*
FI $3	*-0.038*	*0.101*	*1.303*
FI $10	*0.011*	*0.096*	*1.235*
Lottery	*0.032*	*0.100*	*1.288*
Phone call	*-0.035*	*0.057*	*0.735*
Neither (SoC)	*-0.457***	*0.102*	*1.313*
Model fit statistics			
Log Likelihood function		-719.0757	
Chi squared		0.562	
AIC		1450.20	
AIC/N		2.171	
Participants		167	
Observations		668	

Latent class, random parameters interactions (Model 2)				
Attribute	***Class 1***		***Class 2***	
	Coefficient	***SE***	***Coefficient***	***SE***
HIVST only	*0.024*	*0.091*	*0.143*	*0.574*
FI $3	*-0.103*	*0.111*	*0.681*	*1.010*
FI $10	*-0.002*	*0.107*	*0.741*	*1.133*
Lottery	*0.047*	*0.111*	*0.284*	*1.231*
Phone call	*-0.028*	*0.067*	*-0.185*	*0.342*
Neither (SoC)	*-2.483****	*0.408*	*3.313****	*1.331*
Class membership probability	*0.770****		*0.230****	
Model fit statistics				
Log Likelihood function		-568.683		
Restricted log likelihood		-733.873		
Log Likelihood Ratio		300.785		

Chi squared	330.379
McFadden Pseudo R-squared	0.225
AIC	1450.20
AIC/N	2.171
Participants	167
Observations	668

HIVST: HIV self-test; HTS: HIV testing services; SoC: Standard of care; FI $10: US$10 financial incentive; FI $3: US$3 financial incentive; AIC: Akaike information criterion. *0.10, **0.05, ***0.01 level of significance with p-value.

Table S4. *Partner preferences by proxy on male partner linkage to voluntary male medical circumcision (VMMC), latent class model (Model 3) and sociodemographic factors (Model 4)*

Latent class, random parameters interactions (Model 3)				
	Class 1		***Class 2***	
Attribute	***Coefficient***	***SE***	***Coefficient***	***SE***
HIVST only	*0.022*	*0.093*	*0.219*	*0.628*
FI $3	*-0.098*	*0.111*	*14.069*	*0.237*
FI $10	*-0.007*	*0.106*	*14.197*	*0.237*
Lottery	*0.0469*	*0.111*	*13.792*	*0.237*
Phone call	*-0.0342*	*0.063*	*-0.146*	*0.296*
Neither (SoC)	*-2.422****	*0.255*	*16.856*	*0.237*
Class membership probability	*0.774****		*0.226****	
Latent class, random parameters interactions (Model 4)				
Sociodemographic variables	***Class 1***		***Class 2***	
	Coefficient	***SE***	***Coefficient***	***SE***
Women's age	*0.042*	*0.220*	*0.0*	*0.0*
Women's literacy	*-0.185*	*0.631*	*0.0*	*0.0*
Women's health	*-0.986***	*0.396*	*0.0*	*0.0*
Married	*30.8428*	*0.111*	*0.0*	*0.0*
Model fit statistics				
Log Likelihood function		*-563.128*		
Restricted log likelihood		*-733.873*		
Log Likelihood ratio		*311.895*		
McFadden Pseudo R-squared		*0.233*		
Chi squared		*341.490*		
AIC		*1160.30*		

AIC/N	*1.737*
Participants	*167*
Observations	*668*

HIVST: HIV self-test; HTS: HIV testing services; SoC: Standard of care; FI $10: US$10 financial incentive; FI $3: US$3 financial incentive; AIC: Akaike information criterion. *0.10, **0.05, ***0.01 level of significance with p-value.

Table S5. *Baseline characteristics, qualitative study participants*

Variable	Female participants (n=71)*
Clinic of enrolment	
Bangwe	42
Zingwangwa	17
Ndirande	12
Female age group (years)	
Median age	24.0 (range: 18-37)
18-22	31
23-27	18
28-32	18
33-37	4
38-42	0
43+	0
Male partner age group (years)**	
Median age	29.0 (range: 20-45)
18-22	9
23-27	20
28-32	17
33-37	20
38-42	3
43+	1
Partner age difference (years)**	
Median age difference	4 (range: 0-18)
< 5	39
5-9	25
10-14	4
15+	2
Marital status**	
Married	65
Polygamous Marriage	5
Living together as if married	0
Never married	0
Widow	0

Variable	Female participants (n=71)*
Separated	0
Divorced	0
Married but not living together	0
Female education level**	
No school	0
Primary school	2
Secondary school no MSCE	38
Secondary school with MSCE	18
Higher	10
Other	2
Male partner education level**	
No school	0
Primary school	1
Secondary school no MSCE	23
Secondary school with MSCE	20
Higher	22
Other	4
Female occupation**	
Paid employee	8
Paid domestic worker	2
Self-employed	20
Unemployed	39
Other	1
Male partner occupation**	
Paid employee	36
Paid domestic worker	8
Self-employed	20
Unemployed	2
Other	4
General health**	
Excellent	20
Good	47
Fair	1
Poor	2
Ever tested in pregnancy	
Yes	71
No	0

Variable	Female participants (n=71)*
Ever tested with partner	
Yes	0
No	71
Ever self-tested for HIV	
Yes	1
No	70
Male partner circumcision	
Yes	36
No	35
Male partner ever tested**	
Yes	43
No	27
Tested in the last 12-months[§]	
Yes	18
No	25

*Overall, 75/602 (12.4%) of women in the study participated in the qualitative sub-study with the providers sharing their views after the survey. Of these women, four women did not provide any initial information because they opted not to participate in the parent trial after completing the DCE (n=2), and the others (n=2) were ineligible.

**One woman provided incomplete information because she reported her partner lived in Lilongwe now and was no longer eligible.

[§]Male partners tested in the last 12 months was only reported by the 43 respondents indicating their male partner had ever tested before.

7.0 Summary discussion, recommendations and conclusions

7.1 Introduction

This chapter focuses on recapping the key findings from this thesis by providing: (1) summary restating research aims and findings, (2) implications for the global context including policy and implementation considerations, (3) recommendations for future work, (4) reflection of the strengths and limitations and (5) final conclusions.

7.2 Summary of main findings of the thesis

The overarching research question for this thesis was: how should HIVST be optimized for future implementation so that access to affordable and acceptable HIV testing, with timely linkage to care and prevention are improved for men in sub-Saharan Africa? This question was answered through the completion of four different studies presented in this thesis.

The first study, presented in Chapter 3, was a systematic review which assessed available evidence from RCTs that compared HIVST to standard facility-based testing [1]. The primary research question asked: should HIVST be offered as an additional HIV testing approach?

Although only five RCTs were identified, all were focused on reaching men and evidence identified was of moderate to very low quality. Overall, the findings showed that HIVST increased uptake and frequency of HIV testing compared to facility-based testing services. In two RCTs where secondary distribution of HIVST to male partners of pregnant women was implemented, male partner testing also increased. Linkage following HIVST appeared suboptimal, but evidence was very low-quality with only one study reported on this outcome and no studies reported on linkage to prevention methods.

This was the first systematic review to address the impact and effectiveness of HIVST on uptake and frequency of HIV testing services, as well as linkage to care following self-testing. My aim was to include a gendered analysis as far as possible, given my special interest in men as an underserved population critical to reach more effectively. However, the strongest conclusions (from RCTs) were limited to men. This reflected many researchers' awareness of the importance of better providing for men's HIV testing and care services. Demonstrating that uptake and frequency of testing, including by men who had never tested before, could be

increased by self-testing with no major harm, was an important finding that provided the basis for global policy change and greater awareness among funders and implementers of the potential for self-testing to impact this important gap in reaching HIV elimination targets.

Specifically, my review concluded that, based on available evidence from RCTs, HIVST should be offered as an additional HIV testing approach. The findings were critical to the development and implementation of WHO guidelines, which then promoted the concept of secondary distribution of HIVST from antenatal care clinics as a novel strategy to reach men [2, 3]. The review also identified that, although reassuring, there was limited data available on social harm and that data on linkage to care was even more limited and would clearly be challenging to collect under standard programmatic approaches. As a result, I was also able to call for greater focus on prioritising research into these aspects of HIVST, including need to explore ways to optimise future delivery using both male and female preferences to apply to the context of secondary distribution methods. This led directly into my research questions and studies in Chapters 4, 5 and 6.

The second study, presented in Chapter 4, was a cross-sectional survey which pooled the first HIVST questions added to Demographic and Health Surveys from Malawi and Zimbabwe to investigate sociodemographic factors and sexual risk behaviours associated with previously testing for HIV, and past use, awareness of, and future willingness to self-test [4]. The study's primary research question was: what was the prevailing level of awareness, use and willingness to self-test for HIV in Malawi and Zimbabwe?

This study was the first time that Demographic and Health Survey data had been analysed to address these questions - which I personally drafted and lobbied to have included into the HIV testing modules of the Demographic and Health Surveys in 2012 and 2013. Including questions on self-testing allows countries to track trends of awareness of and attitudes toward HIVST, and also provided me with the opportunity to explore which sub-groups within the adult male population were most receptive to HIVST. At the time, these questions about reach and interest were both novel and highly relevant to thinking about just how complementary and impactful HIVST was likely to be among different groups such as those from urban or rural settings, older or younger populations, poorer or wealthier individuals, and those with higher and lower HIV-related risk behaviours.

Key findings were that nearly one-third of Malawian and Zimbabwean men had never tested for HIV and that HIVST awareness and experience was very low. Willingness to self-test was high among Zimbabwean men, especially older men with moderate-to-high HIV-related sexual risk. The highest willingness to self-test was in men aged 35–39 years and those in rural settings, where having never previously tested for HIV was more common than in urban settings. Gaps in awareness and use were also identified with poorer men having less HIVST awareness and use than wealthier men. As such, this analysis highlighted the important gaps in testing among men and suggested high potential for HIVST to contribute to epidemic control, based on the strong willingness to self-test among higher-risk midlife-older men who play a critical role in maintaining HIV transmission, notably to younger women.

This first demonstration of high interest in - and so potentially demand for - HIVST by such a critical group was exciting and suggested that this could be translated relatively easily into strategies able to effectively target midlife-older men. However, the results also highlighted to me that relatively little was known about how both age and gender impact preferences and decision-making relating to HIVST. This led me to formulate my next research project, presented in Chapter 5, which aimed to explore preferences and how implementation may need to consider age and gender-specific factors in order to optimise HIVST delivery.

The third study, presented in Chapter 5, was then a qualitative study among mid-life and older urban and rural Malawians (30–74 years of age) and community-based distributors following HIVST distribution [5]. The primary research question for this study was: how do individual age and gender norms affect sexual risk perceptions and HIV testing and self-testing behaviours?

Participants were guided through a semi-structured questionnaire in either focus group discussions or in-depth interviews, and a life-course theoretical framework was applied to examine the ways in which age and gender are socially enacted in Malawi in ways with potential to impact HIV testing and sexual risk behaviours. Then, the potential for HIVST to address these issues as part of a broader strategy for engaging midlife-older adults in HIV testing, prevention and care was explored.

Key findings were that both age and gender norms were important drivers of HIV risk perception and HIV testing uptake during midlife-older adulthood. Both age and gender norms were found to contribute to poor uptake of conventional HIV testing by middle-aged or older individuals, as

well as preferences for HIVST. Concerns about testing included fears that they would be viewed negatively in the community and that their current and future social status would be affected. HIVST appeared to provide a safe and acceptable alternative for mature adults to test, without challenging social age or gender expectations. Providing an extra kit for a partner and support for the self-testing was preferred by middle-aged and older adults. However, while individuals were inclined to give a self-test to a spouse, none stated they wanted to receive a kit from their partner as it may be linked to undesirable relationship concerns, such as infidelity. Additional age and gender appropriate service delivery options identified also included clinics for women and discreet community collection points and workplaces for men.

This was the first study to directly apply the life-course framework to understand how to optimise HIVST implementation and to focus on HIVST use among midlife-older adults. While previous studies focused on applying the life-course framework to HIV and aging more broadly, this study provided important new insights that despite beliefs that older age groups may be less receptive to new technologies and approaches, HIVST was found to be highly desirable and seen as an important tool to overcome the challenges that hinder midlife-older individuals from accessing HIV testing, as well as onward prevention and care. For example, midlife-older participants indicated that their social status in the community was a key reason they did not access existing HIV testing services, as they did not want to be seen as unrespectable in the community. Because of this, HIVST became an appealing solution for those wanting greater privacy.

Equally, HIV testing uptake was found to be low among midlife-older adults due to misperceptions about HIV in their community and that only younger age groups could be affected. Because of this, despite reporting current and past sexual risk behaviours, midlife-older adults believed that their age alone meant that they had little to no HIV risk and that they did not need HIV testing services. Relatedly, an additional finding also highlighted that midlife-older adults also had a striking lack of understanding of key concepts underpinning the “U = U”, whereby people with HIV on ART who are virally suppressed do not transmit HIV to their partners. Many also had outdated views on HIV care and treatment and believed an HIV diagnosis meant they would die in a hospital and could no longer live a normal and healthy life. At the time these findings were novel – both from the perspective of standard HIV testing and HIVST – and showed the benefit of qualitative research to investigate what had previously appeared to me to be puzzling reluctance to test despite older adults being aware of ongoing HIV risk by themselves or their partner.

I used these findings in presentations to others at WHO and within the HIV implementers forums to advocate for better promotion of U=U messages and understanding, including updated information about HIV prevention and treatment into HIV testing demand generation activities. These findings also influenced the community engagement messaging for a forthcoming community-led HIVST cluster-randomised trial in Malawi that achieved very high uptake of HIV testing among older residents [28]. These findings also influenced my approach to the analysis and interpretation of my final research study that investigated how both male and female preferences can best be utilised to optimise future deliver models, particularly relating to secondary distribution and partner testing using HIVST from antenatal clinics. This was important to guide future programming among midlife-older adults, particularly men who are not being reached by existing services.

The fourth study, presented in Chapter 6, was a discrete choice experiment and qualitative sub-study nested within a six-arm cluster randomised trial that used financial incentives to support male partner linkage to VMMC and ART following secondary distribution from their pregnant female partners. The study incorporated both male and female linkage preferences to address the question of how effective and feasible financial incentives are for supporting linkage to prevention and care following secondary distribution of HIVST from pregnant women to their male partners.

This study was novel in several respects. First, methodologically, it brought together a cluster-randomised trial, discrete choice experiment and a qualitative study into one study which provided a rich source of data and insight to understand differences between actual behaviour and stated preferences. Further, this is one of the first studies to explore preferences by proxy which uniquely engaged women to understand their preferences in addition to the trial which followed male partner linkage alone. Second, because the study design enabled triangulation of different sources of information, it was possible to identify and understand differences between men and women's linkage preferences, particularly towards financial incentives. The study has had high policy relevance, as it addressed a newly developed delivery strategy for using HIVST that was being rapidly adopted in Africa.

Through collecting preferences by proxy from women about their male partner's linkage preferences following secondary HIVST distribution, we learned that women had challenges making accurate predictions. However, findings revealed hidden preferences among women

and concerns about their partners receiving financial incentives. It also identified views that deeper issues that may need to be addressed to improve men's linkage, including mistrust, religious beliefs and inflexible service delivery options. Women's views remain critical as they need to be engaged to deliver HIVST kits to their partners. Overall, the study concluded that although financial incentives increase male partner linkage to VMMC and ART in the short-term, the lack of support from female partners may mean they are not viable in the long-term following secondary HIVST distribution approaches. This was an important and novel contribution to the development of HIVST secondary distribution strategies at a time of rapid roll-out and evolution, and at a time when interest in financial incentives, but awareness of potential for unintended consequences, was high due to some promising findings relating to HIV incidence reductions. Future implementation research is needed to design linkage strategies which are effective and acceptable to both men and women. This will likely be important for the long-term sustainability of secondary HIVST distribution approaches as programmes scale-up.

Ultimately this thesis found that HIVST should be optimized for reaching men in sub-Saharan Africa, as it is a safe and effective approach. Greater efforts are needed to create wider knowledge about and access to HIVST among men in sub-Saharan Africa, as use remains low despite high willingness. HIVST distribution should be tailored toward men, particularly midlife-older men in sub-Saharan Africa who may be more reluctant to take up other testing methods. As part of these efforts, midlife-older adults need HIVST distribution that includes the latest information about HIV in their communities to better understand their risk, as well as targeted "U=U" messaging and the benefits of HIV treatment. Strategies to support male partner linkage, such as financial incentives, are effective and important tools but need to be designed and implemented in ways acceptable to women in order to achieve longer-term success.

7.3 Role of HIVST in achieving UNAIDS 95-95-95 targets

The UNAIDS global targets state that by 2025, 95% of all PLHIV should know their status, 95% of those should be on ART and 95% of those on ART should be virally suppressed. These goals are intended to support efforts to then achieve and maintain low HIV incidence by 2030, often called "epidemic control" [6].

Substantial progress has been made towards these goals and it is estimated that 85% of PLHIV know their status, 75% are on treatment and 68% are virally suppressed and unable to transmit

the virus to sexual partners [7]. HIV testing continues to be critical to achieve these global targets, as 5.9 million PLHIV remain undiagnosed and many of those not on treatment continue to contribute to approximately 1.5 million new HIV infections every year [8]. Strategies that reach midlife-older men are increasingly important as they not only make up the bulk of those with undiagnosed HIV in sub-Saharan Africa [9], but studies in the region show that they are also driving transmission [10].

The reason for these gaps is now well-documented and include barriers, such as masculine norms [11-13], which lead to lower likelihood of men accessing health services, including HIV testing, as well as few male-friendly services and options designed to reach them [14]. Innovative approaches are needed to reach midlife-older men if global 95-95-95 targets and low HIV incidence are to be achieved.

7.4 Reflection on policy development and future WHO guidance

WHO guidelines that I have worked toward developing have played an important role in the introduction and scale-up of HIVST. Starting from the first international consultation on HIVST, in 2013, WHO has highlighted the potential impact self-testing could have and the importance of investing in research, developing policies and ensuring high quality products were available and affordable to low- and middle-income countries through WHO prequalification. Then, in 2016, drawing from the systematic review in this thesis, WHO normative guidelines were developed recommending HIVST. This was an important step because prior to the guidelines, there were no WHO prequalified HIVST products, prices were high, and implementation was limited to high-income countries and primarily only available the private sector.

Since the review and the development of the guidelines, HIVST started to be more widely available and is now considered a standard testing approach. As of July 2022, there were six WHO prequalified products, prices were affordable and 98 countries had national HIVST policies (52 routinely implementing and primarily in east and southern Africa) [15, 16]. Overall, WHO reports there has been a 2.5-fold increase in national policies and a four-fold increase in routine implementation since 2017 [15].

HIVST also became increasingly important during the COVID-19 pandemic as a critical way to keep essential health services going. Many service delivery innovations scaled-up during this

period, such as offering HIVST kits more widely to reduce congestion at facilities, save health worker time and manage staffing shortages. Additionally, when coupled with virtual platforms HIVST kits were delivered to homes or picked up on demand at community friendly spaces and prevented disruptions in prevention services, such as PrEP, among people with high HIV risk [17]. Following a review of HIV testing and ART initiation in sub-Saharan African during the COVID-19 pandemic, HIVST proved to be an important innovation to prevent large disruptions [18]. While WHO recommended HIVST as a way to maintain essential health services during COVID-19 [19], future guidance is needed to expand HIVST access as part of standard and broader emergency preparedness.

Policy development to make self-care and self-testing across other diseases is also needed. To date, WHO guidance for self-testing and self-care approaches now covers HIV [20], HCV [21], COVID-19 [22], self-collection for STIs, as well as for pregnancy and proteinuria [23]. As self-testing becomes more normalized, it is important for future guidance at a global and national level to draw lessons learned from HIVST so that self-testing can more broadly be applied in other disease areas. WHO can apply these principles to accelerate future guideline development processes by using a mixture of indirect and direct evidence to support scale-up of streamlined and integrated self-care approaches. This will be an important shift at country-level so that policies and regulations can enable a wide range of self-testing and self-care options.

7.5 Implementation priorities and research considerations for HIVST

HIV testing among men remains suboptimal, particularly those in midlife and older. There have been many efforts to try to reach men. Efforts, such as through community outreach, door-to-door campaigns and male partner invitation letters through PMTCT programmes, have had some success, but have had challenges often because these approaches are short-term and small scale. Services also generally miss men who are working and therefore away during campaign hours, or who have challenges accessing the clinic. Workplace testing, while shown to be effective for reaching men, is also not widely available due to the lack of HIV policies and fear of stigma and discrimination that could affect future work and income. Even workplaces that do have HIV policies to protect workers, may not always have the space, time or staff to support onsite services when testing and linkage services are desired.

Partner testing and social network testing approaches while effective for reaching many people with HIV, particularly men, who do not know their status and those with high ongoing HIV risk,

are often limited due to resource and staffing constraints and cannot reach mobile populations and those outside of specific geographic areas. There can also be low uptake and challenges when peers and partners have concerns about potential social harm or IPV.

HIVST offers a discreet and convenient way for people with HIV and those at high ongoing HIV risk to learn their status unlike any other testing approach. Because of the flexibility of HIVST it provides autonomy to help people learn their status when and where they want. It can also be integrated into existing service delivery models and make them more feasible and large scale; expanding access to more people. Additionally, by enabling peers and partners to deliver test kits, HIVST can also reach those with limited contact with the health system who may not otherwise test. This explains why HIVST has become so appealing and is now national policy in 98 countries [15].

HIVST has potential to contribute to the first 95 target as well as prevention goals. This is because it has been shown to increase access to and uptake of HIV testing consistently across diverse populations and settings, particularly those in midlife and older life stages. It has been well-documented that reaching this group is critical to achieving global goals in sub-Saharan Africa because that is where the greatest number of undiagnosed HIV infections remain and is the group driving HIV transmission. By increasing access to HIVST, more men will have the opportunity to learn their status and link to ART which is not only important for their individual health, but also for the health of their families.

HIV incidence among women in sub-Saharan Africa remains high, generally because of undiagnosed and untreated HIV among male partners [24]. HIVST has an important role as well to enhance uptake of male partner testing and maternal retesting, which is critical to ongoing efforts toward the elimination of mother-to-child transmission and to end paediatric HIV by 2030 [20]. HIVST is also important for improving greater access to HIV prevention services and averting new infections. HIVST can be used without any further testing to provide onsite or referrals for VMMC and further optimised VMMC service delivery for men. Likewise, HIVST can be used to enhance PrEP delivery [25], including innovative options like the dapivirine vaginal ring and long-acting formulations, by increasing feasibility, reducing clinic visits and enabling implementation of more decentralised delivery models [26]. By integrating with prevention options, HIVST could achieve greater impact among men and women, particularly during high incidence periods such as pregnancy and post-partum [27].

While there is substantial evidence and experience demonstrating the impact of HIVST, gaps remain. Based on the research and findings presented in this thesis, I propose the need to focus implementation research efforts toward addressing how HIVST can be optimised to reach midlife-older men in sub-Saharan Africa. The following table highlights key implementation and research gaps specifically based on the research studies presented in this thesis (Table 1).

Table 1: *Current status, evidence gaps and implementation gaps for HIVST, by outcome, based on thesis findings*

Outcomes	Current status	Research gaps
Uptake	HIVST safely and effectively reaches men, including through secondary distribution by pregnant female partners. Low awareness and use of HIVST in sub-Saharan Africa, particularly among poor men and those never tested before. Poor knowledge of past and current HIV-related risk and latest HIV prevention, treatment and care options among midlife-older adults.	Operationalize effective strategies to reach midlife-older men effectively and affordably, given their importance in driving HIV transmission and poor awareness of their HIV-related risk. Develop demand creation and awareness raising activities for midlife-older men – particularly for those who are poorer and who have never tested before. Develop male focused messaging, particularly for those midlife and older, to address myths about HIV and poor understandings of serodiscordancy, ART, HIV prevention as well as expanding knowledge of U=U.
Linkage and engagement	High value financial incentives increase male partner linkage to ART and VMMC following secondary HIVST distribution, but are disturbing to and cause unease among their partners.	Determine which enhanced linkage and engagement packages following HIVST are most effective for men; including HIVST to support re-engagement in care among those previously diagnosed with HIV and starting or returning to care. Identify linkage strategies, including incentive packages, that are acceptable to female partners as well as male partners. Understand how HIVST should be used to increase men's access to prevention beyond VMMC, e.g. harm reduction, PrEP/PEP and long-acting injectables. Optimize use of HIVST within ANC as well as PMTCT programmes to benefit male partner and also enable maternal retesting among women with high ongoing HIV risk during pregnancy.

7.6 Recommendations

Thesis specific recommendations on HIVST

1. **Expand and standardise secondary HIVST distribution from pregnant women to their male partners**. Lessons learned from this thesis indicate that this strategy should continue to focus on implementation through antenatal and primary health clinics, but should also be further adapted and expanded to include both women diagnosed with HIV to reach partners and to HIV negative women at high risk to offer testing to social contacts and to promote continued male partner engagement, PrEP access and effective use during pregnancy and the post-partum period.

2. **Increase demand creation and awareness activities to increase knowledge of HIV risk, particularly among midlife-older, poor and never tested men in sub-Saharan Africa.** Lessons learned from this thesis indicated that HIVST awareness and use was low, despite high willingness. Additionally, midlife-older adults had limited knowledge of their HIV-related risk, including the latest information on serodiscordancy, and how people with HIV on ART who are virally suppressed cannot transmit to their partners. To address this, targeted information and efforts are needed to reach midlife-older populations with this information and ensure HIVST is accessible.

3. **Incorporate partner and family centred preferences to support linkage strategies**. Strengthen the health system by providing a package of linkage support options for reaching men. Although incentives were desirable to men receiving kits to support linkage, women delivering kits viewed such incentives for their partners negatively with the exception of supporting time off work following VMMC. Future research should explore family centred incentives, which may be more feasible and supported by policy makers. Policy dialogues are needed to advance realistic discussions and resources that support a package of options, such as cash or alternative incentives.

4. **Services should be not just about linkage to prevention, but about leveraging HIVST to support engagement in prevention.** Lessons learned from this thesis on secondary distribution of HIVST and linkage services should be adapted to promote a range of HIV prevention options. Ideally services should be aimed at leveraging HIVST to make VMMC easier to implement and streamlining service delivery to improve efficiency. Likewise, women engaged in providing a kit for their partner, those with high

ongoing HIV risk, should also be given access to HIVST during their pregnancy to encourage male partner engagement, to optimise maternal retesting and to support uptake and effective PrEP use, including the dapivarine vaginal ring, in pregnancy and the post-partum period.

Overarching recommendations on HIVST

1. **Prioritize self-testing evidence and guidance for strategies and approaches to reach men and their partners across disease areas.** There are now a number of self-tests available beyond HIV, such as COVID-19, hepatitis C virus, and other STIs. It is important to adapt the delivery models and strategies developed for HIV to benefit other disease areas.

   One area for further expansion should include syphilis self-testing because of the opportunity to contribute to dual elimination efforts and prevent congenital syphilis. WHO is currently working on the guidelines to support syphilis self-testing, and secondary distribution using self-tests for both HIV and syphilis through antenatal clinics should be further explored for both women and their male partners.

2. **Utilising routine data systems and triangulation methods to assess HIVST impact in reaching midlife-older men, and increasing number on ART, receiving VMMC and other prevention services.** A challenge to current HIVST implementation is the limited understanding of its impact on national programming, especially in the context of secondary distribution. While special studies and surveys have helped provide evidence of HIVST impact, as programmes scale-up routine data should be used to optimise implementation.

   Methods for triangulating data to estimate HIVST impact using routine data have now been proposed, however country uptake of these methods are limited and focus primarily on HIV positivity and ART initiations following self-testing. It is important for countries to start utilising these approaches now to support targeted programming and to be able to assess and adapt services particularly for midlife-older men. Methods now need to work to include linkage and engagement in HIV prevention, such as VMMC and PrEP. This will help provide a fuller picture of HIVST impact and contribution to treatment and prevention targets.

3. **Provide focused HIVST policies and strategies toward reaching midlife-older men in sub-Saharan Africa.** In addition to individual interventions to support men's access to HIV testing, prevention and treatment, a standard package of services needs to be provided as part of a concerted effort to address gaps among midlife and older men in the HIV response.

   This package will need to include service delivery options as well, including scale-up of male-friendly services through greater engagement with workplaces, community sites (like pick-up points and bus depots) for picking up test kits, condoms and ART, as well as clinics that offer flexible hours and weekend services, mobile options and virtual tools.

   Raising men's awareness about the latest information about HIV is also critical. Specifically, it is critical to address men's misperception that they are at low HIV risk during midlife and as they age. Also important is to increase awareness on the many advances in HIV treatment and prevention that are now available, particularly that those on ART and virally suppressed cannot transmit to their partners.

   It is important for these approaches for men to be scaled-up and well-resourced at national and community level, otherwise strategies will remain small scale and miss the opportunity to achieve the UNAIDS 95-95-95 targets.

7.7 Strengths and limitations of the thesis

This thesis combines a systematic review, a cross-sectional survey, a formative qualitative study and a DCE that was uniquely nested within a six-arm adaptive cluster randomised trial. Together these pieces provide insight into the challenges that are causing low coverage of HIV testing, prevention and treatment among midlife-older men, as well as the great value of HIVST to help address the challenges with reaching and engaging midlife-older men, including through secondary distribution by female partners. Because effective and acceptable interventions were identified, there are relevant implications for donors, policy makers and implementers.

Second, this work has directly contributed to the formation of normative and implementation guidance. Starting with the systematic review which informed the first recommendations on HIVST by the World Health Organization, through this thesis I have contributed to supporting HIVST policy development globally and the availability of affordable quality assured HIVST kits in low- and middle-income countries through WHO prequalification. I also directly contributed to

HIVST guidelines and implementation strategies across sub-Saharan Africa and particularly in Malawi. Because this work was designed to have policy and implementation impact, it has helped pave the way for wide-scale HIVST introduction, with 98 countries with national policies supportive of HIVST and six WHO prequalified products.

Through this thesis I also contributed directly to methods for assessing HIVST impact through developing survey questions for Demographic Health Surveys and for providing an analysis of experience, use and willingness from the first two surveys to use these questions. Since then, more researchers have begun using these questions and the use of surveys and routine data systems for assessing HIVST implementation are now becoming standard.

Using a life-course theoretical framework has helped to bring renewed focus to midlife-older men, who have been highlighted as a priority population to reach given the high rates of undiagnosed HIV and transmission in the region. Additionally, this thesis also introduced a novel preference by proxy method which incorporated a DCE within a multi-arm multi-stage cluster randomised trial. The method uniquely engaged men and women about feasible linkage strategies after secondary HIVST distribution and highlights ways for future research to gather information on preferences and feasibility when designing complex interventions.

However, this thesis has several limitations. While the studies were all generally implemented successfully, they took place between 2016 and 2017 and since then HIVST has been scaled-up more widely. Because the contributions were often the first papers and studies to address specific topics, they were exploring HIVST when it was still very new. As a result, this thesis does not sufficiently cover how new emerging issues, such as the COVID-19 pandemic, affected HIVST implementation or further normalised self-testing. Additionally, lessons have been learned through early HIVST implementation which can be used to improve future studies, for example in the cross-sectional surveys only Zimbabwe asked about willingness to self-test among men; Malawians and women were not systematically asked these questions. Thus, this prevented fuller analysis and understanding.

Implementing the DCE within a larger trial proved challenging, particularly as enrolment was conducted in a busy primary clinic. Because of this, not all those completing the DCE were ultimately randomised in the trial. Thus, the sample population may have differed from the trial population. Further, because the trial reported high rates of male circumcision before enrolment and there were supply-side barriers at the time of implementation, the trial used a combined

ART and VMMC outcome, including referrals, in addition to confirmed circumcisions. As a result, the DCE was underpowered for preferences for linkage to VMMC, as was the main trial.

Study designs used in this thesis included observational and qualitative studies examining HIVST, including a cross-sectional survey, DCE, focus group discussions and in-depth interviews rely on self-reported behaviour, preferences and attitudes. While these studies offer important insights, they do not provide direct evidence of causality or final impact or effectiveness of HIVST implementation. For example, the DCE results reported in this thesis did differ from the cluster-randomised trial results, showing that men's real behaviour was different than what their female partners thought it would be. Thus, future research should consider randomised controlled trials and quasi-experimental studies which can more fully determine the effectiveness and impact of HIVST implementation.

7.8 Conclusions

The systematic review presented in this thesis produced the first synthesis of evidence on the effectiveness of HIVST compared to standard HIV testing services and reported that self-testing was both safe and effective for increasing testing uptake, frequency and overall positive HIV diagnoses. This review contributed directly to WHO normative guidelines recommending HIVST, and subsequent implementation guidance, prequalification of test kits and broader scale-up globally, and particularly within sub-Saharan Africa and Malawi. The review also identified that secondary HIVST distribution from pregnant women to their partners as a critical strategy for reaching men.

The cross-sectional survey analysis revealed substantial gaps in testing among men, as well as high willingness to self-test among midlife-older men, particularly those with higher risk. This led to a focus on understanding how HIVST could be better packaged and implemented to reach this group in a formative qualitative study.

The DCE revealed the importance of including women's views in linkage interventions for men following secondary HIVST implementation. While preferences by proxy did not lead to consistent predictions of male partners linkage choices in the parent study, they identified that men receiving high-value (US$10) incentives for ART linkage, though effective, were not desirable to women. Instead, they pointed to problems in the health system that they thought would improve men's linkage, such as improved service delivery strategies that were more

flexible and open after working hours. Linkage strategies acceptable to men and women are important for the long-term sustainability of secondary HIVST distribution.

In this PhD, I combined a systematic review, population survey, qualitative study, and DCE, which shows the importance of HIVST approaches that focus on reaching midlife-older men and are accepted by female partners. These findings provide a pathway for policymakers and implementers to focus their efforts on male-friendly HIVST scale-up for those 35-39 years of age which is critical for achieving the “first 95” – diagnosis of 95% of all people with HIV by 2025 and maintaining low HIV incidence by 2030.

References

1. Johnson CC, Kennedy C, Fonner V, Siegfried N, Figueroa C, Dalal S, Sands A, Baggaley R. Examining the effects of HIV self-testing compared to standard HIV testing services: A systematic review and meta-analysis. J Int AIDS Soc. 2017;20(1):21594-.

2. WHO. Guidelines on HIV self-testing and partner notification: Supplement to consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2016.

3. WHO. HIV self-testing strategic framework: A guide for planning, introducing and scaling up. Geneva: World Health Organization; 2018. Available from: https://www.afro.who.int/publications/hiv-self-testing-strategic-framework-guide-planning-introducing-and-scaling.

4. Johnson C, Neuman M, MacPherson P, Choko A, Quinn C, Wong VJ, Hatzold K, Nyrienda R, Ncube G, Baggaley R, Terris-Prestholt F, Corbett EL. Use and awareness of and willingness to self-test for HIV: An analysis of cross-sectional population-based surveys in Malawi and Zimbabwe. BMC Public Health. 2020;20(1):779.

5. Johnson C, Kumwenda M, Meghji J, Choko AT, Phiri M, Hatzold K, Baggaley R, Taegtmeyer M, Terris-Prestholt F, Desmond N, Corbett EL. 'Too old to test?': A life course approach to HIV-related risk and self-testing among midlife-older adults in Malawi. BMC Public Health. 2021;21(1):650.

6. UNAIDS. Understanding fast-track: accelerating action to end the AIDS epidemic by 2030. Geneva: Joint United Nations Programme for HIV/AIDS; 2015. Available from: https://www.unaids.org/sites/default/files/media_asset/201506_JC2743_Understanding_FastTrack_en.pdf.

7. UNAIDS. UNAIDS Global AIDS Update — Confronting inequalities — Lessons for pandemic responses from 40 years of AIDS. Geneva: Joint United Nations Programme on HIV/AIDS; 2022. Available from: https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update.

8. UNAIDS. Global commitments, local action: After 40 years of AIDS, charting a course to end the pandemic. Geneva: Joint United Nations Programme on HIV/AIDS; 2021. Available from: https://www.unaids.org/sites/default/files/media_asset/global-commitments-local-action_en.pdf.

9. Giguère K, Eaton JW, Marsh K, Johnson LF, Johnson CC, Ehui E, Jahn A, Wanyeki I, Mbofana F, Bakiono F, Mahy M, Maheu-Giroux M. Trends in knowledge of HIV status and

efficiency of HIV testing services in sub-Saharan Africa, 2000-2020: A modelling study using survey and HIV testing programme data. Lancet HIV. 2021;8(5):e284-e93.

10. Fraser C. New data and findings including phylogenetic analysis. International AIDS Conference; 29 Jul - 2 Aug 2022;Montreal, Canada.

11. Creighton G, Oliffe JL. Theorising masculinities and men's health: A brief history with a view to practice. Health Sociology Review. 2010;19(4):409-18.

12. Robertson S. Theories of masculinities and health-seeking practices. "Nowhere Man" Men's Health Seminar;Belfast, Ireland: Nowhere Man Press; 2008.

13. Thorpe RJ, Jr., Wilson-Frederick SM, Bowie JV, Coa K, Clay OJ, LaVeist TA, Whitfield KE. Health behaviors and all-cause mortality in African American men. American journal of men's health. 2013;7(4 Suppl):8s-18s.

14. Choko AT, Kumwenda MK, Johnson CC, Sakala DW, Chikalipo MC, Fielding K, Chikovore J, Desmond N, Corbett EL. Acceptability of woman-delivered HIV self-testing to the male partner, and additional interventions: a qualitative study of antenatal care participants in Malawi. J Int AIDS Soc. 2017;20(1):21610

15. WHO. WHO HIV policy adoption and implementation status in countries. Geneva: World Health Organization; 2022. Available from: https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/who-hiv-policy-adoption-and-implementation-status-in-countries.pdf?sfvrsn=bb35e6ae_6.

16. WHO. New US$ 1 price for HIV self-tests Geneva: World Health Organization; 2022 [cited 2022 12 August]. Available from: https://www.who.int/news/item/27-07-2022-new-1-dollar-price-for-hiv-self-tests.

17. UNAIDS, WHO. Innovate, Implement, Integrate: Virtual interventions in response to HIV, sexually transmitted infections and viral hepatitis. Geneva: Joint United Nations HIV/AIDS Programme 2022.

18. WHO. Assessment of HIV testing services and antiretroviral therapy service disruptions in the context of COVID-19: lessons learned and way forward in sub-Saharan Africa. Geneva: World Health Organization; 2021. Available from: https://www.who.int/publications/i/item/9789240039599.

19. WHO. Maintaining essential health services during the COVID-19 outbreak. Geneva: World Health Organization; 2020. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/related-health-issues.

20. WHO. Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2019.
21. WHO. Recommendations and guidance on hepatitis C virus self-testing. Geneva: World Health Organization; 2021. Available from: https://www.who.int/publications/i/item/9789240031128.
22. WHO. Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing. Geneva: World Health Organization; 2022. Available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1.
23. WHO. WHO guideline on self-care interventions for health and well-being, 2022 revision. Geneva: World Health Organization; 2022. Available from: https://www.who.int/publications/i/item/9789240052192.
24. de Oliveira T, Kharsany AB, Gräf T, Cawood C, Khanyile D, Grobler A, Puren A, Madurai S, Baxter C, Karim QA, Karim SS. Transmission networks and risk of HIV infection in KwaZulu-Natal, South Africa: a community-wide phylogenetic study. Lancet HIV. 2017;4(1):e41-e50.
25. WHO. Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Geneva: World Health Organization; 2022. Available from: https://www.who.int/publications/i/item/9789240053694.
26. Kiptinness C, Kuo AP, Reedy AM, Johnson CC, Ngure K, Wagner AD, Ortblad KF. Examining the use of HIV self-testing to support PrEP delivery: A systematic literature review. Curr HIV/AIDS Rep. 2022.
27. Graybill LA, Kasaro M, Freeborn K, Walker JS, Poole C, Powers KA, Mollan KR, Rosenberg NE, Vermund SH, Mutale W, Chi BH. Incident HIV among pregnant and breast-feeding women in sub-Saharan Africa: a systematic review and meta-analysis. AIDS. 2020;34(5).
28. Indravudh PP, Fielding K, Kumwenda MK, Nzawa R, Chilongosi R, Desmond N, Nyirenda R, Neuman M, Johnson CC, Baggaley R, Hatzold K, Terris-Prestholt F, Corbett EL. Effect of community-led delivery of HIV self-testing on HIV testing and antiretroviral therapy initiation in Malawi: A cluster-randomised trial. PloS Med. 2021;18(5):e1003608.

8.0 Appendices

Appendix 1. *Tools developed and used for the qualitative study*

In-Depth Interviews with Community Household Members (Couple)

Opening statements:
Thank you to both of you for agreeing to spend time to answer some more detailed questions about yourselves and your views of self-testing for HIV. This interview will probably take about two hours and we will be discussing your daily life and the factors that influenced your decision regarding self-testing.

A. Personal & couple characteristics

1. What year were you both born?
2. You made your decision to test or not to test for HIV together, why did you decide together?
3. Can you describe your relationship to me?
   Probes: Length of time together? Type of marriage? Whether they have children together – ages and where these children live? Whether they have other children (not together) and where these children live? Whether they live together (full-time, some of the time)?
4. What ethnic group are you both from?
5. What would you both describe your religion as? How often do you both attend church/mosque and is either of you a member of any groups associated with your religion?

B. Socio-economic and social status

6. Can you please describe the house in which you live (construction/roofing/facilities)?
7. Who would you say earns the majority of the money in your relationship?
8. What activities do you or both of you carry out to earn money?
9. Where does your household get food from (purchasing/agriculture own land/extended family land/ close by/ in village)?
10. Can you describe a typical meal in your household (time, meal composition, eating practices)?

C. Relationship dynamics and household relations

11. Who is the person who makes the majority of decisions in your household? Why? Does this differ according to the types of decisions (financial/education/health)?
12. How many other people live in your household and what are their relations to each of you?

Please could you both consider the following scenarios together, discussing together what you would do when faced with this scenario...

13.1 Your 15 year old son has begun to come home later after school recently. When confronted he says that it is because he is doing his homework at school with his friends. You then receive a report from a teacher that he has been skipping classes...

13. 2 You currently have no regular income coming into the household. It is difficult to provide food for everyone. Your 17 year old daughter, who is still in secondary school begins to contribute without explaining how she is able to this…

D. Perceptions of risks (HIV and testing-related)

13. What kind of things do both of you worry about most in life? Why?
14. What, if any, concerns do you have about HIV?
15. What, if any, concerns do you have about HIV for others in your household?

I am going to provide you with 10 beans each. I would like to ask you a few questions and in answer you each need to pick the number of beans that reflects how likely it is that:

15.1 You will eat nsima tomorrow.

15.2 You are already infected with HIV.

15.3 You will become infected with HIV.

Please do this individually and then compare your responses and explore together why you have selected the particular number of beans in each case.

E. General health status & experience of health services

16. How healthy do you feel you both are in general?
17. Has either of you or anyone else in your household experienced an illness in the past six months? Can you describe this experience?

    Probes: Was this a one off illness or part of a longer term illness episode? Who was the sufferer and who was the carer? Treatment seeking pursued?

18. From the experience recounted or from other experiences, what is your opinion of your local health service?

    Probes: Accessibility & cost (convenience/transport/time taken from other activities)? Quality & trust (patient-provider relations & communication/power issues & perceptions of control)? Type of facility & differences by facility? Type of staff & differences by type of staff?

F. Previous experience of HIV testing

For couples who tested as a couple:

19. Have you ever had an HIV test before as a couple? You do not need to tell me the result.

20. Can you please explain why you decided to test as a couple again or (if you have tested more than once as a couple) what your reasons for repeat testing were?
21. (If yes) Whose idea was it to test as a couple initially and how did you persuade your partner to agree?
22. (If yes) What was the whole experience like?
    Probes: Confidentiality? Trust in results & provider? Location and convenience?
23. (If no) Why did you not decide to test as a couple when offered the opportunity the other day?

For couples who did not test:

24. Have you ever had an HIV test before as a couple? You do not need to tell me the result.
25. (If no) Can you please explain why you decided not to test?
    Probes: Related to risk perceptions? Related to service perceptions? Related to family dynamics? Related to fears and concerns regarding stigma, disclosure or status?

G. Self-testing

26. Can you please describe briefly why you made your particular decision regarding self-testing as a couple when you were offered it the other day?
    Probes: Factors related to individual/couple? Factors related to testing in general? Factors related to self-testing?
27. If self-testing becomes available in the community, would you recommend it to your friends and family? Why?

H. Future of testing

28. In your opinion and whether or not you have tested up to now, what are the most important factors in HIV testing i.e. what factors would persuade you to test?
    Probes: Community or facility-based, integrated or stand-alone venues, home-based outreach services (accessibility)? Level of counselling? Provider-client relations/control of testing (self-testing)? Confidentiality? Confidence & trust in results and test? Accessible referral mechanisms to ART?
29. In your opinions is individually targeted or couple targeted HIV testing a better option? Why?
30. If you plan to test (again) in the future, what kind of testing would you prefer?
31. If we offered you the opportunity to self-test (again) today, would you opt to test or not to test?
32. We have reached the end of the interview. Do you have any questions that you would like to ask me?

Thank you very much for the time you have spent in answering my questions today. Please remember that this information is all confidential. I have learnt a lot from our discussion here today and hope that the time has also been useful to you both.

Cluster resident – Topic guide for focus group discussions

1. Beliefs about HIV amongst people of their age / older groups
    a. Knowledge about HIV
    b. Expectations on HIV diagnosis – hopes / fears
    c. Community beliefs about older people who are found to have HIV – stigma in this age group

What do you know about HIV?

- Probe transmission, risk factors – if traditional diseases raised

What do you think happens to people when they have HIV?

- Probe treatment & prognosis
- Probe fears & expectations

If one of us was diagnosed with HIV, what do you think people would say?

- Probe family (partner & children), friends, community reactions

Do people say different things when old people have HIV, compared to young people?

- Probe young person, old person

2. Perceptions of personal risk amongst people of their age / older groups
    a. What determines perceptions of self-risk
    b. Socially held beliefs / prejudices about who HIV effects

Who do you think is at risk of HIV?

Which groups of people does HIV occur most often in?

Are there certain groups of people who are more at risk? Why?

- Probe – age, gender, socioeconomic class, employment.

Do you think older people are at risk of HIV?

How/Why do you think old people get HIV?

3. Beliefs about testing amongst people of their age / older groups
    a. Beliefs about testing methods (oral, blood) – reliability, accuracy, cost, ease of use, responsibility for doing own test
    b. Barriers to testing – cost, time, fears of pain, fear of stigma

c. Reasons for testing – beliefs about future, to protect others, for control, influence of friends/family
d. Perceptions about confidentiality
e. Social norms around testing – who should / does test within community

What do you know about HIV testing?

What do you think is the best way to have an HIV test?

- Probe – place (hospital, clinic etc), alone or with someone, person doing the test
- Probe – type of test (oral, blood)

What, if anything, makes people go and have HIV tests?

Are there any differences between why older people and younger people have HIV tests?

- Probe family structure (single/married, children), peer group activities, fears, expectations

What, if anything, stops people having HIV tests? Are there any things that people worry about?

Are there any differences between why older people and younger people don't like to have HIV tests?

If people knew that one of us had taken an HIV test, what would they say?

- Probe family, friends, community

Do people say different things when old people have HIV tests, compared to young people?

- Probe young person, old person

4. <u>Decision making process amongst people of their age / older groups</u>
    a. People influencing decision to test – partner, family, other

Do people in your community talk to anyone before having a test?

Who do they talk to? What do they say?

- Probe partner, family, friends, elders, religious groups

Thematic framework

1. HIV knowledge
    1.1. Routes of transmission
    1.2. ARV
    1.3. Prognosis
    1.4. Kanyere
    1.5. Education about HIV
    1.6. Previous exposure to people with HIV

2. Risk perception
    2.1. Promiscuity
    2.2. Money
    2.3. Condoms
    2.4. Alcohol
    2.5. Intergenerational sex
    2.6. Difference in risk with age

3. Counsellors
    3.1. Age
    3.2. Gender
    3.3. Social proximity
    3.4. Assistance offered
    3.5. Relationship with client
    3.6. Confidentiality
    3.7. Respect

4. Means of testing
    4.1. Hospital testing
    4.2. Home testing
    4.3. Oraquick
    4.4. Blood testing
    4.5. Double testing for confirmation
    4.6. Convenience of testing
    4.7. Time taken to test

5. Incentives to test
    5.1. Sickness
    5.2. Access to treatment
    5.3. Promiscuity
    5.4. Planning for future
    5.5. Knowledge of self
    5.6. Material incentives
    5.7. Religion

6. Disincentives to test
    6.1. Fear of diagnosis
    6.2. Psychological impact of diagnosis
    6.3. Impact on relationships
    6.4. Denial
    6.5. Fatality – ‘I am already old’
    6.6. Religion

7. Marriage
    7.1. Faithfulness / cheating
    7.2. Discordance
    7.3. Trust

8. Stigma
    8.1. Of testing
    8.2. Of diagnosis
    8.3. Change over time

9. Social role of older person
    9.1. Role in society
    9.2. Expected behaviour
    9.3. Response to positive diagnosis

Appendix 2. Tools developed and used for the discrete choice experiment

Baseline questionnaire for women in multi-arm multi-stage (MAMS) cluster-randomised trial (CRT) – Partner-provided self-testing and linkage (PASTAL) study

Instructions:

i) Prefix each question with B for baseline.
ii) Variable names which appear in the database come after the question number.

Section A: Identifiers

1. **b01date** Date of interview *[Date]*
2. **b02intid** Interviewer ID *[Numeric 01-10]*
3. **b03ancd** Clinic day # *[Numeric 01-99]*
4. **b04cid** Clinic ID *[Numeric]* ➔ *coded 1=Ndirande; 2=Bangwe*
5. **b05arm** Arm *[Numeric 1-6]* ➔ *1=Standard of care; 2=HIV self-test kits only; 3=HIV self-test kits plus low amount financial incentive; 4=HIV self-test kits plus high amount financial incentive; 5=HIV self-test kits plus lottery financial incentive; 6=HIV self-test kits plus phone call reminder.*
6. **b06name** Full name *[String]* ➔ *indicate both first name and surname*
7. **b07pidw** Woman barcode *[Numeric]* ➔ *scan from barcode sheet, place woman barcode in the health passport; place another on the recruitment log.*
8. **b08pidm** Male partner barcode *[Numeric]* ➔ *scan the barcode on PQ43_male_partner_invitation_letter*

Section B: Woman demographics and antenatal clinic data

9. **b09denom** Total number of women at ANC on that day *[Numeric]* ➔ *automatically filled from a count of completed PQ05 records*
10. **b10dob** What is your date of birth *[date: DD-MM-YYYY]*
    Kodi munabadwa mchaka chanji? Chonde tiwuzeni tsiku, mwezi komanso chaka ngati nkotheka.
11. **b11age** Age *[Numeric]* ➔ *calculate automatically using DOB and today's date but record if DOB is unknown.*
    Kodi muli ndi zaka zingati?
12. **b12mstat** Marital status *[Numeric]* ➔ *1=married; 2=polygamous marriage; 3=living together as if married; 4=never married; 5=widow; 6=Separated; 7=Divorced; 8=married but not living together.*
    Kodi muli pa banja panopa?
13. **b13live** Are you currently living together with your partner? *[Numeric]* ➔ *Depends on answer to 12) marital status. 1=yes; 0=no.*
    Kodi mumakhala limodzi ndi mwamuna wanu?
14. **b14lit** Can you read a letter or a newspaper? *[Numeric]* ➔ *1=yes; 0=no*
    Kodi mumatha kulemba ndi kuwerenga?

15. **b15occ** How can you best describe your main activity or work status? *[Numeric]* ➔ *1=Paid employee; 2=Paid domestic worker; 3=Self-employed; 4=Unemployed; 5=Student; 6=Other*
    Kodi mumagwira ntchito yanji?
16. **b16edu** What was the highest level of education that you have completed? *[Numeric]* ➔ *0=Never been to school; 1=Primary school; 2=Secondary school no MSCE; 3= Secondary school with MSCE; 4=Higher*
    Kodi maphunziro anu munafika nawo pati?
17. **b17phone** Phone # *[Numeric]*
18. **b18genh** How do you rate your general health? ➔ 1=Uli bwino kwambiri (Excellent); 2=Uli bwino (Good); 3=Choncho (Fair); 4=Siwuli bwino (Poor)
    Kodi mukuwona kuti moyo wanu uli bwanji?
19. **b19test** Have you tested for HIV in this pregnancy? *[Numeric]*➔ *1=yes; 0=no*
    Kodi mwayezetsa kachilombo ka HIV mu uchembere uno?
20. **b20selft** Have you ever self-tested for HIV? *[Numeric]* ➔ *1=yes; 0=no*
    Kodi munayamba mwaziyezapo nokha kachilombo ka HIV?
21. **b21couple** Did you test together with your male partner in this pregnancy? *[Numeric]* ➔ *Depends on answer to tested in this pregnancy (19)*
    Kodi mwayezetsa limodzi ndi okondedwa wanu mu uchembere uno?

Section C: questions about male partner

22. **b22dob** What is your male partner's date of birth *[date: DD-MM-YYYY]*
    Kodi mwamuna wanu anabadwa mchaka chanji? Chonde tiwuzeni tsiku, mwezi komanso chaka ngati nkotheka.
23. **b23age** Male partner's Age *[Numeric]* ➔ *calculate automatically using DOB and today's date but record if DOB is unknown.*
    Kodi mwamunayu ali ndi zaka zingati?
24. **b24lit** Can your male partner read a letter or a newspaper? *[Numeric]* ➔ *1=yes; 0=no*
    Kodi mwamuna wanu amatha kulemba ndi kuwerenga?
25. **b25occ** How can you best describe your male partner's main activity or work status? *[Numeric]* ➔ *1=Paid employee; 2=Paid domestic worker; 3=Self-employed; 4=Unemployed; 5=Student; 6=Other*
    Kodi mwamuna wanu amagwira ntchito yanji?
26. **b26edu** What was the highest level of education that your partner completed? *[Numeric]* ➔ *0=Never been to school; 1=Primary school; 2=Secondary school no MSCE; 3= Secondary school with MSCE; 4=Higher*
    Kodi mwamuna wanu maphunziro ake anafika nawo pati?
27. **b27phone** Partner's Phone # *[Numeric]*
28. **b28test** To your knowledge, has your male partner ever been tested for HIV *[Numeric]* ➔ *automatic yes if YES to tested together in this pregnancy; 1=yes; 0=no*
    Malingana ndi momwe mukudziwira, kodi wachikondi wanu anayamba wayezetsapo kachilombo ka HIV?
29. **b29test12m** To your knowledge, has your male partner tested for HIV in the last 12 months *[Numeric]* ➔ *Automatic yes if YES to tested together in this pregnancy. 1=yes; 0=no*

Malingana ndi momwe mukudziwira, kodi wachikondi wanu wayezetsa kachilombo ka HIV mu miyezi 12 yapitayi?

Section D: Participation in the allocated arm

30. **b30part** Will you participate in the study? *[Numeric]* ➔ *1=yes; 0=no*
    Kodi mukuvomera kutenga nawo mu kafukufukuyu?
31. **b31why** Reasons for not participating in the allocated arm *[Text]*
    Kodi ndi chifukwa chiyani simukufuna kutenga nawo mbali mu kafukufukuyu?

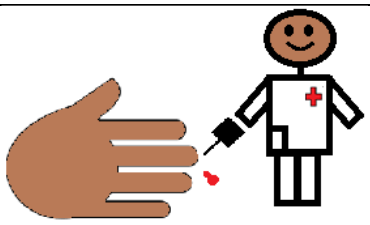
Discrete choice experiment "warm-up" survey: Questions for pregnant women at enrolment or at follow-up within PASTAL Study

Before we start, I'd like to complete a warm-up exercise to get familiar with the pictures and ask you some questions about what you think your partner would prefer to link to HIV prevention (voluntary male medical circumcision) or care.

First, I would like to ask you some questions about what your partner prefers to link to HIV prevention (VMMC) following an HIV-negative test.

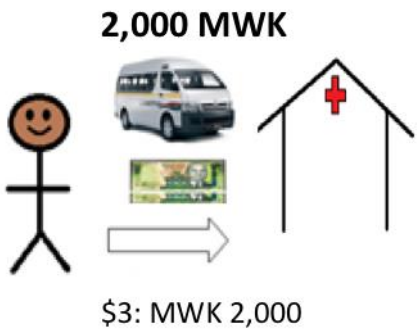
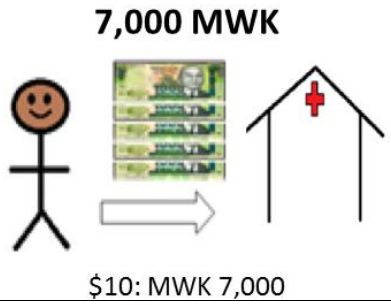
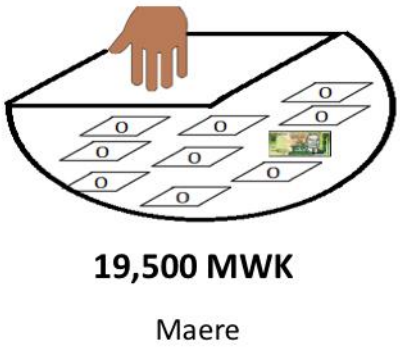
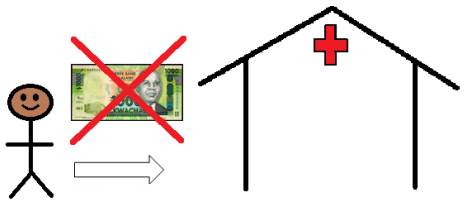
What do you think he would prefer to link to HIV prevention (VMMC)?

Do you think he would prefer standard HIV testing or HIV self-testing?

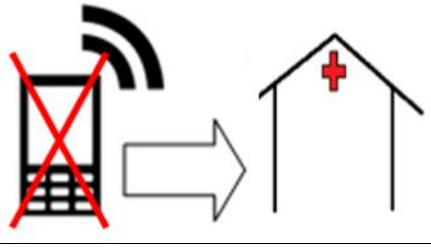
Attributes	Levels	Pictorial illustration
HIV testing	Standard HIV testing	
	HIV self-testing	

Do you think he would prefer financial incentive $3, financial incentives $10, entering a lottery for a chance to winning a financial incentive ($US 30) or no financial incentive?

Attributes	Levels	Pictorial illustration

Financial incentive	$3: MWK 2,000	
	$10 (MWK~7,000)	
	Lottery (US$ 30; MWK 19,500)	
	No incentive	

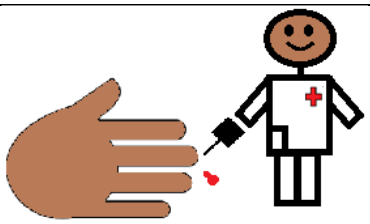
Do you think he would prefer receiving a phone call reminder or no phone call reminders?

Attributes	Levels	Pictorial illustration
Phone call reminder	Yes	
	No	

Now I would like to ask you what you think would motivate your partner to link to HIV treatment and care following an HIV-positive test.

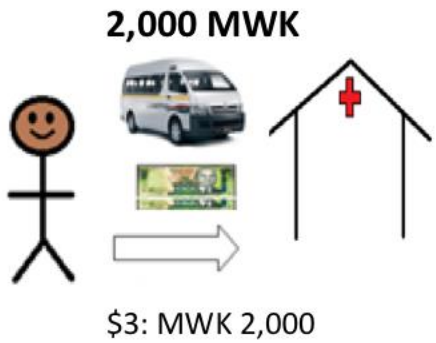
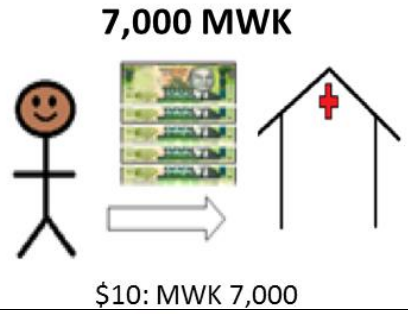
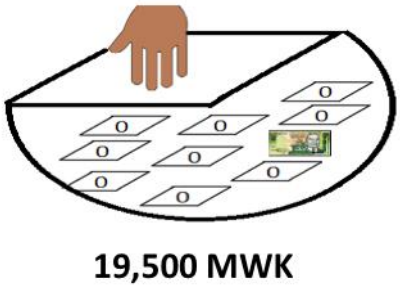
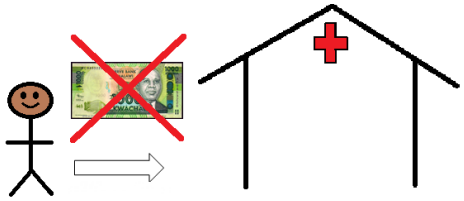
What do you think he would prefer to link to treatment and care?

Do you think he would prefer standard HIV testing or HIV self-testing?

Attributes	Levels	Pictorial illustration
HIV testing	Standard HIV testing	
	HIV self-testing	

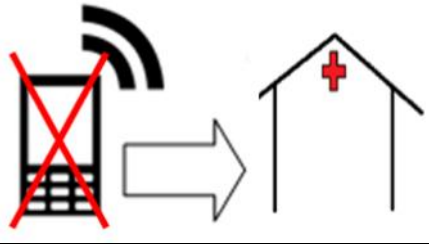
Do you think he would prefer financial incentive $3, financial incentives $10, entering a lottery for a chance to winning a financial incentive ($US 30) or no financial incentive?

Attributes	Levels	Pictorial illustration

Financial incentive	$3: MWK 2,000	
	$10 (MWK~7,000)	
	Lottery (US$ 30; MWK 19, 500)	
	No incentive	

Do you think he would prefer receiving a phone call reminder or no phone call reminders?

Attributes	Levels	Pictorial illustration
Phone call reminder	Yes	

	No	

Now we are ready. I will show you images with different combinations.

Please choose the one you think your male partner will prefer to link to VMMC.

At any point, if you think your partner would prefer neither option, select opt out.

Based on the arrangement of images on the tablet walk the participant through each question and image to see which they think their male partner would prefer.

Complete the linkage to prevention DCE

- *If participants **<u>does not</u>** opt out at any point, prompt the field worker to ask the question:*
    - *Do you think your male partner **<u>would link</u>** to prevention regardless of what he is offered (HIV self-test, standard test, phone call reminder, financial incentives)?*
        - *Yes*
        - *No (field worker enters comment from participant)*

- *If participants opts out of all possible options, prompt the field worker to ask the question:*
    - *Do you think your male partner **<u>would not link</u>** to prevention regardless of what he is offered (HIV self-test, standard test, phone call reminder, financial incentive)?*
        - *Yes*
        - *No (field worker enters comment from participant).*

Now I will show the same images with different combinations but ask you to choose one that you think your male partner would prefer to link to care.

At any point, if you think your partner would prefer neither option, select opt out.

Complete the linkage to care DCE

Based on the arrangement of images on the tablet walk the participant through each question and image to see which they think their male partner would prefer.

- *If participants **<u>does not</u>** opt out at any point, prompt the field worker to ask the question:*
    - *Do you think your male partner **<u>would link</u>** to care regardless of what he is offered (HIV self-test, standard test, phone call reminder, financial incentives)?*
        - *Yes*
        - *No (field worker enters comment from participant)*

- *If participants opts out of all possible options, prompt the field worker to ask the question:*
    - *Do you think your male partner **would not link** to care regardless of what he is offered (HIV self-test, standard test, phone call reminder, financial incentive)?*
        - *Yes*
        - *No (field worker enters comment from participant).*

Thank you very much for completing this questionnaire and for your time and effort in participating in these questions.

After the full DCE start the evaluation survey (completed by field interviewer)

We would like to hear your opinions on the interview process today. Remember there are no right or wrong answers. We are not here to judge you. All the deliberations of this discussion will be treated with our utmost confidence.

Your responses will be analysed by the researchers and will assist us to improve the interview process.

Any comments?

Pictures difficult to recognize?

Concepts not clear?

Do you have any comments about your interview that you would like to share with us?

Appendix 3. Overview of dissemination activities

Table 1: *List of dissemination activities*

Date(s)	**Description of dissemination activity**
March 2017	Invited to present at Bloomsbury School of Public Health Meeting, Mangochi Malawi. Shared briefing on thesis plan, preliminary results and self-testing policy development timeline.
April 2017	Roll-out of the WHO guidelines on HIV self-testing for sub-Saharan Africa and STAR workshop for country implementation. Was lead speaker on behalf of WHO on the guidelines and featuring systematic review results.
July 2017	Invited to lead HIV self-testing debate at the 9th HIV Paediatrics Conference, focused on access to young people.
March 2018	Selected for Georgia State University 40 under 40 for my contributions on HIV self-testing and work at WHO, including my PhD work
July 2018	Invited speaker to talk about HIV self-testing and reaching men at the AIDS 2018 conference and satellite session focused on male engagement with Jhpiego.
January 2020	Presented PhD work focused on self-testing scaled-up and reaching men at the Malawi-Liverpool Wellcome Trust HIV-TB seminar series
July 2022	Invited speaker at the AIDS 2022 conference to share the latest information and updates on self-testing and ‘What can be self-tested for now?’