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Community-based distribution of oral HIV self-testing kits

Experimental evidence from Zambia

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Community-based distribution of oral HIV self-testing kits: experimental evidence from Zambia

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Summary

Background

The HPTN071 (PopART) universal test and treat intervention has successfully provided HIV testing services (HTS) to a large proportion of individuals residing in PopART intervention communities. Nonetheless, HIV testing gaps remain, particularly among men who are often not home during household visits, and individuals who are reluctant to test. In an attempt to reach universal HTS coverage and encourage repeat testing to keep individuals' knowledge of their HIV status up-to-date, we piloted the door-to-door offer of a choice between counselor-provided finger-prick rapid HIV testing (finger-prick HIV testing) or oral HIV self-testing (HIVST) in the presence or absence of the counselor. We measured the impact of this pilot intervention on overall knowledge of current HIV status among community residents. Using qualitative methods, we explored contextual factors influencing decision-making among community members, key populations, mobile individuals and couples opting to perform, or not perform, HIVST. We further explored the possible and actual social impact of HIVST on household social relations and its impact on the role of lay counselors delivering HTS.

Methods

We conducted a cluster-randomized trial nested within four of the PopART intervention sites between January and May 2017. We randomly allocated 66 zones in four PopART intervention communities to the HIVST intervention (n=33) or PopART standard of care (n=33). In intervention zones, we trained existing lay counselors on how to offer and demonstrate the use of oral HIV self-tests to individuals aged 16 years or older. Once trained, lay counselors conducting door-to-door household visits offered those individuals eligible for HTS (individuals not self-reporting knowing their HIV-positive status) the choice of HIV testing using HIVST or HIV finger-prick testing. For individuals aged 18 years or older whose partner was absent during the household visit, lay counselors offered to leave an HIVST kit. The primary outcome was knowledge of current HIV status, defined as self-report of HIV-positive status or uptake of HTS. To collect qualitative data, we conducted a two-phase data collection approach using observations of household distribution, social mapping, individual interviews with those that accepted or rejected HIVST (n=40), and group discussions with neighborhood health committee members, lay counselors and men (n=91 participants). We conducted a prospective economic evaluation from the provider's perspective to calculate the incremental costs and incremental cost-effectiveness ratios of adding HIVST to a door-to-door HTS delivery model.

Results

Between 1 February and 30 April 2017, lay counselors enumerated 13,267 individuals in HIVST intervention zones and 13,706 in non-HIVST zones. Knowledge of current HIV status was 68.0% (n=9,027/13,267) in HIVST zones compared to 65.3% (n=8,952/13,706) in non-HIVST zones (adjusted odds ratio (adjOR): 1.30; 95% Confidence Interval (CI): 1.03-1.65; p=0.03). The effect of the intervention differed by sex. Among males, knowledge of current HIV status was 60.3% (n=3,843/6,368) in HIVST zones compared to 55.1% (n=3,571/6,486) in non-HIVST zones (adjOR: 1.31

95%CI: 1.07-1.60; p=0.009). There was little evidence of an effect among females (75.1% vs 74.5%, respectively; adjOR: 1.05 95%CI: 0.86-1.30; p=0.62). There was no evidence that the effect differed by age (p=0.44), but evidence that it differed by community (p=0.04).

Qualitative findings found that married working men and men whose livelihoods entailed mobility (both daily and seasonal) were considered appropriate populations for HIVST. Couple testing and greater privacy, ownership and control were enabled by HIVST. Other hard-to-reach groups who preferred and opted for HIVST included female sex workers. We found that community uptake of HIVST was influenced by differences in the presence and proportion of middle-class and key populations, livelihood related mobility, physical access, formal and informal economy, poverty levels, alcohol use and history of HIV initiatives. The correct management of kits was facilitated by demonstrations, supervision and pictures. HIVST was experienced as less painful and more hygienic than finger-prick HIV testing. However, the presence of HIV in oral fluids raised questions and doubts. Enacted stigma was avoided with HIVST by allowing testing in the privacy of houses. Internalized stigma remained unchallenged and present. Outcomes of HIVST were mostly favorable, with couple communication and individual knowledge of HIV status enhanced. However, there were a few occurrences of social harms, and lay workers delivering HTS played a key role in alleviating these. Post-test counseling was widely considered critical, especially when people tested HIV-positive and needed psychosocial support and assistance in linking to HIV treatment and care.

Conclusions

Household distribution of HIVST in communities exposed to door-to-door HIV testing increased knowledge of current HIV status, which was driven by an effect among men. Community-based secondary distribution of HIVST may be an effective strategy to reach men in other settings. Lay workers have a clear and vital role to play in adapting HIVST interventions to local contexts and to the safe introduction of HIVST at the household level, including linkage to counseling and care for clients who test HIV-positive.

Keywords: HIV self-testing, lay counselors, door-to-door HIV testing, men

Contents

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Abbreviations and acronyms

adjOR	Adjusted odds ratio
ART	Antiretroviral therapy
CAB	Community advisory board
CHiPs	Community HIV care providers (lay counselors trained and employed by the HPTN071 (PopART) study – each pair responsible for one zone of the community)
CI	Confidence interval
CRT	Cluster-randomized trial
EDC	Electronic data capture
FGD	Focus group discussion
GDP	Gross domestic product
ICER	Incremental cost-effectiveness ratio
IDI	In-depth interview
HIVST	HIV self-testing
HPTN	HIV prevention trials network
HTS	HIV testing services
IFU	Instructions for use
M&E	Monitoring and evaluation
NHC	Neighborhood health committee
PopART	Population effects of antiretroviral therapy to reduce HIV transmission
RDT	Rapid diagnostic test
STAR	Unitaid/PSI HIV Self-testing Africa project
STI	Sexually transmitted infection
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	Voluntary HIV testing and counseling
VMMC	Voluntary medical male circumcision
WHO	World Health Organization

1. Introduction

HIV testing is the gateway to entry into the HIV care continuum and supports access to HIV prevention services, including voluntary medical male circumcision (VMMC) (WHO 2012). Over the last decade, the availability of HIV testing services (HTS) has evolved from primarily facility-based to the widespread availability of community-based HTS, including home-based and mobile HTS (Baggaley et al. 2012; Suthar et al. 2013). As a consequence, the proportion of individuals testing for HIV has increased globally (WHO 2015). In Zambia alone, 80% of women and 64% of men reported ever testing for HIV in 2013/2014 compared to 39% and 12%, respectively, in 2007 (CSO 2009; CSO and ICF Interational 2014). However, in Zambia, as in other countries with a high burden of HIV, there remains a need for alternative strategies to provide HTS to individuals unaware of their HIV status and allow for repeat testing to keep knowledge of status up-to-date.

HIV self-testing (HIVST) is a novel strategy to increase and maintain knowledge of HIV status. HIVST is expected to reach individuals who do not access available HTS by providing increased autonomy regarding when and where to test, and greater confidentiality (Choko et al. 2011; Napierala Mavedzenge et al. 2013). HIVST may also provide a more acceptable option for annual repeat testing among individuals with a history of testing for HIV. Community-based distribution of HIVST kits has the potential to be a cost-effective strategy for delivering HTS (Brown et al. 2014; Cambiano et al. 2014; Johnson et al. 2014).

In Malawi, HIVST has been shown to be feasible, acceptable and the preferred choice for future repeat testing among individuals who report previously testing for HIV (Choko et al. 2011). The provision of HIVST through resident volunteer counselors allowed 77 per cent of community members to use an HIV self-test (Choko et al. 2014, 2015). By the end of two years, HIVST uptake was highest among individuals aged 16–19 years and males (Choko et al. 2014). Among couples, qualitative research found that HIVST encouraged partner testing and disclosure (Kumwenda et al. 2014; Masters et al. 2016). However, concerns remain regarding the potential for social harms, and the implications for post-test counseling and linkage to care (Makusha et al. 2015; Martínez Pérez et al. 2016).

To date, few studies have evaluated the impact of strategies to deliver HIVST. In particular, there is no evidence of whether the door-to-door offer of choice in HIV testing using an oral HIV self-test or lay counselor-administered finger-prick rapid HIV testing (finger-prick HIV testing) increases uptake of HTS relative to an offer of finger-prick HIV testing alone. Studies have shown that the door-to-door delivery of HTS by lay counselors is an effective strategy for reaching populations, and that men found at home are as likely to accept an offer of HTS as women (Sabapathy et al. 2012). The strategy removes numerous barriers to accessing facility-based services, including direct and opportunity costs of going to the health facility, stigma associated with being seen at a health facility and the perception that health facilities are female spaces (Sabapathy et al. 2012; Musheke et al. 2013; Suthar et al. 2013; Hensen et al. 2015). The door-to-door delivery of finger-prick HTS is, however, resource intensive. Providing the option to use an oral HIV self-test during household delivery of HTS may reach more individuals and reduce the resources required to provide door-to-door HTS.

HPTN071 (PopART) is a community-randomized trial of the impact on HIV incidence of a household-based combination HIV-prevention intervention that includes an annual door-to-door offer of point-of-care HTS by lay counselors and support for linkage to immediate treatment and prevention services (Hayes et al. 2014). Although progress has been made in reaching the first 90 of the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 targets, men remain harder to reach through household services, and sustaining coverage among young people has also proved challenging (UNAIDS 2014; Floyd et al. 2017; Hayes et al. 2017). We hypothesized that providing individuals with a choice of how to test for HIV – including the option to self-test with or without a counselor present – during annual household visits in this setting would access harder-to-reach populations with HTS, including men and younger adults.

In this study, we report the findings of a nested cluster-randomized trial (CRT) of community-based distribution of HIVST within four PopART intervention communities in Zambia. In the intervention arm of this trial, PopART lay counselors conducting door-to-door household visits offered individuals the option to perform an HIV test using an oral self-test or finger-prick testing. We estimated the impact of this pilot HIVST intervention on knowledge of HIV status among the general adult and adolescent population.

2. Background

2.1 Study context

Over the past decade, levels of HIV testing have increased markedly across Zambia (CSO 2009; CSO and ICF International). In 2007, 19% of women and 12% of men aged 15–49 years had tested and received the result of an HIV-test in the previous 12 months (CSO 2009); by 2013, these figures were 46% and 37%, respectively (2014). Across Zambia, HTS are predominantly health facility based. Between 2005 and 2008, the number of HIV voluntary testing and counseling (VCT) sites increased from 500 to 1,102 (MoH 2010). In 2006/2007, health facilities implemented provider-initiated HIV testing and counseling. By 2010, progress had been made in scaling-up the delivery of HTS through community settings, including through home- and mobile-based services (MoH 2010).

Despite this progress, in 2015/2016 an estimated 33% of individuals aged 15–59 living with HIV were unaware of their HIV-positive status (ICAP 2016). As in other sub-Saharan African countries, there remain inequities in access to HIV testing and treatment services, with adolescents underserved by available services and men less likely than women to have tested for HIV (UNAIDS 2016). Although a similar percentage (85%) of males and females aged 15–59 who knew their HIV-positive status were receiving treatment, 63% of men were aware of their HIV-positive status compared to 70% of women (ICAP 2016). Despite the availability of facility- and community-based HTS, numerous barriers to access remain, making available services unacceptable to certain sub-populations (MoCDMCH 2015). The uptake of couples testing is also low (Matovu et al. 2016), and individuals within a couple are often unaware of their partner's HIV status. Furthermore, research from Lusaka suggests that, rather than test for HIV, men often infer their status from their partner's HIV status (Musheke et al. 2013).

Effective strategies to increase the uptake of HTS in Zambia are critical to meeting the UNAIDS 90-90-90 targets and supporting the prevention of HIV transmission (UNAIDS 2014). Systematic reviews provide evidence of the acceptability of home-based HIV testing, high levels of uptake of a range of community-based HIV-testing modalities and the effectiveness of strategies to increase men's uptake of HTS (Sabapathy et al. 2012; Suthar et al. 2013; Hensen et al. 2014). Experience from HPTN071 (PopART), a community-randomized trial of universal testing and treatment in South Africa and Zambia, showed that despite door-to-door activities and a high level of consent to participate in the intervention (Hayes et al. 2017), in a second round of service delivery in Zambian communities randomized to the universal testing and immediate treatment arm (termed Arm A) 32 per cent of men and 11 per cent of women aged 18 and older were not contactable by lay counselors (Floyd et al. 2017). Among individuals contacted and participating in Round 2 of the PopART intervention, 64 per cent of men and 63 per cent of women accepted an offer of HTS (Floyd et al. 2017).

Qualitative research conducted in the HPTN071 trial communities prior to PopART implementation highlighted poverty, crime and alcohol abuse as their most salient features (Bond et al. 2016). These traits were considered to contribute to increased vulnerability to HIV-risky sexual behaviors and created barriers to accessing HIV services (Bond et al. 2016). Qualitative research has also shown that variability in characteristics of the PopART communities – including differences in social class, size of the informal economy and presence of HIV stakeholders – likely influence access to and uptake of HIV services and the PopART intervention (Bond et al. 2016).

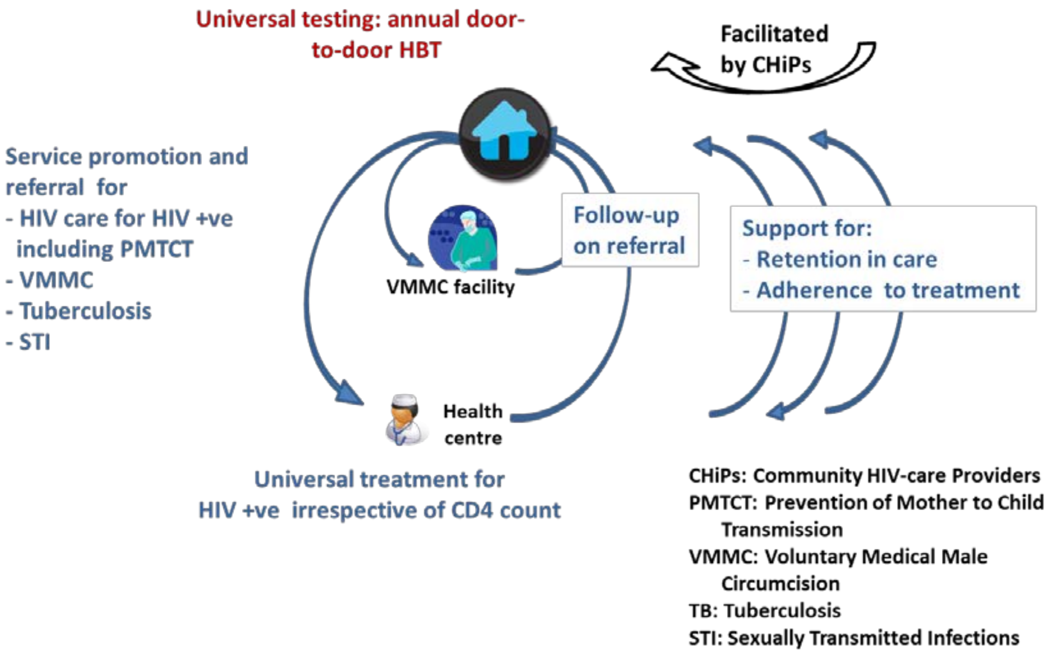
The offer of HIVST is a novel alternative for individuals not accessing currently available services, and may overcome some of the barriers to HTS experienced to date in PopART. The Zambian Ministry of Health aims to incorporate HIVST into their national HIV/AIDS program. Therefore, this study aimed to support in-country decision-making by providing evidence as to whether the door-to-door offer of oral HIVST or a lay counselor-administered HIV finger-prick test increased knowledge of current HIV status relative to an offer of HIV finger-prick testing alone.

3. Intervention overview, theory of change and research hypothesis

3.1 The PopART intervention

The PopART intervention is a household combination HIV-prevention package of interventions, which includes 'annual' rounds of home-based HTS delivery and linkages to prevention and care services (Figure 1) (Hayes et al. 2014; Shanaube et al. 2017). Lay counselors trained and licensed in HIV counseling and testing (including psychosocial and adherence counseling), called community HIV care providers (CHiPs), deliver the intervention to all household members living in intervention areas (Hayes et al. 2014). Within a community, CHiPs work in pairs in a zone (an area of roughly 500 households). Each CHiPs pair visits all households in their zone, asking household members for verbal informed consent to take part in the PopART intervention and permission to collect data on an electronic data capture (EDC) device. Consent to participate in PopART does not necessarily include consent to an HIV test (Shanaube et al. 2017). For individuals consenting to PopART, the intervention includes an offer of rapid finger-prick HIV testing services (HTS) for individuals not self-reporting knowing their HIV-positive status. Individuals who choose to have an HIV test are able to test alone, as a couple or as a household group (Shanaube et al. 2017). CHiPs refer individuals found to be HIV-positive to government clinics for linkage to HIV care and antiretroviral therapy (ART), irrespective of CD4 count, and provide ongoing support for adherence and retention in care. CHiPs provide information on HIV prevention, offer condoms, and screen individuals for symptoms of tuberculosis (TB) and sexually transmitted infections (STIs). CHiPs refer individuals symptomatic for TB and STIs to the clinic for further management. For uncircumcised HIV-negative men, CHiPs offer to make a referral to VMMC services. CHiPs return to households as necessary throughout the year to follow up on referrals and linkages to care, and offer HTS to household members who were initially absent or had previously declined (Shanaube et al. 2017).

Figure 1: Schematic of services offered through the PopART intervention



3.2 The HIVST intervention

In four communities randomized to receive the PopART intervention within the HPTN071 trial, we implemented a strategy to provide individuals with a choice of how to test for HIV. All communities were urban and situated in district towns. Three of the communities were in the Copperbelt, approximately 500 kilometers from Lusaka, and one was in Central Province, almost 200 kilometers from Lusaka. Within the four communities, we randomly allocated 66 CHiP zones to either the HIVST intervention or PopART standard of care (non-HIVST zones).

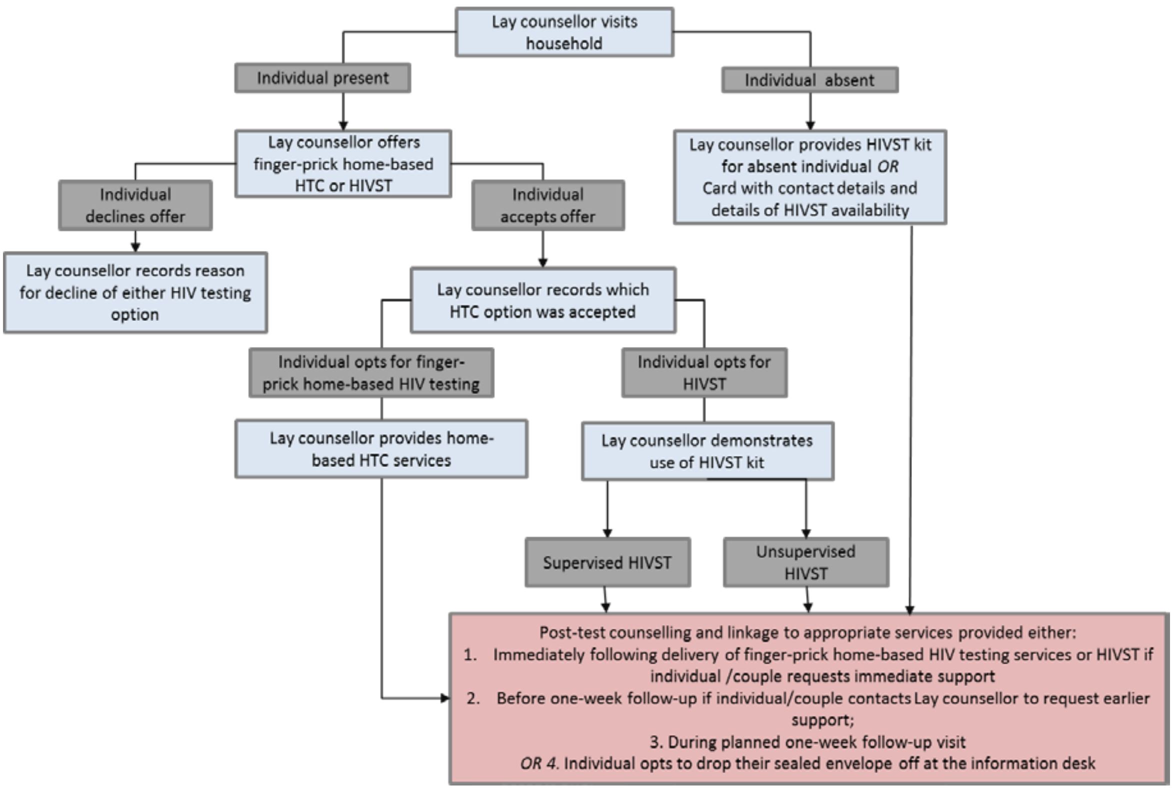
In zones randomized to the HIVST intervention, CHiPs provided individuals choosing to have an HIV test with a choice as to how to conduct this test (Figure 2). CHiPs provided information on the process of HIVST and the advantages and disadvantages relative to finger-prick HIV testing. For individuals opting to self-test, they also provided a demonstration of how to perform the test and read the results using a flipchart with step-by-step instructions, and appropriately translated manufacturer's instructions for use

(IFU) were included in the self-test kits. The level of supervision offered to an individual opting for HIVST was dependent on the individual's preference. If they opted to use the HIV self-test during the CHiP visit (supervised HIVST), the individual performed and read the HIV self-test result, but the CHiP was available to offer help if requested.

If the individual opted for HIVST after the CHiPs visit (unsupervised HIVST), CHiPs conducted a follow-up visit within seven days of leaving an HIVST with the individual. During this visit, CHiPs collected the HIV self-test, read the result (unless the individual did not want the CHiPs to read the result), provided post-test counseling and linked the individual to treatment and care or prevention services, per PopART standard of care. For individuals who did not disclose their HIV self-test result, CHiPs provided generic post-test counseling suitable for an HIV-positive or -negative result. CHiPs informed individuals opting to test in the absence of a CHiP that they could drop the kit off at the clinic in a sealed box at a PopART information desk, thus by-passing the CHiP entirely. Individuals opting for HIVST were given a self-completed results form (Appendix A) to allow them to record the result of the HIV self-test and report any challenges to using the test kit. This form was adapted from a form used in an ongoing CRT of HIVST distribution by community-based distributors in other communities in Zambia (HIV Self-testing Africa (STAR); http://hivstar.lshtm.ac.uk/).

For adults (aged 18 years or older) who reported having a partner that was absent at the time of the household visit, CHiPs offered to leave HIVST kits for secondary distribution. If an individual opted to take an HIVST for an absent partner, CHiPs performed a demonstration of the HIVST kit for the present individual and left a calling card with the CHiP's phone number to allow the absent individual to contact the CHiP. If requested, the CHiP left two HIVST kits with the present individual to facilitate couples testing.

Figure 2: Schematic of offer of HIV testing services by CHiPs (lay counselors)



HIVST is meant to be a screening test for HIV (2014). For individuals reporting a reactive HIVST, CHiPs recommended and offered confirmatory testing using parallel HIV testing with two different rapid diagnostic tests (RDTs) (Determine HIV-1/2™ and UniGold™). CHiPs counseled individuals with a (confirmed) HIV-positive diagnosis and advised them to attend the ART clinic. Once at the clinic, staff entered the individual into an existing database using a unique ID and enrolled the individual into care. For individuals not willing to link to care, CHiPs provided counseling on the value of treatment and care services. For males testing HIV-negative, CHiPs made a referral to VMMC services.

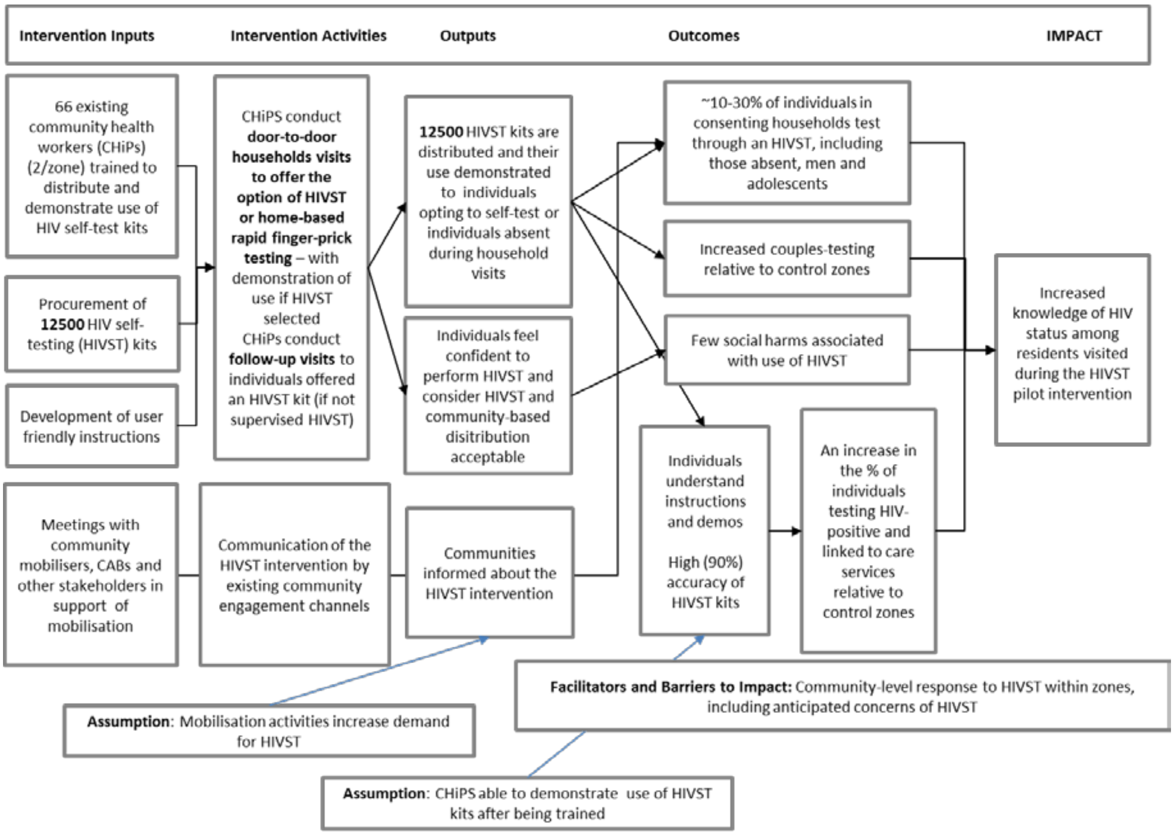
Community engagement played a key role in creating awareness, promoting HIVST services, and securing buy-in from intended beneficiaries. Community engagement built on the existing capacity established for the HPTN071 (PopART) trial, which selected community representatives to sit on representational structures, including community advisory boards (CABs) and district implementation management teams. CABs had representation from various groups, including traditional healers, churches, schools, police, and health-related committees. At the start of the HIVST intervention, community engagement informed the zones randomized to the intervention about the benefits of HIVST, explained the role of CHiPs in providing HIVST services, and provided information on how individuals can access HIVST kits as well as treatment and care or prevention services. The community engagement team ensured that HIVST was promoted within the concept of universal test and treat.

3.3 Study rationale, theory of change and hypothesis

We hypothesized that the door-to-door offer of a choice of how to test for HIV – which included the option to self-test – might encourage people who never previously tested to test for HIV and encourage repeat testing, thereby increasing knowledge of current HIV status. We expected the intervention to achieve this by removing some of the barriers to accessing HTS – such as the direct costs and opportunity costs of accessing facility-based services (Morin et al. 2006) – as well as the costs of accepting an offer of home-based HTS specifically, including perceived lack of confidentiality of HTS delivered by healthcare providers, lack of autonomy of available HTS services, unacceptable home-based visit times offered (particularly to men), and fear of finger-prick HIV testing.

For household members not contactable by the CHiPs, primarily men, we hypothesized that secondary distribution of HIVST would be more convenient to men, as they could then test at a time that suited them rather than need to be home or test at the time of the CHiP household visit. We also expected that HIVST might be more acceptable to adolescents and younger adults by providing greater confidentiality and making young people feel empowered to test themselves. We anticipated that the availability of HIVST would lead to increased participation in the PopART intervention, uptake of HTS and increased knowledge of current HIV status among the general adult and adolescent population (Figure 3).

Figure 3: Hypothesized pathway of how the intervention will increase knowledge of current HIV status



3.4 Primary and secondary outcomes

The primary outcome of the trial was the proportion of resident adolescents and adults (aged 16 years and older) who know their current HIV status. We defined knowledge of current HIV status as an individual self-reporting knowing their HIV-positive status or accepting an offer of HTS from a CHiP. We conducted sub-group analyses by sex, age (adolescents and young people aged 16–29 years, compared with older adults aged 30 years or older), community, and individuals whose HIV status was not known to the CHiP by the end of the second round of PopART service delivery. This included individuals known to be resident during Round 1 and Round 2 of the delivery of the PopART intervention, but who did not participate in either round of service delivery.

Secondary outcomes included a comparison across the two arms of the proportion of individuals:

1. Participating in the main PopART intervention (also among the sub-populations of interest), either because they consented with the CHiP or through secondary distribution of HIVST; and
2. Accepting an offer of HTS, among individuals whose HIV-positive status was not known to the CHiP (also among the sub-populations of interest).

In the intervention arm, we describe the distribution of HIV self-test kits, including the number of kits distributed by CHiPs, the number distributed to the intended user of the test kit, the number of individuals who tested with CHiP supervision and without supervision, and the number of kits returned to the CHiP or clinic (self-reported or observed by a CHiP).

We also assessed, through qualitative research:

1. The factors influencing individuals or groups who chose HIVST over the option of HIV testing using a finger-prick sample;
2. Whether there were any social harms associated with opting to use an HIVST kit;
3. The actual management of HIV self-test kits, including the handling, storage, interpretation, disposal and movement of the kit in households and zones; and
4. The impact of HIVST on the role of CHiPs.

We also measured the incremental cost-effectiveness ratio of adding HIVST to the PopART intervention.

4. Intervention implementation and timeframe

Between 8 and 14 January 2017, CHiPs in zones randomized to the pilot HIVST intervention were trained on how to offer HIVST during household visits; perform and read the results of an oral HIV self-test; identify, categorize and report possible social harms related to HIVST; and perform self-test kit quality assessment and control. On 18 January 2017, the 33 zones randomized to the HIVST pilot intervention started distribution of the HIVST kits. The study team decided a priori that the first two weeks of distribution would be considered a pre-implementation pilot to allow the CHiPs time to adjust to offering HIVST. Analysis of the primary outcome included households that were first visited, and members first enumerated, between 1 February and 30 April 2017.

We expected the HIVST intervention to start in October 2016, in line with the CHiPs' third annual round of household service delivery, as this intervention would form part of their routine PopART intervention delivery. Ethical and regulatory delays meant that we implemented the intervention later than anticipated and therefore had a shorter period of HIVST distribution. CHiPs initiated their third round of service delivery as planned in October 2016, but, prior to the implementation of the HIVST intervention, focused on supporting linkage to care for individuals who had tested HIV-positive in annual Round 2 and visiting new community residents.

5. Data and methods

5.1 Ethical approval

This study received ethical approvals from the University of Zambia Biomedical Research Ethics Committee and the London School of Hygiene & Tropical Medicine Ethics Committee.

Individuals participating in the PopART intervention provided verbal consent (Appendix D). For HIV testing, individuals aged 16 and above provided written consent using nationally accepted consent forms (Appendix E). Individuals collecting HIVST kits on behalf of their partner signed an agreement form stating that the test would only be used by their partner and not for any other purpose (Appendix F). We obtained written informed consent from all participants in qualitative interviews after we informed them about the study, drawing on information sheets written in either English or the local language (Ici Bemba) (Appendix G).

5.2 Quantitative data collection and analysis

This study was a two-arm CRT. Within each community, we restricted randomization on knowledge of HIV status and a decline of an HTS offer by all adults, males, females, younger and older community residents in previous PopART annual rounds. All adolescents and adults (aged 16 years or older) resident in the community were included in the study regardless of prior participation in PopART.

During household visits, CHiPs used their EDC device to enumerate households and collect data on uptake of services by individuals participating in the main PopART intervention. In the EDC, CHiPs recorded whether the individual opted for an HIVST, whether the individual opted for supervised or unsupervised HIVST, and whether an HIVST kit was provided for an absent individual and/or for couples performing HIV testing (Appendix B). During follow-up visits, CHiPs recorded whether the individual used the test, whether the test was read accurately, and the result of the HIVST.

We measured the primary outcome using the data collected by CHiPs on their EDC devices. Data from the EDC are populated into a CHiP database, which is used in the HPTN071 trial to collect process data (Hayes et al. 2017). Prior to the start of the study, we modified the EDCs to allow CHiPs to collect data specific to HIVST. For individuals absent during household visits, the devices collected data on whether the individual used an HIVST kit that was left for the absent individual. Other data collected on the EDCs included reasons for opting for an HIVST, whether the individual opted to test in the presence or absence of the CHiP, whether an absent individual used the HIVST kit left for them, and the result of an HIVST as read by the user and by the CHiP.

We calculated the primary outcome among individuals enumerated between 1 February and 30 April 2017, defined as the full intervention implementation period. To allow time for CHiPs to follow up with individuals enumerated during this period and choosing to self-test, we used follow-up data until 30 June 2017. Using data on follow-up visits conducted until 30 September 2017, we calculated the proportion of individuals with a reactive HIVST that were linked to confirmatory testing. Also using follow-up data through to 30 September 2017, we describe referral to HIV care among individuals newly diagnosed HIV-positive. Among individuals newly diagnosed HIV-positive and referred to care, we describe the proportion followed-up again post-referral. Based on information on those who received follow-up, we used the Kaplan-Meier method for time-to-event analysis to estimate the proportion of individuals linked to HIV care by three months after referral. Including in the denominator all individuals who were referred to care, and in the numerator all individuals who were followed-up by CHiPs post-referral and were recorded as having linked to care within three months of referral, we estimated a minimum estimate of the percentage of individuals who linked to care by three months after referral.

To evaluate the impact of the HIVST intervention, we adjusted for correlation of the outcomes among individuals who were resident in the same CHiP zone. As there were 33 clusters (zones) per arm, we analyzed data at the individual level, using population average logistic regression models to estimate overall knowledge of current HIV status in each trial arm, accounting for clustering by zone. We first describe the primary outcome in each trial arm. As this was a CRT with 33 clusters per trial arm, we expected there to be balance across the two trial arms with regard to factors likely to influence knowledge of HIV status. However, we present the effect estimate adjusted for age, sex and community, as these factors were expected to be strong potential confounders of knowledge of HIV status. We conducted sub-group analyses by sex, age group, community and whether individuals were previously resident in the communities. We investigated whether there was evidence for effect modification by these groups by including an interaction term between each variable and a variable for intervention group in the population average logistic regression models. We obtained corresponding p-values from a Wald test.

5.2.1 Randomization

On 9 December 2016, all PopART intervention staff including CHiPs, supervisors to CHiPs, HIVST nurses, information desk personnel, CAB members, and personnel from the community engagement team in the four HIVST communities were oriented about the study. The general orientation provided information on the study including objectives, methodology, and information on how to use oral HIVST kits. We also discussed possible social harms and plans for community engagement.

During this orientation, we conducted a public randomization ceremony in a two-stage process. CHiPs provided group verbal consent for randomization of their zones to the HIVST intervention or PopART standard of care. In the first stage, using a randomly selected list of 9,999 possible allocations, four individuals selected four numbered balls from a bag (Appendix C). This four-digit number corresponded to a number that allocated each zone to either group 0 or 1. In the second stage, the randomization determined whether group 0 or 1 would be allocated to the HIVST intervention.

5.2.2 Study power

The study had more than 90% power to show a 5–10% reduction in the percentage of adults who did not know their current HIV status in the HIVST arm compared with the non-HIVST arm, assuming the percentage who did not know their HIV status in the non-HIVST arm was 35–40% with a between-zone coefficient of variation k=0.15 and an average of approximately 400 adults enumerated per zone across the 33 zones per trial arm. The study had power of approximately 80% to show a 5–10% reduction in sub-group analysis for men and women, assuming the percentage who did not know their HIV status in non-HIVST arm was 30–45%.

5.3 Qualitative data collection and analysis

We divided qualitative data collection into two phases. Through both phases, qualitative methods were mixed (Appendix H) and included observations at clinics and with CHiPs (n=19), community spiral walks (n=4), in-depth interviews (IDIs; n=40), and focus group discussions (FGDs; n=11; Table 1 and Table 2). Our rationale for this methodological triangulation was to enhance validity by corroborating different descriptions of how community members responded to HIVST. We recruited two social scientists as research assistants.

We conducted Phase 1 within the first two months of the intervention. The aim of this phase was to observe and document the social and physical differences between zones and the actual delivery and management of the HIVST kits, including experiences of use and the impact of using HIVST on significant relationships (including between couples, adolescents and their parents/guardians, and between household members and CHiPs). We also conducted social mapping within group discussions with neighborhood health committee (NHC) members in all four communities. During discussions, participants mapped their respective communities, identifying the main physical features including any major differences between zones. In addition, we conducted a discussion around factors that could potentially influence the uptake of HIVST. After the mapping activity, we conducted a one-and-a-half-day spiral walk where research assistants walked around the communities and interacted with community members, inquiring about their views on HIVST while observing different physical features and socio-economic differences between zones.

In addition, the research assistants accompanied CHiPs in order to observe household visits and understand and document community response to HIVST and its impact on social relations. Research assistants also accompanied the CHiPs on follow-up visits if an HIVST kit had been left in a household for secondary distribution. Research assistants took field notes during and after each household visit, including a description of the particular household, the counseling approach, a description of behavior and interactions of CHiPs and household members. We conducted daily debriefings to crosscheck findings developing from these observations and discuss emerging themes. We fed these themes into the design and development of IDI and FGD guides.

We conducted Phase 2 in the second and third months of implementation. The aim of this phase was to explore acceptability and community experiences of home delivered HIVST, and the implications of HIVST on social relations and the role of the CHiPs. In this phase, we conducted semi-structured interviews with individuals accepting HIVST and individuals not choosing HIVST, as well as FGDs with CHiPs, men and NHC members (Table 1 and Table 2).

The period of observation, meetings, and discussions with the team implementing the HIVST intervention also helped structure the content of the interview and FGD guides. The main themes covered included acceptability, potential future usability, social harms, modes of distribution, impact of HIVST on social relations, role of CHiPs, impact of HIVST on CHiPs, and community response to HIVST. Research assistants conducted these discussions in English or Bemba at the clinic or convenient and relatively private locations chosen by the participants.

During interviews and FGDs, research assistants took notes and audio recorded the activity. Due to the brief nature of the study, we did not do verbatim transcription, but expanded on notes taken during the interviews and FGDs by listening to the recorded interviews and the translation of the IDIs and FGDs from Bemba into English. We conducted a thorough check of the accuracy of the write-ups against the audio recordings to ensure that what we wrote was an accurate representation of what was said by participants. We conducted this check by moving between listening to the audio recordings and checking the note summaries. We added the final documents to Atlas.ti version 7 for management and analysis.

Table 1: Number and characteristics of participants interviewed in the study

Category	Males	Females	Total
Participants choosing to HIVST			
Adults	5	7	**12**
Adolescents	3	5	**8**
Participants choosing not to HIVST			
Adults	0	4	**4**
Adolescents	1	2	**3**
Couples	2	2	**4**
Hard-to-reach populations			
Traders and other busy individuals	3	1	**4**
Formally employed	1	1	**2**
Sex workers	0	1	**1**
Man who has sex with men	1	0	**1**
Heavy alcohol user	1	0	**1**
Total	**17**	**23**	**40**

5.3.1 Selection of study population

We recruited participants using a purposive sampling strategy. This strategy enabled us to solicit a variety of perspectives from different categories of participants. It also allowed us to select a diverse sample of individuals from different age and gender groups as well as occupations, and enabled us to identify household members that fit the selection criteria (in other words, those that choose to self-test or opted not to self-test, mobile men traders or key populations, adult men and women, adolescents and middle-class individuals working in the formal sector). CHiPs were instrumental in the selection of participants, with some participants identified during the research assistants' observation of the CHiPs' delivery of the intervention.

For FGDs (Table 2), CHiPs in different HIVST zones were purposively selected to have a variety of views with regard to delivering HIVST to households across different zones (some of which have different socio-economic profiles). This in turn gave us a better feel of how the intervention was experienced in the whole community. We recruited men from the general population through the NHC and spiral walks, while the NHC chairperson recruited NHC members who participated in the mapping exercise.

Table 2: Number of FGDs and FGD participants by sex

Participants	Number of FGD	Males	Females	Total
NHC members	4	11	29	**40**
Men	3	19	0	**19**
CHiPs	4	12	20	**32**
Total	11	42	49	**91**

Data sources for social harms were reports on management and community engagement activities, and incidents recalled by CHiPs during debriefings with supervisors and FGDs. CHiPs were trained in how to identify and categorize social harms before the study commenced. Some likely social harms were presented as examples in the training. Monitoring and reporting of social harms heavily relied on existing PopART processes, which involved discussions between the CHiPs that identified an incident and the supervisors. The identification and categorization of harms was challenging, particularly in the first two months of the study, because these were rarely reported by community members and the CHiPs themselves were reporting this level of social relations for the first time. Consequently, community engagement activities were streamlined to include a strong focus on discussing and reporting social harms. CABs and community meetings specifically asked for any social-harm-related stories and communicated these to the CHiP supervisors for investigation. Supervisors were also encouraged to have periodic group discussions with CHiPs to provide support and facilitate cross-learning among CHiPs. HIVST participants were also encouraged to call research staff using the calling card that was left with them during distribution of the HIVST kits.

To better understand whether social harms are related to HIVST or HIV testing more generally, we are collecting data in a participatory manner to assess if similar incidents were occurring in non-HIVST zones. A presentation is made of examples of stories and CHiPs' experiences that were collected from other PopART communities and HIVST zones. CHiPs are then divided into groups (HIVST and non-HIVST zones) to reflect on their experiences. In plenary, the groups present and share their practical experiences. This research is ongoing and will be written up at a later date.

5.3.2 Qualitative data analysis

During a one-week data analysis workshop, the social science team discussed and planned data analysis. We developed the analysis plan and a codebook with corresponding code definitions using deductive and inductive approaches. The codebook closely corresponded to the topics covered in the interviews and FGDs. We entered a final list of codes and their descriptions into Atlas.ti version 7 after the workshop, and imported the final write-ups for observations, IDIs and FGDs into the software and indexed or coded the data. We completed coding and analysis concurrently. We used a thematic approach for coding and analysis, where all our data were coded using the codebook developed earlier in the analysis workshop. We then shared the coded data outputs from Atlas.ti amongst the social science team members. Each team member analyzed the data by carefully reading the quotations from the outputs and creating summaries, while taking note of the similarities and differences in the data from the different categories of participants.

5.4 Economic data collection and analysis

We conducted a prospective economic evaluation, from the provider's perspective, to comparatively calculate unit costs of HTS in the HIVST intervention and non-HIVST arm. We also calculated the incremental cost of delivering HTS in the HIVST arm.

5.4.1 Costing

We calculated full annual financial and economic costs incurred from study set-up through to 30 June 2017. Financial costs included all expenditures for resources used in both arms, while economic costs captured the full value of all the resources used to deliver HTS in both arms, including valuation of donated goods or services (Drummond et al. 2005).

Resource use data were sequentially and prospectively collected between 1 December 2016 and 30 June 2017. Costs were adjusted to 2017 United States dollars (USD) using an assumed exchange rate of 9.50 Zambia kwacha to the dollar. Data sources included financial records, CHiPs' monitoring and evaluation (M&E) records and interviews with the intervention team. Table 3 outlines key cost components of this analysis. This report presents only observed costs.

Table 3: Costs included in the pilot HIVST intervention

Component	Description
Intervention costs	These were additional costs of introducing HIVST into PopART. Costs of HIVST: procuring HIVST kits, including the actual cost of kits and transportation up to central level. Cost of supplies: including supplies that directly support implementation of the intervention (e.g. stationery, including teaching aid reproduction, and extra bags for the HIVST kits), and personnel costs for additional supervision.
Research costs	Included costs related to impact evaluation, social science and economic evaluation.
Community sensitization and mobilization	Costs of additional community engagement activities related to HIVST distribution including personnel, supplies, transportation and travel and capital costs (e.g. the cost of sensitization meetings with Ministry of Health at central, provincial and district levels and community sensitization meetings).
Quality assurance	Costs of specific quality assurance/quality control activities related to HIVST disaggregated by personnel, supplies, transportation and travel, and capital costs.
Project coordination	These generally included shared costs related to administrative and project coordination activities, including supervision and mentorship, mostly incurred at central office. Costs associated with technical support from central office (travel costs such as per diems, accommodation and transportation) including personnel costs.
Set-up costs	These are costs incurred before 1 February 2017 to set up the project.
Trainings	Costs of initial trainings; initial protocol training for field staff.
PopART community intervention costs	All costs related to PopART community intervention, including CHiPs costs, finger-prick HIV testing costs and supervision costs.
Cost of the intervention (HIVST) arm	Intervention costs plus PopART community intervention costs.
Cost of non-HIVST	PopART community intervention costs.

5.4.2 Costs of PopART community intervention

The HIVST intervention was nested within an existing door-to-door HTS delivery program. Thus, all capital (in other words, start-up and equipment) costs for the main

PopART intervention were excluded. Costs related to delivering the PopART intervention were calculated using ingredient-based (bottom-up) costing and top-down costing, where we apportioned costs stepwise to their respective cost centers (Beck et al. 2012). This was complemented by interviews with study teams to obtain allocation factors across activities and shared resources.

HIV-testing supplies and personnel were calculated using the ingredient-based approach. Costs were allocated as personnel, HIV testing, and general supplies. Personnel costs included CHiPs, mentoring, supervision and administration costs. The HIV-testing cost category covered costs of first- and second-line HIV RDTs, as well as direct HIV-testing supplies, whereas general supplies included costs of cleaning materials, travel costs (including per diems), mentoring and supervision, as well as stationery and office supplies. Direct personnel costs were fully allocated, whereas overhead personnel (mentoring, supervision and administration) and general supplies costs were apportioned by number of CHiPs. Costs for first- and second-line HIV RDTs supplies were calculated by multiplying the number of tests performed by the unit cost of performing a test. For this calculation, the unit cost of the two HIV RDTs included the costs of the HIV test kit (which comes with buffer and capillary tubes) and direct testing accessories (lancet, gloves, and alcohol swabs).

5.4.3 Costs of HIVST intervention

As with the PopART intervention, costs were calculated using ingredient-based (bottom-up) costing and top-down costing. Costs were allocated into the following input types: equipment, which included all capital items; HIVST kits, which included purchase and shipping costs; supplies costs, which included direct implementation supplies; transportation and travel costs, which included all costs related to travel and vehicle costs; administration, which included project coordination-related costs from implementing partners (Zambart and London School of Hygiene & Tropical Medicine); and personnel costs.

We also allocated costs by project activities: project administration, which included all costs related to setting up the trial (e.g. preparation of HIVST demonstration aids and training activities); central-level administrative activities by implementing partners; supervision and mentorship activities, which included field visits by study managers; and M&E activities, which are challenging to disentangle from evaluation costs, but we considered them as comprising the costs of outcome data collection and management. Other activities were community engagement, which included community sensitization and mobilization activities; quality assurance, which were the costs associated with quality assurance and control of HIVST kits; and field activities/service delivery, which consisted of field activities and HTS delivery activities by CHiPs.

Finally, costs were disaggregated into project components as research and intervention-related costs. Research activities were defined as all activities related to social science, impact evaluation and economic evaluation work (including ethics application costs), whereas intervention implementation activities included intervention delivery, community engagement, quality assurance and field work. Training, M&E and project administration were allocated between research and intervention implementation using allocation factors. Training costs were allocated by trained participants. A decision on how to allocate overhead costs was made with the help of project management, complemented by interviews with particular staff members on how they split their time between research and intervention (Table 4). Cost of HIVST kits was calculated by multiplying the number of kits used by the assumed landing cost of US$3, since the test kits were donated by the STAR project (http://hivstar.lshtm.ac.uk/). In cases of an HIVST positive result, parallel finger-prick HIV testing was performed, which involved performing first- and second-line finger-prick HIV tests concurrently. The cost of parallel finger-prick HIV tests was calculated by multiplying the number of HIVST positive results by the unit cost. The unit cost of parallel testing included the cost of one Determine kit, one UniGold kit, one pair of gloves, one lancet and one alcohol swab.

Costs related to activities before 1 February 2017 (the day on which full implementation of the study started) were considered start-up costs, and all costs from 1 February 2017 were considered implementation costs. All costs related to activities that happened prior to trial orientation and randomization (9 December 2016) were considered research costs. Start-up costs were not annualized because the intervention was observed for a short period.

Table 4: Allocation factors for shared/overhead costs

Cost line	Allocation factor	Research (%)	Intervention (%)
Training	Training attendance	25%	75%
Project administration	Assumed value	50%	50%
Principal investigator	Assumed value	50%	50%
Monitoring and evaluation personnel	Assumed value	50%	50%
Community engagement manager	Assumed value	50%	50%

5.4.4 Effectiveness calculation

In the effectiveness calculation, we extracted data from quantitative findings. For economic evaluation, the following outcome indicators were used: number of persons enumerated, number of persons tested, number of new testers (those who previously never tested with the CHiP) and number of persons newly diagnosed with HIV. For cost analysis, we considered outcomes for the period of 1 February to 30 April 2017 to match the costing period. In the cost-effectiveness analysis, we used the number of persons newly diagnosed with HIV as the primary outcome indicator. To calculate incremental effectiveness (outcome) of the intervention ($\mathbb{Q}$), we subtracted the number of newly diagnosed persons in the control arm (ℓ) from newly diagnosed persons in the intervention arm ($\mathcal{L}$).

$$\mathbb{Q} = \boldsymbol{\mathcal{L}} - \boldsymbol{\ell} \qquad (2)$$

5.4.5 Cost analysis

In our cost cost-effectiveness analysis, we only considered intervention-related costs. We calculated the total cost of implementing HTS activities, cost per person enumerated, cost per person tested, cost per new tester and costs per newly diagnosed persons for both arms. We also calculated total incremental cost in the intervention arm. Incremental cost (Ꞇ) is defined as the difference between the cost of the intervention (ȷ) and the control (ı) arms. In our case, Ꞇ= the cost of implementing HIVST interventions ($\hat{J}$) plus the cost of PopART interventions (í), and the cost of the control arm is the cost of implementing the PopART intervention (í).

C=j - ı

j=Ĵ + í

C=(Ĵ + í) - ı   (1)

In the cost-effectiveness analysis, we divided incremental cost by incremental effectiveness outcome to calculate the incremental cost-effectiveness ratio (ICER) of adding HIVST to PopART intervention delivery.

$$ICER = \frac{C\,(\mathbf{1})}{\mathbb{Q}\,(\mathbf{2})} \qquad (3)$$

6. Results

6.1 Social context of the four study communities

Results from Phase 1 of the qualitative research highlighted features common to the four communities, as well as those that varied across communities. This is presented in Appendix I, Table 1. Features common to all community sites included particular infrastructure, including at least one government health facility, police post(s), primary educational facilities, churches, recreational facilities such as football pitches and drinking places, market areas and transport depots. However, each community had features of difference (Bond et al. 2016). Initially, we wrote up detailed profiles of these four communities in 2013, before the PopART intervention was implemented, and have distributed these short and long narratives and community-specific matrices to the communities and local stakeholders (Bond et al. 2015). Building on this earlier research, key structural and social features of the communities were noted during observations carried out during spiral walks (February 2017) (These are summarized in Appendix I, Table 1). This thick description of the study sites could aid transferability of results to similar settings. Importantly, some of these features had positively or negatively influenced the delivery and acceptance of the HIVST intervention.

Housing in all four communities was mixed, and included informal, poorer-quality housing, formal planned housing, as well as a mix of size and construction. Houses of one type were grouped together and most houses were relatively small (1–3 rooms). However, Community 2 had more low-density modern houses on bigger plots compared to the other three communities, which had smaller houses on smaller plots, reflecting a higher concentration of middle-class individuals. Communities 3 and 4 were dominated by a lower socio-economic working class, although there were new settlers in Community 3 who were middle class. Community 1 was a mix of middle- and lower-income groups.

Road layout and quality varied across the four communities. Heavy rains during the HIVST intervention period were challenging in all communities, but particularly in Communities 3 and 4 and some zones in Community 1, due to varied terrain, paths and roads.

According to CHiPs, the middle class is more resistant to door-to-door interventions and therefore harder to reach using this approach. This resistance was partly a physical barrier imposed by the presence of walls, fences, hedges and dogs, and partly a social barrier emanating from status and a wish to maintain privacy. However, higher education levels within the middle class also provided opportunities to reach them in other ways, including HIVST and secondary distribution of HIVST, which would likely prove popular with this group.

In all sites, children and young adults dominated, and there was a core group of longer-term residents. Women and young girls were more often found in households, and young men were often seen out and about, frequently at transport depots or in bars and other recreational facilities. Community 1 had a plethora of drinking places. In Communities 3 and 4, men consuming alcohol in bars from early in the morning was also noted. Alcohol consumption was widely considered by many respondents to lead to sexual risks in all communities and young people were accused of being ‘careless’ in their sexual behavior. Bars were regarded both as deterrents to and opportunities for HIVST. On the one hand, it was felt these places and the groups within them should be targeted with HTS; on the other hand, approaching people who were drunk was regarded as ethically questionable.

Communities 3 and 4 were closer to the center of town and Community 2 was slightly farther away. Mobility was pronounced in all communities, with traders moving in and out, and Community 1 was particularly porous and chaotically mobile. Formal employment in Communities 3 and 4 was limited, and fishing and farming were key livelihood options in both communities. Communities 1 and 2 had a larger proportion of people employed by government and private companies, but most residents were involved in the informal economy. Many women worked in local markets. Mobility among men encouraged their partners to get HIVST kits for them so that they could test when they returned home. Many women believed that men could not test – not because they did not want to, but because they had no time. Mobility due to livelihood made secondary distribution a strategy that improved men’s access to testing and improved the likelihood of couples testing together.

HIV services at the local government health facility were considered too ‘open’ and exposed to ‘others’ in Communities 1 and 3. There are private clinics in Communities 1 and 4, and drug stores in Communities 2 and 3. Communities 3 and 4 had more community-based projects than Communities 1 and 2. A church in Community 1 preaches that HIV can be cured and that HIV is a demon that can be cast out by a pastor, hence there is no need for people to test and start antiretroviral therapy.

Drawing on an analysis of what differences alter the uptake of HIV services, we can identify what features helped or hindered the introduction of HIVST (Bond et al. 2016). Hence, the following factors increased community resistance to the introduction of HIVST: more middle-class residents, location closer to the town center, a larger-scale informal economy, more livelihood-linked mobility, fewer HIV stakeholders over time, and less commitment to community action. The reverse would facilitate the introduction of HIVST. However, some features that pose initial resistance would lend themselves to HIVST over time. For example, if HIVST could physically reach the middle class in their homes, the privacy it provides would accommodate their desire for confidentiality. When comparing these four communities, Community 1 emerged as likely to be the most resistant to new HIV initiatives such as HIVST, and Communities 3 and 4 were likely the most open to new initiatives; Community 2's relative distance from the center of town and stronger presence of a middle class make it a particularly promising setting for HIVST as a testing option in the longer term.

6.2 Process measures

To deliver the intervention as planned, we trained 66 existing CHiPs on the distribution of HIVST. Between 1 January and 30 June 2017, we procured 11,250 HIVST kits for distribution. Among the 9,020 individuals who were seen by the CHiPs and eligible for HIV testing, the CHiP database reported that 4,561 individuals used an HIVST. Among individuals opting to self-test for HIV, 81.7% (n=3,727) opted for supervised HIVST, 11.2% (n=511) performed an unsupervised HIVST in the absence of the CHiP, and 7.0% (n=323) used a secondary distribution HIVST in the absence of the CHiP (Table 10). Of these individuals, 25 per cent (n=81) were subsequently seen by the CHiP during a follow-up visit to the household, with confirmatory testing performed for individuals with a reactive HIVTS (Table 11). The majority (n=283; 87.6%) of individuals using a secondary distribution HIVST kit were men.

During the HIVST intervention, we conducted 168 community mobilization activities and reached an estimated 10,500 individuals (Table 5). Health talks (n=58) were conducted at the health facility to reach as many people as possible in a single activity. Other activities included door-to-door visits (n=55), stakeholder meetings (n=27) and community meetings (n=10).

Table 5: Community engagement activities conducted and number of people reached through these activities (n=168)

		Number of people reached			
		Males		Females	
Activity	**Number of Activities**	**Youth (16-29)**	**Adult**	**Youth (16-29)**	**Adult**
Health talk	58	1387	720	1928	1451
Stakeholder meeting	27	121	243	143	458
Adolescent CAB meeting	6	29	1	22	3
Adult CAB meeting	8	4	65	0	66
Meeting key populations	4	15	9	25	5
Door-to-door	55	753	869	899	1168
Community meetings	10	27	67	27	71

6.3 Household enumeration and participation in PopART

Between 1 February and 30 April 2017, CHiPs enumerated 13,267 individuals aged 16 years or older in the HIVST zones, compared to 13,706 in the non-HIVST zones (Figure 4 and Table 6). In the HIVST zones, 48.0% (n=6,368) of enumerated individuals were male (Figure 5) and 51.0% (n=6,769) were aged 16–29; in the non-HIVST zones, 47.3% (n=6,486) of individuals enumerated were male and 51.1% (n=7,002) were aged 16–29.

Table 6: Description of the participants enumerated in the HIVST and non-HIVST arms from 1 February to 30 April 2017

		HIVST arm (n, %)	Non-HIVST arm (n, %)
Total enumerated		**13,267**	**13,706**
Sex	Males	6,368 (48.0%)	6,486 (47.3%)
Age group	16-19	2,176 (16.4%)	2,190 (16.0%)
	20-24	2,653 (20.0%)	2,804 (20.5%)
	25-29	1,940 (14.6%)	2,008 (14.7%)
	30-34	1,651 (12.4%)	1,641 (12.0%)
	35-44	2,355 (17.8%)	2,345 (17.1%)
	45+	2,492 (18.9%)	2,718 (19.8%)
Absent during CHiP visit		2,782 (21.0%)	3,018 (22.0%)
Self-reported HIV+ (% of those present)		950 (9.2%)	1,152 (11.0%)
Eligible for HIV testing		9,340 (90.8%)	9,304 (89.0%)
Previously participated in PopART (in same CHiP zone)		8,093 (61.0%)	8,745 (63.8%)
Previously resident in PopART R1 or R2 (in same CHiP zone)		9,376 (70.7%)	9,946 (72.6%)

Among enumerated individuals, 75.1% (n=9,967) in the HIVST zones were initially seen by a CHiP and participated in the PopART intervention, 21.0% (n=2,782) were absent and 1.5% (n=195) refused to participate in PopART (Figure 4). In the non-HIVST zones, 76.3% (n=10,456) of individuals enumerated participated in PopART, 22.0% (n=3,018) were absent and 1.7% (n=232) refused to participate (Figure 4). Among absent individuals, 69.8 per cent (n=1,942) were male in the HIVST and 70.9 per cent (n=2,140) were male in the non-HIVST zones (Figure 5).

In HIVST zones, 90.5 per cent (n=9,020) of individuals seen by the CHiP and participating in PopART were eligible for an offer of HTS (Figure 4). In the non-HIVST zones, 89.0 per cent (n=9,304) were eligible for HTS. Among individuals eligible for an offer of HTS, 42.0 per cent (n=3,787) in the HIVST zones and 41.8 per cent (n=3,890) in non-HIVST zones were men. Over half of individuals eligible for HTS were aged 16–29 in the HIVST zones (n=5,262; 56.3%) and non-HIVST zones (n=5,329; 57.3%; Figure 4).

Figure 4: Flowchart of enumeration, participation in the study and uptake of HIV testing services (overall)

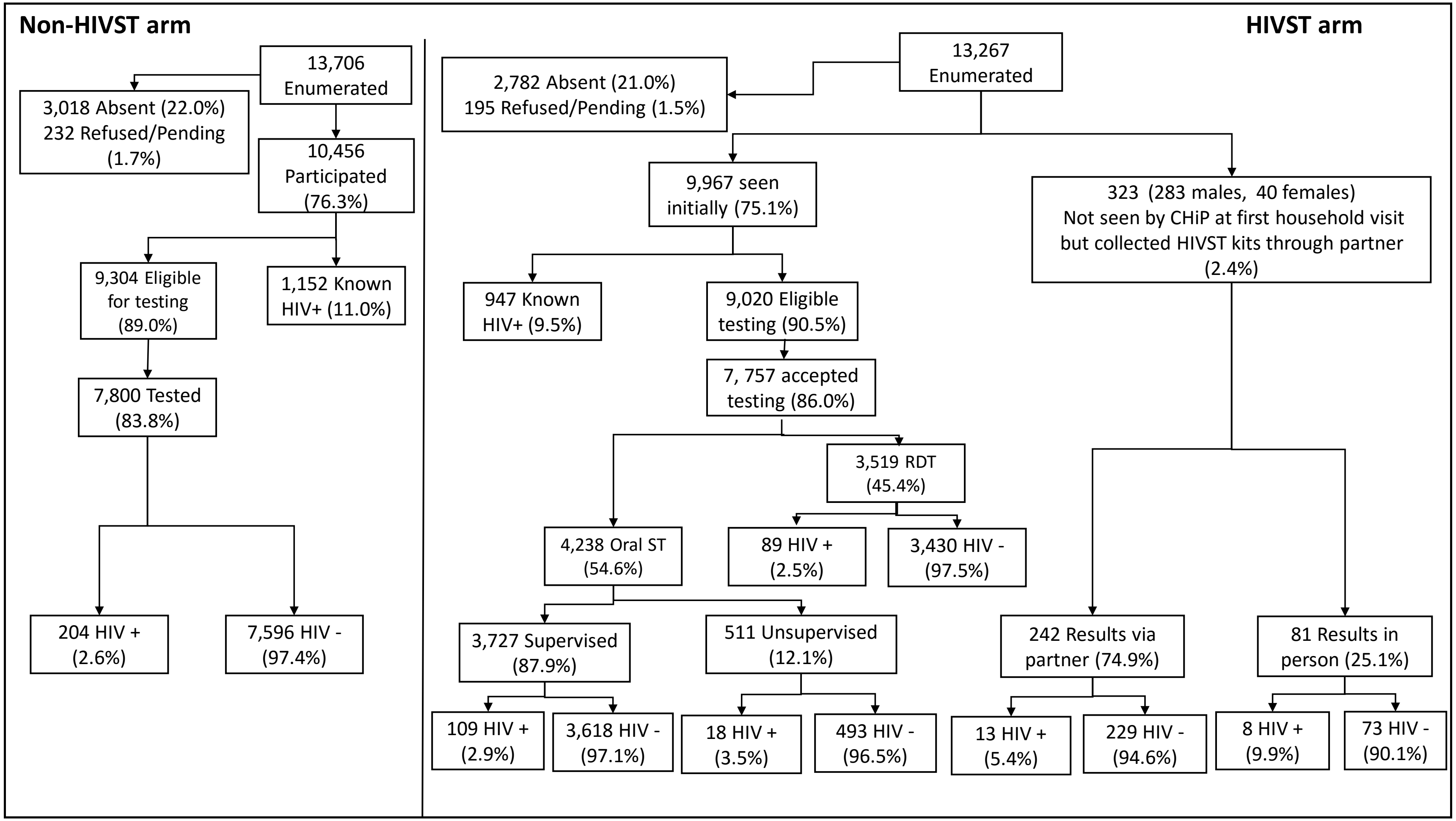


Figure 5: Flowchart of enumeration, participation in the study and uptake of HIV testing services among men

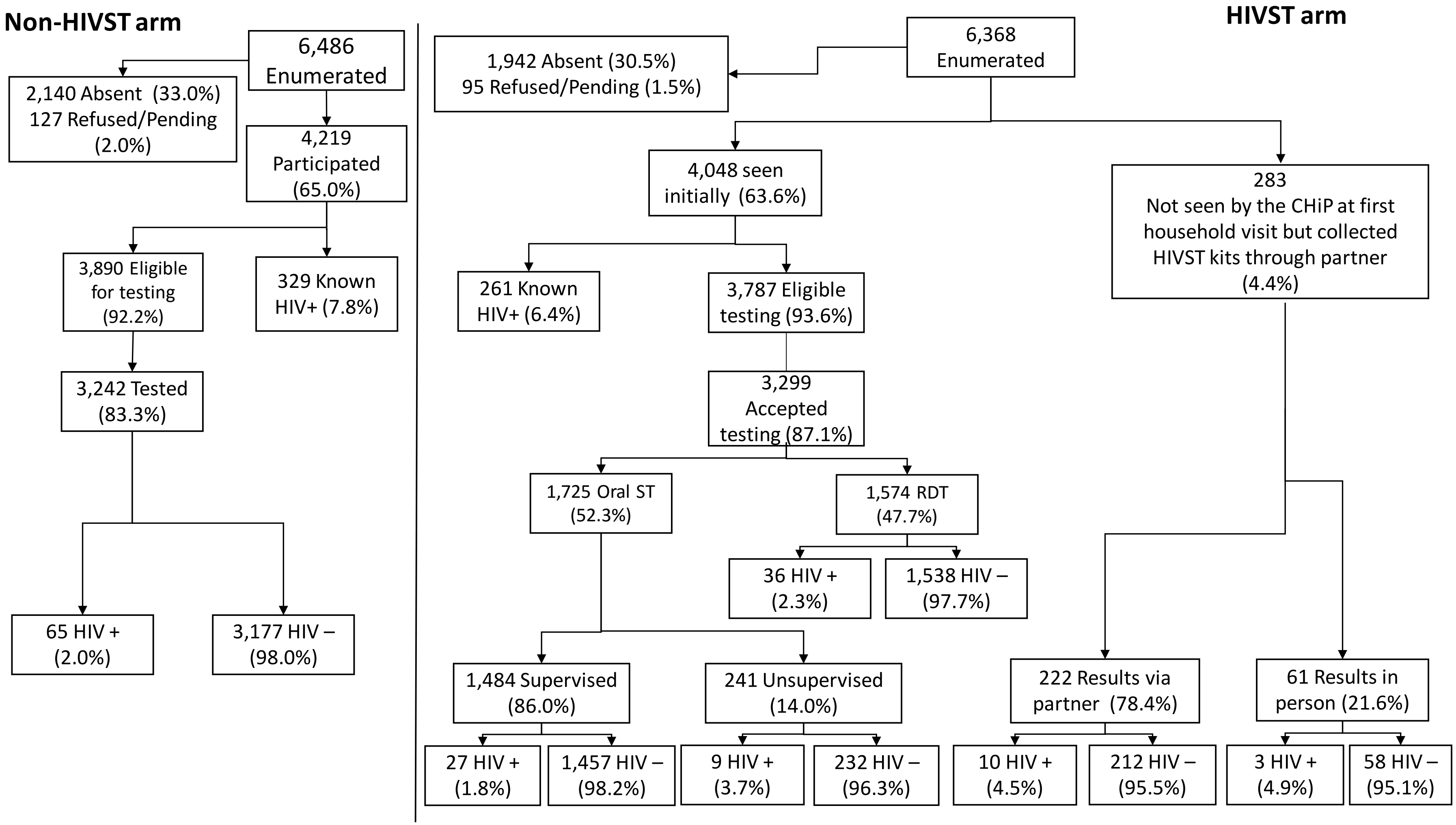
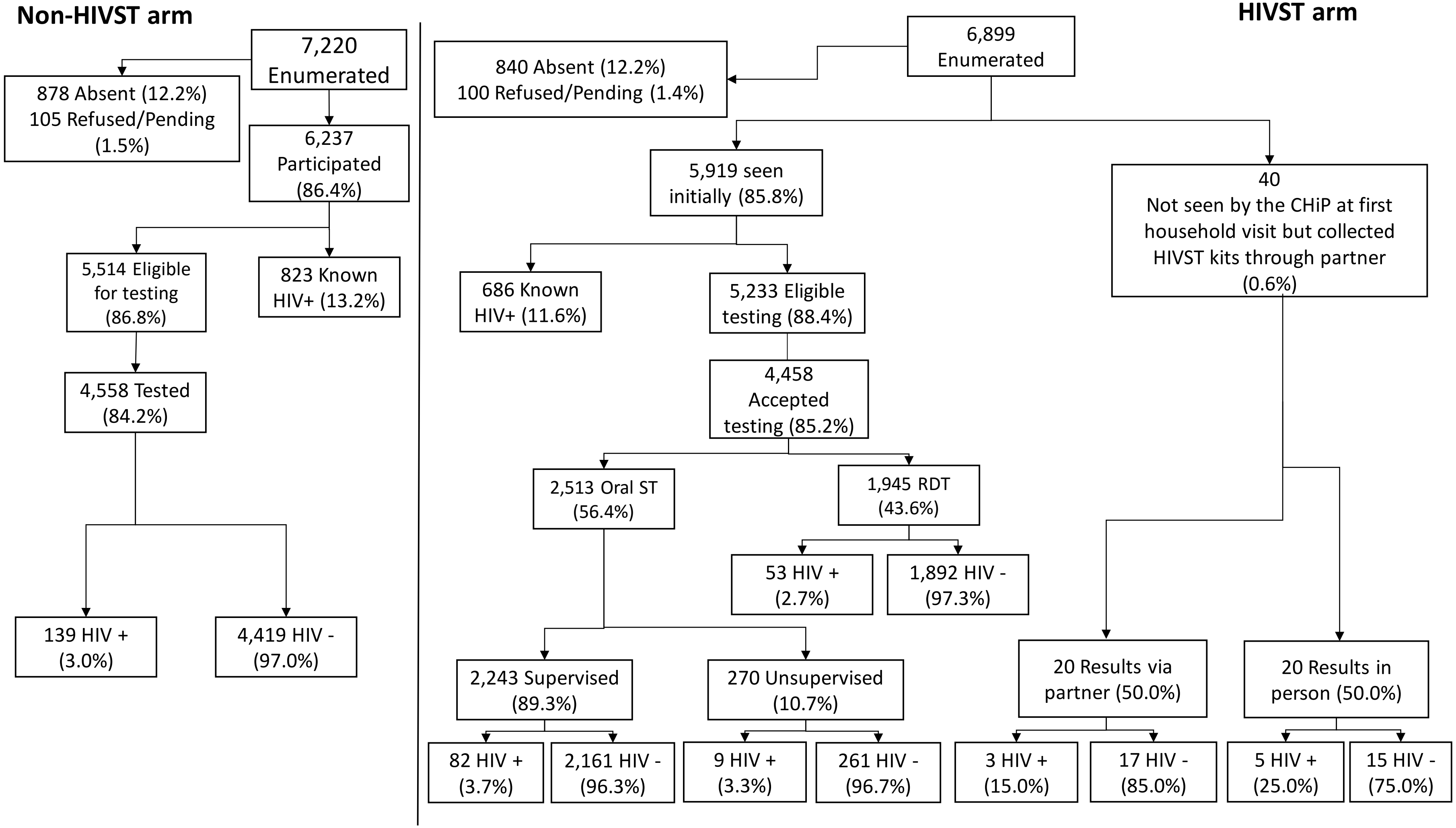


Figure 6: Flowchart of enumeration, participation in the study and uptake of HIV testing services among women



6.4 Effect of the HIVST intervention on the primary outcome

Overall, 68.0% (n=9,027/13,267) of individuals in the HIVST zones knew their current HIV status – this included 947 individuals who reported knowing their HIV-positive status, 4,238 who tested using supervised or unsupervised HIVST, 3,519 who tested through finger-prick HIV testing, and 323 who tested through secondary distribution HIVST – compared to 65.3% (n=8,952/13,706) in the non-HIVST zones (adjusted odds ratio (adjOR) 1.30; 95% confidence interval (95%CI) 1.03-1.65; p=0.03; Table 7 and Figure 4).

There was strong evidence that the effect of the HIVST intervention differed by sex (p-value for effect modification=0.01), with evidence for an effect among males but not females. Among males, 60.4% (n=3,843/6,368) in the HIVST zones knew their current HIV status compared to 55.1% (n=3,571/6,486) in the non-HIVST zones (adjOR 1.31; 95%CI 1.07-1.60; p=0.009). Among females in the HIVST zones, 75.1% (n=5,184/6,899) knew their current HIV status, with a similar level of knowledge in the non-HIVST zones (n=5,381/7,220; 74.5%; adjOR 1.05; 95%CI 0.86-1.30; p=0.62).

When accounting for age, the study found that 73.5% (n=4,972/6,769) of individuals aged 16–29 knew their current HIV status in HIVST zones compared to 70.2% (n=4,917/7,002) in the non-HIVST zones (adjOR=1.31 95%CI 1.05-1.63; p=0.02; Table 7). There was weak evidence of an effect among adults aged over 30: 62.4 per cent (n=4,055/6,498) knew their current HIV status in HIVST zones compared to 60.2 per cent (n=4,035/6,704) in the non-HIVST zones (p=0.07). There was little evidence that the effect of the intervention differed by age (p-value for effect modification by age group=0.44).

There was evidence of an effect among individuals resident in Round 1 and Round 2 of the annual delivery of the PopART intervention, but who did not participate or test for HIV in either round. In HIVST zones, 29.7 per cent (n=173/583) of these individuals knew their HIV status compared to 20.6 per cent (n=117/567) in non-HIVST zones (Table 7). The effect of the intervention on knowledge of current HIV status among other individuals who were not known to be HIV-positive by the end of the second round of PopART intervention delivery is presented in Appendix J, Table 2.

When assessing results by community, the largest effect on knowledge of current HIV status was observed in Community 2 (64.0% versus 49.6%). There was an intermediate effect in Communities 3 and 4, and no evidence of an effect in Community 1 (p-value for effect modification by community=0.04; Table 7).

Table 7: Effect of the HIVST intervention on the primary outcome: knowledge of current HIV status

	HIVST zone % (n/N)	Non-HIVST zones % (n/N)	Adjusted OR (95%CI)[1]	p-value
Overall	68.0 (9,02713,267)	65.3 (8,952/13,706)	1.30 (1.03, 1.65)	0.03
Males	60.4 (3,843/6,368)	55.1 (3,571/6,486)	1.31 (1.07, 1.60)	0.009
Females	75.1 (5,184/6,899)	74.5 (5,381/7,220)	1.05 (0.86, 1.30)	0.62
Young adults (16-29)	73.5 (4,972/6,769)	70.2 (4,917/7,002)	1.31 (1.05, 1.63)	0.02
Older adults (30+)	62.4 (4,055/6,498)	60.2 (4,035/6,704)	1.22 (0.98, 1.52)	0.07
Resident in R1 and R2, not participated in R1 or R2	29.7 (173/583)	20.6 (117/567)	1.76 (1.25,2.48)	0.001
Community 1	59.3 (2,203/3,716)	58.5 (2,221/3,795)	1.04 (0.81, 1.33)	0.75
Community 2	64.0 (1,083/1,693)	49.6 (809/1,631)	1.89 (1.36. 2.63)	<0.001
Community 3	65.6 (3,109/4,738)	64.2 (2,752/4,286)	1.23 (0.90, 1.69)	0.19
Community 4	84.4 (2,632/3,120)	79.4 (3,170/3,994)	1.59 (0.65, 3.91)	0.31
Key: HIVST – HIV self-testing; OR – Odds ratio; 95%CI – 95% Confidence intervals; R – PopART annual round; 1. Adjusted for sex, age, community & clustering by zones				

6.5 Effect of the intervention on secondary outcomes

There was weak evidence that participation in the main PopART intervention differed across study arms (Table 8). Among individuals enumerated by CHiPs, 77.6 per cent (n=10,290/13,267) in the HIVST zones participated in PopART, either through consent with the CHiP or secondary distribution of HIVST, compared to 76.3 per cent (n=10,456/13,706) in the non-HIVST zones (p=0.06).

Among females, 86.4 per cent consented to participate in PopART in the HIVST and non-HIVST zones (n=5,959 and n=6,237, respectively; p=1.0). There was weak evidence of an effect among men: 68.0% (n=4,331/6,368) participated in the HIVST zones compared to 65.1% (n=4,219/6,486) in non-HIVST zones (p=0.06; p-value for effect modification by sex=0.19). By age group, there was little evidence of an effect among younger adults. Among older adults, participation was 74.4 per cent (n=4,833/6,498) in the HIVST zones and 72.9 per cent (n=4,886/6,704) in non-HIVST zones (p=0.09; p-value for effect modification by age=0.68).

There was evidence of an effect among individuals resident during Rounds 1 and 2 of the PopART intervention, but who did not participate in either round. In HIVST zones, 36.4 per cent (n=212/583) participated in PopART Round 3 compared to 28.0 per cent (n=159/567) in non-HIVST zones (p=0.03; Table 8). The effect of the intervention on participation in PopART among other individuals who were not known by CHiPs to be HIV-positive by the end of the Round 2 of PopART intervention delivery is presented in Appendix J.

As with knowledge of current HIV status, there was a suggestion that the effect of the HIVST intervention on participation in PopART differed by community, though there was little statistical evidence of effect modification (p=0.38). The largest effects were seen in Communities 2 and 4, with less of an effect in Communities 1 and 3 (Table 8). In Community 4, a higher number of individuals were enumerated in the non-HIVST zones, suggesting that it took CHiPs longer to enumerate and gain consent from households in the HIVST zones; this is reflected in the higher rate of consent to participate in the HIVST zones.

Table 8: Effect of the HIVST intervention on participation in the PopART intervention

	HIVST zone % (n/N)	Non-HIVST zones % (n/N)	Adjusted OR (95%CI)	p-value
Overall	77.6 (10,290/13,267)	76.3 (10,456/13,706)	1.40 (0.98, 1.99)	0.06
Males	68.0 (4,331/6,368)	65.1 (4,219/6,486)	1.27 (0.99, 1.63)	0.06
Females	86.4 (5,959/6,899)	86.4 (6,237/7,220)	1.00 (0.77, 1.30)	1.00
Young adults (16-29)	80.6 (5,457/6,769)	79.6 (5,570/7,002)	1.21 (0.93, 1.58)	0.16
Older adults (30+)	74.4 (4,833/6,498)	72.9 (4,886/6,704)	1.35 (0.95, 1.91)	0.09
Resident in R1 and R2, not participated in R1 or R2	36.4 (212/583)	28.0 (159/567)	1.56 (1.04,2.33)	0.03
Community 1	71.8 (2,667/3,716)	70.8 (2,688/3,795)	1.17 (0.84, 1.63)	0.35
Community 2	75.2 (1,273/1,693)	68.3 (1,114/1,631)	1.76 (1.22, 2.53)	0.002
Community 3	73.5 (3,481/4,738)	74.7 (3,202/4,286)	1.23 (0.72, 2.09)	0.45
Community 4	92.0 (2,869/3,120)	86.4 (3,452/3,994)	1.97 (0.49, 7.82)	0.34
Key: HIVST – HIV self-testing; OR – Odds ratio; 95%CI – 95% Confidence intervals; R – PopART annual round; 1. Adjusted for sex, age, community & clustering by zones				

Overall, among individuals who were seen and participated in the PopART intervention, uptake of HTS was similar across the HIVST and non-HIVST zones (86.5% versus 83.8%; p=0.32**;** Table 9). As with knowledge of current HIV status, there was evidence of an effect among males (Table 9), but uptake of HTS was similar among women across the HIVST and non-HIVST zones (85.3% versus 84.2%, respectively; p-value for effect modification by sex=0.004).

When accounting for age, there was evidence of an effect among younger adults aged 16–29 (90.8% versus 87.8%, respectively; adjOR=1.41; 95%CI 1.07-1.85; p=0.01) and weaker evidence of an effect among older adults (80.9% versus 78.6%; p=0.22). However, there was no evidence that the effect of the intervention differed by age (p-value for effect modification by age=0.44).

In HIVST zones, a higher proportion of individuals participating in PopART who had not participated in either Rounds 1 or 2 – despite being community residents during previous rounds of PopART service delivery – accepted an offer of HTS in HIVST zones relative to those in non-HIVST zones (80.9% versus 72.2%, respectively). There was, however, no statistical evidence for an effect on acceptance of an offer of HTS among these individuals, but with a wide confidence interval (adjOR=1.27 95%CI 0.61-2.62; p=0.52). The effect of the intervention on HTS uptake among other individuals who were not known by the CHiP to be HIV-positive at the end of the second round of the PopART intervention delivery is presented in Appendix J, Table 3. The effect by community was similar to that seen for the primary outcome and participation in PopART (p-value for effect modification by community=0.11; Table 9).

Table 9: Effect of the HIVST intervention on acceptance of an offer of HIV testing services (among individuals who participated in the PopART intervention and were not known to be HIV-positive by CHiP)

	HIVST zone % (n/N)	Non-HIVST zones % (n/N)	Adjusted OR (95%CI)	p-value
Overall	86.5 (8,077/9,340)	83.8 (7,800/9,304)	1.14 (0.88, 1.46)	0.32
Males	88.0 (3,581/4,069)	83.3 (3,242/3,890)	1.42 (1.10, 1.85)	0.008
Females	85.3 (4,496/5,271)	84.2 (4,558/5,414)	1.05 (0.82, 1.35)	0.68
Young adults (16-29)	90.8 (4,777/5,262)	87.8 (4,676/5,329)	1.41 (1.07, 1.85)	0.01
Older adults (30+)	80.9 (3,300/4,078)	78.6 (3,124/3,975)	1.16 (0.91, 1.48)	0.22
Resident in R1 and R2, not participated in R1 or R2	80.9 (165/204)	72.2 (109/151)	1.27 (0.61, 2.62)	0.52
Community 1	81.1 (1,990/2,454)	81.0 (1,987/2,454)	1.03 (0.68, 1.57)	0.88
Community 2	84.1 (1,001/1,191)	70.8 (738/1,043)	1.86 (1.07, 3.25)	0.03
Community 3	88.3 (2,798/3,170)	84.4 (2,428/2,878)	1.18 (0.76, 1.83)	0.46
Community 4	90.6 (2,288/2,525)	90.4 (2,647/2,929)	0.63 (0.31, 1.29)	0.20
Key: HIVST – HIV self-testing; OR – Odds ratio; 95%CI – 95% Confidence intervals; R – PopART annual round; 1. Adjusted for sex, age, community & clustering by zones				

6.6 Choice of HIVST in HIVST zones

Overall, a similar proportion of individuals, regardless of age, opted for HIVST (Table 10). However, the type of HIVST that individuals chose differed by age and sex. Among females, the proportion that opted for supervised, unsupervised and secondary distribution HIVST was similar across all age groups: nearly 88% opted for supervised HIVST, 11% opted for unsupervised and 2% opted for HIVST through secondary distribution.

In contrast with these findings, men's preferences for HIVST differed by age group: 10 per cent (n=114/1161) of men aged 16–29 opted for unsupervised HIVST compared to 15 per cent (n=127/847) of men aged 30 or above (Table 10). Among men aged 30 or above, 23.4 per cent (n=198/847) were tested through secondary distribution compared to 7.3 per cent (n=85/1161) of those aged 16–29. Overall, 40 per cent of men aged 30 or above undertook either unsupervised or secondary distribution HIVST.

Table 10: Type of HIV testing chosen by individuals accepting HIV testing in HIVST zones

	HIVST				HIV finger-prick testing % (n/N)	Overall % (n/N)
	Supervised % (n/N)	Unsupervised % (n/N)	Secondary distribution % (n/N)	Overall % (n/N)		
Overall	81.7 (3,727/4,561)	11.2 (511/4,561)	7.1 (323/4,561)	56.4 (4,561/8080)	43.6 (3,519/8,080)	86.5 (8,080/9,343)
Overall 16-29	85.8 (2,327/2,712)	10.2 (277/2,712)	4.0 (108/2,712)	56.8 (2,712/4,777)	43.2 (2,065/4,777)	90.8 (4,777/5,262)
Overall 30+	75.7 (1,400/1,849)	12.7 (234/1,849)	11.6 (215/1,849)	56.0 (1,849/3,303)	44.0 (1,454/3,303)	80.9 (3,303/4,081)
Male	73.9 (1,484/2,008)	12.0 (241/2,008)	14.1 (283/2,008)	56.1 (2,008/3,582)	43.9 (1,574/3,582)	88.0 (3,582/4,070)
Male 16-29	82.9 (962/1,161)	9.8 (114/1,161)	7.3 (85/1,161)	56.3 (1,161/2,063)	43.7 (902/2,063)	91.6 (2,063/2,253)
Male 30+	61.6 (522/847)	15.0 (127/847)	23.4 (198/847)	55.8 (847/1,519)	44.2 (672/1,519)	81.2 (1,519/1,871)
Female	87.9 (2,243/2,553)	10.6 (270/2,553)	1.6 (40/2,553)	56.8 (2,553/4,498)	43.2 (1,945/4,498)	85.3 (4,498/5,273)
Female 16-29	88.0 (1,365/1,551)	10.5 (163/1,551)	1.5 (23/1,551)	57.1 (1,551/2,714)	42.9 (1,163/2,714)	90.2 (2,714/3,009)
Female 30+	87.6 (878/1,002)	10.7 (107/1,002)	1.7 (17/1,002)	56.2 (1,002/1,784)	43.8 (782/1,784)	78.8 (1,784/2,264)

6.7 Linkage to confirmatory HIV testing in HIVST zones

Overall, 242 individuals had a reactive HIV-test, after either first testing with a finger-prick HIV test or HIVST (Table 11). These included three individuals who initially opted for supervised HIVST and tested HIV-negative, but then chose to also have finger-prick HIV testing and tested HIV-positive; and two individuals who received an HIVST through secondary distribution and tested HIV-negative, but had a reactive HIVST when subsequently seen by the CHiP.

Among these 242 individuals, 83.1 per cent (n=201/242) either first tested with finger-prick HIV testing (n=89) or they linked to confirmatory testing after an HIV-positive result with HIVST (n=112); 98.5 per cent (198/201) were confirmed HIV-positive.

Among the 109 individuals with a reactive supervised HIVST, one individual was later found to have tested HIV-positive in PopART Round 1 and to have confirmed their HIV-positive status in Round 2 but then not disclosed this initially in Round 3. On further follow-up, one individual was found to have already been on ART at the time of HIVST.

Among the remaining 107 individuals with a reactive supervised HIVST and eligible for confirmatory testing, 82.2% (n=88/107) were linked to confirmatory testing, and 79.4% (n=85/107) were confirmed HIV-positive (n=85/88; 96.6% among individuals linked to confirmatory testing).

Among the 18 individuals with a reactive unsupervised HIVST, one individual was later found to be on ART. Among the remaining 17 individuals, 94.1 per cent (n=16/17) were linked to confirmatory testing and confirmed HIV-positive.

Where HIVST was provided through secondary distribution, none of the 13 individuals whose partner reported that their HIVST was reactive were linked to confirmatory testing with the CHiPs, and it is unknown whether they sought confirmatory testing at the health facility or elsewhere.

Among the eight individuals with a reactive secondary distribution HIVST that were later seen by the CHiP, three later underwent supervised HIVST (n=2) or unsupervised HIVST (n=1) and tested HIV-negative, and they did not subsequently test with finger-prick HIV testing. Two individuals reported knowing their HIV-positive status once they saw the CHiP and this was confirmed from PopART Round 2 data. The remaining three individuals were linked to confirmatory testing and were confirmed HIV-positive.

The two individuals who self-tested HIV-negative, but later met the CHiP and had an HIV-positive test result, first chose to do an unsupervised HIVST and the result was HIV-positive. Both were then linked to confirmatory testing with HIV finger-prick testing and were confirmed HIV-positive.

Overall, 76.4 per cent (n=107/140) of individuals with a reactive HIVST and eligible for confirmatory testing were linked to confirmatory HIV testing.

Table 11: Linkage to and results of confirmatory testing among individuals with an initial reactive HIV test or opting for further HIV testing after a negative test in HIVST zones

	Total	Confirmed HIV-negative (n, row %)	Confirmed HIV-positive (n, row %)	No confirmatory testing among those eligible (n, row %)	Not eligible for confirmatory HTS – HIV-positive in previous PopART round(s) or HIV-negative (n, row %)
HIV+ with HIV finger-prick testing RDT	89	0 (0.00)	89 (100.0)	0 (0.00)	0 (0.00)
Reactive supervised HIVST	109	3 (2.8)	85 (78.0)	19 (17.4)	2 (1.8)
Reactive unsupervised HIVST	18	0 (0.00)	16 (94.1)	1 (5.6)	1 (5.6)
Secondary distribution reactive HIVST (results via partner)	13	0 (0.00)	0 (0.0)	13 (100.0)	0 (0.0)
Secondary distribution reactive HIVST (results in person)	8	0 (0.00)	3 (37.5)	0 (0.00)	5 (62.5)*
Individuals opting for further HIV testing after an initial HIV-negative result					
HIV-negative supervised HIVST	3	0 (0.00)	3 (100.0)	0 (0.0)	0 (0.0)
Secondary distribution HIV-negative HIVST	2	0 (0.00)	2 (100.0)	0 (0.0)	0 (0.0)
	242	**3 (1.2)**	**198 (81.8)**	**36 (14.9)**	**5 (2.1)**

*Three individuals who reported a reactive secondary distribution HIVST and later did (un)supervised HIVST, tested HIV-negative and did not need confirmatory HIV testing

6.8 Linkage to HIV care in HIVST and non-HIVST zones

As of 30 September 2017, 228 individuals were newly diagnosed HIV-positive in HIVST zones, including 13 individuals who undertook HIVST via secondary distribution and whom the CHiPs had not been able to contact in person. Among the 215 individuals contacted in person by the CHiPs, 93 per cent (n=200/215) were referred to HIV care; among these, 8 per cent (n=16/200) did not have confirmatory testing and, as of 30 September 2017, CHiPs had not been able to contact any of these 16 individuals again post-referral. In non-HIVST zones, 204 individuals were newly diagnosed HIV-positive, and 97.6 per cent (n=199/204) were referred to HIV care.

Among those referred to care, in HIVST zones, 62.5 per cent (n=125/200) were followed up with at least once after referral to HIV care, and in non-HIVST zones it was 64.8 per cent (n=129/199). The Kaplan-Meier method for time-to-event analysis estimated that, in HIVST zones, 64.8% had linked to HIV care by three months after referral, compared with 63.8% in non-HIVST zones (hazard ratio comparing HIVST with non-HIVST zones 1.11, 95%CI 0.78, 1.58), with no statistical evidence of a difference between those referred from HIVST and non-HIVST zones. The minimum estimate of the percentage of individuals who linked to care by three months after referral was 41 per cent (n=82/200) in HIVST zones and 41.2 per cent (n=82/199) in non-HIVST zones.

6.9 Qualitative results

6.9.1 Factors influencing a decision to perform HIVST (Objective 1)

The main social factors driving the decision to perform HIVST were: having previously tested HIV-negative; being busy; being mobile; being a married working man; belonging to a more marginalized or higher-status group; convenience, control and ownership; greater privacy and confidentiality; reduced contact with the health facility and health providers; and reduced possibilities for stigma. Counseling was still considered important for those who chose to self-test, particularly if someone tested HIV-positive. Popular options for counseling were being counseled by ‘strangers’ and ‘professionals’ face-to-face or by telephone.

The history of exposure to HIV testing in these communities enhanced the uptake of HIVST. Doing an HIVST as a re-tester was different to testing for the first time. For example, one older widow had tested HIV-negative three times previously with the CHiPs. She opted to try HIVST, openly discussing sexual risks she had taken since she last tested with the CHiP. She was nervous waiting for her results and was visibly relieved when she had an HIV-negative result.

The convenience and control over testing space and time that HIVST provided were appreciated. A degree of empowerment arose from knowing how to conduct a test and read the result. Ownership of the result was also usually enhanced through HIVST. Respondents mentioned privacy and confidentiality as benefits of HIVST. Being able to test in your own bedroom and home was not only convenient; it also meant that no one else saw the results unless you wished them to. As one NHC member explained:

> people test themselves at their own home which are mostly private and they can test even in their own bedroom where no one can see their results unless they decide to share the results with others.

For one woman who chose HIVST, this was also a way to avoid health providers feeling pity if the results were reactive (HIV-positive) since telling someone they have HIV is a heavy responsibility. ‘It’s better you see for yourself your own results’, she commented.

All hard-to-reach key informants felt it was better to test oneself. Informants including a sex worker, an alcoholic, a teacher, a miner and a trader explicitly expressed that it enhanced their sense of control ‘seeing things happen’ in private ‘without anybody there’. For couples who chose to test together, the confidentiality that HIVST provided was valued. A few respondents also valued the reduced contact with CHiPs that accompanied HIVST.

The possibility of testing someone else without them knowing they were being tested for HIV was a concern for one teacher. 'You can just lie that you want to test for some other disease and not tell them you are testing for HIV', she said. One married woman, whose husband refuses to test for HIV, said she might use the kit to 'sneak up' on her 'drunk husband' and test him in his sleep. Forced HIV testing was a documented outcome in a few cases (Table 12).

Reaching busy household members, particularly working men, was cited as a benefit of HIVST by NHCs, CHiPs, men and women. One middle-aged male truck driver said he thought HIVST would work well in communities and 'the country at large' because it would help 'reach everyone, even those who are very busy'. CHiPs said HIVST has helped them capture more couples because, even when one partner is absent, the one who is present gets HIVST kits.

Two wives who collected HIVST kits for their husbands said their husbands were not opposed to having an HIV test, but were too busy to go for HIV testing. Some women opted to test with their husband in this way, after their husbands returned from work. One married man, who had refused to test previously with the CHiPs, used an HIVST to test when his wife was running an errand. Upon reading his own results, he then called her and shared his results with her. In a men's FGD, some individuals said they did not feel pressurized by their wives, but rather felt the need to 'lead by example' and still 'felt in charge' because they were doing the test for themselves. One CHiP narrated how one husband who had always refused HIV testing accepted HIVST. During HIV testing, the husband and wife sat together as a couple checking each other's results.

One miner said the test did not negatively affect his relationship with his wife but rather improved it, as his wife was so happy that she even rewarded him with opaque beer after he agreed to test. In many households where observations were conducted with couples, it was felt that their relationships were not adversely impacted by HIVST. For instance, in the case of one young couple, the husband allowed his wife to swab his mouth and trusted her to read his results in his absence. An adult man who self-tested in the presence of his wife said it helped that she saw the test running and that she did not force him to test or disclose results.

Although it was more common for women to collect HIVST kits for their husbands, occasionally a husband would collect a kit for his wife. For husbands who found out their wives were HIV-positive in this way, the CHiPs said they had to do intensive counseling to get the husband to be understanding about his wife's status (Table 12). CHiPs said that women were more accepting of a man's result than the other way around. They felt that HIVST 'brought happiness and confidence in people's homes and especially with the womenfolk'.

Discussing HIVST as an option with community groups prompted more open criticism of the local health facilities. Congestion and the resulting queues at health facilities were recalled as a deterrent to HIV testing, especially for those busy with seasonal work and livelihoods that required travel, such as mining, fishing, trading, farming and driving.

Criticism of local health facilities was interwoven with fears about being seen going for HIV testing at the health facility. The 'fear of being seen' by family, friends, neighbors and community members – and thereby 'feeling shy to test' when accessing HTS at the local health facility – was a commonly expressed sentiment. Testing at the clinic carried the greatest fear of being seen, exacerbated by congestion. An adult woman described how 'seeing somebody going for VCT at the clinic creates suspicion, rumor-mongering and stigma, which one does not experience when testing at home'.

The link between anticipated stigma, gossip and not testing for HIV was captured in an FGD with men:

> What makes other people shy to go to the clinic for HIV testing is that because the people in the community talk too much about people who are HIV-positive which makes them uncomfortable. As a result, many people do not go to access HIV testing to a place where there is a lot of people...testing alone is better for certain people who fear being seen by community members that they accepted HIV testing

Testing at the clinic, testing at home with CHiPs, and HIVST offer different degrees of privacy and/or exposure, with HIVST being the most private and testing at the clinic being the least private. Men in another FGD explained, 'Door-to-door delivery of HIVST kits was a very good idea because it enhanced confidentiality…it was more private and no other person would know someone is testing for HIV'.

The most common form of stigma was gossip. Respondents referred to the risk of being talked about, being laughed at, being called names, people being suspicious, rumors, and 'spreading information'. One adult man felt people were more vulnerable to this gossip if they were 'too sick and powerless'. Another man mentioned that 'people are predictable, they may just disclose your status when involved in an argument or just during gossip'. A married couple referred to 'communal stigma' as an issue for those considering HIV testing at the health facility.

One concern about HIVST was how people would manage if they found out they had HIV through HIVST. One adolescent felt that HIVST would facilitate denial around a positive test result and even 'deliberate spreading' of HIV. An adult woman also worried that HIVST could lead to people 'infecting others, saying they cannot die alone'. For married women, a positive result was said to be particularly difficult because 'men are difficult to talk to'. One married woman said if she tested HIV-positive said she would just take her drugs in secret.

We also asked participants about the role of counseling if an HIV test was self-administered, and most respondents believed that counseling was still very important, particularly if someone tested HIV-positive. A sex worker who tested herself said she thought counseling after an HIV-positive test would help 'calm people down, especially those who would otherwise want to kill themselves'. A trader emphasized the importance of being 'guided how to live after testing', and a young adolescent man stipulated that 'it is through counseling that people are encouraged, given instructions and full information about what you are testing for'. An adult man felt that people's different background and emotional abilities meant that being supported after an HIV-positive test result was critical. The men's FGD respondents said that counseling HIV-negative people was equally helpful in the community, assisting them to 'live better healthier lives'. There were a handful of respondents who thought counseling linked to HIVST was not valuable.

Respondents identified various counseling options as appropriate after HIVST, including face-to-face counseling as individuals or couples, and telephone counseling. Different circumstances would dictate which counseling option was most appropriate; for example, unmarried individuals should be counseled alone and married people should be counseled as couples. One couple who tested together using HIVST stated that counseling and testing together and sharing results was important so that they could know each other's status and take better care of each another. Being counseled by "strangers" or professionals or clinic counselors was preferable to being counseled by those that knew you. Family counseling was considered by many to be trickier due to stigma and resulting discrimination, and traditional counseling (counseling by elders in the extended family) carried the risk of charms (traditional medicine) and breaches in confidentiality. For example, one adult man said both family and traditional counseling 'could lead to rumor-mongering and spreading private information'. A few respondents were more in favor of family counseling since it would facilitate care and support.

6.9.2 Anticipated and actual social harms (Objective 2)

Relatively few social harms were reported (Table 12). This was partly due to CHiPs being careful to caution spouses about how to introduce HIVST to their partner and because HIVST kits were only left for absent partners of individuals aged over 18. In addition, there was a reluctance for community members to speak freely with CHiPs or community representatives (CABs) about negative social experiences. In any case, women are usually advised not to discuss their marital challenges in public. One female FGD respondent said that incidents only come out in the open when they escalate into full-blown confrontation. An adult man also observed that it is no longer a secret when individuals fight. Less severe social harms were harder to detect. We should note that social harms could be an outcome of any mode of HIV testing, but there are specific risks associated with HIVST as detailed in Table 12 and below.

Reported social harms (Table 12) can be graded on a scale ranging from less to more severe. Those perceived as less severe could become severe depending on how the incident evolves. The reported social harms ranged from mere invasion of privacy to emotional distress, deceit/forced HIV testing, threatening violence or actual violence, to separation of married couples. Some types were exacerbated by pre-existing conditions such as alcohol abuse and a history of gender-based violence.

Emotional distress was a commonly experienced social harm for men and women. It mainly resulted from the challenges people experienced coming to terms with an HIV-positive result, especially in situations where they were blamed by the partner or where they blamed the partner for infecting them. Discordance was a challenge. For example, one discordant couple (the wife tested HIV-negative and the husband HIV-positive) were distressed by the discordant test results, which they found hard to accept. They called for help from the CHiPs. During the CHiPs household visit, the woman wept while the husband was equally distressed and kept pacing around the room. The wife finally pledged support to the husband who eventually started HIV treatment. A 17-year-old domestic worker experienced distress because she did not have someone to confide in and seek help from. Having been asked to test by her employer, she felt she could not even seek care from the local health facility for fear of losing her job if her employer became aware of her HIV-positive status.

Some wives used HIVST as an opportunity to know their husband's HIV status. In two cases, the wives attempted to take advantage of drunken husbands. Men also sometimes used HIVST to force their wives or partners to test, sometimes proving their suspicions that their wife was HIV-positive.

Although in community consultation meetings suicide was anticipated to be a social harm, only one case of attempted suicide was recorded after a woman hit her husband for testing HIV-positive and infidelity ('cheating').

Despite this challenge, respondents suggested ways in which social harms could be detected, such as devising reporting mechanisms within each community. However, the mechanisms for such a reporting system would largely depend on how each community is organized. The door-to-door distribution model was seen as an intrinsic mechanism for detecting social harms because of its potential to allow people to express themselves, and decisions made in a home environment are less likely to be influenced by other people. Making the HIV-testing environment more private and confidential was another related mechanism. FGD and key informant respondents suggested responding to 'warning signs' and thereby deciding to not offer HIVST. Warning signs that might pre-dispose households to harmful outcomes included couples found at home but refusing an offer of couples HIV testing, refusal of a confirmatory HIV test, and pre-existing conditions for gender-based violence. An adult man suggested gauging the mood of the respondent. According to him, a person who has not used an HIVST kit, but who is also emotional or angry, could be in a relationship predisposed to gender-based violence or other challenges. Strategies to address social harms should build on these local suggestions, which reflect what it means to live in these communities and the experience of lay community workers.

Counseling and education/sensitization were frequently mentioned ways for preventing social harms. The presence of CHiPs during HIV testing was seen as advantageous, as they are trained to deal with situations that arise from HIV testing. The offer of HIVST may make it more likely that testing in couples may take place more often in the absence of a professional health worker, including lay workers such as CHiPs. A community member, during a transect walk, suggested that counseling should include a spiritual component since this would give hope to people that test HIV-positive. Educating community members about the benefits of HIVST was also suggested as a mechanism for preventing social harms. One respondent advised that public campaigns should be well resourced and strategically targeted at different population categories. Respondents also suggested that prevention of social harms could be enhanced by couples testing together using HISVT, as well as encouraging those that tested alone to disclose their HIV status to family members.

Table 12: Actual social harms emerging during the HIVST pilot intervention

Source 1	Source 2	Type	Short description
20170329_Z6_FGD (P16-actual)	FGD (CHiPs)	Threatening harm/divorce	The wife tested HIV-positive with an HIVST kit. She also collected a kit for her husband. However, he refused to test, broke the kit, packed it back in its original package and asked the wife to give it back to the CHiPs. He also warned her not to go to the health facility otherwise he would divorce her.
20170329_Z6_FGD (P16-actual)	FGD (CHiPs)	Couple separated	Husband received two HIVST kits; one for his wife, whom he forced to test. His result was HIV-negative while his wife was HIV-positive. The wife confessed to him that she knew her status all along and that she was on treatment already. The CHiPs have heard that the couple has separated but they are yet to confirm.
20170317_Z5_FGD (P17-actual)	FGD (CHiPs)	Invasion of privacy	A married couple tested separately. The wife shared her results with her husband, but he refused to show his. On the self-completed results form, he ticked the question mark meaning he was unsure of the result. The wife thought he was feigning illiteracy. She opened the man's envelope before giving the test kits back to the CHiP and discovered from his results that he was positive. The couple is still together and it appears nothing untoward has happened between them.
20170329_Z1_FGD (P19_1_actual)	FGD (CHiPs)	Deceit/forced testing	The wife received two kits; one for herself and one for her husband. She tried to explain to him the instructions when he returned home. It became apparent that he was struggling to comprehend everything and the wife cleverly and sweetly demonstrated use by successfully swabbing his mouth herself and performing the HIVST. By the time the man realized what had happened she had successfully tested him without his full consent.
20170321_Z6_IDI (P34-actual)	Male (adolescent, accepted, supervised)	Deceit/forced testing	A brother forced his sister to test. He did not tell her that it was the PopART/3ie team that had visited their household. It was too late for the sister to withdraw from the process once she had availed herself and walked into the room where the team was. Not wanting to disappoint 'big brother', she consented to the test. She was later happy she did so as she tested HIV-negative.
20170220_Z6_HIVST (P43-actual)	FGD (CHiPs observation)	Forced testing	A man forced his wife, who is 13 years older than him, to accept to test using the test kit. She initially refused to test but he insisted, saying that as long as he was her husband, she must test. She obliged but refused to read the results, saying she already knew her status (HIV-positive). The man later told CHiPs that he also already knew his partner's status but CHiPs said they did not believe he did because he looked shocked. 'He is normally a jovial person but he was uncharacteristically quiet upon learning about the partner's results'. He probably wanted to use HIVST to confirm the status of his partner.

Source 1	Source 2	Type	Short description
Monitoring visit	Case Study	Attempted forced testing	The wife tried several times to convince her husband to test after collecting a test kit on his behalf. When the CHiPs made a follow-up, they could hear the couple arguing about the kit. He told the CHiPs that he was not against testing but that he found the approach taken by his wife very confrontational. Apparently, he was drunk when the wife tried to force him to test, telling him he had given too many excuses in the past but this time he would test "*no matter what*". He said that his wife had no right to force him to test. He tested with the CHiPs.
Monitoring visit	Case Study	Emotional distress	A CHiP received a distressed phone call early in the morning from a woman who tested using the kit the previous day. She had also collected one for her husband. She revealed that her result was HIV-negative whilst her husband's was HIV-positive and that this had distressed the husband. Confirmatory tests were done and the results were discordant again. The wife started weeping while the man was also clearly distressed, pacing up and down the room, unable to sit still for a moment. The couple was counseled and linked to care; the man has since commenced HIV treatment.
Monitoring visit	Case Study	Marriage Separation	A couple offered to test together but before they reached a decision, the wife seemed uncomfortable and kept dithering, but the man encouraged her. When it came to reading and interpreting the results, she was quite uncomfortable and accused her husband of suspecting her to be HIV-positive. She tested HIV- positive while the husband tested HIV-negative. The CHiPs later learnt that this was her second marriage. She refused previous offers by her husband to go for HIV testing saying that she had tested at the antenatal clinic. The CHiPs visited the couple a week later and learnt from neighbors that the wife had moved out of the house. Later, the husband said he was going to try and bring her back.
Monitoring visit	Case Study	Emotional distress	A wife with an infant accepted HIVST. She also collected a kit for her husband, whom she said was a 'liberal man' and had accompanied her to the health facility recently for mother and childcare services after delivery. At this time they had both tested HIV-negative. But using HIVST, the man tested HIV-positive from using the test kit while the woman tested HIV-negative. The CHiPs found her at home and she gave them the results but it seems the implications of the results had not fully registered. She asked the CHiPs, 'You guys are you sure just like this these results are positive? Please don't joke because I can drop down the baby. How come not so long ago during my pregnancy the results for both were negative?'. She was quiet for some time and looked disturbed. The CHiPs visited her several times to give her support.

Source 1	Source 2	Type	Short description
Monitoring visit	Case Study	Emotional distress	This case involves a 17-year-old adolescent girl who was brought from the village to work as a maid. She accepted HIVST after the head of the household encouraged everyone in the house to test so that they could know their status. She tested HIV-positive but she could not disclose to anyone for fear of being dismissed from her job. This means she has had no support from the family. She is also afraid to come to the clinic because her employer will ask where she has been and this may land her into trouble. The CHiPs engaged a child counselor for her and they have been following up the case.
Monitoring visit	Case Study	Blackmail (using results as evidence against spouse)	A couple who recently married opted to test together. The husband was at home and collected the kits for himself and his wife from the CHiPs. The CHiPs received a call to go and pick up the results but only found the man at home, who told them that the wife's results were HIV-positive whilst he tested HIV-negative. He also told the CHiPs that the wife wept upon seeing the results; she wondered if he was going to leave her. The husband started using the wife's status to extort money from her. Whenever she resisted, he would say, 'In fact you are positive, I am going to tell your relatives', which he proceeded to do anyway. It seems the wife hid his results form and her referral slip from him since the husband called the CHiPs for a new results form and a referral slip. When they refused to give him these, he then contacted the CHiP supervisor.
Monitoring visit	Case Study	Gender-based violence and threatening suicide	Both the husband and wife were at home when the CHiPs visited. The husband was hesitant, but the wife convinced him to test. The husband did not like the finger prick, so both chose HIVST. The husband was HIV-positive while the wife was HIV-negative. The wife was visibly upset and gesturing; she accused the husband of infidelity saying at one time he had an STI, which means that he had another woman. She was clearly disappointed with the husband's results. Later the following week, the woman told the CHiPs she was very annoyed when they left, and she hit her husband. The CHiPs also learnt later that the man attempted to commit suicide; he took a rope to hang himself but the wife intervened and even involved some church members. Later the husband said the threat of suicide was a reaction to the beating by his wife, but otherwise the situation was now fine.

6.9.3 Management of HIVST kits (Objective 3)

HIVST was regarded as novel and therefore interesting to many community members. This novelty, particularly in communities with a long and intensive history of HIV testing, was another factor that influenced individuals to choose HIVST. For example, a 36-year-old woman said her main reason for choosing HIVST was that she had already used the finger-prick method of HIV testing many times before and she wanted to 'try the new thing'.

However, sometimes the novelty of HIVST undermined confidence in it. For example, one young adolescent man said he was afraid of 'making mistakes' because it is 'a new thing' that he was not confident he could use correctly. For some participants, challenges arose from swabbing techniques. Several individuals had challenges handling the HIVST kit. For example, one observed individual shivered (was shaking) a bit when tearing the kit and swabbing her gum. A few others had challenges moving the testing device from the upper to the lower gum without changing the side to swab as advised.

Despite such challenges, conducting and interpreting the results was relatively straightforward for most, either after a demonstration by the CHiPs or unsupervised. Clients who were interviewed and/or observed understood the IFU and read and interpreted their results correctly. They also described and interpreted all possible results correctly. However, there was one situation during a CHiPs observation where the individual could not interpret 'reactive' (HIV-positive) and 'non-reactive' (HIV-negative) result correctly and had challenges in completing his results form. He thought a 'reactive' result meant the test had worked.

Most individuals – supervised, unsupervised and those who accessed HIVST kits through secondary distribution – read (or said they read) their results by comparing the actual results with the pictures on the IFU. The individuals that accepted supervised HIVST often found CHiPs demonstrations helpful because they could imitate the demonstration when using the kit themselves. One trader commented that it was as 'easy as counting'. Some individuals had concerns about the ability of illiterate individuals to use the HIVST kits; however, although literate individuals found it easier to test without assistance from CHiPs, most people observed (educated and uneducated) could correctly use the kit and describe the results.

Some individuals revealed that they read the results before the recommended 20 minutes, while others read their results after more than 20 minutes. According to a miner who accessed the test kit through his wife, 'The test was very easy to do and all instructions were clear and very easy to follow'. He waited 20 minutes after eating to start his test, adding that he removed the testing devices without any challenges and swabbed correctly. He also interpreted all possible results and understood that a positive result requires a confirmatory test and linkage to care.

Avoiding the pain associated with a finger-prick HIV test was one incentive to opt for HIVST. Three men, all representing hard-to-reach populations (miner, fisherman, alcoholic), found HIVST better partly because it was painless. Men in a bar said people do not like being pricked and link blood-based tests to satanism. Several individuals complained about the perceived volume of blood taken during the PopART population cohort study.

There were, however, mixed feelings about HIVST and some participants questioned its accuracy especially because it used oral fluids to test for HIV. Most individuals testing HIV-positive through HIVST had a confirmatory test. Others who had not shared their HIV-positive status with the CHiPs, accepted HIVST as a way of proving whether the HIVST kits really detected HIV. The accuracy of the kit and confusion about finding HIV in oral fluids undermined confidence in the accuracy of the HIVST kits amongst a few people. Several people felt that blood must be more accurate than oral fluids. One older man at a bar asked whether people will 'now be getting infected from kissing'.

HIVST kits left in the household were carefully stored out of sight, and most clients preferred that CHiPs collect kits from them, rather than drop them off at the local health facility. Most individuals stored HIVST kits in handbags or wardrobes in their bedrooms before and after use, while a few stored the used kits in the sitting room cupboard. This pattern is reflected in the following field notes: 'A couple revealed that they kept keep the kit before and after use on top of the cupboard because they had 2 children in their home and also asked the CHiPs to pass through their home the following day and collect the used kits'; 'A wife kept the unused kit in the cupboard but her husband moved it into the bedroom and hung it in a plastic bag against the wall after use'; 'One teenager kept his kit on the sitting room table and moved it to the bedroom during and after testing'.

After HIVST, most individuals re-packed the used kits with care and made appointments for CHiPs to collect them, while busy individuals often left the kits with their partners to return to the CHiPs. This was captured in field notes from observations in one community:

> All the absentee clients' wives during follow ups did not throw away the kits contents but repacked them in the test kit pouches, zip locks and eventually into the envelopes provided. These were later collected by the CHiPs who had promised they would return to collect them.

In one FGD, men said they preferred CHiPs to collect the used kits, arguing that the box is 'too exposed' and individuals could easily be seen dropping off a kit.

6.9.4 Distribution of HIVST kits (Objective 3)

Adolescents, men, women and CHiPs had opinions about where, by whom and how HIVST should be distributed (Table 13). Across all groups, the common places seen as appropriate for distribution were: the government health facility, kiosks (small shop stalls), churches, drugstores and pharmacies, specific community distribution points and bus stations. For adolescents, youth clubs, school anti-AIDS clubs, further education institutions, mobile outreach initiatives and secondary distribution through guardians were also recommended. For adult women, home, antenatal and under-five clinics, water points, fishing camps, the marketplace and family and friends' networks were identified. For adult men and other hard-to-reach groups, the workplace, fishing camps, bars, sports stadiums and other social places, the homes of CHiPs, family and friends' networks, and secondary distribution were identified.

Many people mentioned a need to make such distribution points stigma free and not turn them into clinics. All groups emphasized the importance of pre- and post-test counseling, which are a means of facilitating confirmatory tests and providing access to information on how to use the kits and linkage to care, particularly if someone has a reactive (HIV-positive) result. Any specific distribution points, it was recommended, should be managed by lay workers to facilitate this support. Storage of kits at any distribution point and in CHiPs' backpacks was a concern for a few CHiPs.

6.9.5 Impact of self-testing on the role of CHiPs (Objective 4)

The introduction of HIVST as an additional testing option had some advantages and disadvantages for CHiPs. As highlighted, it helped CHiPs to test people they could not previously reach because of mobility or preference reasons. For example, a miner, a trader, a fisherman and a bus driver accepted HIVST because they did not have time to go to the clinic. Women would sometimes collect kits to test (and/or test with) their husbands. The link to counseling through CHiPs has already been highlighted.

The rapport created between CHiPs and household members improved the acceptance of HIVST. CHiPs mentioned that households listened to them because they have worked in these communities for a long time. Household members stipulated that CHiPs delivering home-based HIV services, including HIVST, should be meek, respectful and tolerant, and that they should be of an appropriate sex and age. 'People feel comfortable to talk to fellow youths or elderly counselors', one CHiP explained. For example, some elderly household members said they felt uncomfortable being counseled on STIs and condoms by young people. Mixed-sex pairs were also preferred by individuals and CHiPs.

HIVST was experienced as an additional task to the routine work of CHiPs. They were in a position to compare their workload before and after HIVST was added to their required tasks, as well as compare with CHiPs not selected to distribute HIVST. Additional explanations (supervised and unsupervised testing), questions, data collection, luggage, calling cards and follow-ups for results and kits increased their workload, and sometimes extended their working day. A few CHiPs suggested that their task should be either to offer HIVST or offer finger-prick HIV testing to reduce their workload. Later, during implementation of the HIVST study, CHiPs developed a strategy of demonstrating HIVST to everyone present in the household (more like group counseling) and then attending to those that wanted to test individually. This strategy accelerated the testing process.

Linkage to care under HIVST was said to be problematic, especially for people conducting unsupervised tests, as these were difficult to find at home. When such individuals tested, it was hard to provide post-test counseling and link individuals to care. In addition, CHiPs worried that such individuals were less likely to be open about their new HIV status since they had not necessarily shared their result with anyone else. CHiPs had to learn to deal with HIV-positive clients wanting to use the kits to check their status, as well as discordance, jealousy and suspicion in couples. Some CHiPs were suspicious that some individuals may claim other people's kit results as their own.

Table 13: Community suggestions for future HIVST distribution

Category	Proposed mode of distribution	Reason
Adolescent	Community distribution points Clinic Mobile distribution Marketplace Church youth clubs Anti-AIDS club at school Colleges and universities Pharmacies and drugstores Kiosks Secondary distribution (through guardians)	These areas were viewed as places young people are generally found. For example, in colleges and universities you will find many adolescents above 18 in one confined place.
Adult Women	Clinic (including antenatal) Marketplace Church Door to door Under-5 meetings Community distribution points Bus stations Fishing camps Water kiosks Family and friends network	Women are mostly found in homes and do most of their work within houses or communities. Participants said that women also may prefer to access the kits through churches, water kiosks and pharmacies because they are involved in church activities, perform domestic work such as drawing water from kiosks, and often visit pharmacies. Bus stops are good distribution points because many women are found trading there.
Adult Men	Clinic Workplace Market The home of CHiPs Bars Stadiums and other social places Churches Community pharmacies Community set/zone-specific points Bus stops Fishing camps Kiosks Family and friends network Secondary distribution	The preference was to distribute kits at places of work, as that is where men and other hard-to-reach persons are often found. Other men are found at different recreational places and facilities. Fishermen gather at fishing camps and can be reached by visiting CHiPs.
CHiPs	Home delivered Secondary distribution for young people Kiosks Workplaces Churches Drugstores and pharmacies Recreation centers Bus stations Community distribution points Clinic (throughout)	The management of HIVST should be conducted by CHiPs at any community distribution points. Distribution points should not be made to look like a clinic in order to reduce stigma. Drugstores and pharmacies should be orientated on how the test kits work and should have strong links with the clinic.

6.10 Costs and incremental cost-effectiveness ratio

6.10.1 Cost analysis

The total cost of implementing HIVST kit distribution alongside the PopART intervention was US$324,205.80, of which US$240,725.18 (74%) comprised costs for research activities (Table 14).

Table 14: Total project costs by activity (US$)

Cost line	Research (US$)	Intervention (US$)	Total (US$)
Start-up period			
Supervision and mentorship	2,232.86	5,867.86	8,100.71
Implementation planning	2,035.82	0.00	2,035.82
Trial design and preparation	28,706.49	0.00	28,706.49
Project coordination/administration	116,296.15	3,223.37	119,519.52
Training	11,018.74	6,114.12	17,132.85
Sub-total	***160,290.05***	***15,205.34***	***175,495.39***
Implementation period			
Supervision and mentorship	10,748.75	17,375.74	28,124.49
M&E	1,155.83	1,580.59	2,736.42
Field activities/service delivery	20,001.11	25,883.08	45,884.19
Project coordination/administration	46,900.82	20,916.05	67,816.88
Quality assurance	205.73	1,212.34	1,418.07
Community mobilization	1,422.89	1,307.48	2,730.36
Sub-total	***80,435.13***	***68,275.28***	***148,710.41***
Total	**240,725.18**	**83,480.62**	**324,205.80**

Total implementation costs of delivering HTS were US$172,069 for PopART standard of care in the non-HIVST zones and US$243,745 for HIVST zones, respectively. HIVST-specific activities accounted for 34 per cent (US$84,135) of the cost of implementing HTS in the intervention zones (Table 15).

Table 15: Total implementation costs by study arm (US$)

Cost line	Non-HIVST zones (US$)	HIVST zones (US$)
PopART costs		
Staff costs	145,694	145,694
General supplies	3,693	3,693
First-line testing supplies	22,004	9,927
Second-line testing supplies	677	296
Sub-total costs	***172,069***	***159,610***
HIVST costs		
Personnel		48,456
Administration		9,844
Transportation and travel		6,796
Supplies		4,089
HIVST kit		13,683
Equipment		613
Parallel HIV testing*		654
Sub-total costs		***84,135***
Total costs	**172,069**	**243,745**
* Parallel HIV testing is when Determine HIV-1/2 and UniGold tests are performed to confirm a reactive HIVST result.		

6.10.2 Cost and cost-effectiveness analysis

Unit costs and incremental costs are shown in Table 16. Cost per person tested was US$22.06 (US$172,069/7,800) in non-HIVST zones and US$30.17 (US$243,745/8,080) in HIVST zones. The cost per new tester was calculated as US$96.89 (US$172,069/1,776) in the non-HIVST zones and US$102.72 (US$243,745/2,373) in the HIVST zones. The incremental costs of distributing HIVST kits alongside PopART community door-to-door testing was calculated to be US$71,675.78, which resulted in an incremental cost per additional person tested of US$255.98 (US$71.675.78/280).

Table 16: Unit costs (US$)

Item	Non-HIVST zones		HIVST zones	
	Outcome	Cost (US$)	Outcome	Cost (US$)
Cost per person enumerated	13,706	12.55	13,267	18.37
Cost per person tested	7,800	22.06	8,080	30.17
Cost per new tester	1,776	96.89	2,373	102.72
Cost per newly HIV$^+$ person identified (not confirmed HIV-positive)	204	843.47	237	1028.46
Cost per HIVST distributed			4,561	18.45
Cost per HIVST tester confirmed HIV$^+$			109	771.88
Incremental values			280	71,675.78
Incremental cost per person tested				255.98

7. Discussion

In this three-month intervention, we found that the door-to-door offer of a choice for how to test for HIV, which included the option to self-test, increased knowledge of current HIV status among the general population of adults aged 16 years or older. There was strong evidence that the effect differed by sex, with evidence of increased knowledge of current HIV status among men in the HIVST zones, but little evidence that the intervention increased women's knowledge of their current HIV status. We found little evidence that the intervention had a different effect on knowledge of current HIV status among younger (aged 16–29) and older adults.

We found that participation in the main PopART intervention was similar across the HIVST and non-HIVST zones overall. There was some evidence that, among individuals resident in the communities during the first and second annual rounds of the PopART intervention (but who did not participate in these rounds of service delivery), participation in PopART increased more in HIVST than in non-HIVST zones, though participation remained low among this group. Among individuals seen by CHiPs and consenting to participate in PopART, who were not known by CHiPs to be HIV-positive, uptake of HTS was higher among men in the HIVST zones than in the non-HIVST zones. This finding suggests that men who were contacted and accepted the offer of testing using HIVST contributed to the effect of the intervention on the primary outcome.

Our linkage-to-HIV-care analyses found little statistical difference between HIVST and non-HIVST zones with regard to rates of linkage to HIV care three months after individuals were newly diagnosed HIV-positive and referred for HIV care services by the CHiPs. Referral to care was lower in the HIVST arm, as individuals testing HIV-positive using a secondary distribution HIVST had not yet been followed up. These findings highlight that, where HIVST is primarily supervised, linkage to care is similar to offering finger-prick HTS. Additional follow-up may be required for individuals reached through secondary distribution.

Our qualitative findings describe how the social profiles of communities influence distribution options and safe uptake of HIVST. Gender- and age-appropriate spaces and sensitivities, the presence or absence of middle-class residents and key populations, the scale of the informal economy, mobility and poverty, the degree of physical access and alcohol consumption patterns, and the history of HIV initiatives and differences in these across communities, should be understood and considered when introducing HIVST as an additional HIV testing option. For example, in communities where men are highly mobile, a secondary distribution strategy will likely be an appropriate strategy to reach them. The qualitative research suggested that Community 2 might be a promising setting for HIVST due to its relative distance from a town center and larger middle-class presence. The quantitative results showed stronger evidence of an effect of the intervention on the primary outcome in Community 2. However, this quantitative finding must be interpreted with caution, as randomization was at zone level. Nonetheless, the findings highlight that deliberations about context would help with planning and identifying options for safe and effective distribution, and in pre-empting any resistance to HIVST.

In the intervention zones and across communities, HIVST was valued as an important option that provided greater privacy, ownership and control. It seemed particularly appropriate for and acceptable to re-testers; busy, mobile, married men; marginalized or higher-status groups; and women who could persuade working husbands to test. There were relatively few documented occurrences of coercion, social harms, and being tested without consent. This could have been due to limited secondary distribution, the role of CHiPs, and underreporting. Emotional distress, forced testing, threatened and actual separation, blackmail, invasion of privacy and one attempted suicide were documented social harms of concern in HIVST zones. Whilst we are not currently in a position to compare this to non-intervention zones, these occurrences are important to note. CHiPs actively managed many of these negative outcomes, alleviating some of them for the individuals and couples concerned. CHiPs are still following up with some of the households involved, and additional social research is currently being carried out to look in more detail at manifestations and interpretations of social harms.

HIVST reduced contact with health providers and facilities. This was an advantage for overstretched health systems and clients with limited time or marginalized identities who wished to test, but more problematic if people tested HIV-positive and needed to link to counseling and care. Respondents emphasized that counseling, especially for people testing HIV-positive, was critical in order to provide continued support and information. There was a surprising preference for being counseled by healthcare workers they did not know, either face to face or via telephone, over family counseling or traditional counseling. This was contrary to CHiPs' experience that HIVST acceptability and uptake built on their familiarity with and rapport in households, and their envisaged counseling role in future HIVST distribution; it was also contrary to their actual role in alleviating social harms.

Some respondents, particularly NHCs and CHiPs, stated that HIVST 'greatly reduces stigma and discrimination'. It enabled more private HIV testing, either at home or by oneself, and reduced experiences of anticipated and enacted stigma as individuals did not have to 'be seen' (and thereby gossiped about) while accessing HTS at a clinic. However, HIVST does not necessarily challenge stigma. If anything, it could (albeit inadvertently) increase or sustain stigma. Similar to ART, by providing deeper degrees of privacy around a disease, HIVST makes HIV more hidden. HIVST carries with it a degree of covertness and evasiveness, whilst allowing households, couples and individuals greater privacy and navigation.

HIVST was also thought to be less painful and more hygienic. The method of demonstrating the kit using flipcharts and the IFU took more time than anticipated, although it facilitated correct usage amongst both educated and less-educated clients. Kits were managed and stored carefully by clients who used them unsupervised. The strategy of CHiPs collecting and disposing of kits was popular compared to testers themselves disposing of kits at the clinic. There was limited detailed understanding of the presence of HIV antibodies in oral fluids and limited confidence in HIV-positive test results.

In our economic analysis, we calculated the incremental cost of adding HIVST to the PopART intervention. We did not annualize investment (start-up) costs, considering the project was implemented for a short period of time, and this undoubtedly increased unit costs. Our economic evaluation results should be interpreted with caution because the analysis was underlined by the fact that the intervention was implemented under research conditions with some restrictions. With a longer implementation time it is likely that the cost of delivering HIVST would decrease, not only due to the start-up and training costs, but also due to greater efficiencies that develop over time as lay counselors and the population become more comfortable with this method of testing. As PopART start-up costs were not included, the analysis does not reflect the cost of delivering a community-based combined HIVST and finger-prick HIV testing model.

The rationale for this pilot intervention and rapid impact evaluation was that, despite offering door-to-door HTS services, the PopART intervention has not been able to reach universal coverage among certain sub-groups, including men and young people. These populations are either not contactable by the CHiPs or they consistently decline an offer of HTS. After annual round one of the PopART intervention, the first 90 of the UNAIDS 90-90-90 target was reached among women and was close to being reached among men (Hayes et al. 2017). Coverage of the intervention was, however, lower among young people, mainly because their knowledge of their HIV status prior to participating in the PopART intervention was lower than among older adults. While the PopART intervention substantially narrowed this gap in knowledge of HIV status between younger and older adults, it did not close it (Hayes et al. 2017). Men remained harder to contact than women. We anticipated that offering HIVST to women to give to their absent male partners would allow the intervention to reach men not contactable by CHiPs. In sub-Saharan Africa, studies of the secondary distribution of HIVST have primarily been conducted in health facility settings (Masters et al. 2016; Thirumurthy et al. 2016). We found that the secondary distribution of HIVST outside of facility settings is effective in reaching men in Zambia. The costs of accessing these hardest-to-reach groups may be expected to be higher than providing such an intervention to a population where access to HTS has been limited. This is especially true for the costs per HIV-positive person identified. In these populations the prevalent HIV-positive cases have largely been identified and therefore yield is lower than in a population that is relatively naïve to HTS.

8. Specific findings for policy and practice

The findings of this study have implications for Zambia and other countries with a high burden of HIV and low coverage of HTS among specific sub-populations. The findings provide evidence that household distribution of HIVST is effective at increasing knowledge of HIV status, particularly among men. In many sub-Saharan Africa countries, men are less likely to test for HIV, and are therefore less likely to know if they have HIV-positive status and link to care (WHO 2011; Hensen et al. 2014; Shand et al. 2014). The finding that secondary distribution of HIVST outside of a facility setting reaches men not easily contactable by community health workers is important new evidence that can inform policymakers and programmers in deciding on implementation strategies to increase HTS coverage among men.

Since 2016, the World Health Organization (WHO) has recommended that HIVST be offered as an additional strategy to deliver HTS (WHO 2016). Alongside the large Unitaid-funded STAR initiative, findings from this study provide evidence to inform the development of WHO normative guidance on delivering HIVST services and international policy.

HIVST was a novel strategy in participating communities. One emerging bottleneck was the added time required for CHiPs to explain HIVST and provide a demonstration. Despite this initial concern, CHiPs in HIVST zones enumerated a similar number of individuals during the implementation period as in the non-HIVST zones. With a longer period of implementation, we expect that communities would have become more familiar with HIVST and less likely to need detailed information, which may reduce the time needed for explanation and further increase efficiency, thereby reducing costs. With time, as HIVST becomes less novel, individuals found at home and opting for supervised HIVST at the time of the CHiP visit may instead opt for finger-prick HIV testing, which may be a more cost-efficient approach and may provide a method for improved targeting for HIVST.

When introducing HIVST as an additional HIV testing option, the qualitative findings highlight key issues that require attention. These include local context, target populations, information about using the kit and HIV in oral fluids, implications for counseling, lay counselors and linkage to services, and the management of social harms. We posit that HIVST is not necessarily appropriate for everyone and in all places. It is appropriate for populations whose mobility, social status and working lives make them harder to reach. It is also appropriate, if safely introduced and acceptable to both partners, for couples and can facilitate couple testing. While novel, for those re-testing it is also easier and regarded as less invasive and painful. Considering our qualitative findings, due to the cost of oral HIVST relative to finger-prick HIV testing and the sensitivity of the oral HIVST, home-based delivery of HTS should provide finger-prick HIV testing for individuals willing to test with this option and reserve HIVST for individuals unwilling to use a finger-prick HIV test or who are absent at the time of household visits. With such a strategy, the inclusion of HIVST in household delivery of services could also reduce the workload on CHiPs and other lay counselors.

Detailed and careful communication and information must accompany distribution of HIVST kits, and this should include demonstrations and pictures. HIVST reduces contact with lay counselors and health facilities, and whilst that is advantageous in relieving the health system and individuals' time, for those that test HIV-positive, reduced contact can make post-test counseling and linkage to care harder to achieve. Lay counselors have a clear role in providing counseling, facilitating linkages and managing kit disposal. Social harms linked to HIVST are hard to detect, particularly if they are less severe and culturally embedded. At household level, it is advisable to only introduce HIVST through lay counselors if there is no strong history of strained relationships and abuse. HIVST may have a differential impact on HIV stigma, reducing experiences of enacted stigma whilst leaving internal stigma unchallenged. Targeted stigma reduction therefore remains necessary.

We restricted secondary distribution to absent partners of individuals aged 18 years or older. This restriction might have limited the impact of the intervention on knowledge of HIV status among adolescents and younger adults. Future studies should explore a strategy that distributes HIVST for any absent household member eligible for HIV testing according to national guidelines.

Cost per person enumerated was higher in the HIVST zones than in the non-HIVST zones. This unit cost may, however, change over time as lay counselors become more familiar with offering HIVST and communities are more aware of HIVST. We found that the cost per new HIV tester was similar in the non-HIVST and HIVST zones. Implementing HTS was more expensive in HIVST zones (US$243,745) than in non-HIVST zones (US$172,069). However, although more people were enumerated in the non-HIVST zones, more people were tested in the HIVST zones. This suggests possible economies of scale in HIVST zones, and that if the program were to run longer, CHiPs might have become more efficient at offering HIVST to individuals that would not be reached by finger-prick HTS.

We calculated the ICER in terms of cost per individual tested. To determine whether an intervention offers value for money, the ICER must be compared to a country-specific monetary threshold that represents the maximum acceptable amount a decision maker is willing to pay for the health outcomes (Fenwick et al. 2006). According to WHO guidelines (WHO 2001), a program is considered cost effective if the ICER is less than three-fold the gross domestic product (GDP) per capita and very cost effective if the ICER is less than one-fold the GDP per capita. In 2016, the per capita GDP in Zambia was US$1,178.39 (World Bank 2017). Recent discussions about ICER threshold for low-income countries argue that the threshold for Zambia should be set at 4–42% of its GDP (Revill et al. 2015). Our analysis found that 280 (n=8,080-7,800) more individuals tested for HIV in the HIVST zones than non-HIVST zones. The ICER was US$255.99 (US$71,675.78/280) per additional individual tested for HIV. However, this finding must be interpreted with caution, as we did not assess the uncertainty surrounding our ICER and, as reported earlier, our costs have some limitations.

This study is also unique in that it is not assessing the costs of delivering testing in populations who have not had previous access to testing, but rather to a population which has been repeatedly exposed to easily accessible HTS. As HTS are scaled up internationally, this will become the norm and perceptions around costs and numbers of individuals newly diagnosed will need to change. Rather than measuring the proportion of the population ever having tested for HIV, it will be important to know that at-risk individuals know their current HIV status, which may involve testing every three months for those most at risk, or less frequent testing for the general population. Qualitative work showed that HIVST may be very appropriate as a means of repeat testing, and with experience of HIVST, costs will be further reduced as community workers can spend less time explaining the test and limit their input to individuals who test HIV-positive.

Based on findings from this study, HIVST has been expanded as standard of care in PopART intervention communities. However, to increase efficiency of HTS delivery and access those not being reached by offering finger-prick HTS, CHiPs are offering HIVST preferentially to individuals who do not want to use a finger-prick HIV test and secondary distribution to individuals absent at the time of the household visit.

This study will have important policy lessons, especially for the future of reaching universal knowledge of current HIV status. It is likely that HTS will be expanded through numerous channels, but may still fail to reach certain population groups, providing a situation similar to that seen in the PopART intervention communities. In this scenario, HIVST is an important addition to the HTS program as a means of reaching those who would otherwise not be reached. We believe that community-based distribution, including secondary distribution, of HIVST has the potential to reach the hardest-to-reach groups and will be an important strategy for repeat testing that will enable all individuals to know their current HIV status.

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Online appendixes

Online appendix A: Self-completed results form
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-a_0.pdf

Online appendix B: Quantitative questionnaire
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-b.pdf

Online appendix C: Restricted randomization of HIVST study
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-c.pdf

Online appendix D: HPTN 071 information sheet and verbal consent form
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-d.pdf

Online appendix E: VCT consent form
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-e.pdf

Online appendix F: Absent member form
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-f.pdf

Online appendix G: FGD and KII information sheets and consent forms
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-g.pdf

Online appendix H: Qualitative data collection tools
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-h.pdf

Online appendix I: Distinctive features of the HIVST study sites
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-i.pdf

Online appendix J: Tables of analyses of the primary and secondary outcomes among individuals whose HIV status was not known to the CHiP by the end of a second round of PopART intervention delivery
http://www.3ieimpact.org/sites/default/files/2019-01/tw2218-hivst-zambiart-online-appendix-j.pdf

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The authors piloted a door-to-door offer of a choice between counselor-provided finger-prick rapid HIV testing, or oral HIV self-testing in the presence or absence of the counselor. Household distribution in communities exposed to door-to-door HIV testing increased knowledge of current HIV status, which was driven by an effect among men. Qualitative findings indicated that married working men and men whose livelihoods entailed mobility (both daily and seasonal) are considered appropriate populations for self-testing. Counselors have a clear and vital role to play in adapting HIV self-testing interventions to local contexts and to introducing testing safely at the household level, including linkage to counseling and care for clients who test HIV positive.

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