Community-based distribution of oral HIV self-testing kits: a pilot intervention and rapid impact evaluation

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Executive 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 coverage of HTS and encourage repeat testing to keep individuals' knowledge of their HIV status up-to-date, we piloted the door-to-door offer of the choice of counsellor provided finger-prick rapid HIV testing (finger-prick HIV testing) or oral HIV self-testing (HIVST) in the presence or absence of the counsellor. 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 for community members, key populations, mobile individuals and couples opting to, or not to, HIVST. We further explored the possible and actual social impact of HIVST on household social relations and its impact on the role of lay counsellors delivering HTS.

Methods

We conducted a cluster-randomised 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 counsellors on how to offer and demonstrate the use of oral HIV self-tests to individuals aged 16 years or older. Once trained, lay counsellors conducting door-to-door household visits offered 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 counsellors 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 2-phased 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 Neighbourhood Health Committee members, lay counsellors and men (n=91 participants). We conducted a prospective economic evaluation from the provider's perspective to calculate 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 counsellors enumerated 13,267 individuals in HIVST intervention 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 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 influenced community uptake of HIVST. 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. Internalised stigma remained unchallenged and present. Outcomes of HIVST were mostly favourable, with couple communication and individual knowledge of HIV status enhanced. However, there were a few occurrences of social harms. Lay workers delivering HTS, played a key role in alleviating the latter. Post-test counselling was widely considered critical, especially when people tested HIV-positive and needed psychosocial support and support to link to HIV treatment and care.

Conclusions

The household distribution of HIVST in communities exposed to door-to-door HIV testing had an effect on increasing knowledge of current HIV status. This 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 context and to safe introduction of HIVST at household level, including linkage to counselling and to care for clients that test HIV-positive.

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

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Abbreviations and acronyms

adjOR	adjusted odds ratio
CAB	Community advisory board
CHiPs	Community HIV Care Providers (Lay counsellors trained and employed by the HPTN071 (PopART) study - each pair responsible for one zone of the community)
CRT	Cluster randomised trial
CI	Confidence interval
EDC	Electronic data capture
FGD	Focus group discussion
ICER	Incremental cost-effectiveness ratio
IDI	In-depth interview
OR	Odds ratio
HPTN	HIV Prevention Trials Network
HIVST	HIV self-test(ing)
HTS	HIV testing services
IFU	Instructions for use
LSHTM	London School of Hygiene & Tropical Medicine
NHC	Neighbourhood health committee
PopART	Population Effects of Antiretroviral Therapy to reduce HIV Transmission
RDT	Rapid diagnostic test
STAR	the UNITAID/PSI HIV Self-Testing Africa (STAR) Project
STI	Sexually transmitted infection
TB	Tuberculosis
UNAIDS	the Joint United Nations Programme on HIV/AIDS
VCT	Voluntary HIV testing and counselling
VMMC	Voluntary medical male circumcision
WHO	the 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 widespread availability of community-based HTS, including home-based and mobile HTS (Baggaley, Hensen et al. 2012, Suthar, Ford 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 2013/14 compared to 39% and 12%, respectively, in 2007 (CSO 2009, 2014). In Zambia, as in other countries with a high burden of HIV, there remains, however, a need for alternative strategies to provide HTS to reach individuals unaware of their HIV status, and allow for repeat testing to keep knowledge of HIV 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 not accessing currently available HTS by providing increased autonomy regarding when and where to test, and greater confidentiality (Choko, Desmond et al. 2011, Napierala Mavedzenge, Baggaley 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, Djimeu et al. 2014, Cambiano, Napierala Mavedzenge et al. 2014, Johnson, Baggaley 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, Desmond et al. 2011). The provision of HIVST through resident volunteer-counsellors, allowed 77% of community members to test using an HIV self-test (Choko, MacPherson et al. 2014, Choko, MacPherson et al. 2015). By the end of two years, HIVST uptake was highest among individuals aged 16-19 years and males (Choko, MacPherson et al. 2014). Among couples, qualitative research found that HIVST encouraged partner testing and disclosure (Kumwenda, Munthali et al. 2014, Masters, Agot et al. 2016). There remain, however, concerns regarding the potential for social harms, and the implications for post-test counselling and linkage to care (Makusha, Knight et al. 2015, Martínez Pérez, Cox 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 the choice of HIV testing using an oral HIV self-test or lay counsellor-administered finger-prick rapid HIV (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 counsellors 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, van den Bergh 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, van den Bergh et al. 2012, Musheke, Ntalasha et al. 2013, Suthar, Ford et al. 2013, Hensen, Lewis et al. 2015). The door-to-door delivery of finger-prick HTS is, however, resource intensive. Providing the option to HIV test using an oral HIV self-test during household delivery of HTS may reach more individuals with HTS and reduce the resources required to provide door-to-door HTS.

HPTN071 (PopART) is a community-randomised trial of the impact of a household-based combination HIV prevention intervention, which includes the annual door-to-door offer of point-of-care HTS by lay counsellors with support for linkage to immediate treatment and prevention services, on HIV incidence (Hayes, Ayles 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 with household services and sustaining coverage among young people has also proved challenging (UNAIDS 2014, Floyd, Phiri et al. 2017, Hayes, Floyd et al. 2017). We hypothesised that providing individuals a choice of how to test for HIV, including the option to HIV self-test, either with or without the counsellor present, during annual household visits in this setting would reach populations harder to reach with HTS, including men and younger adults, with access to HTS.

In this study, we report the findings of a nested cluster-randomised trial (CRT) of community-based distribution of HIVST within four PopART intervention communities in Zambia. In the intervention arm of this trial, PopART lay counsellors conducting door-to-door household visits offered individuals the option to HIV test using an oral HIV self-test or HIV 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 last decade, levels of HIV-testing have increased markedly across Zambia (CSO 2009, 2014). In 2007, 19% of women and 12% of men aged 15-49 years 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 voluntary HIV testing and counselling (VCT) sites increased from 500 to 1102 (MoH 2010). In 2006/7, health facilities implemented provider-initiated HIV-testing and counselling. By 2010, progress had been made in scaling-up the delivery of HIV-testing services through community settings, including through home- and mobile-based services (MoH 2010).

Despite progress, in 2015/16, 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 to 59 who knew their HIV-positive status were on

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). Uptake of couples testing is also low (Matovu, Todd et al. 2016). As such, 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, Bond 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, van den Bergh et al. 2012, Suthar, Ford et al. 2013, Hensen, Taoka et al. 2014). Experience to date from HPTN071 (PopART), a community-randomised trial of universal testing and treatment in South Africa and Zambia, has shown that, despite door-to-door activities and although consent to participate in the intervention is high (Hayes, Floyd et al. 2017), in a second round of service delivery in Zambia, communities randomised to the universal testing and immediate treatment arm (termed Arm A), 32% of men and 11% of women aged 18 and older were not contactable by lay counsellors (Floyd, Phiri et al. 2017). Among individuals contacted and participating in round 2 of the PopART intervention, 64% of men and 63% of women accepted an offer of HTS (Floyd, Phiri et al. 2017).

Qualitative research conducted in the HPTN071 trial communities prior to PopART implementation highlighted poverty, crime and alcohol abuse as the most salient features of the communities (Bond, Hoddinott et al. 2016). These features were considered factors that contributed to increased vulnerability to HIV through risky sexual behaviours, and created barriers to accessing HIV services (Bond, Hoddinott 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 the HIV services and of the PopART intervention (Bond, Chiti et al. 2016).

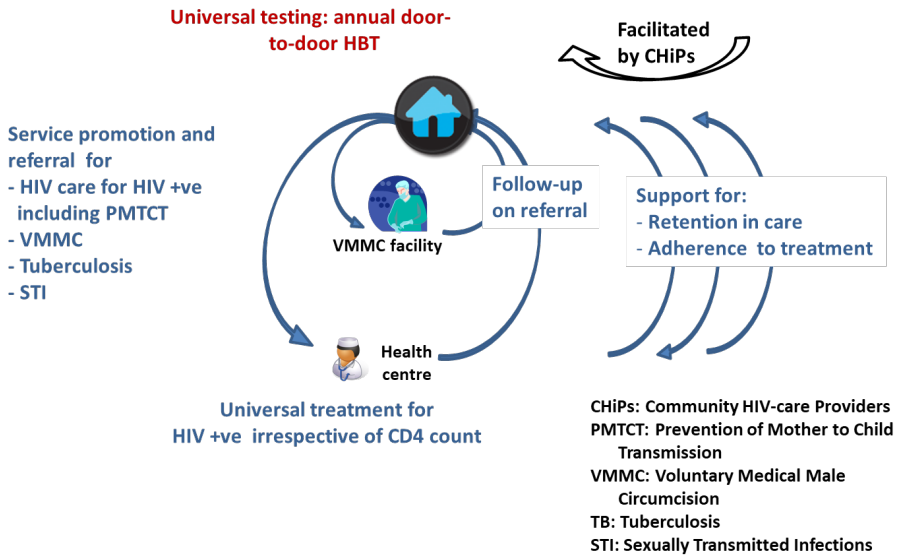
HIVST is a novel alternative for individuals not accessing currently available services. The offer of HIVST may overcome some of the barriers to HTS experienced to date in PopART. The Zambian Ministry of Health aims to incorporate HIVST into their national HIV/AIDS programme. Therefore, this study aimed to support decision-making in-country, by providing evidence of whether the door-to-door offer of a choice of oral HIVST or lay counsellor-administered HIV finger-prick testing 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 delivery of HTS with linkage to prevention and care services (Figure 1) (Hayes, Ayles et al. 2014, Shanaube, Schaap et al. 2017). Lay counsellors trained and licensed in HIV counselling and testing (including psychosocial and adherence counselling), called Community HIV Care Providers (CHiPs), deliver the intervention to all household members living in intervention areas (Hayes, Ayles et al. 2014). Within a community, CHiPs work in pairs in a zone (an area of roughly 500 households). The CHiPs pair visit all households in their zones, 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 HIV test (Shanaube, Schaap et al. 2017). For individuals consenting to PopART, the intervention includes an offer of rapid finger-prick HIV testing services for individuals not self-reporting knowing their HIV-positive status. Individuals who choose to have an HIV test can test alone, as a couple or as a household group (Shanaube, Schaap et al. 2017). CHiPs refer individuals found to be HIV-positive to government clinics for linkage to HIV care and 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 (STI). For individuals symptomatic for TB and STI, the CHiPs refers individuals 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 initially absent or those who previously declined HTS (Shanaube, Schaap et al. 2017).

Figure 1. Schematic of the services offered through the PopART intervention



3.2 The HIVST intervention

In four communities randomised 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, about 500kms from Lusaka; one in Central Province, almost 200kms from Lusaka. Within the four communities, we randomly allocated sixty-six CHiP zones to either the HIVST intervention or PopART standard of care (non-HIVST zones).

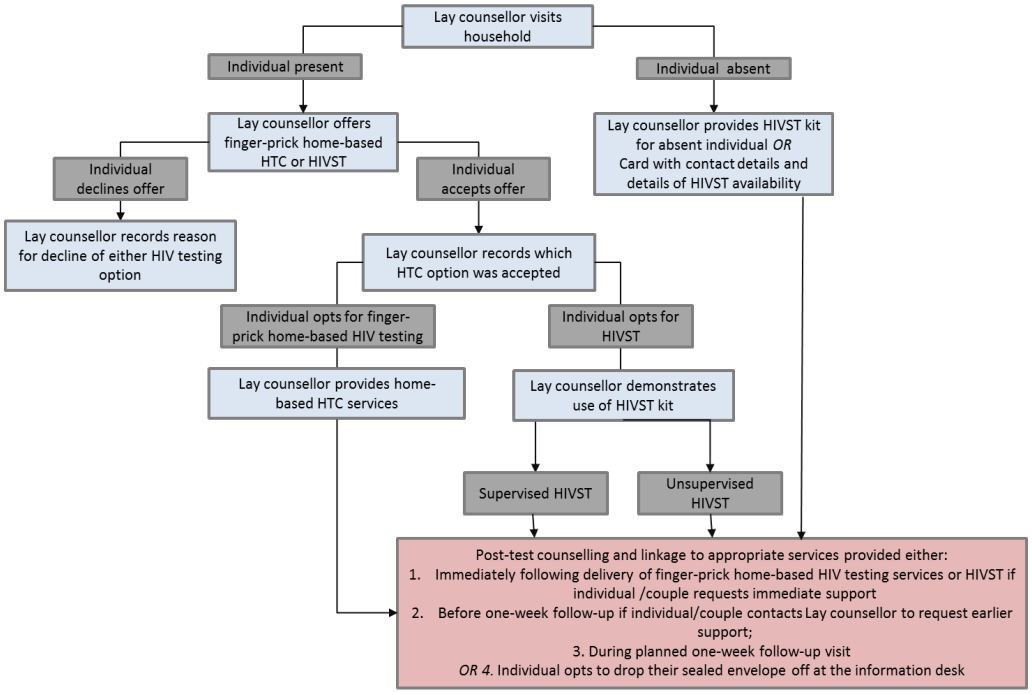
In zones randomised to the HIVST intervention, CHiPs provided a choice for how to test for HIV to individuals choosing to have an HIV-test (Figure 2). CHiPs provided information on the process of HIVST, the advantages and disadvantages relative to finger-prick HIV testing, and, for individuals opting to self-test, a demonstration of how to perform the test and read the results using a flipchart with step-by-step instructions as well as appropriately translated manufacturer's instructions for use (IFU) included in the HIV self-test kits. The level of supervision offered to an individual opting for HIVST was dependent on the individual's preference. If an individual 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 any help requested.

If the individuals opted to HIVST after the CHiPs visit (unsupervised HIVST), CHiPs conducted a follow-up visit within seven days of leaving an HIVST with an individual. During a follow-up visit, CHiPs collected the HIV self-test, read the results of the HIV self-test (unless the individual did not want the CHiPs to read the result), provided post-test counselling and linked the individual to treatment and care, or prevention services as per PopART standard of care. For individuals who did not disclose their HIV self-test result, CHiPs provided generic post-test counselling suitable for an HIV positive or negative result. CHiPs informed individuals opting to test in the absence of the 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 using the test kit. This form was adapted from a form used in an ongoing cluster-randomised trial of distribution of HIVST by community-based distributors in other communities in Zambia (Self-testing for 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 CHiPs 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 counsellors)



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 HIV-tests (RDT) (Determine HIV-1/2™ and Uni-Gold™). CHiPs counselled individuals with a (confirmed) HIV-positive diagnosis and advised them to attend the ART clinic. Once at the clinic, 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 counselling on the value of treatment and care services. For males testing HIV negative, CHiPs made a referral to VMMC services.

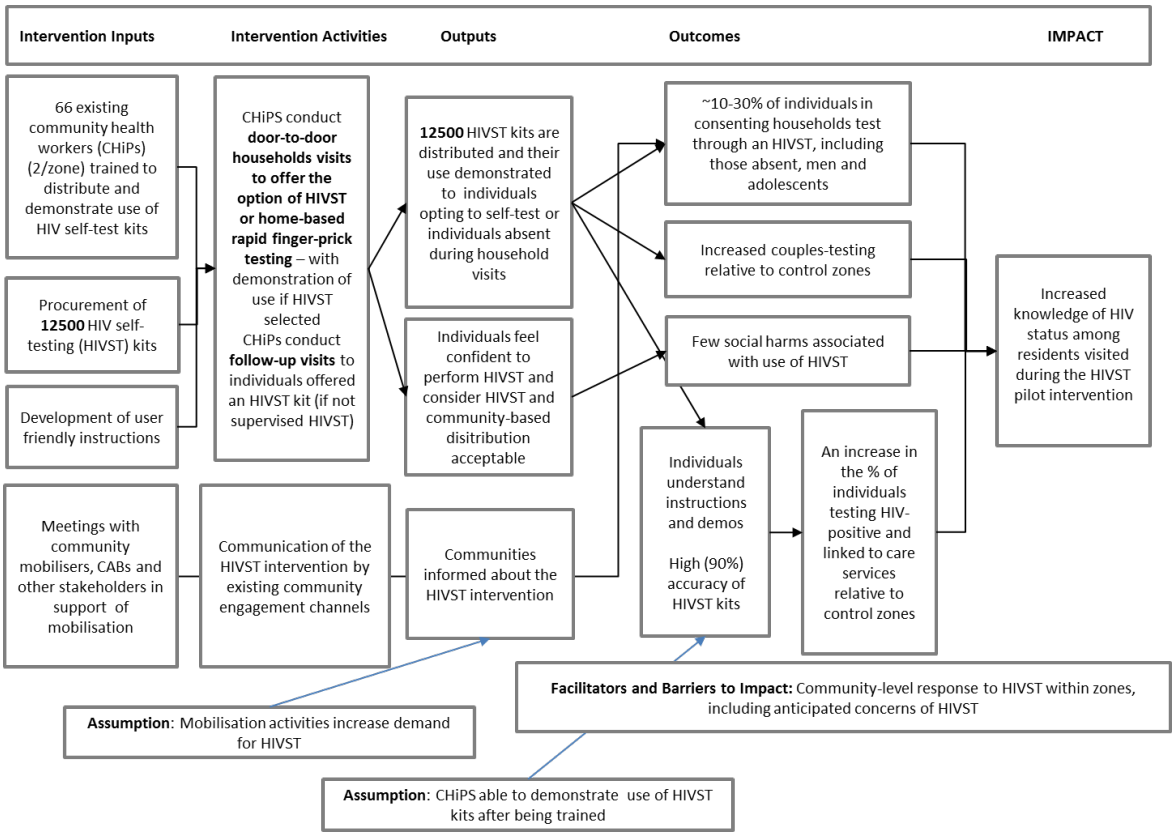
Community engagement played a key role in creating awareness, promoting HIVST services, and securing buy-in from intended beneficiaries. Community engagement built on the existing capacity established for the HPTN071 (PopART) trial, which selected community representatives to sit on representational 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 zones randomised to the intervention about the benefits of HIVST, explained the role of the 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 HIVST was promoted within the concept of universal test and treat.

3.3 Study rationale, theory of change and hypothesis

We hypothesised that the door-to-door offer of a choice of how to test for HIV, which included the option to HIV 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 faced in accessing HTS, such as the direct costs and opportunity costs of accessing facility-based services (Morin, Khumalo-Sakutukwa et al. 2006), and of accepting an offer of home-based HTS specifically, including perceived lack of confidentiality of HTS delivered by healthcare providers, the lack of autonomy of available HTS services, the time at which home-based HTS is offered being unacceptable, particularly to men, and fear of finger-prick HIV testing.

For household members not contactable by the CHiPs, primarily men, we hypothesised that secondary distribution of HIVST would be more convenient to men as they could then HIV test at a time that suited them rather than need to be home or HIV 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 when HIV testing and make 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. Hypothesised 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 the CHiP. We conducted sub-groups analyses by sex, age (adolescents and young people aged 16-29 years, compared with older adults aged ≥30 years), 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 HIV self-test kits distributed by CHiPs, the number of kits 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 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 test using 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
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 randomised 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 self-test kit quality assessment and control. On 18 January 2017, the 33 zones randomised to the HIVST pilot intervention started the 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 two 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 (LSHTM) 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 who participated 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 cluster-randomised trial. Within each community, we restricted randomisation on knowledge of HIV status and decline of an offer of HTS 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 to HIVST, whether the individual opted for supervised or unsupervised HIVST, whether an HIVST kit was provided for an absent individual and/or for couples 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, Floyd et al. 2017). Prior to the start of the study, we modified the EDC to allow CHiPs to collect data specific to HIVST. For individuals absent during household visits, the device 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 a HIVST, whether the individual opted to test in the presence or absence of the CHiP, whether an absent individual used an HIVST kit that was 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 individuals enumerated during this period and choosing to HIVST, 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 for 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 were followed-up, we used the Kaplan-Meier method for time-to-event analysis to estimate the proportion of individuals linked

to HIV care by 3-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 3 months of referral, we estimated a “minimum” estimate of the percentage of individuals who linked to care by 3 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 analysed data at the individual-level, using population average (PA) 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 cluster randomized trial with 33 clusters per trial arm, we expected there to be balance across the two trial arms in factors likely to influence knowledge of HIV status. We, however, 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 by 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 PA logistic regression models. We obtained corresponding p-values from a Wald test.

5.2.1 Randomization

On 9 December 2016, all the PopART intervention staff including CHiPs, supervisors to CHiPs, HIVST nurse, and 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 the study 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 randomisation ceremony in a two-stage process. CHiPs provided group verbal consent for randomisation of their zones to the HIVST intervention or PopART standard of care. In the first stage, using a randomly selected list of 9999 possible allocations, four individuals selected four numbered balls from a bag (Appendix C). This four-digit number corresponded to an allocation number that allocated each zone to either group 0 or 1. In the second stage, the randomisation determined whether group 0 or 1 would be allocated to the HIVST intervention.

5.2.2 Study power

The study had >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 ~400 adults enumerated per zone across the 33 zones per trial arm. The study had power of ~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 (IDI; n=40), and focus group discussions (FGD; 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 the Neighbourhood 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 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 to observe household visits to understand and document community response to HIVST and its impact on social relations. Research assistants also accompanied the CHiPs on the follow-up visits if a 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, counselling approach, description of behaviour and interactions of CHIPs and household members. We conducted daily debriefings to crosscheck findings emerging from these observations and discuss emerging themes. We fed these emerging themes into the design and development of IDI and FGD guides.

We conducted Phase 2 in the second and third month 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, and 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 and impact of HIVST on CHiPs and community response to HIVST. Research assistants

conducted these discussions in English or Bemba at the clinic or at 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 short 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 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 i.e. those that choose an HIVST or opted not to HIVST, 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 CHiP views of 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 FGD and number of 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 made to study management, reports on community engagement activities, and the 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 the existing PopART processes, which involved discussions between the CHiPs that identified an incident and the supervisors. Identification and categorisation 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 of social harms. CABs and community meetings specifically asked for any social harms 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 between the CHiPs. HIVST participants were also encouraged to call research staff using the calling card that was left with them during distribution of the HIVST kit.

To better understand whether the 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 on-going 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. We 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 was coded using the codes from the code book 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, Sculpher et al. 2005).

Resource use data were sequentially and prospectively collected between 1 December 2016 to 30 June 2017. Costs were adjusted to 2017 United States dollars (US$) using an assumed exchange rate of ZMW9.50. Data sources included financial records, CHiPs' monitoring and evaluation (M&E) records and interviews with intervention team. Table 3 outlines key cost components of this analysis. This report presents only observed costs.

Table 3. Costs included in the costing of the pilot HIVST intervention

Component	Description
Intervention costs	These were the 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 cost of supplies that directly support implementation of the intervention; e.g. stationary (including teaching aid reproduction) and extra bags for the HIVST kits. Personnel costs for additional supervision.
Research Costs	Included costs which were 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. For example the cost of sensitization meetings with Ministry of Health at central, provincial and district levels and community sensitization meetings.
Quality Assurance	Costs of specific QA/QC 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 diem, accommodation and transportation – including personnel costs.
Set-up costs	These are costs which were 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 programme. Thus, all capital (i.e. 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 centres (Beck, Avila 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. Cost 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 line and second line HIV RDT 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 stationary 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 line and second HIV RDT supplies were calculated by multiplying the number of tests performed by unit cost of performing a test. For this calculation unit cost of the two HIV RDTs included the costs of 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 (LSHTM)), and personnel cost.

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, M&E activities, which are challenging to disentangle from evaluation costs but we considered as comprising of costs of outcome data collection and management. Other activities were community engagement, which included community sensitisation and mobilisation activities, quality assurance (QA), which were the costs associated to QA and control of the 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, QA and field work. Training, M&E and project administration where 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 spent time between research and intervention (Table 4). Cost of HIVST kits was calculated by multiplying the number of kits used by assumed landing costs of US$3.00, since these test kits were donated by the STAR project (http://hivstar.lshtm.ac.uk/). For HIVST positive result, parallel finger prick HIV testing was performed, which involved performing first and second line finger prick HIV tests concurrently. Cost of parallel finger prick HIV tests was calculated by multiplying number of HIVST positive results by its unit cost. Unit cost of parallel testing included the cost of 1 Determine kit, 1 UniGold kit, 1 pair of gloves, 1 lancet and 1 alcohol swab.

Costs related to activities before 1 February 2017, the day on which full implementation of the study started, were considered to be start-up costs and all costs from 1 February 2017 were considered implementation costs. All costs related to activities which happened prior to trial orientation and randomisation (9 December 2016) were considered to be research costs. Start-up costs were not annualised 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 1 February to 30 April 2017 to match the costing period. In the cost-effectiveness analysis, we used 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 numbers of newly diagnosed persons in the control arm (ℓ) from newly diagnosed persons in the intervention arm ($\mathcal{L}$).

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

5.4.5 Cost analysis

In our cost cost-effectiveness analysis, we only considered intervention related costs. We calculated 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 (C) is defined as the difference between the cost of the intervention (j) and control (ı) arms. In our case, C= the cost of implementing HIVST interventions (Ĵ) plus the cost of PopART interventions (í), and the cost of control arm is the cost of implementing PopART intervention (í).

$$C = j - ı$$

$$j = Ĵ + í$$

$$C = (Ĵ + í) - ı \qquad (1)$$

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.

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

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 and those that varied across communities. This is presented in Appendix I: Appendix table 1. Features common to all community sites included certain infrastructure: 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, Chiti 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, Hoddinott 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 summarised in Appendix table 1. This “thick” description of the study sites could aid transferability of results to other settings that are similar. 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, with 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 roomed). 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 was challenging in all communities but more particularly in Community 3 and 4 and in 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 the likely popularity of HIVST and secondary distribution of HIVST.

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 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 behaviour. 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 centre of town; Community 2 slightly further away. Mobility was pronounced in all communities with traders moving in and out, with Community 1 particularly porous and chaotically mobile. Formal employment in Community 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 considered 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 as well as improved 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 ART.

Drawing on an analysis of what differences make the difference to the uptake of HIV services, we can identify what features helped or hindered the introduction of HIVST. (Bond, Chiti et al. 2016). Hence, more middle-class, being closer to the town centre, having a larger scale informal economy, having more livelihood linked mobility, having fewer HIV stakeholders over time and having less commitment to community action increased resistance to HIVST when it was introduced. 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 fit with their desire for confidentiality. 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 as the most open to new initiatives; with Community 2’s relative distance from the centre of town and stronger presence of middle class making 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 seen by the CHiP 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) did 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% (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 mobilisation 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 visitations (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), 51.0% (n=6,769) were aged 16 to 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 to 29.

Table 6. Description of the participants enumerated in the HIVST and non-HIVST arm 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 the 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 % (n=1,942) were male in the HIVST and 70.9% (n=2,140) in the non-HIVST zones (Figure 5).

In HIVST zones, 90.5% (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% (n=9,304) were eligible for HTS. Among individuals eligible for an offer of HTS, 42.0% (n=3,787) in the HIVST zones and 41.8% (n=3,890) in non-HIVST zones were men. Over half of individuals eligible for HTS were aged 16 to 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)

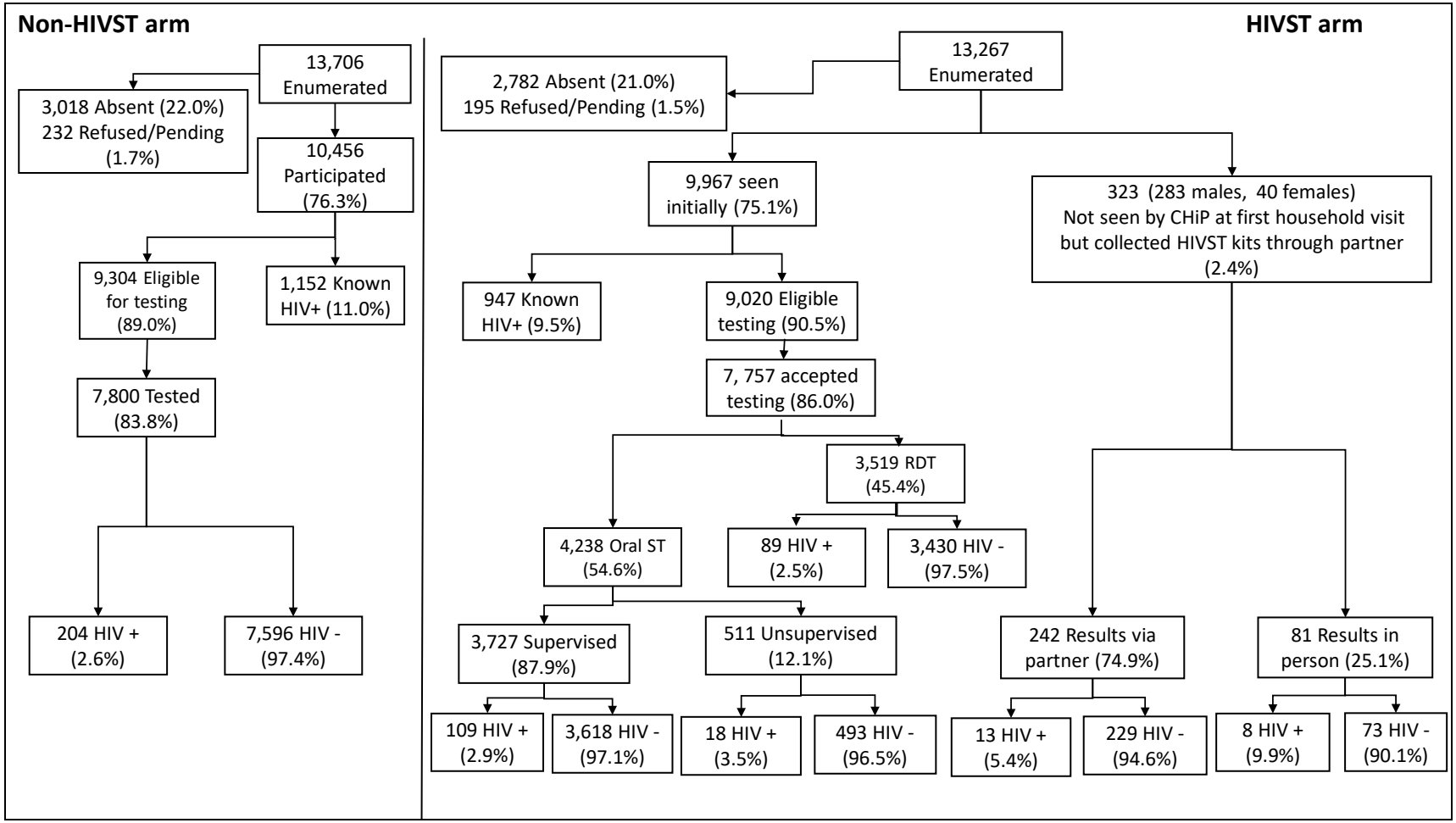


Figure 5. Flowchart of enumeration, participation in the study and uptake of HIV testing services among men

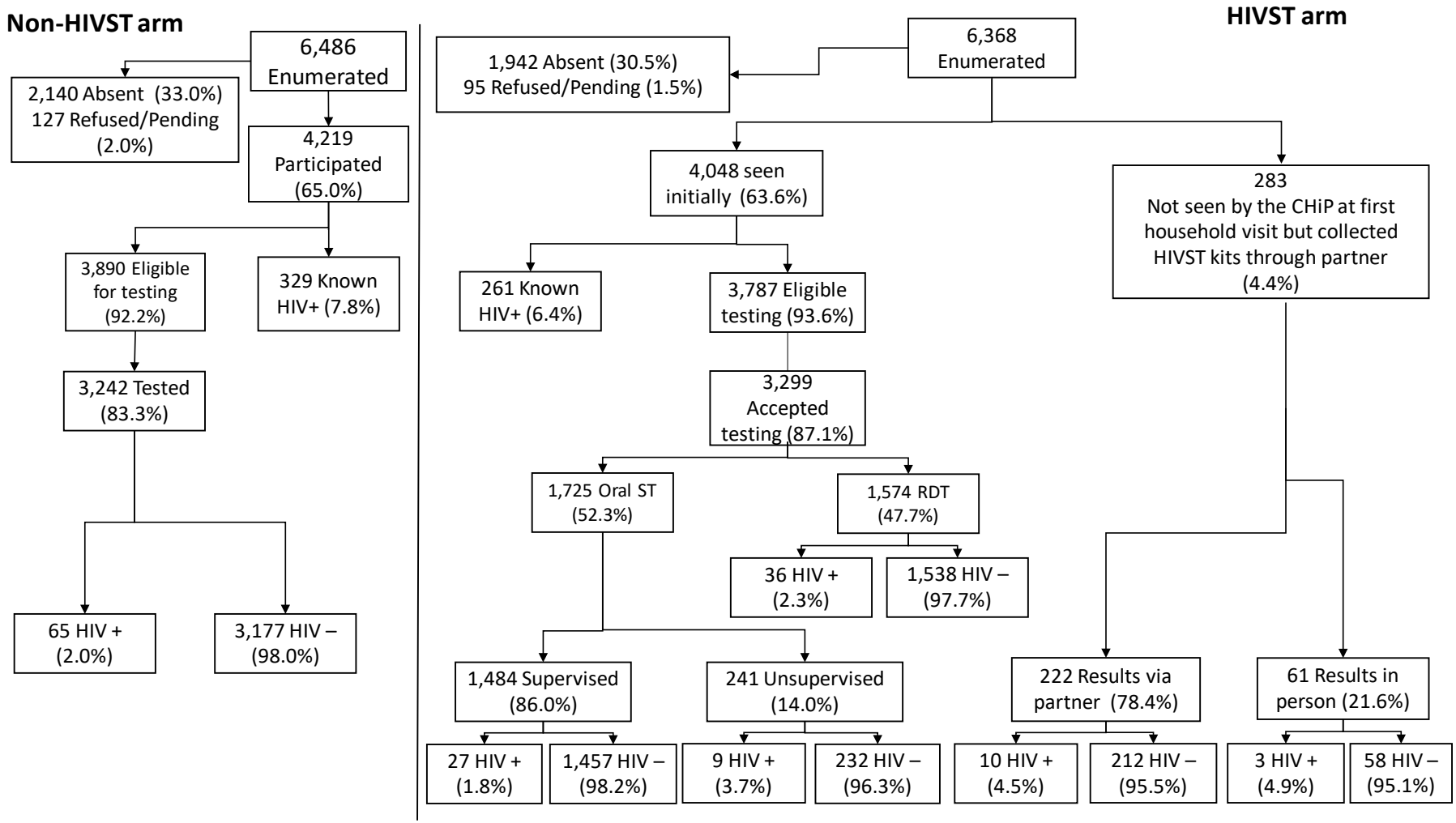
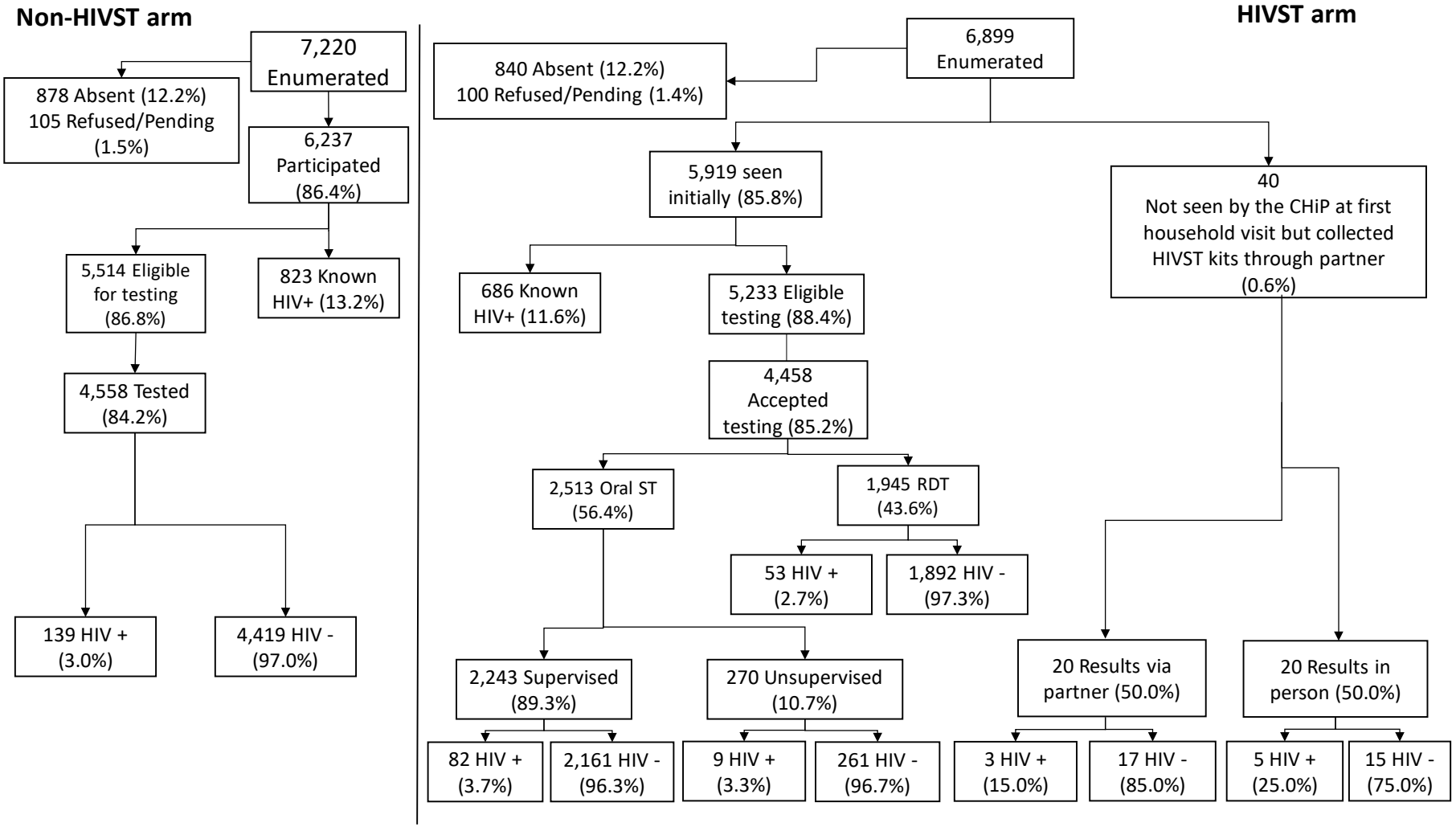


Figure 6. Flowchart of enumeration, participation in the study and uptake of HIV testing services among women



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 testing through finger-prick HIV testing, and 323 testing 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 & Figure 4).

There was strong evidence that the effect of the HIVST intervention differed by sex (p-value for effect modification=001), 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 levels of knowledge of current HIV status similar in the non-HIVST zones (n=5,381/7,220; 74.5%; adjOR 1.05; 95%CI 0.86-1.30; p=0.62).

By age, 73.5% (n=4,972/6,769) of individuals aged 16 to 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% (n=4,055/6,498) knew their current HIV status in HIVST zones compared to 60.2% (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% (n=173/583) of these individuals knew their HIV status compared to 20.6% (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 table 2 (Appendix J).

By community, the largest effect on knowledge of current HIV status was observed in Community 2 (64.0% vs 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% (n=10,290/13,267) participated in PopART, either through consent with the CHiP or secondary distribution of HIVST, in the HIVST zones compared to 76.3% (n=10,456/13,706) in the non-HIVST zones (p=0.06).

Among females, 86.4% 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% (n=4,833/6,498) in the HIVST zones and 72.9% (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 Round 1 and 2 of the PopART intervention, but who did not participate in either round. In HIVST zones, 36.4% (n=212/583) participated in PopART Round 3 compared to 28.0% (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 second round 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 it took CHiPs longer to enumerate and consent households in the HIVST zones, as is reflected in the higher 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 those individuals who were seen and participated in the PopART intervention, uptake of HTS was similar across the HIVST and non-HIVST zones (86.5% vs 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% vs 84.2%, respectively; p-value for effect modification by sex=0.004).

By age, there was evidence for an effect among younger adults aged 16 to 29 (90.8% vs 87.8%, respectively; adjOR=1.41; 95%CI 1.07-1.85; p=0.01) and weaker evidence for an effect among older adults (80.9% vs 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 Round 1 or 2 of PopART, despite being community residents

during previous rounds of PopART service delivery, accepted an offer of HTS in HIVST relative to non-HIVST zones (80.9% vs 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 PopART intervention delivery is presented in Appendix table 4 (Appendix J). 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 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 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 or unsupervised HIVST and those

testing through secondary distribution was similar across all age groups: nearly 88% opted for supervised HIVST, 11% opted for unsupervised and 2% HIVST through secondary distribution.

Unlike with women, how men HIVST differed by age group. Ten-percent (n=114/1161) of men aged 16 to 29 opted for unsupervised HIVST compared to 15.0% (n=127/847) of men aged ≥30 (Table 10). Among men aged ≥30, 23.4% (n=198/847) were tested through secondary distribution compared to 7.3% (n=85/1161) of those aged 16 to 29. Overall, 40% of men aged ≥30 HIVST either through unsupervised HIVST 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)
Males 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, either after first testing with a finger-prick HIV test or after first testing with HIVST (Table 11). This includes 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, testing HIV-negative, but when subsequently seen by the CHiP and had a reactive HIVST.

Among these 242 individuals, 83.1% (n=201/242) either first tested with finger-prick HIV testing (n=89) or they linked to confirmatory testing after testing HIV-positive on HIVST (n=112), and 98.5% (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, and 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% (n=16/17) were linked to confirmatory testing and confirmed HIV-positive.

Where HIVST was through secondary distribution, none of the thirteen 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 did 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% (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 an HIV 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)**

*3 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 HIVST via secondary distribution and who the CHiPs had not been able to contact in person. Among the 215 individuals contacted in person by the CHiPs, 93% (n=200/215) were referred to HIV care; among whom 8% (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% (n=199/204) were referred to HIV care.

Among those referred to care, overall in HIVST zones, 62.5% (n=125/200) were followed-up at least once after referral to HIV care, and in non-HIVST zones 64.8% (n=129/199). The Kaplan-Meier method for time-to-event analysis estimated that, in HIVST zones, overall 64.8% had linked to HIV care by 3 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 3 months after referral was 41.0% (n=82/200) in HIVST zones and 41.2% (n=82/199) in non-HIVST zones.

6.9 Qualitative results

6.9.1 Factors influencing a decision to HIVST (Objective 1)

The main social factors driving the decision to HIVST were: having previously tested HIV-negative; being busy, being mobile, being a married working man, or belonging to a more marginalised 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. Counselling was still considered important for those who chose to self-test, particularly if someone tested HIV-positive. Popular options for counselling were being counselled 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 visibly relieved when she had a 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’*; the sex worker, alcoholic, teacher, miner and 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 man 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 pressurised 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 with one couple, where the husband always refused HIV testing, the husband 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 it 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 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 husband, 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 counselling 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, neighbours 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, rumour 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 a 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, rumours, *'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 counselling if an HIV test was self-administered, and most respondents believed that counselling was still very important, particularly if someone tested HIV-positive. A sex worker who tested herself said she thought counselling after an HIV-positive test would help *'calm people down, especially those who would otherwise want to kill themselves'.* A trader emphasised the importance of being *'guided how to live after testing'*, and a young adolescent man stipulated that *'it is through counselling 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 counselling HIV-negative people was equally helpful in the community, assisting them to '*live better healthier lives'*. There were a handful of respondents who thought counselling linked to HIVST was not valuable.

Respondents identified various counselling options as appropriate after HIVST, including face-to-face counselling as individuals or couples, and telephone counselling. Different circumstances would dictate which counselling option was most appropriate; for example, unmarried individuals should be counselled alone and married people should be counselled as couples. One couple who tested together using HIVST stated that counselling and testing together and sharing results was important so that they could know each other's status and take better care of one another. Being counselled by '*strangers'* or professionals or clinic counsellors was preferable to being counselled by those that knew you. Family counselling was considered by many to be more *'tricky'* due to stigma and resulting discrimination, and *'traditional'* counselling (counselling 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 counselling *'could lead to rumour mongering and spreading private information'.* A few respondents were more in favour of family counselling since it would facilitate care and support.

6.9.2 Anticipated and actual social harms (Objective 2)

Relatively few actual 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 freely talk to CHiPs or the community representatives, the CABs, about negative social experiences. In any case, women are usually advised not to discuss their marital challenges in public. One woman FGD respondent said 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.

The reported social harms (Table 12) can be graded on a scale ranging from the 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. Discordancy 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. For a 17-year old domestic worker, her distress came about 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 the 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 some ways by which social harms could be detected. Devising reporting mechanisms within each community was suggested as one way for detecting social harms. 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. Responding to "warning signs" and thereby deciding to not offer HIVST was another strategy suggested by FGD and key informant respondents. '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 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 community lay workers.

Counselling and education/sensitization were the 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 counselling 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 the 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 upon testing 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 got two HIVST kits; one for his wife whom he forced to test. He was negative while his wife was 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 her 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 doing the actual 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 was going 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.

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. One day 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 the first day 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 neighbours 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 really disturbed. The CHiPs visited her several times to give her support.

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 counsellor 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 the one who found at home by CHiPs and he collected the kits for himself and his wife. The CHiPs received a call to go and pick 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 CHiPs supervisor.
Monitoring visit	Case Study	Gender-based violence and threatening suicide	Both the husband and the 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 went for 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 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 the 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'* which he was not confident he could use correctly. For some participants, challenges arose from swabbing techniques. There were a few individuals who 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 the challenges that came it the novelty of the test, conducting and interpreting the results, either after a demonstration by the CHiPs or unsupervised, was relatively straightforward for most. The clients 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, but, although literate individuals found it easier to test without assistance from the 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 needs a confirmatory test and linking to care.

Avoiding the 'pain' associated with a finger prick HIV test was one incentive for opting 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. A few individuals talked to about HIVST complained about the perceived volume of blood taken during the HPTN071 (PopART) population cohort study.

There were however mixed feelings about and some participants questioned the accuracy of the HIVST kit 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. A few 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 CHiPs to 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 the CHiPs to collect kits while busy individuals often left the kits with their partners for 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 a 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 market place 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 that there is need to make such distribution-points stigma free and not turn them into clinics. There was a strong emphasis on pre-and post-test counselling from all groups. This was important to facilitate confirmatory tests, 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 the back packs of CHiPs 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 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 didn't have time to go to the clinic. Women would sometimes collect kits to test (and/or test with) their husbands. The link to counselling 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 from an appropriate sex and age. *"People feel comfortable to talk to fellow youths or elderly counsellors",* one CHiP explained. For example, some elderly household members said they felt uncomfortable being counselled on STI 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 counselling) and then attending to those that wanted to test individually. This strategy quickened 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 counselling 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 HIV-status and with discordancy, 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 Market place Church youth clubs Anti-AIDS club at school Colleges and universities Pharmacies and drug stores Kiosks Secondary distribution (through guardians)	These places were seen as areas where young people are found. For example, in colleges and universities you will find many adolescents above 18 in one confined place.
Adult Women	Clinic (including Antenatal) Market place 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 kiosk and pharmacies because many women are involved in church activities; they also perform domestic work such as drawing water from kiosks. They often visit pharmacies. Bus stops are good distribution points because many women are found trading there.
Adult Men	Clinic Work place Market The home of CHiPs Bars Stadiums and other social places Churches Community pharmacies Community set/zone specific points Bus stop Fishing camps Kiosks Family and friends network Secondary distribution	To reach men and other hard to reach persons the preference was to distribute the kits at work places because that is where they are often found. Other men are found at different recreational places and facilities and hence these can be used for distribution. For fishermen, they gather at fishing camps and can be reached by CHiPs visiting them.

CHiPs	Home delivered Secondary distribution for young people Kiosks Workplaces Churches Drugstores and pharmacies Recreation centres 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 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

6.7.1 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 & mentorship	2,232.86	5,867.86	8,100.71
Implementation planning	2,035.82	0.00	2,035.82
Trial Design & Preparation	28,706.49	0.00	28,706.49
Project co-ordination/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 & 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 co-ordination/administration	46,900.82	20,916.05	67,816.88
Quality Assurance	205.73	1,212.34	1,418.07
Community mobilisation	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% (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 test supplies	677	296
Sub-total costs	***172,069***	***159,610***
HIVST costs		
Personnel		48,456
Administration		9,844
Transportation & 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 and UniGold tests are performed to confirm a reactive HIVST result

6.7.2 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 HIVST, 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 HIV current status among younger (aged 16 to 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 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 the 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 evidence that linkage to HIV care 3-months after referral to care among individuals newly diagnosed HIV-positive and referred by the CHiP for HIV care services differed in the HIVST and non-HIVST zones. 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 HIV testing services. 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 men. The qualitative research suggested that Community 2 might be a promising setting for HIVST, due to its relative distance from a town centre and larger middle-class presence. The quantitative results showed stronger evidence of an effect of the intervention on the primary outcome in Community 2. This quantitative finding needs to 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, marginalised or higher status groups and for women to 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 the limited secondary distribution, the role of CHiPs and to 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, the occurrence of these is 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 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 marginalised identities who wished to test, but more problematic if people tested HIV-positive and needed to link to counselling and care. Respondents emphasised that counselling, especially for people testing HIV-positive, was critical to provide continued support and information. There was a surprising preference for being counselled by healthcare workers they did

not know, either face-to-face or via telephone, over family counselling or traditional counselling. This was contrary to the CHiPs experience that the acceptability and uptake of HIVST built on their familiarity with and rapport in households, and their envisaged counselling role in future HIVST distribution, as well as contrary to their actual role in alleviating social harms.

Some respondents, particularly the NHC 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 by individuals not having to 'be seen' (and thereby gossiped about) accessing HTS at the clinic. However, HIVST doesn't 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 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 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 intervention implementation was done 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 which develop over time as the lay-counsellors and the population become more comfortable with this method of testing. By not including PopART start-up costs, this 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 CHiP 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, Floyd 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, Floyd et al. 2017). Men

remained harder to contact than women. We anticipated that offering an HIVST to women to give to their absent male partners would 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, Agot et al. 2016, Thirumurthy, Masters et al. 2016). We found that the secondary distribution of HIVST outside of facility settings is effective at reaching men in Zambia. The costs of reaching these hardest to reach groups may be expected to be higher than for when such an intervention is provided 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 HIV testing services.

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 therefore less likely to know their HIV-positive status and link to care (WHO 2011, Hensen, Taoka et al. 2014, Shand, Thomson-de Boor 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 policy-makers and programmers in their decision-making on strategies to implement 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 initiative STAR intiative, findings from this study provide evidence to inform the development of any WHO normative guidance on how to deliver HIVST services and international policy.

HIVST was a novel strategy in these 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 on HIVST, which may have reduced the time needed for explanation and further increase efficiency, thereby reducing costs. With time, as HIVST becomes less novel, the individuals found at home and opting for supervised HIVST at the time of the CHiP visit may have instead opted for finger-prick HIV testing, which may be a more cost-efficient approach and which 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 need attention. These include local context, target populations, information about using the kit and HIV in oral fluids, the implications for counselling, lay counsellors and linkage to services and the management of social harms. We

recommend 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, 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 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 counsellors.

Detailed and careful communication and information need to accompany distribution of HIVST kits, and this should include demonstrations and pictures. HIVST reduces contact with counselling, lay counsellors and health facilities and, whilst that has some advantages for relieving the health system and individuals' time, for those that test HIV-positive reduced contact can make post-test counselling and linkage to care harder to achieve. Lay counsellors have a clear role in providing counselling, facilitating linkage and managing kit disposal. Social harms linked to HIVST are hard to detect, particularly if less severe and culturally embedded. At household-level, it is advisable to only introduce HIVST through lay counsellors 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 counsellors become more familiar with offering HIVST and communities 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 than non-HIVST zones. This suggests that there were possible economies of scale in HIVST zones, and that, if the programme were to run for more time, CHiPs might have become more efficient at offering HIVST to individuals that would not be reached by finger-prick HIV testing services.

We calculated 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, Marshall et al. 2006). According to

WHO guidelines (WHO 2001) a programme is considered cost effective if the ICER is <3-fold the gross domestic product (GDP) per capita and very cost effective if the ICER is <1-fold the GDP per capita. In 2016, the per capita GDP in Zambia was US$ 1,178.39 (WorldBank 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, Ochalek 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 needs to be interpreted with caution as we did not assess the uncertainty surrounding our ICER and as reported earlier, and 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 testing for HIV, it will be important to know that individuals at risk 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 the costs will reduce further as community workers will need to spend less time on explaining the test and can limit their input to those 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 delivering HTS and reach those who are not being reached by offering finger-prick HIV testing services, CHiPs are offering HIVST preferentially to individuals who do not want to test using a finger-prick HIV test and for 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 programme, to support 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 which 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/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-a.pdf

Online appendix B: Quantitative Questionnaire
http://www.3ieimpact.org/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-b.pdf

Online appendix C: Restricted randomisation of HIVST studyOnline
http://www.3ieimpact.org/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-c.pdf

Online appendix D: HPTN 071 information sheet and verbal consent form
http://www.3ieimpact.org/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-d.pdf

Online appendix E: VCT Consent form

http://www.3ieimpact.org/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-e.pdf

Online appendix F: Absent Member form
http://www.3ieimpact.org/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-f.pdf

Online appendix G: FGD and KII Information Sheets and Consent Forms
http://www.3ieimpact.org/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-g.pdf

Online appendix H: Qualitative data collection tools
http://www.3ieimpact.org/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-h.pdf

Online appendix I: Distinctive features of the HIVST study sites
http://www.3ieimpact.org/media/filer_public/2018/10/01/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/media/filer_public/2018/10/01/tw2218-hivst-zambiart-online-appendix-j.pdf