Feasibility and Acceptability of self sampling kits to increase the uptake of HIV testing among black Africans in the United Kingdom: The HAUS Study

Maureen Seguin[1], Catherine Dodds[2], Esther Mugweni[1], Lisa McDaid[3], Paul Flowers[4], Sonali Wayal[1], Ella Zomer[5], Peter Weatherburn[2], Ibidun Fakoya[1], Thomas Hartney[6], Lorraine McDonagh[6], Rachael Hunter[5], Ingrid Young[7], Shabana Khan[8], Nick Fremantle[8], Jabulani Chwaula[9], Memory Sachikonye[10], Jane Anderson[11], Surinder Singh[5], Eleni Nastouli[12], Greta Rait[6,8], Fiona Burns[1,13]*

Author's affiliations

1. Research Department of Infection & Population Health, University College London (UCL), London, UK

2. Sigma research, London School of Hygiene & Tropical Medicine, London, UK

3. MRC/CSO Social & Public Health Sciences Unit, University of Glasgow, UK

4. School of Health & Life Sciences, Glasgow Caledonian University, UK

5. Research Department of Primary Care and Population Health, UCL, London UK

6. National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections at UCL

7. Usher Institute of Population Health Sciences and Informatics, University of Edinburgh

8. PRIMENT Clinical Trials Unit, Research Department of Primary Care and Population Health, UCL, London UK

9. BHA, Leeds, UK

10. UK-CAB, London, UK

11. Centre for the study of sexual health and HIV, Homerton University Hospital NHS Foundation Trust, London UK

12. Virology Department, University College London Hospitals NHS Foundation Trust

13. Royal Free London NHS Foundation Trust, London UK.

*Corresponding author: f.burns@ucl.ac.uk

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Abstract

(word count 500)

Background:

Timely diagnosis enables access to antiretrovirals, which reduces mortality, morbidity, and further transmission in people living with HIV. In the UK late diagnosis among black African people persists. Novel methods to enhance HIV testing in this population are needed.

Objectives:

To develop a self-sampling kit (SSK) intervention to increase HIV testing among black Africans using existing community and healthcare settings (Stage I) and to assess feasibility for a Phase III evaluation (Stage II).

Design: A two stage, mixed-method design. Stage I involved a systematic literature review, focus groups and interviews with key stakeholders and black Africans. Data obtained provided the theoretical base for intervention development and operationalisation. Stage II was a prospective, non-randomised study of a provider-initiated, HIV SSK distribution intervention targeted at black Africans. The intervention was assessed for cost effectiveness. Process evaluation explored feasibility, acceptability and fidelity.

Setting:

12 GP practices and 3 community settings in London.

Main outcome measure:

HIV SSK return rate

Results:

Stage I: The systematic review revealed support for HIV SSKs, but with scant evidence on their use and effectiveness among black Africans. Although the qualitative findings supported SSK distribution in settings already used by black Africans concerns were raised about the complexity of the SSK and the acceptability of targeting. These findings were used to develop a theoretically informed intervention.

Stage II: Of 349 eligible people approached, 125 (35.8%) agreed to participate. Data from 119 were included in the analysis. 54.5% (65/119) of those who took a kit returned a sample; 83.1% of tests returned were HIV negative. 16.9% were not processed due to insufficient samples. Process evaluation showed the time pressures of the research process to be a significant barrier to feasibility. Other major barriers were difficulties with the SSK itself and ethnic targeting in GP settings. Convenience and privacy of SSK were described as beneficial aspects. And those who used the kit mostly found the intervention to be acceptable. Research governance delays prevented implementation in Glasgow.

Limitations:

Due to the study failing to recruit adequate numbers (intended sample 1200) we are unable to evaluate the effectiveness of SSKs in increasing HIV testing in black African people. No samples were reactive so we were unable to assess pathways to confirmatory testing and linkage to care.

Conclusions:

Our findings indicate that although aspects of the intervention were acceptable, ethnic targeting and the SSK itself were problematic, and scale up of the intervention to a Phase III trial isnot feasible. The preliminary economic model suggests that for the acceptance rate and test return seen in the trial, SSK is potentially a cost-effective way to identify new cases of HIV.

Future work:

Sexual and public health services are increasingly utilizing self-sampling technologies however alternative user-friendly SSKs that meet user and provider preferences and UK regulatory requirements are needed, and additional research is required to understand effectiveness and cost-effectiveness for black African communities.

Study registration:

PROSPERO registration number: CRD42014010698. IRAS project ID 184223

Funding details:

NIHR HTA Programme; BHA for Equality in Health & Social Care.

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Alphabetical list of abbreviations

Ab	Antibody
Ag	Antigen
APEASE	Affordability, practicability, effectiveness and cost-effectiveness, acceptability, site-effects/safety, and equity
BASHH	British Association of Sexual Health and HIV
BHIVA	British HIV Association
CBO	Community-based organisation
CE	Conformité Européene
CNWL	Central and North West London NHS Foundation Trust
COM-B	Capability, opportunity, motivation, and behaviour model of behaviour change
CRN	Clinical Research Network
CW	Community Worker
FGD	Focus Group Discussion
GP	General Practice
GUM	Genitourinary medicine
HA	Health Advisor
HCA	Health Care Assistant
HIV	Human Immunodeficiency Virus
HRA	Health Research Authority
ICER	Incremental cost-effectiveness ratio
IDHS	Data safe haven

IDU	Injection drug user
IRAS	Integrated Research Assessment System
MHRA	Medicines and Healthcare Agency
MMC	Mortimer Market Centre
MRC	Medical Research Council
MSM	Men who have sex with men
NATSAL	National Survey of Sexual Attitudes and Lifestyles
NHS	National Health Service
NICE	National Institute of Health and Clinical Evidence
ONS	Office of National Statistics
OR	Odds ratio
PHE	Public Health England
POCT	Point of care testing
QALY	Quality adjusted life years
PN	Practice Nurse
R&D	Research and Development
RCT	Randomised controlled trial
SPCRN	Scottish Primary Care Research Network
SSK	Self-sampling kit
STI	Sexually transmitted infection
STK	Self-testing kit
TDF	Theoretical Domains Framework
TDL	The Doctor's Laboratory

THT	Terrence Higgins Trust
UCL	University College London
UCLH	University College London Hospital
UK	United Kingdom
UK-CAB	United Kingdom Community Advisory Board
USA	United States of America

Glossary

Non-specialist	A person who does not work in field of sexual health or HIV
Service provider community	Medical doctors, nurses, health care assistants, and providers of based sexual health and health promotion services.
Service user	Attendees of sexual health services, GP surgeries and of community based health promotion and HIV prevention services.

Scientific summary

(word count 2384)

Background

Black African people compose over half of heterosexuals living with HIV in the UK, and are more likely than other ethnic groups to present to HIV services with advanced infection. Reducing late presentation to HIV services is the most effective way to reduce morbidity and mortality attributed to HIV.

Innovative HIV testing methods are required to overcome challenges associated with traditional HIV testing options. Though community-based point-of-care testing, blood- and saliva-based self-sampling kits (SSK), and self-testing kits are increasingly available, the evidence base on the acceptability of such options to potential users and distributors is still weak - especially in regard to black African users. To address this evidence gap, the aims of the HAUS Study were: (1) To develop an SSK-based intervention to increase the provision and uptake of HIV testing among black Africans using existing community and healthcare provision (Stage 1), and 2. To conduct an evaluation of selected SSK distribution models to assess the feasibility of a future Phase III evaluation (Stage 2).

Objectives

The HAUS Study involved two sets of objectives.

Objectives for Stage 1

- Examine/evaluate barriers and facilitators to provision, access and use of HIV SSK by black Africans, in primary care, pharmacies and community outreach settings.
- Determine appropriate SSK-based intervention models for different settings.
- Determine robust HIV result management pathways.
- Develop an intervention manual to enable intervention delivery.

Objective of Stage 2

- Determine the feasibility and acceptability of a provider-initiated, HIV self-sampling kit distribution intervention targeted at black African people in two settings:
    - General Practice (GP) surgeries and
    - Community based organisations (CBOs).

Secondary objectives included:

- Establish acceptability of interventions for providers and users.
- Evaluate the effectiveness of self-sampling for HIV in increasing HIV testing by black African people.
- Determine the cost effectiveness of distributing the SSKs among black African people over other screening methods.
- Monitor ability to trace participants with reactive results, confirmatory testing and linkage into specialist care.
- Determine the cost per person kit distributed and cost per HIV diagnosis per setting.
- Assess the feasibility of collecting data for a lifetime cost-effectiveness model.
- Assess feasibility, and if appropriate, the optimal trial design (including sample size parameters) for future Phase III evaluation.

Methods

Stage 1

The objectives of Stage 1 were met through three activities:

1. A systematic literature and policy review,
2. Focus group discussions with non-specialists and service providers and one-to-one interviews with the latter, and
3. Developing a theoretically informed intervention.

The systematic review focused on the feasibility, acceptability and effectiveness of HIV self-sampling in increasing HIV testing. Only studies published since 1st January 2000 in English and conducted in the European Union/European Free Trade Agreement countries, North America, New Zealand or Australia were included. Ten electronic databases were searched and NICE quality appraisal tools were used (last search 3rd May 2016). All papers were appraised independently by two reviewers. PROSPERO registration number: CRD42014010698.

Qualitative methods were used to collect data using focus group discussions (FGDs) and one-to-one interviews. Ethical approval was obtained from the UCL Research Ethics Committee, project ID 3321/001.

Twelve FGDs were conducted: Six of which were with non-specialist members of the public who identified as black African and, and six with professionally, culturally and ethnically

diverse people who provide HIV and other social services to black Africans. From the latter group, nine participants also participated in one-to-one interviews. Analysis was undertaken using a 'blended' thematic approach drawing heavily on framework analysis. NVivo (version 10) software was used to synthesise and code data within a thematic matrix.

The development of the intervention manual for a feasibility trial in Stage 2 followed a systematic four-step approach drawing on the theoretical domains framework.

Stage 2

The objectives for Stage 2 were met through three activities:

1. A feasibility study,
2. A process evaluation, and
3. An economic analysis.

Feasibility study

GP surgeries and CBOs who serve black African communities were trained to offer the intervention during routine appointments or outreach activities. An enrolment log captured demographic information on all potential participants. An intervention script was provided to distributors to introduce the study. Only participants who self-identified as black African, were at least18 years of age, and able to provide informed consent were eligible. The recruitment target was 1,200 across sites in London and Glasgow. Ethical approval was obtained from the East of England- Cambridge South Research Ethics Committee (REC reference 15/EE/0412; IRAS project ID 184223).

Reasons for declining to participate were captured on the enrolment log. Participants also completed a baseline questionnaire, which collected demographic data and a brief risk assessment. The distributors then gave the participant a SSK, briefly explained how to use it and how results would be communicated. Unique ID numbers linked consent and baseline forms, to the kit itself. Paper forms were used in GP settings but either paper or electronic forms were available in CBO settings.

Kit users needed to return a form with three unique identifiers (initials, date of birth and unique ID number) to enable processing of the sample, and were invited to complete an acceptability questionnaire. Participants with negative results were informed by automated SMS delivered from the processing laboratory. If only a landline was provided, or the result

was reactive or unable to be processed (due to under filling of TINY vial or gross haemolysis) the results was passed to a senior Health Advisor (HA) who contacted the participants by telephone to notify them of the result and arrange follow up as appropriate. Postal code information was provided to the HA to enable referral to services appropriate to the participant.

Consent for participation in optional follow-up telephone interviews was obtained at study recruitment. Interviewees were purposively selected to provide diversity in gender, age, recruitment site, and study outcome (those who used and did not return a kit, and those with both negative and insufficient samples). Interviews lasted approximately 30 minutes, were recorded and transcribed verbatim, and interviewees were sent a £10 voucher for their time. Transcripts were coded and analysed using a thematic approach on NVivo software.

Process evaluation

The process evaluation investigated the acceptability, fidelity and reach of the implementation through analysis of ten data points: research diaries, training evaluations, enrolment and weekly logs submitted by distributors, site visit notes, observed data flow, communications between the study team and distributors, site summaries and close-down interviews, and qualitative interviews with study participants.

Economic analysis

A patient level simulation was developed to assess the cost-effectiveness of SSKs amongst black Africans in the UK compared to current practice. The model was developed using published data and results from the HAUS study to predict individual's transitions, costs and health outcomes. The model was created in Microsoft Excel 2010 according to methodological recommendations for evaluations of new health care technologies and interventions. A hypothetical cohort of 8,000 patients was tested under two different HIV screening arms: (i) intervention (SSK); or (ii) comparator (current practice).

Results

Stage 1

Thirteen studies were included in the systematic review, which originally located 4052 articles. The majority of papers focused on non-black African populations outside of the UK. Overall quality of the studies was mixed and relatively poor. Evidence to support the

acceptability, feasibility and effectiveness of SSKs to increase HIV testing was limited, and absent for black Africans people of all sexualities in the UK. A further 11 documents that contained guidance on HIV self-sampling or testing in the UK published between January 2008 and July 2016 were included in the policy review. Most of the policy guidance documents were not specific to SSKs. The reviews confirmed a need for well-conducted trials to assess if self-sampling interventions can increase HIV testing among all high-risk populations and black African people in particular.

The FGDs and one-on-one interviews revealed concern over the amount of time that providers had (particularly general practitioners) to initiate discussion and encourage use of SSKs, and about the amount of blood required to provide a sample. Targeted distribution of SSKs was seen as a broadly positive means of expanding the range of opportunities for black African people to test for HIV. There was specific support for the fact that SSKs could provide an opportunity for the initiation and follow through of an HIV testing discussion in a setting that black African people were already accessing.

The findings of the policy and systematic review, and the FGDs and interviews fed into the four-step process guiding intervention development. The theoretically informed intervention focussed upon the targeted offer of an HIV SSK distributed by in GP clinics and by Community Workers. A scripted discussion that provided a rationale for HIV testing and explained how the kit was used was central to the intervention. Use of the script along with the intervention manual would ensure consistency across Stage 2 of the study.

Stage 2

Results of feasibility study

Staff at 12 GP surgeries and three CBOs in London were trained to offer the intervention, no sites were opened in Glasgow. A total of 349 eligible persons were approached and 125 (35.8%) agreed to participate. Data from 119 were included in the analysis. The mean age was 42.6 years, slightly less than half were male, and the majority (76%) were recruited at GP surgeries. The SSK return rate was 54.5% (65/119); 83.1% of tests returned were HIV negative. However, 11 samples (16.9%) were unable to be processed due to the vial being under filled or sample grossly haemolysed. There were no reactive results.

The two most common reasons for declining to participate were having recently tested for HIV, and low HIV risk perception. Eligible people visiting their GP were significantly more

likely to be recruited than those approached via a CBO (odds ratio 1.96 95% CI 1.2 -3.19). There was no relationship between gender or age and enrolment status.

The majority of participants who returned a SSK also returned the acceptability questionnaire. None felt the location in which they were offered the kit was unacceptable. The majority found the SSK instructions easy to understand and over two thirds were comfortable with taking the sample themselves Just under a third reported watching the online video; of these most found the video helpful and increased confidence. The majority of kit returners reported that they would be willing to use one of these kits again. The least acceptable aspect of the intervention was the targeting of black Africans with over a third reporting it was unacceptable.

Twenty-one participants were interviewed; the median age of interviewees was 40 years; 12 were women; and 17 recruited at GP surgeries. Of the 21, nine had received negative results, four sent samples that were unable to be processed (due to the samples being under-filled), and eight had not returned their sample. The acceptability of the HAUS intervention was compromised by the specific SSK used, as well as issues with follow-up for insufficient samples, and stigma around HIV and HIV testing. Conversely, acceptability was supported by the convenience and privacy afforded by the use of SSKs, clear instructions and trust in the distributor. The interviewees widely reported that targeting black Africans specifically was acceptable.

Many distributors at GP surgeries felt unease at targeting black African patients only, despite the training and provision of a script to initiate this discussion. Despite these misgivings, many primary care staff felt that the intervention was worthwhile and expressed disappointment when the distribution period finished. Some distributors noted that targeting was complicated as information on ethnicity on patient databases is sparse, and there was limited time to check this data prior to appointments. These issues manifested in a large variety of methods employed at GP surgeries to select patients to offer the intervention.

The acceptability of the intervention to staff at CBOs remained high throughout the study, with the SSKs generally viewed as a valuable add-on to service menus. However, significant barriers to recruitment were noted, including stigma around HIV and limited time and capacity to conduct the intervention.

Results of process evaluation

Most distributors found it difficult to recruit to and almost all found it too time consuming to deliver in the context of a busy GP surgery or during community outreach. The research process attached to the intervention was the principal driver of this barrier. Fidelity to the intervention was not the norm. While local adaptations were not always agreed in advance, they maintained the fidelity of form for the intervention, in that they followed the standardised structures and processes and represent reasonable tailoring of the intervention to the specific local context in which it was being delivered. Almost all deviations were intentional, motivated by a desire to speed up the recruitment process.

Results of economic analysis

The model of a SSK test dispensed to black Africans in GP or in community settings suggests that SSKs are potentially a cost-effective way to identify new cases of HIV, with SSK compared to current practice as shown in increased quality adjusted life years for less cost. More work is required to test this result.

Conclusions

Our findings indicate that although many aspects of the intervention were acceptable, scale up of the intervention to a Phase III trial is not feasible. Alternative user-friendly SSKs that meet user and provider preferences and UK regulatory requirements are needed. The preliminary economic model suggests that for the rates of acceptance and return of the test seen in the trial, SSK is a cost-effective way to identify new cases of HIV but further work is needed to validate this result. Importantly the study also found busy services do not have time to 'bolt-on' a SSK intervention or research generally, unless there is a strong incentive to do so.

Research studies comparing acceptability and return rates of different types of self-sampling methods can help better understand their impact on recruitment. Blood-based kits not requiring users 'to milk' blood and diagnostic assays that meet CE criteria for testing saliva are required.

Changes in commissioning of sexual health services, as well as funding for HIV prevention initiatives in the UK, are affecting research capacity. Although efforts are being made to reduce time for obtaining REC and R&D approvals, continually changing systems breed confusion and affect study timelines and feasibility of assessing research questions substantially.

Sexual and public health services are increasingly utilizing self-sampling technologies however additional research is required to understand effectiveness and cost-effectiveness for black African communities and the population as a whole.

Plain English summary

(word count 313)

HIV diagnosis among black African people in the UK often happens long after infection – increasing the likelihood of ill health and further infections. Innovative ways to increase HIV testing are needed.

We wanted to find out if distributing HIV self-sampling kits (SSKs) through community and healthcare services would increase HIV testing among black African people. Self-sampling involves taking your own sample and sending it to a laboratory that lets you know the result.

The first stage of the HAUS study was designing a way to distribute SSK within existing services that was acceptable, workable and affordable. A review of published studies, focus group discussions and interviews helped to develop this. General Practice (GP) and Community Based Organisations (CBO) were chosen to distribute SSK. A script was developed that reassured distributors and potential users about targeting black Africans, and ensured that SSK were introduced consistently.

We had hoped to run Stage 2 in Glasgow and London but due to various reasons could only test the intervention in London, at 12 GPs and 3 CBOs. A third of those approached took part (36%, 125/349). Around half of those who took a kit (55%, 65/119) sent back their sample. No one had a reactive test but 17% sent back samples with not enough blood to be processed. Participants and distributors felt that people liked the idea of SSKs, the location of the intervention, and that the offer encouraged them to test. However, some found it difficult taking blood and many felt uncomfortable about ethnic targeting. The main barrier was time, particularly for those working in GP surgeries. Our economic model suggests that this approach may be cost-effective.

Although our study did not prove feasible, it highlighted the need to develop more user-friendly SSKs. It also found busy services do not have time to 'bolt-on' a SSK intervention unless there is a strong incentive to do so.

Chapter 1: **Background**

HIV infection in the UK

Since 2003, more people have been living with heterosexually-acquired HIV in the United Kingdom (UK) than HIV acquired via sex between men. Black Africans account for 55% of people with heterosexually acquired HIV and 2% of new HIV diagnoses in men who have sex with men (MSM); thus people of black African ethnicity account for almost one third of the 103,000 (95% credible interval 97,500-112,700) adults estimated to have HIV in the UK.(1) This equates to nearly four out of every 100 black Africans being HIV positive. (2)

Effective antiviral therapy means HIV incidence is likely to be driven by the undiagnosed fraction of people living with HIV and most HIV-related morbidity and mortality is increasingly associated with diagnosis at a late stage of infection (as defined by a CD4 count of <350 cell/mm^3).(2-4) Black Africans in the UK are more likely to present to HIV services with advanced infection than other ethnic groups.(5, 6)

Late diagnosis is associated with a tenfold increased risk of death in the first year post diagnosis when compared to people who are diagnosed with less advanced infection.(2) Late diagnosis also implies that a person has been living with undiagnosed HIV for a substantial period of time, which increases the risk of HIV transmission to other people. Reducing late presentation to HIV services is the single most useful way of decreasing the ill health and death associated with HIV, and reducing late diagnosis is the only HIV-specific indicator within the *Public Health Outcomes Framework*.(7) HIV prevention efforts have increasingly focused on increasing opportunities for people to have an HIV test, which reduces both late presentation and undiagnosed HIV infection. UNAIDS have set a global target of 90% of people living with HIV to be aware of their diagnosisby 2020, increasing HIV testing is the only means by which this can be achieved.(8)

HIV testing among black African communities in the UK

HIV testing in the UK is predominantly offered at sexual health clinics. Black Africans are less likely to use these services compared to other higher risk communities.(1) General practice *is* accessed by this population, but opportunities for earlier HIV diagnosis are often missed.(9) Black African men in particular have high rates of undiagnosed infection and late presentation,(10) partly because they have less contact with health services than women. In addition, concerns regarding confidentiality,(11, 12) stigma and discrimination(11-13) and

fear of HIV positive status(14) present barriers to effective testing initiatives. These obstacles are compounded by structural issues which discourage access to HIV prevention, diagnostic, and treatment services such as poverty, unemployment and lack of childcare,(11) the reticence of non-specialist health staff to offer HIV testing,(15) a lack of political will to recognise the pervasive health inequalities faced by many migrants,(16) and a lack of African representatives in decision-making processes.(14) Despite these obstacles, there is evidence to suggest that many black Africans will test for HIV if provided the opportunity.(10, 17)

At a population level, no single intervention is likely to control HIV. However, HIV testing is the starting point from which to build effective strategies. A negative test results can support individual vigilance to remain uninfected. For those testing positive, it opens treatment and prevention options. Timely diagnosis and treatment means that those affected can expect near-normal life expectancy.(18)

Due to the challenges associated with traditional HIV testing options for black Africans, innovative methods to increase the uptake and opportunities for testing amongst this population are required. Interventions should extend testing opportunities and directly address the barriers that foster late and undiagnosed infection. Such interventions could incorporate developments in testing technology that reduce the need to attend specialist services (for example use of self-sampling or self-testing kits) or through targeting testing interventions to specific populations (e.g. considering the psychosocial and socio-cultural contexts of target populations such as black African communities rather than general population). These interventions must also address the barriers that exist at a service provider level. Interventions need to be time and cost efficient, easy to use and deliver, and supported by robust clinical pathways.

Self-sampling kits

The range of HIV testing options continues to expand, with community-based point-of-care testing (POCT) and blood and oral self-sampling kits (SSKs) increasingly available.(19) HIV self-testing kits are also now licensed for use in the UK. Self-sampling negates the need for dedicated staff or special infrastructure for specimen collection, and can be used at a time and in a setting of the users' choice. SSKs accessed via clinical settings and online have been shown to be an acceptable and feasible alternative to clinic attendance for HIV testing, and may increase testing among hard-to-reach men who have sex with men (MSM).(20-22) Testers have shown an overall preference for oral-based sample rather than blood-based,

especially amongst first-time testers.(23) Research among young men in the UK also demonstrated acceptability of SSKs for HIV testing, with healthcare settings being the preferred venue for accessing kits.(24)

Despite the burgeoning research base focused on SSKs, there is little evidence to support the acceptability or feasibility of using SSKs to increase the uptake of HIV testing among black Africans in the UK. A pilot study initiated by Terrence Higgins Trust/HIV Prevention England and Dean Street At-Home has documented success in reaching black African people through internet-based SSK distribution.(25) Though the study had greater success in uptake among MSM than black African people of all sexualities, it found that 9.8% of the 7,761 kits requested were by black Africans and 7.3% of those were returned, with a positivity rate of 2.6%.

Embedding SSKs within existing health services (including health promotion initiatives and National Health Service [NHS] screening) may facilitate the uptake of HIV testing. A cross-sectional study undertaken among black Africans in England revealed that nearly one third of participants without diagnosed HIV said they would prefer to have a future HIV test at their GP surgery.(26) This may indicate the acceptability of offering SSKs via existing primary care venues. However, a lack of evidence persists regarding testing preferences by ethnicity, gender, and age.

In 2012 the National Institute of Health Research Health Technology Assessment (NIHR HTA) released a commissioned call (12/138) driven by the following research question: What is the feasibility and acceptability of interventions to overcome individual and healthcare professional barriers to the provision and uptake of HIV testing in black African adults in the UK?

The hypothesis behind the following research was that embedding SSKs for HIV testing in existing services is an acceptable and feasible means to increase the provision and uptake of HIV testing among black Africans residing in the UK.

1.1 Aims

The overall aims of our research were:

1. To develop an SSK-based intervention to increase the provision and uptake of HIV testing among black Africans using existing community and healthcare provision (Stage 1 of project).

2. To conduct an evaluation of selected SSK distribution models to assess feasibility, and optimal trial design for future Phase III evaluation (Stage 2 of project).

In order to answer the research question, the following objectives and outcomes were established.

1.2 Objectives

Stage 1

1. Examine/evaluate barriers and facilitators to provision, access and use of HIV SSK by black Africans, in primary care, pharmacies and community outreach settings
2. Determine appropriate SSK-based intervention models for different settings
3. Determine robust HIV result management pathways
4. Develop an intervention manual to enable intervention delivery.

Stage 2

1. Determine the feasibility and acceptability of a provider-initiated, HIV self-sampling kit distribution intervention targeted at black African people in two settings

    a. General Practice (GP) surgeries

    b. Via community based organisations (CBOs).

Secondary objectives

1. Establish acceptability of interventions for service providers and service users.

2. Evaluate the effectiveness of self-sampling for HIV in increasing the uptake of HIV testing by black African people.

3. Determine the cost effectiveness of distributing the SSKs among black African people over other screening methods.

4. Monitor ability to trace participants with reactive results, confirmatory testing and linkage into specialist care.

5. Determine the cost per person kit distributed and cost per HIV diagnosis per setting.
6. Assess the feasibility of collecting data for a lifetime cost-effectiveness model.
7. Assess feasibility, and if appropriate, the optimal trial design (including sample size parameters) for future Phase III evaluation.

1.3 Outcomes

Primary outcome: HIV SSK return rate.

Secondary outcomes:

1. Point of delivery outcomes:
    a. Acceptability of targeted HIV SSK distribution,
    b. Acceptability and feasibility of targeted SSK distribution among specified service providers.
2. Data collection outcomes:
    a. Ability to record the numbers of people offered SSK, accepting SSK, and returning SSK.
    b. Feasibility of collecting correct contact details enabling follow-up, reminders and communication of results.
3. Pathway to care outcomes:
    a. Proportion of those whose samples are reactive who:
        i. Are informed of results in person and
        ii. Who attend for confirmatory testing at an NHS setting of their choice.
4. Overarching outcomes:
    a. Cost per person kit distributed and cost per HIV diagnosis per setting.
    b. Attrition rates.

5. Confirmatory testing, proportion of those receiving an HIV positive diagnoses, and clinical stage at diagnosis.

Feasibility and sensitivity of outcome measures (testing, behavioural and economic) for a definitive trial.

1.4 Structure of the report

The report is structured according to the aims and objectives of Stages 1 and 2 of the study. Chapters 2 through 5 address the objectives of Stage 1, and Chapters 6–10 through address the objectives for Stage 2, with discussion and conclusions in Chapter 11.

Chapter 2: **Study design and methodology of Stage 1**

In order to develop an SSK-based intervention to increase the provision and uptake of HIV testing among black Africans using existing community and healthcare provisions we first needed to address the following objectives:

- Examine/evaluate barriers and facilitators to provision, access and use of HIV SSK by black Africans, in primary care, pharmacies and community outreach,
- Determine appropriate SSK-based intervention models for different settings,
- Determine robust HIV result management pathways, and
- Develop an intervention manual to enable intervention delivery.

The objectives were met via three main research activities:

1. Conducting a systematic literature and policy review exploring the feasibility and acceptability of self-sampling for HIV testing, and the effectiveness of self-sampling for HIV in increasing the uptake of HIV testing (see Chapter 3),
2. Conducting focus group discussions with non-specialists and service providers and one-to-one interviews with the latter to gain stakeholder input into the development of an acceptable SSK distribution pathway and protocol via community-based health and HIV prevention services already accessed by black African people (see Chapter 4)
3. Developing an intervention manual for the feasibility trial in Stage 2, drawing on theoretical frameworks and findings from the first two research activities (see Chapter 5).

The remainder of this chapter focuses on the methodological and analytical approaches to the literature review; qualitative data collected through focus group discussions and one-to-one interviews; and the intervention manual development.

2.1 Methodology of the systematic literature review

2.1.1 Search strategy and identification of studies

Ten electronic databases were searched using detailed search strategies. The search strategy used for OvidSP MEDLINE is provided in Appendix F.

- OvidSP MEDLINE
- OvidSP Embase Classic+Embase
- OvidSP Global Health
- OvidSP Social Policy and Practice
- OvidSP PsycINFO
- Ovid SP HMIC Health Management Information Consortium
- EBSCO CINAHL Plus with Full Text
- Cochrane Library
- Web of Science™ Core Collection
- SCOPUS

Only studies written in English were included. The results were downloaded into a de-duplicated database in EndNote 7. The initial search was undertaken on 26 September 2014. Two further searches to update the database were undertaken 17 April 2015 on and 3 May 2016. Additional grey literature was retrieved from websites operated by the following organisations:

- Avert (www.avert.org)
- Terrence Higgins Trust (www.tht.org.uk)
- National AIDS Trust (www.nat.org.uk)
- Lambeth Council (http://www.lambeth.gov.uk/consultations/lambeth-southwark-lewisham-sexual-health-strategy-consultation)
- Naz Project London (http://naz.org.uk)
- Sexual Health Sheffield (http://www.sexualhealthsheffield.nhs.uk)

2.1.2 Inclusion and exclusion criteria

Only studies published since 1st January 2000 were included since studies published earlier would be unlikely to reflect current technology or attitudes to HIV testing. Only studies conducted in the European Union/European Free Trade Agreement countries, North America, New Zealand or Australia were included, as studies conducted in other locations (particularly resource-poor settings) would likely have markedly different contexts and thus their results would not be applicable to the UK. Study populations that included lay groups as well as health professionals were included. Only studies that examined home/self-sampling for HIV were included as intervention studies. Studies without comparators were also included as well as studies that compared home/self-sampling for HIV with routine service provision or other HIV testing interventions. Studies were included if they reported on any of the following outcomes:

- Increase / decrease in number of HIV tests
- Proportion /number of confirmatory tests
- Proportion /number of participants linked into care
- Adverse events associated with HIV self-sampling
- Proportion/number of false positives or failed tests
- Increase / decrease in the reported history and frequency of taking HIV tests
- Increase / decrease in the number and types of venue where HIV testing is offered

Qualitative studies were included only if they reported either or both of the following:

- Barriers or facilitator to self-sampling reported by general population
- Barriers or facilitators to self-sampling reported by service providers

The following study designs considered for inclusion:

- Randomised or non-randomised controlled trials
- Prospective or retrospective cohorts
- Cross sectional studies / prevalence studies
- Pilots or feasibility studies
- Qualitative studies (using in-depth interviews, focus group discussions, and document analysis)

Studies that examined the use of, or views about, self-sampling for HIV in healthcare workers were excluded because the review focus was on uptake among testers not service providers as were all conference communications because of insufficient detail and lack of peer review.

Studies that focussed solely on, or whose outcomes were predominantly about self testing for HIV also were excluded at the study selection stage.

2.1.3 Study selection

Studies were selected using a two-stage screening approach. Reviewers Ibi Fakoya (IF) and Esther Mugweni (EM) devised a checklist to independently screen titles and abstracts (See Appendix F). Where a consensus could not be reached about study inclusion, a third reviewer (Fiona Burns [FB]) was consulted. Full paper copies of the selected studies were screened and assessed independently by IF and EM using a screening tool (see Appendix F). Updated searches were screened using the same approach by Caroline Park (CP), Thomas Hartney (TH) and Lisa McDaid (LMcD). Inter-reviewer reliability scores of the different stages of the review were calculated using Kappa in Microsoft Excel. The full paper screening achieved a Kappa score of 1.0, which indicates a high level of agreement between reviewers.

2.1.4 Data extraction, analysis, and synthesis

Structured data extraction tools were developed to capture the required information from the included papers on study types, populations, SSK interventions, and acceptability, feasibility and efficacy outcomes. Data were extracted by CP and checked by TH.

A meta-analysis was not conducted due to the heterogeneity of the study designs and methods, samples and outcomes of the included studies. There are a number of narrative approaches to data synthesis, including integrative synthesis to primarily combine and summarise data and interpretative synthesis that aims to generate new concepts and theory (27). An integrative approach to summarise and present the data was appropriate to this review. The narrative synthesis is supported by tables in the findings section that outline the key characteristics and findings of each included study, as relevant to the research questions. To reduce bias, the extracted data were first summarised by LMcD and then reviewed by TH. Disagreements in interpretation were resolved through discussion between the two authors.

2.1.5 Quality appraisal

Quality of the eligible papers were appraised by TH using the NICE quality appraisal checklist for quantitative papers (28) and the NICE quality appraisal checklist for qualitative papers (28). Each quantitative paper was assigned a score for internal and external validity, from ++ (high quality) to – (poor quality). Each qualitative paper was assigned a single overall score. The appraisal process was validated by a second researcher (LMcD) assessing a sample of papers with high agreement reached. Any papers that did not present self-sampling

data separately to other forms of testing were excluded, but papers were not excluded on the basis of quality.

2.2 Methodology of focus group discussions and one-to-one interviews

Qualitative research methods were used to collect data using focus group discussions (FGDs) and one-to-one interviews in late 2014. Ethical approval was obtained from the UCL Research Ethics Committee (REC), project ID 3321/001.

The study team conducted 12 FGDs, a method which was selected in order to maximise the extent of interaction between research participants in order to establish group similarities as well as differences by encouraging discussion, exchange and justification of divergent viewpoints.(29) Six of these groups were conducted with non-specialist members of the public who identified as black African and, and six with professionally, culturally and ethnically diverse people who provide HIV and other social services to black Africans. From the latter group, nine participants also participated in one-to-one interviews, a choice that was made to primarily enable interviewers to tailor the topic guide in ways that would help to best capture the specific world-view of these expert interviewees.(30)

Topic guides for the non-specialist and service provider FGDs (see Appendices A and B respectively) were developed in consultation with members of the steering group and study team. The topic guide for the one-to-one interviews was adapted from that for service provider FGDs. These guides structured flexible discussions about participant views toward SSKs, community trust of SSKs, practicalities and rationales for selecting potential community settings outside of sexual health clinics, mechanisms for returning the sample and communicating and confirming results to users, and the content of SSK packs. Group facilitators and interviewers sought to create a balance between the *a priori* issues outlined above while also harnessing participant-led articulation of perspectives, social norms and discourses.

During the FGDs participants were shown a video produced by the producers of the TINY Vial SSK (http://www.tdlpathology.com/test-information/test-service-updates/tdl-tinies). In a number of groups participants were also shown an instructional video developed by a community organisation (https://www.youtube.com/watch?v=FSm0zP1TGUo) on self-use of dried blood spot sampling kits. TINY Vial SSKs were displayed, distributed and discussed in all groups. As it was known that the use of an oral fluid kit was not possible within the

context of the HAUS study, no oral-based kit was demonstrated during the groups. However, these kits were discussed by participants.

Participatory methods such as ranking activities were used to enhance data collection and participant engagement during FGDs.(29) The study team members who collected qualitative data in this stage were: CD, EM, SW, CP, GP and IW. CD, SW and IW already posessed extensive training and experience in this format of data collection in the HIV field among specialist service providers and non-specialists alike, and CD and IW in particular were responsible for the training and oversight of research development of EM, GP and CP respectively. Intially, all focus group discussions were led by those with the greatest experience, and 'seconded' by EM, GP and CP, and over time these roles started to switch as the latter group gained familiarity and experience with the method and the research tools being used. Two researchers attended every group to better enable data capture (including observation). All those involved in data collection had considerable opportunity to discuss challenges, successes and possible improvements to data collection during fortnightly core team meetings, designed to assist such exchange. EM and GP undertook all one-to-one interviews, and each had considerable experience with and training in this method.

2.3 Non-Specialist black African focus group discussions

Participants in the non-specialist FGD included members of the public who self-identified as black African (n=48). Three of the FGDs occurred in Greater Glasgow, and three in Greater London. The participants were recruited via social media (n=1) and African embassies in London (n=6), as well as university student groups (n=16), and community based organisations (n=24) in both Glasgow and London (missing=1). Participants were eligible if they self-identified as being black African and were aged 18 years and over. The sample was purposively selected sequentially during recruitment (with some interested individuals being set aside into a 'pool' of recruited participants in case they were needed at a latter stage) to ensure diversity of age, region of birth, and HIV testing experience. Men were slightly overrepresented in the sample, numbering 28 out of 48 participants (58%), compared to 20 women (42%). The age ranged from 18 to 60 years old. Participants were born in various regions of Africa, including East Africa (n=17), Southern Africa (n=10), West Africa (n=10), Central and North Africa (n=3), and some born in the UK, Europe or United States of America (USA) (n=7) (missing data n=1). In order to ensure a balance of voices, one of the

FGDs was comprised only of people under the age of 30 (in London), another of men only (in London) and a further group of people living with diagnosed HIV (in Glasgow). The other three FGDs were mixed in terms of gender, age, and HIV testing experience (London and Glasgow). Nineteen participants had never tested for HIV. The black African non-specialist FGD participants were compensated £25 for participating in the discussion. Each FGD lasted between one and a half to two hours, with an average of nine participants in each group (range between 7 and 11). The FGDs were audio recorded and transcribed verbatim.

2.4 Service provider focus group discussions and interviews

Six FGDs were conducted with service providers: three in Glasgow and three in London. Sequential purposive sampling (undertaken with the support of simple screening questions asked during the recruitment process) ensured a diversity of service providers from a range of professional backgrounds, all provided HIV-related or other social services to black Africans. Black African ethnicity was not a criterion for involvement in these FGDs. General Practices were recruited via the Clinical Research Networks (CRNs) in London, and through established working relationships with members of the research team in both cities. Community workers in both cities were recruited from organisations with extensive experience of delivering HIV prevention and care as well as a range of other non-HIV-specific services to black Africans. The research team approached pharmacies within areas with high concentrations of African residents in both cities, with support from local pharmacy associations. Almost all specialist FGDs comprised those from diverse working backgrounds in order to elicit contrasts within working and experiential contexts.

In total, 53 service providers participated in either an FGD or a supplementary interview. Those taking part in FGDs included HIV CBO staff (n=15), pharmacists and pharmacy assistants (n=9), GPs (n=7), black African service providers (non-HIV focused) (n=5), GP practice and specialist nurses (n=3), African faith leaders (n=3), and a Health care assistant (HCA) (n=1). The service provider FGD participants were offered reimbursement for their travel and their time given to the study. The level of reimbursement varied according to profession. The service provider FGDs lasted between one and a half to two hours, with an average of seven participants in each group (range between 4 and 10). These sizes fall within the ideal range to prompt discussion while ensuring the participation of everyone in the group.(30)

Following the FGDs, interviews with ten highly specialised HIV service providers (including HIV clinicians, HIV service managers and service commissioners) in London (n=3) and Glasgow (n=7) were conducted, to help check the acceptability of intervention and procedures. This approach was undertaken in order to include diversity of voice in FGDs, accompanied by highly specialised expertise gained through interviews. Each interview lasted between 30 and 45 minutes. The FGDs and interviews were audio recorded and transcribed verbatim.

2.5 Analysis of focus group discussions and interviews

Analysis of the qualitative data was undertaken using a 'blended' thematic approach drawing heavily on framework analysis.(31) NVivo (version 10) software was used to synthesise and code data within a thematic matrix to enable elucidation of conceptual associations. Both *a priori* concepts used in the development of the FGD topic guide as well as emergent concepts arising from the data informed the process of identifying the key thematic categories used in data coding. Two researchers devised an agreed coding frame, which was then used to index and chart the findings. The integrated model of behavioural prediction and change was used as the theoretical framework to assess attitudes, willingness, and perceived behavioural control to use HIV SSKs.(32)

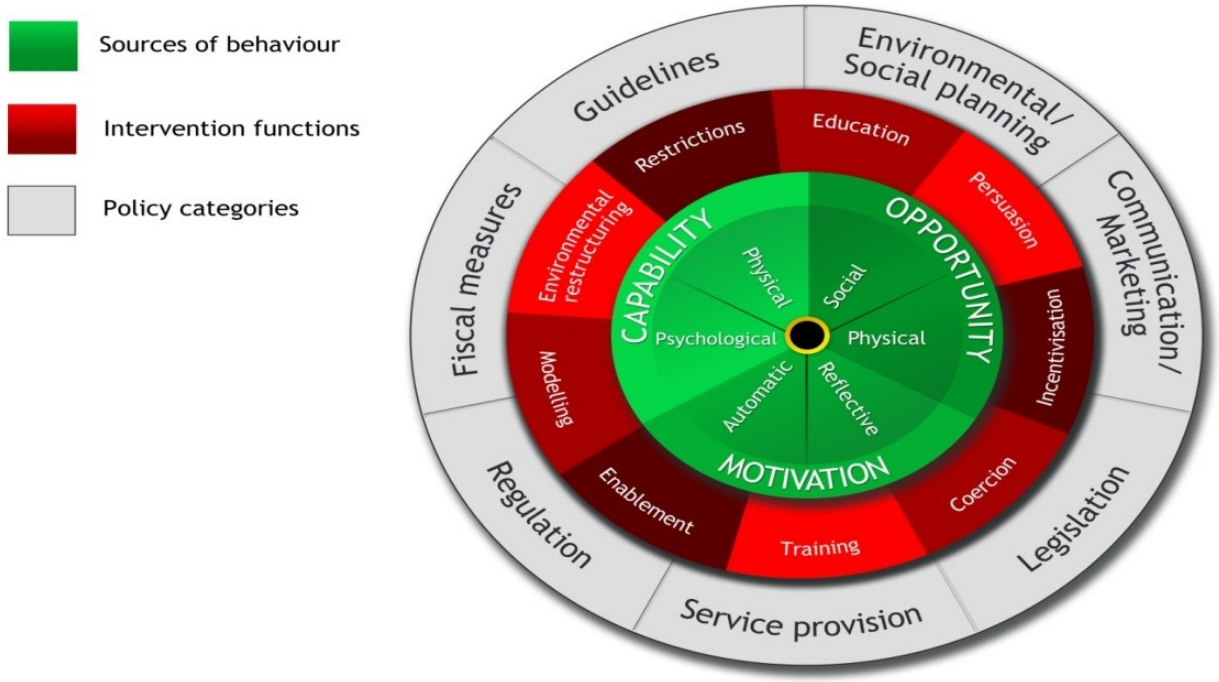
Broad descriptive themes included the feasibility and accessibility of HIV testing, existing knowledge and uptake of SSKs, and the practicalities of distribution emerged. Cross-cutting themes also surfaced which influenced our analysis, particularly those concerned with trust and HIV-related stigma. The themes were then refined to devise a more detailed participant-led, inductive, thematic framework. Researcher-team discussions and iterative analysis focussed upon the internal coherence and face validity of the resulting analytic structure.

2.6 Methodology and analytic approach of intervention development

At the outset, it was recognised by the study team that successful interventions to increase HIV testing are particularly challenging due to the sexual transmission aspect and stigma associated with HIV, the latter being particularly prevalent among African communities in the UK. To mitigate the complexity inherent in developing and implementing an HIV SSK, a systematic four-step approach to intervention development was adopted drawing on the Behaviour Change Wheel(33) (see Figure 1).

Figure 1: The Behaviour Change Wheel

(from Michie et al, Implement Sci 2011))



2.6.1 Step 1: Delineate key intervention components

The intervention development process began with identifying and conceptualising the diverse intervention components arising from a combination of existing SSK distribution practice, and process-oriented data emerging from Stage 1. The research team considered their sequential flow across social contexts, health professionals, SSK recipients and clinical governance procedures. In this way, the study team systematically considered the segmentation and flow of the intervention chain. This conceptual work also assisted in informing the topic guides for follow-up interviews with participants who agreed to take an SSK (regardless of whether they ultimately used it) (see Appendix C) and the choice of analytic approach for the intervention development work that followed.

2.6.2 Step 2: Intervention barriers and enablers and relation to theoretical domains

Step 2 involved further consideration of the key intervention components identified in Step 1 by utilising Stage 1 data on barriers and facilitators to the intervention. Appendix D provides an example of how the study team analysed the relevant data regarding the component 'the

appearance and packaging of the HIV SSK.' Key barriers and facilitators were then mapped onto the Theoretical Domains Framework (TDF).(34)

The TDF is a meta-theoretical framework which integrates key theoretical domains known to be important in understanding behaviour change across a range of populations. It provides a coherent way of organising explanations of why things do or do not happen in relation to either behaviour change or the implementation of particular intervention components. It enables insights into potential mechanisms of action for developing or optimising interventions. Table 1 below illustrates the key domains of the TDF and provides a brief explanation of the content to which the particular domain refers.

Table 1: Theoretical Domains Framework – Domains and Explanatory Statements

Domains	**Explanatory Statement of the domain**
Knowledge	An awareness of the existence of something
Skills	Ability or proficiency acquired through practice
Professional roles/identity	Coherent set of behaviours and personal qualities of an individual in a work setting
Beliefs about capabilities	Acceptance of the truth or validity of an ability that a person can put to constructive use
Optimism	Confidence that things will happen for the best or that desired goals will be obtained
Beliefs about consequences	Acceptance of the truth or validity about outcomes of a behaviour
Reinforcement	Increasing the probability of a response by arranging a dependent relationship between the response and a contingency
Intentions	Conscious decision to perform a behaviour or act in a certain way
Motivation and goals	Representation of outcome that individual wants to achieve
Memory and decision processes	Ability to retain information, focus selectively, and choose between two or more alternatives
Environmental context and resources	Any circumstances of a situation or environment that discourages/encourages development of skills, abilities and competencies
Social influences (norms)	Interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours

Domains	Explanatory Statement of the domain
Emotions	Complex reaction pattern, involving experiential, behavioural and physiological elements
Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions

Adapted from Cane, O'Connor & Michie. Implement Sci, 2012.(35)

Analysis and the mapping of barriers and facilitators to the TDF domains were discussed within a single all-day event attended by the research team. Differences of opinion were resolved through consensus.

2.6.3 Step 3: Identifying intervention components that could overcome barriers and enhance the enablers

In step 3, an ideal hypothetical intervention that minimized key barriers and amplified key facilitators was constructed. The behaviour change wheel was then used to structure the intended intervention guided by the ideal intervention.

The behaviour change wheel links the domains of the TDF to the COM-B ('capability,' 'opportunity,' 'motivation' and 'behaviour') model of behaviour change (36) (see Figure 2). The COM-B model suggests that behaviour change is related to three key factors: capability, opportunity and motivation. These three factors can be broken down into finer-tuned categories and eventually to the TDF domains. Table 2 below shows how the TDF domains relate to each COM-B component.

Figure 2: The COM-B model
Adapted from the original figure (see Michie et al, Implement Sci 2011) through inclusion of description of the three domains

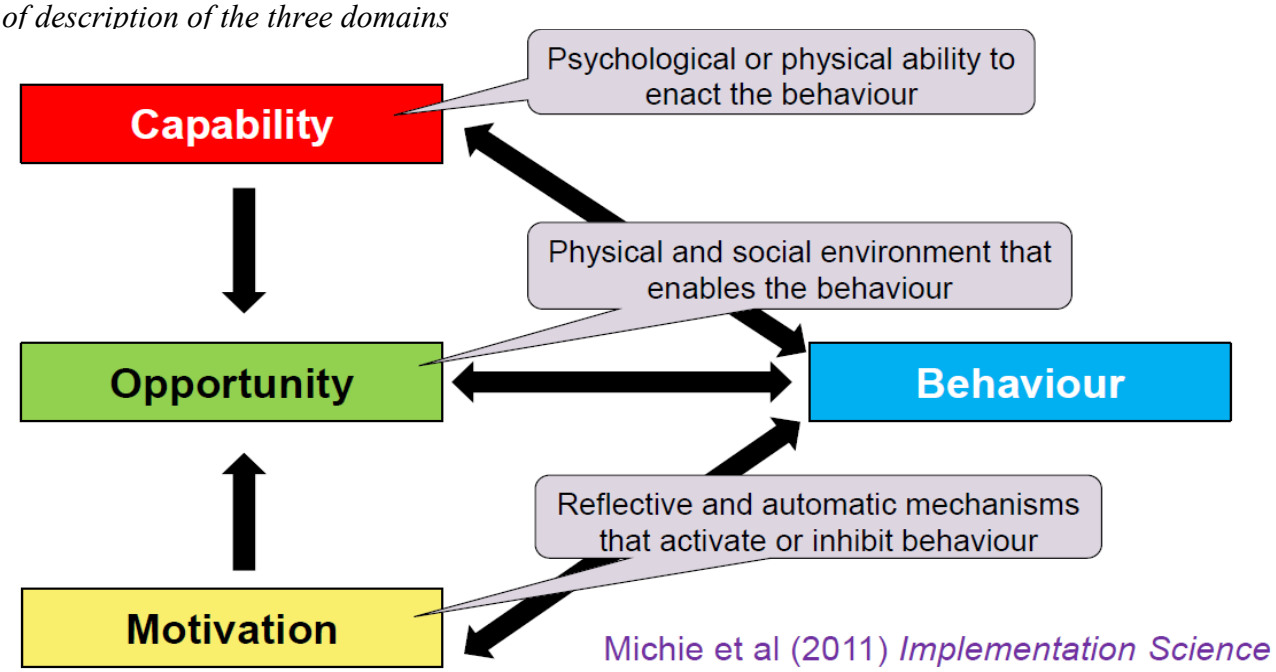


Table 2: Connection between COM-B and Theoretical Domains Framework (TDF) components

COM-B component		**TDF Domain**
Capability	Psychological	Knowledge
		Cognitive and interpersonal skills
		Memory, attention and decision processes
		Behavioural regulation
	Physical	Skills
Opportunity	Social	Social influences (norms)
	Physical	Environmental context and resources
Motivation	Reflective	Professional roles/identity
		Beliefs about capabilities
		Optimism
		Beliefs about consequences
		Motivation and goals
		Intentions
	Automatic	Reinforcement
		Emotions

Adapted from Webster et al.Translational Behavioral Medicine, 2016.(36)

2.6.4 Step 4: Viability of intervention

The outcome of Step 3 provided a range of potential ways in which the intervention could be structured that would reflect key mechanisms of action and reduce barriers to effective implementation. However, it was important to ensure that the resulting intervention was viable within busy service delivery contexts. Thus, the study team evaluated the intervention content with the APEASE criteria (Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Site-effects/safety, and Equity)(32) assessing the viability of

intervention function and behaviour change techniques for a real world intervention implementable within the UK.

2.7 Summary of Stage 1 methods

This chapter has described and provided a rationale for each of the activities undertaken to meet the key objectives for this stage of the project, namely:

- Reviewing the available literature on SSKs with regard to feasibility, acceptability and effectiveness of this technology at increasing HIV testing uptake;
- Gain insight from experts and non-experts into the best means of targeted distribution of SSKs for the benefit of black African people in the UK, as well as their perspective on kit use and functionality; and
- Conversion of these insights using a a systematic four-step approach to intervention development drawing on the Behaviour Change Wheel.

2.7.1 Strengths and limitations

Although limited in scope and scale, the range of methods used in Stage 1 enabled the team to select a mix of data sources and analytical approaches in their systematic, theoretically driven approach to intervention development.

Findings of the formative Stage 1 focus group discussions and interviews with specialist service providers and non-specialist members of the public, and the ensuing intervention development process are presented in Chapters 4 and 5 respectively. The next chapter presents the methodology and results from the policy and systematic literature review.

Chapter 3: **Systematic policy and literature review**

A systematic literature and policy review exploring the feasibility and acceptability of self-sampling for HIV testing, and the effectiveness of HIV self-sampling in increasing the uptake of HIV testing was conducted. The overall purpose of this exercise was to address the first three objectives of Stage 1: to clarify barriers and facilitators to provision, access and use of HIV SSK by black Africans, in primary care, pharmacies and community outreach, to determine appropriate SSK-based intervention models for different settings, and to determine robust HIV result management pathways. This review also informs the fourth objective, to develop an intervention manual to enable intervention delivery. This Chapter contains the methodology and results of the policy and systematic literature review.

The systematic review was registered on PROPERO (study number CRD42014010698).

3.1 Policy Review

A policy review was conducted with the aim of summarising current approaches to and policies/protocols around use of SSK for HIV in the UK to add context and to inform the development of the HAUS SSK intervention manual. Eleven policy statements, clinical guidelines, reports and strategies that contained programmatic or clinical guidance on HIV self-sampling or on HIV testing in the UK or specific guidance on HIV testing for black Africans in the UK published between January 2008 and July 2016 were included (Appendix E). Below we provide an overview of the policy approaches and recommendations relevant to SSK.

3.1.1 Policy approaches and recommendations relevant to self-sampling kits

Most of the policy guidance documents yielded by this search were not specific to SSKs. The UK National HIV testing guidelines were produced by the British HIV Association (BHIVA), the British Association of Sexual Health and HIV (BASHH) and the British Infection Society in 2008 against the background of late HIV diagnosis and undiagnosed HIV status in the UK.(37) The guidelines advocated for expansion of HIV testing services including routine offering of HIV testing in general practice in areas where the prevalence is higher than 2 per 1000 among 16-59 year olds, to patients attending specified services such as sexual health clinics or pregnancy termination services, and to patients who report high risk behaviour and patients with indicator conditions.(37) Implementation of these guidelines was

assessed using eight pilot projects in acute medical settings, emergency departments, primary care and community settings.(38) Findings from the pilot projects showed that the implementation of guidelines to expand HIV testing in the medical and community settings was both feasible and acceptable; HIV SSKs were successfully used in one of the pilot projects. A later review by Public Health England (PHE) on the evidence of the effectiveness of HIV testing in medical and community settings noted that self-sampling could broaden the available testing options.(39) Other strategies have advocated for self-testing as an alternative option.(40) Indeed, the national response to HIV continues to evolve and in April 2014 HIV self-testing kits (STKs) became legal in the UK.(41, 42)

With regard to policy specific to the black African community, the National Institute of Health and Clinical Evidence (NICE) published specific guidance on increasing HIV testing among black Africans in 2011.(43) In 2014, NICE provided detailed recommendations for commissioners including local authorities, Clinical Commission Groups and NHS England on delivering HIV testing services (44). NICE recommended that commissioners assess local need for HIV testing for black Africans and then develop a local HIV testing strategy with clear referral pathways, particularly for outreach point of care services. To address undiagnosed HIV and late diagnosis of HIV, NICE recommended that commissioners promote HIV testing including the use of modern HIV tests and reduce barriers to HIV testing among black Africans. In line with the 2008 guidelines mentioned above,(37) NICE recommended that HIV testing be offered by health professionals in primary and secondary care. Although SSKs were not specifically mentioned in these guidelines, SSKs have been commissioned by some local authorities as part of their HIV testing services. ~~These~~ NICE guidelines ~~are currently being~~were updated ~~and new guidance to address late diagnosis in groups at risk is expected be published~~ in ~~late~~ December 2016, and ~~. In the draft guidelines issued for consultation earlier this year,~~ SSKs ~~and self-testing kits~~ were ~~endorsed~~ considered a potentially~~as~~ innovative way~~s~~ of increasing uptake of HIV testing among black Africans given that they may ~~potentially~~ address ~~the~~ known barriers to HIV testing in this risk group.(45) Despite support within the policy documents for HIV SSK as a means of increasing uptake of testing, evidence on the impact of SSK on uptake compared to clinic-based testing was limited to one study.

3.2 Results of systematic literature review

A total of 4,052 documents were retrieved, of which 1,994 were duplicates. Reviewers identified 85 eligible for full paper screening, with 1,973 excluded as they did not meet the inclusion criteria. Seventy-two papers were excluded after full paper screening due to: not including SSK for HIV testing or only presenting combined results with other types of testing (n=38), inappropriate publication type (n=26), inappropriate study type (n=6), and irrelevant country setting (n=2). Figure 3 contains a flow chart of the study search and selection process. Thirteen studies were selected for inclusion in the literature review.

3.2.1 Description of included studies

Table 3 presents the description of the 13 studies included in the review. Of the included studies, nine were conducted in the USA and four in the UK. Eight were cross-sectional surveys, three were prospective cohort studies, one was qualitative and one a randomised controlled trial (RCT). The total sample size across the papers was 15816, with an average response rate of 78% (range: 38%-100%; information not provided in two studies.(46, 47) The majority of the studies included communities at high risk of HIV infection. Ten included MSM, three included injection drug users (IDUs), and three included non-specified at-risk individuals or clinic populations. Only two focused on high-risk heterosexual populations (both in the USA); all of the UK studies included only MSM. The only RCT in the included studies was conducted with IDUs. Most studies reported a predominantly white sample, although the sample in the RCT was 48% African-American. Where provided, the average age of participants ranged from 18-47 years.

Figure 3:Flow chart of study search and selection

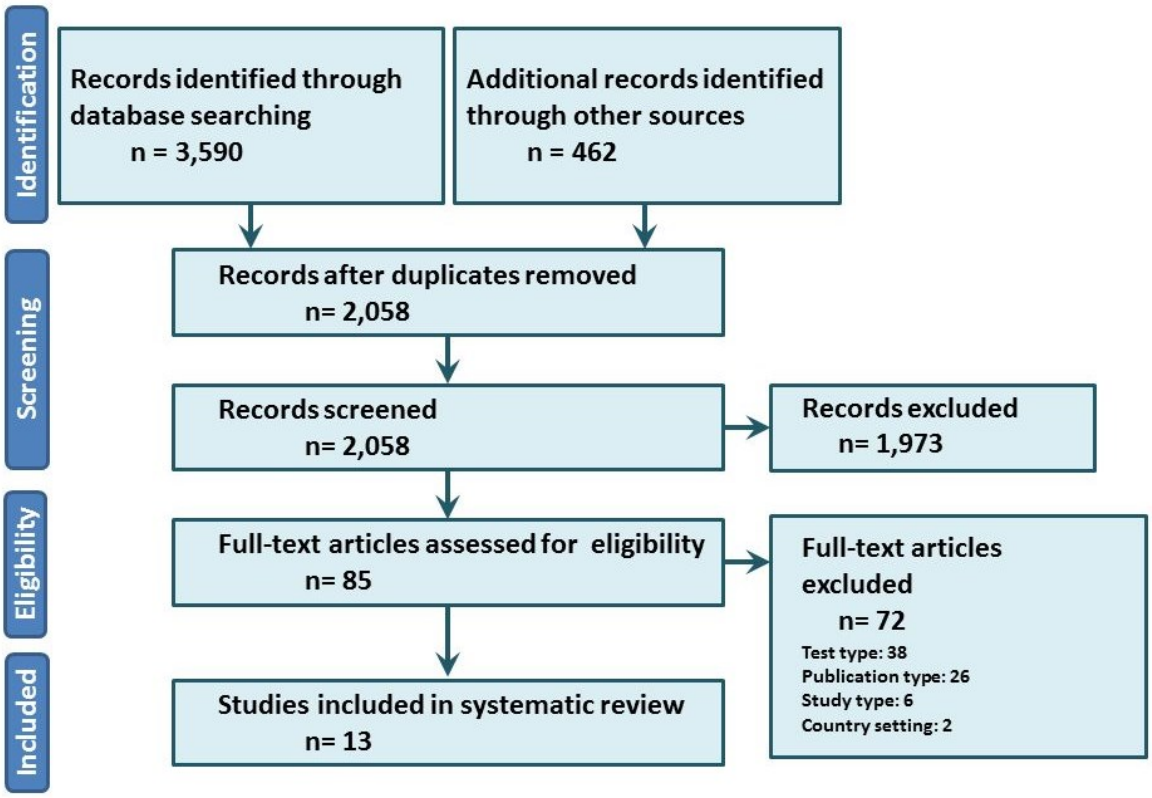


Table 3: Description of included studies

Study Number	Author (year)	Study design	Study aims	Setting	Population (ie clinic, internet, MSM etc)	Sample size	Response rate	Sample characteristics (ie, age, gender, ethnicity)	Type of HIV testing sample	Method of SSK distribution	Method of return	Quality appraisal score (internal / external)
1	Bartholow (2005)[55]	RCT	To compare the likelihood of HIV testing and obtaining test results between participants randomized to Traditional Counselling and Testing and Consumer Controlled Testing among methadone maintenance, detoxification, and out-of treatment drug users	USA	IDU	489	92%	Mean age 40, 71% male, 48% African American	Dried blood spot	Provided in drug clinic	Post	++ / ++
2	Colfax et al. (2002)[46]	Multiple cross sectional surveys	An examination of intent to use SSK, actual use and barriers to use among persons at high risk of HIV infection	USA	MSM, IDU, high risk hetero-sexuals	3471	Not reported	74% male, 44% white	Dried blood spot	Purchased (presumably from pharmacy)	Not specified	+ / +
3	Fisher et al. (2015)[50]	Prospective observational cohort	To determine uptake of SSKs for HIV and STIs compared to conventional clinic-based testing, and to determine whether the availability of SSKs would increase STI testing amongst HIV infected MSM and those attending a community-based HIV testing service compared to historical controls	UK	MSM	433 (80 for HIV testing)	75%	Median age 33, 84% white British	Oral fluid	By post	Post	+ / +
4	Formby, Hirst & Cripps	Cross sectional survey	To evaluate the Time 2 test pilot study which was based on the use of SSKs	UK	MSM	126	100%	Median age 24, 89% white British	Oral fluid	Postal and public sex environment	Post	- / -

Study Number	Author (year)	Study design	Study aims	Setting	Population (ie clinic, internet, MSM etc)	Sample size	Response rate	Sample characteristics (ie, age, gender, ethnicity)	Type of HIV testing sample	Method of SSK distribution	Method of return	Quality appraisal score (internal / external)
	(2010)[51]									s		
5	Greensides et al. (2003)[49]	Cross sectional survey	To determine the levels of awareness and use of alternative HIV tests (SSKs and rapid tests among people at high risk of HIV infection	USA	MSM, IDU, high risk hetero-sexuals	2836	66%	Mode age 25-34, 73% male, 39% white	Dried blood spot	Not specified	Not specified	+ / +
6	Osmond et al. (2000)[54]	Cross sectional survey	To test the feasibility of obtaining HIV test results by SSK from a probability telephone sample of MSM	USA	MSM	490	78%	Urban areas, 67% white, 71% aged 18-29	Oral fluid	Mailed	Post	++/ +
7	Sharma, Sullivan & Khosropour (2011)[56]	Cross sectional survey with randomisation	To describe the factors associated with willingness of internet-using MSM to take a free anonymous home HIV test as part of online prevention activities	USA	MSM	6163	68%	Median age 18-24, 43% white, 31% Hispanic	Not specified	Not specified	Post	+ / +
8	Sharma et al. (2014)[53]	Cross sectional survey	To investigate attitudes towards six different HIV testing modalities presented collectively to internet -using MSM and identify which options rank higher than others in terms of intended usage preferences	USA	MSM	973	38%	Median age 26, 77% white	Dried blood spot	Not specified	Not specified	+ / +
9	Skolnik et al. (2001)[52]	Cross sectional survey	To examine preferences for specific types of HIV tests (public clinic test, doctor test, SSK, home self-test) as well as for test attributes such as cost,	USA	Public clinics	354	96%	Mean age 34, 77% male, 63% white	Dried blood spot	Mailed or pharmacy	Post	+ / +

Study Number	Author (year)	Study design	Study aims	Setting	Population (ie clinic, internet, MSM etc)	Sample size	Response rate	Sample characteristics (ie, age, gender, ethnicity)	Type of HIV testing sample	Method of SSK distribution	Method of return	Quality appraisal score (internal / external)
			counselling and privacy									
10	Spielberg et al. (2000)[21]	Prospective cohort	To assess the feasibility and acceptability of bimonthly home oral fluid and dried blood spot collection for HIV testing among high risk individuals	USA	At-risk individuals enrolled in vaccine study	241	84%	Mainly white male, 58% MSM, mean age 36	Dried blood spot or oral fluid	Choice of mailed or collected from study site	Post	++ / +
11	Spielberg et al. (2001)[57]	Cross sectional survey	To evaluate attitudes about SSK and telephone counselling among participants, HIV counsellors, community advisory board members and cohort participants	USA	Clinic staff and at-risk individuals	126	~80%	Mean age 35, 71% male, 54% white	Dried blood spot or oral fluid	Not specified	Post	-/ -
12	Wayal et al. (2011)[48]	Qualitative interviews	To explore preferred mechanism for offering home-sampling kits, perceptions about using SSKs to screen for STIs and HIV and views about STI clinic use and SSKs	UK	MSM	24	80%	Median age 39, mainly white	Not specified	Range of options assessed	Several options	+ (overall)
13	Wood, Ellks & Grobicki (2015)[47]	Prospective cohort	To compare the results of a pilot outreach STI service using nurse-delivered screening and SSKs at a sex on premises venue against screening within a sexual health clinic	UK	MSM	90	NA	Median age 47	Dried blood spot	Collected in sauna	Post	- / +

The majority of the studies evaluated a dried blood spot SSK (n=8), while five assessed an oral fluid test (two assessed both types of sampling and another two did not specify type).

The methods by which SSKs were distributed varied across the studies with five including the option of kits being mailed out to participants and six requiring participants to pick up a SSK from a study site (including pharmacies, drug clinic, public sex environment, sauna or unspecified study site). Three offered participants a choice of both options and four did not specify how kits were distributed. Nine studies required participants to return kits by post (the remainder did not specify the method of return or it was not applicable to the study type). The qualitative study assessed a range of options with participants.(48)

3.2.2 Quality appraisal

According to the criteria used for both qualitative and quantitative studies only a few high-quality papers were identified that related to the study outcomes. The majority of studies took the form of cross sectional surveys (8 of 13 papers), with only one RCT identified.

Only the RCT scored ++ for both internal and external validity. Two of the three prospective cohort studies scored '+' or higher for both categories, as did six of the eight cross sectional studies. The qualitative study scored '+' overall. Two of the cross sectional studies assessed the acceptability of a hypothetical offer of self-sampling, and overall few of the studies directly compared the efficacy of different forms of testing. Those studies that scored poorly on both categories commonly featured a small sample size and/or deficient level of analysis.

3.2.3 Acceptability, feasibility and effectiveness of self-sampling

All but one of the included studies(49) reported on some measure of the acceptability of self-sampling (Table 4). In total, only five studies (three from the USA and two from the UK) reported on the distribution and return of SSKs. Within these, 1652 SSKs were distributed (range: 80-716) and 1373 participants returned a specimen (range: 60-665). This suggests a medianreturn rate of 77.5% (range: 47.6%-92.9%). The two UK studies (50, 51 respectively), distributed 80 and 126 HIV SSKs, with 62 (77.5%) and 60 (47.6%) returned, respectively. Both of these studies used oral fluid sampling, and no inadequate samples were reported. Twelve of the included studies did include (self-reported) data on acceptability of SSK to participants, but measures used were inconsistent. Self-reported acceptability was generally high, with self-sampling reported to be broadly acceptable to participants (see Table 4). For example, Spielberg et al. (2000) reported that 98% of participants agreed to take part in either

oral fluid or dried blood spot bimonthly sampling in the future.(21) Similarly, Fisher et al. (2015) reported that 81% of MSM found (oral fluid) SSK to be acceptable.(50) However, Colfax et al, Wood, Ellks & Grobicki (2015), Skolnik et al. (2001) and Sharma et al. (2014) reported that few took up the offer of testing and/or found it to be the least preferred option among participants – it is notable that all of these used blood sampling.(46, 47, 52, 53) In terms of comparing the different types of tests, Spielberg et al. (2000) found no difference in testing rates between dried blood spot and oral fluid testing, but this was the only study to compare the two method.(21) Acceptability did not vary significantly by distribution method.

In terms of feasibility, only six studies included any documentation of how tests were completed, errors in testing, communication of results, or linkage to care. Three of these studies used oral samples, two blood, and one both. There were few reports of errors in testing. Spielberg et al. (2000) reported that 99% of both oral fluid and dried blood spot samples were adequate for testing, (21) while Osmond et al. (2000) reported two indeterminate results and 10 insufficient samples (out of 412 returned oral fluid samples)(54) and Formby, Hirst & Cripps (2010) reported that seven equivocal oral fluid samples had to be re-tested (out of 126) (all tested negative).(51) Wood, Ellks & Grobicki (2015) reported that 3/30 tests of dried blood spot samples were not processed.(47) Spielberg et al. (2000) reported that staff was concerned about the efficacy of telephone counselling(21) and Osmond et al. (2000) found that only half of those tested telephoned for their results.(54) Similarly, Bartholow (2005) reported that 22% of those tested did not report receiving their test results(55) and Wood, Ellks & Grobicki (2015) reported that 4/30 test results were not communicated to participants.(47) Fisher et al. (2015) reported that 2/62 required a reminder to return their sample.(50) Formby, Hirst & Cripps (2010) also reported that oral fluid samples were delayed in getting to the laboratory, which required participants to be contacted and asked to re-send their samples to ensure accuracy of results.(51) Linkage to care was not assessed because most studies (n=9) had no reactive results. The studies that did have reactive results were unable to check on outcomes for linkage to care due to features of their methodology.

Table 4: Acceptability, feasibility and efficacy of self-sampling for HIV

Study No	Author (year)	No. SSK returned / No. SSK distributed	Completion rate (%)	HIV positivity rate	Self-reported acceptability	Feasibility	Efficacy (ie, increases in HIV testing uptake)
1	Bartholow (2005)[55]	174 / 240 (self-reported; not clear if all self-sampled tests)	72.5%	3.4% (6/174)	Those in SSK arm rated satisfaction higher than those in clinic testing arm.	37 (22%) of those who reported being tested did not report receiving their test results.	Those in SSK arm were twice as likely to have tested in past month. However, they were not more likely to obtain their results.
2	Colfax et al. (2002)[46]	NA	NA	NA	19% chose SSKs for their next test in first survey (pre-marketing), but in second survey only 1% had used them.	NA	Availability of SSKs had not increased testing rates among those not tested previously.
3	Fisher et al. (2015)[50]	62 / 80	77.5%	0% (0/62)	Acceptable to 81% of MSM in sexual health clinic setting.	2 out of 62 required reminder to return sample.	Greater acceptance compared to clinic-based testing (62.5% vs 37.5%)
4	Formby Hirst & Cripps	60 / 126	47.6%	0% (0/60)	Pre-study survey showed 52% of MSM chose SSKs	Some samples were delayed in getting to laboratory, meaning participants had	Pilot successfully reached those not regularly engaging with HIV testing,

Study No	Author (year)	No. SSK returned / No. SSK distributed	Completion rate (%)	HIV positivity rate	Self-reported acceptability	Feasibility	Efficacy (ie, increases in HIV testing uptake)
	(2010)[51]				as preferred method of testing. Anecdotal evidence suggested demand for pilot to continue.	to be contacted to re-send. 7 samples had equivocal results and were re-tested (all negative). Capacity issues within virology for processing oral samples.	including higher than expected numbers of bisexual men, men not otherwise tested in last year and those not accessing GUM
5	Greensides et al. (2003)[49]	NA	NA	NA	-	NA	High levels of awareness, but low reported usage of SSK use in past year (4%).
6	Osmond et al. (2000)[54]	412 / 490	84%	1.5% (6/412)	Many participants commented on how easy it was to provide oral fluid samples.	Two indeterminate test results. 10 insufficient samples. 6 new diagnoses made. Only half of those tested telephoned for their results.	SSK found to be effective method at estimating population seroprevalence among MSM.
7	Sharma Sullivan & Khosropour (2011)[56]	NA	NA	NA	62% likely and 20% somewhat likely to take an offered SSK	NA	SSK is acceptable, and future research and interventions should focus on addressing self-identified barriers faced by MSM to testing

Study No	Author (year)	No. SSK returned / No. SSK distributed	Completion rate (%)	HIV positivity rate	Self-reported acceptability	Feasibility	Efficacy (ie, increases in HIV testing uptake)
							using SSKs.
8	Sharma et al. (2014)[53]	NA	NA	NA	SSK was least likely option among those available: appealed to less than half participants	NA	Novel approaches needed to increase HIV testing frequency, including combination packages.
9	Skolnik et al. (2001)[52]	NA	NA	NA	1% preferred SSK option of clinic or self-testing.	NA	Most preferred self-testing and clinic testing to SSK.
10	Spielberg et al. (2000)[21]	665 / 716	92.9%	0% (0/665)	98% agreed to participate in bimonthly testing in future. 99% said easy to use.	Staff concerns raised about efficacy of telephone counselling. Anxiety reported among 28% of male IDU. 99% test adequacy: no positive diagnoses made.	No detectable difference in testing rates between dried blood spot and oral fluid samples.
11	Spielberg et al. (2001)[57]	NA	NA	NA	92% of participants willing to enrol in monthly SSK study.	NA	Despite staff concerns, majority expressed willingness to submit regular SSKs.

Study No	Author (year)	No. SSK returned / No. SSK distributed	Completion rate (%)	HIV positivity rate	Self-reported acceptability	Feasibility	Efficacy (ie, increases in HIV testing uptake)
12	Wayal et al. (2011)[48]	NA	NA	NA	Acceptability of oral specimens examined with different parameters; broadly acceptable to MSM.	NA	SSKs could be a viable alternative to meet the increasing demand for sexual health services, but to improve uptake the method of service provision must be culturally sensitive and acceptable.
13	Wood, Ellks & Grobicki (2014)[47]	NA	NA	NA	Lower rates of acceptance for SSKs than nurse delivered testing (33 over the pilot vs 80 tests)	3/30 tests not processed. 4/30 test results not communicated	Combination outreach screening approach, including SSKs, is effective in targeting MSM using sex on premises venues.

Only six studies provided data on the effectiveness of SSKs for HIV in increasing the uptake of HIV testing. In the one RCT included in the review, Bartholow (2005) reported that those in the self-sampling arm were twice as likely to have tested for HIV in the past month, but they were not more likely to obtain their results compared to those in the clinic-based testing arm.(55) In the USA, Colfax et al. (2002) reported that the availability of SSK had not increased testing rates among those not tested previously, or significantly changed testing behaviour among those who do get tested.(46) In the UK studies, Formby, Hirst & Cripps (2010) reported that SSK offered an alternative means of testing, with 35% of participants having never tested for HIV before,(51) while Fisher et al. (2015) reported greater uptake of SSK (62.5%) compared to clinic-based testing (37.5%).(50) Formby, Hirst & Cripps (2010) concluded that the pilot successfully reached those not regularly engaging with HIV testing, including higher than expected numbers of bisexual men, men not otherwise tested in last year and those not accessing existing sexual health services.(51) Other studies provided data in support of this stance as well. For example, the only qualitative study included in the review noted SSK could be a viable alternative to meet increasing demand for sexual health services, but to improve uptake the method of service provision must be culturally sensitive and acceptable.(48) Wood, Ellks & Grobicki (2015) concluded that including self-sampling in outreach settings could be effective in targeting MSM using sex on premises venues.(47) Finally, four studies reported the HIV positivity rate, which was an average of 0.9% (12/1311). Two studies (both with MSM in the UK) reported a positivity rate of 0%.

3.2.4 Barriers, facilitators and motivators to self-sampling for HIV

The final section of the review assessed the barriers, facilitators and motivators to HIV self-sampling (Table 5). Key barriers included anxiety, concerns over the accuracy of testing, concerns about confidentiality, privacy and the lack of face-to-face counselling, and fears about the difficulty or pain involved in collecting samples. On the other hand, one of the UK studies reported that there was no difference in uptake related to importance of accuracy of results or willingness to wait for results.(50) Test reliability was reported to be a barrier in the other UK study.(51) Wayal et al. (2011) additionally reported potential barriers to uptake among British MSM to include preference for medical venues (which were perceived as discrete and appropriate, especially if symptomatic), fear that distribution in gay social venues could trivialise testing or promote stigma, concerns about unreliability of postal service for delivering samples, and anxiety over waiting for results.(48)

Conversely, reported facilitators to SSKs were the availability of telephone (as opposed to face-to-face) counselling, and perceived anonymity, accuracy, convenience and ease of use. Finally, additional motivating factors that were reported to contribute to the acceptability of self-sampling were awareness of the seriousness of HIV(48) and the benefits of regular/early testing,(21, 55) and agreement or awareness of being at risk of HIV.(21, 48, 53, 55) Two studies also noted that a cash incentive could be a motivating factor to test.(54, 56)

Table 5:Barriers, facilitators and motivators to uptake of self-sampling for HIV

Study No	Author (year)	Barriers	Facilitators	Motivators (ie factors contributing to the acceptability of SSK)
1	Bartholow (2005)[55]	Difficulty of collecting blood sample. Negative reactions from others if diagnosed.	Attendance at syringe exchange.	Perceptions of personal risk of HIV. Perceived benefits of regular testing.
2	Colfax et al. (2002)[46]	Most common concern was accuracy (56%)		
3	Fisher et al. (2015)[50]	No difference in uptake related to importance of accuracy of results or willingness to wait for results	-	-
4	Formby, Hirst & Cripps (2010)[51]	Reliability of test result. Speed of obtaining test results.	Ease of use of kit. Ease of following instructions. Lack of embarrassment.	Number of partners in previous year.
5	Greensides et al. (2003)[49]	Concerns raised about accuracy, privacy and cost by those who had not used self-sampling.	Convenience and privacy cited as main advantages. Ease of use also mentioned.	Awareness of alternative testing methods.
6	Osmond et al. (2000)[54]	42% (241/568) of study subjects expressed concerns: • unsure about accuracy (130/568; 23%) • lack of in-person counselling (81; 14%) • worried about confidentiality (26; 5%) (22%; 28/125 among those who declined)	-	Cash incentive used to recruit to study (resulting in high uptake among those with previous HIV diagnosis)
7	Sharma Sullivan & Khosropour (2011)[56]	Barriers cited: • Accuracy of test results (519/1047; 47%) • Unwillingness to provide address (396;	-	Hypothetical cash incentive being offered to test.

Study No	Author (year)	Barriers	Facilitators	Motivators (ie factors contributing to the acceptability of SSK)
		36%) • Desire for counselling (391; 36%) • Living with others (311; 28%) • Recently tested (277; 25%) • No need for test (245; 22%) • Not wanting to prick finger (217; 20%) • Not wanting to know status (61; 6%)		
8	Sharma et al. (2014)[53]	-	-	Motivations for HIV test (across all methods) • Test routinely (55%) • new partner (25%) • opportunity (21%) • recent unprotected anal intercourse (15%) • partner with STI (10%) • symptoms of STI (10%) • partner with HIV (3%) • felt need to test (2%)
9	Skolnik et al. (2001)[52]	99% selected other test methods, most important attributes: • accuracy/timeliness • privacy of results disclosure • linking of test results	Reasons for selecting self-sampling as first choice (n=2): • Anonymity • Convenience • Accuracy	-

Study No	Author (year)	Barriers	Facilitators	Motivators (ie factors contributing to the acceptability of SSK)
10	Spielberg et al. (2000)[21]	Reasons for refusal to participate in the study: • lack of time (19/45; 42%) • collecting samples would be too difficult or painful (10; 22%) • not wanting to collect specimens at home (6; 13%) • anxiety (5; 11%)	• Frequency of projected use inversely dependent on cost • Availability of telephone rather than face to face counselling	Agreement that early treatment for HIV results in prolonged health
11	Spielberg et al. (2001)[57]	Anxiety over receiving regular test results. Fear of pain of collecting sample. Concerns over inaccuracy of results. Waiting time for blood spots to dry.	Key themes convenience (51%), ease of use (32%), time efficiency (29%)	Help with reducing high-risk behaviour.
12	Wayal et al. (2011)[48]	• Preference for medical venues, perceived as discrete and appropriate, especially if symptomatic • Distribution in gay social venue may trivialise testing or promote stigma • Concerns about unreliability of postal services • Anxiety over waiting for results: mixed feelings over 'no news is good news' policy	• Desire for kits to be packaged as 'health check' to promote discretion • Availability in routine commercial venues • Being able to drop samples off in clinic • Having multiple options for receiving results • Testing for multiple STIs at once • Convenience of self-sampling	• Desire for peace of mind • Having a negative sexual experience • Need to be aware of HIV status due to serious implications

Study No	Author (year)	Barriers	Facilitators	Motivators (ie factors contributing to the acceptability of SSK)
			• Availability of oral sample kits	
13	Wood Ellks & Grobicki (2015)[47]	-	Clear supporting information and opportunity to access health promotion advice.	-

3.3 Summary

Few studies have examined the acceptability or feasibility of self-sampling for HIV testing and only 13 studies met the inclusion criteria to be included in this review. The majority of the evidence came from cross-sectional surveys or cohort studies, and there was only one qualitative study and one randomised controlled trial. Most studies were conducted in the USA, with just four in the UK. The majority of the studies, and all of those conducted in the UK, focused on MSM. Overall quality of the studies was mixed and relatively poor.

Few studies assessed acceptability and feasibility in terms of actual uptake and return of tests, with only five studies assessing distribution and return of SSK. Acceptability varied by sample type. The majority of the studies evaluated a dried blood spot SSK and these appeared somewhat less acceptable to participants than oral fluid sampling.(46, 47, 52, 53) However, the one study that directly compared the two found no difference in testing rates between dried blood spot and oral fluid sampling.(21) Only one UK study (with MSM) included dried blood spot SSK and the method proved less acceptable than nurse-led testing.(47) The methods by which SSK were distributed varied across the studies, but acceptability did not differ substantially by distribution method. It was not possible to assess acceptability by method of return because all of the studies that specified a return method reported that SSK were returned by post. Overall, feasibility was mixed and problems were reported with the return of tests and communicating results to participants. Again, there did not appear to be any significant difference by sample type; three of the studies reporting on feasibility having used oral samples, two blood, and one both. Evidence on linkage to care was particularly lacking and not assessed because most studies had no reactive results.

Evidence on the effectiveness of self-sampling for HIV in increasing the uptake of HIV testing was also limited. In the one RCT included in the review, Bartholow (2005) reported that those in the self-sampling arm were twice as likely to have tested for HIV in the past month, but they were not more likely to obtain their results.(55) Two of the UK studies reported increased testing among groups never tested before, including higher than expected numbers of bisexual men, men not otherwise tested in last year and those not accessing existing GUM services, but neither study included African communities.(50, 51) Although other studies reported that SSK could be a viable means of reducing pressure on existing sexual health services,(47, 48) the HIV positivity rate (where reported) was low for the high

risk populations included (two studies with MSM in the UK reported a positivity rate of 0%, (50, 51) suggesting that those most at risk of HIV were not using this method of testing.

Despite the limitations in assessing acceptability, feasibility and efficacy, all 13 studies in the review included some data to inform understanding of how SSK could work in practice, with concerns about anxiety over testing process, the accuracy of testing, confidentiality, and privacy being key barriers. The qualitative study also noted that there was a preference among the MSM interviewed for testing to remain in clinical settings. Conversely, key facilitators were the availability of telephone (as opposed to face-to-face) counselling, perceived anonymity, accuracy (although the latter was also identified as a barrier), convenience and ease of use (again, somewhat in contrast to opposing fears about difficulties in collecting samples). A number of studies also noted that awareness and perceived personal risk of HIV were motivating factors for testing.(21, 48, 53, 55, 57)

3.3.1 Strengths and limitations

The studies included in this review were of relatively poor quality, with most data derived from cross-sectional studies and only one RCT included in the review. Most studies were conducted in USA, which raises questions about the transferability of the findings to the UK context. Most, and all of the UK studies, were conducted with MSM, which again raises questions about the transferability of the findings to black Africans not identifying as MSM in the UK. Furthermore, data on actual uptake and return of tests, effectiveness of self-sampling in increasing HIV testing and effectiveness of processes for linkage to care were largely absent and represent key knowledge gaps. The lack of standardised reporting of outcomes also made it difficult to compare findings across studies. Only one qualitative study was yielded by the search, despite the potential for such studies to inform the design and implementation of self-sampling for HIV interventions.

3.5 Conclusion

Self-sampling for HIV testing has been suggested as an approach to broaden the available testing options,(39) and was successfully used in one pilot project set up to assess implementation of the UK National HIV testing guidelines.(37) NICE guidance on increasing HIV testing among black Africans did not specifically recommend self-sampling,(43) but SSKs were commissioned by some local authorities as part of their HIV testing services. These guidelines are currently being updated and new guidance to address late diagnosis in groups at risk is expected be published in December 2016. In the draft guidelines issued for

consultation, SSK and self-testing kits are endorsed as innovative ways of increasing uptake of HIV testing among black Africans. However, our review suggests that evidence to support the acceptability, feasibility and effectiveness of this as an approach to increase HIV testing is limited, and absent for black Africans people of all sexualities in the UK. There is a need for well-conducted trials of self-sampling interventions to assess acceptability, feasibility, and whether the approach can increase HIV testing among all high-risk populations and black African people in particular. It is important that these studies include detailed description of processes for, and the acceptability, feasibility and effectiveness of the processes for linkage to care including uptake of confirmatory testing and methods for linking those who test HIV-positive to care and treatment services. This will be particularly important for self-sampling (and self-testing) interventions to be implemented in practice.

The next Chapter presents the findings yielded via focus group discussions with non-specialists and service providers and one-to-one interviews with the latter regarding the development of an acceptable SSK distribution pathway and protocol via community-based health and HIV prevention services already accessed by black African people.

Chapter 4: **Findings from focus group discussions and one-to-one interviews**

As stated in Chapter 1, the aim of Stage 1 of the HAUS Study was to develop a SSK-based intervention that could increase the provision and uptake of HIV testing among black Africans using existing community and healthcare provisions. In doing so, it was important to understand the barriers and facilitators to HIV testing in general, to consider how participants responded to the SSK itself, and gain their insights into the most feasible distribution, collection and communication of results procedures. This Chapter presents qualitative findings drawing on FGDs and interviews, as described in section 2.2 above.

4.1 Perceptions of HIV testing interventions

Non-specialist black African participants demonstrated awareness of the range of settings in which most HIV testing currently takes place. It was clear amongst all participants, however, that specialist sexual health and HIV services were regarded as playing a crucial role in recommending and facilitating HIV testing, as well as providing ongoing social support for those who are diagnosed with or affected by HIV. Experience of, and opinions about, community and non-HIV/sexual health clinic offers of HIV testing were various, with most mentioning HIV testing during antenatal care, new GP registrations in high prevalence areas and POCT in community-based HIV charities. The vast majority regarded HIV testing as an acceptable and effective intervention due to the universal availability of anti-retroviral treatment in the UK.

Some service providers highlighted that undocumented African migrants were often isolated from the UK medical system and unaware of free access to HIV treatment, presenting barriers to HIV testing. One commented:

> *I think on a social level, from what I have experienced while working, is that a lot of people who are undocumented in this country don't understand the fact that the test is free, and the treatment is free [London non-specialist group 3].*

Furthermore, there was some concern that a profusion of HIV testing interventions could lead to a disjointed and confusing service landscape. Some felt that unfamiliarity with the NHS could mean that a proportion of black African people may be unaware of the confidentiality provisions, particularly those pertaining to HIV and sexual health.

There was considerable agreement that the stigmatising association of HIV with ‘sexual immorality’ and promiscuity (an association that many FGD participants and interviewees

described as being heightened within black African communities) provides an ongoing disincentive to test.

Aligned with findings from previous research (9, 58), some service provider and non-specialist participants alike pointed out that testing uptake may continue to be low because an HIV diagnosis was regarded as having profound health, social, financial, insurance and immigration implications. These views were often based on assumptions or considerably outdated information, even among service providers. One service provider queried with regard to HIV testing:

> *I don't know if I'm right about this, but does that not affect your credit rating? [Glasgow service provider group 1].*

Furthermore, a strong association between HIV and mortality among black Africans was repeated across service providers and non-specialists.

Some participants also believed that HIV exceptionalism had structurally prevented HIV testing integration into mainstream health services such as primary care. They described the historic requirements for pre- and post-test counselling and the requirements of careful results management barriers for both offers and uptake of tests.

4.1.1 Recognition of risk as a precursor to HIV testing

In many cases, a crucial factor that determines whether or not an individual undertakes an HIV test is the recognition that they have faced an elevated risk of exposure to HIV (i.e. a motivation to test), along with having the capacity and opportunity (time and skills) to act on that concern. With the exception of interviews undertaken among HIV clinicians and some service providers in London, improved recognition of personal HIV risk and the need for awareness of the disproportionate impact of HIV among black African people in the UK were rarely linked with the need for improved HIV testing uptake in this population. The findings summarised in this Chapter draw attention to the ways that HIV-related stigma and fear are inevitably linked to inaccurate risk perception, which in turn influences the motivation and capacity to test for HIV.

Perhaps unsurprisingly, the findings reveal a dissonance in perceptions of HIV risk between the epidemiological data on black African communities' and the way that the risk is perceived by individuals within such communities. What we are referring to here specifically is the lack of awareness (and acceptance) of surveillance estimates that reveal people of black

African ethnicity account for almost one third of adults with HIV in the UK.(1) Some participants felt that where potential targets were unaware of the scientific rationale for segmenting the population in relation to epidemiological categories, such approaches would be met with resistance.

> *I just see there being a bit of a disconnect, unless people are made to understand that this is, these are the clear [epidemiological] results that have been found, and this is why we're, you know, suggesting to you. Until that gap is bridged, I just don't. I just believe you're going to be almost, you know, you're just going to be met with, you know…"Uh"? [London non-specialist group 3].*

At least some service provider participants felt that the dissonance that emerged between individual risk perception and community risk profiling was a challenge that may often be beyond the capacity of the service provider to bridge in 'one-off' encounters. These findings demonstrate that the diverse range of participants had pervasive concerns about the interpersonal and wider social implications of targeting HIV testing interventions for black African people in the UK.

4.1.2 Competing imperatives

The relatively low priority of HIV screening among people who had many more pressing needs to be met was frequently raised, as was lack the time or funds to reach a testing site. In addition, some participants highlighted that there are those who lack the freedom or control in their lives to undertake a test while maintaining adequate levels of privacy to avoid HIV related stigma. Qualms were also expressed about the extent to which confidentiality within health services could be trusted, which meant the prospect of disclosure presented too much risk for vulnerable individuals.

4.1.3 Targeting HIV testing on the basis of actual or perceived ethnicity

A range of issues emerged among participants about the underlying inequalities that can impede the success of HIV testing interventions designed to target black Africans. There were intense concerns about such offers being perceived to be driven by racism and discrimination across both service providers and non-specialist participants, awareness of the particular sensitivities that targeting could fuel anti-migrant discourse, and the threat that targeting would be perceived as divisive. Similalry concern was expressed that targeting all people considered, by a service provider, to be black African implied complicity with the homogenisation of highly diverse cultures and communities. Finally there was discomfort with the assumption that targeting would probably rely on appearance and colour of skin

(being 'black enough', as one specialised HIV health care provider mentioned). Therefore, imbalances of power pervade accounts of black African people's engagement with HIV testing to a considerable extent. Participants reflected on the way that such imbalances affected offers and uptake of HIV screening, and this is amplified rather than minimised when it comes to interventions that are designed to disproportionately benefit black African people.

This concern was further evidenced by a few non-specialist participants who raised concerns about HIV testing interventions in acute services that they perceived to be based on skin-colour rather than an individual's actual HIV risk. It was argued that black African people had valid reasons to distrust the health service, due to previous experiences of racism, being patronised, not given fully informed consent, or being exposed to racial micro-aggressions in these settings (59).

> *Participant 1: By the way, if you find yourself in an A&E, and if you're black African, you will get a test anyway. So…[Others laugh]*
> *Participant 2: He is right.*
> *Participant 1: They will just… They will just, you know, shove it into you, and when you ask a question, why didn't you tell me, they go, oh, oh we are very sorry. But it's always like that. It's just not new, particularly if you're in South London [London non-specialist group 2].*

Concerns were also expressed about the difficulty of ensuring fully informed consent in the busy and emotionally heightened environment of acute care services. Others mused that they assumed that most bloods drawn for routine purposes were already being screened for HIV, and that HIV screening was happening 'behind closed doors'. In both types of discussions, non-specialists demonstrated little confidence in mainstream NHS providers' judgment and communication strategies when it came to HIV.

Not all discussion about targeted approaches focussed on their negative impact or repercussions. Some service providers noted that rationalising limited resources made sense within a current climate of reduced public spending. As such, although targeting HIV testing to black Africans was seen as problematic for a number of reasons as outlined above, it was often counterbalanced by the epidemiological and practical need for such targeting:

> *Participant 1: I have trouble just targeting just Black communities with that kit, for me it has to be universal for everyone I wouldn't like to just target a specific population group.*

Participant 2: This is screening! If the epidemiological studies that there're high prevalence and new incidence rate in that race, in that particular community, that is really...really where resources should be [London service provider group 2].

Epidemiological evidence was presented as a neutral counterpoint to the barriers to targeting:

I think you can target in a way that's honest…. Because, for example, I think it's very clear and honest to say, if you are from a high prevalence area – if you've had unprotected sex in a high prevalence area of HIV and then name where the high prevalence areas are – you are at more risk of acquiring it [London service provider interview 1].

Furthermore, some service providers argued that the offer of an HIV test may be catalytic for individual testing decisions. From a provider perspective, acknowledging the consequences of not offering an HIV test to a black African service user or patient was considered as one way to support providers in deciding to offer the test, even where they acknowledge that a challenging discussion could follow.

Finally, participants focused on reducing barriers to targeting through participant-led and culturally sensitive 'approaches to enhancing targeting'. These included embedding the offer of an HIV test within a wider 'bundle' of targeted interventions to diffuse the specific stigma of HIV, for example, within offers of targeted approaches to address sickle cell or bone marrow transplant donations or hypertension. A culturally sensitive approach to targeting that ensured the co-production of targeting approaches with representatives of black African communities was also suggested, as was the introduction of such interventions by black African providers. These approaches were seen to reduce barriers to targeting by being particularly sensitive to the ethnic mix of those involved within the targeting interaction. Participants further noted that attention needs to be paid to the potential of health promotion or research materials which can which link HIV to black Africans in the minds of the general public, and the harmful social outcomes that could result if such interventions were misconstrued by a wider audience.

4.2 Perspectives on the use of HIV Self Sampling kits

There was considerable (although not universal) enthusiasm around the abstract notion of distributing SSKs to black Africans.

4.2.1 Device practicability

Prior to taking part in this research, awareness of SSKs was not widespread amongst the non-specialist participants, and only a handful disclosed having used one in the past. A

considerable proportion initially assumed that results would be instant (ie. self-testing) as there were national media reports about that technology being licenced just before the period of research. Additionally, participants were invariably surprised by the volume of blood (400 microlitres) required for a sufficient TINY Vial sample, and service providers in particular stressed routinely that they did not think that most members of the public would be able to produce a sufficient sample.

> *I mean, we do health checks and we take blood from the finger and our machines just been changed to take a much smaller sample, we have to take 40 microns of the blood, not a big amount which is why I kind of, I was a bit shocked at this. And just getting that amount of blood is actually sometimes quite traumatic for a person [London service provider group 1].*

While fear of needles and blood was also discussed, a few pharmacists, nurses and GPs held the view that physiologically, their black patients often struggled to produce fingerprick samples because of thickened skin on the fingertips.

Many of the service providers and non-specialist participants felt that the TINY Vial kits would prove to be too complex for most people to use correctly. As one participant in a service provider group in Glasgow expressed:

> *I think that will be quite tricky. Certainly, I don't think it's one that you can tell them it's that easy to do [...] maybe if the test was simpler [Glasgow service provider group 3].*

Furthermore, a number of participants expressed concern that SSKs could be easily contaminated by users. Participants questioned the robustness of the technology and procedures on offer to the public, and also whether samples would be mismatched between two users. There was also an underlying worry that unskilled members of the public who used SSKs might introduce risk to others (through contamination or spills) or increase the chance of invalid/inconclusive results in some way.

> *Can I be very honest? I don't like this, and the reasons why I don't like it is because it isn't simple… It isn't easy and, of course, this will not be popular. […] By the time people put a jab and then put their hands and blood starts dripping, one, two, three, four, five, six, seven, eight, up to 20, I find it a bit… very, very cumbersome. It makes it very, very… It's liable to a lot of mistakes. And so what do you then do? [London non-specialist group 2].*

In many of the discussions with service providers, they raised comparisons between these HIV SSKs and a range of kits for other conditions that are now designed for self-sampling. These comparisons highlighted that many such kits had not been a great success (chlamydia

and bowel screening kits in particular were perceived as under-used and not cost-effective). In contrast, HIV service providers with experience using dried blood spot kits for HIV self-sampling among MSM were encouraged by the benefits that self-sampling could bring to black African users.

4.2.2 HIV Stigma and the need for privacy and discretion

HIV-related stigma was among the most pervasive concern emerging within this data data which supports extensive theoretical and empirical work in the field more broadly.(13, 60, 61) All participants were clear about the profound challenges that HIV stigma presents for prevention and testing interventions. The role of stigma was particularly evident in the concerns about potential isolation and resulting harm that could be experienced by SSK users. Indeed, it is this pervasive stigma that continues to make the promotion of HIV testing within this population so challenging. Stigma predicates against self-perception of risk and promotes profound fear about being seen to be accessing an HIV testing service due to of the social implications that may follow. It also makes providers uncomfortable in offering the test because they too are aware of these social implications. While SSKs were considered by many participants as having some scope in reducing these social risks of discovery, they were simultaneously understood to be a means of 'keeping HIV underground', providing cover to those who desired increasingly secretive means of confirming whether or not they are infected.

Closely connected to the matter of HIV stigma, and directly related to the feasibility and acceptability of SSK community distribution, were the many facets of privacy that participants discussed. Although service providers may consider health providers and pharmacists to be trusted professionals who understand and adhere to data protection requirements, non-specialists were far less likely to share this view. Not only did they worry that presenting in such environments and requesting an HIV test might result in judgment and bias, it was also clear that a considerable proportion of these participants held deep-seated fears about who else may acquire access to their most personal health information as a result of such an interaction. In conjunction with this concern, other non-specialist participants pointed out that some potential users may lack power vis-à-vis their partner in order to independently use an SSK. One participant offered a scenario of a husband and wife, where the former possessed control over the latter and prevented her from using the SSK, or where intention to use the SSK led to conflict in the household.

Among the many beneficial elements identified, privacy, discretion and the capacity to determine one's own status in an environment of relative anonymity were regarded as considerable strengths, particularly among potential lay users of the kit. Participants felt that the ability to use a kit privately was an essential benefit for those who were frightened about attending a sexual health clinic, raising the issue in a clinical setting, or seeking out a community organisation that provides HIV testing. To this extent, taking a sample in private was regarded as a means of avoiding the stigma that is heavily associated with those who seek out an HIV test.

> *[It's] quite hard for some people to go and approach GPs or doctors to explain their situation. Like myself, I've been thinking about it. It's been in my mind for a long time to do a test, because I've been hearing people, I've been watching this, I've been… you know what I mean, media's talking about it, so I don't even know my status, but when something like this came up, if it's, like you said, I think it's an opportunity for people like me to take the chance to do it [Glasgow non-specialist group 3].*
> *But you've got to understand, most people, especially with location, where people live, they don't have that time to go to the hospital and go through the whole process of getting a HIV test. And it's not even a matter of going to the hospital. It's a matter of I could just come home, I could do this and I could keep going with what I do in a normal day and then get my results, like they did [with] chlamydia tests [London non-specialist group 1].*

Thus for some, SSK distribution was regarded as a way to access to HIV testing that is non-stigmatised, highly accessible, and convenient, potentially increasing appeal to those who had not considered testing in the past.

4.2.3 Choice and autonomy as both opportunity and risk

The findings described above should not be interpreted to mean that SSKs were perceived by research participants as a means of replacing traditional and POCT HIV testing. Instead, SSKs were described as a means to bolster the array of options on offer.

> *I like the idea of home sampling because it gives more choice, flexibility and opportunity for people to have an HIV test. So for example, if people are worried about confidentiality, they can do the test in the privacy of their own home. And even though they still have to send the result in to a lab, at least it's not done through a third person, having to disclose their history and why they're worried about HIV [London service provider interview 1].*

Service providers and non-specialists alike were interested in the extent to which the SSK increased individual's autonomy over their health, their HIV testing options, and their decision-making around how, when and where to have a test. There was also an extent to which this autonomy introduced a sense of liberation around HIV, and a few participants

(mainly service providers) mentioned that making SSKs available in public spaces for private use might help to tackle HIV stigma at a structural level. Not everyone agreed with this last point, however, as it was also mentioned that increasing the extent of privacy through the use of SSKs may serve to hide HIV even further away.

Chief among the concerns expressed about SSK distribution was that the kits appeared to circumvent the provision of sustained interpersonal engagement and support. In almost all groups and several interviews, participants voiced their concern that users would be alone while *waiting* to hear their results and most crucially when *discovering* the results. In a considerable proportion of groups and interviews, participants felt that the risk of suicide and self-harm was elevated among SSK users learning of a reactive result, because they would not be in the physical presence of a professional for this discussion. Where self-testing for HIV was discussed, this concern was even greater, and the SSK was at least regarded as a means of better ensuring linkage to care than self-testing technologies. There was an assumption embedded within these exchanges that linkage to support and care services was far more assured with face to face testing services, and there was considerable doubt that this could always be achieved with SSKs.

To some extent, such comments reveal a fundamental concern about the loss of systems control that SSKs represent. This is ultimately a direct consequence of increased user autonomy. It is not surprising that this was a key tension that emerged among participants with regard to this technology, and of note that potential isolation as a key drawback of SSKs was raised by service providers and non-specialist participants in equal share.

4.2.4 SSKs and Point of Care Testing

There was also considerable discussion about ensuring that HIV testing is accompanied by a talking intervention given by a skilled professional, enabling risk assessment, pre-test counselling (and potentially, advice on the use of an SSK). To this extent, guidance suggesting that pre- and post-test discussions are not entirely necessary is not universally accepted by service providers or non-specialists (62). In all focus groups and several interviews there were those who made it clear that their preferred testing pathway involved direct contact and risk assessment discussion with a skilled service provider, followed up by immediate on-site POCT. Such individuals considered SSKs to be a ‘poor relation’ to POCT. One participant queried, “If you're going to start offering it as an anonymous kind of thing

that's not connected to services, well, what's the reason for doing that? What problem are you trying to solve by offering that?" [Glasgow service provider interview 1].

Those who thought testing should be delivered with interpersonal engagement said it seemed peculiar to distribute SSKs when POCT afforded immediate sample and results collection, with full support and advice on offer.

Essentially, these findings highlight participants' ambivalence to SSKs. On the one hand, they expressed enthusiasm about the freedom and autonomy that this technology offers. However, they were also concerned that this comes at the sacrifice of immediate results, professional contact, support and clinically robust procedures. It was widely held by most participants that SSKs needed to be embedded in larger support interventions that involved discussions with skilled professionals.

4.3 SSK distribution options

The privacy afforded to individuals in each potential SSK distribution setting was ultimately the overriding factor in participants' assessments of their suitability. However, for every setting, there were disagreements as to whether privacy and confidentiality could be guaranteed. Therefore, while some saw GP surgeries as providing an ideal combination of privacy and medical expertise, others worried that Home Office officials could be notified of an outcome via the medical facility, and there were concerns that even the discussion of an HIV test could persist on a medical file with negative consequences.

Furthermore, while some argued that ordering such a kit to be delivered through the post at home might be ideal, this suggestion was almost always vetoed by others who felt that most black African people did not live alone, and the arrival of such a kit in the post (or even the carrying of a package that is distributed in the community) would always elicit questions about what is inside.

> *I worry that we're not understanding the home environment in which this will land in enough. That needs to be understood. There are so many other issues going on with our communities that the context in which this lands, it needs to be understood [London service provider group 3].*

Many participants favoured voluntary pick up of SSKs in key community sites (similar to what has been done with chlamydia self-sampling kits), rather than service provider-initiated distribution, as this affords greater privacy while simultaneously reducing the potential for black Africans to feel targeted and potentially stigmatised. At the same time, it was

recognised that promotion of the kit to reluctant or unfamiliar users would be required. Indeed, there was considerable support for the proposition that first-time users should be shown how to use the kit, in order to ensure efficiency in SSK use and uptake.

Some participants delineated the need for a user-led approach within a fuller HIV prevention paradigm, starting with a discussion about HIV awareness, elevated prevalence among black Africans in the UK, individual risk-perception, and the importance of prompt access to antiretroviral treatment for people with HIV, prior to a potential offer to take away an SSK. To this extent, it was agreed that assumptions of universal willingness (or indeed need) to use SSKs among all black African people were problematic, and that on balance, it was recommended that often a user-led and needs-led approach involving some dynamic interaction with a skilled distributor would be required. To this end, service providers suggested that such distribution would be best placed within existing service specifications, with additional resourcing to ensure adequate staffing and promotion.

In terms of the best sites for accessing SSKs in the community, there was near uniform support for distribution of the kits to black African people through GP surgeries. The confidentiality and privacy afforded in a GP setting was seen by many as a 'gold standard' option for SSK distribution. However, there was concern about the capacity of surgery staff to appropriately target black Africans while avoiding racist and stigmatising approaches.

> ***[Interviewer: Do you think it's possible to target these [SSKs] mainly, or exclusively at black Africans?]***
> *Participant 1: I think in General Practice that would be quite difficult.*
> *Participant 2: Yes, it's difficult from the point of view that you shouldn't discriminate [Glasgow service provider group 3].*

Some were confident that developing cultural competence training for GP practice staff could help to overcome this risk. Furthermore, it was thought that on balance, the strong accessibility of the setting could outweigh the perceived shortcomings of distributors.

Other concerns, voiced particularly by service providers, included the time that such an intervention would take during the brief ten minute appointments typically allocated in primary care, given that raising the topic of HIV requires some sensitivity, and the complex TINY vial kits (in particular) needed to be explained and demonstrated. There was considerable variation opinion on the role that various GP surgery staff could play in active/passive distribution of SSKs, with a consensus on the fact that a specific appointment should not be required to acquire a kit. Some favourable comparisons were made with the

way in which chlamydia self-sampling kits were made discreetly available in such locations. However, the majority of service providers took the view that nurses and general practitioners should actively target and initiate distribution in order to increase cost effectiveness by sharing information and assessing the likelihood of need, and increasing motivation.

There was also nearly universal approval of HIV specialist community organisations distributing SSKs alongside current outreach work. This workforce was deemed to have the expertise required to target this population sensitively, with less risk of causing offense or generating responses that might exacerbate HIV related stigma

> *You can say: You know what? We've got these kits and you can test in your home. The results won't come back to me. I don't really need to know until maybe you are confident enough maybe to discuss it with me. So I think it's a good opportunity [Glasgow service provider group 2].*

In the main, SSK distribution by African-focussed HIV-specialist community service providers was regarded as having the potential to work seamlessly with community HIV promoters' existing skills and approaches, as well as benefitting from existing relationships and infrastructures for setting access and referrals.

Further discussions were prompted about the appropriateness of pharmacies, faith-based organisations, higher education institutions, dental surgeries, hairdressers and salons with high proportions of African users, as well as targeted online ordering systems for home delivery of kits. While the 'normalisation of HIV' was regarded as a potential strength of all of these distribution sites, the overriding response from service providers and non-specialist participants alike was that clinical governance concerns ruled out these options.

> *It's because in a pharmacy it's not like a GP. There'll be someone else picking up different drugs or waiting behind you or whatever. So that's where you feel, "God, there's someone right here….". There's no, like, privacy in the pharmacy. You're not going into the little room; you're going to a counter [Glasgow non-specialist group 1].*
> *I would say nobody would be courageous enough, especially if they are married or even if they want to get married in the next year or so to go to your pastor and ask for an HIV test kit, that's almost impossible [London service providers group 3].*

Lack of privacy (including the arrival of a kit through the post), and lack of appropriate HIV expertise, impartiality, or guarantees of confidentiality amongst other distributors were at the forefront of participants' rejection of using such settings for targeted distribution of SSKs to black African people.

4.4 Summary

The data from this stage of research fed directly into the process of intervention development, described in section 2.4. In particular, these findings are perhaps best summarised in relation to the COM-B model of behaviour change(36) which was ultimately applied to determine the best way forward for the intervention development for Stage 2 which is described in Chapter 5 below.

With regard to capability of service users and providers to distribute and use the SSK, concerns were highlighted about the amount of time that service providers had (particularly general practitioners) to initiate discussion and encourage use, and furthermore there was also a fundamental concern raised in all groups about the amount of blood required to provide a TINY vial sample.

On the other hand, targeted distribution of SSKs was seen as a broadly positive means of expanding the range of opportunities for black African people to test for HIV. There was widespread enthusiasm about SSKs as one of many new technologies that comprise an improved array of HIV testing options for black Africans. There was specific support for the fact that SSKs could provide an opportunity for the initiation and follow through of an HIV testing discussion in a setting that black African people were already accessing, so convenience was regarded as a significant gain.

Finally, these findings offer us considerable insight into the potential motivation issues arising with targeted offers of SSKs. Participants advised that targeted offers (particularly those made in healthcare settings and/or made by non-black Africans to black African service users) needed to be couched in clear terms, using epidemiological evidence to help people consider their likely risk, and to work to avoid the perception that offers were being made because of racist or xenophobic sentiment. Instead, it was deemed of utmost importance that distributors were regarded as trustworthy, knowledgeable, non-judgemental and that they could encourage a realistic degree of reflection about HIV risk among those to whom they encouraged SSK use. There was a universal view that SSK distribution needed to actively resist HIV stigma rather than potentially reinforce it.

Ultimately, this data demonstrates that we cannot underestimate the extent to which considerations of privacy (and its limits) are at the centre of considerations for SSK feasibility and acceptability among black African people in the UK. Central to this concern is

the pervasive presence of HIV-related stigma, impacting on service providers and black African people alike. Finding the correct mechanisms for highlighting epidemiological realities among members of ethnic minority communities, without engendering feelings of imposed stigma and blame, are not easy.

4.4.1 Strengths and limitations

Although limited in scope and scale, the range of recruitment methods used for our FGDs helped to ensure that we had a diverse mix of non-specialist participants, most of whom were unlikely to have taken part in similar research previously. We started to approach data saturation by the time of the latter focus groups and interviews, demonstrating that our use of purposive sampling for both specialist and non-specialist participants had helped to achieve a balanced range of perspectives and experiences. The decision to make some of the non-specialist groups more homogeneous (all male; younger; HIV positive) was a benefit overall, as it helped to ensure careful consideration of distinct subject positions during both data collection and analysis. Although the decision to hold one to one interviews with HIV clinicians and other decision-makers ultimately resulted in divergent and multiple data sources for this phase, the option of mixing them in groups with other specialist providers was not only less feasible in terms of availability to attend, but it was also clear that given the strongly divergent insights expressed by those in this sample (influenced by clinical experience and policy involvement), it was ultimately best to collect their data separately.

Ultimately, the use of these qualitative methods to collect data in two geographically distinct locations enabled the study team to: triangulate findings across study populations and geographic areas; compare and contrast specialist / non-specialist perspectives on SSKs and their targeted distribution, and their rationales for these viewpoints; and to directly address these perspectives in the design of the intervention to be assessed in Stage 2 of the study.

4.4.2 Conclusion

While the introduction of this new technology is meant to assist in circumventing the problems of low HIV testing uptake among black Africans, these findings remind implementers to be cautious about not introducing new problems while trying to address existing ones. The next Chapter builds upon the findings presented in this Chapter to develop the intervention which was implemented in Stage 2 of this study.

Chapter 5: **Intervention development**

This Chapter addresses the first aim of Stage 1, to develop an SSK-based intervention to increase the provision and uptake of HIV testing among black Africans using existing community and healthcare provision.

The methods for intervention development comprising a four-step process, informed by the behaviour change wheel are described fully in section 2.3. The four-step process is as follows:

- Step 1: Delineate key intervention components
- Step 2: Map barriers and enablers of the implementation of intervention components in relation to theoretical domains
- Step 3: Identify potential intervention components that can overcome modifiable barriers and enhance the enablers within a future intervention;
- Step 4: Ensure viability of the intervention using APEASE criteria.

The sections below discuss the results at each point of this process.

5.1 Step1: Delineate key intervention components

The research team identified eight key intervention components:

1. Setting and location
2. The targeted offer of an HIV SSK to black African people
3. Participant personal information collection
4. The self-sampling kit itself
5. The appearance and packaging of the HIV SSK
6. Information leaflet and instructions for correct use of SSK
7. Kit return, and
8. Result communication.

In order to facilitate focused consideration of the key intervention components, each component and its implications for the research team, participants, and service providers are presented in Table 6. Each component is then explored in detail within step 2.

Table 6: Key intervention components

Intervention components	**Requirements**	**Notes regarding component and associated behavioural domains**
Setting and location	Research team needs to engage with professionals and black African, non-specialist, members of the public to assess relative opportunities presented by a range of potential testing settings and their acceptability and assess the pragmatic aspects of intervention delivery within these diverse settings.	Not a behavioural domain per se • Raises questions of the scale of locations and smaller places within them (e.g. reception are of GP practice) • Needs to be explored by both a range of health professionals and black African members of the public • Presents a central question for subsequent acceptability and feasibility study if multiple settings are compared
The targeted offer of an HIV SSK	Two distinct behavioural domains for health provider suggested: i) identifying black Africans ii) and subsequently offering the HIV SSK	• Which health providers could implement this approach? • How would the offer work within their routine practice? Or should the interaction be specific rather than within routine practice? • Amenable to an analysis of theoretically relevant barriers and facilitators to imagined implementation
Participant personal information collection	Participant must provide accurate information to enable processing of sample and provision of results	• Scope for health provider to intervene here or relevant documentation to be considered as an active part of the intervention • High degree of sensitivity required given HIV related stigma and for some, issues relating to migrant status • Amenable to an analysis of theoretically relevant barriers and facilitators to imagined implementation • Central to both the acceptability and feasibility aspects of the intervention
The self-sampling kit itself	Use of a CE approved kit - not amenable to change or modification	• The choice of SSK is subject to relevant regulations. • Central to both the acceptability and feasibility of the intervention

Intervention components	Requirements	Notes regarding component and associated behavioural domains
	Or seek permission to proceed with non- CE marked kit	
The appearance and packaging of the HIV SSK	Participant and outreach distributor must transport the SSK without damaging it and may wish its content to remain unknown to others	• The participant must transport the kit from the site in which it was offered to the site in which they intend to use it. • Given the stigma of HIV and HIV testing within these communities the appearance of the kit has particular sensitivities • There is scope for the packaging to be considered as an active part of the intervention, particularly if it was also used to deliver behaviour change techniques that could boost uptake and engagement or compliance with the kit. • Amenable to an analysis of theoretically relevant barriers and facilitators to imagined implementation • Central to the acceptability of the intervention
Information leaflet and instructions for correct use of SSK	Participant must comply with kit instructions and understand result process and meaning.	• Compliance with kit instructions is complex and involves multimodal sequential behaviour domains • High levels of literacy required (although visuals are also provided) • Central to the acceptability of the intervention
Kit return	The participant must return the kit to get it processed within the lab and to enable results to be communicated	• Amenable to an analysis of theoretically relevant barriers and facilitators to imagined implementation
Result communication	Researchers and providers to give results in acceptable ways and specify patient pathways where relevant	• The decision for choice of return options is subject to best practice and standards of care. • Central to both feasibility and acceptability of the intervention.

5.2 Step 2: Intervention barriers and enablers and relation to theoretical domains

Key theoretical domains (see Table 1, Chapter 2) were important for most, if not all, intervention components. Skills, beliefs about consequences, social influence and environmental context and resources were particularly important theoretical domains across many of the intervention components and their target populations. Below, we map the key barriers and enablers that we identified for each intervention component; these could relate to the service provider (SP), user (U) or both (B).

Setting and location: Not a behavioural domain but important to secure locations that maximise opportunities to reach African communities, and settings that could facilitate trust in the intervention process. Also the limited amount of time with a potential user in some settings may prohibit intervention delivery on top of meeting the individual's presenting needs.

The targeted offer of an HIV SSK: A central dimension of the intervention outline contained within the NIHR's commissioned call was the specificity to black Africans. It was imperative to reflect upon which person or persons would be most appropriate to make a targeted approach. It was also important to consider the point in the path of the patient/client journey through routine services was the most appropriate time to make an offer of a self-sampling kit. It was equally vital to address risks about the potential implementation of the targeted offer to minimise harm and maximise uptake.

Key barriers in relation to relevant TDF domain:

- Knowledge: Lack of knowledge as to why would target HIV testing at black Africans (SP)
- Skills: Lack of skills in initiating conversations about targeted self-sampling (SP)
- Social/professional identity: Service providers may or may not see routine or universal testing as part of their day to day role (SP)
- Beliefs about capabilities: Sense of low self-efficacy and capability concerning targeted offer of a kit (SP)
- Beliefs about consequences: Perceptions a targeted offer will be perceived as racist and this may compromise their relationship with person they have targeted and other community members and lead to damaged reputation (SP)

- Intentions: Potential service users and providers may have prior intentions of testing through other routes (not self-sampling) (B)
- Environmental context and resources: Population level exposure to targeting of black African populations may lead to heightened stigma and disincentivise testing (B)
- Social influences: Strong social norms concerning the avoidance of conduct which can be perceived as racist and discriminatory within a cultural context of xenophobia, racism, intergroup conflict, identity and social identity (SP)
- Emotion: Service providers distress and negative affect will be a barrier to targeted offer of a test (SP)

Participant personal information collection: Recipients of SSKs must provide accurate personal information to enable their sample to processed and results returned to them. This is central to facilitate the later communication of negative, unsuitable sample, or reactive test results and secure an entry into HIV care for anyone who obtained a reactive result. Although providing this information is within the behavioural domain of the participant, the service provider who makes the targeted offer of the SSK may be instrumental in explaining or reassuring the participant of the need and safety of disclosing personal information within the context of the HIV test

Key barriers in relation to relevant TDF domain:

- Beliefs about consequences: Personal details may not be confidential and be seen by others or shared across agencies impacting negatively upon future health and social care (U)

Key facilitators in relation to relevant TDF domain:

- Beliefs about consequences: Clear information detailing exactly how personal information would be used and why it was required would reduce perceptions of negative future consequences (U)
- Environmental context and resources: Use minimal information to enable the lab to contact the participant (U)
- Environmental context and resources: Use online systems for completing study procedures and data collection (U)

The testing kit itself: While not a behavioural domain the choice of self-sampling kit represents a central component of the intervention. Regulatory and clinical standards limit

options and create challenges if wanting to use non-CE approved kit or enhance current kit options (see section 5.3.1).

The appearance and packaging of the HIV SSK: There were three particularly important dimensions to consider. First, how to ensure that the kit was packaged in a way to lessen the risk of damage during transport from the setting in which it was offered to the setting in which it was used. Second, the team considered how to address and minimise the effects of social stigma associated with being seen to be in possession of an HIV test. Third, the team reflected on how the intervention packaging could support the recipient in their testing behaviour.

Key barriers in relation to relevant TDF domain:

- Beliefs about consequences: The packaging may be recognised as an HIV SSK and the users 'reputation' within their communities may be damaged (U)
- Environmental context and resources: Use of any external label/packaging that mentions HIV or test kit (B)
- Environmental context and resources: Concerns relating to the safety of the kit and potential damage to it (B)
- Social influences: Perceived HIV stigma shaping interpretations of carrying a kit if it is recognisable to others (U)

Key facilitators in relation to relevant TDF domain:

- Environmental context and resources: Use brown paper bags (or other generic material) to distribute/carry kit (B)
- Environmental context and resources: Use non transparent materials to distribute/carry kit (B)
- Environmental context and resources: The kit has to be convenient to carry (B)
- Environmental context and resources: Tight, secure packaging that will not break/open/tear prior to use of the kits (B)

Information leaflet and instructions for correct use of SSK: Given that SSK recipients were likely to use the kit without the support of the service provider who distributed it, potentially days after this interaction and predominantly in a domestic setting, it was important to optimise the information on the participant information sheet and kit instructions

for acceptability and usability. Irrespective of the complexity of the intervention components, the correct use of the kit represents a complex multidimensional behavioural domain as it involves 13 distinct steps (see supplementary information).

Key barriers in relation to relevant TDF domain:

- Skills: Lack of English language skills could hamper use of kit (U)
- Skills: Lack of perceived skill in compliance with complex instructions (U)
- Beliefs about capabilities: Concerns that test instructions may be too complex and difficult to follow (U)
- Beliefs about capabilities: Concerns that language used will not be understood (U)
- Memory & decision processes: Perception that instructions are too difficult and complex to follow (U)
- Memory & decision processes: The medical language concerning test results may be confusing and impact negatively on testing decisions (perceptions of test efficacy) (U)
- Environmental context and resources: Perception that readability and font size of instructions are too small to read (U)
- Environmental context and resources: Medical language and terminology could be alienating to participants ('Lancet', 'non-dominant hand') (U)
- Emotion: Words/Graphics on the printed instructions or instructional video could increase anxiety and fear and may lead to avoiding the kit (U)
- Emotion: Anxiety levels and fear of test results may influence compliance with instructions (U)

Key facilitators in relation to relevant TDF domain:

- Skills: Video/Voice provision of test instructions to facilitate compliance with test instructions (U)
- Beliefs about capabilities: Use of clear simple messages and pictures (U)
- Beliefs about capabilities: Translate into other languages (U)
- Environmental context and resources: Having additional on-line video of someone using the kit (U)
- Social influences: Perceived need for the service provider to have used the test themselves (U)

- Social influences: Perceived need for the service provider to explain the test process in person (U)
- Social influences: 24 hour access to pre- and post-test counselling service may facilitate uptake (U)
- Social influences: Signal clearly sources of and easy access to social support regarding testing within instructions to facilitate testing (U)

Kit return: A further core component was the process of the participant returning the collected sample with sufficient information to enable processing and result communication. This element again represented a relatively complex self-managed behavioural domain. Having used the kit, the participant must properly enclose the sample along with an identification label and sample return form within the protective packaging and ensure that it is posted via the supplied postage-paid, addressed envelope.

Key barriers in relation to relevant TDF domain:

- Beliefs about consequences: Perception that participants will not return the kit if they believe it will get lost or spoiled within the postal system (U)
- Environmental context and resources: Royal mail system would disincentivise kit return through widespread perception of distrust with the system (U)
- Social influences: Returning kit to community setting, eg Faith leaders (as potential distributor) linked to privacy concerns and disincentivising kit return (U)
- Emotion: Concerns about the affective impact of information if the testing process was not confidential (U)

Key facilitators in relation to relevant TDF domain:

- Skills: Previous competence with on-line tracking systems may facilitate kit return (U)
- Beliefs about consequences: Participants should be given a choice of how to return the kit to accommodate beliefs about consequences (U)
- Intentions: intentions to test in situ at distributor venue may enable uptake (U)
- Memory & decision processes: Having choices of ways of returning the kit was seen as facilitating test kit return (U)

- Environmental context and resources: Post boxes are ubiquitous and can enable kit return with minimal effort (U)

- Environmental context and resources: Medical facilities such as GP surgeries were trustworthy with management of samples (U)

Result communication: The final component of the intervention related to the processing and communication of test results. These processes are subject to clinical governance regulations and identifying mechanisms by which best practice would be delivered was crucial (see section 5.3.3).

5.3 Step 3: Intervention components to overcome the modifiable barriers and enhance the enablers

Table 7 illustrates the mapping of the key barriers and facilitators to potential intervention implementation against COM-B elements and the concomitant specific behaviour change theory (BCT) that could enhance implementation. The intervention components each present different foci in relation to the COM-B elements, for example, some highlighting the need for focus upon capability (the targeted offer of a SSK and compliance with kit instructions) and some with a focus upon opportunity (the appearance and packing of the SSK). The table also highlights how different components demand the use of different intervention functions (i.e. the way that the intervention content should be delivered). For example, the table shows that much of the proposed intervention content relating to the targeted offer of a test should be delivered within training and education of providers. In contrast, much of the active intervention content regarding the appearance and packaging relates to the redesign of the pack and persuading people to use the kit.

Finally the table addresses the particular behaviour change techniques that could be used within an intervention (adding much more specificity in relation to the broad and more generalised COM-B elements). The numbers provided relate to behaviour change technique taxonomy (63). For example, the motivational elements of training providers to deliver a targeted offer of the test, can be achieved through the specific use of techniques which increase motivation to offer the test, i.e. technique 'Provide information about health consequences (5.1)'- wherein, within training sessions, providers are given detail about the consequences of late diagnosis for potential test users in order to motivate them to overcome

Table 7: Intervention components, COM-B intervention functions and selection of BCTs for intervention implementation

Requirement	**COM-B Analysis**	**Broad function for training and intervention and**	**Potential behaviour change techniques (Numbers refer to behaviour change techniques taxonomy)**
The targeted offer of an HIV SSK	**Capability** Major psychological Some physical **Opportunity** Some physical Some social **Motivation** Major reflective Some Automatic	**C**- Education, training, persuasion and modelling, enablement Environmental restructuring **O-** Training, restructure environment **M**- Training, incentivisation, coercion, environmental restructuring	Within training sessions • Instructions on how to perform targeting via individual risk assessment. Advise and agree on how to do targeting (4.1) • Demonstration of the behaviour – provide an observable performance of targeting (6.1) • Behavioural practice/rehearsal- increase habit and skill though rehearsal of targeting (8.1) • Verbal persuasion about capability- within training - tell providers they can perform targeting and argue against self-doubts, asserting that they can succeed (15.1) • Provide information about health consequences- provide detail about late diagnosis information (5.1) • Salience of consequences –use methods designed to emphasize the consequence of performing targeting (5.2) – e.g. reduced new infections, future health of some patients instead of disability • Feedback on outcomes of behaviour – let providers know if any patients have tested positive to encourage more targeting within trial (2.7) • Behavioural experiments- Ask providers to test their hypotheses about targeting and see how people respond (4.4) • Verbal persuasion about capability- within training tell providers they can perform

Requirement	COM-B Analysis	Broad function for training and intervention and	Potential behaviour change techniques (Numbers refer to behaviour change techniques taxonomy)
			targeting, and/or risk assessment and argue against self-doubts, asserting that they can succeed (15.1) • Anticipated regret – raise awareness of expectations of future regret about not performing targeting via risk assessment – so how will providers feel if they know they avoided offering a test and later found out someone had an AIDS diagnosis or long term problems through late diagnosis (5.5) • Verbal persuasion about capability- within training tell providers they can perform targeting, and/or risk assessment and argue against self-doubts, asserting that they can succeed (15.1) Homework –post training • Behavioural experiments- Ask providers to test their hypotheses about targeting and see how people respond (4.4) Within trial • Feedback on behaviour – give providers information and evaluation of their recruitment within trial (2.2) • Social comparison – draw attention to other providers performance to allow comparison with providers own performance (6.2)
Participant personal information disclosure	**Capability** Minor physical Minor Psychological		In provider script: • Ask the person to affirm statements indicating commitment to supply personal information (1.9) • Social comparison – draw attention to other patients provision of information to

Requirement	COM-B Analysis	Broad function for training and intervention and	Potential behaviour change techniques (Numbers refer to behaviour change techniques taxonomy)
	Opportunity Major Physical Minor social **Motivation** Major reflective No automatic	**O**- Training, restructure environment (design a process to minimise perceived barriers) **M**- Education, persuasion and modelling (to improve disclosure)	allow comparison with the persons own performance (6.2) • Present verbal communication from a credible source (provider?) in favour of providing personal information (9.1) • Advise the patient to identify and compare the reasons for wanting and not wanting to provide the personal details (9.2) • Focus upon past success- provider asks patient to think about or list previous successes in providing personal information (15.3) • Prompt observations of the consequences for others of giving personal details – i.e. test results (16.3) • Restructure the physical environment by simplifying the instructions, using easier language, simple messages and pictures and providing information in a number of languages (12.1)
Appearance and packaging	**Capability** Minor physical Minor Psychological **Opportunity** Major Physical Minor social	**O**- Training, restructure environment (design pack) **M**- Education,	• Restructure the physical environment by ensuring that non transparent materials are provided, that generic commonly used materials are used, that they are secure and they can be easily carried (12.1)

Requirement	COM-B Analysis	Broad function for training and intervention and	Potential behaviour change techniques (Numbers refer to behaviour change techniques taxonomy)
	Motivation Major reflective No automatic	persuasion and modelling (to take kit and carry)	
Participant must comply with kit instructions	**Capability** Major Physical Major Psychological **Opportunity** Minor Physical Minor Social **Motivation** Major reflective Minor Automatic	**C**- Training, education, environmental restructuring, enablement, modelling (redesign kit instructions) **O-** Training, restructure environment **M**- Education, persuasion, modelling and enablement	*Design of kit* • Restructure the physical environment by simplifying the instructions, using simple language and pictures, providing information in a number of languages and add an instructional video s (12.1) • Add objects to environment – provide new kit instructions (compared to one in FGs) as well as instructional video (12.5) *Within interaction with provider* • Credible source – the provider should be credible and trustworthy (9.1) • Problem solving –analyse or prompt patient to analyse factors influencing the use of the kit and generate strategies to overcome barriers to using kit (1.2) • Social support (practical) – provide practical help for performance of the behaviour (3.2) • Instructions on how to perform the behaviour. Advise and agree on how to do use instructions (4.1) • Demonstration of the behaviour – provide an observable performance using the SSK instructions (6.1) • Behavioural practice/rehearsal- increase habit and skill though rehearsal using kit instructions (8.1)

Requirement	COM-B Analysis	Broad function for training and intervention and	Potential behaviour change techniques (Numbers refer to behaviour change techniques taxonomy)
			• Verbal persuasion about capability- within interaction tell patient they can utilize the instructions and argue against self-doubts, asserting that they can succeed (15.1) *Within interaction with provider* • Identification of self as role model (13.1) • Draw attention to others performance (the providers own) to allow comparison with the persons own performance (6.2) • Problem solving –analyse or prompt patient to analyse factors influencing the use of the kit and generate strategies to overcome barriers to using kit (1.2) • Within interaction with provider • Advise on ways of reducing negative emotions to facilitate compliance with kit instructions (11.2) • Advise on, provide, emotional social support for compliance with kit instructions (3.3) *Within kit itself/and or with provider* • Information about emotional consequences – provide information about emotional consequences of performing the behaviour (5.6)
Participant kit return	**Capability** Minor Physical Minor Psychological		• Goal setting – Agree that the return sample will be returned (1.3) • Restructure the physical environment by not holding details on GP records, or within a distributor, to facilitate an alternative reminder mechanism (12.1) • Behavioural contract (1.8) - Sign a contract with the patient that she will return

Requirement	COM-B Analysis	Broad function for training and intervention and	Potential behaviour change techniques (Numbers refer to behaviour change techniques taxonomy)
	Opportunity Major Physical Minor Social **Motivation** Major Reflective Minor automatic	**O** -Restructure environment **M**- Education, persuasion, modelling and enablement	the kit (1.8) • Prompt detailed planning of performance of sample return from home –ask patients to state an implementation intention (1.4) • Restructure the physical environment by simplifying the instructions, using simple language and pictures, providing information in a number of languages (if went to full trial) and add an instructional video (12.1)

their perceived barriers for the targeted offer of a test. Equally motivating the providers to overcome their perceived barriers could be achieved by using the technique 'Salience of consequences (5.2)'. In this way motivation to overcome perceived barriers for the targeted offer of a test is achieved by highlighting the consequence of effectively performing targeting– e.g. reduced new HIV infections, or detail regarding the future health of patients rather than their future disability. Using the behaviour change wheel thus enables a range of highly specific potential intervention elements that can be used in relation to each of the intervention components.

5.4 Step 4: Viability of the intervention

5.4.1 Challenges to the development of an optimal SSK intervention

One of the key components of the HAUS intervention is the SSK itself. The type of specimen (saliva or blood) can have implications on its acceptability and on the accuracy of test results. The following section presents an overview of the UK regulations for medical devices for HIV testing and its implications for development and viability of an optimal SSK intervention for HIV testing.

Current UK regulations for HIV testing and diagnostics

SSKs are required to meet the legal criteria aimed to ensure quality and performance of these kits. They have to be approved by the Medicines and Healthcare Agency (MHRA) and the European Medicines Agency. They cannot be sold without the Conformité Européene (CE) mark, which indicated that the manufacturer has met the required standards in relation to test performance, directions for use and labelling.

HIV SSKs can appear in many forms, employing dried blood spot, saliva, and blood collection devices. This is because the diagnosis of HIV infection is usually made on the basis of a serological test; the detection of HIV-1/2 antibodies (Ab) or simultaneous detection of HIV-1/2 Ab and HIV-1 p24 antigen (Ag). In the UK, HIV testing using 'fourth generation' assays (i.e., combined antibody and HIV p24 Ag detection) is recommended over 'third generation' assays that detect only Ab against HIV.(37) The ability to detect HIV-1 p24 Ag has enabled the reduction of the window period between exposure to HIV and detection of infection from three months to one month, thereby enabling detection of recent infections. Currently, all saliva-based testing options and a lot of Point of Care Tests using whole blood are third generation only.

Although we did not formally assess the acceptability of various HIV self-sampling methods in FGDs (as we did not believe we would have a choice) strong concern about the proposed TINY vial collection device arose (see Chapter 4).

5.4.2 Discordance between acceptable self-sampling methods among study participants and UK regulations for HIV testing and diagnostics

The discordance between preferences of black African communities, service providers and UK regulations for HIV testing had several implications on development of an optimal intervention.

Preference for oral specimen collection compared to blood collection device among users and service providers

Stage 1 of the project elicited significant concerns about the only CE marked SSK available currently available in the UK. This SSK relies on the collection of 400ul of blood into a vial. A finger is pricked with a lancet and droplets of blood are collected. Collecting a blood sample was viewed as a significant barrier to HIV testing for this population in community settings. As set out in section 4.2 concerns about the volume of blood required, the fear of needles, presumed difficulty in using the kit, fear of contamination of the vial, and fears about contaminating others were expressed. Among those familiar with SSKs, collection of an oral specimen using a swab was identified as an easier alternative to the TINY vial - both in terms of use, acceptance and the amount of support required to promote its use. Due to these reasons, the study team perceived usage of the TINY vial device constituted a barrier to the successful delivery of the intervention.

Lack of availability of CE marked assay for saliva HIV testing and implications for development of HAUS intervention

Due to the concerns over the TINY vial, the study team proposed to use an oral self-sampling device such as OraSure which is commercially available and CE marked in order to optimize testing in the study population. However, there is currently no CE marked saliva-based HIV assay available in the UK. In the original grant application, we proposed to use the GENSCREEN™ ULTRA Ag-Ab assay for HIV testing. This test is CE marked for use on human blood serum and plasma but not saliva. When used with plasma and serum, it is considered a fourth-generation assay, and has a sensitivity of 100% (93.2% in the seroconversion scenario) according to the manufacturer (64).The test is a reliable indicator when a result is negative, which is important to consider as incident infection in the black

African population in the UK is likely to be low.(1) However, when used with saliva it is regarded as a third generation assay as it is unable to reliably detect HIV-1 p24 Ag. This means it is less sensitive to very recently acquired infection and can detect HIV that was caught more than 14 weeks ago. The performance of the GENSCREEN™ ULTRA Ag-Ab assay with saliva has been evaluated and is considered appropriate for use.(65) All people with indeterminate and reactive results are strongly advised to attend confirmatory testing using serum or plasma (according to standard practice of NHS centre that they attend) so any false positives would be identified.

Given that the GENSCREEN™ ULTRA Ag-Ab assay for testing saliva for HIV is not CE marked, we obtained MHRA guidance on whether we would be able to use the assay on saliva within our research study. The MHRA responded positively on the proviso that a NHS Trust would accept liability for using a product 'off-label' for research purposes. Indeed, due to user and provider demand for kits that use saliva, there are commercial and NHS services throughout the UK who are willing to take on this liability and use saliva-based HIV SSK (66). Exploring these options took up a considerable amount of time at a key point in our intervention development.

UCLH NHS Foundation Trust agreed to be our clinical partner organisation and assume the liability for using the GENSCREEN™ ULTRA assay off label, conditional to the study team obtaining permission from the NIHR to use the assay. However, The Doctors Laboratory (TDL) – the processing laboratory for this study - declined to assume liability to test saliva specimens in the context of a research study, even though they provide saliva testing for some NHS services and the SSK could not be seen as NHS service provision (as UCLH do not offer a saliva-based self-sampling service).

UCLH also stipulated that the only way they could accept the clinical responsibility for proceeding with a saliva option was if a formal evaluation of the kit was included in the study design as this was not a test the service was providing and therefore not evaluated previously. This would entail participants being provided both sampling options (blood and saliva) and both needing to be returned to TDL for processing. This was not a viable option as it would represent a significant shift in the original research question and design. Further, the requirement for both samples raised ethical issues about what to do should only a saliva kit be returned. Following consultation with the study steering committee, the research team

decided that such a radical alteration in our proposed study design was not an appropriate option for HAUS.

The steering committee advised that Stage 2 of the study proceed, despite not being able to proceed with the optimal kit in terms of user and provider preference. Thus, it was agreed to continue with TINY vials as part of the HAUS intervention. This decision was also supported by the NIHR because it was felt that that the usage of the TINY method would not comprise a shift in the research design of the study. The Stage 2 evaluation was also considered worthwhile because a national HIV prevention initiative in the UK is based on HIV SSK using TINY vials, with currently little evidence to support its effectiveness or cost-effectiveness, in particular for black African communities. The Stage 2 study would demonstrate whether the approach and distribution methods were feasible and acceptable, along with the return rate. Additionally, the evaluation plan (which included qualitative interviews both with people returning and with not returning kits) would assess kit acceptability.

5.4.3 Aligning study protocol with quality care and research governance framework

The best practices for provision of sexual health care in England are outlined in the 'Standards for the management of sexually transmitted infections' developed by the British Association of Sexual Health and HIV.(67) These clinical recommendations also apply to Wales and Northern Ireland. Sexual Health service standards for Scotland were published by NHS Quality Improvement Scotland in 2008.(68) Both these standards provide guidance for achieving safe, high quality services for management of STIs. According to these guidelines, development of clear care pathways to be utilised by all STI service providers both statutory and non-statutory is vital component of STI management. Specialist GUM providers are advised to have an explicit leadership role for clinical expertise and clinical governance in the management of STIs. Provision of results as quickly as possible to service users, whether positive or negative, is emphasised for effective clinical management of infection and for user satisfaction. The recommended time-period between consultation and receipt of results is ideally no more than 14 working days, taking account of the laboratory turnaround times. The guidelines emphasise that people accessing non-specialist or outreach services should receive the same standard of care as those accessing any other service for the testing and treatment of STIs. The Research Governance Framework for Health and Social Care outlines the responsibilities of researchers and care providers that apply to all research within the remit of

Secretary of State.(69) Ensuring confidentiality and quality of care provided to research participants is at the core of this framework.

In the context of SSK for HIV testing, clear and robust pathways of care are needed for participants: to send specimens for testing; delivery of test results; offering retest to those with indeterminate results and confirmatory tests to those with reactive results; and linking those who test HIV positive to care. In order to align with the principles of the governance framework and given the sensitivities around HIV, the research team felt it important that an organisation with previous experience of managing HIV results, and ideally SSKs, were involved – this organisation would also need to be willing to assume the liability for the quality of care provided. Establishing collaboration with an organization willing to accept duty of care for all study participants and not just those with reactive (positive) results took considerable time and led to substantial delay. The reasons for the delay are described below.

The study team collaborated with TDL for the provision and processing of SSKs. An NHS Trust initially agreed to take responsibility for duty of care for all study participants. However, this arrangement was complicated by the fact the team intended to use an 'off-label' assay to test for HIV. Although this Trust had previously provided the same saliva-based SSKs using the GENSCREEN™ ULTRA Ag-Ab assay as part of outreach work to increase HIV testing in the gay community, they were unwilling to assume liability in the context of a research study. Eventually the Trust withdrew their support to fully partner the study and in particular to take responsibility of care for those participants that did not require direct personal contact. Cost pressures within the Trust leading to reduction of staff due to restructuring of commissioning of sexual health services also made involvement problematic. Besides, for a NHS trust to assume liability for the assay, the assay would need to be supported by a performance evaluation. This was not feasible, since the Trust did not house the required laboratory.

Similarly, other NHS Trusts with SSK experience approached by the study team were unwilling to provide duty of care to participants testing negative because they would effectively have no contact at all with the individual (the kits being distributed in the community, processed by TDL and informed of the result via text message sent by TDL). Eventually UCLH agreed to be the 'organisation providing care' for all study participants; with laboratory services provided via a sub-contract with TDL and a sub-contract with

Central & North West London NHS Foundation Trust (CNWL) to deliver all results requiring direct contact with participants given UCLH did not have prior experience or services in place to provide this service. The process of establishing the clinical care pathways and necessary contracts took over 10 months, which adversely affected the ability to deliver the study on time and at scale.

5.4.4 Collaborating with GP/CBOs

One of our study aims was to assess the feasibility of using existing services for an SSK intervention for future Phase III evaluation. Based on results from Stage 1, the study team decided to distribute HIV SSKs targeted at black African people in (GP) surgeries and CBOs working in HIV prevention in both London and Glasgow. Unfortunately, implementation of the Haus study in Glasgow and collaborations with CBOs in London did not occur as intended.

Recruitment of GP sites in Glasgow

Recruitment of GPs surgeries for research purposes in Scotland is carried out by the Scottish Primary Care Research Network (SPCRN). Due to the SPCRNs previous experience of delays in gaining ethics approval and its impact on the willingness and interest of surgeries in participating in research, the SPCRN now declines to make contact with GP surgeries without ethical and NHS Research and Development (R&D) approvals being in place. In fact, no information on research projects can even be sent to GP surgeries prior to these approvals being in place, making it difficult to gauge interest and likelihood of support for a project. The NHS R&D approvals in Scotland were also dependent on an agreement between GP practices in Glasgow and UCL – something not required in London as no financial reimbursement would occur between London GP sites and UCL. Because CRN support differs between England and Scotland, there was a need for some reimbursement to Glasgow practices from UCL to ensure they received the same support as their London counterparts. Despite beginning the contracting process in November 2015 it took until the end of April 2016 before these were in place.

The SPCRN were provided with an introduction letter to the project which was distributed to 17 GP surgeries across three regions within the Greater Glasgow and Clyde health board, namely Glasgow City, Clydebank and Paisley. Unfortunately, none of the surgeries responded to either accept or decline the request to participate. Due to the lack of response, another letter was distributed, which did not yield any responses from surgeries. It is not

possible to know the reasons behind this lack of willingness to participate. Anecdotally, staff at the SPCRN believed recruitment would be low due to the low numbers of black Africans attending GP nurse appointments within the Greater Glasgow and Clyde region. Due to lack of research sites yielded in Scotland, the Haus intervention could not be implemented through GP surgeries in Glasgow.

Recruitment of CBOs

A total of 10 CBOs were intended CBO partners in London, however several declined to participate because at the time of setting up this study these organisations had to cease their services that had previously delivered HIV prevention that targets black African people due to funding cuts. This meant that the burden of recruiting the required sample size for the study had to be shared by fewer CBOs than originally planned.

Waverly Care in Glasgow were involved in the project from its inception. One of the first exploratory focus groups (see section 2.1.2) was held on their premises and many of their staff attended as they had a great interest in the development of and participation in the intervention. Unfortunately, due to the delays in getting REC approval, they withdrew as distributors in order to work on developing their own HIV testing intervention which was to be implemented for World Aids Day in 2015. As such, the HAUS intervention could not be implemented through CBOs in Glasgow

5.4.4 Final intervention content

Table 8 illustrates the intervention functions and behaviour change techniques that were agreed across the team to become part of the HAUS intervention. These are the core components to be used within the intervention manual and within intervention training. As described in section 2.3 (step 4) they were derived after systematically having applied the APEASE criteria (Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Site-effects/safety, and Equity).(32) These criteria assess the viability of intervention function and behaviour change techniques for a real world intervention implementable within the UK. In this way the content of the HAUS intervention was finally agreed and drafted.

Table 8: Final intervention content following application of APEASE criteria

Intervention component	**Following application of Appease criteria:** **Intervention function and BCTs to be used within the HAUS intervention within both training and manual**
The targeted offer of an HIV SSK	**Intervention functions** Education of health professionals, Training of health professionals, Persuasion and modelling to health professionals **Behaviour Change techniques to be employed within training** • Demonstration of the behaviour – provide an observable performance of targeting (script provided within manual) (6.1) • Behavioural practice/rehearsal- increase habit and skill though rehearsal of targeting (8.1) • Provide information about health consequences- provide detail about late diagnosis information within training session (
Participant personal information disclosure	**Intervention functions** Persuasion **Behaviour change techniques employed** Present verbal communication from a credible source (service provider) in favour of providing personal information (9.1)
The appearance and packaging	**Intervention functions** Environmental restructuring **Behaviour change techniques** Restructure the physical environment by ensuring that non transparent materials are provided, that generic commonly used materials are used, that they are secure and they can be easily carried in a neutral bag provided to people (12.1)
Compliance with kit instructions	**Intervention functions** Persuasion, modelling and enablement **Behaviour change techniques** Credible source – the service provider should be credible and trustworthy (9.1) Problem solving –analyse or prompt patient to analyse factors influencing the use of the kit and generate strategies to overcome barriers to using kit (1.2) Instructions on how to perform the behaviour. Advise and agree on how to do use instructions (4.1) Verbal persuasion about capability- within interaction tell patient they can utilize the instructions and argue against self-doubts, asserting that they can succeed (15.1) Demonstration of the behaviour – provide an observable performance using the instructions (and via video link) (6.1)
Kit return	**Intervention functions** Persuasion **Behaviour change techniques** Prompt detailed planning of performance of sample return from home –ask participants to state an implementation intention (1.4)

5.5 Conclusion of the development of HAUS Phase 2

A theoretically informed and implementable intervention was developed specifying the active ingredients of the intervention content. It focussed upon the targeted offer of an HIV SSK distributed by both Practice Nurses in GP clinics and by Community Workers from community organisations. The study recruiters were trained using the training manual to offer black Africans a SSK using a scripted discussion that provides a rationale for HIV testing and explains how the kit is to be used. Use of the script would ensure consistency of approach across distributors. Intervention recipients were given a brief explanation of how to take the sample. They were asked to return their sample within two weeks using a stamped, addressed envelope provided with the kit. Using a structured approach to intervention development enabled a high degree of specificity regarding the content of the intervention training, and intervention manual and enabled clarity of focus for both process and outcome measures within trial evaluation. The intervention manual and training materials are available upon request.

Chapter 6: **Study design and methodology for Stage 2**

The aim of Stage 2 was to assess the feasibility, appropriateness of settings and optimal intervention design for future Phase III evaluation. The objectives of Stage 2 were addressed through three main research activities:

1. A feasibility study
2. A process evaluation
3. An economic analysis.

This chapter focuses on the study design and methodology for the feasibility study (section 6.1) and the process evaluation (section 6.2). The methodology and findings of the economic analysis are presented separately in Chapter 11.

Ethical approval was obtained from the East of England- Cambridge South Research Ethics Committee (REC reference 15/EE/0412; IRAS project ID 184223).

6.1 Methodology and design of the feasibility study

6.1.1 Study settings

The intervention was intended to be offered in GP surgeries and CBOs in both London and Greater Glasgow. Unfortunately for the reasons described in section 5.4.4, implementation of Stage 2 of the Haus study in Glasgow did not occur. London GP surgeries

Recruitment was to be focussed on areas with relatively large black African communities. South London, particularly Lambeth, Lewisham, and Southwark, Croydon and Bexley were identified via 2011 census data. Many GP surgeries within East London had recently participated in an HIV point of care testing intervention (70), so this area was initially excluded from recruitment despite having a large black African population.

In mid-November 2015, staff at the South London Clinical Research Network (CRN) introduced the HAUS Study via email to Practice Managers whose surgeries were members of the 'Research Sites Initiatives' scheme. This was followed by email communication to contacts at practices not part of the scheme in late November. In December 2015, the chief investigator of HAUS delivered a presentation on the study at a research event at Guy's Hospital, London, to an audience of GP Practice Managers (PM) located in south London. This event introduced the study to a wide variety of practices, and resulted in interest in participation in HAUS from GP surgeries outside of the initial target boroughs. As practice

recruitment was slower than expected, the geographical recruitment area was expanded to include all areas in South London excluding Richmond, Kingston, Sutton, and Bromley, and eventually to North London. The study team were careful to ensure the HAUS intervention would not interfere with recent interventions aiming to increase POCT.(70)

Twelve GP surgeries agreed to deliver the intervention. These sites were trained over a period spanning from mid-March to mid June 2016 (training materials are available upon request). All attendees evaluated the training received. All training sites received a Trial Site File, which contained the study protocol and study instruments.

London Community-Based Organisations

CBOs involved with HIV prevention in London were also recruited as distribution settings. Only organisations with experience of targeting black African people, and whose existing scale and scope of work with this population was strong were approached for involvement in the study.

A longlist of 10 London-based HIV CBOs that serve African people was drafted based on the extensive contacts held by members of the study. Of these, those with a predominant focus on HIV prevention were shortlisted (n=8) and approached to attend Phase 1 focus group discussions. This enabled the study team to identify four well-placed CBOs to be potential distributors, and one further was identified at that stage to make a total of five. Ultimately, because two of these CBOs lost funding to undertake HIV prevention activity prior to the start of fieldwork (following a pattern that unfolded across the HIV sector during our study), we ultimately had three CBOs recruited as study distributors: Positive East (http://www.positiveeast.org.uk), NAZ Project London (http://naz.org.uk), and KwaAfrica (http://kwaafrica.org). Initial training sessions occurred in February 2016 before appropriate contracts outlining their involvement and obligations to the study were finalised. There was a delay of several months between the training session and the signing of the contracts (see section 5.4.3). As such, the CBO sites required re-training due to the delay and staff turnover. These training sessions were delivered in April and May 2016 and focussed more on data processing.

Each attendee was invited to evaluate the training sessions (the results of which are reported in section 9.3.1). Each CBO received a Trial Site File that contained the study protocol and study instruments.

6.1.2 Inclusion and exclusion criteria

To be eligible, potential participants needed to consider themselves to be ethnically black African, 18 years of age or older, and able to provide informed consent. Potential participants were excluded if they were unable to read and understand English and or could not provide a means of contact for result notification.

6.1.3 Statistical Methods and Sample size calculation

The sample size is based upon the precision of the estimate of the return rate (eg the width of the confidence intervals). The numbers were estimated using the well known Wald Approximation. As the primary measure is based upon attrition (the return rate) no further allowance has been made for precision.

HIV SSK projects in the UK (which primarily target MSM online) have achieved return rates in the region of 60% (20). Given that in the UK HIV testing rates tend to be lower in black African communities the study team assumed a return rate of 50%. Distribution of a total of 600 kits per setting would enable a precision rate of at least ±4.0%, and distribution of a total of 380 kits per setting would enable a precision rate of at least ±5.0%. Should the return rate be lower or higher with a fixed sample size the size of the standard error would be smaller and the resulting confidence intervals narrower.

More SSK were to be distributed in London than in Glasgow because the former has a larger population of black Africans and recruitment was limited in Glasgow to GP surgeries. We planned to distribute 600 SSKs in each site (GP surgeries and CBOs) in London and 380 in GP surgeries in Glasgow. Prior to the commencement of SSK distribution, it became clear that no SSKs would be distributed from Glasgow sites (for reasons outlined in section 5.4.4). Accordingly, the recruitment target was reduced from 1,580 to 1,200.

Proportions were described using the number and percentage, and continuous data are described using the median and IQR. The relationship between baseline characteristics and enrolment is described using simple univariate logistic regression models. All analyses were conducted in SAS 9.4 (SAS Institute; Cary, North Carolina)

6.1.4 Self- sampling Kit

The TINY collection device in conjunction with ROCHE HIV Combi assay was used to test for the presence of HIV antibodies in participants who consented to take part in this study. The ROCHE HIV Combi is a 4th generation assay, used for the detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2. It can detect HIV that was acquired more than 4 weeks ago and is CE marked. The ROCHE HIV Combi has a sensitivity of 100% (lower 95% CI 99.8%) and a specificity of 99.63% (95% lower CI 99.42).(71) This test requires collection of 400 ul of blood (obtained by pricking a finger with the supplied lancet) in a small collection tube. The test enables the specimen to be transported to a lab, by post, in a vial that contains preservatives which stabilize the sample for up to 21 days if temperatures are between 4° C and 37° C.

The package distributed to participants included: the TINY kit sample collection device (including self-retracting lancets); a sample data form (see supplementary documents) which required three unique sample identifiers from the participants in order for the laboratory to be able to process the sample and to enable result notification; the acceptability questionnaire (see Appendix J); a paid return envelope for sample and questionnaire return to the lab, and the sample collection instruction sheet. The instruction sheet provided information on how to collect the sample, a link to a video demonstration (www.haus.org.uk), information on labelling the sample and postage, information on how the result would be communicated and why they may be contacted, and a reminder about completion of the acceptability questionnaire. Both the instruction sheet and the video demonstration used black African imagery.

The Doctors Laboratory (TDL), a CPA accredited pathology provider who take part in NEQAS (National External Quality Assurance Scheme), supplied the kits each featuring a unique identifier. Sites were instructed to store the kits in a locked cupboard until distribution to avoid tampering and theft. Kit distribution to all sites was tracked by the project manager.

6.1.5 Screening Procedures

GP Surgeries

The plan was for Practice Nurses (PNs) at GP surgeries to go through their patient list each morning and identify potentially eligible patients. Ethnicity information is often routinely gathered for new patients at GP surgeries in London and available on the electronic patient record, thus enabling identification of eligible patients; this information was recorded on an

enrolment log. Where ethnicity information was not available, or patients attended unexpectedly, recruiters were also encouraged to offer the intervention to others who were potentially eligible and to record this retrospectively.

Community-Based Organisations

Details of all potential participants were also to be listed by CBO workers on the enrolment log, regardless of whether or not the potential participant ultimately enrolled into the study. CBOs did not always have the information required for the enrolment log such as age for all potential participants (especially those who did not enrol into the study). The study team asked community workers to insert approximate age ranges where exact ages could not be ascertained.

6.1.6 Participant recruitment

An intervention script was provided to distributors in both GP surgeries and CBOs to introduce and initiate discussion about the study. This was supplemented by an *aide memoire* in the form of key bullet points derived from the longer script. It was anticipated that this scripted interaction with potential participants would occur during routine consultations at GP surgeries, or regular outreach activities undertaken by CBOs. Interested eligible potential participants were given the Participant Information Sheet (PIS), asked to read it, and given the opportunity to ask any questions. At this point potential participants were invited to enrol in the study, and if accepted eligibility established.

If the participant declined, distributors were instructed to state, “That’s absolutely fine. We would really like to understand why people do not want to participate in the study. On this card are some of the common reasons why people say no”. They then showed them a card with nine reasons why people may not want to participate. The listed reasons were:

1. I have recently tested for HIV
2. I do not believe I am at risk of HIV
3. I would prefer to test elsewhere
4. I would prefer not to use a self-sampling kit
5. I would prefer not to know my HIV status
6. I do not like being offered an HIV test just because I am black African
7. I already know that I am HIV positive
8. I would prefer not to say

9. Another reason

If asked what was meant by the term 'black African,' distributors were instructed to clarify that this category included anyone who identified themselves as black African, whether they were migrants from Africa, African descendants or African nationals. A 'frequently asked questions' section was provided in the intervention manual to support distributors in fielding any questions they may receive about HIV or the study process. If the potential participant was ineligible, the distributor thanked them for their interest, explaining that they did not meet the eligibility criteria, and suggested an alternative method of HIV testing.

Consent process

Informed consent was obtained from all participants. Though the study team intended for the majority of consents to be obtained via the tablets, most sites used paper forms. In the case of GP surgeries, there was overwhelming preference for paper forms. Reasons for this preference usually centred on the lack of dependable wifi at GP surgeries, and concern that the tablets would be stolen. As such, only the CBO sites were provided with study tablets, though the CBOs also relied upon paper forms when the tablets were not feasible. Responses entered via tablets were automatically recorded and stored in the study database. Completed paper consent forms were sent to the trial manager via secure fax or email.

The consent forms contained both mandatory and optional components. For those participants recruited from GP surgeries, notification of general practitioner of HIV test result was an optional consent item. If consent to this item was granted, the general practitioner was notified via letter from the chief investigator. The general practitioner was not informed if consent was not obtained for this item, and were not informed if a participant decided not to return the kit to the laboratory for analysis. Participants recruited at both sites were given the option of consenting to be contacted for follow-up telephone interviews.

Baseline data

Participants were asked to complete a short baseline questionnaire (see Appendix H) in situ *either on paper or via tablet. The baseline questionnaire collected demographic data and a brief assessment asking country of birth, duration of UK residence, HIV testing history and sexual activity within the last 12 months. The baseline data was for research and governance purposes and was not intended to be used or seen as a risk assessment screening toolDistribution of the kit*

The distributors then gave the participant a SSK and briefly explained the processes involved with kit use. Distributors also explained how results would be communicated. Additional information on how to use the self-sampling kit, how to access the online video of someone using the kit, the importance of posting the sample to the laboratory for processing and the use of reminder texts to participants should the sample not be received at the lab was highlighted in the PIS and instruction sheet.

6.1.7 Sample Collection and Analysis

Participants who self-collected a sample were also required to complete the sample form with three unique identifiers (initials, date of birth and unique ID number) to enable the sample to be processed at the laboratory. The ID number was pre-populated on both the sample form and the acceptability questionnaire.

6.1.8 Follow-up of participants

Acceptability questionnaire: Every kit included an optional brief acceptability questionnaire (see Appendix J) which was completed and returned with the sample. The questionnaire explored the acceptability of being offered an SSK in the setting, acceptability of targeting, and the process of using the kit. The unique ID number enabled linkage with test results and baseline data.

Telephone interviews: At enrolment, participants were asked if they would be willing to take part in optional follow-up telephone interviews. The study team initially aimed to complete 30 interviews, purposively sampled to include participants across age ranges and genders and to ensure a balance between who did and did not return a sample, in each of the intended study cities, as well as those recruited through each distribution setting (CBO or GP surgery). Because the overall recruitment target was not met, and this stage did not ultimately take place in Glasgow, the number of participants targeted for interviews was revised to 20. We sought to maintain a balance between those who did and did not use the kit. Furthermore, as this stage of the study progressed a substantial proportion of kits were returned with insufficient samples so we expanded our purposive sample to ensure we interviewed a balanced sample between three groups: those who accepted a kit but did not return a sample those who used a kit and received a negative result, and those whose sample was unable to be processed due to under-filling of the blood vial. Interviewing those with reactive results was never part of our purposive sampling strategy as we felt this would likely cause distress, as it was no reactive results emerged from within the study sample. This revision of the purposive

sampling strategy enabled us to be responsive to the conditions and realities faced by our study population as they emerged in real-time.

A topic guide (see Appendix C) exploring kit distribution, kit use and return, and implications of the intervention was used for the interviews. Participants provided verbal consent to proceed with the interviews at a mutually convenient time. Interviews lasted approximately 30 minutes and interviewees were sent a £10 voucher for their time. Interviews were recorded and transcribed. Detailed notes were taken during non-recorded interviews in lieu of transcription.

Anonymised transcribed interviews along with notes from non-recorded interviews were imported into an NVivo 10 file for coding and analysis. The interviews were analysed using a thematic approach.

6.1.9 Results communication and management

Anonymised results were communicated from TDL to the project manager at UCL on the same day that sample analysis occurred, via secure encrypted email. There were three possible test results: HIV not detected, reactive sample, or insufficient sample (due to either under filling of TINY vial or gross haemolysis). UCLH provided duty of care to all participants who returned a self-sampling kit, regardless of whether they were recruited at GP surgery or a CBO. However, duty of care was passed to CNWL for reactive results, insufficient samples, and those without a mobile number. This arrangement arose because UCLH does not currently provide a self-sampling or HIV result notification service for patients. CNWL do and have clinical expertise in the provision of HIV results. If a participant were to require confirmatory testing duty of care would pass to the health care institution attended.

Non-reactive results

In line with standard practice in most NHS sexual health clinics, non-reactive results were delivered via text message. TDL, under contract to UCLH, was responsible for the delivery of these messages. If a participant only provided alternative contact means (landline) then the study team tasked a Health Advisor (HA) at CNWL to notify the participant as per normal clinic practice.

Reactive results, and insufficient samples

Participants with reactive results or insufficient samples were notified by telephone by CNWL HAs. Health advisors attempted to make contact directly with participants, rather than leaving a message for the participant to call back.

TDL notified the project manager at UCL of any reactive or insufficient results on the day of the sample analysis via secure encrypted email. At this stage, the names of participants with reactive samples are unknown to all parties as only initials are required with SSK return. The study manager would link the study ID number to the associated consent form and baseline questionnaire, thus obtaining their name. This information was passed to the HA in person, enabling them to contact the participant. Should any reactive results have been obtained, the HA would also have made follow-up phone contact with the participant to ensure linkage to care had occurred. It was anticipated that this would also provide an opportunity to identify any unexpected consequences of the testing process.

For those with reactive results, the study team planned to offer follow-up for confirmatory testing within 24 working day hours of the test result. As postal code information was gathered, HAs were enabled to contact the sexual health clinic nearest any participant with a reactive result, to arrange for confirmatory testing. Thus, there was a process in place to ensure that any participant with a reactive result would be linked to specialist care.

For those with insufficient samples a process identical to that in the case of reactive results was followed. The participant with the insufficient sample was offered three options via telephone communication: to have a second SSK posted, to be advised on where to access alternative HIV testing, or to discuss alternative testing options with their GP.

For both reactive results and insufficient samples, the HA was responsible for documenting the pathways into care, to record follow-up attempts and next steps including linkage to care.

A schematic of the HAUS fieldwork process is provided in Appendix I.

6.2 Methodology and design of the process evaluation

6.2.1 Purpose and scope of the evaluation

An understanding of what was implemented and how it was implemented are integral to explaining how an intervention works, in order to address questions of feasibility; or whether it was possible to deliver the intervention as planned in the chosen settings.

The principal concern of early process evaluation frameworks was capturing what was delivered in practice in order to avoid dismissal of sound intervention theories due to a failure to implement them effectively.(72) Most frameworks focus on the precise 'form' of delivery in terms of whether this represents fidelity to what was intended to be delivered, as well as measuring the reach of delivery (the dose). There is debate about whether adaptations in programme delivery, decided locally, enhance intervention effectiveness or lead to poorer outcomes.(72, 73)

Advocates of strict fidelity(74) argue that fidelity is essential if effective interventions are to be replicated, especially when an intervention's 'active ingredient' may not be known. Advocates of local adaptation argue that interventions need to be tailored to local circumstances.(73) Durlak and DuPre (2008) propose a compromise whereby the 'core components' of an intervention should be delivered in standard form, but less central intervention components or features can be modified to fit local needs.(75) They present research that suggests a balance between fidelity and adaptation is likely to be most effective, with the precise balance dependant on the specific intervention.

The process evaluation was informed by MRC guidance(76, 77) and the wider implementation science literature.(78-80) It investigated not just implementation of the intervention (that is, fidelity, reach and acceptability) but also considered mechanisms of action (impact in context) and potential future normalisation of the intervention. These three areas of exploration are described in fuller detail below.

i. Implementation

- Were standardised intervention components implemented with fidelity of form?
- Where deviations from fidelity of form occur, do these reflect intentional adaptation (and if so with what motivation), unintentional drift or simple omission?
- What was the reach of the intervention?
- How did reach and acceptability vary across key sub-groups of African people and what contextual factors appear to affect this?

ii. Mechanisms of action

- Does the intervention increase access to HIV testing (opportunity)
- Does the intervention provide an acceptable and viable option to establish HIV status (capability)

- Does the intervention increase motivation to test for HIV
- Are any potential harms suggested by qualitative data

iii. Normalisation

- Is the intervention likely to be supported by key stakeholders in future funding and delivery of SSK? Do they:
    a. view the intervention as coherent?
    b. commit to future participation?
    c. commit to collectively take on the work arising from the intervention?
    d. review progress implementing it?

To address these areas the process evaluation collated information from the inception of Stage 2. Figure 4 contains a flowchart of the data collection points relevant for the process evaluation. The following data were intended to be collected:

1. Study diaries – the study team routinely recorded challenges and issues encountered by in all aspects of the implementation of the feasibility study.

2. Training evaluation - distributors were asked to complete a before/during/after survey assessing the value of the training, the extent to which the training meets its stated aims, and their comfort and confidence in delivering the HAUS intervention

3. Screening and recruitment logs - This data assisted in monitoring progress during recruitment and facilitated early intervention if support in recruitment was required.

4. Distributor weekly log - Distributors were asked to complete a weekly log to monitor their recruitment progress and report any problems with recruitment (see Appendix I). They were asked to rate how they felt about recruiting people to the HAUS study, their confidence level in targeting black African people and in answering questions about the study, and whether they used techniques provided in the training session or study manual.

5. Site Visits - Up to two site visits were planned with each distributor to support implementation of the intervention. Detailed notes were taken during the visits to aid

with understanding of the environments and circumstances in which the intervention was being delivered.

6. Data flow - The speed and success of data flow through all elements of Stage 2 was monitored to assess intervention feasibility.

7. Support queries and responses - Any contact with the study team by distributors or study participants was logged.

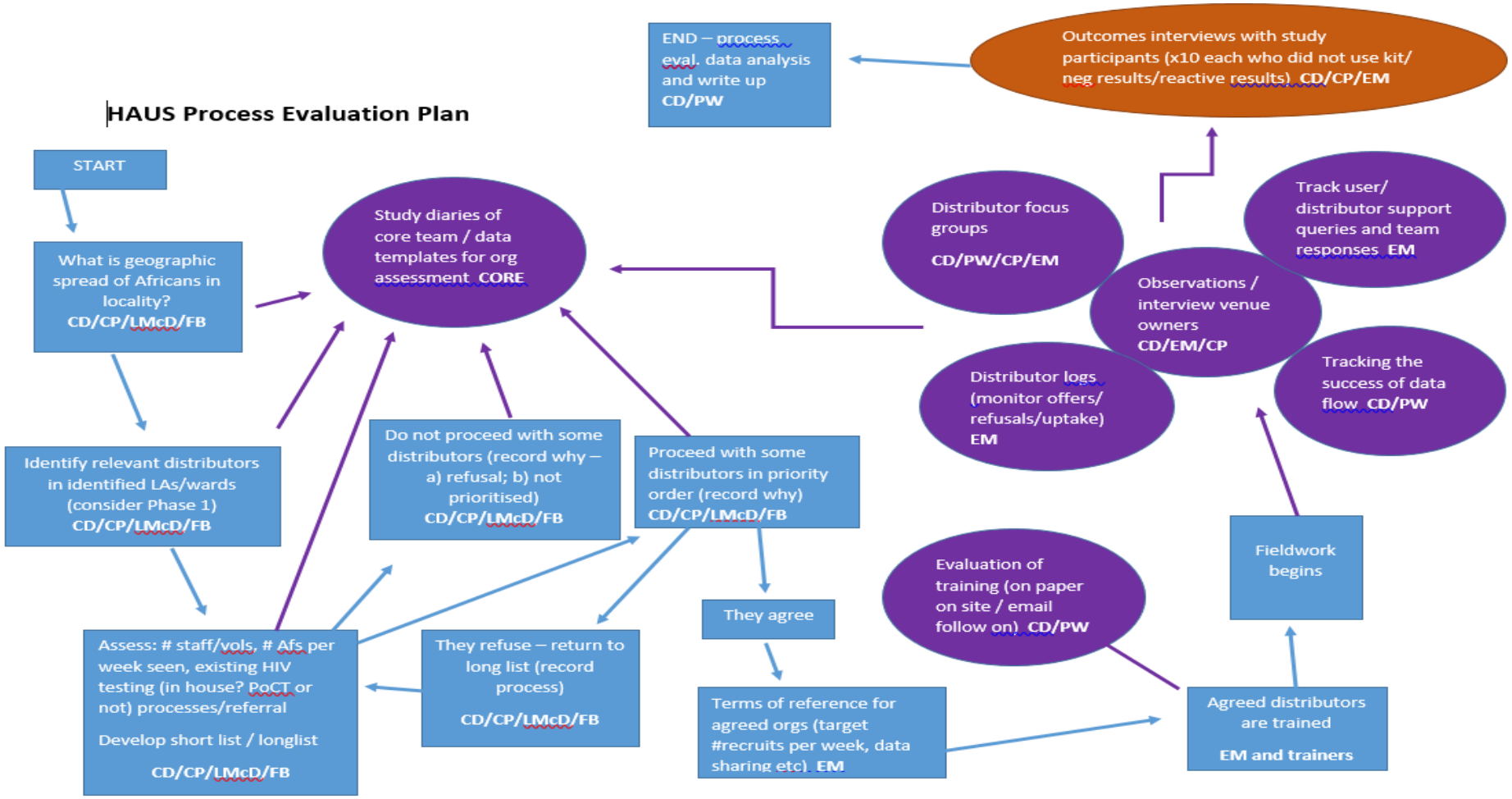
8. Site summaries - Throughout the distribution period, data from distributors was collated and synthesised into a one-page intervention summary for each site, describing their key successes, challenges and experiences along the way. Each summary was cross-checked by the project manager, and then emailed to each distributor in turn for their consideration and comment.

9. Site close-down interviews – the site summaries were used as the basis for undertaking a final face-to-face interviews with distributors at each site. Focus groups were originally planned however, as few individuals at each site undertook distribution (in many cases, only one individual), one-to-one or small group interviews were a more feasible format. Interviews lasted for approximately 30 minutes (range 5 to 60 minutes). A semi-structured topic guide (see Appendix K) was used to structure these discussions. The focus of the interviews was to gauge acceptability of the intervention, distributors' experience of undertaking targeting, recruitment and consenting procedures, and fielding questions. The interviews were recorded where possible, and notes were taken throughout. Annotations formed the basis of analysis, with recordings providing backup where needed

10. Qualitative interviews with study participants - The process evaluation also drew upon the qualitative follow-up interviews with participants described in section 6.1.8 above.

The raw and synthesised data was then coded and analysed with a focus on eliciting themes relevant to the organising principles of feasibility (fidelity) and acceptability.

Figure 4: HAUS process evaluation plan



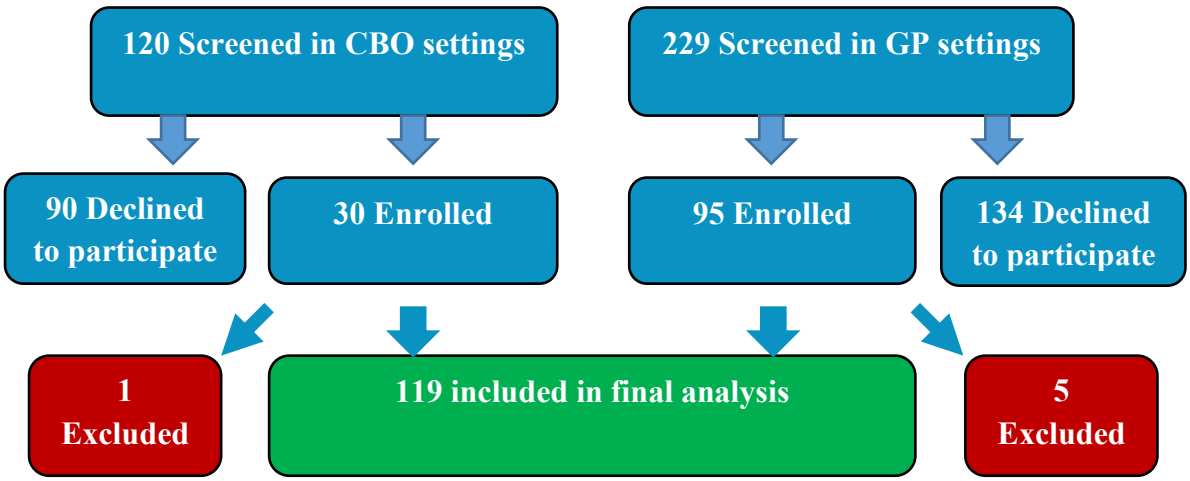
Chapter 7: **Results**

The recruitment period for London-based CBOs and GP surgeries was reduced from 6 to 4 months (April to July 2016) due to delays caused by the kit selection and governance issues (see section 5.4). As such, the study team anticipated that recruitment would fall short of the revised target of 1,200 SSKs.

7.1 Overall results

The recruitment rate from all sites (even when accounting for truncated recruitment period) was substantially slower than expected, with only 349 eligible persons approached in total; 229 from GP settings and 120 in CBO settings. Of those approached 125 (35.8%) agreed to participate. Six participants however, all who returned their SSK, subsequently had to be excluded due to errors with the consent process, providing a final total of 119 participants. Figure 5 illustrates the participant flow from screening to enrolment for GP and CBO settings.

Figure 5: Participant flow from screening to enrolment per recruitment setting



The most common reason for declining to participate was that the person had recently tested for HIV (25%), followed by lack of perceived risk (18.7%) (see Table 9). Six (2.7%) people stated they did not like being offered an HIV test just because they were black African and a further 17.4% declined as they wanted to either test elsewhere or not use a SSK. We were unable to assess whether reasons for declining varied according to whether recruitment was

in a GP or via a CBO due to the number of reasons presented and insufficient degrees of freedom.

Table 9: Reasons for declining to participate (as specified by respondent)

Reason for declining to participate	**Frequency (%)**
I have recently tested for HIV	56 (25.0%)
I do not believe I am at risk of HIV	42 (18.7%)
I would prefer to test elsewhere	19 (8.5%)
I would prefer not to use a self-sampling kit	20 (8.9%)
I would prefer not to know my HIV status	15 (6.7%)
I do not like being offered an HIV test just because I am black African	6 (2.7%)
I already know that I am HIV positive	4 (1.8%)
I prefer not to say	19 (8.5%)
Another reason (unspecified)	43 (19.2%)
Total	224 (100%)

Eligible people visiting their GP were significantly more likely to be recruited than those approached via a CBO (odds ratio [OR] 1.96 95% CI 1.21 to 3.19). There was no observed relationship between gender or age and enrolment status (OR for greater recruitment among women 1.12 95% CI 0.72 to 1.75; and OR for greater recruitment with increased age 1.02; 95% CI 0.997 to 1.034).

Table 10: Socio-demographic characteristics of HAUS participants

Characteristic	**Overall (%) N-119**	**SSK returned**	
		Yes (%) n=66	**No (%) n=53**
Age median (Inter-quartile range)	42.6 (32.7, 51.7)	41.6 (32.7, 51.6)	44.6 (36.7, 53.7)
Male (%)	58 (48.7%)	33 (50.8%)	25 (46.3%)
Recruitment site (n=119)			
GP	90 (75.6%)	45 (50.0%)	45 (50.0%)
CBO	29 (24.4%)	21 (72.4%)	8 (27.6%)
Country of birth (n=109)			
Africa	89 (74.8%)	45 (50.6)	44 (49.4)
Elsewhere including UK	20 (16.8%)	12 (60.0)	8 (40.0)
Time in UK (n=113)			
Less than one year	6 (5.0%)	3 (50.0%)	3 (50.0)
1-2 years	1 (0.8%)	0 (0%)	1 (100)
2-5 years	7 (5.9%)	4 (57.1%)	3 (42.9)
5-10	16 (13.4%)	8 (50.0%)	8 (50.0)
>10 years	6 (5.0%)	36 (52.9%)	32 (47.1)
Born in UK	15 (12.6%)	9 (60.0%)	6 (40.0)
Time since last HIV test (n=113)			

Never previously tested	30 (26.5%)	12 (40.0%)	18 (60.0)
< 1 year ago	19 (16.8%)	10 (52.6%)	9 (47.4)
1-2 years	17 (15.0%)	12 (70.6%)	5 (29.4)
2-5 years	17 (15.0%)	11 (64.7%)	6 (35.3)
>5 years	22 (19.5%)	12 (54.5%)	10 (45.5)
Prefer not to say	8 (7.1%)	3 (37.5%)	5 (62.5)
Sex in the past months (n=113)			
I have not had sex	21 (18.6%)	15 (71.4%)	6 (28.6)
With both men and women	1 (0.9%)	1 (100%)	0 (0)
Only with the opposite sex	86 (76.1%)	41 (47.7%)	45 (52.3)
Unsure or prefer not to say	5 (4.4%)	3 (60.0%)	2 (40.0)

In total 119 participants were correctly enrolled: median age 42.6 (range 18-79 years); 58 (48.7%) were men; the majority (90 (75.6%)) recruited from GP practices (Table 10). The SSK return rate was 55.5% (66/119); 95% CI 46.1% to 64.6%.

There was a reduced odds of SSK return with increasing age although this was not statistically significant (OR 0.98, 95% CI 0.96-1.01; p= 0.212). Similarly, there was a non-significant reduction in the odds of returning a kit among women compared to men (OR 0.84 95% CI 0.41 - 1.72; p= 0.627). Kit return may vary according to whether recruitment occurred in a GP compared to a CBO (OR 2.63 95% CI 1.05 - 6.54). Twelve people who returned a kit had never previously tested for HIV, and a further 12 had not tested over five years.

The majority (83.1%) of tests returned HIV negative. However, 11 samples (16.9%) were unable to be processed due to the vial being under filled or sample grossly haemolysed. There were no reactive results. Of the 11 participants who returned insufficient or grossly haemolysed samples, only one requested a further SSK be mailed to them (unfortunately this was also returned as an insufficient sample). Three were unable to be directly contacted and after three attempts, a text message informing them of the outcome was sent. Most (n=5) opted to discuss alternative testing options with their GP when they next attended.

7.2 Acceptability data

Of the 65 participants who returned a SSK, 62 (95.4%) also returned the acceptability questionnaire (see Appendix I). The offer of the test directly helped 79.0% of respondents decide to test for HIV. The overwhelming majority (93.7%; 59/62) also reported that the person who offered the kit helped them feel more confident about knowing their HIV status. Just under a third (32.2%, 19/62) reported watching the video online; of these 19 people all

found the video helpful, and 14 (83.3%) felt it made them feel more confident. The majority of kit returners (73.2%) reported that they would be willing to use one of these kits again.

Participants were asked to rank how they found aspects of the intervention (Table 11) using a visual scale (see Figure 6).

Figure 6: Visual scale used with acceptability questionnaire

The least acceptable aspect of the intervention was the targeting of black Africans with just over a third (34.5%) reporting it was unacceptable. No one felt the location in which they were offered the kit was unacceptable. The majority (82%) found the SSK instructions easy to understand and most (67.7%) felt comfortable with taking the sample themselves.

Table 11: Acceptability of the intervention as reported by SSK returners (n=62)

Item	**Unacceptable (-2)**	**(-1)**	**Neutral**	**(+1)**	**Acceptable (+2)**
Acceptable to be offered an HIV test in this manner	0 (0%)	3 (4.8%)	7 (11.3%)	9 (14.2%)	43 (69.4%)
Acceptable to be offered an HIV test because you are African (n=61)	18 (29.6)	3 (4.9%)	13 (21.3%)	3 (4.9%)	24 (39.3%)
Location where offered the kit (n=60)	0 (0%)	0 (0%)	4 (6.7%)	10 (16.7%)	46 (76.7%)
	Very difficult (-2)	**(-1)**	**Neutral**	**(+1)**	**Very easy (+2)**
Instructions in the kit easy to understand (n=61)	4 (6.6%)	2 (3.3%)	5 (8.2%)	17 (27.9%)	33 (54.1%)
Item	**Uncomfortable (-2)**	**(-1)**	**Neutral**	**(+1)**	**Comfortable (+2)**
How felt about taking the sample themselves (n=61)	10 (16.4%)	4 (6.6%)	10 (16.4%)	14 (23.0%)	23 (37.7%)

7.3 Limitations

The small sample size limits our ability to make associations and draw conclusions as to who did and did not participate and or return their sample. The baseline demographic and behavioural data of participants however suggests the the intervention was reaching a black African population at risk of living with undiagnosed HIV and four people approached to participate disclosed they were already known to be HIV positive.

Acceptability data in this format is only provided on those who returned their sample and by definition, this is the group most likely to have found the intervention acceptable. Further qualitative data exploring acceptability with participants who did and did not return their sample is provided in Chapter 9. Finally the failure of intervention implementation in Glasgow means we were unable to assess whether acceptability or feasibility may vary across the UK. We had specifically wanted to test the intervention in two distinct health care systems, which differed in the proportion of Africans within their population, and in the provision of HIV and community services, in case this impacted on the acceptability and cost effectiveness of the interventions.

7.4 Summary

Our findings demonstrate that users of the SSK liked being able to access HIV testing in this manner and in the locations provided. The proactive opportunistic offer of the kit was directly responsible for the majority of kit users deciding to have an HIV test. Although numbers are small there is a suggestion that distribution of HIV SSK in these settings could help increase HIV testing in black African communities as 12 (18.5%) of kit returners had never previously tested, and a further 12 (18.5%) had tested over 5 years ago. However, recruitment was low with only 128 (35.8%) of people approached consenting to participate. While it is reassuring that 56 (25%) declined as they had recently tested, 42 (18.7%) did not perceive themselves to be at risk and a further 15 (6.7%) did not want to know their HIV status - both potentially reflecting the impact of HIV related stigma. A further 39 (17.4%) may have tested if an alternative method or location were available.

Although acceptability of the intervention is likely higher in those returning a kit over one third still reported that it was not acceptable to be offered an HIV test because of their ethnicity. It is unclear as to whether these participants were aware that they had been explicitly targeted as a black African as the findings from the follow up interviews (see section 9.1.4) suggest not all participants had realised this. Only six (2.7%) of those declining to participate indicated that targeting was responsible for their decision.

The kit return rate of 55.5% is in keeping with similar projects (66) and somewhat concerningly, so is the proportion of samples received that were unable to be processed due to under filling or gross haemolysis. Our finding that 16.9% (11/65) of samples were unable to be processed is similar with the 15.4% reported by the national HIV self-sampling service among their 1125 black African users to date.(81) This suggests that an alternative to the TINY vial is required if HIV SSK are to be an effective means to increase HIV testing in black African communities. There is also the potential that a negative experience with a SSK may put people off alternative or future HIV tests - therefore choice of SSK and its acceptability to participants should not be compromised in future research.

Chapter 8: **Process evaluation - Intervention fidelity and reach**

The HAUS study aimed to establish whether it was feasible and acceptable to distribute and monitor the distribution of HIV SSK to black Africans using GP surgeries and community outreach services. This chapter describes findings from key elements of the process evaluation, which linked to the feasibility trial allow fuller interpretation of the findings for potential further application

There were three broad areas of interest within the purview of the process evaluation related to the implementation of the HAUS intervention: fidelity, reach, and acceptability. This chapter addresses fidelity and reach; the acceptability of the intervention for kit users and service providers is explored in Chapter 9.

8.1 Purpose and scope of process evaluation

8.1.1 Fidelity

The HAUS intervention was designed to be implemented with highly standardised inputs and processes with little or no site-specific tailoring. However, in practice substantial local tailoring was observed. Therefore, our approach to evaluating implementation focuses both on fidelity of form and fidelity of function. Fidelity of form refers to the extent to which the intervention follows the standardised structures and processes developed for Stage 2 of the HAUS study, as described in Chapter 6. This process evaluation examines the extent to which these standardised intervention components were implemented with *fidelity of form*. Where we observe deviations from *fidelity of form* we assess whether these were intentional adaptations (and if so, what motivated them), unintentional drift or simple omission; and whether the adaptation runs with or against the logic of our theory of change (that behaviour is an outcome of three necessary conditions - capability, opportunity and motivation). This is a substantial issue in HAUS as the intervention was delivered across 12 GP practices and three African CBOs throughout London. We also examine *fidelity of function*, that is the extent to which locally decided adaptations to the intervention processes were consistent with the overall theory of change.

8.1.2 Reach

Reach is the extent to which the target audience come into contact with the intervention. Moore et al. (2015) recommend that process evaluations should include quantitative

assessments of reach, in terms of, for example, proportions of the target audience who are aware of and come into contact with the intervention (76).

Assessing awareness reach of the HAUS intervention across the whole population of black African people in England and Scotland was not appropriate or feasible within the context of this study. Unfortunately, we were also unable to accurately determine what proportion of eligible persons in contact with the recruiters were actually exposed to the intervention. It was intended that the enrolment log would capture this information but in reality these were often poorly completed. The data we have shows that 349 people were offered the intervention with 125 agreeing to participate. In excess of 37000 black Africans are resident in the borough of Lambeth alone .

8.1.3 Normalisation

A further component of this process evaluation is to better understand the process by which interventions might best become embedded in distributors routine policies and systems of service delivery. This is often described in terms of 'normalisation' or 'sustainability.'

There are a variety of frameworks which help evaluators assess intervention normalisation (e.g. the RE-AIM framework (82, 83). However, the study team chose to use normalisation process theory (78). The focus of this theory is to consider how implementers can enable the embedding of interventions within institutions and social contexts so that they are ultimately integrated (78). The theory suggests that whether this happens depends on the following four "generative mechanisms" that those working on implementation engage in individually and collectively:

- coherence (how people make sense of a new practice);
- cognitive participation (the willingness of people to sign-up and commit to the new practice);
- collective action (their ability to take on the work required of the practice); and
- reflexive monitoring (activity undertaken to monitor and review the practice).

8.2 HAUS fidelity and feasibility

We start by examination of those areas where fidelity to the intended 'form' (by this we mean the structural and procedural issues) of the intervention either proved difficult or required adaptations to the agreed protocol. The second part of this section relates to aspects in which fidelity to key aspects of the intervention 'function' proved difficult for some distributors

and/or participants. Intervention function relates to the central mechanisms that underpin the intended study and intervention design. Quotes are taken from the weekly distributors' experience survey, from emails to the Project Manager, and the final distributor interviews.

8.2.1 Distributors

Within CBO settings it was intended that community outreach workers would be the distributors of the SSKs, and this was what was reported from these distributors. While the distributors within GP settings were intended to be Practice Nurses (PNs) during the training it became clear that this was not always going to be feasible. A range of GP locations told the Project Manager from the outset that other staff members in the surgery would be undertaking study recruitment and distribution, including: General Practitioners, Health Care Assistants (HCAs) and Practice Managers. In all, eight of the 12 practices used one or more of these alternate members of staff as recruiters and distributors for the study.

Discussions during site visits established that each practice took a different approach to managing staff workloads. This sometimes meant that HCAs were regarded by their senior colleagues as having more time to devote to research tasks than others, even if that was not actually the experience of HCAs. Alternatively, in a number of cases, GPs with a particular interest in sexual health took on responsibility for recruitment and distribution themselves. Though they were working under time pressures to stay within the typical 10-minute appointment schedule, they distributed the SSKs as they had a particular commitment to the issue. The following quote is from a GP surgery where two GPs participated as distributors:

> *[Interviewer: Why was it you two who did this?*
> *GP1: Because we volunteered for it! We were the ones who were interested*
> *GP2: You got the email, didn't you?*
> *GP 1: Yeah, and I knew you would be keen*
> *GP2: Because we are doing a lot of gynae, and sexual health generally. So, it's an area of interest.*

In the main, we can conclude that in the majority of GP surgeries, it was not PNs (or not PNs alone) who recruited participants into the study and distributed kits. This action, while deviating from study intention, facilitated recruitment by increasing the opportunities in which it could be delivered, and as such should be considered a logical adaptation.

The intervention was designed to work alongside distributors' existing commitments. However it was reported to us by one GP practice that staff members' days off were used to attend HAUS training, and in another instance, a GP came into the surgery on her days off in

order to undertake recruitment. Other distributors explained that it took a lot of additional time in the day (including overtime and loss of breaks) to fit in study recruitment, kit distribution and the associated research tasks.

8.2.2 Targeting

Within CBO outreach settings it was intended that community workers would identify black African people whom they encountered in their routine outreach activities and locations to approach for study participation, and this is what was (in the main) what was reported by these distributors. In some cases, they also undertook special outreach events at settings such as barbershops, in order to specifically recruit to the study.

Within GP practices it was intended that eligible individuals would primarily be identified from patient lists (using recorded ethnicity and/or country of birth data) at the start of the day, prior to the initiation of appointments. That way, a prepared enrolment log could be in front of each distributor, ready for when the patient came to them, and they could log the patient's reason for refusal, or their agreement to take part on the enrolment log. This method was also intended to eliminate the need for practice staff to try to identify a patient's ethnicity visually, or to ask them their ethnicity prior to offering them the intervention.

Five GP surgeries informed us that there was usually or always insufficient data available to them to identify potential participants' ethnicity in this way. As a result, practices resorted to a variety of alternate means of targeting black Africans. Staff in at least four practices described using visual cues (both in the waiting room and in the consultation room) to identify potential participants. One practice in particular reported that this meant that many of those approached were ultimately found to be ineligible, as the majority were black Caribbean rather than black African. Other tactics were additionally used to identify potential participants, in particular knowledge of patient backgrounds especially for those recruited in primary care. Having a range of practices to assess potential eligibility could cause confusion, as indicated by this comment:

> *Dr X asked the patient, who was happy to participate. I'm not sure if this particular patient fitted into the category though so was a little confused. The patient was born in the UK, so I could not remember whether this mattered or not.*

Some practices did effectively use ethnicity data contained within their databases to identify some or all those eligible for participation. One practice designed a prompt to remind the distributor to introduce the study to come up on the practitioner's screen when that patient

was being seen. Another practice wanted to initiate such a system, but was ultimately unable to do so.

One GP practice used the ethnicity data that they held on patient lists to screen for eligibility and then contacted patients to invite them to make an appointment so that the HAUS study could be introduced and discussed. This represents a considerable departure from the intention that the intervention was to take place alongside existing routine service delivery in GP settings when patients presented for other reasons.

8.2.3 Script to introduce the study

It was intended that distributors in CBO and GP practice settings would use the agreed script to present the study to eligible participants. The script and its importance were underlined at all training events, and laminated cards with the script wording were made available in each site manual.

When asked at follow up about the extent to which they had adhered to the script, eight study sites said they had not used the script consistently. Most said that they had used either the script or the Participant Information Sheet (PIS) to become familiar with what information was to be communicated, and then they summarised it in their own words. One distributor remarked, "I used my own words, because it's something I do on a daily basis. I just use my words, and the statistics are very important, they don't lie. As well, I try to find out what part of Africa they are from". Another clarified that s/he did not follow the script work for word, preferring to memorise the key facts and stating it in their own way.

It was felt that reading from a card could undermine confidence in the distributor, and one distributor said he was "not a robot" and therefore needed to put things into his own words.

It was clear that in most cases, the number of approaches made by each distributor in a single day or even a single week was too low to expect them to have committed the script to memory. Furthermore, at many GP practices, study paperwork (including the site file) may not have been in the same room as the distributor, so they needed to raise the issue opportunistically and then find the relevant Participant Information Sheet and Consent form afterwards. None of the CBO distributors reported adherence to the intervention script, as once again, they had found it more comfortable to summarise and put things into their own words. Again, this can be regarded as a purposeful deviation from the intended intervention design, based on the practicalities of delivering it in busy settings, and the professional

expertise of healthcare staff to put things in language most appropriate for a particular patient or situation.

When asked to confirm that they had all introduced the study in a way that made it clear that black African people were being targeted for distribution due to higher prevalence in this population, all distributors agreed that they had made this clear in their tailored introductions to the study.

8.2.4 Recruitment process

In the intervention protocol, it was intended that one single distributor took the participant through the entire recruitment process themselves, and that this all happened within one 10-minute time period. Research paperwork (consent form and baseline questionnaire) was to be completed within this period, along with kit distribution and answering of any questions.

In the main, all CBO distributors attempted to adhere to this process and all struggled to keep required components to a 10-minute timeframe. On at least one occasion during distribution at a barbershop, the barber first introduced the study to potential participants and sent interested participants to community workers at the back of the shop

This practice of 'funnelling' potential study participants to other distributors who would then take them through the eligibility criteria and the study documentation was also evident in a few GP practices. In these cases, a PN or a GP would introduce the study, and then send interested individuals on to a designated colleague to complete the process. This was regarded as a means of extending reach, while utilising time and expertise efficiently. One distributor explained, "It was easy to do in surgery as another member of staff does the consent."

Another variation, applied in a few practices, was for staff to break the recruiting process down into distinct stages, in order to avoid appointments backing up. For example, GPs at one surgery introduced the study during the appointment, and then asked interested individuals to go out into the waiting room to review and complete the study documentation on their own. These patients were then called in between appointments until all questions were answered and all documents completed. Again, this represents an opportunistic departure from intervention fidelity as an attempt to undertake at least some recruitment in this setting.

At another practice, an HCA approached patients who looked to be black African and introduced the study to them in the waiting room (rather than in private as had been intended). Individuals were left with a copy of the PIS and invited to approach the HCA in her consultation room if they wanted to take part, and the rest of the process was carried out there. Finally, a HCA at a third practice said he tended to introduce the study at the start of the consultation, and then based on their response gauged the remaining consultation time. If they seemed interested, the distributor tried to make sure he had time to go through all the stages of study recruitment by the end of the appointment. He felt that this tactic helped to prioritise the patients' presenting health needs over the needs of the research study, while also ensuring that they did not leave the consultation without his having mentioned it.

Although in CBO settings it was suggested that the instruction video could be shown to potential participants as a part of the recruitment process, this option was not often utilised due to time pressures, internet connectivity problems and because it was felt it could be "off-putting" by at least one distributor.

8.2.5 Study procedures

It was intended that the introduction and recruitment components of the study, including sharing of the PIS, and completion of the consent and baseline questionnaires would take no more than 10 minutes. Feedback from almost all distributors indicated that it took considerably longer to get through the entire process, which in the particular case of oversubscribed GP surgeries caused major feasibility issues.

> *The only problem is the time, as no extra time has been allocated for this study while some minutes are needed to provide the information to patients as well as when patients asked questions to understand more about the study.*
> *Difficult time wise to fit/ add into a 10 min. GP consultation when all the time has already been used up with the patient's agenda/ symptoms.*

There was a considerable burden of data management and data tracking expected of each distributor. A few sites (particularly CBOs) found it difficult at first to keep a log of those that they had approached who had refused, partly because of the perception that the study team needed an age and other data for each person who had refused, as well as a reason for refusal. Once the study team intervened to suggest that estimates and null values were acceptable entries in the enrolment logs, tracking of refusals improved.

Furthermore, it was essential that in all cases an identical kit ID number was attached to the paperwork an individual had completed, which matched with the kit ID number on their SSK.

In at least one case, the SSK kit ID did not match that on the paperwork received by the study team.

There was a range of dataflow that was essential to the smooth running of the research study, including electronic or faxed copies of consent and baseline forms and enrolment logs being sent to the Project Manager, and completion of weekly distributor logs to identify and respond to emergent challenges. Both sets of data were generally very slow to be returned to the study team. This introduced a number of unintended challenges, as the Project Manager was frequently not in possession of the consent form or contact details of a participant who had, for instance, sent back an insufficient sample, and who therefore needed to be called by telephone to be advised of their options (see section 6.1.9). In this way, the participants, the Royal Mail and TDL were able to jointly act with far greater efficiency than the distributors and the study team in terms of relaying required information through to one another. These logjams occasionally meant results could not be clearly communicated to individuals until the paperwork had caught up. Occasionally these logjams took a number of weeks to resolve, and in a small number of cases the paperwork never materialised, so the individuals had to be excluded from the study. All individuals who returned a sample were informed of their results regardless of whether they were subsequently included in study.

8.2.6 Connection to other HIV testing interventions

The HAUS study was not intended to be delivered alongside (either as a follow-on from or pre-cursor to) any other HIV testing interventions being undertaken by the distributing agencies. However, it was reported by one CBO that following an event where the SSKs had been introduced, a group of interested people accompanied the individual back to the CBO office to undertake a POCT HIV test, because they regarded this testing option as more acceptable than the SSK on offer in the HAUS study.

8.2.7 Distributor support to take blood sample

The study was designed to assess the acceptability and feasibility of the targeting and use of HIV SSKs among black African people. However, two distributors (one CBO and one GP surgery) described assisting participants with the blood sample collection. In the case of the GP surgery, the Practice Manager decided that the kit was so difficult to use, she would support every single participant she recruited, and reported that the entire time spent with each participant was between 30 and 40 minutes. The following excerpt is from an enrolment log:

I helped another patient today, and again the whole process took ages to complete. This was because the patient's blood wouldn't flow from her fingers, we used all the lancets in the box plus another 4, in the end the nurse came in to help but the patient's blood seemed to be clotting the minute it started to flow. I'm not sure whether there is enough blood in the bottle to test. We really persevered and the patient said that if she was at home she would have discarded the whole thing. For me it's becoming a very time consuming exercise.

Two further GP practices reported that they had requests from participants to support them with use of the kit, due to its complexity, but each of these distributors refused, owing to a desire to maintain fidelity with the research protocol.

There was further data emanating from one CBO (and the participants whom they recruited) that during one distribution event in a barbershop, at least some participants took their blood samples together at the same time, with support from the distributor.

8.2.8 Location for sample return

There was one reported instance where a sample was returned to a GP surgery rather than being posted by the participant to TDL via Royal Mail. Because the distributor in this practice was not working on the day the sample arrived, it was stored in the practice refrigerator until a few days later when that staff member returned to work and was informed about the sample. The distributor then posted it.

Further data collected from distributors and participants at the CBO also leads us to infer that after this event at the barbershop, it is likely that the distributor posted the samples via Royal Mail, rather than the participants doing this themselves.

8.2.9 Communication with participants after sample return

There were a number of occasions when participants and distributors reported that a two week text reminder to return a sample was sent to people who had already returned their sample. This created some concern among participants about the potential for lost samples, and made some doubt the veracity of their results.

Although it was intended that a HA at CNWL would have access to the secure database to enable them to directly obtain contact information for those participants with reactive or insufficient results, this did not occur as sites predominantly used paper forms so there was delay in getting this information onto the database. Instead, the Project Manager notified the HAs directly when an insufficient sample had been received at TDL. Occasionally due to missing or delayed consent and baseline data forms, there was a delay in access to sufficient

information to contact the participant immediately. Furthermore, due to the HAs' working context, there were occasionally further delays between notifying the HA team and communication of result to a participant. The protocol does not state a time limit for these activities, but in the training distributors were told to inform participants that it could take up to 5 days for them to receive a result.

It was also reported that in at least a few cases, a negative result was received by participants via text from TDL within 24-48 hours of a sample being posted, which appears to have caused concern among some participants that the result may not be trustworthy as it had arrived more quickly than anticipated.

8.3 Summary

The planned SSK intervention was not feasible in GP surgeries or during outreach from CBOs and progression to a future Phase III evaluation is not supported. While some form of the intervention was delivered by almost all distributors, most distributors found it difficult to recruit to and almost all found it too time consuming to deliver in the context of a busy GP surgery or during community outreach. The research process attached to the intervention was the principal driver of this barrier.

Totally fidelity in relation to the proposed intervention structures was not the norm as local adaptations were common in most of the GP surgeries and all of the CBOs. While these adaptions were not always agreed in advance almost all might be considered reasonable tailoring of the intervention to the specific local context in which it was being delivered.

Most local adaptions maintained the *fidelity of form* for the intervention, in that they followed the standardised structures and processes developed for Stage 2 of the HAUS study. Examples include broadening the range of staff recruiting to the intervention within a GP surgery or breaking up the offer and sign-up of patients into smaller blocks of time to better suit the workflow of GP staff. The exception of this was the routine distributor support offered at two sites. This fundamentaly changed the structure of the interventio from one of routine offer and self-completion of SSK to a fully assisted intervention. Almost all the deviations from the proscribed fidelity of form for the intervention were intentional, and were motivated by a desire to speed up the process of recruitment or offer the intervention to a larger proportion of patients.

Chapter 9: **Acceptability of Haus Intervention**

This chapter seeks to address the objective for Stage 2 of establishing the acceptability of the intervention to black Africans and service providers. The chapter is divided into two sets of findings; acceptability of the intervention to participants, followed by acceptability of the entire study process and the intervention among distributors. For each we discuss findings related to those aspects of the intervention which compromised acceptability, followed by aspects which promoted acceptability. In quotes from study participants, the age, sex, and HIV test outcome are stated in the square brackets. A range of data sources were used in this analysis, including interviews with a sample of study participants and with staff from all distributing organisations, study team diaries and site visit notes, emails exchanged with distributors, and weekly distributor experience surveys.

9.1 Acceptability to black African community

9.1.1 Descriptive results

The total number of study participants interviewed was 21, median age was 40 (range of 18 to 67); 12 were women. Of the 21, nine had received negative results, four sent samples that were unable to be processed (due to the samples being under-filled), and eight had not returned their sample. Seventeen interviewees were recruited at GP surgeries and four at CBOs. Approximately half of the interviewees (n=9) had previously had an HIV test. However, the majority were unaware that SSKs existed prior to participation in the study. Some interviewees had a notion that a kit could be ordered online, but did not have a more specific knowledge of either SSKs or self-testing kits before enrolment.

9.1.2 Barriers to acceptability of SSKs

There were five interrelated themes which emerged as barriers to the acceptability of the SSKs. The first three all pertained specifically to the kit used (fear of needles, insufficient blood flow, and issues with the vial). The latter two meant several interviewees submitted an under-filled sample, resulting in their being contacted by HAs who explained their sample could not be processed and described future testing options (see section 6.1.9 above). Those who experienced this problem reported several concerns which impact the acceptability of the intervention. Finally, interviewees identified stigma, fear, and taboo surrounding HIV and

HIV testing as a barrier not only to SSKs but to all methods of HIV testing. Each of these themes are discussed in greater detail below.

9.1.3 Fear of needles

Of the interviewees who had not returned their sample, fear of needles and pricking one's own finger were commonly-mentioned obstacles to using the SSK. One interviewee recounted that she opened her SSK when she returned from her GP appointment and could not bring herself to prick her own finger. She explained, "I opened it, but I can't do it by myself. I can't use the needle to pinch myself. I can't do it" [45-year-old female, non-returner]. She subsequently returned to her GP surgery for a health check, and requested assistance from two nurses in drawing blood for the SSK. They apparently stated that they could not help, so the interviewee brought the SSK back home and did not try to use it. Another interviewee shared,

> *The reason why I didn't [use the SSK] is because even though the Doctor explained that it was really simple, I'm scared of needles, so I was actually waiting for someone to be with me to do it, in case, like, I started freaking out. [...] I'd prefer, like, a friend to do it, rather than me, 'cause if I see a needle I'll, like, freak out. Even though it was explained that it's really easy. But I don't know what's easy in [GP's] terms. Like, for me, it's not easy at all to, like, prick myself [23-year-old female, non-returner].*

When asked whether they would consider using a SSK in the future, a number of participants replied that they would not consider future use due to a lack of comfort pricking one's own finger and seeing one's own blood. However, not all interviewees were squeamish about the lancets, and many found the lancets acceptable.

9.1.4 Insufficient blood flow

The interviews were replete in accounts describing the difficulties faced in maintaining sufficient blood flow to fill the vial. One woman who had consecutively submitted two insufficient samples expressed dissatisfaction and frustration with the process of drawing blood. She recounted,

> *The first time when I used it I thought the blood was enough and then […] I posted it and they called that the blood wasn't enough and then I got another [SSK] and then they said still the blood wasn't enough, so I just couldn't be bothered [26-year-old woman, insufficient sample].*

This interviewee recalled that it had taken approximately a half an hour each time she took the sample. She described being offered alternative HIV testing via a sexual health clinic near

her home during a phone call from a HA, but was discouraged due to her negative experiences using the SSKs. She shared,

> *They explained I can go and get a HIV test in [an area in London] or in where I live but I said, I say I can't be bothered. They wanted to give me another home test but I say no, 'cause two times, shew.*

One interviewee, a 52-year-old female, attributed issues in getting blood to flow to a pre-existing nerve problem. Her sample was under-filled, even though she used all of the lancets and "tried everything" to get the blood to flow, including milking her finger.

9.1.5 Issues with TINY vial

Frustration was also expressed regarding difficulty in getting blood to drop into the vial provided in the SSK. Lack of clarity over the best angle to hold the finger to facilitate the flow of blood into the vial was voiced, along with feedback that the vial was too narrow to allow the blood droplets to collect at the bottom. A few interviewees reported that the process was quite messy due to these issues.

> *This is where the flaws come into it. You know like you use the lancet, and then you try to get the droplets of blood to go in at a certain angle […] it's very hard to get the blood to drop freely as well, and it doesn't collect enough. [39-year-old woman, insufficient sample]*

Another interviewee recounted,

> *It took me a while to get the rhythm of it. I mean basically the first finger was a dud. I completely mucked it up. Blood was everywhere and I think it was partly the nerves. […] I couldn't get it into [the vial]. […] So I basically abandoned that finger and moved onto the second one and that one was much better. Yes.*
> ***[Interviewer: Why do you think it went better?]***
> *I don't know. Because I had a second go at it and probably made mistakes the first time around I would have been more aware the second time round. Like I didn't handle my finger right in terms of how it was sort of placed above the little one tube. So when I changed the angle the blood was more prone to coming out in droplets that way than the other way. The other way was sort of messy […] With the little bottle thing, the blood had a tendency not to go all the way down. It would sort of float at the top. [25-year-old man, negative].*

The issues of inadequate blood flow and difficulty in collecting blood droplets into a narrow vial were echoed in the following account:

The most difficult part was trying to get the blood out of my finger and I managed to put blood all over the table, and my mom came in and she thought that I was not doing it properly, so she helped me to do it, and I think that was just the most difficult part getting the blood to come out my finger and put it into that little tube [18-year-old woman, negative].

When asked whether they would be willing to consider using an SSK in the future, the vial was frequently cited as a factor that discouraged participants from future use. It was viewed as 'tricky' to use and a few interviewees specifically recommended providing a wider vial to improve the ease of blood droplet collection.

Despite such comments, not all interviewees reported problems in filling the vial. For instance, a 67-year-old man reported that his blood flowed very easily. In fact, he reported that taking his sample had been a very positive experience: "It was so easy. It's stress free. I really enjoyed it." Similarly, an 18-year-old female reported that she had trouble stopping her finger from bleeding, even after she had filled the vial. A 49-year-old female whose first sample was indeterminate, and second was negative, recounted that the second time drawing blood had been much easier than the first.

Many interviewees, especially those who did not return their sample or returned an insufficient sample, felt that issues regarding needle squeamishness, blood flow, and collection in the vial could be overcome by having GPs and other health staff assist participants in taking their blood samples. One young female interviewee stated,

If they had been offered to me in the Doctor's and then he, sort of, helped me do it, I think it would've been a lot easier. But I think sometimes, when you take things away it's, sort of, kind of, like, it's a lot harder to get round to doing it, if that makes sense, and then there's the whole hassle of having to send it off. That, sort of, factors in and it's just… it might not be the best way to get, like, someone like me to do something [23-year-old woman, non-returner].

Another participant, who did not return her kit, was uncomfortable drawing her own blood, and similarly would have preferred a health care professional to take the blood for her. She shared,

It would be good if you invite the person in the hospital or somewhere and then do it for them, because if you give it to me like this I can't use the needle to pinch my finger. It's very hard for me to do it. […] If someone is doing it for me I would do it, but doing it for myself I can't. […] It would be better if they can do it in the surgery or hospital. They invite you. You know, when you go and they can take your blood and then do it. That would be better if it was possible for that [45-year-old woman, non-returner].

This was echoed in a suggestion offered by a 52-year-old female who returned an insufficient sample. She thought that the aspect of the patient posting the kit could be retained, but that the sample collection could be assisted by a health care professional for those who had difficulty maintaining blood flow. Another interviewee, whose sample was indeterminate, suggested that providing a walk-in option where people could go to receive assistance using the SSK would be beneficial. She stated, "perhaps have a place within each locality where one could just walk in and do the test and have someone to assist them with the test as well. That could be another alternative as well" [39-year-old woman, insufficient sample].

9.1.6 Issues with follow-up for insufficient samples

Several of the interviewees whose samples were unable to be processed due to being under-filled were critical of the way in which they received their result, and the options offered for further testing. One such interviewee was distributed two kits consecutively. The first one was never received by the laboratory. After receiving a reminder text from the study team to send in her sample, she returned to her GP surgery to obtain a second kit and presumed that the first one had been lost in the post. The second sample was insufficient as it was under-filled. She recalls being contacted by a HA:

> *Someone called me from the study. Said there wasn't a sufficient sample, and then I did a sample, I did the test twice. One, the study never received it, then the second one they didn't get in time or something like that, and then they didn't send me another kit or anything like that again. And I just thought okay, well, can I come in to do a face to face or, if need be, can I not just come in face to face and get it done as well, and that wasn't offered. […] I think going forward what would be useful would be to have the option of coming into a centre, not necessarily…like any of the hospitals, whichever was in that locality, or even up to the GP to obtain a sample [39-year-old woman, insufficient sample].*

As the HAs were instructed to offer another SSK to anyone producing an insufficient sample it would appear to conflict with the interviewee's statement that an offer to send another kit was not made. Notably, she attributes the problem with the second kit to the study team not receiving the kit in time, which was not the case – the problem was that the vial was under-filled. She also stated that she was not offered a face-to-face test, although according to the records kept by the study team she was advised by the HA to discuss alternative testing options with her GP upon her next visit. These anomalies demonstrate the gap between the process outlined in the study protocol for handling indeterminate samples and the process as perceived by the study participant.

This interviewee also referenced the delay she experienced between sending in the sample and hearing the result:

> *[Results notification] takes five days and no one knows what's happening in between that five days before they call you, and then they'll call you to say…I mean, I had two calls where I was told that they hadn't received and I sent a text back and nobody actually replied back to that actual text, but you phoned back and said actually I did send it. […] So I think maybe a better communication will be better as well. Also five days, depending on some people […], they would feel more anxious. I wasn't, but some people might have been. So, to alleviate that kind of anxiety, […] if there's another number for people to call. Because I got a call from somebody and they left a mobile number and, again, it wasn't clear enough. Sometimes, it's very hard to say what you want to say in a more succinct way. So, maybe better communication in terms of who calls and when they call, etc., and if there's a standalone number that someone can leave a message and say call me back. Sorry, not a standalone number, but an actual mobile that's actually manned as opposed to just you leave a message and then whoever will come back to you at a time that's even more inconvenient because it's convenient for them [39-year-old woman, insufficient sample].*

Contained in this passage are several learning points for future interventions featuring SSKs and/or text messaging to participants. The respondent points out that no one responded to her text, which is accurate; the study protocol did not plan for study staff to respond to text messages received from participants who were sent reminder text messages by the study team. As this participant may have been comforted by receiving a text message back from the study team, future interventions may be improved by adding this capability into the process. Moreover, she suggested that an improved communication pathway with the HA is needed, as there was a lot of back-and-forth and leaving of messages by herself and the HA in this particular scenario.

Despite these experiences, other interviewees with insufficient samples found the follow-up process unproblematic. No participants had a reactive sample so pathways for linkage to confirmatory testing remained untested.

9.1.7 Stigma, taboo, and fear regarding HIV and HIV testing

Many interviewees cited stigma, taboo, and/or fear around HIV testing in general as a barrier to acceptability of the SSK. Several felt that others would rather remain ignorant of their HIV status than be tested (via a SSK or otherwise) and potentially face the stigma associated with an HIV positive status, even when they recognised their behaviours may have put them at risk. One interviewee stated that some African people would never willingly be tested, based on a belief that HIV only becomes problematic once it is diagnosed.

9.1.8 Facilitators to acceptability of SSKs

The convenience of the SSK emerged as a very salient theme in the data. The comprehensive kit was thought to have many positive features, including the lancets (perceived by many interviewees as non-threatening) and clear instructions - features which were frequently cited as making the SSK acceptable to use. Additionally, participant trust in the SSK distributor facilitated SSK acceptance. Each of these facilitators is discussed in the sections below.

9.1.9 Convenience

Comments on the convenience of the SSK were widespread, and centred on related themes regarding ease of use, speed and the delivery mechanism of results, flexibility on when and where to use the kit, and privacy afforded by the kit. An 18-year-old female whose test was negative remarked on the convenience of not having to provide a blood sample at a medical facility, supervised by staff: "I would not need to come back another time to come and redo the test, and I could do it in the comfort of my own home, without anyone pestering me, or having to watch me do the test." The privacy afforded by the test was recognised even by an interviewee who did not return her test, who stated "It's not like you going to a centre, standing there they take your blood, other people are watching; so you do it yourself. And then you post it" [41-year-old female, non-returner].

Though some potential participants voiced preference for point-of-care testing due to immediacy of results, those who used the SSKs recognised that the SSK process delivered results quicker than some sexual health clinics.

> *Sometime before, two years ago, when I did it they just told me that they wanted to try using a pack to do a HIV test and I said I'm interested and they asked me to go to King's College for the blood and they send the result to them and the nurse phoned me and said that I was negative. It took almost a week to get the result. This one it does not take, it's almost within 24 hours I got my result. [**Interviewer: And you didn't have to travel to the hospital or anything like that?]***
> *Exactly. I would have to take a bus to the hospital. [66-year-old male, negative]*

Several interviewees appreciated that using a SSK negated the need to schedule time specifically for an HIV test at a clinic. Coupled with the speed of the result, the lack of need to travel to give the blood sample was cited as an attractive feature of the SSK. Related to this is the convenience of posting the sample once complete, though a minority of interviewees voiced concerns over the sample going missing in the post or felt that posting a sample was a 'hassle.' One shared, "I worried, because I did not know if it was going to get delivered to the right place" [18-year-old female, negative]. In at least one case, a participant erroneously

received a text message prompting her to return their kit when she had already returned it, causing the participant to wonder whether the kit had arrived at its intended destination. She later received a phone call from a HA as her sample was insufficient, which relieved her anxiety over whether the SSK had gone missing. She received and used another SSK, and was more confident about it not going missing in the post the second time as it had arrived the first time.

Convenience of receiving the result via text message was frequently linked to the speediness of this result notification method. The majority of those who received negative results via text message were comfortable with this method. In fact, some specifically stated that they were more comfortable with a text message than with a phone call, as the latter method would have made them feel more nervous. When prompted to elaborate why he felt this way, an interviewee explained,

> *I probably would have felt more awkward if it was like a phone call. I probably would've gotten more nervous with a phone call. […] Because you try to read into it. You try and read into the person's tone and how they sound over the phone. And you try to like guess what it is before they say it [25-year-old male, negative]*.

Some interviewees specifically commented that the content of the text message was clear, and due to its format as a text message could easily be sent to others if desired. For instance, one interviewee recounted:

> *I did not expect [the test result] so soon. […] I was happy because it was negative. So I was very happy. It was very straightforward and I sent it to my girlfriend […] so that she would know that I am free [64-year-old male, negative]*.

However, one respondent felt that the message reporting the negative result could be misconstrued or misunderstood by some, as 'negative' may be interpreted as meaning 'bad news' rather than the absence of HIV antibodies.

Interviewees received a texted reminder if more than two weeks passed between obtaining an SSK and reception of the SSK at TDL. This appeared to be an effective method to remind participants to use and post their SSKs. One interviewee recounts how the texted reminder prompted him to use the SSK:

> *I was reminded because you know I got the kit – I put it somewhere where I can usually see it. But I received a text message to remind me of it. […] So that was when – it is like oh, I have been reminded now I think I have to do it [50-year-old male, negative]*.

The majority of interviewees, including those who submitted insufficient samples, stated that they were willing to use a SSK in the future, based on the convenient nature of the kits.

> *I'd be willing to use something similar to this, yeah. Definitely. […] Because I just think the privacy is definitely like a win-win situation. I would prefer to not have to go somewhere I think. Yeah, I'd rather just do it in my own environment. If you do it where you're comfortable as well, if you need the support of someone else close to you, you can do it with them. It's just, yeah, I think it's a really good idea [18-year-old female, negative].*

One interviewee felt that the SSKs could be made even more convenient by storing them behind the counter at GP surgeries, and have them available upon request to anyone who wanted one without having to book an appointment with health staff.

9.1.10 Non-threatening lancet

Though some interviewees (especially those who did not return their samples) were fearful of pricking their own fingers to draw the blood sample, many other interviewees found the supplied lancets acceptable and less 'scary' than other types of needles used to draw blood. One 25-year-old male liked the lancets because the sharp needle was not visible (it only emerged when the device was pressed against the finger, and then it retracted). Another man favourably compared the SSK lancets to needles used at hospitals to draw blood, and reported that having blood drawn by the latter method was "very painful" and "caused anxiety" for him. He viewed the lancets, in contrast, as "very easy and simple." He recounts,

> *I pressed [the lancet against the finger] and there was blood coming out. It was very easy and very simple. Simple, easy, anxiety free, painless. I'm okay. I did enjoy it. If I had to do it every week I would do it [66-year-old male, negative].*

Similarly, a male 26-year-old explained that he was motivated to use the SSK as it seemed a "less inconvenient and less painful" HIV testing option compared to other testing methods. The lancets were also deemed acceptable by a 39-year-old woman, who recounted her first impression of the lancets in the following: "Then I looked at the lancet, and it wasn't something that I was like oh it's going to hurt me or anything like that, and I just did it."

9.1.11 Clear instructions

Several interviewees opined that the instructions, both the paper version included with the SSK and the online version, assisted them in using the SSK. One young woman felt that the process seemed very complicated initially, until she referred to the instructions. She recounted her impression when she first opened her SSK at home:

Well, it looked very complicated because there was so many things inside the kit. But once I laid it out into where it is meant to go and read the instructions, it was actually a lot less than I expected, because most of it was just packaging and some of it I did not even have to use. It was just extras [18-year-old female, negative].

General comments about the video were positive, with one interviewee speculating that it would particularly appeal to young SSK users. One interviewee shared the following positive opinion: "I liked the video – you had the video which helped to go through the instructions a lot easier" [18-year-old female, negative].

A minority felt that the written instructions were too complicated, and could have been simplified or made less 'wordy.' The small text of the instructions was also referenced as a potential area of improvement.

9.1.12 Trust in distributor

A small number of interviewees mentioned that a high level of trust and regard for the distributor who offered the test motivated them to accept a SSK. Examples of this were evident in recruitment from both CBOs and primary care. One interviewee who was offered the SSK via a CBO at a barbershop and was encouraged by his trusted barber to take the test. Similarly, a GP-surgery recruited participant referenced his high level of comfort and rapport with the HCA as motivating him to enrol into the study. One interviewee, a 50-year-old male, suggested that having black African distributors who had personally used an SSK may increase trust in distributors and thereby increase acceptability of the kits and HIV testing more generally.

9.1.13 Awareness-raising of HIV testing and treatment

Increasing awareness of HIV testing and treatment options arose as a major theme when interviewees were prompted to suggest other or better ways to encourage black African people to be tested for HIV more regularly. One woman provided several suggestions on how to increase awareness:

Well, there's like family planning clinics, church groups, invite people from various communities, from the Black community, talk a bit more, put it into music, into sports, into drama, just get it out there and just try and…just try and talk to people in the community where you can do. You can do it with like a part of a general health thing, like if they're doing a health focus on diabetes and other blood borne viruses and other things, pneumonia, keeping well, health awareness sort of programme. Why not attach this along with it? [39-year-old female, insufficient].

A 36-year-old male suggested that the SSKs and/or point-of-care testing could be offered out of health vans, or at events organised by African organisations.

Another interviewee argued that increasing awareness could 'normalise' discussions about HIV, to decrease fear and stigma and thereby facilitate HIV testing efforts, including SSKs.

9.1.14 Acceptability of targeting to African people in London

Over half of the participants interviewed indicated that they did not mind that the intervention targeted black African people specifically. One interviewee commented that the way she was offered the kit was non-discriminatory, even though it was made clear that the intervention was targeting only black Africans. Another interviewee mentioned that he liked the way his doctor approached him about the SSK, mentioning that his doctor 'invited' him to take part and he felt privileged to be given a kit. Several interviewees thought that the intervention was a good idea and should be expanded to be offered to other ethnic groups, even if they were not offended that it was limited to black Africans. One pointed out that sexual relationships are not necessarily formed within ethnic boundaries, so the intervention should similarly not be limited according to ethnicity. She stated, "It becomes an African thing, like you know this test, there is intermarriages of different nationalities. […] What about those who are married with the Africans, or those Africans who are married with the whites?" [45-year-old female, insufficient sample]. Only one interviewee, a 26-year-old male whose sample was negative, felt offended that he had been offered the test due to his ethnicity. He stated that the targeting of black Africans was "quite racist," and surely the SSK could have been beneficial for other groups as well.

Though the majority of the interviewees were not personally offended by the targeted aspect of the intervention, some participants speculated that the targeting of black Africans may offend other African people. For instance, a 50-year-old male speculated that some would react to the offer of a SSK by thinking,

> Oh, why Africans, why not other people? […] They may get the message wrongly thinking oh it is just for Africans, why not for Americans, why not for other people from other races. […] Some people might feel offended. Oh, why Africans, oh, they have come again, why Africans. No. You see such people might need some maybe literature to read [50-year-old man, negative]

He suggested that informing black Africans of the reasoning behind the targeting would help in acceptance of the SSKs. He recommended, "Such people need to be informed, need to be lectured so that they understand why it is being carried out, otherwise they will get the message wrong."

A minority of interviewees stated that they were unaware that the intervention was targeted at all. This may reflect the nervousness expressed by some sites to make clear that the intervention was targeted exclusively at black Africans, or simply misunderstandings amongst the interviewees about the targeted nature of the intervention. One interviewee described the interaction with a practice nurse when he was offered the kit which appears to support the former:

> ***Interviewer: How did you feel about being offered the HIV test because you were African?***
> *I didn't think about that. Because it was on the sign up form so it was generic and for everybody. It never crossed my mind that it was because I was African or anything. You know?*
> ***Interviewer: Right. So no one specifically said that this was a program that had been set up for the African community?***
> *No [25-year-old man, negative].*

In cases where interviewees were apparently unaware about the targeted nature of the intervention, the project manager contacted the sites from where the interviewee was recruited to inquire whether the distributors were fully informing potential participants of the targeting aspect of the study. In all of these instances, the distributor reported that they were indeed informing all potential participants that the SSKs were being offered only to black Africans.

9.2 Acceptability to service providers

Thirteen GP surgeries and three CBOs in London judged the HAUS SSK intervention as likely to be acceptable to their staff and clients when they volunteered for the study and all but one GP surgery maintained this judgement through the process of training prior to implementation. That London surgery withdrew from the study during training when substantial opposition was voiced by a range of staff, both on the grounds of insufficient time and as a consequence of concerns about targeting black Africans.

9.2.1 Acceptability and utility of training

All distributing organisations undertook mandatory training prior to the initiation of fieldwork. In total 18 training sessions were delivered across London. These were delivered in the premises of 12 GP practices and three community–based organisations (CBOs) that participated, with the CBOs receiving two training sessions each. Some distributors asked for and received follow up sessions, either to review key elements, or to catch up staff that were unable to attend the first training.

In total 70 people attended the training sessions following which 47 (67%) people voluntarily completed and returned an evaluation form anonymously. The participants identified their job roles as follows: professional health worker including GPs, GP practice nurses, pharmacists, health care assistants (n=33); peer support worker (n=4), community based organisation service manager (n=8), and other (n=2).

Training sessions typically lasted around 2 hours, and participants were asked to complete an evaluation form at the outset and following the training. These brief evaluations were primarily intended to be used iteratively to improve subsequent training sessions, but they also help assess the overall value that the training makes to intervention delivery.

Participants were asked to rate components of the training on a scale of 1 to 5, where 1 was "no benefit" and 5 was "great benefit" (see Table 12). Each of these components received an average score of between 4 or 5, with the two highest rated items being the overview of self-sampling kits and study paperwork, as well as the clarification of study inclusion criteria. Some feedback demonstrated that a few participants were less confident about the benefit of the training to help them describe and model use of the kit, and to explain to participants how their sample results will be delivered, but these views were very much in the minority.

Table 12: Training evaluation components rated 1= no benefit to 5=great benefit

Component of Training	**Average score**
Clarification of inclusion criteria	4.6
Overview of self-sampling kits and study paperwork	4.5
Overview of the intervention	4.45
Explaining how results will be delivered	4.44
Alleviating concern and motivating potential participants	4.42
How to target individuals and gain consent	4.36
How to describe and model use of kit	4.29
Building confidence in potential participants	4.1

The vast majority (96%) agreed that the range of topics covered within the training was good. When asked, "Did you get what you were looking for from the training event?" One third (n=16) said they had "completely" got what they wanted, with half (n=23) saying that they

had “mostly” got what they wanted. Four were ambivalent in their responses with “somewhat”. All those who responded to “The training has increased my understanding of the HAUS study and what is expected of me as a distributor” agreed with this statement (n=45, 2 missing). Similarly the majority (87%) reported that any questions or concerns they had at the start had been answered, with the remaining 6 people neither agreeing or disagreeing.

Each individual was asked to summarise what they understood the HAUS study to be about and their role within it both at the start and at the completion of training. Following the training all participants gained a stronger understanding of the study aims and objectives, and clarity about their roles and responsibilities also became more pronounced. A range of other responses further reflected on the excitement participants felt at having a new way to encourage HIV testing, and a comment that this could be a helpful route to ensure ongoing support for African people with diagnosed HIV.

The clear shift in participants’ responses indicates that participation helped to increase knowledge about the study and their roles as recruiters. Indeed several GP distributors at the subsequent exit interviews (see 9.2.2) indicated that prior to the training they were unaware of the epidemiology relating to HIV in the UK in general and to HIV and black African communities in particular.

9.2.2 Acceptability of HAUS intervention to primary care staff

Broadly speaking, the acceptability of the intervention to staff at GP surgeries remained relatively high even after, in many cases, a relatively unsuccessful period of intervention implementation.

The only universal impediment to the acceptability of this intervention in primary care was the time it took to recruit to the study. In the context of 10-minute consultations the research requirements of the study were the major impediment. Moreover, some felt there was insufficient time to describe and execute the SSK intervention without causing a backlog of other patients. All the GP surgeries struggled to find sufficient time to implement the intervention routinely and most offered the intervention to far less patients than they had hoped due to pressure of time. Problems with the time it took to deliver the research requirements were exacerbated by concerns about the kit itself among some distributors, especially among those surgeries that allowed the patient to take the sample on site. However, there did remain a degree of enthusiasm about the potential use of SSKs in GP settings as

'add-ons' for patients, especially where phlebotomy was based off site or POCT was not perceived as feasible. In our closing interviews, a number of GP based distributors talked about the way that an SSK could benefit some of the people they see, and in the main it tended to be the research process that prevented timely distribution. There was even more support for SSKs that used an oral sample, or a blood based sample provided it would be simpler to use than the TINY vial (for African people and for all potential users).

The other key issue in the perceived acceptability of the intervention was targeting. The majority of recruiting staff found the concept of targeting black Africans acceptable at least during training and relatively few reported adverse reactions from patients once the intervention was implemented, though some patients required an explanation as to why they were being targeted. One distributor noted, "The black community are more receptive and recognise [HIV] is an issue. Don't take it personally, not a slight."

Some surgery staff found the process of targeting difficult, usually because it was not feasible to establish the ethnicity of patients from the patient database as this were often incomplete, contained erroneous data, or because they did not have the time to check through patient notes. In the absence of pre-existing data, clinics adopted a range of strategies to identify potentially eligible patients that often varied between staff even in the same clinic. In some settings, there was discomfort with the concept of targeting based on visible race because this often led to a discussion about the intervention with patients who were not ultimately eligible. This was especially pertinent in areas where the majority of black patients were of Caribbean rather than African origin.

In up to half of clinics some (but often not all) distributors felt some unease with targeting black African patients. The concept of targeting black Africans raised concerns about exacerbating both HIV-related stigma and xenophobia. In three clinics, the proposed targeting based on ethnicity was accepted during HAUS study training but rejected once the distribution period began, resulting in little or no recruitment occurring at these sites. In all these sites most recruiters seemed uncomfortable with the concept of targeting black Africans largely for fear of causing offence.

In one clinic, after training staff decided that discussing the study openly with patients or even asking patients whether they were black African could be considered offensive and give rise to accusations of racism. In other surgeries, there was some mild concern that targeting migrants and visible ethnic minorities might exacerbate racism and xenophobia. One

distributor noted, "I am always a bit cautious about offering based on ethnicity because of what has been happening, in our country, and people feeling a bit uneasy about the colour of their skin and where they are from."

9.2.3 Acceptability of HAUS intervention to staff of CBOs

The acceptability of the intervention to staff at CBOs remained high throughout the study, in spite of substantial recruitment difficulties. CBOs maintained that SSKs were a useful additional intervention for their menu of services when targeting black Africans. They also felt that the SSKs were considered convenient by their clients, though HIV stigma clearly presented a barrier to some enrolment. Broadly speaking, SSKs remained acceptable to CBO staff in spite of evidence that SSKs were not necessarily a feasible add-on intervention to the outreach activities that formed a large part of their existing funded work. For all CBOs, pre-existing commitments to funded interventions meant they had limited capacity to recruit to HAUS. Among CBO staff, perceived acceptability among black African people was variable with concerns about HIV stigma, the time required to complete research processes and process of using the kit itself.

While the staff and volunteers at one of the CBOs struggled to implement the intervention they reported it "felt good" to be able to offer SSKs as an option for their clients. Further, they reported that participation in HAUS increased morale among staff, partly because "they had something concrete to give out to people" but also because it allowed them to have a dialogue with clients about HIV testing. Staff at this CBO had hoped to integrate the SSK offer into the standard outreach work they are funded to provide to black Africans, but this proved difficult because the HAUS process was too time consuming. They reported trialling the intervention at three "events" at barbershops in Lambeth, but that there was some resistance to their activities in these settings with a high volume of refusals, which they assumed was a consequence of a lack of privacy in these settings.

Staff from another CBO had a little more success with recruitment but still found it difficult to implement the intervention. In spite of difficulties, the intervention remained acceptable to the organisation and its staff and they reported less acceptability concerns for their clients compared to staff from the first CBO described above. They were comfortable targeting Africans (they too were black African) and were comfortable with the element of providing information required alongside the intervention, though this could be time-consuming. Staff at both CBOs felt participating in HAUS was a good experience as it filled gaps in their

existing range of services. For instance, even though they had a mobile testing unit, HAUS allowed them to distribute kits where the mobile unit could not go.

Staff at the third CBO expressed considerable enthusiasm about the HAUS study during initial contact and training. Like staff at the other participating CBOs, they felt the HAUS SSKs would give them an important new tool to engage with service users, and would help to supplement their office-based POCT HIV testing service. Distributors felt that their service users had benefitted from the intervention, although not many kits were distributed, they felt that awareness of testing had increased due to the discussions prompted by the SSK offer.

All CBOs reported that they approached many eligible people who refused to participate. CBOs reported two key barriers to participation which might be considered evidence that the intervention was not acceptable to the intended target audience. The primary acceptability problems identified by the CBOs were very similar to the GP surgeries, with the added complication that the CBOs' recruitment tended to focus their recruitment efforts on outreach interventions rather than selecting among their existing clients.

While CBOs had no initial qualms about targeting only black African people, they subsequently reported that some people approached were hostile about being targeted and even aggressive. African men were reported as especially challenging to engage. Given all three CBOs have experience of recruiting Africans to other HIV prevention interventions all expressed surprise that there was still so much stigma associated with HIV among the wider community of African people in London. They felt disappointment that the intervention was limited to black Africans, as it disqualified other black groups from participation. This issue was a bit off-putting to some black people approached, as they would indicate interest in the SSK only to be turned away due to black Caribbean status. This issue became especially problematic when the SSK was offered to a group of people, some of whom were eligible for participation and some not. One CBO also reflected that the usual users of their office-based HIV testing service were highly self-selecting, in that they were already primed to consider HIV testing, which was not the case in the wider community. The extent of disengagement from HIV, framed in hostile or suspicious responses was described as being difficult to bear during kit distribution. Some staff felt that ignorance of HIV (including beliefs that HIV was a conspiracy, or could be cured with prayer), were a barrier to using a SSK but this is likely to be a disincentive to all types of HIV testing.

The second major barrier to recruitment was the amount of time it took to explain the study, fill out the paperwork, and go over the kit contents. All CBOs intended to distribute SSKs in outreach sessions already scheduled for other funded projects, but this was not always feasible as it took much more time than they expected to explain the study to potential participants, especially if they showed the video to potential testers.

As in the GP surgeries, CBO distributors reported problems with the actual intervention, including the amount of blood needed to fill the vial, the requirement to provide personal details to receive the result, and the preference of some people to know the outcome of the test immediately. Some distributors reported that potential participants felt that they should be paid to participate in the research study.

9.3 Summary

The interviewees widely reported that the targeting of black Africans specifically was acceptable. This was in contrast to the experience of distributors at GP surgeries, who despite the training and provision of a script to initiate this discussion often felt unease at targeting black African patients only. Concerns about exacerbating HIV-related stigma and xenophobia were expressed. Lack of willingness to target black Africans ultimately led to little or no recruitment at three GP surgeries. Despite these misgivings, many primary care staff felt that the intervention was worthwhile and expressed disappointment when the distribution period finished. Distributors at GP surgeries also reported having been unaware of the HIV epidemiology in relation to black African communities in the UK prior to participation in the study. Provision of this information did facilitate the targeting process for many.

Some distributors at GP surgeries noted that targeting was complicated as information on ethnicity on patient databases is sparse, and moreover there was limited time to check this data prior to appointments. These issues manifested in a large variety of methods employed at GP surgeries to select patients to offer the intervention.

The acceptability of the intervention to staff at CBOs remained high throughout the study, with the SSKs generally viewed as a valuable add-on to service menus. However, significant barriers to recruitment were noted, including stigma around HIV testing and limited time and capacity to conduct the intervention.

The acceptability of the HAUS intervention was also compromised by the specific SSK used, as well as issues with follow-up for insufficient samples, and stigma, fear, and taboo around HIV and HIV testing. Conversely, acceptability was supported by the convenience and privacy afforded by the use of SSKs, clear instructions and trust in the distributor. In a broad sense, users felt that acceptability not only for SSKS but for all HIV testing could be increased through awareness-raising activities.

Based on these findings, suggestions to improve the acceptability of the SSK specifically include development of a more user friendly SSK and ideally the option of both saliva and blood based kits.

Chapter 10: **Cost effectiveness**

The aim of the economic model was to determine if offering an HIV SSK is a cost-effective means to increasing the provision and uptake of HIV testing among black Africans in the UK compared to current practice from health care perspective. The model assessed the lifetime cost per quality adjusted life year (QALY) gained of SSKs compared to current practice in black Africans in the UK.

10.1 Methodology

We developed a hypothetical cohort of 8,000 individuals of black African descent to populate the model. The hypothetical cohort was representative of the current black African population in the UK in regards to age, gender and HIV status. The cohort size was chosen so that sufficient cases of HIV were present in the model to test the hypothesis but not so great that the model could not run due to computational load. All patients were aged 18 to 80 years, and proportioned according to current sex and age-band distributions as defined in Table 13.

Sex-specific prevalence rates of HIV, including diagnosed and estimated undiagnosed, were used to determine the baseline number of HIV cases in our model population.(1) Data from Public Health England also provided information on proportion of individuals in early and late stage HIV, and proportion on ART(1) (see Table 13).

10.1.1 Population

Table 13: Population characteristics of black Africans in the UK

	Male	Female	Male and Female	Reference
Age Distribution (black African population in the UK)				
0-15	137,565	140,073		(84)
15-24	80,175	80,468		(78)
25-49	205,934	230,281		(78)
50-64	39,182	40,322		(78)
>=65	10,500	13,241		(78)
Total	335,791	364,312		(78)
Black African Population HIV positive				

	Male	Female	Male and Female	Reference
Diagnosed	8 312	17 730		(1)
Undiagnosed	1 530	2 380		(1)
Percentage at each CD4 count				
< 350			20%	(1)
350 - 499			25%	(1)
≥ 500			55%	(1)
Proportion on ART - all			85%	(1)
Proportion on ART and CD4 <350			89%	(1)
Average viral load for people infected with HIV (log copies/ml)			4	(85)

10.1.2 Model structure

A patient level simulation was developed to assess the cost-effectiveness of SSKs in black Africans in the UK, compared to current practice. The model was developed using published data and results from the HAUS trial to predict individual's transitions, costs and health outcomes. The model was created in Microsoft Excel 2010 according to methodological recommendations for evaluations of new health care technologies and interventions.(86, 87)

The same hypothetical cohort of 8,000 patients was tested under two different HIV screening arms, similar to the trial: (i) intervention (SSK); or (ii) comparator (current practice) (see Figure 7).

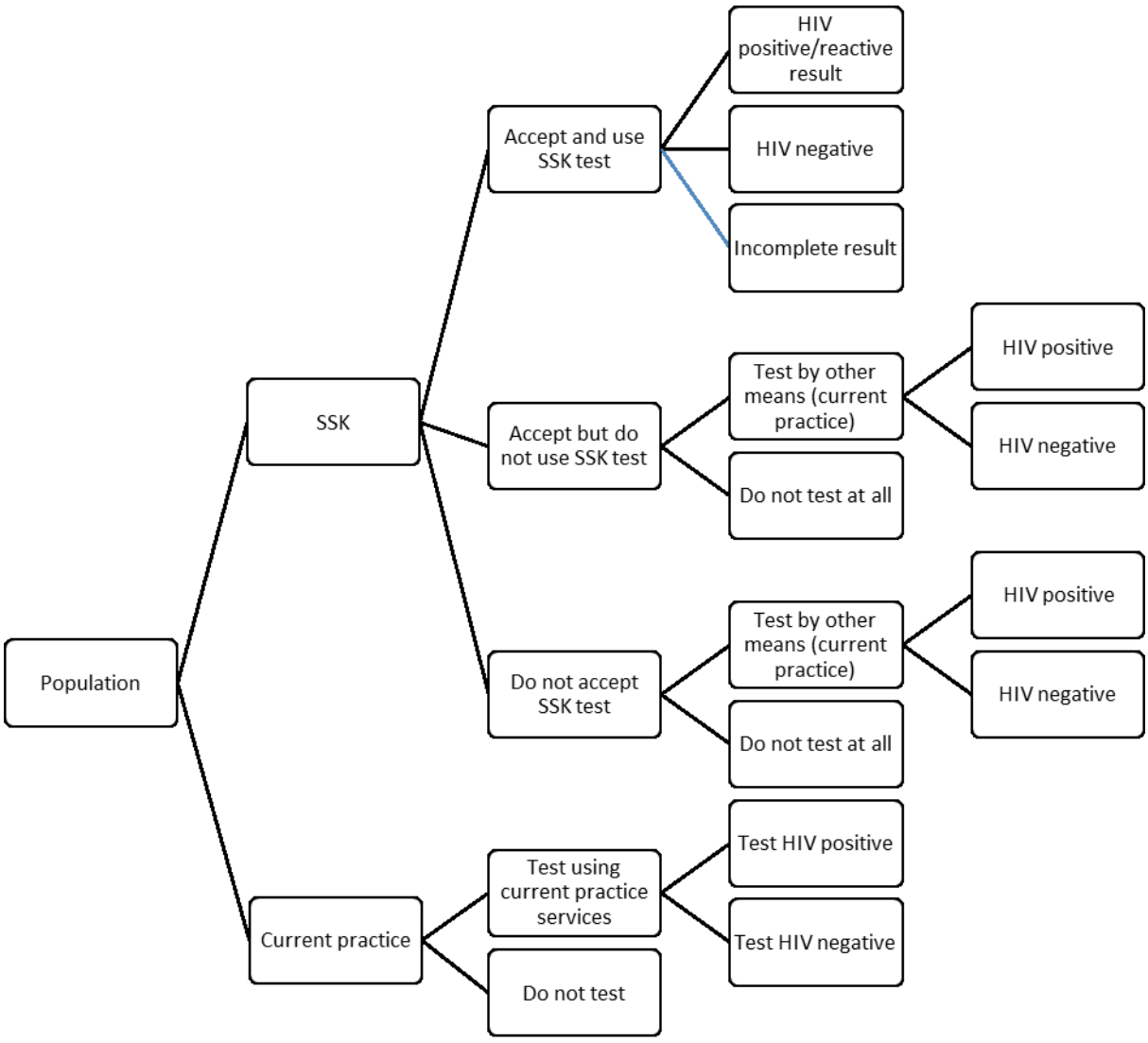
The patient level model is a lifetime patient level simulation with the following three components:

1. Simulation of HIV disease progression
2. The probability of HIV transmission from HIV positive to HIV negative patients
3. Effectiveness of SSKs in increasing HIV testing and reducing the number of undiagnosed and untreated cases of HIV in black Africans in the UK.

The model consists of cycles of 3 months duration. In each cycle patients are in one of 6 health states or 2 death states (see Figure 8). All patients enter the model alive and in one of the six health states. There is a 10-cycle run in period to stabilise the model during which no

outcomes are measured. After the 10th cycle patients that are not dead and not in the state "diagnosed HIV" are offered a SSK when they are in the SSK screening arm.

Figure 7: Decision tree of patient movements through the model

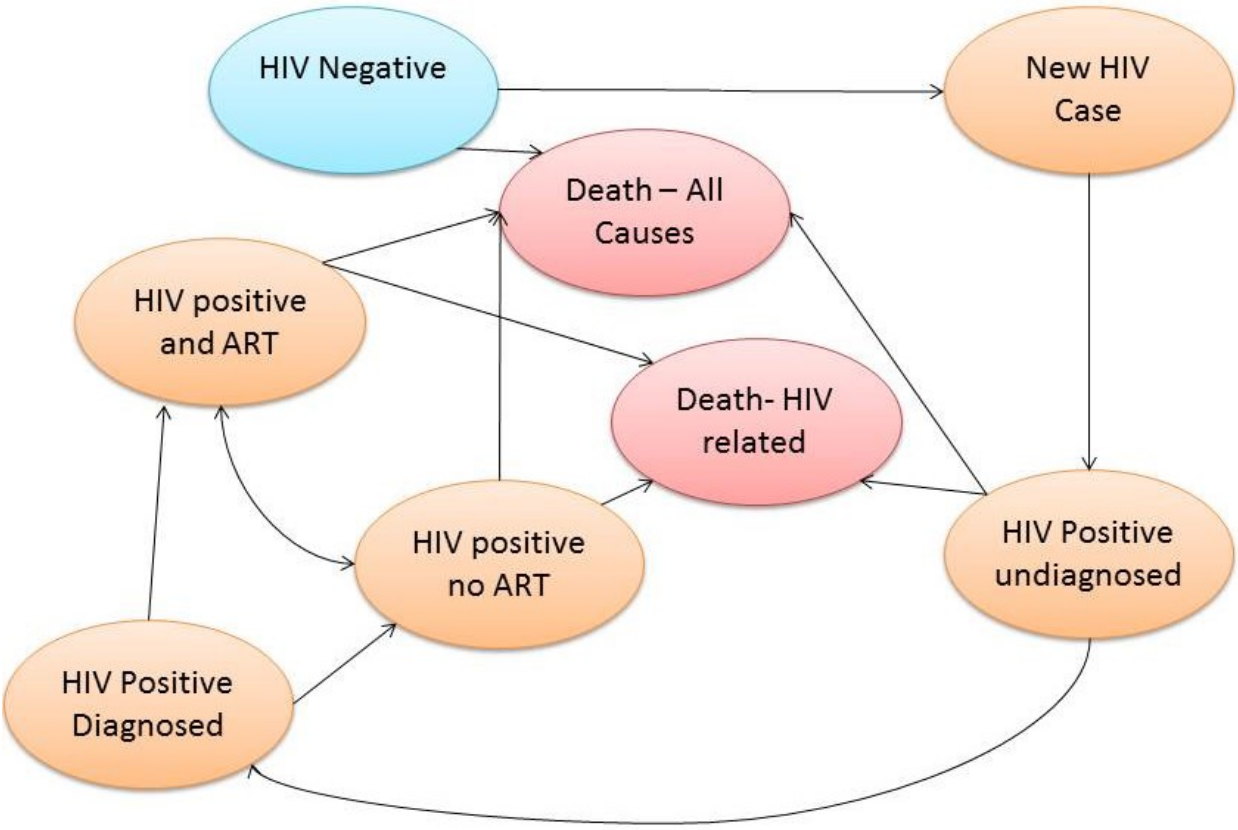


During each cycle patients can remain in their current health state, or move to a new one based on the following rules:

- Only sexually active patients can move from HIV negative to new HIV positive.

New HIV positive patients move directly into "HIV undiagnosed" in the next cycle. Patients can only move from "HIV undiagnosed" to "HIV diagnosed" if: (i) they are in the SSK arm and accept and return a SSK test; (ii) through current screening practices in both arms.

Figure 8: Model structure for health states



- Once a patient is "HIV diagnosed" they have a probability of being either on anti-retroviral therapy (ART) or not on ART. In both regimes patients that are diagnosed as HIV positive receive ART, in line with HIV best practice guidelines where all patients start ART following diagnosis regardless of CD4 count(88)
- Diagnosed and undiagnosed HIV patients have a 3-month probability per cycle of either HIV related causes or death from other causes. HIV negative patients have a risk of death from other causes only. This was taken from Office of National Statistics (ONS) life tables.(84)
- All patients continue to cycle through the model until they reach an absorbing state of dead.

In the primary analysis, the SSK screening tool was only offered at one time point (baseline). A secondary analysis evaluated offering SSK screening tools at multiple time points (annually).

10.1.3 Effectiveness of screening tools

Our model assessed two HIV screening tools: (i) SSKs and current practice and (ii) current practice only.

The effectiveness of screening tools is dependent on

- The percentage of HIV negative and undiagnosed HIV patients that are given an HIV SSK (acceptance rate).
- The percentage of patients given a SSK that return the SSK (return rate).
- The percentage of returned tests that provide a complete result.
- The percentage of patients with undiagnosed HIV that are diagnosed as HIV positive after using the screening tool (dependent on the sensitivity of the screening tool used)

The SSK screening tool employed in this study, was a blood test sampling kit, with a sensitivity and specificity of 0.999 (95% confidence interval (CI), 0.999 to 1) and 0.992 (95% CI, 0.982 to 0.998) respectively. The percentage of patients that are given a SSK and return the SSK are based on data from the HAUS trial. A range of values of acceptance and return rates were tested within sensitivity tests of the model.

HIV screening tools in current practice settings such as sexual health clinics, GP clinics and antenatal services are typically blood tests. The sensitivity and specificity of current practice screening tools was assumed to be the same as SSKs. The probability of testing was taken from the National Survey of Sexual Attitudes and Lifestyles survey 3 (NATSAL 3) where the 5 year rate of HIV testing in black African men and women was 43.9% (95%CI, 30.3 to 58.6%) and 46.1% (95% CI, 35.6 to 57.0%) respectively. The probability of having a test in the past 5 years was based on HAUS trial data in a sensitivity test.

All individuals in the model who are diagnosed using a SSK receive confirmatory testing in current practice settings. In addition, all those that are not diagnosed as HIV positive and are sexually active could have additional testing in current practice settings as per current practice testing rates.

10.1.4 Transition probabilities

In our model, events were assumed to have occurred when the patient specific probability of an event was greater than a random number generated in Excel. For example, if an individual who was HIV negative had a probability of HIV infection in a cycle of 0.4% and the random number generated was 0.001 (0.1%), the individual would move to the "new HIV" state. If, however, the random number generated was 0.553 (55.3%), the patient would stay in the HIV negative health state. Events for patients were carried over cycles and hence the model has memory of past health states for each patient.

The probability of being infected with HIV was determined by four factors;

i. The transmission rate of HIV to HIV negative patients for HIV positive patients on ART(89)

ii. The transmission rate of HIV to HIV negative patients for HIV positive patients not on ART(89)

iii. The prevalence of HIV in the model population during that cycle.

iv. The probability that HIV negative patients are sexually active. This was taken from the African Health Survey 2013-14 that reported 84.2% of men and 73% of women had a sexual partner in the previous year(26). A sensitivity analysis was conducted using the percentage sexually active reported in the HAUS study.

A weighted average risk of HIV infection was applied to all those that were HIV negative and sexually active in the model.

Those that were HIV positive progressed through the stages of HIV (Stage I, Stage II, Stage III, Stage IV: death from HIV). At baseline, individuals with HIV were proportioned to stage of disease. The proportion of individuals in early and late stage of disease was equal to the proportions of patients in each group reported by Public Health England in 2015(90) (see Table 14). Individuals who were free of HIV at baseline and subsequently infected with HIV during the model, entered stage I of disease upon infection. Progression through the stages of HIV was determined by changes in CD4 count, where Stage I, II, and III was given by a CD4 count of >499, 350 to 499, and <350 respectively. Baseline CD4 count for those newly infected and change in CD4 count was calculated using the algorithms reported in an economic model of lifetime outcomes and costs of HIV in men-who-have-sex-with-men in

the UK.(85) Those that were HIV positive and receiving ART and compliant, change viral load and CD4 count in line with the algorithm set out in Nakawaga et al. (2015) based on treatment strategy and adherence.(85)

The probability of dying from HIV was applied to all HIV positive patients. Risk was stratified by sex and CD4 count, where risk increased 10-fold for those in late stages of HIV (CD4 count <350). One-year probabilities were converted to three month rates and then probabilities.(91)

The probability of dying from non-HIV related causes was calculated from the ONS 2015 data,(84) where death from non-HIV causes was equal to total mortality minus HIV related mortality (ICD-10 codes B20 to B24 as per ONS guidelines). As mortality is higher in those with HIV, the probability of death from non-HIV related causes was increased by 50%.(85) The risk of death from non-HIV related causes was age and sex specific. We conducted a sensitivity analysis increasing the probability of death by 100% for non-HIV related causes.

10.1.5 Effectiveness of ART

The effectiveness of ART was applied to the transmission probability of HIV, where those on ART were at lower risk of transmitting HIV than those who were not. All those newly diagnosed with HIV were assumed to be prescribed ART in line with current guidelines. Adherence with ART was based on the rate of adherence from PHE HIV statistics (90) (see Table 14).

10.1.6 Costs

Costs included in our model were the cost of the HIV screening tool and the cost of HIV. The cost of the HIV screening tool included the cost of SSK's and/or current practice screening tools, the cost of confirmatory testing, any additional testing, and pre- and post-test counselling.

Table 14: Data inputs for cost-effectiveness model

Variable	Value	Reference
Effectiveness of SSK		
Specificity	99.24%	(92)
Sensitivity	100%	(92)
Effectiveness of confirmatory/other testing of HIV		
Rate of HIV testing in previous 5 years		
Male	44%	(93)

Variable	Value	Reference
Female	46%	(93)
Specificity	99.24%	(92)
Sensitivity	100%	(92)
1 year probability of Death from HIV causes		
Early stage (CD4 count >350[1])		
Male	0.005	ONS 2015
Female	0.003	ONS 2015
Late stage (CD4 count <350)		
Male	0.05	ONS 2015
Female	0.03	ONS 2015
Death from non-HIV related causes		
On ART	0.03	(89)
Not on ART	0.022	(89)
Compliance with ART	0.85	(90)
Proportion of population sexually active		
Male	0.842	(26)
Female	0.73	(26)
Viral load[2] for people newly infected with HIV	4	(85)
Viral load change for all those with HIV and not on ART		
0 - <3	0.11	(85)
3 - <3.5	0.13	(85)
3.5 - <4	0.14	(85)
4 - <4.5	0.15	(85)
4.5 - <5	0.17	(85)
5 to <5.5	0.18	(85)
5.5 - <6	0.20	(85)
6 - <6.5 (max)	0.21	(85)
CD4 count change for all those with HIV and not on ART		
0 - <3	-0	(85)
3 - <3.5	-0.016	(85)
3.5 - <4	-0.04	(85)
4 - <4.5	-0.12	(85)
4.5 - <5	-0.04	(85)
5to <5.5	-0.08	(85)
5.5 - <6	-1.6	(85)

Variable	Value	Reference
6 - <6.5 (max)	-2	(85)
Costs		
Current practice/confirmatory testing		
Of those tested, percentage tested in each setting		(38)
GP Clinic	10%	
Sexualhealth clinics	61%	(38)
Antenatal clinics	29%	
Cost per test for each setting		
GP Clinic	£8.67	
Sexual health clinics	£9.12	
Antenatal clinics	£8.90	
Cost Behaviour counselling/hour	£41.06	
HIV events on ART		
CD4 > 200	£11,960	(94)
CD4 ≤ 200	£7,307	(94)
HIV events not on ART		
CD4 > 200	£3,145	(94)
CD4 ≤ 200	£7,307	(94)
Undiagnosed HIV	£3,145	(94)
Utility scores for QALYs		
Healthy	0.82	
HIV positive utility decrements		
On ART, VL ≤ 50, CD4 ≤ 200	-0.13	(95)
On ART, VL ≤ 50, CD4 > 200	-0.11	(95)
On ART, VL > 50, CD4 ≤ 200	-0.15	(95)
On ART, VL > 50, CD4 > 200	-0.11	(95)
Stopped ART, CD4 ≤ 200	-0.18	(95)
Stopped ART, CD > 200	-0.13	(95)
Never started ART, CD4 ≤ 200	-0.17	(95)
Never started ART, CD > 200	-0.04	(95)

[1] *CD4 count is in cells/mm^3*

[2] *Viral load is presented on the log_{10} scale*

The cost of the SSK was calculated from the HAUS study and includes the cost of the test kit itself as well as the time to deliver the kit. The cost of the current practice screening tool was calculated as £9.33.(38) In addition, pre- and post-test counselling was valued at £46.45 per test.

The cost of HIV was extracted from an economic analysis of early access to HIV services.(94) The cost of HIV included the cost of hospital inpatient, outpatient and day ward services, determined by the mean number of days spent in each service. The cost of HIV was stratified by CD4 count and presence of ART. For undiagnosed HIV, the cost was estimated to be equivalent to individuals with early stage HIV (CD4 count >200) and not on ART as these individuals are likely to have more illnesses/visits to the doctor than HIV negative individuals.

All costs were inflated to 2015 values using relevant national price index conversion rates (96).

10.1.7 Outcomes

The outcomes assessed in this analysis included societal and individual level outcomes. Societal outcomes included the number of HIV cases prevented, whilst individual level outcomes included the impact of HIV on mortality and morbidity.

The mortality and morbidity impact was evaluated using QALYs as recommended by NICE in the UK (97). QALYs are calculated by multiplying a preference based value of a health state (a utility score) by the amount of time spent in that health state, where 1 represents perfect health and 0 represents death. All individuals who were HIV negative were assumed to be in a 'healthy' state with a utility score of 0.824. If an individual had HIV, a utility decrement was applied (95). This was applied at the time of infection as well as every cycle thereafter until the individual died. The utility values were taken from a cross-sectional study of health-related quality-of-life of people with HIV compared to the general population. Utility decrements were dependent on viral load, CD4 count, and use of and adherence with ART. As individuals progressed through disease stages, and/or use of ART changed, the utility decrement applied was updated accordingly.

Cost-effectiveness was evaluated as the mean incremental cost per QALY gained of 8,000 patients over a life-time time horizon.(98) The incremental cost effectiveness ratio (ICER) for HAUS is defined as the total discounted cost of the intervention (SSKs) less the total discounted cost of current practice, divided by the total discounted QALYs of the intervention less the total discounted QALYs of current practice. An ICER of £30,000 per QALY is generally reported as the maximum value that NICE is likely to approve the implementation of a new technology. Claxton et al. (2015) though have calculated that it currently costs £12,936 to generate an additional QALY in the English NHS.(99) As a result,

it has been argued that this value may represent a more appropriate cost-effectiveness threshold to use.

The random numbers in the model meant that each run of the model would result in a different result. As such, we took the average of each parameter in the ICER from 10 runs of the model. A Monte Carlo Error from the 10 runs of the model is reported to provide an estimation of the precision of 10 runs of the model.

All future benefits (QALYs) and costs were discounted at 3.5% per annum, converted to a three month rate.(97)

10.1.8 Sensitivity analyses

We conducted a number of sensitivity analyses. The analysis was conducted in line with the Decision Support Unit guidance (100).

10.2 Results

The average age of the hypothetical population in the model was 37 years old and 53% of the population were female. This compares with the HAUS population from the trial with an median age of 42.6 and 51.3% female. In the baseline population the prevalence of HIV positive was of 4.2% or a total of 335 HIV positive cases per 8,000 patients. Of the 335 HIV positive 48 patients (14%) are undiagnosed.

As reported in section 7.1 of the report, 125 out of 349 (35.8%) patients approached agreed to partake in the HAUS trial. Of those six were excluded from the trial as a result of problems with the consent process. For the purposes of this analysis the patients excluded for consent reasons are considered to have “accepted to use SSK” as the consent process is separate to accepting to take a SSK. Removing the six participants left 119 eligible participants remaining in the trial, 65 (54%) of whom returned the SSK. Of those 11 (16.7%) were incomplete and contacted for a retest. In the model we assume that 100% of the patients who have incomplete tests are contacted to retake the test.

Qualitative investigation of the research process suggested that of the 15-20 minute appointment that the nurses, community worker or health care assistant had with patients to conduct the study, the majority of time was spent on the research process (explaining the study, taking consent and administering baseline questionnaires) with only a few minutes dedicated to explaining the SSK and how to use it. As a result a conservative estimate of 5

minutes with the patient per kit was used. The cost of the highest paid professional, a practice nurse, to give the test to the patient and explain how to use it was estimated as £4 for the 35.8% of patients that agreed to use a SSK. The test itself cost £3.24 if not used and a returned kit cost £13.24 or £15 if including the cost of retest for incomplete tests.

In addition to the conservative estimate of time, and staff with a lower cost per minute dispensing the kit, there was discussion as well of the possibility of patients being able to collect the kit from reception or pharmacies, further reducing the cost of dispensing SSK. This was tested as part of a sensitivity analysis.

The results of 10 runs of the model for SSK versus current practice are reported in Table 15. There were 8 new cases detected using SSK, with a cost per case detected of £6,431. SSK dominated current practice resulting in an additional 24 QALYs and a cost saving of £17,208 over 8,000 patients and a maximum of 75 years or until they died. The Monte Carlo error for the difference in QALYs was 735. As a result the 95% confidence interval for the difference in QALYs between SSK and current practice is -432 to 480 QALYs. The Monte Carlo error for costs was 515,078, with a 95% confidence interval for a difference in costs of -£336,451 to £302.035.

Table 15: Number of HIV cases, costs, QALYs, and ICERs per 8,000 black Africans in the UK for SSK compared to current practice averaged across 10 runs of the model.

Outcomes	**SSK**	**Current Practice**	**Difference**
Total tested using SSK	1502	0	1502
Total HIV positive diagnosed using SSK	8	0	8
Diagnosed other services	57	60	3
Total new HIV infections	37	39	2
Costs SSK test	£48,883	0	£48,883
Cost of other screening	£1,530,123	£1,528,834	£1,289
Cost of HIV treatment	£39,425,225	£39,648,006	-£222,781
Total Cost (undiscounted)	£41,004,231	£41,179,840	-£172,609
Total Cost (discounted)	£21,319,574	£21,336,782	-£17,208
Total QALYs (undiscounted)	1,	1,107,969	274
Total QALYs (discounted)	509,704	509,680	24
Incremental cost-effectiveness ratio (discounted)			Dominant

To test the robustness of some of the values used in the model values from completion of the questionnaires completed as part of HAUS were used in the model instead. In HAUS 50% of patients report having been tested for HIV in the past 5 years. This is similar to the value reported in the National Survey of Sexual Attitudes & Lifestyles 3 who report 45% of black Africans have been tested for HIV in the past year. In HAUS 81% of patients reported being sexually active. This is compared to 79% as reported in African Health Survey 2013-2014 (26). Changing the values in the model to those reported in HAUS does not result in significant changes to the results.

The results of the sensitivity tests are reported in Table 16. None of the changes made to the model had an impact on the results

Table 16: Sensitivity analyses of SSK compared to current practice per 8,000 black Africans in the UK for each HIV screening tool averaged across 10 runs of the model

Results	**Updated for results of trial**	**65% accept SSK test**	**75% return the test**	**5% of tests returned incomplete**	**Assume death for HIV related causes is twice as high for <200 CD4 count**	**SSK dispensed by reception**	**SSK dispensed by GP at £50 per patient**
SSK							
Total HIV positive diagnosed using SSK	8	12.4	10	8	8	8	8
Cost SSK test	£49,375	£87,304	£60,041	£46,739	£49,133	£42,875	£246,217
SSK – total number of new infections	35	34	36	34	33	35	36
SSK – total cost inc. HIV treatment (discounted)	£21,824075	£20,706,392	£22,082,340	£21,736,367	£19,991,397	£21,313,567	£21,809,262
SSK – QALYs discounted	509,956	509,853	509,899	509,877	509,633	509,956	509,816
Current Practice							
Current – total number of new infections	38	39	39	39	35	39	39
Current – total cost inc. HIV treatment (discounted)	£21,360,691	£21,336,782	£21,336,782	£21,336,782	£20,562,684	£21,336,782	£21,336,782
Current – QALYs discounted	509,645	509,680	509,680	509,680	509,531	509,680	509,680
ICER	£1,489	Dominant	£3,407	Dominant	Dominant	Dominant	£3,468

10.3 Summary

This preliminary model of a SSK test dispensed to black Africans in the GP or in community settings suggests that SSK are a cost-effective way to identify new cases of HIV with SSK dominating current practice, resulting in more QALYs for less cost. Using the Monte Carlo error to test uncertainty there does not appear to be significant differences in QALYs or costs. The results would benefit from additional runs of the model. This was not possible within the limited timelines of the project and computational power to run the model.

Chapter 11: **Discussion**

The overarching principles in selection of our intervention was that it had to expand on current HIV testing opportunities for black Africans, that it had be acceptable to intervention users and providers, and that it had to be sustainable in the current economic climate. It also had to address the known barriers to HIV testing for these communities. This chapter is comprised of a discussion focused on how the aims and objectives of this study were addressed.

11.1 Discussion of Stage 1

11.1.1 Barriers and facilitators to use of SSK

The first objective of Stage 1 was to clarify barriers and facilitators to provision, access and use of HIV SSK by black Africans, in community settings. The policy review revealed a facilitative environment for STK and SSK for HIV, with use of these kits viewed as an innovative method of increasing uptake. Guidelines have shown HIV testing in medical and community settings as both feasible and acceptable, with SSKs suggested as a route to broaden testing options. Evidence on the use and effectiveness of SSKs however, was scant-especially for black African groups.

The data yielded through interviews and FGDs echoed many of these reported barriers and facilitators to SSK use. The privacy and convenience afforded by SSKs were viewed as major strengths, as they negated the need to attend a sexual health clinic and potential stigma. Service providers and non-specialists alike felt that SSKs increased individual autonomy and testing opportunities. However, both FGD participants and interviewees voiced concern over the amount of blood required to provide a TINY vial sample. Service providers in particular voiced doubts over the ability of members of the public to produce a sufficient sample. Participants also pointed out that fear of needles and blood, and the complexity of using the kit could discourage some from using the SSKs. Another concern was the potential isolation that could be experienced by users of the SSKs.

Many participants mentioned the stigmatising association of HIV with ‘sexual immorality’ and promiscuity (an association that many FGD participants and interviewees described as being heightened within black African communities) as a barrier to testing among black Africans. SSKs however helped mitigate the risk of others discovering one was testing for

HIV due to the privacy afforded, however, as described above, what was regarded as the 'benefit' of privacy by some was regarded by others as carrying a risk of increased isolation for those receiving news of a reactive result

The difference between individual and community-level risk perception was also viewed as a barrier, with participants stating that those targeted may not appreciate the epidemiological data used as justification to target black Africans exclusively for the intervention. Participants recognised that due to the low risk perception and stigma an opportunistic provider-led offer of a SSK was more likely to increase HIV testing than a user-led model. The participants warned that offers of SSKs exclusively to black Africans may be perceived as racist and as fuelling anti-immigrant rhetoric.

11.1.2 Determine appropriate SSK-based intervention models for different settings

As participants in FGDs and interviewees recognised that black Africans were already accessing primary care and CBOs, the addition of SSK into their service menus was viewed as a convenient extension that would immediately increase testing opportunities. There was almost universal approval of CBOs working with African communities and HIV prevention to be involved in distribution, as they were seen as possessing the expertise required to target black Africans in a sensitive manner. CBOs however would not be extending their outreach activities and HIV testing was already widely integrated into their services, thus there was some concern from the research team that this would not significantly increase HIV testing opportunities for the wider African community.

Participants advised that targeted offers needed to be couched in clear terms, using epidemiological evidence, and to avoid the perception that offers were being made because of racist or xenophobic sentiment. It was deemed of utmost importance that distributors were regarded as trustworthy, knowledgeable, and non-judgemental in order to foster a realistic degree of reflection about HIV risk among those to whom they encouraged SSK use, all of which staff in General Practice settings and outreach teams in CBOs were felt to possess. Ultimately, there was a universal view among participants that SSK distributors needed to actively resist HIV stigma rather than potentially reinforce it.

The formative work revealed concerns about the limited amount of time available to providers to initiate discussions and gain informed consent, especially in GP surgeries. Embedding the intervention into routine practice was considered a critical component by the

research team if it were to be sustainable. Therefore, specific appointments for intervention delivery should not be part of the model.

Prior to intervention development it was apparent that ideally a saliva based or more user friendly SSK would be preferable to the TINY vial. Unfortunately despite this knowledge as described in section 5.4 we were unable to proceed with an alternative option as we could not identify an service provider that was willing to assume the liability for using a product off license in the context of a research project. Currently the TINY vial is the only CE approved HIV SSK available in the UK. An alternative option would have been be to formally test a salivary SSK against the TINY vial however this would have represented a significant shift in the original research question and design which was not considered an appropriate option for HAUS.

The final intervention model for both settings utilised a theoretically informed scripted conversation in conjunction with distribution of a SSK during a routine encounter. The script was to assist providers in overcoming anxieties in targeting black African communities (addressing the issue of capability) while also motivating users and increasing opportunities for HIV testing; it also provided consistency of message to enable intervention fidelity. The information supplied with the kit (including weblink to video demonstration) and via the provider was designed to further increase capability and motivation of service users. The study team were not able to deliver the intervention with what they believed would be the optimum SSK due to governance and regulation restrictions. A copy of the intervention and training manuals are available on request.

The model

11.1.3 Determine robust HIV result management pathways

The formative work highlighted a disconnect between accepted current practice of delivery of results by text message or phone call, and the relatively widespread concern that SSK users may be isolated and at risk of self-harm when receiving test results. Use of SSKs was perceived to reduce opportunities for HIV prevention messaging, with lack of recognition that there is no strong evidence that routine pre or post-test counselling subsequently affects behaviour for those testing negative. Participants also warned that a profusion of HIV testing interventions could lead to a disjointed and confusing service landscape.

The clinical pathways within HAUS were all subject to clinical governance regulations and designed to ensure best practice would be delivered. The research team felt it important that an organisation with experience and expertise in managing HIV results, and ideally SSKs, were involved to ensure appropriate and sensitive delivery of test results, including the offering of retest to those with indeterminate results and confirmatory tests to those with reactive results; and linking those who test HIV positive to care.

The process of establishing these clinical pathways highlighted uncertainty and confusion over where duty of care and liability should lie for a SSK intervention delivered in community settings by non NHS Trust employees.

Provision of results as quickly as possible to service users, whether positive or negative, is emphasised throughout clinical standards and the recommended time-period for receipt of results is ideally within 48 hours and no more than 14 working days. The process evaluation demonstrated that while this was achieved for everyone testing negative for those with insufficient samples there was occasionally delay while information from recruiting sites was awaited. The FGDs had highlighted significant concerns regarding confidentiality and privacy among potential users, this had led us to request only initials rather than a name with the returning sample which in hindsight was an error as it meant we could not make contact with participants until the additional information was received from the recruitment site. All negative results were delivered by SMS via an automated system and this worked well. No reactive results were received so the processes for confirmatory testing and linkage to care were not tested. There was also concern that people may not test if their General Practitioner was automatically informed of the result. As a consequence we obtained specific consent to notify GPs of results; 98.9% of participants recruited through primary care consented to this, suggesting this concern was unfounded.

11.2 Discussion of Stage 2

In November 2015, PHE launched a national HIV self-sampling service. This initiative enabled people at higher-risk of HIV across the country to order an HIV SSK online. Self-sampling is further promoted by the London HIV Prevention Programme which is aimed at black African communities and MSM. Through its 'Do it London' website (https://doitlondon.org/), users can click on a link to directly order a SSK. Similarly sexual health services are increasingly trying to reduce costs by encouraging asymptomatic individuals to utilise self-sampling technologies usually through web portals. To comply with

BHIVA guidance (use only approved SSKs and that testing should be fourth generation) most of these initiatives use the TINY vial SSK (88). Despite this relatively rapid expansion of sexual health and HIV testing through self-sampling, there remains little evidence to support its effectiveness or cost-effectiveness for communities beyond MSM.

The aim of Stage 2 was to conduct an evaluation of selected SSK distribution models to assess feasibility of a future Phase III evaluation. The specific objectives are discussed in the sections below.

11.2.1 Establish feasibility and acceptability of interventions for providers and users

The primary objective of Stage 2 was to determine the feasibility and acceptability of a provider-initiated, HIV SSK intervention targeted at black African people in two settings: GP surgeries and CBOs. Our findings indicate that although many aspects of the intervention were acceptable, scale-up of the intervention to a Phase III evaluation is not feasible. All sites reported that the time it took to offer the kit and complete the research-relevant forms (consent, baseline questionnaire, and enrolment log) was a major impediment to the feasibility and acceptability of the trial. With hindsight a pilot of Stage 2 in a GP surgery and a CBO might have identified some of these issues, however project timelines and resources did not enable this. Consent at an individual level was sought to enable collection of baseline data, tracking of data and follow up interviews. Consent at a group (GP or CBO) level and limiting data collection to service evaluation may have proved more feasible and better reflected how the intervention would be implemented in practice.

Although interviewed participants reported that the targeting of black Africans was acceptable, this is in contrast to the large proportion of respondents who indicated on the acceptability questionnaire that it was not acceptable to offer an HIV test based on ethnicity. Many distributors, especially at GP surgeries, also continued to express unease at targeting black African patients only, despite the provision of training and a script designed to specifically overcome these barriers. This unease arose from concerns about exacerbating HIV-related stigma and xenophobia.

Our findings highlighted that community providers as well as many black Africans would prefer to use SSKs that involve collection of an oral specimen as opposed to a blood specimen. However, currently in the UK there are no CE marked HIV testing assays that can be used on saliva. Not being able to proceed with a saliva based option directly impacted on the study feasibility. It meant took the SSK took longer to distribute as there was more to

explain and motivate; it was no longer possible to demonstrate kit use in the field; and the more complicated procedure to collect the sample is likely to have influenced the return rate and is likely responsible for the extremely high rate (16.9%) of insufficient samples. This figure is remarkably similar to that reported by the national HIV self-sampling service among their black African users to date (personal communication). This suggests that an alternative to the TINY vial is required if HIV SSK are to be an effective means to increase HIV testing in black African communities.

11.2.2 Evaluate the effectiveness of self-sampling for HIV in increasing the uptake of HIV testing by black African people

Due to the failure of the study to recruit adequate numbers we are unable to evaluate the effectiveness of SSKs in increasing HIV testing in black African people.

The fact that 12 of the 65 participants who returned a kit reported never previously testing and that most kit returners tested because of the opportunistic offer of the test suggests that if distribution of HIV SSK in these settings were rolled out at scale as part of the range of HIV testing options there would be the potential for increasing HIV testing. However, at a structural level these services do not have time to 'bolt-on' an SSK intervention (or indeed anything else) unless there is a strong benefit or incentive to do so.

11.2.3 Determine the cost effectiveness of distributing the SSKs among black African people over other screening methods

The model of a SSK dispensed to black Africans in GP surgeries or in CBOs presented in Chapter 10 suggests that SSKs may be a cost-effective way to identify new cases of HIV as SSK resulted in more QALYs for less cost.

We showed it was feasible to collect data as part of the HAUS trial to update values in the model. There were ~~some~~ challenges in collecting data on the time taken to explain SSKs to ~~patients~~participants. This was due to concerns by clinical staff involved in the study regarding the amount of paperwork involved. Although there was limited data available on the time taken this proved inconsequential to the model given that SSKs could cost as much as £50 per test and still be cost-effective.

The estimation of the uptake rates of SSK taken from HAUS and used in the model may not reflect real life. Uptake rate for SSK might be higher as patients may have been put off by the research process. It is also possible that use of an alternative SSK that is easier to use may

increase return rates and reduce the number of incomplete results. It is likely that these improvements would improve the cost-effectiveness of the SSK.

Further work required includes running the model more times and probabilistic sensitivity analysis where values in the model are varied within given confidence intervals and distributions to provide an estimate of the probability that SSK is cost-effective compared to current practice. Extra value of perfect information (EVPI) would provide a monetary estimate of the value of additional research to provide more certainty of the result. The computational load required to run this analysis though is significant, potentially taking days to run and was not possible as part of this study.

11.2.4 Monitor ability to trace participants with reactive results, confirmatory testing and linkage into specialist care.

No reactive results were obtained so we were unable to assess the ability to trace participants with reactive results through the process of confirmatory testing and linkage to care.

11.2.5 Determine the cost per person kit distributed and cost per HIV diagnosis per setting.

Data on cost per kit distributed was collected as part of the trial. This is dependent though on who distributes the SSK. If a conservative upper estimate was made of a practice nurse taking five minutes to explain the kit, the cost of staff time is £4. The economic model did not determine cost per setting as originally planned. It is unlikely that Community workers would be paid more than a Practice Nurse thus the cost-effectiveness could expect to be greater in CBO settings unless time taken to explain the kit differed by setting. A limitation of the model is that the time to specifically target the individual and explain the kit could not be determined as within the study the research components were so enmeshed with this process.

The cost of the SSK itself was £3.24 if not used and a returned kit cost £15 (as this included the cost of retest for incomplete tests). In a lifetime patient level model of 8,000 black Africans in the UK, the cost per case detected of HIV using SSK was £6,000. However, SSK resulted in more QALYs for a total lower cost once the cost of treating HIV was included, dominating current practice. The Monte Carlo confidence interval of 10 runs of the model suggested a significant increase in QALYs, but not cost.

11.2.6 Assess the feasibility of collecting data for a lifetime cost-effectiveness model alongside the potential Phase III evaluation

Limited data was able to be collected to inform the cost-effectiveness model due to a need to reduce the time taken for patients to complete questionnaires as part of baseline assessment. The values that were collected as part of questionnaire that could inform the model (percentage of patients sexually active and proportion of people tested in the past 5 years) tallied with the best available data in the literature suggesting that data from the literature is likely to be adequate and a better source of information. We were able to obtain better estimates of the proportion of people that agreed to use SSK and that returned the SSK to inform the model, although real life scenarios rather than trials are likely to provide more realistic data.

11.2.7 Assess feasibility, and if appropriate, the optimal trial design for future Phase 3 evaluation.

Based on the findings of the HAUS study, in particular the challenges with recruitment in both GP and via CBOs, a future Phase III evaluation was not considered feasible by the study team.

11.3 Patient and public involvement

The HAUS project has been about listening to black African people and community based service providers with the aim of adapting HIV testing practice to better meet their needs. We found the additional perspectives of community representation to be invaluable in the design and implementation of our research. The project has also benefitted from the inclusion of participants who were recruited via community contacts as we believe this improved our focus group diversity.

Our findings will be fed back to participating sites over the coming months and a summary of the findings will be published on www.haus.org.uk, our study website.

11.4 Conclusions

Our findings indicate that although many aspects of the intervention were acceptable, scale up of the intervention to a Phase III trial is not feasible. Alternative user-friendly SSKs that meet user and provider preferences and UK regulatory requirements are needed. In particular blood-based kits not requiring users ‘to milk’ blood and diagnostic assays that meet CE criteria for testing saliva are required. The preliminary economic model suggests that for the rates of acceptance and return of the test seen in the trial, SSK is a cost-effective way to

identify new cases of HIV but further work is needed to validate this result. Importantly the study also found busy services do not have time to 'bolt-on' a SSK intervention or research generally, unless there is a strong incentive to do so.

To maximize the individual and public health benefits of HIV testing interventions we must consider the technological, psychosocial and socio-cultural contexts of HIV testing. The increasing diversification of the tests available demand systematic consideration of the right test for particular circumstances and particular sub-populations and recognize that over time the same person may well require different testing methods and settings.

There is a danger that by not grasping the complexity of HIV testing that we only reach the low hanging fruit; designing, evaluating and implementing testing interventions that work for limited groups of people but do not impact on the actual drivers of HIV transmission such as HIV related stigma. This is particularly important when considering how to implement NICE HIV testing guidance which recommends expansion of targeted testing in community settings for at-risk populations - including black African communities.(43, 101) Ethnic targeting remained problematic; despite couching the scripted intervention in epidemiological terms this was not always perceived as neutral and was the least acceptable aspect of the intervention for service users.

Research studies comparing acceptability and return rates of different types of self-sampling methods can help better understand their impact on recruitment.

Challenges in setting up reliable pathways of care for research participants who accepted a SSK was reflected in the lack of willingness of the NHS Trusts to accept duty of care for these participants as they were accessing SSK at sites distinct to their own service provision sites. Yet to offer the benefit of having results managed by service providers experienced in HIV to research participants, or users of SSKs outside research, necessitates this arrangement. Given that existing national initiatives in the UK and non-NHS service providers are offering SSK for HIV testing, standardised protocols for setting up pathways of care should be developed and be made accessible to service providers as well as researchers conducting SSK research.

Changes in commissioning of sexual health services, as well as funding for HIV prevention initiatives in the UK, are already affecting research capacity. Our experience also demonstrates how the variation in funding models of the CRN and SPCRN has implications

for research studies that work across national borders. Researchers doing studies in different regions of the UK need to be aware of these differences and budget accordingly. Despite efforts to reduce time for obtaining REC and R&D approvals, continually changing systems breed confusion and affect study timelines and feasibility of assessing research questions substantially.

While our intervention was not suitable for scale-up to a Phase III evaluation due to process related factors this does not mean the intervention is not feasible in practice and we hope that our findings will prove useful for future service provision through evidence synthesis.

Future work

Sexual and public health services are increasingly utilizing self-sampling technologies however alternative user-friendly SSKs that meet user and provider preferences and UK regulatory requirements are needed, and additional research is required to understand effectiveness and cost-effectiveness for black African communities and the population as a whole

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Contribution of authors

All authors contributed to the design of the study and have approved the final report.

Dr Maureen Seguin (Research Associate) was responsible for project management and data collection for Stage II of the study. She led on the authorship of the report.

Dr Catherine Dodds (Assistant Professor of HIV and Sexual Health) was lead investigator of Stage I of the project. She also contributed to all qualitative components throughout the study including the process evaluation. She led on engagement with community based organisations and led development of the study website and video.

Dr Esther Mugweni (Senior Research Associate) was responsible for project management and data collection for Stage I of the study. She led on developing the intervention manual.

Dr Lisa McDaid (Programme Leader - Social Relationships and Health Improvement) led on the systematic review and project oversight in Glasgow. She contributed to analysis of the focus group discussions and intervention development.

Dr Paul Flowers (Professor of Sexual Health Psychology) led on the intervention development and contributed expert knowledge on the theory of behaviour change in relation to health, and its application to intervention development.

Dr Sonali Wayal (Research Associate) advised on the content of questionnaires and topic guides, the systematic review process and assisted with the focus group discussions and analysis of qualitative work. She led on sections in the report to do with challenges to implementation.

Dr Ella Zomer (Health economist) contributed to the development of the cost effectiveness model and led on this section of the report.

Mr Peter Weatherburn (Director Sigma Research) led on the process evaluation and contributed to analysis of qualitative data from Stage I. He also helped develop the study website.

Ms Ibidun Fakoya (Research Associate) contributed to the systematic review protocol, screening of abstracts, she advised on the content of questionnaires and topic guides, the intervention development and provided expertise on engaging black African communities.

Mr Thomas Hartney (PhD student) helped with data extraction and quality appraisal for the systematic review, he led on writing up this section for the report.

Dr Lorraine McDonagh (Research Associate) undertook participant interviews and assisted with the coding, analysis and writing up of this section.

Dr Rachael Hunter (Health economist) was lead investigator on the cost effectiveness and economic components of the study.

Dr Ingrid Young (Chancellor Fellow) provided project oversight in Glasgow for Stage I, she undertook focus group discussions and contributed to their analysis and writing up.

Ms Shabana Khan (Senior Data Manager) helped create the study database and study instruments. She contributed expert knowledge on trial processes

Prof Nick Fremantle (Senior Statistician) contributed expert statistical knowledge and advice. He conducted the analysis of the quantitative data in Stage 2.

Mr Jabulani Chwaula (Associate Director of Programmes, BHA) provided patient and public involvement throughout the project, he advised on the content of questionnaires and topic guides, the intervention script, and plain English summary. He also provided expertise on working and engaging with Community Based Organisations.

Ms Memory Sachikonye (Co-ordinator, UK-CAB) was the lead for patient and public involvement. She advised on the content of questionnaires and topic guides, the intervention script, plain English summary and contributed to production of the intervention video.

Prof Jane Anderson (Consultant physician, Clinical Director HIV) provided expertise in engaging with service providers and black African communities on HIV. She also contributed expert knowledge on epidemiology of HIV and public health interventions.

Dr Surinder Singh (Senior lecturer in General Practice) advised on the content of questionnaires and topic guides, and the intervention script. He also provided expertise on working and engaging with General Practice.

Dr Eleni Nastouli (Consultant Virologist) provided duty of care for all participants in Stage 2, oversaw all clinical governance aspects and provided expert advice on HIV testing and diagnosis.

Dr Greta Rait (Reader in Primary Care/GP and Trialist) contributed expertise in design, implementation and evaluation of complex interventions. She advised on the content of questionnaires and topic guides, and the intervention manual. She also provided expertise on working and engaging with General Practice.

Dr Fiona Burns (Reader & Honorary Consultant Physician, HIV) was principal investigator with overall responsibility for the study and was lead investigator on Stage 2. She advised on all elements of data collection and analysis and is the corresponding author for the report.

Data sharing

Researchers who are interested in accessing the HAUS data should contact the corresponding author with a description of their proposal.

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Appendix A: Topic Guide for Phase 1 Non-Specialist FGD

Date: **Facilitators' Initials:** **Location:**

Materials needed:

- Payment / and payment record sheet
- Sign in sheet
- Images
- Participant info sheets in hard copy
- Light refreshments
- Pens
- 2 digital recorders (and back up batteries)
- Note paper for observations
- Stickers for name tags
- Consent forms printed
- ****NEW – Participant Number Cards***

Introduction (10 mins)

- We are….. [names / institutions and research background BRIEFLY]
- The information sheets gave you a lot of detail about our study – so we will just give you a short background before we start.
- Many people with HIV in the UK do not know they are infected and are missing the chance to benefit from drug treatments that can prevent the development of AIDS, allowing people to live healthy lives.
- A lot of these undiagnosed people are from African backgrounds, preventing them from accessing beneficial and effective treatments to keep them, and their partners, well.
- Health services in the UK must increase the numbers of people of African background who are regularly taking HIV tests.
- One of the ideas is for people to take a blood sample themselves, either at home or another private place, then send this away to be tested. We think that this might make HIV testing more convenient and hope it will increase the numbers people who take a test.

- Today we would like to hear your views on this, to look at the test kits, to talk about whether you think that people might like to use them and to talk about how to give them the test kits, the sort of support people might want and how they might like to hear about the test results and be helped to access treatment and care.
- We are most interested in how people talk to each other about things and to find out where you all agree and disagree. We are happy to answer any factual questions at the end but are really interested in how the group discusses the topics. It is our job to try and make sure everyone take parts and sticks to the agenda. Nothing you say will be traced back to you, and everything discussed in this room is entirely confidential.
- We will switch on the digital recorders soon. That is because we can not write down everything you say as quickly as you say it. Only those working directly on this study will have access to those recordings, and when it is all written down we will completely remove any mention of names or other details that might possibly identify an individual.

Any Questions?

[All consent forms collected before starting…..]

Ice breakers (5 mins)

A. Before we talk about these things we'd like to ask you each to introduce yourselves to the group (first name only)

Recording starts

B. Now that the recorders are on, can you please go around the room and state your participant number (using card in front of them), and then just say one place you know of where you could get an HIV test if you wanted one, or where would you tell a friend to go if they wanted one?

As group feeds back, focus on the contrasting and similar responses and group them (largely) into the following categories (quickly):

Clinic:

- *Hospital or clinic based test – because you have asked for one*
- *Hospital or clinic based test – because you are unwell*
- *Routine unanonymised testing (ante-natal) **but not blood donation, nor all clinic blood samples*

Community:

- *Community organisation*

- *GP*

- *Draw out the different waiting times that people are aware of, as well as various sampling methods / requirements*

Introduction to SSK (25 min)

Introduce the SSK – using two **VIDEOS*

- Please speak instructions aloud for TINY vial video

- Give out sample TINY kits, ask participants to explore how they look / feel / operate

1. What do you think about these kits?

Prompts:

- *Issues related to self-sampling and collecting a small vial of blood*
- *Perceptions of accuracy / efficacy - any different than conventional blood test for HIV?*
- What would be the advantages / disadvantages compared to current ways of getting an HIV test?
- Who would struggle with these kits? Why?
- Who would use them?

2. What would you like a kit to look like?

Prompts:

- *Is there anything about the look and packaging that would make people more or less likely to take it and use it?*
- *branding*
- *setting*

Distribution: Acceptability/practicalities of community distribution of testing kits (20 min) CD

3. Where do you think these kits should be available?

***hand out labelled photos/or printed scenarios of different locations to initiate talk*

Ask about best place/worst place

- advantages/disadvantages
- Any others places you think might be good?
- Should people have a choice about where to go?

Why is this important?

Prompts:

What is most private?

Most Trustworthy?

Most professional?

4. Do you feel that in each of these places, someone needs to be there to actively give out the kits and answer questions?

   Prompts:

   GP

   Pharmacist (boots)

   Dentist

   Hairdresser

   University staff

   Faith leader

   Community outreach worker

5. Would it be better for a person to give out the kit or for people to be able to pick it up without talking to anyone?

6. For the next part of our study, we will actually have to ask people about taking part, and agreeing for us to follow up with them to find out what they thought about using the kit. For that purpose, what personal details other than a name and contact number do you think people would be happy to provide when they collect the kit?

   ○*identify any firm boundaries / no-go areas?*

Self-sample collection – preferred venue (5 min) CD

7. Once someone has the kit, where do you think that most people may want to actually collect their sample? Will that always be back at home?

   ***Use image cards to provoke discussion:*

   ○*Might there be issue with doing the sample at home?*

   ○*in a community venue?*

   ○*somewhere else?*

   ○Why?

Return of sample – preferred method CD

8. What do you think is the best way to get the sample back to the lab?

   Prompts:

   - *post the sample personally*
   - *return it to the venue where they got the kit?*
   - Why? – privacy and confidentiality

Communicating and confirming HIV test results (15 mins) EM

Explain what the possible results are:

- *What does it mean to get a negative result*
- *What does it mean to get a reactive result*
- *The risk and meaning of false positives*

9. What might be the best way to explain all of this to people considering the sampling kits, particularly the idea of false positives?

Currently many sexual health clinics will use HIV test results where the result is given instantly, in person. If they have to send the result to a lab, they may need to ask the person to return for another appointment to get their result, or they may agree that any negative results will be communicated by text, or a phone call, but all HIV positive results are given in person. There are home sampling schemes in operation now that give HIV negative results by text, and that call those whose test result is reactive. There will be a clinic in charge of each patient receiving news of a negative or a reactive result – just in case they need more information, a confirmation test, or further support.

10. What is the best way for people to be told about the result of their test?

    Prompts if needed:

    - *Text with actual results*
    - *Text saying the results are ready*
    - *Home visit*
    - *Phone*
    - *Secure web login*
    - *Posted letter*
    - *Other: What?*_____

11. What kind of language should be used to communicate test results?
12. If a person was receiving a negative result, saying they did not have HIV, do you feel that is all they should be told? Is there anything else you might expect them to get in terms of information /advice?
13. If a person was receiving a reactive result, indicating that they may have HIV, what sort of support should they receive?
    - Should this information be passed on the same way no matter what the result?
    - What kind of follow on information, support, advice should they receive?
    - Is that appropriate to do on the phone? Or is it best in person?

14. If someone has a positive test with the home sample kit they would need to have another test to confirm that they are HIV positive. How and where should that be done?

15. Do you feel that people who you know might be interested in using one of these kits? Why / Why not?

Marketing (5 mins) EM

Mock up packs have already been distributed to the group.

16. Should there be anything else included with the kit when people collect it?

    Prompts:

    - *Condoms?*
    - *Additional testing kits*
    - *HIV prevention / information?*
    - *Support information / contact details?*

Group Closure (5 mins) EM

17. If you had to say one thing about Home Sampling Kits what would you want to say?

Just before we close, is there anything you wanted to add that you did not get a chance to, or things you feel we should have discussed?

- Thanks for your time / honesty.
- Explain process for rest of Phase 1.
- Website / Twitter for ongoing updates about progress.
- Sort out payments / receipts etc.

<END>

Appendix B: Topic Guide for Phase 1 Service Provider FGDs and interviews

Date: Facilitators' Initials: Location:

Materials needed:

- Payment / and payment record sheet
- Sign in sheet
- Images
- Participant info sheets in hard copy
- Light refreshments
- Pens
- 2 digital recorders (and back up batteries)
- Note paper for observations
- Stickers for name tags
- Consent forms printed
- ****Participant Number Cards** NEW**

Introduce Researchers / institutions / HAUS Study (10 mins)

The aim of the HAUS Study, as you will have gathered perhaps already, is to develop the best means of distributing HIV home sampling kits in the community in a way that will increase the provision and uptake of HIV testing among black Africans using existing community and healthcare provision.

We plan to clarify what may help / hinder distribution of these kits, what might support black African people who don't know their HIV status to access them and use them, and to explore what might be the best settings for distribution. After this first consultation phase through these focus groups and a few interviews with key stakeholders, we will develop intervention manuals for next stage of the larger study (Stage II feasibility trial).

Any Questions?

[All consent forms collected before starting…..]

Names around the room (5 mins)

Please tell others your name / what work you do and where

Recording begins – recorders will now be switched on

Please state your participant number and the extent of your experience working with African service users in your place of work.

Background

Just for those of you who may not be experts in HIV in the UK we wanted to briefly review a few points:

- More than 100,000 people in the UK have HIV
- About half of this number are people of black African descent who are the single ethnic group in this country that are disproportionately affected by HIV
- About ¼ of ALL those who are infected are unaware of their infection, and late diagnosis is most acute among black African people (particularly men)
- HIV testing has traditionally been undertaken in GUM clinical settings. Increasingly, community based HIV prevention organisations have started to offer point of care HIV testing in a range of non-clinical settings (sometimes, but not always using GUM staff to undertake some element of the test).
- [TEXT FOR LONDON GROUPS] These community based tests were traditionally commissioned within National intervention plans (such as HIV Prevention England), or by local PCTs. Since the Health and Social Care Bill and the changes it has meant for public health, some of that point of care testing has been commissioned by Local Authorities who now have responsibility for HIV prevention in the community, however there has been a lot of variability in the way that HIV testing is now commissioned from place to place.

Black African service users and targeted work (5 mins)

a. What do you feel are the biggest challenges in terms of encouraging routine and regular HIV testing among black African people in the UK?

Self-testing / sampling technologies (5 mins)

b. Newer testing options include both home sampling and home testing kits (*need to describe the difference*)

- Have you heard of each of these before?
- Do you have any thoughts or questions that immediately come to mind before we look at the kits in greater detail?

******30 minute time check******

Introduction to SSK (35 min)

*Brief introduction to SSK using two VIDEOS **Please talk through instructions of TINY test***

and distribution / exploration of sample TINY kits so that participants see how they look / feel / operate

Acceptability/practicalities of community distribution of testing kits

[use image cards to support this discussion – can distribute a couple of sets among participants – will focus the discussion]

c. What are your initial thoughts about making these sorts of kits available in:

- Community outreach in local businesses and locales
- Pharmacy *[focus here on any pharmacists in the group]*
- What sorts of self-testing kits for other conditions are pharmacies distributing?
- Is this a way of reaching those in greatest need?
- Are black African using pharmacies to support self-diagnosis and in what ways?
- GP offer at:
- initial registration (are new patient checks happening?)
- cervical testing
- sexual health check
- 40+ check
- GP targeting of high-risk group members at their next consultation
- Colleges/universities
- Dentists
    - ***Please vote on your top three from this selection. Any others to add? Prompts****:*
- *Acceptability*
- *Barriers / facilitators*

- *How will it be best to reach target audience in each setting without stigmatising?*

d. (**for direct contact service providers**) Do you think it would be a good idea to distribute these kits where you work?

And could you see a way to ensure that those taking the kits away were disproportionately (or exclusively black African?)

- *Why / why not?*
- *Are those reasons structural / political / practical / personal?*

What resources would you need to make this possible?

- *Verbally*
- *Printed materials*
- *Electronic material / QRS scanning code*

e. What are your thoughts on where people should collect their sample and how they should return it for testing?

Prompts:

- *Only for use away from community venue / user returns sample by post*
- *Collect kit in community venue / sample in venue / return sample to venue*
- *Community venue / sample is undertaken elsewhere / return sample to venue*
  - *What are the pros and cons of these options?*
  - *What is most / least practical for those working in such settings?*

****APPROX ONE HOUR TIME CHECK****

Clinical governance, communicating results and referrals (30 mins)

f. **(for direct service providers only)** What information would your service be prepared to collect at kit distribution - - eg. Record of numbers, characteristics of users etc.

- What would be the benefits of anonymity at the time of collection?
- What has been your experience with self-sampling for other STI testing?

g. **(for direct service providers only)** Would your service be prepared to manage reactive results?

- How would the service deliver result to clients?

h. **(for direct service providers only)** Do you have any thoughts about how HIV negative / non-reactive results should be managed? How would your service prefer negative results managed

    - Are there comparable models for results delivery from self-testing/sampling for other infectious diseases that we could use / adapt / avoid?

i. ***[OPTIONAL QUESTION, DEPENDING ON PARTICIPANTS, AS SOME COMMUNITY GROUPS MAY NOT FIND IT RELEVANT, WHEREAS THOSE WITH TESTING EXPERIENCE WILL…]***

What clinical governance / referral pathways do you see as being necessary for distribution of such kits in the community?

Prompts:

- *What existing models should we be using / adapting / avoiding?*
- *How might current procedures need to be modified for SSK?*
- *What comparable rapid-referral models might be used / adapted?*

j. What other support/care/services could be provided, in addition to receiving an HIV test result?

- Provision of additional HIV prevention support with a negative test result (how, what and when?)
- Information about other sexual health test kits
- Information about blood-borne viruses (some African communities also at higher risk of hepatitis B and Hep C, thus should referral procedures should be flexible enough to identify these as well?)

k. Reflecting on our conversation, what issues do you see as being the same / different with regards to Home Testing Kits?

Prompts:

- *Attitudes*

        - *Use*
        - *Practical issues at local service provider level*
        - *Data collection issues*
        - *Referrals / confirmatory testing provision*
    - What would be your preference? Why?

Just before we close, is there one final thing that you might each like to say about these kits – just in one sentence?

- Thanks for your time / honesty.
- Explain process for rest of Phase 1.
- Website / Twitter for ongoing updates about progress.
- May be in contact with regards to Phase 2.
- Sort out payments / receipts etc.

<END>

Appendix C. HAUS Study Semi-Structured Interview topic guide

SSK unique code _____

Interviewer initials _____

Date_____

PARTICIPANT CONSENT

Before we start I need to ensure that you **understand** the nature of the interview you are about to take part in and are happy to proceed.

This interview will involve me asking you **questions about your experience of being approached to consider using the HIV self-sampling kit, and your decision about using it**. We will also ask people who used the kit about their experience of using it. This interview should take around **30 minutes**. Your participation is **voluntary** and you may stop the interview at any point or refuse to answer any question with which you are not comfortable. You will be sent a **£10 voucher** at the end of the interview.

I would like to **audio-record** the interview: this is because I am not able to write down everything you say quickly enough.

The recording will be kept **strictly confidential** and no one outside of the HAUS study team will have access to it. When we are finished taking notes from the interview, the recording will be safely destroyed, so there will be no record of your voice or any of your identifying details remaining. In any report or presentation that we write about this study, **we may use some of your exact words, but we will do that in a way that makes sure no one could identify you**. In the future, other qualified researchers might also be allowed access to the written record of your interview, but not your recording. Before sharing the written copy we would remove any names or places from the written copy that could identify the person being interviewed.

- Do you have any questions about the interview?

Note any questions raised:

I would like to start the interview now which means turning on the recording is that ok? □ Yes □ No

I just need to ask you a few confirmation questions again so that we have an audio record of you saying that you are happy to go ahead based on what we have just discussed.

- We have just discussed what the interview is about, and how we will store the personal information you give us until it is destroyed. Are you fully aware what your participation involves?

  □ Yes □ No

- Do you consent to the interview being digitally recorded?

  □ Yes □ No

- Are you happy for us to get started?

  □ Yes □ No

Section 1 – Kit distribution

1.1 Is being tested for HIV something that you had done or considered before you were asked to consider using this self-sampling kit?

[prompts: prior access to traditional HIV testing and associated benefits/challenges, personal considerations of risk]

1.2 Before you were approached to consider taking/using an HIV self-sampling kit, did you know that such kits were available?

[probes: prior thoughts about SSKs/change in thinking/immediate response when learning about them for the first time]

1.3 Can you think about the time you were offered this kit and let me know what do you recall about it?

[prompts: location, distributor characteristics, what was said]

1.4 How did you feel about being offered an HIV test because you are African?

Why/why not?

1.5 How did you feel about being offered an HIV test in [location]?

Why/why not?

1.6 Why did you agree to consider using the kit?

[prompts: relevance of distributor characteristics/information; personal reasons, convenience]

Section 2 – Kit Use and Sample return

2.1 Did you actually open the kit and attempt to use it?

□ No - Why was that?

□ Yes - Tell me how that went and what you thought of using the kit.

2.2 In the end, you *did [OR] did not* return the sample. How did you return it? Did you have any issues with that?

[probes: confidence, privacy, kit characteristics]

2.2a We did not ask people to put their names on the sample vial. If you had been asked to put your name on it, would you have been happy to do so?

2.3 **only ASK if sample was returned**

How did you feel about the way that your test results were communicated to you?

Section 3 – Implications of this approach

3.1 Would you be willing to use the same kind of HIV self-sampling kit in the future?

- Why/why not?

- Are there particular circumstances that would influence your decision? What are they?

3.2 What was your overall experience of using this kit to test for HIV? Please tell me what you liked, and what you think needs to be changed.

[prompts: consider this in relation to the discussion/the kit/the sample return/communicating the results/being targeted]

3.3 In your view, do you think other black African people like you would like to use a kit like this to find out their HIV status?

- Why do you feel that way?
- Is that the same for everyone, or are there some for whom this is a better or worse option

3.4 Do you think there are other ways, and maybe even better ways to encourage more black African people to test for HIV regularly?

3.5 Is there anything else you would like to say before we finish the interview?

That is the end of the interview.

Thank you very much for your time and your openness.

[explain how voucher will be sent – confirm email address]

[give website address: www.HAUS.org.uk *in case they want to keep up with study findings]*

Appendix D: Barriers and facilitators relevant to the intervention component 'the appearance and packaging of the HIV SSK'

Thinking about improving the acceptability of your component		
Key Barriers ***to implement (Indicate score out of ten to indicate relative strength)***	**Key facilitators** ***to implement (Indicate score out of ten to indicate relative strength)***	**Conceptual coherence** (What is the specific focus of barrier/facilitator)
Clear plastic bag containing the kit (9) will not be acceptable as it will be difficult to carry them around.	Non-transparent material bags for packaging the kits (9)	Confidentiality-packaging material
Avoid using packaging that is unique / can be identified as the one used only for HIV testing kits (9) as it will lead to involuntary disclosure of HIV test seeking/breach of confidentiality	Use generic / commonly used materials for packaging the kits like brown paper bags or coloured bags (9)	Confidentiality-packaging material/design
Concerns about the kit being tampered with/opened/torn prior to being used (7) leading to contamination and subsequent impact on reliability of the test results	Tight, secure packaging that will not break/open/tear prior to use of the kits (6)	Contamination-secure packaging
Concerns about contamination of the specimens when posting back to the lab (9)	Good packaging to send the specimens back to the lab and assurance that it does not get contaminated (9)	Contamination-secure packing for specimens
Not very big or long kit (5)	Small, compact packaging that can be easy to carry (4)	Convenience-size of packaging
No mention on HIV on the package (10) due to concerns of privacy and confidentiality	Plain packaging with no reference to the kit containing a test for HIV	Confidentiality-packaging design

Appendix E. Overview of policies and guidelines relating to HIV testing and self-sampling in the UK between 2008 and 2016

Author/Source	Year	Title	Policy Content	Policy change over time/policy in practice
BHIVA/BASHH	2008	UK National Guidelines for HIV testing 2008	National Guidelines to address late diagnosis and undiagnosed HIV in the UK by expanding HIV testing services beyond antenatal and genitourinary medicine (GUM) clinics. The guidelines advocate for routine offering of HIV testing in general practice where the prevalence rate is higher than 2 per 1000 among 16-59 year olds; to patients attending specified services such as GUM clinics or pregnancy termination service; those who report high risk behaviour and those with indicator conditions. The guidelines discuss two types of tests to use namely venepuncture and a screening assay and rapid point of care tests (POCT). The guidance does not specifically discuss the use of self-sampling kits and how they might address the burden of undiagnosed HIV.	A recent review of national HIV testing by Public Health England indicates high national coverage of HIV screening and testing in GUM clinics; antenatal services, needle exchange and other drug services (PHE, 2014). However, coverage remains low among patients with indicator conditions or attending termination of pregnancy services, hospital general medical admissions, and primary care settings. Coverage in community settings where self-sampling kits are used in addition to rapid test kits has been reported as both feasible and acceptable.
Health Protection Agency (HPA) [now Public Health England]	2011	Time to test: Expanding HIV testing services in community and healthcare settings in the UK	This report describes eight pilot projects that were commissioned by the Department of Health after publication of the BHIVA HIV testing guidelines. The pilot projects assessed how the guidelines might be implemented in acute admissions unit; emergency departments; primary care settings and in community and outreach settings. HIV self-sampling kits were successfully used in one of the pilot projects.	Findings from the pilot projects indicated that HIV testing in various medical and community settings was feasible and acceptable further supporting the implementation of the BHIVA HIV testing guidelines.
NICE	2011	Increasing uptake of HIV testing among black Africans in England	National guidance providing specific recommendations on methods of increasing the uptake of HIV testing among black Africans in the UK. Suggested recommendation includes engaging the black African community and promoting HIV testing; planning services in line with local need; developing a strategy and commissioning services in areas of identified need; promoting HIV testing among black Africans and reducing barriers to HIV testing for black Africans. The guidelines also recommend routine offering of HIV testing by	Guidance has been influential in the expansion of HIV testing services for black Africans, however this guidance is being updated and new recommendations will be published in 2016.

Author/Source	Year	Title	Policy Content	Policy change over time/policy in practice
			health care professionals in all health care setting and development of clear referral pathways for patients who test positive or negative.	
NATIONAL AIDS TRUST (NAT)	2012	HIV testing in African communities: the case for an annual test recommendation	Policy briefing suggesting that NICE introduce annual HIV testing for black Africans in order to reduce undiagnosed HIV. The policy briefing does not discuss self-sampling specifically but reiterates the need for wide scale testing in primary, secondary and community settings as indicated in the BHIVA 2008 HIV testing guidelines.	NICE recommends regular testing for individuals with new or casual sexual partners however NICE has not specified frequency of testing for black Africans.
NAT	2012	HIV Testing Action plan to reduce late HIV diagnosis in the UK	This strategy provides rationale and evidence supporting increasing HIV testing and screening to address late HIV diagnosis in the UK. In line with the 2008 BHIVA guidelines, the paper advocates priority actions to reduce undiagnosed HIV including offering of opt out HIV testing in areas of high HIV prevalence; opt out HIV testing to patients attending specific services such as GUM clinics; better prioritisation and resourcing of partner notification services for those newly diagnosed with HIV; regulating HIV self-testing HIV self-testing in the UK; increasing offering of HIV testing in general practice; increasing funding for HIV testing initiatives.	This paper is based on the 2008 guidelines and the national response to HIV has changed for example the legislation of self-tests in 2014.
Department of Health	First published 2012 revised 2015	Public Health Outcomes Framework 2013 to 2016	The Framework details the national public health vision, the national public health outcomes to be achieved as well as measurable indicators which can be used to evaluate and monitor the progress towards achieving the given outcomes. The proportion of persons presenting at a late stage of HIV infection that is with CD4 count <350/ mm^3 has been identified as an indicator of essential actions to be taken to protect the public's health.	Addressing late diagnosis of HIV is a high public health priority for addressing the epidemic in the UK and this indicator provides measurable progress towards addressing late diagnosis.
NICE	2014	HIV Testing	Guidance and recommendations for local authorities and other clinical commissioning groups on delivering HIV testing services. NICE recommends that commissioners conduct an assessment of local need for HIV testing for black Africans and	Although this guidance does not discuss commissioning of HIV self-sampling initiatives by local authorities; under the Health and Social Care Act 2013, local authorities are responsible for

Author/Source	Year	Title	Policy Content	Policy change over time/policy in practice
			then develop a local HIV testing strategy with clear referral pathways particularly for outreach point of care services. To address undiagnosed HIV and late diagnosis of HIV among black Africans, NICE recommends that commissioners promote HIV testing including the use of modern HIV tests and reduce barriers to HIV testing among black Africans. In line with the BHIVA 2008 guidelines, NICE recommends that HIV testing is offered by health professionals in primary and secondary care.	commissioning comprehensive sexual health services including HIV testing. HIV self-sampling has been offered in community settings and medical settings (NAT, 2012).
HIV Scotland	2014	HIV Result Instant Self testing in Scotland: Addressing key questions and recommending good practice	This document provides guidance on HIV self-testing in Scotland. It provides rationale for self-testing; discusses legislation of HIV self-testing in the UK and elaborates on how self-testing kits may address known barriers to HIV testing and possible ways of supporting patients through the process.	Self-testing kits are now in use in the UK. Their impact on late diagnosis has not yet been evaluated.
Westrop et al (Public Health England -PHE)	2014	Addressing Late HIV Diagnosis through Screening and Testing: An Evidence Summary	This report provides rationale and evidence supporting increasing HIV testing and screening to address late HIV diagnosis in the UK. It provides a brief overview of national policies on HIV testing and how this impacts uptake of HIV testing. In addition, evidence is reviewed on the effectiveness and cost effectiveness of HIV testing in medical and community settings. The report specifically discusses testing in non-medical settings such as community HIV testing and how self-sampling and self-testing for HIV broaden the HIV testing options available. The acceptability and feasibility of both approaches is described.	Self-testing became legal in 2014 and viewed as another innovative testing strategy in addition to HIV self-sampling.
NAT	2015	Instant result HIV test kit: information for the public in England and Wales	Patient information sheet on the use of self-sampling kits including the meaning of results and linkage into care and support.	Although self-testing kits became legal in 2014, there are no publications evaluating this type of test in the UK.

Author/Source	Year	Title	Policy Content	Policy change over time/policy in practice
NICE	2015	HIV Testing: Encouraging most at risk groups in draft version due to be published in 2016	Consultation for this guidance ~~is ongoing~~at the time of writing was ongoing, however the ~~and~~ the final guidance ~~will be~~has now been published ~~in 2016~~[45]. It gives an update to the 2011 guidance on increasing uptake of HIV testing among black Africans and MSM in the UK. ~~Among other this,~~ NICE provide guidance on interventions to raise public awareness and interventions to increase the type and opportunities for HIV testing. The guidance specifically identifies ~~home~~ self sampling and ~~home~~ self testing as possible ways to increase HIV testing.	To be published in 2016 NICE guidelines were updated in December 2016, and SSKs were considered a potentially innovative way of increasing uptake of HIV testing among black Africans given that they may address known barriers to HIV testing in this risk group.(45)"

Appendix F. Systematic review screening criteria and OvidSP MEDLINE search strategy
Systematic review of SSK acceptability

Inclusion criteria- quantitative studies

Population – any lay population in any country

Intervention – SSK for HIV

Comparison – any other HIV testing method

Outcomes – Completion of SSK for HIV; participant-reported acceptability; adverse events; first time testers; test/strategy; linkage; accuracy; cost-effectiveness

Study design – any randomised or non-randomised evaluation or observational design

Publication date: 2000 to present

Language: English

Inclusion criteria – qualitative studies

Studies in any population group in any country describing, summarising or analysing the experiences and perceptions of any population group about SSK for HIV. This will include studies of experiences of and responses to personal completion of SSK for HIV and also perceptions and opinions of potential use. Any text-based qualitative research methodology will be included: interviews, focus groups, ethnography. Studies published from 2000 until the time of searching will be included.

Screening

Titles and abstracts of studies retrieved using the search strategy and those from additional sources will be screened by two researchers to identify studies that potentially meet the inclusion criteria outlined above. Studies excluded at this stage will be excluded as "not relevant to SSK for HIV" and will be counted to allow completion of the PRISMA diagram. At this stage, both quantitative and qualitative studies of SSK for HIV will be retained together. Where an abstract is not available and the title cannot be used to assess relevance, the article will be retained for full text screening

The full text of these potentially eligible studies will be retrieved and assessed for eligibility. All the pdfs files will be incorporated to the bibliographic database, which will be delivered to the rest of the team. A more detailed coding scheme for exclusion reasons will be developed and recorded for completion of the PRISMA diagram. Eligible quantitative and qualitative studies will be separated at this stage and treated separately in the PRISMA diagram.

At each stage the two researchers (EM & GP) will:

- Complete a 5% sample of records in parallel to check consistency and feasibility of inclusion/exclusion criteria application
- Split the remaining records and screen individually, with a 10% sample being double screened

Any disagreement between the two researchers (EM & GP) over the eligibility of particular studies will be resolved through discussion and where needed a third researcher will be consulted (FB and/or CD?). For all the excluded references, the exclusion reason will be recorded in endnote/Excel spreadsheet.

The researchers will contact investigators for clarification where eligibility cannot be determined from the published study and for any new studies or references that may not be published yet and to check that the search has captured important articles in the field. We will review backward & forward citation for Web of Knowledge for the publications finally identified as relevant after the screening process.

Full paper Screening

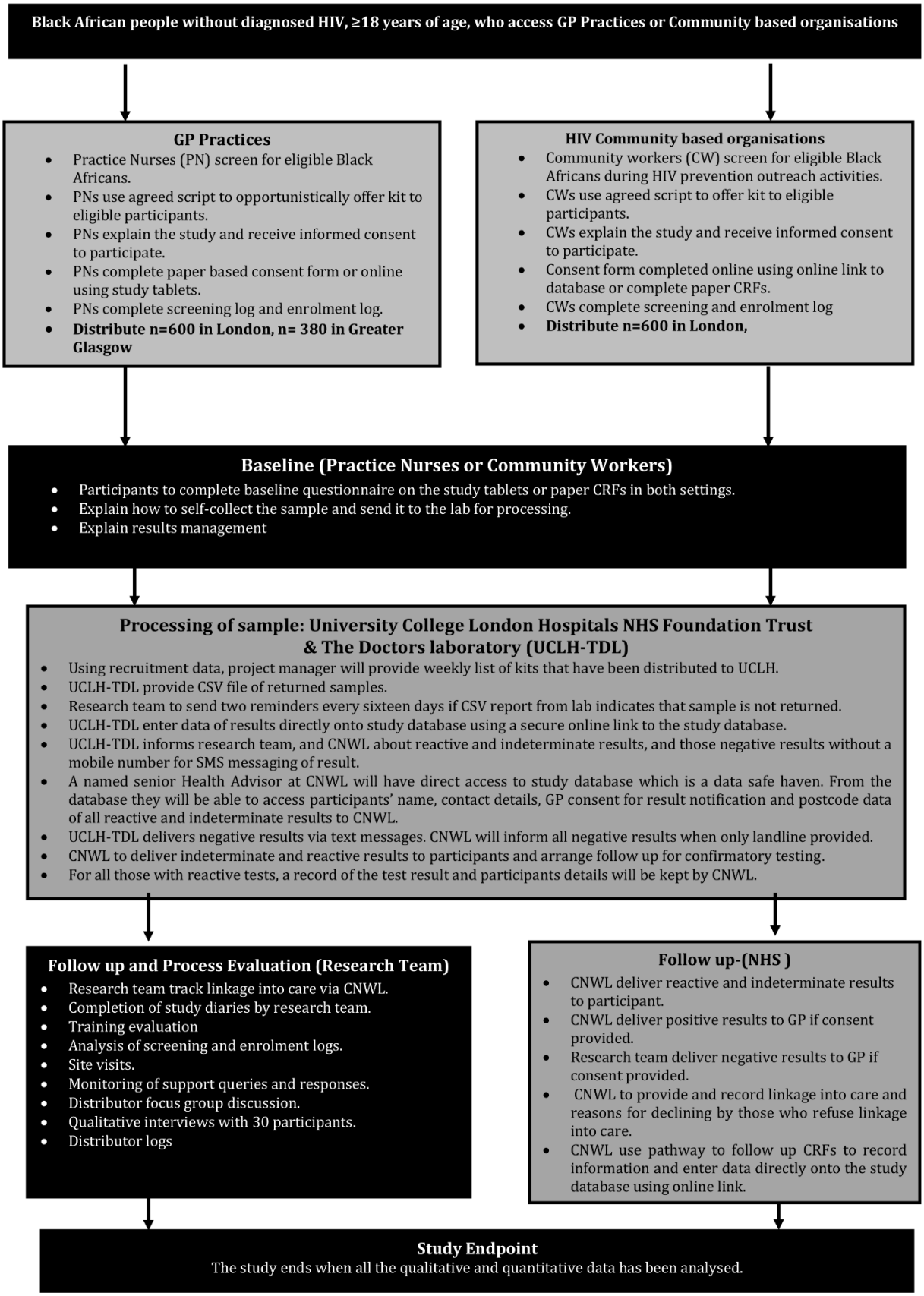
1.	**11.4.2 Was the study carried out in any of the following countries?** Australia, Austria, , Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea Rep, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Slovak Republic, Spain, Sweden, Switzerland, United Kingdom, United States	YES/UNCLEAR – go to Q2	NO – exclude
2.	**11.4.3 Was the study published in 2000 or later?**	YES/UNCLEAR – go to Q3	NO – exclude
3.	**11.4.4 Does the paper include information about self-sampling for HIV?**	YES/UNCLEAR – go to Q4	NO – exclude
4.	**11.4.5 Is the paper/study about interventions that include any of the following outcomes:** • Increase / decrease in number of HIV tests • Proportion /number of confirmatory tests • Proportion /number of participants linked into care • Adverse events associated with HIV self-sampling • Proportion/number of false positives or failed tests • Increase / decrease in the reported history and frequency of taking HIV tests • Increase / decrease in the number and types of venue where HIV testing is offered • Barriers or facilitator to self-sampling reported by general population • Barriers or facilitators to self-sampling reported by providers* *qualitative only	YES/UNCLEAR – go to Q5	NO – exclude
5.	Does this paper describe a primary study or is a review (of primary studies)? E.g. randomised or non-randomised controlled trials, prospective observational, retrospective observational, cost benefit analysis; cost-consequence analysis; cost-effective analysis and cost utility analysis	YES/UNCLEAR – go to Q6	NO – go to Q6
6.	Is the study exclusively measuring the validity or diagnostic effectiveness of different types of HIV test;	YES - Exclude	NO/Unclear – Include for Full

	Are the interventions examining testing following exposure to HIV in the workplace?		paper review

Date range: 1946 to September Week 3 2014

1. exp HIV Infections/ (238345)
2. exp HIV/ (86013)
3. hiv.ti,ab. (225871)
4. “hiv1".ti,ab. (710)
5. "hiv2".ti,ab. (149)
6. "hiv type 1".ti,ab. (3784)
7. "hiv type 2".ti,ab. (186)
8. human immunodeficiency virus.ti,ab. (69068)
9. human immunedeficiency virus.ti,ab. (4)
10. human immuno-deficiency virus.ti,ab. (186)
11. human immune-deficiency virus.ti,ab. (245)
12. (human immun* adj3 deficiency virus).ti,ab. (435)
13. acquired immunodeficiency syndrome.ti,ab. (14483)
14. acquired immunedeficiency syndrome.ti,ab. (10)
15. acquired immuno-deficiency syndrome.ti,ab. (94)
16. acquired immune-deficiency syndrome.ti,ab. (4904)
17. (acquired immun* adj3 deficiency syndrome).ti,ab. (5037)
18. Sexually Transmitted Diseases, Viral/ (1207)
19. or/1-18 (313426)
20. (sample adj1 collect*).ti,ab. (5944)
21. home dried blood spot.ti,ab. (0)
22. (alternative adj3 test*).ti,ab. (3862)
23. (option* adj1 test*).ti,ab. (270)
24. ((Home* or self* or mail*) adj3 (collection* or sampl* or specimen* or test* or kit)).ti,ab. (10969)
25. or/20-24 (20907)
26. 19 and 25 (1003)
27. limit 26 to (english language and yr="2000 -Current") (673)

Appendix G: Fieldwork Schematic Diagram



Appendix H: Baseline Questionnaire

Thank you for taking part in this study. Please complete the following information. The questionnaire is confidential and should take less than 5 minutes to fill in.

First Name _____

Surname _____

Affix Kit number here

Are you: Male☐ Female ☐

What is your date of birth: ☐☐/☐☐/☐☐

Mobile number: ☐☐☐☐☐☐☐☐☐☐☐

Alternative contact method (landline):

_____

What is the first half of your postcode: ☐☐☐☐

1. In what country were you born?
Please write it down:

_____

2. How long have you been living in the UK?

☐ Less than one year
☐ 1 – 2 years
☐ 2 – 5 years
☐ 5-10 years
☐ More than 10 years
☐ All my life

3. When did you last have an HIV test? (please tick one)

☐ Never
☐ Less than one year ago
☐ 1 – 2 years ago
☐ 2 – 5 years ago
☐ More than 5 years ago
☐ I am unsure or prefer not to say

4. In the last 12 months, who have you had sex with

☐ I have only had sex with men
☐ I have only had sex with women
☐ I have had sex with men and women
☐ I have not had any sex
☐ I am unsure or prefer not to say

When you have finished this please return it to the person who you have been talking to about the HAUS study
Thank you.

Appendix I. Distributor weekly log

HAUS

NHS National Institute for Health Research

LONDON'S GLOBAL UNIVERSITY

UCL

Weekly Log

Name	
Organisation	
Date	

1. How did you feel about recruiting people to the Haus study this week? (circle a face)

Why do you say that?

_____

_____

2. How confident do you now feel about targeting Black African people to take part in the Haus study?

- ☐ Very confident
- ☐ Quite confident
- ☐ Not sure
- ☐ Not really confident
- ☐ Not at all confident

3. Do you use the techniques provided in the training sessions or study manual to encourage people to take part?

- ☐ Always
- ☐ Most of the time
- ☐ Some of the time
- ☐ Rarely use
- ☐ Never

4. How confident do you now feel when answering people's questions about the study?

- ☐ Very confident
- ☐ Quite confident
- ☐ Not sure
- ☐ Not really confident
- ☐ Not at all confident

5. Is there anything you would like to add about your experience of being a Haus distributor this week?

_____

_____

_____

_____

_____

_____

_____

Appendix J: Acceptability questionnaire

Please fill in this survey AFTER you have taken your sample. Thank you.

We would like to know your thoughts about this way of testing for HIV. Your answers will help us to improve this HIV testing service.

The questionnaire is confidential and takes only a couple of minutes to fill in.

1. **Is it acceptable to be offered an HIV test in this manner? (circle a face below)**

   Acceptable  Unacceptable

2. **Is it acceptable to be offered an HIV test because you are African?**

   Acceptable  Unacceptable

3. **What did you think about the location where you were offered this kit?**

   Acceptable  Unacceptable

4. **Did the offer of this kit help you to decide to test?**

   Yes ☐ No ☐

5. **Did the person who offered you the kit help you feel more confident about knowing your HIV status?**

   Yes ☐ No ☐

6. **Were the instructions in the kit easy to understand?**

   Very easy  Very difficult

7. **How did you feel about taking the sample yourself?**

   Comfortable  Uncomfortable

Why did you feel that way? _____

8. **Did you watch the online video about using this kit?**

   Yes ☐ **No** ☐

   If yes - How did watching someone else use the kit make you feel?

Confident  Unsure

How helpful was the video?

Helpful  Unhelpful

9. **How willing would you be to use one of these kits again in the future?**

Very willing  Not at all willing

10. **Can you tell us why you accepted this kit when it was offered to you?**

11. **We are very interested in your views on this service. Please tell us which aspects you particularly liked or you think we should change.**

Please put this completed questionnaire in the free post envelope with your sample.

Thank you again for your time.

Appendix K: Study Close Down Interviews/Group Interviews with Distributors

Interviewer: Location:

Date: Consent collected for recording: Y/N

1. How did you feel about offering an HIV test specifically to black Africans?

2. You were asked to closed follow the intervention wording we provided as you targeted black African people. How did you find that worked in reality?

3. Do you feel your organisation benefitted in any way from distributing these kits? What about those who use your services, did they benefit in any way?

4. How feasible is this approach in the future for you? What would you change?

   *PROBE about whether it was the script/kit/or the research process and paperwork that needs changing

5. In your view, do you think black African people would like to use a kit like this to find out their HIV status?

   *Probe: why/why not? Was it the same for everyone? How could that be different for different people?

6. Anything else you might like to add before we finish?

Appendix L: Further Acknowledgements

Distribution Sites

Community Based Organisations

KwaAfrica: Amanda Amito, Daniel Baliikya, Martha Bisirikirwa, and Esther Namutoosi

Naz: Parminder Sekhon Priyanka Goel

Positive East: Amanda Amito,Daniel Baliikya, Martha Bisirikirwa and Esther Namutoosi

General Practice

Brigstock Medical Practice: Dr Dipti Gandhi, Nilgun Ahmed, and Pat Southam

Crawley Road Medical: Dr Rameet Singh Uberoi and Shiraaz Ibrahim

Eagle House Surgery: Drs Claire Murphy and Margaret Barnes.

Manor Place Surgery: Ahmed Faheem, Mohammad Halim

Minet Green Health Practice: Dr Louise Medforth and Sue Chard

Morden Hall Medical Centre: Drs Fiona White and Ravi Patel; Emma Scerri

Open Door Surgery: Dr Punam Mittal and Paula Batson

Paxton Green: Dr Stephen Miller **&** Alison Peat

Royal Arsenal Medical Centre: Dr Yann LeFeuvre

Sir John Kirk Close Surgery: Dr Richard Proctor and Mohammad Halim

Streatham Common Practice: Dr Ruth Danson and Tracy Hayward-Allingham

The Corner Surgery: Dr David Wickstead, Filipa Pereira and Michelle Panton

Advisory Group Membership

Public Health England	Dr Anthony Nardone
Terrence Higgins Trust & King's College Hospital NHS Foundation Trust	Dr Michael Brady
Pharmacist	Mr Alistair Murray
Positively UK	Ms Rebecca Mbewe

Study Steering Committee

Dr Philippa James (Chair)	GP, Cornbrook Medical Practice, Manchester
Dr Suzanne Audrey	University of Bristol
Dr Claudia Estcourt	Queen Mary University of London

Collaborators

Dr Alan McOwan	Chelsea & Westminster Hospital NHS Foundation Trust
Prof Graham Hart	University College London