

Self-sampling kits to increase HIV testing among black Africans in the UK: the HAUS mixed-methods study

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Declared competing interests of authors: Fiona Burns reports grants from the National Institute for Health Research (NIHR) for other projects during the conduct of the study, and personal fees and other from Gilead Sciences Ltd (London, UK), outside the submitted work. Rachael Hunter reports grants from the NIHR Health Technology Assessment (HTA) programme for other projects, during the conduct of the study. Ibadun Fakoya reports a grant from NIHR for another project, during the conduct of the study. Eleni Nastouli reports personal fees from Roche (Burgess Hill, UK), grants from Viiv Healthcare (London, UK), grants from the European Union (H2020) and personal fees from NIHR, outside the submitted work. Lisa McDaid reports grants from the NIHR HTA programme for other projects, during the conduct of the study. Jane Anderson reports grants and personal fees from Gilead Sciences Ltd, and personal fees from ViV Healthcare, Merck Sharp & Dohme Limited (Hoddesdon, UK), Bristol-Myers Squibb (Uxbridge, UK), Jansen-Cilag Limited (High Wycombe, UK) and AbbVie (M Maidenhead, UK), outside the submitted work.

Published April 2018

DOI: 10.3310/hta22220

Scientific summary

The HAUS study

Health Technology Assessment 2018; Vol. 22: No. 22

DOI: 10.3310/hta22220

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Black African people constitute over half of heterosexual people living with HIV (human immunodeficiency virus) in the UK, and are more likely than other ethnic groups to be diagnosed with advanced infection. Reducing late diagnosis of HIV 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 (SSKs) 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 with regard to black African users. To address this evidence gap, the aims of the HAUS study were to (1) develop a SSK-based intervention to increase the provision and uptake of HIV testing among black Africans, using existing community and health-care provision (stage 1); and (2) 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 to, and facilitators of, provision, access and use of HIV SSKs 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 for stage 2

- Determine the feasibility and acceptability of a provider-initiated, HIV SSK distribution intervention targeted at black African people in two settings:
 1. general practice (GP) surgeries
 2. community-based organisations (CBOs).

Secondary objectives

- Establish the acceptability of interventions for providers and users.
- Evaluate the clinical effectiveness of self-sampling for HIV in increasing the uptake of HIV testing by black African people.
- Determine the cost-effectiveness of distributing the SSKs among black African people compared with other screening methods.
- Monitor the ability to trace participants with reactive results, confirmatory testing and linkage into specialist care.
- Determine the cost per 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 a future Phase III evaluation.

Methods

Stage 1

The objectives for stage 1 were met through three activities:

1. a systematic literature and policy review
2. focus group discussions (FGDs) with non-specialists and service providers, and one-to-one interviews with the latter
3. development of a theoretically informed intervention.

The systematic review focused on the feasibility, acceptability and clinical effectiveness of HIV self-sampling in increasing the uptake of HIV testing. Only studies published since 1 January 2000 in English and conducted in the European Union/European Union free trade agreement countries, North America, New Zealand or Australia were included. Ten electronic databases were searched and the National Institute for Health and Care Excellence quality appraisal tools were used (the last search was conducted on 3 May 2016). All papers were appraised independently by two reviewers.

Qualitative methods were used to collect data using FGDs and one-to-one interviews. Ethics approval was obtained from the University College London Research Ethics Committee, project identification (ID) number 3321/001.

Twelve FGDs were conducted, six of which were with non-specialist members of the public who identified as black African, and six with professionally, culturally and ethnically diverse people who provide HIV-related services 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 (QSR International, Warrington, UK) 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
3. an economic analysis.

Feasibility study

General practice surgeries and CBOs that 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, who were at least 18 years of age and able to provide informed consent, were eligible. The recruitment target was 1200 participants across sites in London and Glasgow. Ethics approval was obtained from the East of England – Cambridge South Research Ethics Committee [reference number 15/EE/0412; and Integrated Research Assessment System (IRAS) project ID number 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 an automated short message service (SMS) text message delivered from the processing laboratory. If there was only a landline telephone number provided, or the result was reactive or unable to be processed (because of underfilling or gross haemolysis), the result was passed to a senior health advisor (HA), who contacted the participants by telephone to notify them of the result and arrange a follow-up as appropriate. Postal code information was provided to the HA to enable referral to services that were appropriate for 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 10 data points: (1) research diaries, (2) training evaluations, (3) enrolment logs, (4) distributor logs, (5) site visit notes, (6) observed data flow, (7) communications between the study team and distributors, (8) site summaries, (9) close-down interviews and (10) qualitative interviews with study participants.

Economic analysis

A patient-level simulation was developed to assess the cost-effectiveness of SSKs among black Africans in the UK compared with 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 (Microsoft Corporation, Redmond, WA, USA) in accordance with methodological recommendations for evaluations of new health-care technologies and interventions. A hypothetical cohort of 8000 patients was tested in two different HIV screening arms: (1) intervention (SSK) or (2) 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 the UK. Overall, the quality of the studies was mixed and relatively poor. Evidence to support the acceptability, feasibility and clinical effectiveness of SSKs to increase HIV testing was limited, and absent for black African 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 the uptake of HIV testing among all populations at a higher risk of contracting HIV, and black African people in particular.

The FGDs and one-to-one interviews revealed concern over the amount of time that providers had (particularly general practitioners) to initiate discussion and encourage the use of SSKs, and about the

volume 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 a 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 focused on the targeted offer of a HIV SSK distributed 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 the 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 people were approached and 125 (35.8%) agreed to participate. Data from 119 participants were included in the analysis. The mean age was 42.6 years, slightly less than half of the participants were male and the majority (76%) were recruited at GP surgeries. The SSK return rate was 54.6% (65/119); 83.1% of tests returned were HIV negative. However, 11 samples (16.9%) were unable to be processed as a result of the vial being underfilled or the sample being grossly haemolysed. There were no reactive results.

The two most common reasons for declining to participate were (1) having recently being tested for HIV and (2) a perception of being at low risk of exposure to HIV. Eligible people visiting their GP were significantly more likely to be recruited than those approached via a CBO (odds ratio 1.96, 95% confidence interval 1.20 to 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 that the location in which they were offered the kit was unacceptable. The majority found the SSK instructions easy to understand, and over two-thirds of participants were comfortable with taking the sample themselves. Just under one-third reported watching the online video; among those who watched it, most found that the video was helpful and increased their 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 one-third of participants reporting that it was unacceptable.

Twenty-one participants were interviewed; the median age of interviewees was 40 years, 12 were women and 17 were recruited at GP surgeries. Of the 21 participants, nine received negative results, four sent samples that were unable to be processed (because of the samples being underfilled) and eight did not return 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 African people 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 with potential participants. 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 these data prior to appointments. These issues manifested in a large variety of methods being employed at GP surgeries to select patients to whom to offer the intervention.

The level of 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 options. However, significant barriers to recruitment were noted, including stigma around HIV and limited time and capacity to conduct the intervention.

Results of the process evaluation

Most distributors found it difficult to recruit participants and almost all found it too time-consuming to deliver the intervention 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. Although 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 represented 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 the economic analysis

The model of a SSK test dispensed to black Africans in GP or community settings suggests that SSKs are a potentially cost-effective way to identify new infections of HIV; SSKs showed increased quality-adjusted life-years for less cost, as compared with current practice. 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, SSKs are a cost-effective way to identify new infections of HIV, but further work is needed to validate this result. Importantly, the study also found that 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 the acceptability and return rates of different types of self-sampling methods can help to better understand their impact on recruitment. Blood-based kits that do not require users to 'milk' blood and diagnostic assays that meet the *Conformité Européenne* 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 the length of time taken to obtain the necessary regulatory approvals, continually changing systems breeds confusion and affect study timelines and the feasibility of assessing research questions substantially.

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

Study registration

This study is registered as PROSPERO CRD42014010698 and IRAS project ID 184223.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research, and the BHA for Equality in Health and Social Care.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.236

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 12/138/02. The contractual start date was in June 2014. The draft report began editorial review in October 2016 and was accepted for publication in June 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

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