Study Protocol

Acceptability and feasibility of electronic vending machines for delivering HIV self-testing and STI self-sampling kits: a mixed methods study

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1.0 Study Summary

| Title | Acceptability and feasibility of electronic vending machines for delivering HIV self-testing and STI self-sampling kits: a mixed methods study. |
| Rationale | To investigate whether HIV self-testing and STI self-sampling kits delivered by vending machines in Brighton and Hove and Bristol, North Somerset and South Gloucestershire (BNSSG), UK, offer an acceptable and practical option to encourage and facilitate testing. |
| Study Outline | Vending machines that dispense HIV self-testing and STI self-sampling kits have been installed in five locations throughout Brighton and Hove and four locations in Bristol, North Somerset and South Gloucestershire (BNSSG). We intend to use a questionnaire and semi-structured interviews to understand whether this offers an acceptable and practical adjunct to current testing options. Additionally, to explore and understand motivations for use of the vending machine and identify further barriers to testing. |
| Key Aims | ● Describe demographics of the population using the vending machines to obtain the kits.  
● Quantify the number of HIV self-test and STI self-sample kits dispensed by the vending machine.  
● Quantify the number of STI self-sample kits that are returned to the laboratory.  
● Explore acceptability, practicality and motivations of using a vending machine for HIV and STI testing. |
2.0 Introduction

2.1 Background

Human immunodeficiency virus (HIV) is a retrovirus that weakens the immune system against infection and cancer. In 2020, there were an estimated 37.7 million people living with HIV globally and 680,000 people died of HIV-related illnesses\(^1\). In 2014 the Joint United Nations Programme on HIV/AIDS (UNAIDS) launched their 95-95-95 target, which aims to ensure 95% of people who are HIV positive are aware of their status\(^2\). Despite there being no curative treatment currently available for HIV, the use of antiretroviral therapy (ART) causing an undetectable viral load leads to individuals living healthy lives, with similar life expectancies to the general population\(^3\). Regular testing and early diagnosis facilitates prompt treatment with ART, leading to improved survival rates\(^4\) and reduction in transmission to others\(^5\).

Approximately 1 million sexually transmitted infections (STIs) are diagnosed each day\(^6\). Four STIs – chlamydia, gonorrhoea, syphilis and trichomoniasis – are treatable with antibiotics. However, left untreated they can lead to pelvic inflammatory disease, infertility and, if transmitted vertically, neonatal death\(^6\). The term ‘epidemiological synergy’ describes the relationship of co-infection between STIs and HIV - STIs lead to an increased risk of HIV acquisition and HIV leads to prolonged infectiousness of STIs\(^7\).

In the community there are two available routes for independent testing. Self-testing (HIV only) allows testers to conduct a finger-prick test using a kit that gives a result within 15 minutes allowing autonomy and privacy in the timing, location (i.e., can be done at home) and disclosure of test and result. UNAIDS have advocated for the use of self and home-based testing for HIV, as part of their FastTrack campaign\(^2\). Self-sampling (HIV and STI) allows the individual to collect a small blood sample, vaginal/anal/throat swab or urine sample and return it via post for laboratory analysis. Results of these are communicated some days later via phone or text by local sexual health services.

In the UK, it is estimated that 1 in 16 people living with HIV are unaware they are positive and 42% of people diagnosed in 2019 were at a late stage of infection\(^8\). The British HIV Association (BHIVA) recommends regular HIV testing for people from an area of high seroprevalence (more than 1%)\(^9\). In the UK, Brighton and Hove (B&H) has the highest prevalence of HIV outside of London (7.8% amongst 15 to 59 year-olds in 2019)\(^10\). Bristol is also a high HIV prevalence city (2.7 per 1000 population aged 15-59)\(^11\). In both areas these rates are higher for certain at-risk groups such as men who have sex with men (MSM) and individuals from a black African and black Caribbean (BA/BC) communities\(^8,12\). The impact of sexually transmitted infections (STI) is highest in young people aged 15 to 24 years\(^13\). In the Southwest of England and Bristol specifically, the detection rate for chlamydia is lower than the national average indicating more testing is needed\(^14\).

In 2017, a novel strategy for HIV self-testing kit distribution was implemented via vending machines (VMs) in B&H with highly encouraging results\(^15\). Since then, 4 further VMs have been installed into The Jubilee Library, Portland Road, The Wellsbourne Centre and the Black and Minority Ethnic Community Partnership (BMECP) Centre. They will be advertised from Martin Fisher Foundation media accounts. A further 4 machines have been procured by Unity Sexual Health, Bristol, South Gloucestershire and North Somerset's integrated sexual health service led by University Hospitals Bristol and Weston NHS Foundation Trust who subcontract elements of the service to partners including Terrence Higgins Trust (THT) and Brook and will be placed in sites in Bristol North Somerset South Gloucestershire (BNSSG) aimed at increasing testing.
amongst MSM, BA/BC communities and young people and will be available for use from July 2022.

This study will involve mixed methods primary research to investigate whether the use of VMs to deliver HIV self-testing and STI self-sampling kits offer an acceptable and practical adjunct to current community testing options using online questionnaires and semi-structured interviews. Potential contributions include establishing VMs as a successful strategy to increase testing that could be expanded and replicated to other venues across the UK and globally. If acceptability and feasibility are less than anticipated, this study will explore reasons and motivations to inform future strategies for HIV and STI testing.

2.2 Current literature

B&H became the first UK Fast Track City in 2016, a global partnership between 90 high-burden HIV cities where governmental, healthcare, community and non-governmental actors collaborate to accelerate the response to HIV16.

During the COVID-19 pandemic, sexual health and HIV centres closed and, at the time of writing, many are operating a telephone triage service to prioritise urgent problems17. With reduced capacity of traditional local services, there is a need to increase capacity in the community to ensure prompt diagnosis and treatment. Latest data from Public Health England shows a 30% decrease in HIV testing by sexual health services from 2019 to 2020, however this was skewed with a 7% reduction for MSM but 34% for BAME men18. 46% of people used internet-based services, an increase on the previous year18, demonstrating current acceptability and potential demand of home-testing methods. Additionally, there was an 18% reduction of HIV self-sample kits returned via the national scheme18. Furthermore, there has been a rise in STIs, particularly gonorrhoea and syphilis, in recent years but a 25% reduction in testing from 2019-202019, highlighting the importance and need for an integrated testing service.

Whilst striving for progress across all population groups, there are demographics that make individuals more susceptible to HIV and/or STIs, and so testing campaigns should be targeted appropriately. The VM locations aim to reflect these demographics to promote access to tests. MSM engage in a higher rate of unprotected anal intercourse (UAI), greater number of partners and higher prevalence of drug and alcohol associated sex20. Previous research in B&H shown that the 56% of MSM test for HIV less than once a year15, compared to guidance suggesting 3 monthly with a history of UAI9. BAME individuals account for 1.8% of the UK population but 34% of new HIV diagnoses21. Missed testing opportunities are a major component of this, with one study finding that of newly diagnosed black Africans in London, 74% had seen their GP in the previous year and 15% been a hospital inpatient22. A qualitative study in B&H revealed an acceptable rate of willingness to use a VM as a method of testing within BAME communities23. The impact of sexually transmitted infections (STI) is highest in young people aged 15 to 24 years13. A systematic review of barriers and facilitators to chlamydia testing in general practice for young people identified embarrassment as a barrier to testing24. For instance, being offered a testing kit by reception staff, others overhearing the offer and carrying a kit through the reception area were disliked due to embarrassment. In contrast self-sampling kits were viewed positively because they made testing more convenient and could be done in a comfortable and discreet setting.

Prior to 2017, VMs had not been used to deliver HIV self-testing kits in the UK. That study implemented a VM in a sauna (sex premise) in B&H, frequented by MSM. Data from this study demonstrates uptake of tests was significantly higher compared with outreach testing by community workers in the same venue and online questionnaires coupled with qualitative interviews illustrated high acceptability of VMs, the primary advantage being increased confidentiality15. A central piece of feedback from this study was participants were concerned that increased availability of HIV tests may decrease the frequency they attend sexual health clinics for full screening25. Therefore, the VMs now distribute STI self-sample kits for chlamydia, gonorrhoea, and syphilis.
Globally, the use of VMs in high-risk areas has found to be acceptable, feasible and effective in countries including New Zealand, China, and USA\textsuperscript{26-28}. Increasing HIV and STI testing requires a multifaceted and innovative approach, which VMs offer.

2.3 Study Rationale

Increasing the uptake of HIV and STI testing requires a multifaceted and innovative approach, with different populations and individuals having differing needs and values. If the VM is successful as a route to testing, this is a strategy that could be expanded and replicated in other similar venues, a wider range of venues across the UK and globally. If the acceptability of the VM is less than anticipated this study will give us the opportunity to understand the reasons for this and inform our future strategies for encouraging HIV and STI testing.

3.0 Research Question

1. Will electronic vending machines delivering HIV self-test and STI self-sampling kits offer an acceptable and practicable adjunct to current testing methods and routes of delivery?

2. What motivates users to use the vending machine and HIV/STI testing as an adjunct to, or substitute for, conventional testing routes and methods?

4.0 Study Aims

This study aims to:

1. Describe demographics of the population using the VM to obtain kits.
2. Quantify the number of HIV self-test and STI self-sample kits dispensed by the vending machine.
3. Quantify the number of STI self-sample kits that are returned to the laboratory.
4. Explore acceptability, practicality, and motivations of using a VM for HIV and STI testing.

5.0 Study Outcomes

5.1 Primary Outcome

1. The number of HIV self-test and STI self-sample kits distributed by the electronic vending machine.

5.2 Secondary Outcomes

1. The number of STI self-sample kits returned back to the laboratory.
2. Participant views on the acceptability and practicality of the electronic vending machine.
3. Key themes in determining use and acceptance of vending machine distributed test kits.
6.0 Study Plan

6.1 Study population

The study population will include those accessing the VMs at all the intended sites, visiting or working in settings with the VMs.

The study population in B&H will be those over the age of 18 and in BNSSG those over the age of 16 (to reflect the age at which online testing is available as per local commissioning). As participants are self-recruited, there is no definitive way to check ages. However, they will have to enter their age before being presented with study details so there is no prior incentive to change their age.

6.1.1 Exclusion Criteria

Participants in B&H under the age of 18 and those in BNSSG under the age of 16 will not be included in this study.

6.1.2 Inclusion Criteria

Participants will be included in the interview if they meet all the following criteria:

- Users of the vending machines
- Service provider in the site a vending machine is placed
- People using the site of the vending machine

6.2 Study Procedures

6.2.1 The Study Site

The VMs are currently located at:

- Brighton Sauna
  - A sex premise for MSM.
  - 76 Grand Parade, Brighton, BN2 9JA
- Jubilee Library
  - The main public library in Brighton.
  - Jubilee Street, Brighton, BN1 1GE
- Portland Road
  - Between Wish Park Surgery and Kamson Pharmacy.
  - 191 Portland Road, Hove, BN3 5JA
- The Wellsbourne Centre
  - GP Surgery in east Brighton.
  - Whitehawk Road, Brighton, BN2 5FL
- BMECP Centre
  - A community centre for the black and minority ethnic community.
  - 10A Fleet Street, Brighton, BN1 4ZE

- 4 sites across BNSSG will be determined/decided following workshops with public contributors and stakeholders

6.2.2 Study Duration

We intend to conduct the study and collect data over a 12-month period, with the intended start date of 01/04/2022, pending ethical approval.
6.2.3 The Vending Machine

Description

In B&H the VMs have been developed as part of an ongoing Martin Fisher Foundation (MFF) project to improve HIV testing and are commissioned by B&H council. In BNSSG the VMS have been procured by Unity Sexual Health, BNSSG’s integrated sexual health service led by University Hospitals Bristol and Weston NHS Foundation Trust (UHBW).

The VMs are either wall mounted or standalone (see appendix 2) and maintained by staff at the premises and outreach workers from local sexual health services. Briefly, participants obtain information from a digital screen on the VM, input anonymous epidemiological information (age, sex, sexuality, residence in B&H, BNSSG or not, when their last STI/HIV tests was) and then type in their mobile telephone number. A numerical code is sent to them by text message which is required to release the test kit. The telephone number is stored in an encrypted format (and therefore not accessible to the study authors) in order to limit individuals to one test per fortnight and prevent secondary distribution for profit. The staff have an override facility for participants unwilling to give their mobile phone numbers, where epidemiological data can still be collected and a kit subsequently dispensed.

The VMs dispense Biosure HIV self-test kits which require a finger prick blood sample.
http://hivselftest.co.uk and STI self-sampling kits that are part of the existing provision of testing SHAC online testing service https://brightonsexualhealth.com/online-sti-testing/ which corresponds to the interface.

Data Collection

Vendlive, the online platform for managing stock and vends, records the number of tests distributed at each site. The study team has experience in interpreting the data collected by the machines. Each test kit generates an anonymous unique transaction ID code which can be tracked using NHS online databases to determine whether the STI kit has been posted back to the laboratory, if the participant has tested positive at all, and if they have engaged with treatment or care in B&H.

6.2.4 The Questionnaire

Description

Participants using the VM will be invited to complete a short, anonymous online questionnaire regarding their views and experience of using the VM and the kit, containing basic demographics - taking approximately 5 minutes to complete. The link for the questionnaire is attached to the SMS text message users currently received when obtaining a kit from the VM. They can do this at any point in their own time. In B&H, users will receive a £10 high street voucher for completing the questionnaire. In BNSSG, participants who complete the questionnaire will be entered into a cash prize draw of £100.

In B&H the online survey platform is provided by Online Surveys. BSMS has a licence for use of the site. https://www.onlinesurveys.ac.uk

In BNSSG, the online survey platform is provided by REDCap a secure online data capture system. University of Bristol(UoB) have a licence for use of the site.
https://redcap.blogs.bristol.ac.uk/

Data Collection

We aim to collect a minimum total of 150 completed questionnaires during the study period.

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6.2.5 Interviews

Description

At the end of the survey there will be an option for participants to provide contact information and details about consenting for further interview. Users will be invited to participate in short (30-minute) semi-structured interviews on their experience of use of the VM and/or for their motivations and experience of using, or not using. Interviews will be either via Microsoft teams or face to face.

With the arrangement and support of the management in each vending machine setting, a member of the study team will also approach the vending machine staff involved in the running of the machines and invite them to take part in an interview. Potential recruits will be offered the Patient Information Sheet, invited to ask questions about the study and left time to read and consider. Interested participants will be invited to sign a consent form, and verbal consent will also be recorded during the interview. The interview will take place in a discrete room provided by the setting. This recruitment method is similar to recruitment in other settings. Interviews with staff will be arranged via email and in-person contact (as above).

Recruitment

Participants will have the option to provide their email and/or phone number to be contacted to arrange a Microsoft Teams or face-to-face interview at a day and time of their choosing (Mon-Fri 9AM – 9PM).

A member of the study team (Dr Syra Dhillon and Dr Maya Gobin) will contact those who are interested and offer potential recruits the PIS, they will be invited to ask questions about the study and left time to read and consider. Interested participants will be invited to sign a consent form, alternatively verbal consent will be recorded during the interview. Face-to-face interviews will take place in a discrete room either on site of the VM or in a BSMS study room (Audrey Emerton Building). The researcher’s work will be conducted within University guidelines and the ‘Safe Lone Working Code of Practice’.

We will offer a £20 high-street voucher incentive and provide refreshments to those that wish to participate in the interview, using the approved topic guide. Email addresses and phone numbers will be destroyed once the online-questionnaire, the digital or face to face interviews, and distribution of incentives is complete.

In B&H we aim to conduct approximately 20 interviews.

In BNSSG, data collection and analysis will occur in parallel to allow for consideration of the adequacy of the sample size. The decision to end data collection will be informed by factors relating to the concept of ‘information power’24: the breadth of the aim, the sample specificity (characteristics of the participants relating to the phenomenon under study), quality and depth of the interview data and the analysis approach. Based on our previous experience in similar studies, up to 45 participants in total are anticipated to achieve information power. We will aim to conduct 45 interviews these will include 10-15 interviews per vending machine site.

Data Collection

In order to explore a range of views we will follow a purposive sampling strategy to include those across different age brackets, different gender and sexualities with a range of previous testing histories.

Interviews will be digitally recorded with consent recorded and stored securely.

In B&H, the recordings will be either be transcribed by hand, using the Microsoft Teams transcription aid or via a professional transcribing service (Essential Secretary) with whom BSMS has a confidentiality contract.
In BNSSG, the recordings will be transcribed by Bristol Transcription Services, a UoB approved transcription company and a confidentiality agreement will be signed prior to this work commencing.

6.2.7 Health Advisors

It is routine care for newly diagnosed HIV patients to visit a health advisor in SHAC at the University Hospitals Sussex. If patients disclose they were diagnosed through an HIV self-test obtained from the VM the health advisors will provide potential participants with a copy of the PIS and it will be the individual’s responsibility to contact the research team regarding participation in this study.

Reporting will be anonymous – to protect patient identity no patient identifiable information, including name, date of birth, clinic/hospital number or date of clinic review, will be disclosed.

7.0 Data Analysis

7.1 Epidemiological Data

Descriptive and inferential statistics will be used to describe the number of self-testing and self sampling kits distributed by the VM, age of participants, previous testing history and positive HIV results. The statistical software package SPSS Statistics 28 will be used for analysis.

For the data acquired through NHS records on STI test kits that get sent back to the lab and the subsequent results, similar statistical tests will take place. This will be compared in part to current data on the return rate of postal STI kits sent by SHAC.

7.2 Questionnaire responses

Similar statistics will be used to present responses to the questionnaire. The statistical software package SPSS Statistics 28 will be used for analysis. In addition free text answers will be qualitatively reviewed and examples used directly to illustrate views where relevant.

7.3 Interview transcripts

Interview transcripts will be analysed using NVivo software and a thematic analysis approach. Open coding of the transcripts will be used to generate, interpret, and analyse themes relating to the motivations for use, and non-use, of the VM and self-testing for HIV as an adjunct or alternative to conventional testing methods.

8.0 Regulatory Issues

8.1 Informed Consent

Informed consent will be gained from all study participants.

8.1.1 The Questionnaire

All questionnaire participants will be given a participant information sheet at the beginning of the questionnaire. The questionnaire will explicitly state that completion of the questionnaire implies participant’s consent to take part.

8.1.2 The Interviews

All interview participants will be given a patient information leaflet prior to consenting.
8.2 Confidentiality

8.2.1 Vending Machine Users
VM use will be anonymous – no participant identifying details such as name or date of birth will be requested. The producers of the VM will not have access to any information. All data will be stored on NHS databases, password protected.

8.2.2 Questionnaire
Completion of the online questionnaire will be anonymous - no participant identifying details such as name or date of birth will be requested.

Although participants will need to provide email and/or telephone contact details in order to receive incentives and to be contactable to arrange interviews, we will not be asking for names or date of birth and all contact information will be destroyed once their use in the study is completed.

8.2.3 Interviews
No participant identifying details such as name or date of birth will be recorded for the interview. Interviews will be conducted in private and participation will be confidential.

8.2.5 Health Advisors
It is routine care for newly diagnosed patients with HIV to visit a health advisor. If patients disclose the route of diagnosis was from the VM and self-test the health advisors will, with patient permission, inform the study team.

Reporting will be anonymous – no patient identifiable information including, name, date of birth, clinic/hospital number or date of clinic review will be disclosed to protect patient identity.

8.3 Data Management

8.3.1 Epidemiological Data
Numerical data from the VM will be stored in SPSS for analysis.

8.3.2 Questionnaire Responses
In B&H online questionnaire responses will be accessible via Online Surveys using the BSMS licence to access and generate an account.

In BNSSG online questionnaire responses will be accessible via REDCap using the UoB licence to access and generate an account.

All responses will then be stored in SPSS.

8.3.3 Interview recordings and transcripts
Recordings will be stored securely at BSMS for B&H and UoB for BNSSG, they will not be shared with study authors to protect participant anonymity. Anonymised transcripts will be stored electronically to be used for thematic analysis.

8.4 Good Clinical Practice
In line with Research Governance Framework for Health and Social Care 2005, all study authors have completed Good Clinical Practice. Dr Jaime Vera and Dr Gillian Dean are medical
consultants, highly experienced in this research field. Dr Syra Dhillon is undertaking this research project as part of her Academic FY2 project and her Global Health MSc dissertation project.

8.5 Study Funding

The funds for this study will come from the core department of Global Health and Infection at BSMS. The Martin Fisher Foundation has funded installation and maintenance of the VMs in B&H in collaboration with B&H council.

The project in BNSSG is funded by Unity Sexual Health Services, University Hospitals Bristol and Weston NHS Foundation Trust (UHBW).

9.0 Appendices

9.1 Co-investigator details

Dr Syra Dhillon is an academic FY2 doctor in the Global Health and Infection department and Brighton and Sussex Medical School. She is also undertaking a Global Health MSc, where this project will comprise her dissertation. In B&H, she will be the project lead, undertaking all data collection, analysis and dissemination under supervision of JV.

Dr Gillian Dean is a consultant in HIV and sexual health with an interest in improving access to testing and involving service users in service development. She was pivotal in developing the VMs and acts as an important gatekeeper to community champions within B&H.

Professor Jeremy Horwood, Professor of Social Sciences and Health. Jeremy will oversee the project and support the PI.

Dr Maya Gobin will carry out qualitative data collection, analysis and dissemination under the supervision of JK.

Dr Lindsey Harryman Consultant in Genitourinary Medicine, Unity Sexual Health, Bristol, South Gloucestershire and North Somerset’s integrated sexual health service led by University Hospitals Bristol and Weston NHS Foundation Trust. Lindsey is co-lead for developing and implementing the new self-testing service model.

Dr Sarah Stockwell Consultant in Genitourinary Medicine, Unity Sexual Health, Bristol, South Gloucestershire and North Somerset’s integrated sexual health service led by University Hospitals Bristol and Weston NHS Foundation Trust. Sarah is co-lead for developing and implementing the new self-testing service model.

Dr Sarah Denford, Research Fellow at Bristol Medical School, University of Bristol. Sarah will provide expertise in intervention development and optimisation.

Dr Jo Copping, Consultant in Public Health Medicine, Bristol City Council. Co-author of Bristol’s HIV Health Needs Assessment (2020). She is Bristol City Council’s lead for Sexual Health and HIV and Public Health including work within the Integrated Care System around population health, prevention and inequalities. Her team leads the commissioning of sexual health services (including PrEP) across Bristol, North Somerset and South Gloucestershire. As well a public health input, she will provide Bristol City Council support for the study including supporting the approvals for vending machine locations.
Ms Lottie Lawson, Public Health Principal (Sexual Health, Drugs & Alcohol), South Gloucestershire Council. Lottie will provide South Gloucestershire Council support for the study including support for the approvals for vending machine locations.

Mr Sam Hayward, Consultant in Public Health Medicine North Somerset Council. Sam will provide North Somerset Council support for the study including support for the approvals for the vending machine locations.

9.2 Machine Interface

10.0 References


24. McDonagh LK, Saunders JM, Cassell J, et al. Application of the COM-B model to barriers and facilitators to chlamydia testing in general practice for young people and primary


