Assessing the impact of introducing online postal self-sampling for sexually transmitted infections into sexual health provision within the UK on health inequalities, access to care and clinical outcomes (ASSIST)

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Co-Chief Investigators:
Prof Fiona Burns, f.burns@ucl.ac.uk
Dr Jo Gibbs, PhD, jo.gibbs@ucl.ac.uk

UCL Institute for Global Health
Mortimer Market Centre
off Capper Street
London WC1E 6JB

Sponsor Representative:
Mr Pushpsen Joshi,
UCLH.randd@nhs.net

Joint Research Office
(part of the Research Support Centre)
1st Floor Maple House (Suite B)
149 Tottenham Court Road
London W1T 7DN

PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated and finalised by	Reasons for update
	0.1	25 March 2021	Dr Alison Howarth; Dr Jo Gibbs; Dr Fiona Burns	Draft submission for JRO
	0.2	31 March 2021	Dr Alison Howarth; Dr Jo Gibbs; Dr Fiona Burns	Sent to Pushpsen Joshi on 10.05.21
	0.3	21 May 2021	Dr Alison Howarth; Dr Jo Gibbs; Dr Fiona Burns	Inclusion of referral to supplementary protocol
	0.4	8 June 2021	Dr Alison Howarth; Dr Jo Gibbs; Dr Fiona Burns	Inclusion of amendments to address JRO comments
	1.0	16 June 2021	Dr Alison Howarth; Dr Jo Gibbs; Dr Fiona Burns	Submission to IRAS
	2.0	29 September 2021	Dr Alison Howarth; Dr Jo Gibbs; Prof Fiona Burns	Incorporating amendment 1
	3.0	5 November 2021	Dr Alison Howarth; Dr Jo Gibbs; Prof Fiona Burns	Incorporating amendment 2
	4.0	15 February 2022	Dr Alison Howarth; Dr Jo Gibbs; Prof Fiona Burns	Incorporating amendment 3
Current	5.0	28 June 2022	Dr Alison Howarth; Dr Jo Gibbs; Prof Fiona Burns	Incorporating amendment 5

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DECLARATIONS

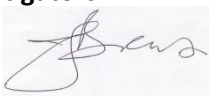
The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Sponsor.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Co-Chief Investigators:

Signature:  **Date:** 16/06/21

Print Name(in full): Professor Fiona Burns

Position: Professor in HIV medicine / Honorary Consultant

Signature:  **Date:** 16/06/21

Print Name(in full): Dr Jo Gibbs

Position: Senior Clinical Research Associate / Honorary Consultant

On behalf of the Study Sponsor:

Signature: Pushpsen Joshi **Date:** 18/06/21

Print Name(in full): Mr Pushpsen Joshi

Position: Research Governance Manager

STUDY SUMMARY

Identifiers		
IRAS Number	295506	
REC Reference No	21/SC/0223	
Sponsor Reference No	140431	
UCL Data Protection Reference No	Z6364106/2021/04/36 health research	
Full (Scientific) title	Assessing the impact of introducing online postal self-sampling for sexually transmitted infections into sexual health provision within the UK on health inequalities, access to care and clinical outcomes	
Problem studied	To assess the impact of online postal self-sampling services on health inequalities, access to care, and clinical and economic outcomes, and to identify the factors that influence the implementation and sustainability of these services	
Study Type	Theoretically informed mixed-methods evaluation of three case study areas implementing online postal self-sampling services	
Target sample size (qualitative research)	Up to 135 service users Up to 100 healthcare staff and other stakeholders	
Target sample size (quantitative research)	>5,000 service users	
STUDY TIMELINES		
Study Duration/length	39 months (including 3-month set up phase)	
Expected Start Date	September 2021	
End of Study definition and anticipated date	Key findings written up by March 2024	
Key Study milestones	First participant to be recruited into study by August 2021 Data collection completed by September 2023	
FUNDING & other support		
Funding	NIHR Health Services and Delivery Research (HS&DR) Programme NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) University of Southampton, Alpha House, Enterprise Road, Southampton, SO16 7NS	
KEY STUDY CONTACTS		
Co-Chief Investigators	Prof Fiona Burns T: 07958 549860 E: f.burns@ucl.ac.uk	Dr Jo Gibbs T: 07725 528168 E: jo.gibbs@ucl.ac.uk
Study Coordinator	Dr Alison Howarth T: 020 3108 2070 E: alison.howarth@ucl.ac.uk	
Sponsor	Mr Pushpsen Joshi T: 020 3447 5696 E: UCLH.randd@nhs.net	
Funder	NIHR T: 02380 597501 E: netspostawardsetup@nihr.ac.uk	
Committees	**Study Steering Committee**	

	An independent (75% of membership) committee appointed by the NIHR to provide overall supervision for a project on behalf of the Sponsor and Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice: Professor Flis Henwood – chair (F.Henwood@brighton.ac.uk) Professor Graham Hart (g.hart@ucl.ac.uk) Dr Ana Manzano (A.Manzano@leeds.ac.uk) Dr Joanna Thorn (Joanna.Thorn@bristol.ac.uk) Ms Sarah Fisher (sarah100fisher@gmail.com)

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

KEY WORDS

Implementation; Realist evaluation; Online postal self-sampling; HIV; Sexually transmitted infection; Sexual health; Digital

LIST OF ABBREVIATIONS

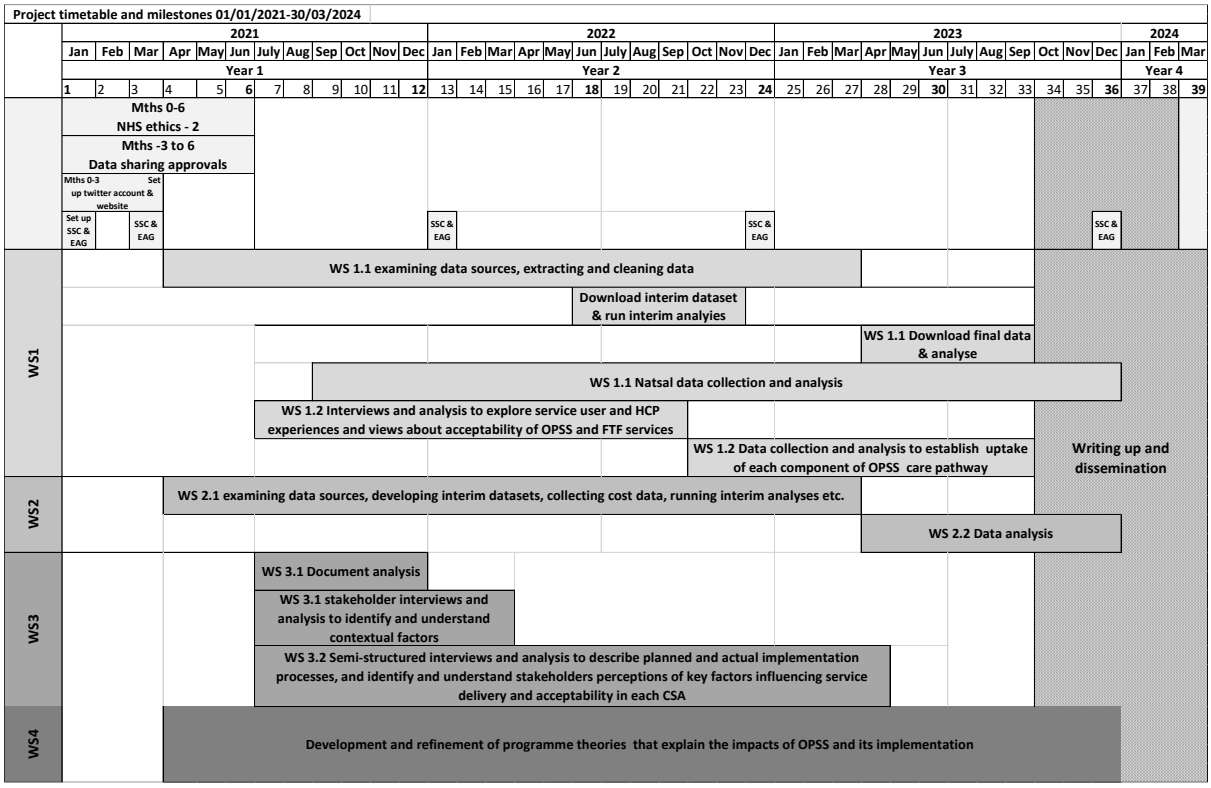
BASHH	British Association for Sexual Health & HIV
CI	Chief Investigator
CMOCs	Context-mechanism-outcome configurations
CNWL	Central and North West London NHS Foundation Trust
CQC	Care Quality Commission
CRN	Clinical Research Network
F2F	Face-to-face
GDPR	General Data Protection Regulation
GUMCAD	Genitourinary Medicine Clinic Activity Dataset
HIV	Human immunodeficiency virus
HRA	Health Research Authority
HS&DR	Health Services and Delivery Research
IMD	Indices of Multiple Deprivation
LGBTQ+	Lesbian, gay, bisexual, transgender and questioning
MFT	Managed File Transfer
NaSH	National Sexual Health System
Natsal	National Surveys of Sexual Attitudes and Lifestyles
NHS	National Health Service
NICE	National Institute for Health & Care Excellence
OPSS	Online postal self-sampling
PI	Principle Investigator
PIS	Participant Information Sheet
PPIE	Patient and Public Involvement and Engagement
REC	Research Ethics committee
REDcap	Research Electronic Data Capture
SHL	Sexual Health London
SOP	Standard operating procedure
STI	Sexually transmitted infection
THT	Terrence Higgins Trust
UCL	University College London
UCLH	University College London Hospitals NHS Foundation Trust
UK	United Kingdom

CONTENTS

1 INTRODUCTION

Sexual health is a UK public health priority. Numbers of diagnoses of sexually transmitted infections (STIs) are increasing in England and Scotland (1,2,12), causing significant morbidity and substantial health costs (3). There is growing unmet need, STI diagnoses and antibiotic resistance are increasing, yet funding has reduced and services are fragmented (1,4–7). Provision of online postal self-sampling (OPSS) for STIs and HIV is seen as a means to address these challenges. There is an active drive to channel people who are asymptomatic away from face-to-face (F2F) services and towards OPSS (8), with F2F services being reduced or centralised in many areas (4,7), yet the effectiveness and cost-effectiveness of this approach is unknown. The urgent need for evaluation of OPSS increased further as a result of the COVID-19 pandemic. Sexual and reproductive health service provision has dramatically altered in terms of both initial access (with many walk-in services no longer being available), and remote (e.g. phone) consultations being introduced as standard methods of service delivery in clinic-based services. In this study, we refer to "clinic-based" services as those involving assessment by a healthcare professional whether face-to-face, by telephone or video.

This study will conduct a wide-ranging evaluation of OPSS services to determine their impact on health inequalities, access, clinical and public health outcomes, service delivery, and other healthcare services (7,9,10). It will provide transferable learning to similar regional sexual health online services, across the UK and internationally, as well as other Local Authority/NHS services nationwide. It will evaluate the effectiveness and cost-effectiveness of this digital intervention, and identify what works well, for whom, and when. In addition, the evaluation will provide much needed evidence to develop national quality measures and standards of care for OPSS services. This evaluation goes beyond asking 'does it work', by identifying what works for whom, why and in which contexts to inform future service delivery.



2 BACKGROUND AND RATIONALE

Sexual health is a UK public health priority. In 2019, 468,342 new STI diagnoses were made at sexual health services in England (1); 17,336 diagnoses of genital chlamydia and 3,776 diagnoses of gonorrhoea were reported in Scotland (2); and, in the UK, a total of 4,453 new cases of HIV were reported in 2018 (13); all conditions associated with significant morbidity and substantial health costs. The total number of new STI diagnoses increased by 5% from 2018-2019 in England, and there was 6% increase in chlamydia and 17% increase in gonorrhoea over the same period in Scotland (1,2). Increasing antimicrobial resistance is also reported (15). STIs disproportionately affect those with barriers to accessing services (16,17) and large health inequalities exist, with young people, lesbian, gay, bisexual, trans, queer or questioning (LGBTQ+), ethnic minorities and those living in more deprived areas disproportionately affected by poor sexual health (18).

Sexual health services are suffering due to fragmented commissioning and service delivery (4,19). This has been compounded by large scale disinvestment in sexual health, at a time of increasing unmet need (4). These challenges were highlighted in the 2019 UK House of Commons Health Select Committee Report, which noted the concerning trends and inequalities in access to sexual health care and called for a new national strategy to improve access to STI prevention, screening and treatment (7).

In response to the increase in demand and reduced resources, and in line with NHS digital- and self-managed health strategies in England (20) and Scotland (21,22), novel models of care have been introduced (4). These include online services for: triage, appointment booking, OPSS for STIs and HIV, and contraception/treatment provision.

There is an overwhelming consensus that to meet healthcare's triple aim of better health, better care and reduced costs, health care systems must embrace digital technology (23). However, despite substantial investment in development, successful implementation of digital health interventions into routine clinical practice is limited, and there are concerns about the lack of robust evaluation of these interventions (9). In addition, even when a digital innovation is shown to work, there are challenges in terms of replicating it and building the infrastructure to support implementation cross a whole healthcare system (24).

In sexual health, online services may improve access, improve service user experience, optimise use of F2Fservices, and reduce cost (25). Or they may increase health inequalities, worsen health outcomes through lack of opportunistic screening and case finding, missed diagnoses, lack of safeguarding, and ineffective treatment due to fragmented pathways or lack of understanding, e.g., of results or how to take treatment (10). OPSS may also displace costs to other parts of the system and introduce new unanticipated costs.

The inclusion of OPSS services within service specifications is recommended within English national guidance (26). There is an active drive to channel people who are asymptomatic from F2F to online services, with F2F services being reduced or centralised in many areas (4). The number of online chlamydia tests has increased dramatically over the past 10 years (27-29), with 20.2% of all tests in 15-24 year olds in 2019 being done via OPSS services, and an increase of 22.2% between 2018-2019 (1). Since it was first introduced, testing has been expanded to encompass a broader range of STIs (e.g. gonorrhoea, syphilis and HIV). The effectiveness and cost-effectiveness of this approach is unknown, and it is not known whether asymptomatic people with other needs (e.g. safe-guarding, contraception, HIV prevention, vaccination) are being sign-posted and followed-up appropriately. In 2020, as a result of significant changes in service delivery due to the COVID-19 pandemic, there was a two-fold increase in internet consultation since April 2020. Approximately 26% of consultations were delivered online between January-March 2020, and this rose to 45% in April 2020 and continued to be raised in May (46%) and June (41%) (14). At the same time, the proportion of STI & HIV testing accessed via OPSS increased substantially, rising from approximately 22% in January-March 2020 to nearly 60% in April 2020 (14).

Existing UK evidence on OPSS is often based on implementation in a single service (30–33), with the focus on assessing uptake rather than clinical (e.g. treatment, partner notification) outcomes. Data from a single centre shows OPSS can increase total testing activity, and that it is possible to shift simple STI testing online, freeing up clinic services for more complex cases (34). But initial evidence suggests OPSS is accessed by a higher proportion of people who are of white ethnicity (31,32,35), female and living in less deprived areas (32,35). Return rates for online STI tests vary (30,32,33,35) with non-return associated with being a heterosexual male, symptomatic, and living in more deprived areas (30).

Where OPSS treatment outcomes (e.g. proportion of people known to have received treatment) are reported, they are worryingly low, e.g. 46% (n=172/382) (31). Preliminary evidence suggests that time to treatment may be longer in those diagnosed online (31), increasing STI transmission potential. Virtually no data exist on partner notification outcomes (36), an intervention known to be more effective at reducing STI transmission than targeting wider populations for screening (37).

Costs and outcomes of OPSS services compared to clinic-based services are poorly understood (38–40). One US study provided evidence that an OPSS service could be cost-effective, but this was a small study based on modelled data (38). Online sexual health services also need to be considered as part of the changing sexual health economy and not simply as a 'bolt on' or standalone service (41).

Within the UK, the combination of poor treatment outcomes and potentially poor partner notification outcomes could have an adverse effect on clinical sequelae and transmission dynamics. This could therefore negatively impact public health outcomes and cost effectiveness of OPSS services. There are concerns that the most disadvantaged and vulnerable are likely to be most at risk of poor outcomes. Public Health England have highlighted 'a critical need to evaluate the impact of changes in service delivery on health inequalities…' (14).

3 AIMS AND OBJECTIVES

Overarching aim: to assess the impact of OPSS services on health inequalities, access to care, and clinical and economic outcomes, and to identify the factors that influence the implementation and sustainability of OPSS services.

Implementation involves all activities that occur between making an adoption commitment and the time that an innovation either becomes part of the organizational routine, ceases to be new, or is abandoned.

Our overarching aim will be achieved through four inter-linking workstreams (***Appendix 1***). The objectives for each workstream are described below.

Primary Objectives

Workstream 1 objectives are to:

- establish what has been the change in access to care and service delivery as a consequence of the introduction of OPSS
- determine the impact of OPSS services on health inequalities and key clinical and public health outcomes
- determine who is accessing online services and clinic-based services, in what context, and why
- explore user and provider experience of OPSS services

Workstream 2 objectives are to:

- analyse the costs and outcomes associated with OPSS services compared to clinic-based services
- explore impacts on health equity associated with different models of service provision

Workstream 3 objectives are to:

- identify, characterise and understand the following implementation factors and how they relate to observed variation in uptake, use, clinical outcomes, costs and overall impact on health inequalities and public health:
    1. key contextual factors for each case study area
    2. planned and actual implementation interventions in each case study area
    3. stakeholder perceptions of key factors influencing service delivery, acceptability and observed outcomes

Workstream 4 objective is to:

- bring together the data from each workstream into a coherent whole; it will ensure that the initial programme theories of impact and implementation of OPSS are iteratively refined into more detailed realist programme theories using relevant data from across all workstreams

4 STUDY DESIGN & METHODS OF DATA COLLECTION

Summary

Over 39 months (1 January 2021 to 31 March 2024), a theoretically informed mixed-methods evaluation of three case study areas (Birmingham, London and Sheffiled) implementing OPSS services will be conducted (42). The areas all serve diverse populations in terms of socio-economic status and proportion of people from ethnic minorities, LGBTQ+ and young people, enabling investigation of the impact of OPSS in conjunction with the wider determinants of health. The variation in time since the decision to provide OPSS across the case study areas presents a unique opportunity to understand the processes involved in the embedding and integration of an intervention.

The target population is sexual health service users accessing online and clinic-based services within the 3 case study areas, with sub analyses for young people, LGBTQ+ and people from ethnic minorities.

Theoretical framework

This study uses realist evaluation methodology. Realist evaluation is a theory driven form of evaluation which focuses on explaining how and why interventions produce outcomes under different contexts (43). These explanations are expressed in the form of context, mechanism, outcome configurations, that explicitly link the influence of context on mechanisms which then produces outcomes (43).

The realist evaluation approach is well suited to this project because OPSS has been implemented and run very differently in the UK with varying results. In addition, some services have been in place for more than four years and others are just starting. In other words, different OPSSs, in different settings and delivered in different ways have the potential to produce different outcomes. Our experience of evaluating such ‘messy’ interventions is that realist evaluation is an ideal approach to use.

Our implementation evaluation (see below: ***Workstream 3***) is based on Normalisation Process Theory (44). Normalisation process theory is a substantive middle-range theory that will be used as the starting point to develop the initial programme theory for the implementation of OPSS. It focuses on the work required for initiating, integrating and embedding (normalising) OPSS into routine practices (45,48), recognising the contingent and iterative nature of implementation. The role of context and adaptations of OPSS to different settings will be explored (46).

The above theories were used in developing our data collection mechanisms and are the candidate theories for data analysis, which will be iteratively informed by the data that are collected.

Settings

Our case study areas are selected to maximise diversity in geography, demographics, time since introducing OPSS services, and contextual factors known to be important in implementation at macro level (including policy priorities, commissioning systems, legislation, financial and accountability structures). The areas provide consistency in their urban nature, with all serving diverse populations in terms of socio-economic status and proportion of ethnic minority, LGBQT+ and young people, enabling investigation of the impact of OPSS in conjunction with the wider determinants of health (see ***Appendix 2***):

- Birmingham and Solihull
- London
- Sheffield

We will collect clinical data on use of OPSS services from across London that is captured by Sexual Health London (SHL). SHL is a consortium led by Preventx Limited which provides the online service; the data controller is City of London; and the clinical governance lies with Chelsea and Westminster NHS Foundation Trust.

Within London, two districts have been purposively selected for in-depth evaluation to capture areas that have high representation of our populations of interest (as above) including a high index of deprivation. These districts are served by:

- Central and North West London NHS Foundation Trust (CNWL)
- All East Sexual Health, Barts Health NHS Trust

In London, detailed clinic level data collection and recruitment for qualitative work will mainly occur within the above two areas to ensure our methods are feasible and have the depth of data required. Stakeholders and healthcare professionals from Chelsea and Westminster Hospital NHS Foundation Trust, City of London and Preventx Limited will also be invited to participate in qualitative interviews in London, as key collaborators on the delivery of Sexual Health London.

Overview of workstreams

Our study comprises four inter-linking workstreams which are summarised below (and described in more detail on pp 12-18):

Workstreams 1 and 2 provide an impact evaluation of the effect of OPSS on access to care, health inequalities and clinical and economic outcomes:

> ***Workstream 1*** examines the impact of introducing OPSS services on health inequalities, access and clinical outcomes, using quantitative analysis of existing surveillance data, clinic/OPSS datasets, and qualitative interviews with service users and healthcare professionals.
>
> ***Workstream 2*** analyses the costs and outcomes associated with OPSS services compared to clinic-based services, through undertaking an economic analysis based on the resource use, clinical outcomes and cost data collected from each case study area.

Workstream 3 is an in-depth evaluation of the implementation process of OPSS. It describes and evaluates how implementation processes and service delivery models contribute to observed variation in clinical- and cost-effectiveness. It uses document analysis, in-depth interviews, contextual observation and normalisation process theory.

Workstream 4 ensures that the initial programme theories of impact and implementation of OPSS are iteratively refined into more detailed realist programme theories using relevant data from across all workstreams (11). It will start with one or more initial programme theories that explain impact and implementation. It will iteratively use and synthesize the data from across workstreams 1, 2 and 3 to further develop and refine our initial programme theories (11) over the course of the evaluation. It will allow us to say 'what works, for whom and under what circumstances' for the impacts and in implementing and sustaining OPSS services.

Workstream 1 (Impact evaluation)

Aim: to determine the impact of OPSS on health inequalities, access to care and clinical outcomes to establish what works for whom, in what contexts, to what extent, how and why.

Workstream 1 is divided into Workstream 1.1 (Measurement of impact of OPSS on health inequalities, access, clinical and public health outcomes) and Workstream 1.2 (Service user and healthcare professional experiences and views about acceptability of OPSS and Face-to face services).

Workstream 1.1 - Measurement of impact of OPSS on health inequalities, access, clinical and public health outcomes

Workstream 1.1 – Design and methods

1. Use of routinely collected data (e.g. National Sexual Health system and clinic datasets) within each case study area to determine the demographics and key clinical outcomes of people accessing OPSS services and clinic-based sexual health services, and how this has changed over time (2015-2022) (see example datasets, ***Appendix 3***). The data will be examined to explore whether change differed between the areas, and whether change in clinical outcomes differed by population characteristics (reflecting a change in health inequality). Access to routinely collected data from national datasets requires Public Health England Office for Data Release approval, so this part of the study is described in a supplementary protocol v1.0 08.06.21.
2. Analyses of detailed behavioural and biological data within each case study area pre and post the implementation of OPSS services, including clinic and eService level, and data from large population surveys (e.g. British National Surveys of Sexual Attitudes and Lifestyles (www.natsal.ac.uk)). This will enable evaluation of triage/safe-guarding systems and impact on wider sexual health needs (e.g. HIV/STI prevention, vaccination, contraception). Population level data from outside sexual health settings will help contextualize health inequality and clinical findings.

Workstream 1.1 – Outcome measures

The primary outcomes are chlamydia, gonorrhoea, syphilis and HIV testing activity, chosen because they are important, captured by routinely collected data and sufficiently common to detect change over time. The analysis will determine whether the introduction of OPSS services is associated with overall changes in these activity measures and with differential change according to population characteristics (including age, gender, ethnicity, sexuality and Indices of Multiple Deprivation (IMD)), reflecting a change in health inequality.

Secondary outcome measures will capture the impact the introduction of OPSS has had on access to care, time to treatment, and other key public health and sexual health outcomes. These will include:

- Rates of new diagnoses of bacterial STIs and HIV

- Proportion of people diagnosed with chlamydia receiving treatment
- Proportion of people testing positive for gonorrhoea who receive appropriate treatment
- Proportion of people testing positive for gonorrhoea who have a test of cure
- Proportion of people with reactive tests who have confirmatory tests for HIV and syphilis
- Partner notification rates for those diagnosed with chlamydia, gonorrhoea and HIV

For each of these outcomes, our analysis will explore whether change differs between the areas during the time-period being analysed, and whether change in clinical outcomes differ by population characteristics (including age, gender, ethnicity, sexuality and IMD).

Workstream 1.1 – Sample size

Three contrasting settings have been selected to serve as case studies. Our key objective which is most 'demanding' of the data, and hence drives the power calculation, is the detection of differences in the change in the primary outcomes after introduction of OPSS by key population characteristics. Data will be obtained over a continuous period before, during and after implementation of OPSS. However, to simplify the power calculation (and to be conservative) the comparison of one-year periods before and after OPSS are considered (different for each area).

As an example, analysis of data from one area is considered - Birmingham, and the testing rate for STIs excluding chlamydia for which data are publicly available. The rate changed from 193 per 1000 population in 2014 (pre OPSS) to 198 per 1000 in 2016 (post OPSS). With around 140,000 tests per year there is more than 99% power to detect a change as small as 1% in the proportion of those testing with a particular characteristic (e.g. ethnic minority group or gender) whatever the proportion before OPSS.

Workstream 1.1 – Data collection

Routinely collected data is captured by existing surveillance systems in England (e.g. Chlamydia Testing Activity Dataset, GUMCAD STI surveillance, HIV self-sampling dataset).

Data on clinical outcomes will be collected from routine information held by service providers in the case study areas. In each area, service user information is collected on electronic patient record systems and website databases. For each area, work will be undertaken to specify the fields to be included in the data extraction from service user records and website databases.

The decennial **National Surveys of Sexual Attitudes and Lifestyles** ('Natsal') are among the largest surveys of sexual behaviour in the world. The surveys use probability sampling to randomly select people living in Britain to take part, which means that the results are broadly representative of the British general population. Natsal-3 was undertaken in 2010-2012, and Natsal-4 data collection will commence in May 2022 (for 18 months), with the plan of an interim dataset being made available in 2023. In addition, two Natsal-COVID web-panel surveys have been developed to measure the impact of COVID-19 on sexual behaviour and health, including the use, and demand for, sexual and reproductive health services in Britain. The first survey ran from 31st July to 10th August 2020, and the second survey will run from the end of March 2021 for a similar length.

Workstream 1.2 - Service user and healthcare professional experiences and views about acceptability of OPSS and face-to face services

Workstream 1.2 – Design, methods and data collection

The following mixed-methods approach will be taken to explore and understand the impact of the introduction of OPSS services on acceptability of sexual health services (OPSS and clinic-based), user and provider experience and user requirements of sexual health services, as well as why some potential OPSS users opt to use clinic-based services:

1. Quantitative: Establish the uptake of the different components of the clinical care pathways, e.g. ordering vs. returning of test-kits, and how this differs according to age, gender, ethnicity, sexuality and IMD (49), using OPSS service level and clinic level data.
2. Qualitative: Interview previous users of OPSS (*10-15 per case study area*), users of clinic-based services who would be eligible to use OPSS (*10-15 per area*) and service users who have used both (*10-15 per area*). Interviews will be conducted F2F, by telephone or by video, by a qualified qualitative researcher. The following quotas will be used for each type of service user:

   Primary quotas
   - 7-10 men aged ≤ 24 years, 3-5 men aged >24 years
   - 7-10 women aged ≤ 24 years, 3-5 women aged >24 years
   - 3-5 gender diverse people

   Secondary quotas
   - 7-10 patients from ethnic minority backgrounds
   - 3-5 men who have sex with men

   Following a brief pre-interview questionnaire (***Appendix 4***) to collect background data, the interviews will explore the user's own experiences in different contexts (e.g. testing positive for an STI, contact of infection, routine screen), as well as using scenarios to explore how different contexts may impact on acceptability and use. The contents of the interviews will also be informed by the data patterns discovered from Workstream 1.1 and also our initial programme theory. For example, if from Workstream 1.1 our initial analyses indicate that in a particular area, there is a very low uptake of OPSS, then data will be sought to help understand why. The interviews will allow us to explore if low uptake reflects factors relating to the user such as digital literacy, or presence of other needs, or for example how OPSS is offered by services.

   Similarly, if our initial programme theory suggests that people may not wish to use OPSS because using it is too time consuming and complicated, then data will be deliberately sought out data to understand on what this is based and what if anything could be done to overcome these concerns.

   It is anticipated that the interviews will also explore users' experiences of the whole online postal self-sampling journey and what influenced their decisions to access testing through OPSS and/or clinic-based services, whether their needs were addressed, and if/how they could be improved. Service users who have used both will be asked to compare their experiences and what led them to use either online postal self-sampling or face-to-face services in each circumstance. Interviews will also explore how regularly face-to-face and or online services are used and if the availability of online services has influenced the frequency of their use of testing services.

   Interviews with healthcare professional interviews (*10-15 per area*) will explore experiences and views about the acceptability of OPSS and clinic-based services and will also be responsive to findings from earlier parts of the study.

Workstream1.2 – Outputs

The outputs for Workstream 1.2 will be (i) an understanding of the uptake of the different components of the OPSS and clinic-based clinical care pathways; and (ii) an in-depth understanding of service user and healthcare professional experience of OPSS and clinic-based services since the introduction of OPSS services.

Workstream 2 (Economic evaluation)

Aim: to evaluate the cost-effectiveness of OPSS services, by comparing costs and outcomes for OPSS and clinic-based services.

Workstream 2 – Design and methods

The economic analysis will analyse the costs and outcomes associated with OPSS services compared to clinic-based services. If OPSS services are effective in improving clinical outcomes for patients, there are likely to be important cost implications for the healthcare sector. Online sexual health services are part of the changing sexual health economy and not simply a 'bolt on' or standalone service (41).

The primary base case analysis will therefore adopt a healthcare perspective, in keeping with NICE guidance (50) and in line with the focus of the study on different models of care delivery (51,52). This workstream will involve a cross-sectional analysis of routinely collected data on STI and HIV testing activity from OPSS and clinic-based services in the case study areas. A secondary analysis will examine the health equity impacts associated with different types of service provision, in terms of age, gender, ethnicity, sexuality and indices of multiple deprivation, using methods which are currently being refined (53,54).

Workstream 2 – Data collection

Resource use and cost data will be collected from each area to estimate the overall costs associated with OPSS services compared to clinic-based services. The cost data to be collected will include: (i) cost of the self-sampling kits; (ii) costs associated with the dispatch and postage of kits; (iii) laboratory costs; (iv) the costs associated with the maintenance of websites etc. for online provision; (v) clinic costs associated with consultations; (vi) costs associated with test processing, result notification and partner notification; and (vii) treatment costs for index patients and partners.

Information on unit costs or prices will be sourced to attach to each resource use item using published information (e.g. (55)). Where necessary, local cost information for each area will also be obtained from accounting systems within finance departments, service and finance leads, and laboratory managers.

Data on patient resource use and clinical outcomes will be collected as per Workstream 1.1. Resource use data requested from service providers will include: clinic services accessed by patients, consumption of test kits, test processing, confirmatory testing activity, follow up activity, treatment, and partner notification. Patient outcomes will be collected from routine information and will include testing uptake, test results, appropriate treatment, partner identification and treatment.

Workstream 3 (Implementation evaluation)

Aim: to identify, characterise and understand how implementation processes and service delivery models contribute to observed variation in clinical and cost-effectiveness and impact on health inequalities of OPSS, with a view to informing sexual health policy in this area, including future rollouts of similar services.

Workstream 3 – Design and methods

Our initial programme theory, based on normalisation process theory, posits that at each stage of normalisation, (initiation, embedding and integration), the 4 constructs of coherence, cognitive participation, collective action and reflexive monitoring will predict and explain observed actions and outcomes. Normalisation process theory recognises that normalisation is a non-linear, iterative and contingent process. This initial programme theory will be used to inform the data that are needed. It will also be used to integrate the data gathered to understand and explain how enacted implementation processes alter contextual factors, which in turn 'trigger' causal mechanisms to cause the observed variation in quantitative outcomes of uptake, use, clinical and economic outcomes, and impact on health inequalities (see Logic model, see ***Appendix 5***). These data will be gathered from the perspectives of provider and users at each stage of implementation.

Workstream 3 – Data collection

Workstream 3 is divided into two sections which seek to address its objectives to identify and understand (i) key contextual factors for each case study area (Workstream 3.1); (ii) planned and actual implementation interventions in each case study area, and stakeholder perceptions of key factors influencing service delivery, acceptability and observed outcomes (Workstream 3.2).

Sampling and numbers interviewed will be driven by the logic of our programme theory and achieving data saturation, but estimated numbers of participants have been provided for each sub-workstream. Some interviewees will be able to provide data addressing all three sub-workstreams, whereas others will only provide data pertaining to one or two of them. Interviewees may be interviewed more than once, and topic guides will be adapted accordingly. Interviews will be conducted F2F, by telephone or by video, by a qualified qualitative researcher.

Workstream 3.1: Contextual drivers

Document analysis and interviews with key informants / stakeholders (commissioners (England), clinicians, health advisors, voluntary sector) will identify and map the intervention components and actions required for incorporation and normalisation within a service. The factors that influence this and OPSS outcomes will be identified, e.g. characteristics of the local and national contexts and changes in patient flow (see Logic model, ***Appendix 5***).

Document analysis will utilise (i) national and local policy and local authority minutes; (ii) service specification, strategy documents, and consultation documents; and (iii) service-level minutes from management meetings and consultant meetings that describe the decisions around how OPSS was provided and sustained.

Key informant/stakeholder interviews (*5-10 per case study area*) with people (including if possible the lead commissioner and the clinical lead for the online service) involved in the decision to offer OPSS as part of a service (historical) in addition to contemporaneous perspectives on the contextual factors perceived to influence the implementation process.

The interviews will address the following questions:

a) What were the drivers for deciding to start and continue to provide OPSS?

b) What contextual factors enabled or inhibited the set-up of the service and its continued use and why?

Workstream 3.2: Planned and actual implementation processes

Semi-structured interviews with NHS Board members/commissioners (*6 across all areas*), the tendering team (*8-10 across all areas*), clinical leads, service managers and clinical healthcare professionals who came together to decide how to deliver OPSS (*10-12 across all areas*). Interviews will be used to explore the provider experience of implementing, working within and with OPSS services.

Interviews will address the following questions:

a) What processes were devised to implement OPSS and why?

b) What processes were actually used to implement OPSS and how and why did they impact on initiation, embedding and integration?

c) What were the key factors influencing service delivery and acceptability?

d) What were people's experiences of providing an OPSS service?

Documents will be collected that pertain to the planned and actual implementation process including relevant local authority minutes, tender documents and annual service reviews.

Contextual observation that involves brief periods of work shadowing will be used with a smaller number of healthcare professionals and administrative staff (*max 3-5 per area*) to better understand

the actions and adaptation required to fit OPSS with work practices and their lived experiences of providing the OPSS journey. Handwritten field notes will record day-to-day work practices and information about online services and will be written up in narrative form. Contextual observations will comprise:

(i) In person observation of healthcare professionals during clinical consultations

(ii) Think aloud exercises about OPSS consultation scenarios with healthcare professionals (for example, with someone notified they are a contact of someone who has a STI; a routine screen; someone with symptoms or who will find out they have tested positive for chlamydia, HIV)

(iii) Observation and think aloud exercises with administrative staff about managing clinical records and/or administrative tasks (the observer will position themselves so as not to see the clinical records or staff will use 'dummy records' to demonstrate processes)

(iv) Observation of how information about online services features in the physical space of clinics (for example, how prominent it is and whether it is up to date).

The specific observations will be tailored to each clinic setting, in consultation with service professionals in each setting. Contextual observation will not include observation of patient identifiable data or remote consultations with service users.

Workstream 3 – Outcome

The outcome of this workstream will be an understanding of what services have done or would need to do for OPSS to be part of routine practice, including implications for patient flow and service model (e.g. to augment or replace clinic-based services), and an understanding of how implementation processes and service delivery models impact differentially on health inequalities and underserved or vulnerable populations.

Workstream 4 (Development of programme theories)

Workstream 4 runs alongside the other workstreams and brings together the data from each into a coherent whole. In other words, the focus of Workstream 4 is to ensure that the initial programme theories of impact and implementation of OPSS are iteratively refined into more detailed realist programme theories using relevant data from across all workstreams.

Workstream 4 – Design and methods

As is expected in any realist evaluation, at the start of the evaluation the initial programme theories will be developed (11) – one for the impact of OPSS and another related to its implementation. The initial programme theories will be developed by the project team drawing on the team's content expertise of the topic area and implementation (and especially normalisation process theory). They will set out how and why OPSS is thought to 'work' to generate the outcome(s) or impacts of interest. As mentioned above, our initial programme theory of implementation will be based on normalisation process theory. Our theories will be progressively refined over the course of the evaluation and 're-cast' in realist terms using relevant data drawn from all of the work streams. In other words, they will be developed such that they describe the contexts in which, populations for which, and main mechanisms by which, particular outcomes are, or are expected to be, achieved.

Workstream 4 – Data collection

Data to inform our interpretation of the relationships between contexts (C), mechanisms (M) and outcomes (O) will be sought across the different data sources from each workstream (e.g. mechanisms inferred from one source could help explain the way contexts influenced outcomes in a different source). Synthesising data from different sources is often necessary to compile CMO configurations, since not all parts of the configurations will always be found in the same source.

5 STUDY SCHEDULE

The study will begin on 1st April 2021 and end on 31st March 2024 which is the 36-month period when staff are fully funded to conduct the study. Data collection will commence once approvals are in place.

When service users recruited in clinic or via social media volunteer to take part in an interview, a member of the research team will contact them by telephone, email or encrypted online messaging service (e.g. WhatsApp) (according to preference) within a week. The researcher will determine eligibility, explain the study and arrange a convenient time for the interview.

Service users recruited online will provide information to determine eligibility using a secure online form. A member of the research team will contact them by telephone, email or encrypted online messaging service (e.g. WhatsApp) (according to preference) within a week to explain the study and arrange a convenient time for the interview. The online information will explain that not all interview volunteers will be contacted.

Service user interviews will take 60-90 minutes and service users will be interviewed only once. Healthcare staff and stakeholders will take 45-60 minutes and participants may be interviewed more than once if they consent to be re-contacted about a second interview.

Interview participants will be able to re-consider taking part in the study by cancelling the interview appointment, or any time during the interview, or within 4 weeks of the interview taking place (after which time the transcripts will be incorporated into analysis) by contacting the research team.

6 ELIGIBILITY CRITERIA

6.1 Inclusion Criteria

Sexual health service users aged 16 years and older, who have accessed online and/or clinic-based services within the past 12 months within the three case study areas.

Healthcare professionals, staff, commissioners and other stakeholders involved in implementation of OPSS services within the three case study areas.

6.2 Exclusion Criteria

Those unable to give fully informed consent or with insufficient understanding of English will not be included.

7 RECRUITMENT

The following section describes how participants will be recruited for interviews in Workstream 1.2 and Workstream 3.

Workstream 1 (Impact evaluation)

Workstream 1.2 - Service user and healthcare professional experiences and views about acceptability of OPSS and clinic-based services

Service user interviews

Three different populations of services users will be recruited:

- Users of clinic-based services (*10-15 per area*)
- Users of online postal self-sampling services (*10-15 per area*)
- Service users who have used both (*10-15 per area*)

Users of clinic-based services will be identified and recruited by a member of the healthcare team on the day of their consultation (which may be conducted face-to-face, by telephone or by video). Targeted responsive recruitment of specific patient profiles within clinics will include understanding and tailoring recruitment processes to local inter-disciplinary teams, providing regular feedback on relative recruitment success, and iteratively developing responsive action plans. Where research nurses or clinical trial practitioners are available, they are likely to support patient identification and recruitment, however elsewhere reception, nursing or medical staff may assist in this process. The first name and preferred contact details for each service user identified will be emailed to the research team at UCL using nhs.net email accounts.

Users of online postal self-sampling services only will be recruited via (i) information posted on the OPSS website with a link taking them to an online form (held securely within the UCL Data Safe Haven) where they will be asked to complete their contact details and screening information; and (ii) advertisements using social media and the study website, and local community settings (***Appendix 6***). They will email the research team at UCL with their first name and preferred contact information.

Service users who have accessed both types of service will be recruited using all of the methods described above.

When a member of the research team contacts service users recruited in clinic or via social media to explain the study, they will check eligibility using a short screening questionnaire (***Appendix 7***) in order to fulfil the sampling criteria according to age, gender, ethnicity, sexuality and OPSS service usage. Service users recruited via an OPSS website will provide information relating to eligibility and the sampling criteria when they submit their contact details. A member of the research team will contact those who are eligible and fulfil the sampling criteria to explain the study.

Interviews will be conducted at a mutually convenient time either F2F on clinic or university premises or via phone, or online meeting (e.g. Microsoft Teams, Skype) according to participant preference. It is expected that most interviews will take 60-90 minutes. All interviews throughout the programme will be digitally recorded, transcribed verbatim by professional services, and fully anonymised. Participants will be reimbursed £30/ interview.

Healthcare professional interviews

Healthcare professional interviews (*10-15 per area*) exploring experiences and views about acceptability of OPSS and clinic-based services will also be responsive to findings from earlier parts of the study. If initial data suggest that healthcare professionals may not wish to provide OPSS because using it is complicated and time-consuming, then data will be deliberately sought to explore and test this. It is anticipated that the interviews will also explore what influences their preference to providing testing through online services (or not) and/or clinic-based services, whether their opinions and experiences were sought and or addressed and if/how they could be improved. These interviews link with those in Workstream 3.2 (as below).

Workstream 3 (Implementation evaluation)

Participants for Workstream 3 will be recruited purposively to ensure a balance of perspectives from across the two study areas from a range of different stakeholders (as detailed below), according to their availability and willingness to take part. Participants may take part in more than one interview if they consent to do so.

Workstream 3.1: Contextual drivers

Key informant/stakeholder interviews (*5-10 per area*) with people involved in setting up and implementing OPSS.

Workstream 3.2: Planned and actual implementation processes

Semi-structured interviews with NHS Board members/commissioners (*6 across all areas*), the tendering team (*8-10 across all areas*), clinical leads, service managers and clinical healthcare professionals who came together to decide how to deliver OPSS (*10-12 across all areas*).

Contextual observation with a range of already identified members of NHS staff (*max 3-5 per area* which are likely to include a member of the administrative staff, a health adviser and a nurse/clinician) who will be approached by a member of the research team via email.

8 CONSENT

Service users

Users of clinic-based services will be identified and recruited by a member of the healthcare team on the day of their consultation (which may be conducted face-to-face, by telephone or by video). The healthcare team will provide an information leaflet (***Appendix 8***) and explain that participation in the interview is voluntary and will take about 60-90 minutes. *Users of online postal self-sampling services* will be recruited either (i) by a member the healthcare team if they have a face-to-face, telephone or video consultation, or (ii) will approach the research team directly having seen online information about the study (***Appendix 6***).

A member of the research team will then contact the service user, explain the study and what taking part involves, and assess capacity to provide informed consent. They will check eligibility according to the sampling criteria using a short screening questionnaire (***Appendix 7***) for those who have not already provided this information. The member of the research team will send the Participant Information Sheet containing full details of the study by email or post, or via link to the study website (as preferred), and arrange a convenient time for the interview to take place. All participants will be able to ask questions about the research before agreeing to take part. Before the interview, participants will be able to change their mind about taking part and cancel the interview appointment.

The researcher will obtain written informed eConsent using REDcap, or verbal informed consent (as preferred among those interviewed by telephone or video) before commencing the interview. REDCap is a secure web client which will be run from within the UCL Data Safe Haven. Service users will be told that they can withdraw at any time during the interview and that, if they decide to leave the study, any information already collected will be retained and used for the purpose of the study but no additional data will be collected. At the end of the interview, they will be asked to confirm if they are still happy for their data to be included in the study.

Participation will depend on the ability to understand English sufficiently to be able to provide informed consent and answer the questions. Due to the sensitive nature of the topic, it is not appropriate for a translator to be present with the researcher and participant. It is anticipated that only a very small proportion of those approached to participate in the research will be unable to understand English sufficiently.

Healthcare staff and stakeholders

Healthcare staff and stakeholders will be invited to take part in key informant interviews. The Participant Information Sheet containing full details of the study will be emailed to them. If they are interested in taking part, a member of the research team will contact them and arrange a convenient time for the interview to take place. They will be able to ask questions about the research before agreeing to take part. The researcher will obtain written informed eConsent using REDcap, or verbal informed consent (as preferred among those interviewed by telephone or video) before commencing the interview. Healthcare staff and stakeholders may be interviewed more than once and the option to re-contacted about a second interview will be included in the consent form.

Contextual observation

NHS staff will be invited to take part in a contextual observational interview and the Participant Information Sheet will be emailed to them. If they are interested in participating, a mutually convenient day will be determined. It will be emphasised participation/non-participation will not affect their employment with the participating clinic in any way. After determining that they fully understand the nature of the research, informed consent will be obtained using REDcap, as described above.

A member of the clinical care team will inform service users on the day of their consultation if the healthcare professional they are to see is participating in planned contextual observations. They will explain the study observations to potential participants, and provide a Participant Information Sheet in advance of their clinic appointment. A member of the clinical care team will go through the consent procedures, answer any questions they may have about the study, and will complete the consent process with them prior to the scheduled appointment. If the service user does not want their consultation observed then the researcher will not observe the consultation even if the healthcare professional has provided consent.

When contextual observation involves observing work processes managing clinical records and/or administrative tasks, the observer will either position themselves so as not to be able to see the clinical records or ask staff to use 'dummy records' to demonstrate processes.

Observation of information in the clinic about online services will not involve observing or taking notes on any interactions between staff or service users. The researcher will not seek to observe patient identifiable data.

9 DATA ANALYSIS

Workstream 1 (Impact evaluation)

Workstream 1.1 - Measurement of impact of OPSS on health inequalities, access, clinical and public health outcomes

For each case study area and primary outcome separately:

- Change will be analysed after introduction of OPSS in the overall number of tests and the proportion of those testing with particular population characteristics
- Change will be expressed in the rate of testing per year and, informally using estimates of the catchment area population size, change in the rate of testing per 1000 population per month, using Poisson regression and adjusting for population characteristics to address any possible confounding
- Change will be formally assessed in health inequality by testing for differential change over time (pre and post OPSS) by population characteristic (e.g. gender, ethnic minority group) through including interaction terms in the regression models
- Data will be pooled across the three areas to test for different change between areas

Analyses of Natsal-3 and Natsal-4 will provide estimates of the change over time in key outcomes within the general population, and insight into whether change is greater in areas that fully implemented OPSS services than others.

Our initial analysis is expected to be robust to confounding due to population change. To further address the possibility of confounding arising from other service changes that may have occurred at a similar time to OPSS, and the immediate impact of the COVID-19 pandemic, an analysis will be conducted based on an in-depth understanding of the health service provision over the full range of

time 2015-2022 in our case study areas. By collecting the dates of other changes in provision and pre-specifying the likely lag for these changes to affect our outcomes, Poisson regression models can be developed for our outcomes in continuous time that permit an 'interrupted time series' analysis to attempt to address the specific effect of OPSS adjusting for the effects of other changes.

Workstream 1.2 - Service user and healthcare professional experiences and views about acceptability of OPSS and clinic-based services

1. Quantitative data: The uptake of each component of the intervention will be analysed using logistic regression modelling for each component, stratifying by age, gender, sexuality, ethnicity, and IMD.
2. Qualitative data: All qualitative data collected in Workstreams 1 and 3 will be analysed using a realist logic of analysis aimed at developing iterative refinements of the initial programme theory to include contexts (C), mechanisms (M) and outcomes (O) configurations (CMOCs). Some of these CMOCs will likely relate to the four constructs of NPT (coherence, cognitive participation, collective action and reflexive monitoring) at the three stages of normalisation (initiation, embedding and integration) as this is our candidate theory for analysing the implementation process. Other CMOCs will relate to the constructs found within the different relevant formal theories that will be used to explain those parts of the programme theory that cannot be accounted for by NPT alone.

   The topic guides for the semi-structured interviews will therefore be theory informed and developed by the project team including those with direct of experience of working in or using sexual health services. All qualitative data will be transcribed verbatim by professional services, fully anonymised and entered into NVivo to facilitate analysis.

   The planned analysis will be multi-staged. Stage 1 will use inductive thematic analysis to identify emergent themes around the characteristics of the users, provider, decision making and the OPSS journey. Data will also be analysed deductively into themes based on concepts from formal theories. Stage 2 will use a realist logic analysis to build CMOCs from the data within and across the themes generated. In this stage, data will also be sought from within and across the themes to inform our interpretations of where the CMOCs developed fit within our initial programme theory - thus gradually refining it.

   Where possible and relevant, observed variation in quantitative outcomes as collected in Workstream 1 (e.g. in uptake, use, clinical and economic outcomes, and impact on health inequalities) will be used as well to develop and refine CMOCs.

Workstream 2 (Economic evaluation)

An economic evaluation will be undertaken to compare the costs and benefits for screening asymptomatic individuals undertaken using self-sampling kits ordered online, compared with screening of the same group in a clinic setting, across the case study areas. As a secondary analysis, the potential impacts on health equity associated with different types of service provision will be assessed (56).

The economic evaluation will be conducted and reported in accordance with relevant guidelines (51,52). Initially a cost-consequence analysis will be presented which involves reporting all costs and outcomes in a disaggregated manner (51). An incremental economic analysis will be conducted using the primary outcome of cost per positive case identified and the secondary outcomes of cost per patient screened, cost per patient treated and cost per partner identified / treated (if data quality on partner notification permit this). The economic component will explore how different service configurations can be used to achieve the optimal level of health benefit, within existing resource constraints. This element will identify and model patient pathways across the case study areas, assess comparative costs and outcomes, and analyse different scenarios for service configuration.

As a secondary analysis, impacts on equity will be analysed. Currently these methods are being refined and a range of possible methods will need to be considered (56). For example, recommended approaches include equity impact analysis (analyses distributional impacts on different groups) and equity trade-off analysis (examining trade-offs between improving total health and reducing health inequality) (53). Variations of multicriteria decision analysis have also been proposed as possible methods (54). As such methods have not previously been used in a sexual health context, a review of the literature will be conducted to assess the most appropriate approach and be informed by emerging practice (e.g. (57,58)). This approach will then be applied as a secondary analysis to allow decision-makers to access both a traditional analysis and a fuller analysis taking into account equity considerations.

Deterministic and probabilistic sensitivity analyses will be conducted to explore the effects of the uncertainty in the parameter estimates on the results (59). Deterministic sensitivity analysis involves varying one or more parameters while keeping the others at their baseline value. A probabilistic sensitive analysis involves varying all parameters simultaneously, and multiple sets of parameter values are sampled from defined probability distributions (60).

Workstream 3 (Implementation evaluation)

The data from Workstreams 3.1, and 3.2 will be analysed as a whole, using a realist logic of analysis to refine the initial programme theory as described above (Workstream 1.2, p22). The refined programme theory will include actions required and adaptations made to both the OPSS service, and the implementation programme. Where possible and relevant, observed variation in quantitative outcomes as collected in Workstream 1 (e.g. in uptake, use, clinical and economic outcomes, and impact on health inequalities) will be used to develop and refine our context mechanism and outcome configurations.

Workstream 4 (Development of programme theories)

Within the analytic process, interpretive cross-case comparison will be used to understand and explain how and why observed outcomes have occurred, for example, by comparing how outcomes may differ according to population group or service model, to understand how context, problem or diversity have influenced findings. Where appropriate, the following forms of reasoning will be used to make sense of the data:

- Juxtaposition of data: for example, where data about uptake of OPSS in one source enables insights into data about uptake in another source.
- Reconciling of data: where data differ in apparently similar circumstances, further investigation is appropriate in order to find explanations for why these differences have occurred.
- Adjudication of data: on the basis of whether threats to the validity of data in one source might make us question their trustworthiness compared to data from another source.
- Consolidation of data: where outcomes differ in particular contexts, an explanation can be constructed of how and why these outcomes occur differently.

The evaluation will move iteratively between the analysis of particular examples, refinement of programme theory, and further data collection to test particular parts of our programme theories. This will allow us to say ‘what works, for whom and under what circumstances’ for the impacts and in implementing and sustaining OPSS services.

10 PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE)

The ASSIST study is committed to meaningful patient and public involvement and engagement (PPIE) and David Crundwell (co-applicant and PPIE lead) has been actively involved since the inception of the study.

The British Association for Sexual Health & HIV (BASHH) and the Terrence Higgins Trust (one of the UKs leading HIV and sexual health charities) have established a joint Lay Research Panel, comprising a diverse range of lay reviewers who have received training in peer review. The panel reviewed the ASSIST lay summary and is strongly supportive of this study. Links have also been developed with NAZ (a charity focusing on sexual health improvement and HIV support services for ethnic minority communities), as the impact on ethnic minority communities will be one of our key outcomes.

The BASHH/THT Lay Panel and NAZ welcome our focus on young people, LGBQT+, and ethnic minority groups disproportionately affected by STIs and HIV, as both organisations are concerned that online services may only attract certain communities. Our three case study areas all serve large diverse populations enabling our evaluation to determine the impact on health inequalities. The panel also had concerns around data security which will be explored within the in-depth interviews.

David Crundwell will be involved at all stages of the work, and will attend all co-investigator research meetings. He will be involved in all aspects of planning and delivery, particularly design and selection of research, and will assist with overall direction, interpretation of findings and content of dissemination materials. His expertise in improvement of operational efficiencies through the application of Corporate Affairs, and his wide experience in community advocacy will facilitate our communication strategy.

While the BASHH/THT public panel is currently suspended because of the COVID pandemic, consultations with NAZ will continue to help inform our PPIE strategy. Regular updates will be provided, and advice sought on relevant issues. NAZ will help identify community members for our PPIE Panel, sought from groups most affected by poor sexual health. Individuals from the NIHR ARC North Thames Research Advisory Panel with experience of PPIE have been recruited to sit on our Expert Advisory Group and Study Steering Committee.

As well as providing invaluable advice on the design and conduct of the study, involvement from members of the public and community groups will assist with access to people in groups particularly relevant to our study and is essential for wider engagement. PPIE will assist with the tone, pitch and content of communications and the study website. Advice will be sought from the NIHR PPI Centre on our overall approach.

All PPIE will be supported according to INVOLVE guidance. Research in this area of health can be stigmatising for some, and in order to be inclusive, involvement will be offered via email as well as face-to-face activities, out-of-office hours activities, flexible levels of input and the ability to contribute anonymously. PPIE training will be provided if needed through our links with local CRN PPIE teams and Patient Research Ambassadors.

11 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCLH/UCL Joint Research Office, and deemed sufficient to cover the requirements of the study. Participant identification and recruitment within the NHS will be supported via the Local Clinical Research Network.

The research costs for the study have been supported by the NIHR HS&DR Programme (£1,071,987.02, 27 May 2020).

12 DATA HANDLING AND MANAGEMENT

This study has been registered with the UCL Data Protection Office, as data will be stored in the UCL Data Safe Haven. The study is registered under reference number Z6364106/2021/04/36 health research.

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regard to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer is data-protection@ucl.ac.uk. The data processors are University of Birmingham and University of Oxford.

All information collected will only be used for research purposes. Research data are retained for a minimum of ten years after publication (in line with UCL Research Data Policy) and personal data will be stored for a maximum of 12 months after the end of the study (as described below).

The study will be collecting the following data (see data flow diagrams in ***Appendix 9***):

12.1 National surveillance, routine data and survey datasets

Depersonalised electronic routinely collected data from existing surveillance systems in England will be transferred from Public Health England to the UCL Data Safe Haven via Managed File Transfer (MFT). The UCL Data Safe Haven has been certified to the ISO27001 information security standard and conforms to the NHS Information Governance Toolkit. Depersonalised data on clinical outcomes will be collected from routine information held by service providers in the case study areas. In each area, service user information is collected on electronic patient record systems and website databases. For each area, local data managers will transfer anonymised datasets to the UCL Data Safe Haven via MFT. A unique study identifier will be given to each case in the surveillance and clinic datasets.

Anonymised data from Natsal will be accessed from restricted-access password-protected drives at UCL. All anonymised datasets will be stored on restricted-access password-protected drives at UCL accessible only by named individuals.

Fully anonymous routine data will be transferred to restricted-access password-protected drives at UCL for analysis and will be transferred by MFT to co-investigators for collaborative analysis. The password will be provided by phone or encrypted online messaging service (e.g. WhatsApp) message.

12.2 Interview data collection

Personal information about service users recruited in clinic who are willing to be contacted will be transferred via nhs.net email accounts (first name, personal email and/or telephone number) from the clinic to a member of the research team at UCL. Personal information for service user participants recruited in clinic or via social media will be stored in nhs.net behind the NHS firewall for recruitment purposes.

Service users recruited via OPSS websites will enter personal information (first name, personal email and/or telephone number) directly into the UCL Data Safe Haven via REDCap. If service users are not eligible or do not meet the sampling criteria, all information that they have provided via REDCap will be deleted within two weeks.

Participants will be asked if they would like to receive a summary of the findings. Contact details will be deleted if participants do not consent to be interviewed or once the interviews have taken place (for those who do not wish to receive a summary) or after the summary has been sent (for those who do). The personal data of any potential participants who are not consented into the study will

be deleted if they do not respond to three attempts to contact them or within two weeks of the first contact for recruitment purposes.

Data from the short screening questionnaire (***Appendix 7***) and brief pre-interview questionnaire (***Appendix 4***) will be collected via the REDCap secure web client using an encrypted laptop or secure UCL computer, within the UCL Data Safe Haven. Each participant will be given a unique study number that will be used to link their background information to their interview transcript.

Password-protected encrypted audio-recorders will be used for the interviews. Interview recordings will be uploaded from the recorder directly to the UCL Data Safe Haven using a secure university computer via Managed File Transfer (MFT). Recordings will be labelled with the unique study number. Following data transfer, all recordings will be immediately deleted from the audio-recorder. A GDPR-compliant UCL approved professional transcription service will operate under a signed confidentiality agreement and will transcribe all audio-recordings. Recordings will be transferred from the Data Safe Haven to the transcription company via MFT and a code provided to them (via telephone) to download the files. The transcript company will transfer the transcript file to the Data Safe Haven via MFT.

Transcripts will be checked for accuracy and psuedonymised through removal of any identifiable information (including names, places and other personally identifiable information). Audio-recordings will be destroyed once the transcripts have been checked. Anonymised transcripts will be held securely on restricted-access password-protected drives at UCL accessible only by named individuals. Anonymised transcripts may be shared via MFT with co-investigators for collaborative analysis. The password will be provided by phone or encrypted online messaging service (e.g. WhatsApp).

Direct quotations from interview participants may be used in publications. All quotations will be pseudonymised so that individuals cannot be identified.

13 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL.

The Sponsor considers the procedure for obtaining funding from the NIHR HS&DR programme to be of sufficient rigour and independence to be considered an adequate peer review.

The study was deemed to require regulatory approval from the following bodies:

- NHS Research Ethics Committee Favourable Opinion
- Health Research Authority

Before any site can enrol patients into the study, the Co-Chief Investigators/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, and NHS Confirmations of Capacity and Capability and Sponsor green lights are in place.

For any amendments to the study, the Co-Chief Investigators or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Co-Chief Investigators or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA will be retained. The Co-Chief Investigators will notify the Sponsor and REC of the end of the study.

It is the Co-Chief Investigators' responsibility to produce the annual progress reports when required; an Annual Progress Report will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Co-Chief Investigators will notify the Sponsor and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Co-Chief Investigators will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

14 ASSESSMENT AND MANAGEMENT OF RISK

Participants will be fully informed about what taking part involves before they provide consent to participate. Before the interview, the Participant Information Sheet and Consent Form will be sent by email or post, or via a link to the study website (as preferred) to all service users who express an interest in taking part. This will inform them about the interview topic and purpose of the research, and gives them ample time to consider whether they would like to take part. The sheet provides contact details for the research team. A member of the research team will explain the study procedures to participants and they will have time to ask any questions they may have.

Research staff are trained to assess participants' understanding of the study procedures, and may make the decision to end the research activities if at any time it is clear that participants are unable to fully consent. Participants will be informed that they are free to withdraw from the study, without giving a reason, and without affecting the usual care they receive in the clinic. Before the interview, they will be informed that they have the option of not answering any question they feel uncomfortable answering.

The research team is conscious that consent is a dynamic process in the context of qualitative research. Participants may reveal information that they had not expected to share and may not wish to include in the study. Consent will therefore be revisited as required with participants. Participants will be reimbursed £30 in gift cards (depending on type of research activity) in recognition of their time, even if they do not complete the research activity.

The subject matter of both the interviews may be delicate and possibly emotive. This research is conducted by a highly experienced team led by Prof Fiona Burns (Professor in HIV medicine at UCL / Honorary Consultant and Clinical Lead at The Royal Free Hospital with over 15 years of research experience in HIV and STIs) and Dr Jo Gibbs (Senior Clinical Research Associate at UCL / Honorary Consultant, CNWL, with 10 years' research experience in STIs and HIV). The interviewers have extensive experience of collecting sensitive data and are trained in strategies for dealing with participants who are uncomfortable with the interview questions (e.g. acknowledging their feelings, asking them if they want to break from the interview, to discontinue the area of conversation or, if necessary, to discontinue participation).

In addition, members of the research team collecting data will have a resource pack containing helpline numbers and health promotion materials in order to provide information to participants, if required. Contact details of both the hospitals' patient liaison service and the research team will be provided to all participants, as well as details of details of organisations that can provide further advice and support. The researchers will follow an agreed plan for managing any distressed participants, including referral to appropriate health professionals.

Participation in the interviews is likely to take 60-90 minutes for service users and 45-60 minutes for healthcare staff and stakeholders. The topic guides have been reviewed by our lay representative, David Crundwell and the Expert Advisory Group. They have been designed to ensure that only relevant and important information is collected.

There are no direct benefits to the research participants, although they may enjoy the experience of taking part and may find it enlightening. They may benefit indirectly on a population level from the results of this research.

Safeguarding and disclosure of harm

Persons aged 16 and above are included in this study because the prevalence of bacterial STIs is high among young people, and people who are 16 and above are eligible to access OPSS, so it is important to understand how OPSS affects their care.

The members of the clinical care team in the participating sexual health services will determine if people are suitable to participate in the study. Participants who indicate their willingness to be part of the research process online will not be contacted if safeguarding concerns have been flagged.

If a participant who is under the age of 18 shares suicidal ideation or issues like intimate partner violence or sexual abuse with the researcher or experiences distress, the researcher will offer the participant information about appropriate services. Before taking part in the study, participants will be informed through the Participant Information Sheet and by the researcher about our duties and legal limitations to confidentiality under "Working to Safeguard Children". Guidelines will be followed according to which if participants disclose that the health, safety or welfare of themselves or anyone else under the age of 18 are at grave risk, we would initially seek to persuade them to disclose the risk to a responsible adult themselves. The researcher will consult with Co-Chief Investigators, Prof Fiona Burns and Dr Jo Gibbs, before disclosing risk to any third parties such as the clinical service safeguarding team, and will keep the young person informed. The research team have the contact details for the Named Professional for Safeguarding at each clinic.

For those over 18, similar procedures will be followed. If a participant shares suicidal ideation or issues like intimate partner violence or sexual abuse with the researcher or experiences distress, the researcher will offer the participant information about appropriate services. The researcher will consult with Co-Chief Investigators, Prof Fiona Burns and Dr Jo Gibbs, before disclosing risk to any third parties such as the clinical service safeguarding team, and will keep the participant informed.

The researcher will consult with Co-Chief Investigators, Prof Fiona Burns and Dr Jo Gibbs, on any allegations of poor practice discovered during the course of the study. These will be reported directly to the local Head of Service and Service Manager.

Confidentiality and data protection

Participants will be assured that all information obtained will only be used for research purposes and no findings will be released in a way that could identify an individual. Healthcare professional participants will be asked not to disclose any information that would identify patients.

Interviews will be recorded using password-protected encrypted audio-recorders. A UCL approved transcription service will transcribe all audio-recordings, operating under a signed confidentiality agreement. Transcripts will be checked for accuracy by the researcher and pseudonymised through removal of any identifiable information. Transcripts will be stored in locked filing cabinets and on restricted-access password-protected drives at UCL.

15 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

Research related incidents are unintended or unexpected events that could have led, or did lead to harm for participants, staff or members of the public receiving care, delivering services or visiting any study sites for the duration of the research study. A reportable incident may significantly affect:

a) the rights or wellbeing of a research participant

b) the scientific value of the study

c) the compliance of the study/research staff with relevant legislation, e.g. General Data Protection Regulation (2018), the U.K. Policy Framework for Health and Social Care Research, or the Human Tissue Act (2004), etc.

d) UCL's organisational reputation, and that of participating organisations.

All events and incidents (and near misses) that occur to participants and/ or staff that are **unexpected** and directly **related** to the research study will be reported to the Sponsor via research-incidents@ucl.ac.uk or the UCL REDcap incident reporting form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo) and host sites via their Trust reporting systems as soon as becoming aware, and documented in the Study Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the CI or PI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

15.1 Personal data breaches

In some instances, despite risk management and mitigations, personal data breaches may occur throughout the duration of the study. GDPR broadly defines personal data breaches as a security incident that has affected the confidentiality, integrity or availability of personal data. In short, there will be a personal data breach whenever any personal data is lost, destroyed, corrupted or disclosed; if someone accesses the data or passes it on without proper authorisation; or if the data is made unavailable, for example, when it has been encrypted by ransomware, or accidentally lost or destroyed.

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer, Alex Potts (email: a.potts@ucl.ac.uk), and to the Sponsor via the UCL REDcap incident reporting form (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their incident reporting mechanisms, and will document this within their Study Master File/Investigator Site File.

15.2 Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy; for participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures was undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from the Patient Advice and Liaison Service and the Sponsor where necessary.

16 MONITORING AND AUDITING

The Co-Chief Investigators will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensuring adequate data quality.

The Co-Chief Investigators will inform the sponsor should they have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

An independent Study Steering Committee will provide overall supervision for a project on behalf of the sponsor and funder and ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

17 TRAINING

The Co-Chief Investigators will review and provide assurances of the training and experience of all staff working on this study, including training in qualitative methods for all interviewers. Training and supporting materials will be provided for all members of staff identified at each site who will approach patients about participation. Appropriate training records will be maintained in the study files.

18 INTELLECTUAL PROPERTY

The project aims to assess the clinical and public health impact of online postal self-sampling for sexually transmitted infections and HIV. The case studies will be conducted in facilities across three cities, each of which has developed and adopted slightly different systems. The project has been discussed with UCL Business Ltd. (www.uclb.com), which has determined that no access to any background IP is required to conduct this research.

All parties involved have agreed to share required clinical data for the purpose of this research. Relevant site-specific literature, SOPs or guidelines maybe be required for evaluation, and this will be organised and authorised by each site's R&D department, with a named member of staff at each site having responsibility for accessing the documents. However, such literature will not be included in the final project report, publications or potential IP.

19 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this study is being carried out within NHS Trusts, the Trust continues to have a duty of care to the participant of the study. University College London does not accept liability for any breach in the NHS Trust's duty of care, or any negligence on the part of NHS Trust employees.

Participants may also be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

NHS sites selected to participate in this study shall provide negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London upon request.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity.

20 ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Co-Chief Investigators confirm that they will archive the study master file at UCL for the period stipulated in

the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Study Master File will be archived at UCL, in accordance with the UCL Retentions Schedule and Policy. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

21 PUBLICATION AND DISSEMINATION POLICY

The six key audiences for this research are: 1) Current and future service users, and members of the public; 2) Service providers; 3) Commissioners; 4) Professional associations (e.g. British Association for Sexual Health & HIV (BASHH)); 5) External statutory organisations (e.g. CQC, NHS Digital); 6) Academia.

Our dissemination strategy has been developed to access and engage all of these audiences with our findings and recommendations in a timely manner. The strategy will follow The Health Foundation's Communicating your research – a toolkit (61) and leverages existing resources within the participating organisations, such as their academic infrastructure, professional relationships and community networks fully. UCL and all partner universities have well-established Public Engagement Units or teams, and we will work closely with them alongside communication teams and press offices to relay information about the project to the wider public.

In order to facilitate the dissemination of our findings and recommendations to these audiences, along with the strategies mentioned above, the following will be undertaken:

- Production of **an infographic summary** and **PowerPoint slide set** of key findings (available to download on our website) to enhance accessibility of key messages that address audience priorities. These will be co-developed with our PPIE team, collaborators, and Expert Advisory Group to tailor communications to the relevant sectors. Participants will be asked if they would like to receive a copy of the summary.
- **Seminars and forums**: introduction of our study and local presentation of findings to sexual health services, patient groups and community-based organisations. This will be facilitated through strong links with BASHH and BHIVA, as well as our collaboration with the BASHH/THT (Terrence Higgins Trust) Public panel and NAZ (https://www.naz.org.uk/).
- Hosting of a **dissemination and networking event** for stakeholders at the end of the project. This will be live streamed to enhance reach and uploaded to YouTube. The intended audience will include academics, health care providers, service users, policy makers, sexual health advocacy groups, charities, CRN and the HS&DR programme. Our aim will be to disseminate findings, contribute to policy and practice debate, inform service development and set an agenda for future research.
- **Social media**: a study website will be set up and a Twitter account to tweet about the project, lessons learnt and related work. Active engagement of a wide audience will be sought through targeted social media from the project outset.
- **Protocol** and **NIHR final report**: will be written up. The protocol will be published in an open access journal and the NIHR final report will be freely available on open-access from NIHR journals (www.journalslibrary.nihr.ac.uk).

This proactive dissemination strategy offers the breadth to reach out to multiple audiences. Moreover, because our PPIE, clinical co-applicants, and collaborators, have stressed the

importance of getting messages out early, dissemination of findings will begin within 12 months of starting the project using our website and social media.

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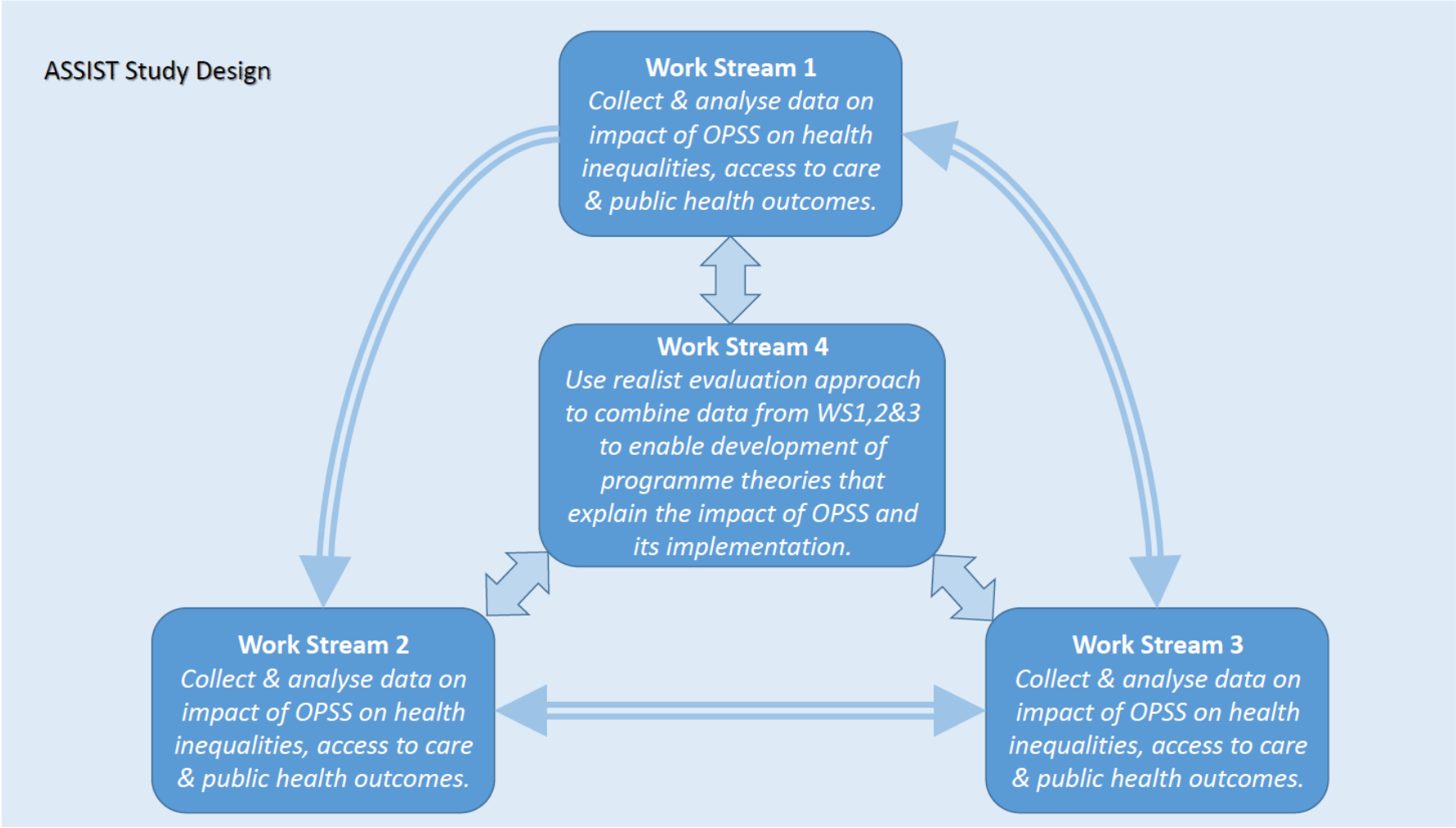
23 APPENDICES

Appendix 1 – ASSIST study design



Appendix 2 – Case study areas

Birmingham and Solihull: The Umbrella service (https://umbrellahealth.co.uk/) was established in August 2015 as a new sexual health provider for Birmingham and Solihull serving a population of 1.3 million. It comprises a consortium of services which includes the NHS, local authorities and third sector. Each year Umbrella has over 110,000 patient contacts across nine clinic sites, via OPSS and through a network of 120 pharmacies. OPSS accounts for 20% of activity but this proportion is increasing year on year.

London: The London Sexual Health Programme is a unique collaboration, involving 30 London borough councils and the Corporation of the City of London. The programme introduced a new online sexual health service offering OPSS for STIs and HIV in January 2018 (https://www.shl.uk/). This service covers 28 of London's authorities, with an estimated population of over 7 million. London has the highest rate of STIs in England with 131,400 new STI diagnoses in 2016, 36% occurring in young people (aged 15-24) (47).

Sheffield: Sexual Health Sheffield (https://www.sexualhealthsheffield.nhs.uk) was contracted as the current model in November 2019, as Level 3 provider of sexual health for Sheffield, serving a population of 550,000. The service has over 50,000 contacts, face-to-face and via OPSS. OPSS accounts for 30% of activities.

Appendix 3 – Clinical datasets

Example local dataset
Online testing activity & clinic-based
Field - demographics
Request date (online only)
Study_ID
Kit Type
Age
Gender
Ethnicity
Sexual identity
LSOA
Index of Multiple Deprivation Decile
Field – reason for access
Symptomatic
Contact-of STI (by individual infection)
Field – risk assessment
Unprotected sex with Someone who was born or raised outside uk or northern Europe
Were you born or raised outside EU
Sex with other Men
Sex with 6 or more men in the last 6 months
Unprotected Anal Sex
Sex with someone living with HIV
Born Outside UK
Region of Birth
Alcohol Score
Dast 10 Score
Attending due to rape/SA
Experienced Abuse
Used drugs other than Med Reason
Field – user journey (online only)
Delivery Method
Date Kit Collected
Kit Received
Date Kit Returned
Valid sample received
Sample received
All samples tested
Sample Tested
Infection Tested for
Field – user journey & HCP interaction (clinic-based only)
Staff type of who saw the patient(same day)
Staff Band of who saw the patient(same day)
Treatment given same day?
Was sample Taken
Sample Taken
All Samples Tested
Sample Tested
Infection Tested for
Field – test results and management
Test Results
Patient Notified
All Infection Treated
Field – healthcare professional interaction for treatment
Staff type treating or last seen by Patient (+ diagnosis only)
Staff banding treating or last seen by Patient (+ diagnosis only)
Management of infection/reactive result
Treatment_date
Treatment Location
Appointment Type For Treatment
Appointment Duration (Treatment)
Initial Confirmation Result (HIV roche/Syphilis Total)
Final Confirmation Result (HIV Vidas/Syphilis TPPA/TPHA)
Patient Came back for HIV counselling
Patient known previously Treated for Syphilis
New Patient
Field - Other sexual health service access in period either side of testing
Attended in the last 3 months(prior to kit request)
Method of Attendance in the last 3 months(prior to kit request)
No. of Clinic Attendance 3 months Prior kit Request
First Clinic Appointment Date (following kit return)
First Clinic Appointment Attendance Type (following kit return)
Subsequent_Att at Clinic within 4 months following Kit Returned
No. of subsequent Booked appointment within 4 months following Kit Returned
No. of subsequent Attended appointment within 4 months following Kit Returned
Field – contact/follow-up related to episode of care
HA Telephone CLinic undertaken
No. HA Tel Clinic taken
HA Tel Clinic Successful Contact
First Tel HA chase Date

Field – partner notification
Partner in last 3mos
Outcome Verified
Outcome Reported

Outcome Not Traceable
Outcome Blank
Duplicate

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
Clinic of attendance					
1	ClinicID	Predefined ODS code		Yes	
2	Clinic_Type	01 Specialist - Level 3 02 SRH - Level 2 03 Online - Level 2 04 GP - Level 2 05 Prison - Level 2 10 Other - Level 2 11 Other - Level 1		Yes	
Patient Demographics					
3	PatientID	Predefined code		Yes	
4	Patient_Type	1 Prisoner 2 Sex worker NA Not applicable / Not asked		Modified	SHHAPT codes
5	Gender_Identity	1 Male (including trans man) 2 Female (including trans woman) 3 Non-binary 4 Other Z Not Stated X Not Known		Modified	Fewer categories (not including non-binary)
6	Gender_Birth	Y Yes - gender identity is the same as gender assigned at birth N No - gender identity is not the same as gender assigned at birth Z Not Stated X Not Known		No	
7	Age	Number in whole years 999 Not known			
8	Sex_Ori	1 Heterosexual or Straight 2 Gay or Lesbian 3 Bisexual		Yes	

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
		4 Other U Unsure Z Not stated 9 Not known			
9	Ethnicity	White A British B Irish C Any other White background Mixed D White and Black Caribbean E White and Black African F White and Asian G Any other mixed background Asian or Asian British H Indian J Pakistani K Bangladeshi L Any other Asian background Black or Black British M Caribbean N African P Any other Black background Other Ethnic Groups R Chinese S Any other ethnic group Unclassified 99 Not Known Z Not Stated		Yes	
10	Country_Birth	ZZZ Not stated XXX Not known		Yes	
11	LA	Predefined ONS code		Yes	

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
		E* England W* Wales S* Scotland N* Northern Ireland L99999999 Channel Islands M99999999 Isle of Man X99999998 Not applicable (outside the UK) X99999999 Not known			
12	LSOA	Predefined ONS code E* England W* Wales S* Scotland 9* Northern Ireland L99999999 Channel Islands M99999999 Isle of Man X99999998 Not applicable (outside the UK) X99999999 Not known		Yes	
Episode_Activity					
13	Consultation_Referral	1082321000000109 Self-referral 1086251000000108 SRH (referral from) 108161000000109 GP (referral from) 1066011000000104 Prison (referral from) 1086261000000106 NCSP (referral from) 1086391000000108 Online service (referral from)		No	
14	Consultation_Date	CCYY-MM-DD		Yes	
15	Consultation_Medium	01 Face to face consultation 02 Telephone consultation 07 Online consultation		Modified	Face to face consultation Telephone consultation
16	Consultation_Type	01 New (initial / first / rebook) 02 Follow-up		Yes	

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
17	Consultation_Speciality	01 Integrated STI/SRH care 02 STI care 03 SRH care 04 HIV care 96 Other care		No	
				PN	SHHAPT codes – PN initiated / Whether a contact
18	Consultation_PN	Y Yes - the consultation is a result of Partner Notification follow-up N No - the consultation is not a result of Partner Notification follow-up NA Not applicable		No	
19	Consultation_Symptomatic	Y Yes – the patient has symptoms (symptomatic) N No – the patient does not have symptoms (asymptomatic)		No	
20	Episode_Activity	SNOMED / SHHAPT / READ codes		Yes	SHHAPT codes
21	Diganosis_Confirmed	01 Confirmed (at this service) 02 Confirmed elsewhere (at a different service) 03 Initial reactive NA Not applicable		Modified	SHHAPT codes
22	Diagnosis_Site	01 Genital 02 Rectal 03 Pharyngeal 04 Ocular 96 Other NA Not applicable		Modified	SHHAPT codes
23	Diagnosis_Treated	01 Yes - treatment provided 02 No - treatment not required 03 No - referred elsewhere for treatment		No	

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
		04 No - patient refused treatment 05 No - patient walked out (before treatment could be provided) NA Not applicable			
Opposite sex partners – men & women who have sex					
24	OSP	01 0 02 1 03 2-4 04 5+ ZZ Not stated UU Not known NA Not applicable / Not asked		No	
25	OSP_New	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
26	OSP_CL	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
Same sex partners – men who have sex with men					
27	MSM	01 0 02 1 03 2-4 04 5+ ZZ Not stated UU Not known NA Not applicable / Not asked		No	
28	MSM_HIV_Pos	Y Yes		No	

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
		N No Z Not stated U Not known NA Not applicable / Not asked			
29	MSM_CL	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
30	MSM_CL_Rec	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
Same sex partners – women who have sex with women					
31	WSW	01 0 02 1 03 2-4 04 5+ ZZ Not stated UU Not known NA Not applicable / Not asked		No	
32	WSW_New	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
Partner Notification					
33	PN_Date	CCYY-MM-DD		No	
34	PN_Partners	- Any number 0-999 NA Not applicable / Not asked		No	

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
35	PN_Contacts	- Any number 0-999 NA Not applicable / Not asked		No	
36	PN_Contacts_Att_Rep	- Any number 0-999 NA Not applicable / Not asked		No	
37	PN_Contacts_Att_Ver	- Any number 0-999 NA Not applicable / Not asked		No	
Behaviour					
38	PrEP_Eligibility	01 MSM / Transgender woman 02 HIV positive partner 96 Other high risk NA Not applicable / Not asked		No	
39	PrEP_Uptake	01 Accepted 02 Declined - patient refused PrEP 03 Obtained elsewhere - patient is obtaining PrEP elsewhere NA Not applicable / Not asked		No	
40	PrEP_Regimen	01 Daily (or nearly daily) 02 Event based (coital) ZZ Not stated UU Not known NA Not applicable/ Not asked		No	
41	PrEP_Prescription	01 30 tablets 02 60 tablets 03 90 tablets 96 Other amount ZZ Not stated UU Not known NA Not applicable / Not asked		No	
42	PrEP_Stop_Reason	01 Adverse event 02 HIV acquisition 03 Patient choice		No	

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
		04 No longer eligible 96 Other ZZ Not stated UU Not known NA Not applicable / Not asked			
43 - 44	Alcohol_1 Alcohol_2	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
45	Drugs_Used	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
46 - 61	Drugs_1 to Drugs_16	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
62	Drugs_Inject	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
63	Drugs_Share_Eqp	Y Yes N No Z Not stated U Not known NA Not applicable / Not asked		No	
64	Drugs_Sex	Y Yes		No	

GUMCAD STI Surveillance System v3				GUMCAD STI Surveillance System v2	
	Field name	**Description**		**Included**	**Notes**
		N No Z Not stated U Not known NA Not applicable / Not asked			

CTAD Chlamydia Surveillance System		
	Field name	**Description**
6	Gender	Person stated gender
7	Age	Person age
8	Ethnicity	Ethnic category
9	LSOA	LSOA of usual address
10	LSOA_GP	LSOA of GP
11	Registered_GP_Code	Code of GP
12	Postcode_Testing_ Service	Postcode of testing service
13	Venue_code	Site or organisation code
14	Specimen_Type	Specimen type
15	Testing_Service_Type	Service type
16	NCSP_Clinic_Code	NCSP clinic code
17	Specimen_Date	Date sample collected
18	Receipt_Date	Date sample received by lab
19	Date_Result_ Authorised	Date result authorised at lab
20	CT_Result	Result of chlamydia test

HIV Self-Sampling (Preventx: November 2015 – October 2019)		
	Field name	**Description**
1	Index	id
2	LocalAuthority	Lower tier local authority code
3	Final Result	Result of tested kits
4	Non-Reactive	Flag
5	Reactive	Flag
6	Equivocal	Flag
7	Unconfirmed	Flag
8	Borderline	blank
9	COI Initial	##.##
10	COI Final	##.##
11	Assay	4th 5th generation
12	Received	date
13	Tested	date
14	Working Days	Received-Tested
15	Confirmed	Blank
16	Negative	Blank
17	Sex	cis and trans male cis and trans female
18	Age	15-99 (under 16 dropped)
19	Ethnicity	African Bangladeshi British Caribbean Chinese Indian Irish Other Asian Background Other Black Background

HIV Self-Sampling (Preventx: November 2015 – October 2019)		
	Field name	**Description**
		Other Ethnic Group Other Mixed Background Other White Background Pakistani White and Asian White and Black African White and Black Caribbean Unknown
20	Sex With	Men Women Both
21	Unprotected 12	No Unknown Yes, with 1 partner Yes, with 2-5 partners Yes, with 6-12 partners Yes, with more than 12 partners.
22	Last HIV Test	Within the last year Over 1 year ago Never tested Unknown
23	New Partners 12	No new partners Just 1 partner 2-5 partners 6-12 partners More than 12 partners Unknown
24	Under Influence	Always Usually Sometimes Never Unknown
25	HIV Risk Born	No Yes Blank
26	HIVRisk Drug Use	No Yes Blank
27	HIVRisk Paid Sex	No Yes Blank
27	HIVRisk Partner	No Yes Blank

HIV Self-Sampling (SH24: October 2019 onwards)		
	Field name	**Description**
1	Index	id
2	lsoaname	lsoa name

HIV Self-Sampling (SH24: October 2019 onwards)		
	Field name	**Description**
5	reasonforvisit	Asymptomatic screen
6	defaultla	PHE
7	laofresidence	Blank
8	site	Freetesting.hiv Hub
9	age	16-99
10	gender	Female Male Non-binary
11	genderatbirth	Female Male
12	ethnicity	African Arab Bangladeshi Caribbean Chinese Gypsy_or_Irish_Traveller Indian Irish Latin_American Other_asian_asian_british Other_black_african_caribbean_black_british Other_ethnic_group Other_mixed_multiple_ethnic_groups Other_white Pakistani White_and_asian White_and_black_african White_and_black_caribbean White_english_welsh_scottish_northern_irish_british Prefer_not_to_say Not_known
13	sexualpreference	Men Women Both
14	unprotectedsexinlast3days	No Yes
15	unprotectedsexinlast5days	No Yes FALSE
16	sexuality	Bisexual Gay_man Heterosexual Homosexual Lesbian Other Prefer_not_to_say
17	testregime	HIV HIV & Syphilis

HIV Self-Sampling (SH24: October 2019 onwards)		
	Field name	**Description**
18	clinicvisited	No Not_asked
19	attendedclinic	No Yes
20	createdat	date created
21	createdatmonthyear	date created
22	dispatchedat	date kit dispatched
23	dispatchedatmonthyear	date kit dispatched
24	labreceiptat	date kit received at lab
25	notifiedat	date kit received at lab
26	notifiedatmonthyear	date result notified
27	labresultsat	date result notified
28	labresultsatmonthyear	date lab result
30	previouslydiagnosedwithhiv	No
31	previouslytreatedforsyphilis	No Yes
32	syphilis	Result: Haemolysed Insufficient Missing Negative No_results Not_requested Reactive
33	hiv	Result: Haemolysed Insufficient Missing Negative No_results Not_requested Reactive
34	chlamydia	Result: Haemolysed Insufficient Missing Negative No_results Not_requested Reactive
35	gonorrhoea	Result: Haemolysed Insufficient Missing Negative No_results Not_requested Reactive
36	hepb	Result: Haemolysed Insufficient Missing Negative No_results

HIV Self-Sampling (SH24: October 2019 onwards)		
	Field name	**Description**
		Not_requested Reactive
37	hepc	Result: Haemolysed Insufficient Missing Negative No_results Not_requested Reactive
38	testforchlamydiaurine	not_requested
39	testforchlamydiaoral	not_requested
40	testforchlamydiarectal	not_requested
41	testforchlamydiavaginal	not_requested
42	testforgonorrhoeaurine	not_requested
43	testforgonorrhoeaoral	not_requested
44	testforgonorrhoearectal	not_requested
45	testforgonorrhoeavaginal	not_requested
46	utla18nm	Upper tier local authority name
47	lasthivtest	Within_the_last_year Over_1_year_ago Never Not_asked Unknown
48	previoussyphilistreatment	No Yes Not_asked
49	paidsexworkriskassessment	No Yes Not_asked Prefer_not_to_say
50	numpartnershadcondomlesssexwithi	Zero One Two to five Six to twelve More than twelve Prefer not to say Not asked
51	drugusefrequency	Always Often Sometimes Never Not asked

Appendix 4 – Pre-interview questionnaire

ADMINISTRATION	
Participant study ID	

Do you own a smartphone (an internet-enabled phone)?	
	Yes
	No
	Prefer not to say

If yes, what type of smartphone do you own?	
	iPhone
	Android
	Other (please state): _____
	Prefer not to say

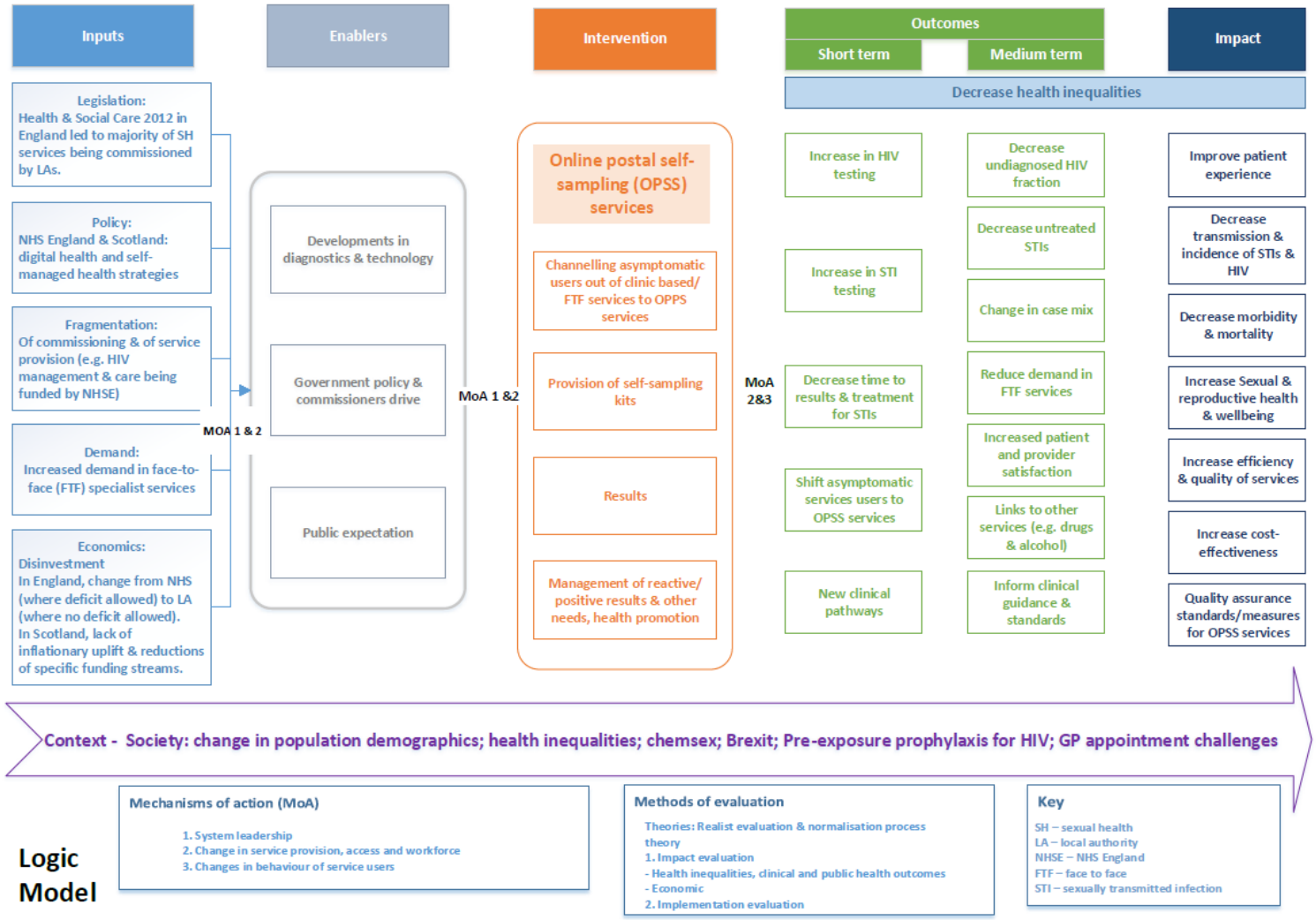
If yes, how long do you spend accessing apps / the internet on your phone each day?			
Accessing apps		**Accessing the internet**	
	Less than 30 minutes		Less than 30 minutes
	30 minutes to 1 hour		30 minutes to 1 hour
	1 to 2 hours		1 to 2 hours
	2 to 4 hours		2 to 4 hours
	More than 4 hours		More than 4 hours
	Prefer not to say		Prefer not to say

What language do you speak most often at home?	
	English
	Other (please state): _____
	Prefer not to say

What is your highest educational qualification?	
	I have no educational qualifications
	GCSEs/O-Levels/National 5/BTEC Firsts (level 1 or 2) or equivalent
	A-levels/Scottish Highers/BTEC Nationals (Level 3) equivalent
	Higher education below degree level (e.g. HNC, HND)
	Degree or higher
	Other
	Prefer not to say

What is your postcode? _____	
	Prefer not to say

Appendix 5 – Logic model



Appendix 6 – Social media advert

Appendix 7 – Screening questionnaire

ADMINISTRATION	
Participant study ID	
Participant's clinic (if applicable)	
Participant's area	Birmingham / London / Sheffield
Date of screening completion	
Name of person conducting screening	
Method of recruitment	Clinic referral / OPSS / online advert

Have you ever used a home STI and/or HIV testing kit that you ordered online?	
	Yes
	No
If yes, when was the last time? _____	

Have you ever used an STI and/or HIV testing kit that you were given in a clinic to use at home?	
	Yes
	No
If yes, when was the last time? _____	

Have you seen a healthcare professional at an NHS sexual health service about your sexual health [including face-to-face, telephone and video assessments]?	
	Yes
	No
If yes, when was the last time? _____	
What type of appointment was it? (face-to-face / telephone / video)	

How old are you? _____

Which of the following options best describes how you think of yourself?	
	Male (including trans man)
	Female (including trans woman)
	Non-binary
	Prefer to self-describe: _____
	Prefer not to say

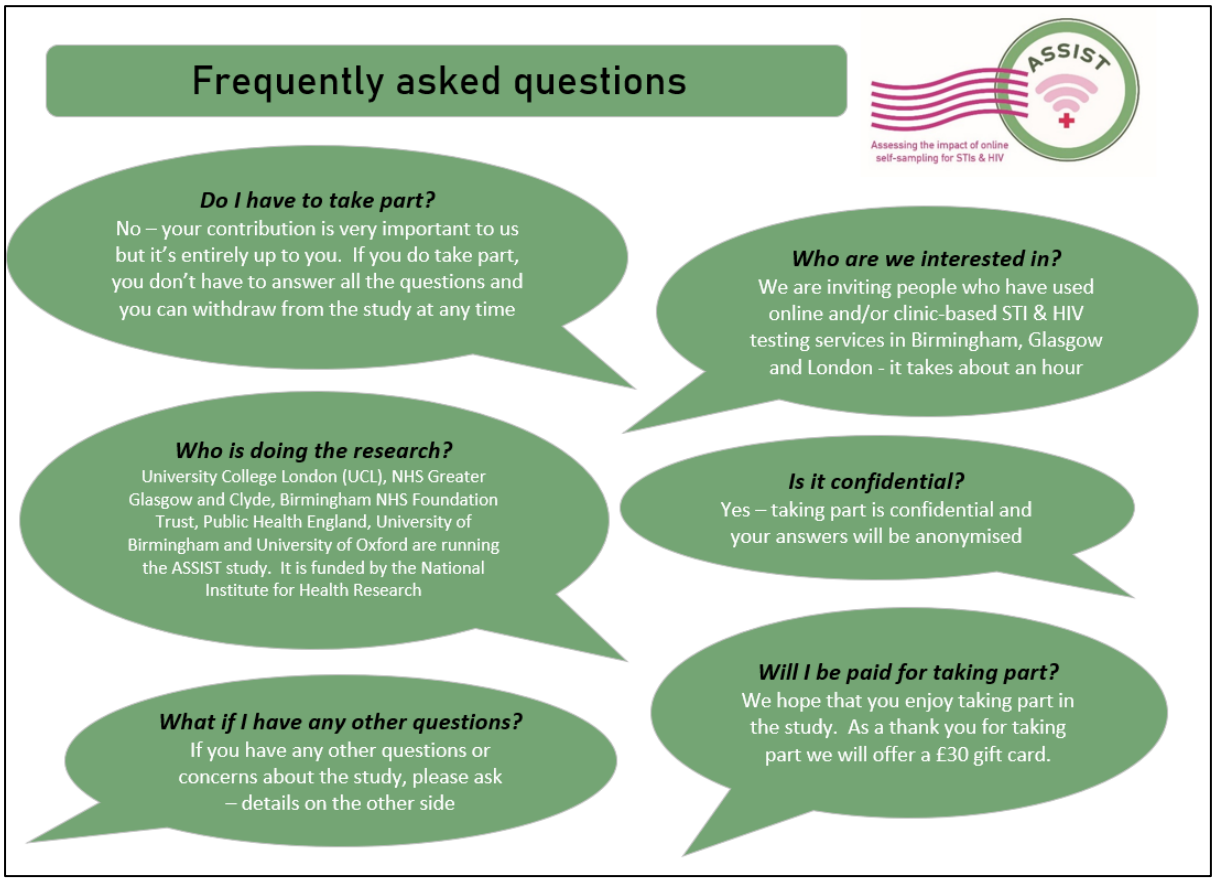
Is your gender identity the same as the sex you were assigned at birth?	
	Yes
	No
	Prefer not to say

What is your ethnic group?	
	Asian / Asian British
	Black / African / Caribbean / Black British
	Mixed / multiple ethnic groups
	White
	Other ethnic group: _____
	Prefer not to say

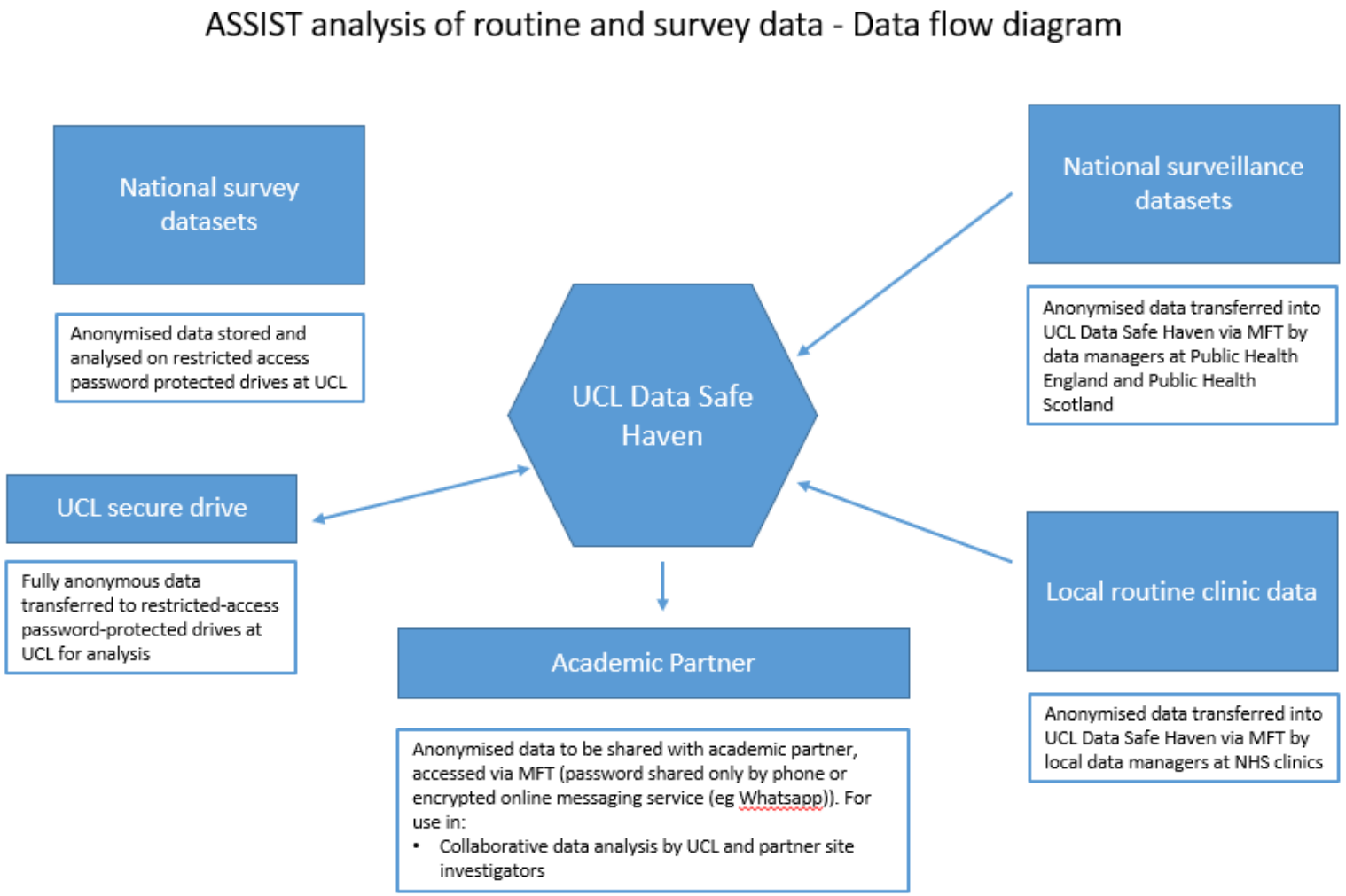
Which of the following best describes how you think of yourself?	
	Heterosexual or straight
	Gay or lesbian
	Bisexual
	Other (please describe): _____
	Prefer not to say

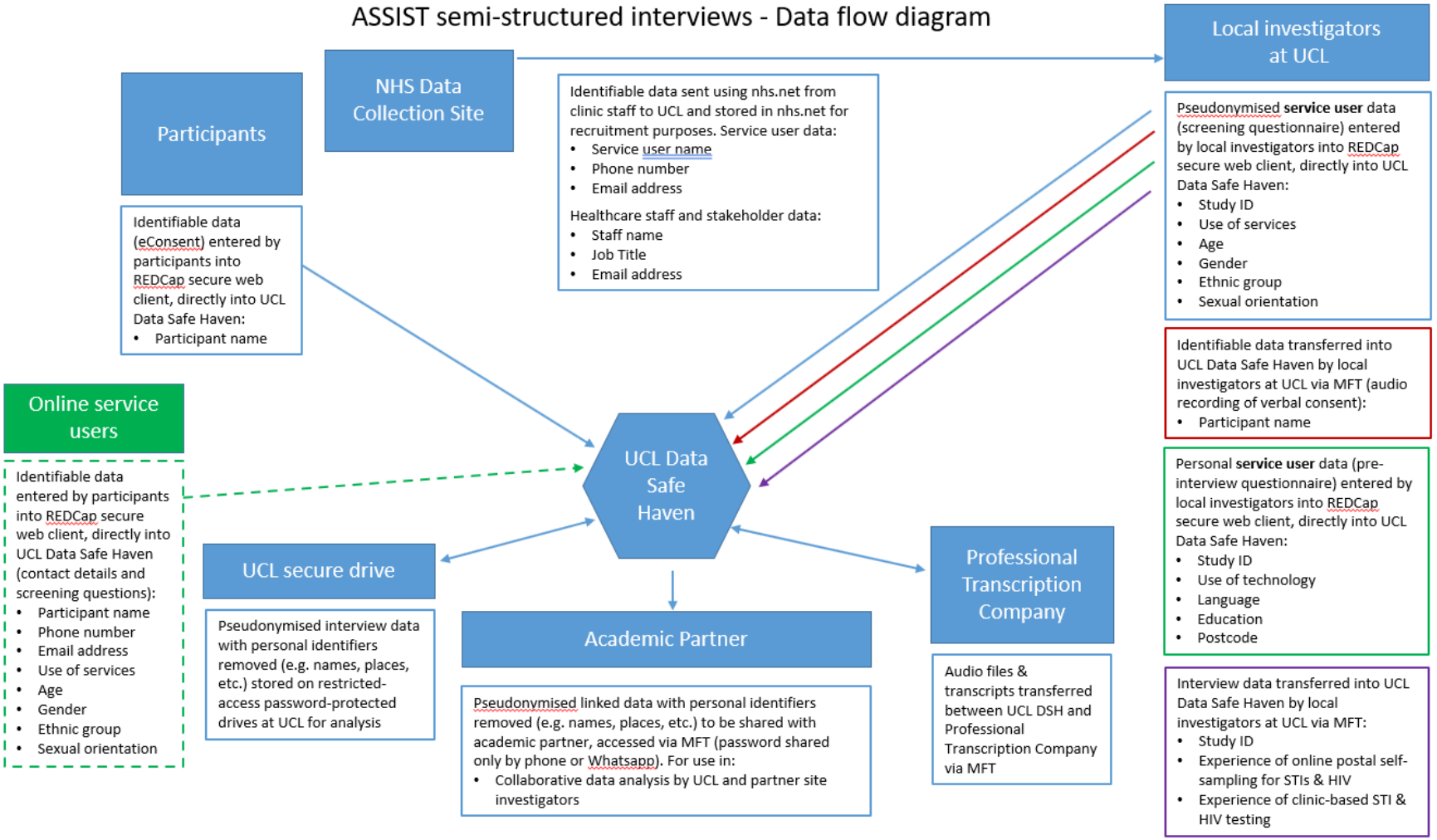
INTERVIEW ARRANGEMENTS	
Name of interviewer	
Date of interview	
Time of interview	
Mode of interview	

Appendix 8 – Service user leaflet



Appendix 9 – Data flow diagrams




ASSIST semi-structured interviews - Data flow diagram
Participants
NHS Data Collection Site
Local investigators at UCL
Identifiable data (eConsent) entered by participants into REDCap secure web client, directly into UCL Data Safe Haven:
• Participant name
Identifiable data sent using nhs.net from clinic staff to UCL and stored in nhs.net for recruitment purposes. Service user data:
• Service user name
• Phone number
• Email address
Healthcare staff and stakeholder data:
• Staff name
• Job Title
• Email address
Pseudonymised service user data (screening questionnaire) entered by local investigators into REDCap secure web client, directly into UCL Data Safe Haven:
• Study ID
• Use of services
• Age
• Gender
• Ethnic group
• Sexual orientation
Identifiable data transferred into UCL Data Safe Haven by local investigators at UCL via MFT (audio recording of verbal consent):
• Participant name
Online service users
Identifiable data entered by participants into REDCap secure web client, directly into UCL Data Safe Haven (contact details and screening questions):
• Participant name
• Phone number
• Email address
• Use of services
• Age
• Gender
• Ethnic group
• Sexual orientation
UCL Data Safe Haven
Personal service user data (pre-interview questionnaire) entered by local investigators into REDCap secure web client, directly into UCL Data Safe Haven:
• Study ID
• Use of technology
• Language
• Education
• Postcode
UCL secure drive
Pseudonymised interview data with personal identifiers removed (e.g. names, places, etc.) stored on restricted-access password-protected drives at UCL for analysis
Academic Partner
Pseudonymised linked data with personal identifiers removed (e.g. names, places, etc.) to be shared with academic partner, accessed via MFT (password shared only by phone or Whatsapp). For use in:
• Collaborative data analysis by UCL and partner site investigators
Professional Transcription Company
Audio files & transcripts transferred between UCL DSH and Professional Transcription Company via MFT
Interview data transferred into UCL Data Safe Haven by local investigators at UCL via MFT:
• Study ID
• Experience of online postal self-sampling for STIs & HIV
• Experience of clinic-based STI & HIV testing

ASSIST contextual observation - Data flow diagram